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Technical Support Document For Water Quality-based Toxics Control

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TECHNICAL SUPPORT DOCUMENT FOR WATER QUALITY-BASED TOXICS CONTROL

This copy represents the second printing of this document.

Changes made to this document reflect corrections of typographical errors and the following update of the interim guidance on criteria for metals: The Agency has issued "Interim Guidance Interpretation and Implementation Aquatic Life Criteria for Metals." The interim guidance supersedes criteria document statements expressing criteria in terms of a acid soluble analytical method and also the metals discussion of Section 5.7.3. The availability of this document appeared in the June 5, 1992 Federal Register (Vol. 57, No. 109, pg. 24401).

March 1991
Office of Water Enforcement and Permits
Office of Water Regulations and Standards
U.S. Environmental Protection Agency
Washington, DC 20460

FOREWORD

The U.S. Environmental Protection Agency (EPA) and the State pollution control agencies have been charged with enforcing the laws regarding pollution of the natural environment. Environmental pollution is an urgent and continuing problem and, consequently, the laws grant considerable discretion to the control authorities to define environmental goals and develop the means to attain them. Establishing environmentally protective levels and incorporating them in a decisionmaking process entails a considerable amount of scientific knowledge and judgment. One area where scientific knowledge is rapidly changing concerns the discharge of toxic pollutants to the Nation's surface waters.

This document provides technical guidance for assessing and regulating the discharge of toxic substances to the waters of the United States. It was issued in support of EPA regulations and policy initiatives involving the application of biological and chemical assessment techniques to control toxic pollution to surface waters. This document is agency guidance only. It does not establish or affect legal rights or obligations. It does not establish a binding norm and is not finally determinative of the issues addressed. Agency decisions in any particular case will be made applying the law and regulations on the basis of specific facts when permits are issued or regulations promulgated.

This document is expected to be revised periodically to reflect advances in this rapidly evolving area. Comments from users will be welcomed. Send comments to U.S. EPA, Office of Water Enforcement and Permits, 401 M Street, SW, Mailcode EN366, Washington, DC 20460.

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EXECUTIVE SUMMARY

The revised *Technical Support Document for Water Quality-based Toxics Control* (TSD) provides States and Regions with guidance on procedures for use in the water quality-based control of toxic pollutants. It presents recommendations to regulatory authorities faced with the task of controlling the point source discharge of toxic pollutants to the Nation's waters. The document provides guidance for each step in the water quality-based toxics control process from standards development to compliance monitoring. Both human health and aquatic toxicity issues are incorporated into the discussions throughout the document. The overall approach in this revised document provides additional explanations and rationales based on accumulated experience and data for the various recommendations that were made in the original TSD. The following is a brief synopsis of the guidance provided in the TSD.

Approaches to Water Quality-based Toxics Control

The Environmental Protection Agency's (EPA) surface toxics control regulation, 54 *FR* 23868, June 2, 1989, established specific requirements that the "integrated" approach be used in water quality-based toxics control. The "integrated" approach consists of whole effluent and chemical-specific approaches as a means of protecting aquatic life and human health. As techniques are made available for implementing biocriteria, they too should be integrated into the water quality-based toxics control, thus creating a triad of approaches: whole effluent, chemical-specific, and biological assessments. Each approach has its limitations and thus, exclusive use of one approach alone cannot ensure required protection of aquatic life and human health. The advantages/disadvantages of each approach and how the integrated approach creates an effective toxics control program are discussed in the text.

The whole effluent approach to toxics control involves the use of toxicity tests and water quality criteria for the parameter "toxicity" to assess and control the aggregate toxicity of effluents. New references and information in support of the whole effluent toxicity assessment and control approach have been included in Chapter 1 and associated appendices (e.g., precision data, justifications for acute-to-chronic ratio recommendations, information on analytical variability in toxicity testing). The chemical-specific approach to aquatic life toxics control relies on numeric water quality criteria in State standards and interpretations of State narrative standards to assess and control specific toxicants individually.

Water Quality Standards and Criteria

Where specific numerical criteria for a chemical or biological parameter (such as toxicity) are absent, compliance with water quality standards must be based on the general narrative criteria and on protection of the designated uses. For many pollutants, EPA's recommended criteria may be used, or criteria may be developed using data from the Integrated Risk Information System, or data on the toxicological effects of the pollutant found either in the literature or required of a discharger.

Aquatic impacts occur not only from the magnitude of a pollutant, but also from the duration and frequency with which criteria are exceeded. EPA's recommended aquatic life criteria for both individual toxicants and whole effluent toxicity are specified as two numbers: the criterion continuous concentration is applied as a 4-day average concentration; and the criterion maximum concentration is applied as an 1-hour average concentration. The frequency with which criteria are allowed to be exceeded depends on site-specific factors as explained in the text.

Strictly speaking the term "criteria" means EPA guidance formally published under the authority of Section 304(a) of the Clean Water Act. The toxicity level recommendations have not been so published. However, they represent EPA's carefully developed technical recommendation, and so are referred to in this document in the same manner as other criteria.

EPA's recommended criteria for whole effluent toxicity are as follows: to protect aquatic life against chronic effects, the ambient toxicity should not exceed 1.0 chronic toxic unit (TU_c) to the most sensitive of at least three different test species. For protection against acute effects, the ambient toxicity should not exceed 0.3 acute toxic units (TU_a) to the most sensitive of at least three different test species.

EPA has developed recommended human health criteria, which are called reference ambient concentrations (RACs). In the absence of EPA's recommended criteria, States may calculate RACs based on the equations in the text. In addition, the need for sediment and biological criteria in State water quality standards is discussed.

Effluent Characterization

This chapter contains completely revised effluent characterization discussions and recommendations. It includes streamlined procedures (as compared to the original TSD) for predicting the likely impacts of toxic effluents on aquatic life and human health. Recommendations are provided for determining, either with or without actual effluent data, whether a discharge causes, has the reasonable potential to cause, or contributes to an excursion above a State water quality standard. These effluent characterization procedures can be performed in one step and do not include initial screening followed by definitive data generation as was recommended in the original TSD.

The revised effluent characterization procedures for assessing potential human health impacts now include control of bioaccumulative chemicals.

Exposure and Wasteload Allocation

A goal of permit writers is to determine what effluent composition will protect aquatic organisms and human health. Exposure assessment includes an analysis of how much of the waterbody is subject to the exceedance of criteria, for how long, and how frequently. The first step is to evaluate the effluent plume dispersion. If mixing is not rapid and complete and if State standards allow a mixing zone, the wasteload allocation also must be based

on a mixing zone analysis. Chapter 5 describes the means to assess dilution at the edge of a mixing zone. As with the original TSD, ambient criteria to control acute toxicity to aquatic life may be met within a short distance of the outfall. However, this provision is no longer restricted to outfalls that have a high-rate diffuser.

If mixing is rapid and complete, there are several models that can be used to assess exposure. Steady-state models assume that the effluent concentration is constant and that the duration and frequency with which criteria are exceeded can be reflected entirely by selecting a design flow in the receiving water of appropriate averaging period and frequency.

Another means of modeling exposure is to use computer models that incorporate variability of the individual inputs (such as effluent flow and concentration, receiving water flow, temperature, background concentration, etc.). These models are termed dynamic models and are more accurate than steady-state models in reflecting or predicting exposure provided adequate data exist. The acceptable effluent condition derived using these models is expressed as the effluent long-term average and variance, which greatly simplifies derivation of permit limits. Three dynamic modeling approaches are described along with instructions for their use.

Permit Requirements

The requirements of a wasteload allocation (WLA) must be translated into a permit limit in the wastewater discharge permit. In many cases permit limits will be different than the WLA to reflect different assumptions and means of expressing effluent quality. Three types of WLAs are identified, and recommendations are provided for deriving permit limits to properly enforce each type of WLA. Other permit-related issues such as permit documentation and how to express limitations are discussed. In addition, guidance for requiring and conducting toxicity reduction evaluations is presented.

Compliance Monitoring

The compliance monitoring and enforcement process for water quality-based permits summarized in Chapter 6 is based on existing regulation and guidance. As with technology-based permits, any failure to meet a limit is a violation, and every violation must be reviewed to determine the appropriate response. Whole effluent toxicity monitoring and enforcement concepts embodied in the *Compliance Monitoring and Enforcement Strategy for Toxics Control* (January 19, 1989) have been added to this revision.

LIST OF ABBREVIATIONS

AA	atomic absorption
ACR	acute-to-chronic ratio
ADI	acceptable daily intake
AML	average monthly limit
ATC	acceptable tissue concentration
ATE	acute toxicity endpoint
AVS	acid volatile sulfides
BAF	bioaccumulation factor
BAT	best available technology
BCF	bioconcentration factor
BCT	best conventional technology
BMP	best management practice
BOD	biochemical oxygen demand
BPJ	best professional judgment
BPT	best practicable technology
CCC	criteria continuous concentration
CEAM	Center for Exposure Assessment Modeling (EPA)
CETTP	Complex Effluent Toxicity Testing Program
CFR	Code of Federal Regulations
CHC	chemical of highest concern
CMC	criteria maximum concentration
CTE	chronic toxicity endpoint
CV	coefficient of variation
CWA	Clean Water Act
DF	dilution factor
DMR	discharge monitoring report
DO	dissolved oxygen
EC	effect concentration
ECAO	Environmental Criteria and Assessment Office
EMS	Enforcement Management System
EP	equilibrium partitioning
EPA	Environmental Protection Agency
ERL	Environmental Research Laboratory (EPA)
FAV	final acute value
FDA	Food and Drug Administration
FM	food chain multipliers
GC/MS	gas chromatograph/mass spectrometer
HHC	human health criteria
HPLC	high-pressure liquid chromatography
IC	inhibition concentration
IRIS	Integrated Risk Information System (EPA)
LA	load allocation
LC	lethal concentration
LOAEL	lowest observed adverse effect level
LOEC	lowest observed effect concentration
LTA	long-term average
MCL	maximum contaminant levels
MDL	maximum daily limit
MERS	Monticello Ecological Research Station
ML	minimum level
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NPDES	National Pollutant Discharge Elimination System
NTIS	National Technical Information Service
ONRW	outstanding national resource waters
PCS	Permit Compliance System
POTW	publicly owned treatment works
PQL	practical quantitation limit
q_1^*	cancer potency factor
QA/QC	quality assurance/quality control
QNCR	quarterly noncompliance report
QSAR	quantitative structure-activity relationships
RAC	reference ambient concentration
RfD	reference dose
RWC	receiving water concentration
SQC	sediment quality criteria
STORET	storage and retrieval of water quality information
TIE	toxicity identification evaluation
TMDL	total maximum daily load
TRE	toxicity reduction evaluation
TSD	technical support document
TSS	total suspended solids
TTO	total toxic organics
TU	toxic unit
TU_a	acute toxic unit
TU_c	chronic toxic unit
WQS	water quality standard
WLA	wasteload allocation

MODELING ABBREVIATIONS

ARM	agricultural runoff model
CHNTRN	Channel Transport Model
CETIS	Complex Effluent Toxicity Information System
CIS	Chemical Information System
CORMIX 1	Cornell Mixing Zone Expert System
CTAP	Chemical Transport and Analysis Program
DESCON	computer program that estimates design conditions
DFLOW	computer program that calculates biologically based design flows
DYNHYD4	hydrodynamic model
DYNTOX	dynamic toxics model
EXAMS-II	Exposure Analysis Modeling System
FCM2	WASP Food Chain Model
FETRA	Finite Element Transport Model
FGETS	Food and Gill Exchange of Toxic Substances
FLOSTAT	U.S. Geological Survey computer program that estimates the arithmetic mean flow and 7Q10 of rivers and streams
HHDFLOW	historic daily flow program
HSPF	Hydrologic Simulation Program - FORTRAN
MEXAMS	Metals Exposure Analysis Modeling System
MINTEQA2	Equilibrium Metals Speciation Model
MICH	Michigan River Model
NPS	Nonpoint Source Model for Urban and Rural Areas
PSY	steady-state, two-dimensional plume model
SARAH2	surface water assessment model for back calculating reductions in biotic hazardous wastes
SERATRA	Sediment Contaminant Transport Model
SLSA	Simplified Lake/Stream Analysis
TODAM	Transport One-Dimensional Degradation and Migration Model
TOXIWASP	Chemical Transport and Fate Model
TOXI4	a subset of WASP4
TOXIC	Toxic Organic Transport and Bioaccumulation Model
UDKHDEN	three-dimensional model used for single or multiple port diffusers
ULINE	uniform linear density flume model
UMERGE	two-dimensional model used to analyze positively buoyant discharge
UOUTPLM	cooling tower plume model adapted for marine discharges
UPLUME	numerical model that produces flux-average dilutions
WASP4	water quality analysis program
WASTOX	Estuary and Stream Quality Model
WQAB FLOW	water quality analysis system flow data subroutine

GLOSSARY

absolute toxicity is the toxicity of the effluent without considering dilution.

acute means a stimulus severe enough to rapidly induce an effect; in aquatic toxicity tests, an effect observed in 96 hours or less typically is considered acute. When referring to aquatic toxicology or human health, an acute affect is not always measured in terms of lethality.

acute-to-chronic ratio (ACR) is the ratio of the acute toxicity of an effluent or a toxicant to its chronic toxicity. It is used as a factor for estimating chronic toxicity on the basis of acute toxicity data, or for estimating acute toxicity on the basis of chronic toxicity data.

acutely toxic conditions are those acutely toxic to aquatic organisms following their short-term exposure within an affected area.

acute toxicity endpoints (ATE) are toxicity test results, such as an LC_{50} (96 hours) and EC_{50} (48 hours), which describe a stimulus severe enough to rapidly induce an effect on aquatic organisms.

additivity is the characteristic property of a mixture of toxicants that exhibits a total toxic effect equal to the arithmetic sum of the effects of the individual toxicants.

ambient toxicity is measured by a toxicity test on a sample collected from a waterbody.

antagonism is the characteristic property of a mixture of toxicants that exhibits a less-than-additive total toxic effect.

antidegradation policies are part of each State's water quality standards. These policies are designed to protect water quality and provide a method of assessing activities that may impact the integrity of the waterbody.

aquatic community is an association of interacting populations of aquatic organisms in a given waterbody or habitat.

averaging period is the period of time over which the receiving water concentration is averaged for comparison with criteria concentrations. This specification limits the duration of concentrations above the criteria.

bioaccumulation is the process by which a compound is taken up by an aquatic organism, both from water and through food.

bioaccumulation factor (BAF) is the ratio of a substance's concentration in tissue versus its concentration in ambient water, in situations where the organism and the food chain are exposed.

bioassay is a test used to evaluate the relative potency of a chemical or a mixture of chemicals by comparing its effect on a living organism with the effect of a standard preparation on the same type of organism. Bioassays frequently are used in the pharmaceutical industry to evaluate the potency of vitamins and drugs.

bioavailability is a measure of the physicochemical access that a toxicant has to the biological processes of an organism. The less the bioavailability of a toxicant, the less its toxic effect on an organism.

bioconcentration is the process by which a compound is absorbed from water through gills or epithelial tissues and is concentrated in the body.

bioconcentration factor (BCF) is the ratio of a substance's concentration in tissue versus its concentration in water, in situations where the food chain is not exposed or contaminated. For nonmetabolized substances, it represents equilibrium partitioning between water and organisms.

biological assessment is an evaluation of the biological condition of a waterbody using biological surveys and other direct measurements of resident biota in surface waters.

biological criteria, also known as **biocriteria**, are narrative expressions or numeric values of the biological characteristics of aquatic communities based on appropriate reference conditions. Biological criteria serve as an index of aquatic community health.

biological integrity is the condition of the aquatic community inhabiting unimpaired waterbodies of a specified habitat as measured by community structure and function.

biological monitoring, also known as **biomonitoring**, describes the living organisms in water quality surveillance used to indicate compliance with water quality standards or effluent limits and to document water quality trends. Methods of biological monitoring may include, but are not limited to, toxicity testing such as ambient toxicity testing or whole effluent toxicity testing.

biological survey or biosurvey is the collecting, processing, and analyzing of a representative portion of the resident aquatic community to determine its structural and/or functional characteristics.

biomagnification is the process by which the concentration of a compound increases in species occupying successive trophic levels.

cancer potency slope factor (q1*) is an indication of a chemical's human cancer-causing potential derived using animal studies or epidemiological data on human exposure. It is based on extrapolating high-dose levels over short periods of time to low-dose levels and a lifetime exposure period through the use of a linear model.

chronic means a stimulus that lingers or continues for a relatively long period of time, often one-tenth of the life span or more. Chronic should be considered a relative term depending on the life span of an organism. The measurement of a chronic effect can be reduced growth, reduced reproduction, etc., in addition to lethality.

chronic toxicity endpoints (CTE) are results, such as a no observed effect concentration, lowest observed effect concentration, effect concentration, and inhibition concentration based on observations of reduced reproduction, growth, and/or survival from life cycle, partial life cycle, and early life stage tests with aquatic animal species.

coefficient of variation (CV) is a standard statistical measure of the relative variation of a distribution or set of data, defined as the standard deviation divided by the mean.

community component is a general term that may pertain to the biotic guild (fish, invertebrates, algae), the taxonomic category (order, family, genus, species), the feeding strategy (herbivore, omnivore, predator), or the organizational level (individual, population, assemblage) of a biological entity within the aquatic community.

completely mixed condition means no measurable difference in the concentration of a pollutant exists across a transect of the waterbody (e.g., does not vary by 5 percent).

continuous simulation model is a fate and transport model that uses time series input data to predict receiving water quality concentrations in the same chronological order as that of the input variables.

criteria continuous concentration (CCC) is the EPA national water quality criteria recommendation for the highest instream concentration of a toxicant or an effluent to which organisms can be exposed indefinitely without causing unacceptable effect.

criteria maximum concentration (CMC) is the EPA national water quality criteria recommendation for the highest instream concentration of a toxicant or an effluent to which organisms can be exposed for a brief period of time without causing an acute effect.

critical life stage is the period of time in an organism's lifespan in which it is the most susceptible to adverse effects caused by exposure to toxicants, usually during early development (egg, embryo, larvae). Chronic toxicity tests are often run on critical life stages to replace long duration, life-cycle tests since the most toxic effect usually occurs during the critical life stage.

design flow is the flow used for steady-state wasteload allocation modeling.

designated uses are those uses specified in water quality standards for each waterbody or segment whether or not they are being attained.

discharge length scale is the square root of the cross-sectional area of any discharge outlet.

diversity is the number and abundance of biological taxa in a specified location.

effect concentration (EC) is a point estimate of the toxicant concentration that would cause an observable adverse effect (such as death, immobilization, or serious incapacitation) in a given percentage of the test organisms.

equilibrium partitioning (EP) is a method for generating sediment criteria that focuses on the chemical interaction between sediments and contaminants.

final acute value (FAV) is an estimate of the concentration of the toxicant corresponding to a cumulative probability of 0.05 in the acute toxicity values for all genera for which acceptable acute tests have been conducted on the toxicant.

frequency is how often criteria can be exceeded without unacceptably affecting the community.

genotoxic is the ability of a substance to damage an organism's genetic material (DNA).

harmonic mean flow is the number of daily flow measurements divided by the sum of the reciprocals of the flows. That is, it is the reciprocal of the mean of reciprocals.

inhibition concentration (IC) is a point estimate of the toxicant concentration that would cause a given percent reduction (e.g., IC_{25}) in a nonlethal biological measurement of the test organisms, such as reproduction or growth.

lethal concentration is the point estimate of the toxicant concentration that would be lethal to a given percentage of the test organisms during a specific period.

lipophilic is a high affinity for lipids (fats).

load allocations (LA) are the portion of a receiving water's total maximum daily load that is attributed either to one of its existing or future nonpoint sources of pollution or to natural background sources.

lognormal probabilistic dilution model calculates the probability distribution of receiving water quality concentrations from the lognormal probability distributions of the input variables.

log P (also expressed as log k_{ow} or as n-octanal/water partition coefficient) is the ratio, in a two-phase system of n-octanol and water at equilibrium, of the concentration of a chemical in the n-octanol phase to that in the water phase.

lowest observed adverse effect level (LOAEL) is the lowest concentration of an effluent or toxicant that results in statistically significant adverse health effects as observed in chronic or subchronic human epidemiology studies or animal exposure.

magnitude is how much af a pollutant (or pollutant parameter such as toxicity), expressed as a concentration or toxic unit is allowable.

minimum level (ML) refers to the level at which the entire analytical system gives recognizable mass spectra and acceptable calibration points when analyzing for pollutants of concern. This level corresponds to the lowest point at which the calibration curve is determined.

mixing zone is an area where an effluent discharge undergoes initial dilution and is extended to cover the secondary mixing in the ambient waterbody. A mixing zone is an allocated impact zone where water quality criteria can be exceeded as long as acutely toxic conditions are prevented.

Monte Carlo simulation is a stochastic modeling technique that involves the random selection of sets of input data for use in repetitive model runs in order to predict the probability distributions of receiving water quality concentrations.

no observed adverse effect level (NOAEL) is a tested dose of an effluent or a toxicant below which no adverse biological effects are observed, as identified from chronic or subchronic human epidemiology studies or animal exposure studies.

no observed effect concentration (NOEC) is the highest tested concentration of an effluent or a toxicant at which no adverse effects are observed on the aquatic test organisms at a specific time of observation. Determined using hypothesis testing.

nonthreshold effects are associated with exposure to chemicals that have no safe exposure levels (i.e., cancer).

permit averaging period is the duration of time over which a permit limit is calculated (days, weeks, or months).

persistent pollutant is not subject to decay, degradation, transformation, volatilization, hydrolysis, or photolysis.

priority pollutants are those pollutants listed by the Administrator under CWA Section 307(a).

probability is a number expressing the likelihood of occurrence of a specific event, such as the ratio of the number of outcomes that will produce a given event to the total number of possible outcomes.

probability distribution is a mathematical representation of the probabilities that a given variable will have various values.

practical quantitation limit (PQL) is a correction factor, sometimes arbitrarily defined, used to account for uncertainty in measurement precision.

reasonable potential is where an effluent is projected or calculated to cause an excursion above a water quality standard based on a number of factors including, as a minimum, the four factors listed in 40 *CFR* 122.44(d)(1)(ii).

receiving water concentration (RWC) is the concentration of a toxicant or the parameter toxicity in the receiving water after mixing (formerly termed "instream waste concentration" [IWC]).

recurrence interval is the average number of years within that a variable will be less than or equal to a specified value. This term is synonymous with return period.

reference ambient concentration (RAC) is the concentration of a chemical in water that will not cause adverse impacts to human health. RAC is expressed in units of mg/l.

reference tissue concentration (RTC) is the concentration of a chemical in edible fish or shellfish tissue that will not cause adverse impacts to human health when ingested. RTC is expressed in units of mg/kg.

reference dose (RfD) is an estimate of the daily exposure to human population that is likely to be without an appreciable risk of deleterious effect during a lifetime; derived from nonobserved adverse effect level or lowest observed adverse effect level.

relative toxicity is the toxicity of the effluent when it is mixed with the receiving water, or a dilution water of similar composition for toxicity testing.

slug flow sampling is a monitoring procedure that follows the same slug of wastewater throughout its transport in the receiving water. Water quality samples are collected at receiving water stations, tributary inflows, and point source discharges only when a dye slug or tracer passes that point.

steady-state model is a fate and transport model that uses constant values of input variables to predict constant values of receiving water quality concentrations.

STORET is EPA's computerized water quality data base that includes physical, chemical, and biological data measured in waterbodies throughout the United States.

sublethal means a stimulus below the level that causes death.

synergism is the characteristic property of a mixture of toxicants that exhibits a greater-than-additive total toxic effect.

threshold effects result from chemicals that have a safe level (i.e., acute, subacute, or chronic human health effects).

total maximum daily load (TMDL) is the sum of the individual wasteload allocations and load allocations. A margin of safety is included with the two types of allocations so that any additional loading, regardless of source, would not produce a violation of water quality standards.

toxicity identification evaluation (TIE) is a set of procedures to identify the specific chemicals responsible for effluent toxicity.

toxicity reduction evaluation (TRE) is a site-specific study conducted in a stepwise process designed to identify the causative agents of effluent toxicity, isolate the sources of toxicity, evaluate the effectiveness of toxicity control options, and then confirm the reduction in effluent toxicity.

toxicity test is a procedure to determine the toxicity of a chemical or an effluent using living organisms. A toxicity test measures the degree of effect on exposed test organisms of a specific chemical or effluent.

toxics are those pollutants that have a toxic effect on living organisms. The CWA Section 307(a) "priority" pollutants are a subset of this group of pollutants.

toxic pollutants are those pollutants listed by the Administrator under CWA Section 307(a).

toxic units (TUs) are a measure of toxicity in an effluent as determined by the acute toxicity units or chronic toxicity units measured.

toxic unit acute (TU_a) is the reciprocal of the effluent concentration that causes 50 percent of the organisms to die by the end of the acute exposure period (i.e., 100 LC_{50}).

toxic unit chronic (TU_c) is the reciprocal of the effluent concentration that causes no observable effect on the test organisms by the end of the chronic exposure period (i.e., 100/NOEC).

water quality assessment is an evaluation of the condition of a waterbody using biological surveys, chemical-specific analyses of pollutants in waterbodies, and toxicity tests.

wasteload allocation (WLA) is the portion of a receiving water's total maximum daily load that is allocated to one of its existing or future point sources of pollution.

water quality criteria are comprised of numeric and narrative criteria. Numeric criteria are scientifically derived ambient concentrations developed by EPA or States for various pollutants of concern to protect human health and aquatic life. Narrative criteria are statements that describe the desired water quality goal.

water quality limited characterizes a stream segment in which it is known that water does not meet applicable water quality standards, and/or is not expected to meet applicable water quality standards even after application of technology-based effluent limitations.

water quality standard is a law or regulation that consists of the beneficial designated use or uses of a waterbody, the numeric and narrative water quality criteria that are necessary to protect the use or uses of that particular waterbody, and an antidegradation statement.

whole effluent toxicity is the total toxic effect of an effluent measured directly with a toxicity test.

INTRODUCTION

Purpose

The purpose of this revised *Technical Support Document (TSD) for Water Quality-based Toxics Control* is to provide the most current procedural recommendations and guidance for identifying, analyzing, and controlling adverse water quality impacts caused by toxic discharges to the surface waters of the United States. The original TSD was published in September 1985. Since then, the Clean Water Act (CWA) was amended in 1987 with an emphasis on controlling toxic pollutants. New policies and regulations have been promulgated and a vast amount of knowledge and experienced has been gained in controlling toxic pollutants. Because of these changes, EPA revised and updated the TSD.

This guidance document is intended to support the implementation of the CWA water quality-based approach to toxics control. As such, the recommendations and guidance found in this document are not binding and should be used by regulatory authorities with discretion. The guidance in this document has been developed as the most current representation of knowledge in the field of assessment and control of toxic discharges. Some of the guidance in this document is based on ongoing research and development (bioaccumulation methods, Chapter 3) and should not be used until the procedures are finalized.

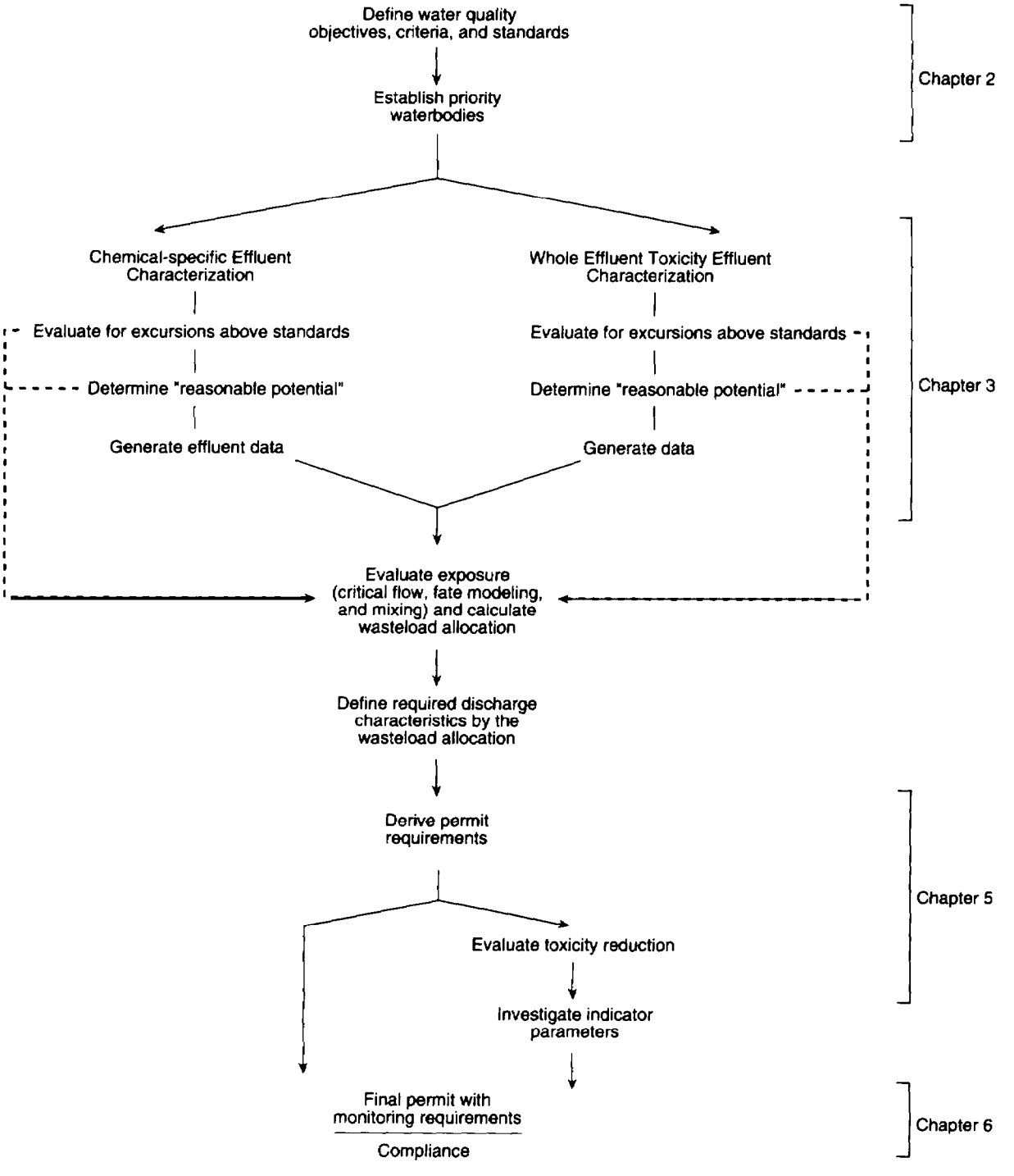
Background

The EPA surface water toxics control program, represented diagrammatically in the figure, relies on portions of the national pretreatment program, the effluent limitations guidelines program, the sludge program, the combined sewer overflow program, the stormwater management program, the 304(l) program, the water quality standards program, and the National Pollutant Discharge Elimination System (NPDES) program. States are authorized by EPA to implement certain portions of the national toxics control program, such as the NPDES program. Scientific and technical guidance is developed and published by EPA to assist the States. EPA is required by the CWA and federal regulations to play an oversight role to ensure that States authorized to implement various program requirements do so in accordance with federal regulations.

States are given discretion in the CWA to establish and implement water quality standards. As such, there may be differences in toxics control programs between States. EPA's oversight role is to ensure that each State's program is technically sound and that each State fully implements its program.

Throughout the evolution of the toxics control program, EPA has provided guidance concerning new program initiatives, statutory developments, and regulatory requirements. In 1980, EPA emphasized in its preamble to NPDES regulations (45 *FR* 33520) that NPDES permit limitations must reflect the most stringent of technology-based, water quality-based controls, or other standards required by the CWA (e.g., ocean discharge requirements under Section 403 and toxics standards or prohibition under Section 307[a]). EPA reiterated the significance of surface water toxics control in 1984 through the publication of its national policy statement entitled, "Policy for the Development of Water Quality-Based Permit Limitations for Toxic Pollutants" (49 *FR* 9016, March 9, 1984). EPA recommended the use of "biological techniques as a complement to chemical-specific analyses to assess effluent discharges and express permit limitations" (49 *FR* 9017). The preamble to additional regulations promulgated in 1984 (49 *FR* 37998) stressed the importance of establishing effluent limitations in NPDES permits to control toxic pollutants. Regulatory provisions promulgated on June 2, 1989 (54 *FR* 23868), clarify EPA's surface water toxics control program and the use of whole effluent toxicity, and implement CWA Section 304(l) concerning the identification of impaired waters and the development of individual control strategies.

The control of toxic discharges to the Nation's waters is an important objective of the CWA. To effectively accomplish this objective, EPA recommends the use of an integrated water quality-based approach for controlling toxic discharges. EPA's integrated "standards to permits" approach, illustrated in the figure, starts with water quality criteria, objectives, and standards and results in NPDES permit limits to control toxic pollutants through the use of both chemical-specific and whole effluent toxicity limitations. Limitations are essential for controlling the discharge of toxic pollutants to the Nation's water. Once NPDES permit limits are set, compliance is essential. Compliance can be ascertained by continual routine monitoring of effluent quality. Water quality-based effluent limitations when developed in accordance with the procedures in this document, will protect water quality and prevent the violation of State water quality standards.



Overview of the Water Quality-based "Standards to Permits" Process for Toxics Control

1. APPROACHES TO WATER QUALITY-BASED TOXICS CONTROL

1.1 INTRODUCTION

In this chapter, basic principles are presented that cover the protection of aquatic life and the protection of human health from impacts caused by the release of toxics to the Nation's surface waters. Protection against toxic releases is called for under Section 101(a)(3) of the Clean Water Act (CWA), which states that "it is the national policy that the discharge of toxic pollutants in toxic amounts be prohibited." In addition, CWA Section 303(c) requires States to develop water quality standards to protect the public health or welfare, enhance the quality of water, and serve the purposes of the CWA. The control of the discharge of toxics is a paramount objective of the National Pollutant Discharge Elimination System (NPDES) and water quality standards programs. The CWA and Environmental Protection Agency (EPA) regulations (described in Appendices B-1 and B-4, respectively) authorize and require the use of the "integrated strategy" to achieve and maintain water quality standards. In addition, EPA policy and guidance have long advocated this approach (see Appendices B-2 and B-3). For the protection of aquatic life, the integrated strategy involves the use of three control approaches: the chemical-specific control approach, the whole effluent toxicity control approach, and the biological criteria/bioassessment and biosurvey approach. However, for the protection of human health, technical constraints do not yet allow for full reliance on an integrated strategy, and thus primarily chemical-specific assessment and control techniques should be employed.

The integrated approach to water quality-based toxics control, including the use of toxicity testing and whole effluent toxicity limits, chemical-specific testing and limits, and biological criteria using bioassessments/biosurveys, relies on the water quality standards that each State has adopted. All States have water quality standards consisting of both chemical-specific numeric criteria for individual pollutants, and narrative "free from toxics in toxic amounts" criteria. Currently, a few States have incorporated biological criteria into water quality standards.

The narrative water quality criteria in all States generally require that the State waters be free from oil, scum, floating debris, materials that will cause odors, materials that are unsightly or deleterious, materials that will cause a nuisance, or substances in concentrations that are toxic to aquatic life, wildlife, or human health. The use of toxicity testing and whole effluent toxicity limits is based upon a State's narrative water quality criterion and/or in some cases, a State numeric criterion for toxicity.

Chemical-specific numeric criteria have been adopted by each State. In many cases, States have adopted EPA-recommended water quality criteria as a part of their water quality standards [1, 2]. (See Chapter 2, Water Quality Criteria and Standards, for further information.) These State-adopted numeric chemical criteria provide the basis upon which specific chemicals can be limited in permits. Where States have not developed chemical-specific numeric criteria, States may interpret their narrative standards for specific chemicals by using EPA criteria updated with current quantitative risk values.

Biological criteria provide a direct measure of ambient aquatic life and overall biological integrity in a waterbody. Biological criteria constitute one basis for limits that will protect the biological integrity of a surface water.

The integrated approach must include the control of toxics through implementation of the narrative "no toxics" criterion and/or numeric criteria for the parameter toxicity, the control of individual pollutants for which specific chemical water quality criteria exist in a State's standards, as well as use of biological criteria. Reliance solely on the chemical-specific numeric criteria or the narrative criterion or biological criteria would result in only a partially effective State toxics control program. In the discussion that follows, each control approach is described in greater detail as well as how each of the approaches complement the other two by providing additional information for the protection of water quality.

1.2 CHEMICAL-SPECIFIC APPROACH FOR AQUATIC LIFE PROTECTION

The chemical-specific approach to toxics control for the protection of aquatic life uses specific chemical effluent limits in NPDES permits to control the discharge of toxics. These limits are developed from laboratory-derived, biologically based numeric water quality criteria adopted within a State's water quality standards. Water quality criteria are adopted by a State for the protection of the designated uses of the receiving water. Chemical-specific water quality-based limits in NPDES permits involve a site-specific evaluation of the discharge and its effect upon the receiving water. This may include collection of effluent and receiving water data and result in the development of a wasteload allocation (WLA) and a total maximum daily load (TMDL) through modeling, a mixing zone analysis, and the calculation of permit limits. Once a numeric water quality criterion is adopted, chemical-specific limits must be developed in NPDES permits to ensure that a permittee's discharge does not exceed acute or chronic water quality criteria for the pollutant in a receiving water if there is a reasonable potential for that discharge to cause or contribute to excursions of the criterion. These steps are discussed in Chapters 3, 4, and 5.

EPA water quality criteria for the protection of aquatic life are developed under the requirements of CWA Section 304(a)(1) and are published by EPA in separate criteria documents and summarized in the Quality Criteria for Water [1]. Water quality criteria are derived scientifically and attempt to consider a wide range of toxic endpoints including acute and chronic impacts and

bioaccumulation. Each criteria consists of two values—an acute and a chronic value. Criteria are developed using the latest scientific knowledge on the kind and extent of identifiable effects on organisms, such as plankton, fish, shellfish, wildlife, and plant life, which may be expected from the presence of pollutants in any body of water. Water quality criteria also reflect the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes, and the effects of pollutants on biological community diversity, productivity, and stability of the receiving water [1]. They can be used to assess and control a variety of water quality impacts. Chapter 2 provides a more detailed discussion of the derivation of numeric criteria. Recommendations for using chemical-specific data to determine which individual toxicants need to be controlled are found in Chapter 3. Legal requirements, including chemical-specific limits in permits, are found in Chapter 5.

1.2.1 Correlation of Chemical-specific Measurements to Actual Receiving Water Impacts

EPA has conducted a series of studies to determine whether its water quality criteria concentrations are protective of aquatic life in receiving water systems. The first study was conducted at Shayler Run, Ohio, to evaluate the applicability of laboratory-generated toxicity data to a natural stream artificially dosed with copper to provide steady concentrations [3]. The results of the study indicate that several characteristics of site-specific water quality affect the toxicity of copper. The results also indicate that avoidance of elevated concentration areas by instream organisms can produce observable ecological changes at concentrations below those found to be harmful in laboratory toxicity tests. No instream effects were observed at continuous exposure concentrations near EPA's current chronic criterion, applied at the water hardness of Shayler Run.

Studies performed on experimental streams at EPA's Monticello Ecological Research Station (MERS) indicate good agreement between EPA's criteria concentrations and the instream concentrations producing aquatic life effects under steady exposure conditions [4-13]. EPA's water quality criteria are not threshold levels above which definite measurable instream effects are always expected. Rather, the criteria embody conservative assumptions such that small excursions above the criteria should not result in measurable environmental impacts upon the biota. The data indicate that if the ambient water quality criteria are met, then the biota in the receiving water system will be protected from unacceptable impacts caused by the chemical of concern. The studies conducted by MERS are described in greater detail in Box 1-1 and Tables 1-1 and 1-2.

1.2.2 Chemical-specific Analytical Method Precision

Tables 1-3 to 1-5 illustrate the types of precision commonly seen in inorganic, organic, and nonmetal inorganic chemical analyses that are routinely used for determining concentrations of specific pollutants in effluents. These tables show the observed variability. The variability of chemical measurements increases as one approaches the limit of detectability for a chemical. Table 1-3 shows the interlaboratory precision of 10 metals. The coefficient of variation (CV), defined as the standard deviation divided by the mean x 100, for these analyses ranges from 18 percent to 129 percent [15]. Table 1-4 shows the interlaboratory precision

Box 1-1. Correlation of Chemical-specific Criteria to Instream Impacts

In studying the field applicability of EPA's water quality criteria in freshwater systems, MERS (Monticello Ecological Research Station) conducted studies in experimental streams [4-14] to determine the level of protection provided by the individual chemical criteria. Each of the streams was one-quarter mile long with alternating mud-bottomed pools and rocky riffles. Fish were stocked into the streams to a known population density while other plants and animals were the result of natural colonization.

The chemicals studied were ammonia, chlorine, chlorine combined with ammonia, selenium, and pentachlorophenol. Some studies were conducted during a summer (pentachlorophenol) while others continued for more than 2 years (selenium IV). Tables 1-1 and 1-2 show sample data on ammonia and ammonia combined with chlorine. In all experiments, the streams were dosed continuously with the chemical(s) being studied and the biological effects were determined statistically by a comparison to the control streams. The concentration at which biological effects occurred were then compared to the EPA criteria continuous concentration (CCC) for that compound.

With the exception of chlorine in the presence of ammonia, the data from the other experiments indicate that slight or no effects were found in the streams at the CCC. This indicates that the CCC is providing chronic protection at the recommended concentration for that particular chemical. In the case of chlorine combined with ammonia, a substantial impact was found, but only on one species, the channel catfish. Because the CCC is designed to protect most, but not all of the species all of the time (see discussion in Chapter 2 on EPA Ambient Water Quality Criteria), slight impacts may be expected under continuous exposure conditions.

Table 1-1. Effects in Streams Exposed to Ammonia [8-13]

Indicator	Effects		
	Criteria[a]	3X[b]	9X[c]
Fish			
Fathead minnow	0[d]	0	0
Bluegill	0	0	++
Channel catfish	+	++	+++
White sucker	0	0	0
Rainbow trout	0	0	++
Walleye	0	0	++
Benthic Invertebrates	0	+	++
Zooplankton	0	+	+

Notes
[a] Criteria = 0.05 mg/l unionized ammonia (NH_3) at average stream pH and temperature; 1.0 mg/l total ammonia was added to reach this concentration; concentrations of unionized ammonia varied daily and seasonally due to natural pH and temperature fluctuations.
[b] 3X = Three times criteria concentration based on input of 3 mg/l total ammonia.
[c] 9X = Nine times criteria concentration based on input of 9 mg/l total ammonia.
[d] 0 = No difference from controls; +'s represent gradation of differences from controls ranging from slight (+) to dramatic (++++).

Table 1-2. Effects in Streams Exposed to Ammonia and Chlorine [8-13]

Indicator	Effects		
	4 ug/l[a]	35 ug/l	122 ug/l
Fish			
Channel catfish	++[b]	++	+++
Bluegill	0	0	0
Benthic invertebrates	0	+	++
Zooplankton	0	0	0
Bacteria	+	++	+++
Periphyton	0	0	0
Primary production	0	0	0
Litter decomposition	+	+	++
Aquatic plants	0	0	0

Notes
[a] Average concentrations of TRC in presence of 2mg/l to 3mg/l total ammonia; national criteria for chlorine = 11 ug/l.
[b] 0 = No difference from controls; +'s represent gradation of differences from controls ranging from slight (+) to dramatic (++++).

Table 1-3. Interlaboratory Precision of Inorganic Analysis at the Low End of the Measurement Detection Range [15]

Analyte	No. of Labs	CV (%)
Aluminum	37	43
Cadmium	63	66
Chromium	72	40
Copper	86	36
Iron	78	38
Lead	64	46
Manganese	55	129
Mercury	76	79
Silver	50	18
Zinc	62	118

Table 1-4. Interlaboratory Precision Ranges for Organic Chemical Analysis

Chemical	No. Labs	CV (%)	% Data Discarded*	EPA Document Referenced
Benzene 4 Chlorobenzenes Ethyl benzene Toluene	20	31-64	10	600/S4-84-064
23 Halocarbons	20	16-29	?	600/S4-84-064
4 Halocarbons	20	40-50	?	
11 Phenols	20	20-45	20	600/S4-84-044
		38-64	?	
Benzidine 3,3-Dichlorozidine	17	38-69	?	600/S4-84-062
6 Pthalate esthers	16	?	22	600/S4-84-056
3 Nitrosamines	17	?	19	600/S4-84-051
24 Organochlorine Pesticides and PCBs	22	>12-45	?	600/S4-84-061
16 PNAs	?	16-91	?	600/S4-84-063

* Discarded as outliers.
It is important to note that in many chemical analyses a decision may be made that certain anomalous data points, or outliers, are unusable and are not reported as valid data points. This type of data evaluation is made because in chemical analyses it is routine to repeat the analysis with the same sample and reference standard until an acceptable result is obtained.

Table 1-5. Interlaboratory Precision of Nonmetal Inorganic Analyses Over the Measurement Range [15]

No. Lab	*Parameter*	*CV (%) Range*
17	Alkalinity	4.9-14
>20	Residual chlorine	13-25
16	Ammonia nitrogen	15-58
6	Kjeldahl nitrogen, total	38-41
15	NO_3 nitrogen	17-61
6	Total P	25-40
58	BOD	15-33
58	COD	6.9-34
21	TOC	4.6-70

associated with organic chemical analyses. The CVs range from 12 percent to 91 percent. Table 1-5 demonstrates the interlaboratory precision of nonmetal inorganic analyses at the lower end of the measurement range. The CVs for this type of analyses range from 4.6 percent to 61 percent [15]. The data in Tables 1-3 to 1-5 reflect testing in reagent grade water. Actual CVs from testing effluents can be higher due to matrix effects. However, in 40 *CFR* Part 136 analytical methods, matrix effects are acknowledged.

1.3 WHOLE EFFLUENT APPROACH FOR AQUATIC LIFE PROTECTION

The whole effluent approach to toxics control for the protection of aquatic life involves the use of acute and chronic toxicity tests to measure the toxicity of wastewaters. Whole effluent toxicity is a useful parameter for assessing and protecting against impacts upon water quality and designated uses caused by the aggregate toxic effect of the discharge of pollutants [16]. Whole effluent toxicity tests employ the use of standardized, surrogate freshwater or marine (depending upon the mixture of effluent and receiving water) plants, invertebrates, and vertebrates. EPA has published extensive written protocols listing numerous marine and freshwater species for toxicity testing [17, 18, 19].

An acute toxicity test is defined as a test of 96-hours or less in duration in which lethality is the measured endpoint. A chronic toxicity test is defined as a long-term test in which sublethal effects, such as fertilization, growth, and reproduction, are usually measured, in addition to lethality. Traditionally, chronic tests are full life-cycle tests or a shortened test of about 30 days known as an early life stage test. However, the duration of most of the EPA chronic toxicity tests have been shortened to 7 days by focusing on the most sensitive life-cycle stages. For this reason the EPA chronic tests are called short-term chronic tests. Box 1-2 summarizes the short-term chronic tests currently recommended by EPA. The acute and short-term chronic methods recommended by EPA are presented in three methods manuals [17, 18, 19].

In a laboratory acute toxicity test, an effluent sample is collected, diluted, and placed in test chambers with the chosen test species. After 24, 48, 72, and 96 hours, the number of live organisms remaining in each test concentration and in a control is recorded. In a laboratory chronic toxicity test, an effluent sample is collected, diluted, and placed in test chambers. An example of a dilution series used in chronic or acute tests is 100, 50, 25, 12.5, and 6.25 percent, and a control. Test organisms are placed in these test chambers for specified periods of time. At various times during the exposure period, the organisms in each chamber are observed. In the short-term chronic tests, at test termination, the lowest effluent concentration that causes a significant adverse impact on the most sensitive endpoint for that test is calculated (this endpoint can be mortality, reduced fertilization, lower fecundity, reduced growth, etc.). In the acute tests, at test termination, the number of dead organisms are recorded and an LC_{50} is calculated.

Dilution water is an important part of toxicity testing. Dilution water may either be standard laboratory water and/or the receiving water. Sometimes the receiving water is used to dilute the effluent because it more closely simulates effluent/receiving water interactions. This may be especially important in the case of saline receiving waters. The salinity of the receiving water should be matched as closely as possible to the salinity in the test chambers (within the salinity range constraints of a particular method) for the purposes of conducting the tests.

Quality control and quality assurance are an integral part of whole effluent toxicity testing. Use of a standard control water and a reference toxicant test are both recommended to ensure quality assurance in chronic testing. It is important to understand that each of the chronic tests has minimum criteria of acceptability for each endpoint that is measured in the controls (i.e., 80 percent survival and minimum criteria for growth, reproduction, and fertilization). The acute tests also have criteria of acceptability measured in the controls.

Acute toxicity endpoints (ATEs) commonly include lethal concentrations (LCs) and are described in terms of effluent concentrations. The LC is the concentration of toxicant at which a certain percentage of the test organisms die, e.g., the LC_{10} or LC_{50}. An exposure duration also is included in the endpoint such as 24, 48, 72, or 96 hours (e.g., 96-hour LC_{50}).

Commonly used chronic toxicity endpoints (CTEs) include the no observed effect concentration (NOEC), the lowest observed effect concentration (LOEC), and the effect concentration (EC). The NOEC is the highest concentration of toxicant, in terms of percent effluent, to which the test organisms are exposed that causes no observable adverse effect. The effects measured may include decreases in reproduction and growth, or lethality. The LOEC is the lowest concentration of toxicant to which the test organisms are exposed that causes an observed effect. Again, the same effects are usually observed. The EC is the toxicant concentration that would cause an adverse effect upon a certain percentage of the test organisms, (e.g., EC_{10} or EC_{50}).

In chronic toxicity tests, the exposure duration in the EPA testing protocols is almost always assumed to be the 7-day short-term period unless otherwise specified in the protocol. For example, the *Ceriodaphnia* test must be continued until at least 60 percent

Box 1-2. Short-term Chronic Toxicity Methods

Species/Common Name	Test Duration	Test Endpoints
Freshwater Species		
Ceriodaphnia dubia Cladoceran	Approximately 7 days (until 60 percent of control have 3 broods)	Survival, reproduction
Pimephales promelas Fathead minnow	7 days	Larval growth, survival
Pimephales promelas Fathead minnow	7-9 days	Embryo-larval survival, percent hatch, percent abnormality
Selenastrum capricornutum Freshwater algae	96 hours	Growth
Marine/Estuarine Species		
Arbacia punctulata Sea urchin	1.5 hours	Fertilization
Champia parvula Red macroalgae	7-9 days	Cystocarp production (fertilization)
Mysidopsis bahia Mysid	7 days	Growth, survival, fecundity
Cyprinodon variegatus Sheepshead minnow	7 days	Larval growth, survival
Cyprinodon variegatus Sheepshead minnow	7-9 days	Embryo-larval survival, percent hatch, percent abnormality
Menidia beryllina Inland silverside	7 days	Larval growth, survival

of the females produce three broods. This may require more or less than 7 days to occur.

It is useful to note that LCs and ECs are point estimates statistically derived from a mathematical model that assumes a continuous dose-response relationship. NOECs and LOECs, statistically determined using hypothesis testing, are not point estimates [18]. In order to overcome the difficulty in statistically deriving the NOEC using hypothesis testing, a new statistical procedure has been developed. This procedure, referred to as the inhibition concentration (IC), is a point estimate interpolated from the actual effluent concentrations at which measured effects occurred during a chronic test. The IC is an estimate of the toxicant concentration that would cause a given percent reduction in a biological measurement of the test organisms, including reproduction, growth, fertilization, or mortality. For example, an IC_{25} for reproduction would represent the effluent concentration at which a 25-percent reduction in reproduction occurred.

Since the IC is a point estimate, a CV can be calculated. A CV cannot be calculated if hypothesis testing is used because results are only available for the effluent concentrations used. For this

reason, estimates of test precision cannot be calculated for NOECs derived by hypothesis testing.

The IC also is not dependent upon the selection of the effluent concentrations. In contrast, NOECs calculated by hypothesis testing are dependent upon the concentrations initially selected. For example, if a chronic test is conducted using 100, 50, 25, 12.5, and 6.25 percent effluent concentrations, and the LOEC exhibited by the data is at 25 percent effluent, the NOEC calculated by hypothesis testing is estimated to be the next lowest dilution, or 12.5 percent. However, the true NOEC value may lie somewhere between 25 percent and 12.5 percent effluent.

Comparisons of both types of data indicate that an NOEC derived using the IC_{25} is approximately the analogue of an NOEC derived using hypothesis testing (see Figure 1-1). For the above reasons, if possible, the IC_{25} is the preferred statistical method for determining the NOEC.

Another important issue in conducting both acute and short-term chronic toxicity tests is the dilution series. The EPA methods manuals recommend six dilutions, including the control. The only exception to this is a toxicity test conducted on ambient receiving waters. Then, each ambient receiving water is compared statistically to the control without dilutions. It is not accurate to assume that two dilutions (the receiving water concentration [RWC] and control) are all that are ultimately necessary for determining compliance with a toxicity limit. If the toxicity tests are conducted with only the control and one effluent concentration (i.e., the RWC), the error and variability associated with this type of statistical analysis is large [20].

For the above reasons, EPA recommends the use of five effluent concentrations and a control to determine the magnitude of toxicity. When conducting compliance monitoring, an option is to choose the five concentrations that bracket the RWC (two concentrations above and two below). This would result in the determination of compliance status as well as a statistically valid estimation of the NOEC. The information provided from the full dilution series would indicate how close the test endpoints are to the permit limit and how close to violating the limit the discharger is, and, if measured over time, the variability of the effluent.

1.3.1 Toxic Units

Since toxicity involves an inverse relationship to EC (the lower the EC, the higher the toxicity of the effluent), it is more understandable to translate concentration-based toxicity measurements into toxic units (TUs). In this way, the potential confusion involving the inverse relationship is overcome and the permit limit derivation process is better served. The number of toxic units in an effluent is defined as 100 divided by the EC measured:

$$TU_a = 100/LC_{50}$$

$$TU_c = 100/NOEC.$$

For example, an effluent with an acute toxicity of an LC_{50} in 5 percent effluent is an effluent containing 20 TU_as.

A very important aspect of toxic units is that two different types are used depending on whether acute or chronic aquatic toxicity is measured. The proper expressions for toxic units are TU_a and

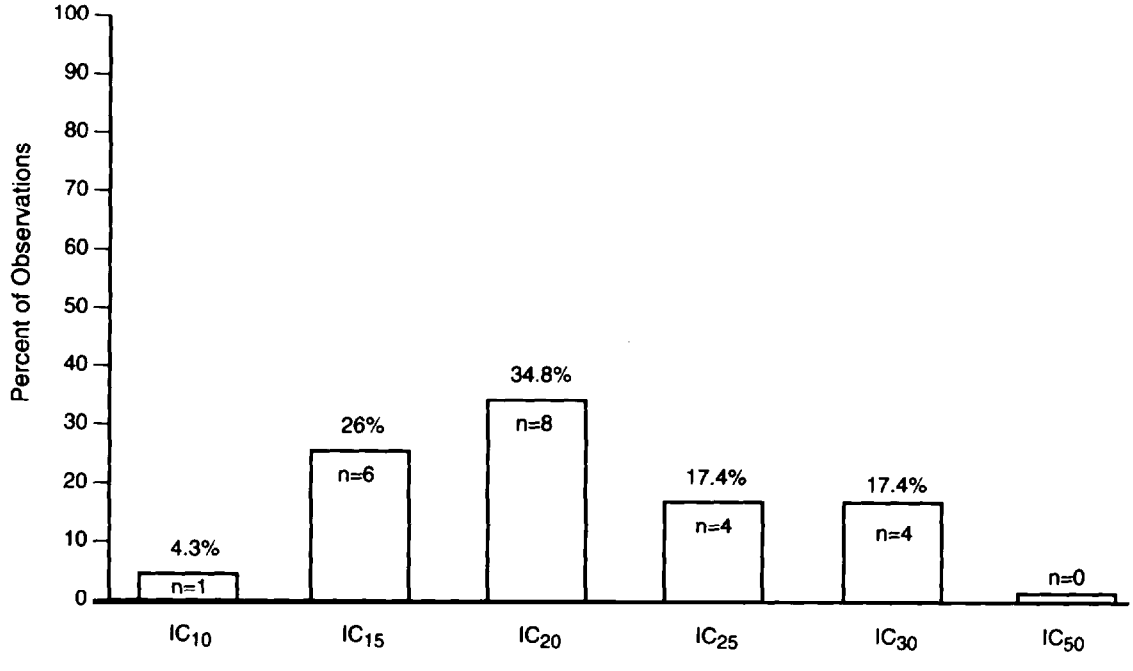


Figure 1-1. This figure represents the percentage of the time the mean NOEC was approximately equivalent to an IC_{10}, IC_{15}, IC_{20}, IC_{25}, IC_{30}, and IC_{50} for all 23 effluent and reference toxicant data sets analyzed. The data sets included short-term chronic toxicity test for *Ceriodaphnia dubia, Pimephales promelas* (fathead minnows), *Arbacia punctulata* (sea urchin), *Cyprinodon variegatus* (sheepshead minnows), and *Champia parvula* (red algae) [21].

TU_c. TU_a is the measurement of acute toxicity units and TU_c is a measurement of chronic toxicity units. (See the glossary for a definition of these terms.) They are not the same measurement and should not be used interchangeably. Acute and chronic TUs make it easy to quantify the toxicity of an effluent and to specify water quality criteria based upon toxicity. For example, an effluent sample that contains 20 TU_cs is twice as toxic as an effluent that contains 10 TU_cs.

1.3.2 Correlation of Whole Effluent Toxicity Measurements to Actual Receiving Water Impact

EPA conducted the Complex Effluent Toxicity Testing Program (CETTP) that examined sites in both freshwater and saltwater systems to investigate whether or not an evaluation of effluent toxicity, when adequately related to receiving water conditions (i.e., temperature, pH, salinity), can give a valid assessment of receiving system impacts on waters that support aquatic biota [22-25]. Summaries of these site studies are provided in Box 1-3 (freshwater) and Box 1-4 (saltwater). In addition, three other studies, presented in Box 1-3, were conducted to address this issue: a comparative investigation conducted by the University of Kentucky [26], a second study on the Trinity River in Texas conducted by the University of North Texas [27], and a third study conducted by the North Carolina Division of Environmental Management [28].

It is important to note that in these studies, different objectives were addressed. The CETTP freshwater studies attempted to correlate receiving water chronic toxicity measured by EPA toxicity tests to instream observed impacts (Figure 1-2). The CETTP saltwater studies compared effluent toxicity to ambient receiving water toxicity using dye studies to measure receiving water concentrations of effluent. The North Carolina study compared effluent toxicity to receiving water impact using *Ceriodaphnia* chronic toxicity tests and receiving stream benthic macroinvertebrates (Figure 1-3). The Kentucky study examined the relationship between effluent toxicity tests and instream ecological parameters. The Trinity River study attempted to spatially compare the biological, physical, and chemical water quality and sediment quality of Trinity River reaches above and below the Dallas/Fort Worth area (Figure 1-4).

Together, these studies comprise a large data base specifically collected to determine the validity of toxicity tests to predict receiving water community impact. In order to address the correlation of effluent and ambient toxicity tests to receiving water impacts, EPA evaluated the results of the studies discussed above [29]. The results, when linked together, clearly show that if toxicity is present after considering dilution, impact will also be present.

Parkhurst et al., were requested by representatives of industrial and municipal discharges to critique the CETTP studies [30]. One major criticism was that the EPA study sites were not selected randomly and therefore the results of the studies cannot be extended to all waters. EPA agrees that the CETTP sites were not selected to represent a statistically valid sampling of all types of waterbodies in the United States. A representative sampling of receiving water would require assessment of more sites than EPA could study in a comprehensive manner. Such a sampling was beyond the capability of EPA's resources. However, the CETTP and corresponding studies such as the Trinity River study [27] did show unequivocally that a strong correlation exists between toxicity and a biological impact.

EPA believes that it is reasonable to assume in the absence of data showing otherwise that this relationship is basically independent

Box 1-3. Correlation of Toxicity Measurements to Receiving Water Impact (Freshwater)

EPA conducted eight freshwater site studies in which ambient toxicity was compared to the receiving water biological impact. These site studies were a part of the Complex Effluent Toxicity Testing Program (CETTP). Testing was done onsite concurrent with the field surveys. Sites exhibiting biological impacts in Oklahoma, Alabama, Maryland, West Virginia, Ohio, and Connecticut were included. Organisms were exposed to samples of water from various stations and tested for toxicity. Biological surveys (quantitative field sampling of fish, invertebrate, zooplankton, and periphyton communities in the receiving water areas upstream and downstream of the discharge points) were made at these stations at the same time the toxicity was tested to see how well the measured toxicity correlated to the health of the community. These studies have been reviewed and published in the EPA publication series [23, 31-38].

Figure 1-2 illustrates the data from the CETTP studies. A robust canonical correlation analysis was performed to determine whether or not statistically significant relationships existed between the ambient toxicity tests and instream biological response variables and to identify which variables played an important role in that relationship [29]. Influential variables were then used to classify stations as either impacted or not. *Ceriodaphnia dubia* productivity and/or *Pimephales promelas* weight were used as the basis for predicting impact. Fish richness was used to classify streams as impact observed or impact not observed.

Box 1-3. Correlation of Toxicity Measurements to Receiving Water Impact (Freshwater) (continued)

Classification was based on the relative performance of the stations on each stream in the study. Percentiles of the appropriate distribution (normal for toxicity variables, and Poisson for fish richness) were used to set cutoffs for classification. Two-way contingency tables representing stations as impact predicted or not, and impact observed or not were prepared from a variety of cutoffs (percentages). The exact test for independence was performed on each contingency table.

If toxicity test results were used to classify sites as impacted or not (predicted classification) and if a strong relationship does exist between ambient toxicity and biological response, then the classification of stations according to biological response should closely match the predicted classification. Hence, the errors in misclassification should be small.

Figure 1-2, developed using a 95 percent-95 percent cutoff, shows that false positives (impact predicted but none found) occurred at 7.5 percent of the 80 stations. The probability of getting no more than 7.5 percent false positives under the null hypothesis that there is no relationship between ambient toxicity and biological response is less than $p=0.001$. As discussed above, this is the only definitive error that can be identified in such comparisons. The correct or noncontradictory findings (no measured toxicity but observed impacts) were 92.5 percent of the stations. A variety of other cutoff criteria combinations were evaluated and the number of false positives remained in the 7 percent to 8 percent range. Therefore, a discharger's chance of being charged incorrectly with causing instream toxicity is low if and only if dilution in the receiving water is considered.

A comparative time series study conducted on the Trinity River in Texas that used the same classification method as the CETTP studies also showed a strong relationship between ambient toxicity and instream biological response (Figure 1-2). False positives (impact predicted but not observed) had a frequency of 8.3 percent. Overall there was a 91.7-percent accuracy of prediction or noncontradictory findings [29], and the probability of a false positive (impact predicted but not observed/impact predicted) ranged from 8 percent to 11 percent in these studies.

Another study conducted by the North Carolina Division of Environmental Management indicated the high accuracy of predicting receiving water impacts from whole effluent toxicity tests. Forty-three comparisons were made between freshwater flowing streams using the *Ceriodaphnia dubia* chronic test and a qualitative macroinvertebrate sampling. Overall there was 88 percent accuracy of prediction (Figure 1-3) [28].

In addition, another comparative study was conducted in the Kentucky River Basin [26]. This study consisted of a comparative ecological and toxicological investigation of a secondary wastewater treatment plant and measured instream effects at 10 stations including reference sites. The principal objective of the study was to assess downstream persistence of aquatic contaminants, to quantify their effects on structure and function of aquatic communities, and to evaluate the fathead minnow embryo-larval test for measuring instream toxicity and estimating chronic effects on aquatic biota. The results of the study indicate a good predictive correlation between embryo-larval survival and independent ecological parameters, especially species richness of macroinvertebrates. The correlation coefficients for species richness and embryo-larval survival was 0.96, and for embryo-larval survival and diversity, it was 0.93. The estimated toxicity (LC_1) correlated closely with the actual percent instream effluent dilution observed at the first downstream station at which no ecological impact was discernable.

Using the statistical classification previously described in the CETTP and Trinity River studies, an analysis was conducted on the combined data sets of the CETTP, Trinity River, and Kentucky River Basin data. Because the North Carolina study was based on the *Ceriodaphnia dubia* chronic test and a qualitative macroinvertebrate sampling, the data were not amenable to this type of statistical analysis. This combined analysis is illustrated in Figure 1-5. The probability of getting no more than 9.4 percent false positives (impact predicted/impact not observed) when the null hypothesis (no relationship between ambient toxicity and biological response) is less than $p=0.0028$.

Box 1-4. Correlation of Effluent Toxicity Measurements to Receiving Water Toxicity (Saltwater)

In saltwater systems, as in freshwater systems, receiving water impact should only be seen where receiving water waste concentrations are at or above the effect concentrations. Dilution in marine and estuarine systems may be greater due to large and/or complex mixing than most freshwater systems. As a result, there is a less likely chance for receiving water impacts to be observed in saltwater systems as predicted by toxicity tests.

Figure 1-6 illustrates the comparison between predictions of saltwater receiving water toxicity and whole effluent toxicity. Toxicity test data from 79 ambient stations (four study sites) were compared to effluent toxicity test results from an isolated discharge at each site. All receiving water toxicity to effluent toxicity correlations are based on dye studies conducted at each of the four sites to determine the actual dilution.

Most of the sites were selected because the discharge was isolated from other point sources and potential impacts from other point sources was anticipated to be negligible. Two of these studies indicated near-field effects, generally within the mixing zone. One study conducted at Fernandina Beach, Florida [25], showed impacts outside the proposed mixing zone. Results of another study (East Greenwich) indicated the existence of poor water quality well beyond the influence of the East Greenwich Sewage Treatment Plant and suggests that other sources (point or nonpoint) may contribute significantly [25, 39, 40]. This condition may be typical in some of the more stressed estuaries.

In a total of 79 comparisons, 11 out of 15 (73 percent) of the receiving water samples predicted to be toxic were toxic. This constitutes 14 percent of the total comparisons. Toxicity was not predicted in the receiving water and toxicity was not seen in the receiving water 59 out of 64 times (92 percent). This constitutes 75 percent of the total comparisons.

In 5 percent of the total comparisons there was a false negative prediction, or the toxicity tests predicted no toxicity when the receiving water was toxic [24]. As previously discussed, toxicity is only one possible adverse influence. Since only toxicity is measured, a very high correlation should not be expected necessarily because receiving water biological impacts may be attributed to other sources or factors.

The results of the studies at these four sites indicates a 94 percent accuracy when using the marine and estuarine toxicity tests to predict receiving water impacts. In only 6 percent of the cases did effluent toxicity tests predict receiving water toxicity that was not present (false positive).

of waterbody type. Also, this was not the objective of the CETTP studies. The CETTP purpose was to determine if toxicity and impacts to biological communities are found concurrently in receiving waters. Therefore, EPA disagrees that this is a reason to conclude that the CETTP studies failed to show the validity of toxicity tests to predict water quality impact.

Another criticism was the studies did not investigate replication of results over time. However, toxicity results cannot be expected to be replicated over time in waters where river flow and other time-variant factors change the degree of ambient toxicity. Indeed, the Kanawa River and Five-Mile Creek data showed that ambient toxicity did not occur at high river flows whereas it was found at low flows; this was an expected result. The objective of the CETTP studies was to see if impact was present when effluent toxicity exceeds the available effluent dilution. This objective was achieved by the studies.

Another major criticism was the correlation between toxicity tests and biological impact relied extensively upon maximum impact responses and that correlation was poor when data from high flow events and lesser toxicity discharges (minimal impact responses) were added. EPA acknowledges that impact correlations will be higher where higher toxic impact occurs and lower where impacts are expected to be minimal. Such a response is expected given the complexity of ecosystems and that biological communities and species have different sensitivities to toxicants and may respond differently. Also, higher river dilution will reduce the potential instream impact from effluent toxicity. However, this observation does not disprove that the CETTP and other studies showed a statistically sound relationship to correlate toxicity to the existence of a biological ambient impact. Therefore, EPA still concludes that control of toxicity is a valid approach for protecting ambient water quality.

In addition, other studies confirm that effluent toxicity, when adequately related to ambient conditions, can give a valid assess-

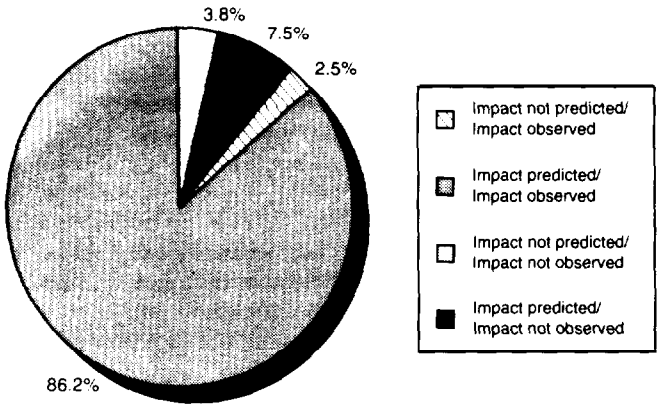


Figure 1-2. Comparison of Ambient Toxicity and Instream Impact—EPA Study [23, 31-38]

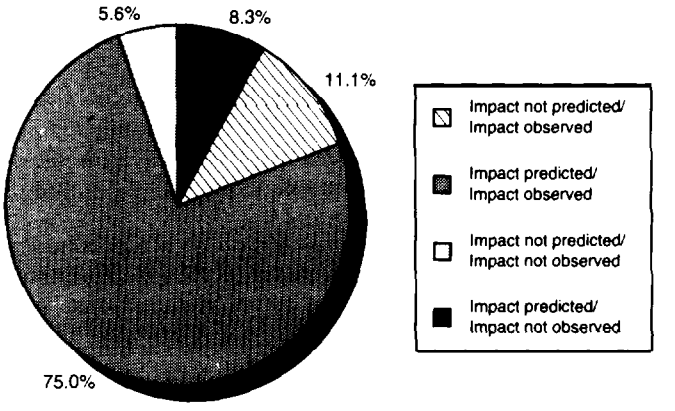


Figure 1-4. Comparison of Ambient Toxicity and Instream Impact—Trinity River [29]

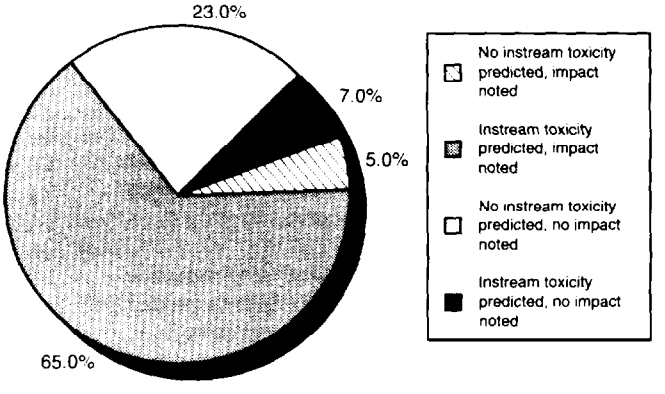


Figure 1-3. Comparison of Effluent Toxicity of Receiving Water Impact Using *Ceriodaphnia* Chronic Toxicity Tests and Freshwater Receiving Stream Benthic Invertabrates at 43 Point Source Discharging Sites in North Carolina [28]

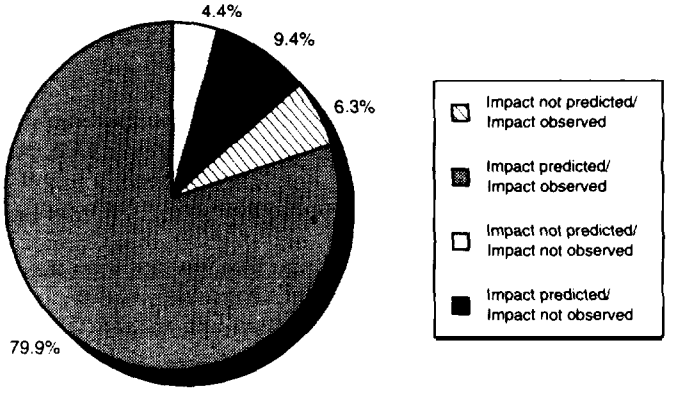


Figure 1-5. Comparison of Ambient Toxicity and Instream Impact—EPA Study, Trinity River Study, and Kentucky Study [26]

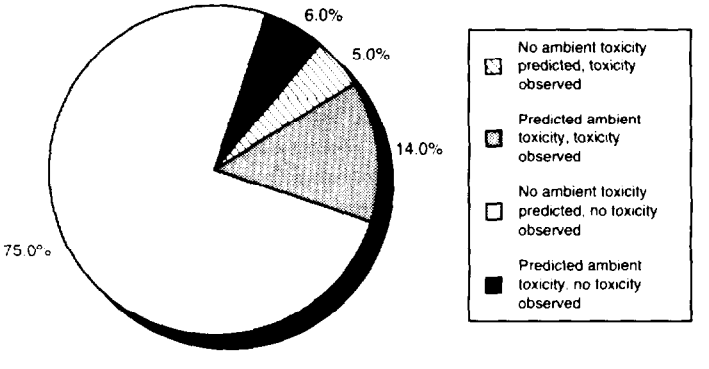


Figure 1-6. Comparison of Predictions of Receiving Water Toxicity Based on Effluent Toxicity and Ambient Receiving Water Testing in Saltwater Environments: 79 Ambient Stations and 4 Dischargers [24, 25, 39, 40]

ment of receiving water impact [3, 24, 26-29, 39, 41]. These studies tested waters other than those studied under CETTP.

It is important to recognize that toxicity caused by contaminants in the effluent, as measured by the whole effluent toxicity tests, is only one of many influences that determine the health of a biological community. **Impact from toxics would only be suspected where effluent concentrations after dilution are at or above the toxicity effect concentrations.** Influences from substrate differences and physical conditions, such as dissolved oxygen, temperature, channelization, flooding and weather cycles, also can affect the biological community adversely. These other types of influences may be better evaluated by using a bioassessment approach. However, the existence of these other factors concurrently with toxicity does not absolve a regulatory authority from controlling the discharge of toxicity if the State has established a designated use to protect aquatic biota.

The value of the toxicity test is its ability to assess the impact of discharged toxicants independent of effects from other factors. This allows regulatory authorities specifically to identify and control the portion of the impact caused by the discharge. Biological, physical, and chemical factors of the community can influence the actual effects that effluent toxicity may cause in the receiving water, and further emphasize the need for a totally integrated water quality-based approach.

1.3.3 Toxicity Test Method Precision

Like all measurements, toxicity tests exhibit variability. Toxicity test variability can be described in terms of two types of precision—"within" or intralaboratory precision, and round robin or interlaboratory precision. Intralaboratory precision is the ability of trained laboratory personnel to obtain consistent results repeatedly when performing the same test on the same species using the same toxicant. Interlaboratory precision (or round robin tests) is a measure of how reproducible a method is when conducted by a large number of laboratories using the same method, species, and toxicant or effluent. Generally, intralaboratory results are less variable than interlaboratory results.

EPA believes that several toxicity test methods have a precision profile that can be reasonable to evaluate compliance with NPDES permits. The appropriateness of a given method can be determined in a permit proceeding or, in part, by rulemaking. EPA has proposed a range of whole effluent toxicity test procedures in 40 *CFR* 136 and may promulgate these methods soon. Current data, however, show that the precision profiles of a number of whole effluent toxicity tests is similar to already approved chemical-specific methods.

Research into the precision of whole effluent toxicity methods by various groups (including EPA) has shown that toxicity test procedures exhibit variability [17-18, 19, 42-49]. In chronic toxicity tests, variability is measured close to the limit of detection because the endpoint of the test is already at the lower end of the biological method detection range (i.e., an NOEC). This is in contrast to acute toxicity tests where the test endpoint is normally calculated at midrange (i.e., LC_{50}), but is sometimes calculated at the lower end of the biological detection range (i.e., LC_1). CVs cannot be calculated for NOEC endpoints determined using an analysis of variance (hypothesis testing) because this procedure does not produce a statistical point estimate. However, CVs can be calculated for NOECs if they are determined using the IC statistical procedure, and for EC and LC endpoints because they are all statistical point estimates.

To facilitate the comparability between different NOEC calculations using the IC_{25} and the analysis of variance (hypothesis testing), Appendices A-1 and A-2 list NOEC results in terms of both. In some instances the IC_{25} could not be calculated based on statistical assumptions and available data. In addition, there are some instances where an IC_{25} cannot be calculated because there was no toxic effect. In these cases, the CV for a method and reference toxicant was calculated using only data where IC_{25}s could be calculated.

A more detailed discussion of precision can be found in Box 1-5. Tables 1-6 and 1-7 summarize the intralaboratory precision for all 10 EPA short-term chronic whole effluent toxicity tests and some acute toxicity tests. In addition, Table 1-8 summarizes the interlaboratory precision for three chronic test species and two acute test species using a variety of different compounds.

In summary, whole effluent toxicity testing methods can represent practical tests that estimate potential receiving water impacts. Permit limits that are developed correctly from whole effluent toxicity tests should protect aquatic biota if the discharged effluent meets the limits. It is important not to confuse permit limit variability with toxicity test variability. Chapter 5 discusses permit limit variability.

1.3.4 Considerations Involved When Implementing the Whole Effluent Toxicity Approach

An understanding of some basic considerations and toxicological principles is important in order to apply routinely the whole effluent approach to the assessment and control of municipal and industrial effluents. The following sections provide a more indepth discussion of each of these factors and principles. (Chapters 3 and 5 discuss specific details for characterizing an effluent and deriving permit limits.)

Onsite versus Offsite Toxicity Testing

Comparisons of toxicity data between tests conducted onsite and tests conducted offsite on samples shipped to Environmental Research Laboratory (ERL)-Duluth and (ERL)-Narragansett via airfreight have, with a few exceptions, shown little variation. For many effluents, onsite or offsite test data do not appear to be significantly different. The major consideration is cost. Cost also should be weighed against data needs to make the onsite/offsite determination.

For example, if the presence in the effluent of nonpersistent compounds (i.e., chlorine or other volatiles) is suspected or known, then the regulatory authority may want to conduct onsite testing. If it is not considered important to the analysis of toxic impact, offsite testing is as acceptable as onsite testing. In general, offsite testing would be acceptable for most effluents except those with volatiles. When conducting flow-through toxicity tests which require a continuously pumped sample, onsite testing is strongly recommended. Regardless, cost considerations should not over-

Box 1-5. Toxicity Test Method Precision

Precision can be described by the mean and relative standard deviation (percent coefficient of variation, or CV=standard deviation/mean x 100) of the calculated endpoints from the replicated toxicity tests. Several factors can affect the precision of the test, including test organism age, condition, sensitivity, temperature control, salinity, pH control, handling and feeding of the test organisms, and the training of laboratory personnel. For these reasons, it is recommended that trained laboratory personnel carefully conduct the tests in strict accordance with the test manuals for acute and chronic toxicity testing. In addition, acute and chronic toxicity testing quality assurance practices should be fully performed. Simple quality assurance procedures, which are described at the beginning of each manual, include:

- Single laboratory precision determinations, using reference toxicants, on each of the tests procedures to determine the ability of the laboratory personnel to obtain consistent, precise results. These determinations should be made before attempting to measure effluent toxicity, and routinely confirmed as long as routine whole effluent toxicity tests are being conducted.
- Use of reference toxicants to routinely evaluate the quality and sensitivity of the test organisms to be used in each test.
- Development of "control charts" should be prepared for each reference toxicant/organism/protocol combination to determine if the results are within prescribed limits. The control chart consists of successive data added with each reference toxicant test, and is the basis for evaluating data once the control chart" is established.
- The minimum criteria of test acceptability specific for each protocol.

Guidelines for recommended quality assurance practices are found in each manual [17, 18, 19].

Within-laboratory precision data are routinely calculated on a minimum of two reference toxicants as part of the EPA methods development process. These data have been established for each of the four EPA freshwater chronic methods and each of the six marine/estuarine chronic methods. Within-laboratory precision is detailed at the end of each of the methods sections in the methods manuals [17, 18, 19] and is summarized in Appendix A (Tables A-1-1 to A-1-18 for the marine/estuarine methods and Tables A-1-19 to A-1-31 for the freshwater methods) and summarized in Tables 1-6 and 1-7. Intralaboratory precision data also are presented for acute toxicity tests and are summarized in Table 1-8. Each laboratory should be establishing a reference toxicant "record," including a control chart. EPA's reference toxicant numbers are only meant to show precision of the methods within EPA laboratories and to serve as guidance for other laboratories. Each laboratory's reference toxicant data will reflect conditions unique to that facility, including dilution water, culturing, etc. However, each laboratory's reference toxicant CVs should reflect good repeatability.

The CVs may be calculated for acute LC_{50} and chronic EC_{50}, IC_{25}, and IC_{50} data. A mean and range is given for the chronic no observed effect concentration (NOEC) precision data because an NOEC is not a point estimate and is dependent on the tightness of the concentration interval employed in the reference toxicant tests (i.e., the closer the NOEC concentration range the more precise the test is for the reference toxicant). The closer the CV is to zero, the better. However, CVs should only be compared with the same test protocol/species tested against the same reference toxicant. Estimates of variability (CVs) should only be applied for specific protocols against a specific chemical using the same concentration intervals.

Reference toxicant data should be required for each of the methods stipulated by the permit authority as part of routine quality assurance/quality control (QA/QC) for checking the reliability of the tests conducted by the permittees. In addition, Criteria of Acceptability for each of the 10 chronic methods are listed in the methods manuals, and should be used as a check for whether the compliance data submitted is minimally acceptable [18, 19]. (See Table 1 of each of the 4 freshwater methods and Table 2 of each of the 10 marine/estuarine methods entitled, "Summary of Recommended Effluent Toxicity Test Conditions.")

To date, interlaboratory precision (round robin) tests have been completed for the 7-day **Fathead Minnow Larval Survival and Growth Test, the Cladoceran, *Ceriodaphnia* Survival and Reproduction Test, and the Sheepshead Minnow Larval Survival and Growth Test.** The results of these round robin studies show good reproducibility for these three methods. Results of the round robin testing will show greater variability (i.e., larger CVs) due to a larger number of variables introduced by many round robin laboratories participating. Researchers

Box 1-5. Toxicity Test Method Precision (continued)

have found that a two- to threefold increase in CV values is acceptable with biological testing [46, 50, 51]. Interlaboratory data also are presented from several acute toxicity tests [46]. The data from these round robin tests can be found in Appendix A (Tables A-1-5, A-1-23, A-1-24, A-1-27, A-1-28, and A-1-30) and are summarized in Table 1-8.

Researchers agree that the precision of these tests is acceptable. Rue, Fava, and Grothe concluded that whole effluent toxicity test methods "are comparable to accepted analytical methodologies" [50]. Another study by Grothe, Kimerle, and Malloch also concluded that when comparing "...CVs for select effluent toxicity test methods and commonly accepted analytical methods...the precision of both techniques is similar" [51]. This has led the Agency to conclude "...that toxicity test methods, where properly followed, exhibit an acceptable range of variability" (see the discussion of toxicity testing requirements for POTWs, 55 *FR* 30082 at 30112, July 24, 1990) [52].

ride the need to characterize adequately a given effluent and the factors unique to the discharge situation.

Flow-through versus Static and Renewal Toxicity Testing

Several factors should be considered in making the choice of toxicity test system. These include the type of toxicity being measured (i.e., is the effluent highly variable or not; is the discharge continuous or intermittent?); the amount of data needed (variable effluents may require more data); and, as between different systems that will provide adequate data, expense.

Two basic types of testing systems are available to measure effluent toxicity: flow-through systems and static systems. A flow-through toxicity test is conducted using a diluter system and a continuous feed of effluent and dilution water. A static toxicity test is conducted in test chambers (without a serial diluter delivery system) into which effluent and diluent are added manually. Usually, only one effluent sample is collected and used at the beginning of a static test. A variation of the static procedure is the renewal toxicity test. This test uses the same delivery system as that of a static test but the test solutions are changed, or renewed, on a predetermined schedule (i.e., every 24 hours). Fresh effluent samples generally are collected to renew the test solutions.

Online continuous flow-through testing can sample and measure "peaks" of toxicity should they occur during the testing period. In variable effluents, however, the test organisms would only be exposed to peak toxicity for periods proportional to the flow-through rate, the duration of the peak in toxicity and length of the test. Static and static renewal tests also can measure peaks in effluent toxicity depending on the type of sampling used, and if the sampling occurs at the time of the toxicity peak.

If the effluent is highly variable and continuously discharged, either a flow-through or renewal test would be appropriate. If the effluent is highly variable with an intermittent discharge, a flow-through or a renewal test also would be appropriate. However, the effluent sample collected for the renewal test should be a composite collected over the period of the discharge. If the effluent is not considered variable, such as a discharge from a 30-day retention basin, then a static or renewal test using a grab or 24-hour composite sample would be an appropriate test system. For a chronic toxicity test, a 24-hour composite effluent sample is most appropriate. For an acute test, four grab samples taken 6 hours apart or four 6-hour composite samples are most appropriate to measure the peaks of toxicity in an effluent.

Cost also is a factor. Flow-through tests are more resource intensive and require complex delivery systems. Consequently, less data can be generated per unit cost than with static or renewal testing. Where more data at less cost are desirable, static or renewal testing probably is more appropriate. Typically, more samples using renewal is preferable to fewer samples using flow-through for the same total cost since this would allow better characterization of effluent variability.

Grab Sampling versus Composite Sampling

The use of a grab sample or a composite sample is based upon the objectives of the test and an understanding of the long-term operations and schedules of the discharger. If the toxicity of the effluent is variable, grab samples collected during the peaks of effluent toxicity provide a measure of maximum toxic effect. Collection of grab samples may be necessary if there is little dispersion or mixing of the effluent in the receiving water. In these instances the peaks could persist in the receiving water. Although a grab sample has the potential of revealing the toxicity peak in an effluent, the sample has to be collected at the time of the toxicity spike. Therefore, in a variable effluent, the grab sample has a high probability of missing the toxicity peak. On the other hand, a 24-hour composite sample may more readily catch the toxicity peak(s), but the compositing process may tend to dilute the toxicity resulting in a misleading measure of the maximum toxicity of the effluent. Composited samples are, therefore, more appropriate for chronic tests where peak toxicity of short duration is of lesser concern. More detailed discussions of the type of toxicity tests and the best sampling methods are provided in the manuals for the acute and chronic, freshwater and marine toxicity testing procedures [17, 18, 19] and in Chapter 3.

Variability

There are three important sources of differences in a water quality impact analysis:

Table 1-6. Intralaboratory Precision of Chronic Whole Effluent Toxicity Test Methods

Test Method	NOEC Range	Mean IC_{25}	CV(%)	Mean IC_{50}	CV(%)	Compound	Water Used
Cyprinodon variegatus—Survival and Growth							
	>0.05 - 0.05 mg/l	0.07	41.8	0.13	40.8	Copper	AS
	0.5 - 1.0 mg/l[1]	1.5	31.4	1.9	31.8	SDS[3]	AS
	31 - 125 ug/l[2]	300.4	33.0	396.9	19.2	Copper	NS
	1.3 - 2.5 mg/l[1]	2.2	27.6	2.6	35.3	SDS	NS
Embryo larval survival and teratogenicity							
		EC_{10}		EC_{50}			
	200 - 240 ug/l[2]	202	2.8	233.5	2.5	Copper	AS
	2.0 - 4.0 mg/l[1]	1.9	35	11.7	2.9	SDS	AS
Menidia beryllina — Survival and Growth							
	31 - 125 ug/l[2]	209.9	43.7	340.8	50.7	Copper	NS
	1.3 + 0 mg/l	1.3	43.2	1.9	9.4	SDS	NS
Mysidopsis bahia —Survival, Growth, and Fecundity							
	<0.3 - 5.0 mg/l[4]	5.7	35.0	6.9	47.8	SDS	NS
	63 - 125 ug/l[1]	138.3	18.0	185.8	5.8	Copper	NS
Arbacia punctulata —Fertilization							
	5.0 - 12.5 ug/l[1]	23.5	54.6	45.7	47.9	Copper	AS
	1.2 - 3.3 mg/l[1]	1.7	29.7	2.4	23.3	SDS	AS
	<6.1 - 24.4 ug/l[2]	22.9	41.9	29.9	48.2	Copper	NS
	0.9 - 1.8 mg/l[1]	2.58	28.7	3.2	33.3	SDS	NS
Champia parvula— Reproduction							
	0.5 - 1.0 ug/l[1]	1.79	61.09	3.35	34.5	Copper	NS
	0.5 - 1.0 ug/l[1]	0.93	63	1.4	38.6	Copper	AS/NS
	0.09 - 0.48 mg/l[2]	0.31	69.0	0.36	37.0	SDS	AS/NS
	0.15 - 0.60 mg/l[2]	0.46	62.3	0.75	22.92	SDS	NS
Pimephales promelas— Survival & Growth							
	128 - 256 ug/l[1]	—[5]	—	—[5]	—	NAPCP[6]	FW
	0.011 - 0.013 mg/l[1]	—[5]	—	—[5]	—	Cadmium	FW
Embryo larval survival and teratogenicity				LC_1			
	0.011 - 0.013 mg/l	—	—	0.0068	62	Cadmium	FW
	0.011 - 0.013 mg/l	—	—	1.51	41.3	Diquat	FW
Ceriodaphnia dubia — Reproduction							
	0.10 - 0.30 mg/l[1]	0.22	41.13	0.3	27.9	NAPCP	FW
	0.25 - 1.00 mg/l	0.91	20.5	1.24	15.2	Sodium Chloride	
Selenastrum capricornutum — 96-hour Survival				LC_{50}			
	2.1 - 2.8 g/l[4]	—	—	2.4	10.2	Sodium chloride	FW

[1]Difference of one test concentration.
[2]Difference of two test concentrations.
[3]Sodium dodecyl sulfate.
[4]Difference of four test concentrations.
[5]Raw data were unavailable, so IC_{25} and IC_{50} could not be calculated.
[6]Sodium pentachlorophenol.

AS—artificial seawater.
NS—natural seawater.
FW—freshwater.
—: Data not available.
Note: Data used in this table are found in Appendix A-1.

Table 1-7. Intralaboratory Precision of Acute Whole Effluent Toxicity Test Methods

	N (number of tests)	CV(%)	Compound
*Pimephales promelas**	12	40	NAPCP
(96-hour)	9	22	SDS
	9	86	Cadmium
*Daphnia pulex**	14	36	NAPCP
(48-hour)	10	43	SDS
	9	21	Cadmium
*Daphnia magna**	13	10	NAPCP
(48-hour)	8	29	SDS
	8	72	Cadmium

*Data taken from Draft 1990 Acute Manual.

Table 1-8. Summary of Interlaboratory Variability Data for Whole Effluent Toxicity Test Methods [17, 18, 19, 46]

Test Method	NOEC Range	IC_{25} CV(%)[1]
Chronic		
1. *Cyprinodon variegatus* 7-day growth and survival	1 - 3.2% effluent[2]	44.2
2. *Pimephales promelas* 7-day growth and survival	<3.0 - 6.0 mg/l[2] potassium chromate	31.0
3. *Ceriodaphnia dubia* 7-day reproduction	0.25 - 0.30 mg/l NAPCP[3]	41.1
4. *Ceriodaphnia dubia* 7-day reproduction	6 - 12% effluent[2]	—
5. *Ceriodaphnia dubia* 7-day reproduction	<0.25 - 1.0 mg/l sodium chloride	29.0
6. *Ceriodaphnia dubia* 7-day reproduction	0.25-1.0 mg/l sodium chloride	20.5

Acute	Toxicant	LC_{50} CV(%)
7. *Cyprinodon variegatus*		
96-hour static	endosulfan	37.7
96-hour flow-through	endosulfan	46.2
96-hour static	silver nitrate	34.6
96-hour flow-through	silver nitrate	50.1
8. *Mysidopsis bahia*		
96-hour static	endosulfan	59.5
96-hour flow-through	endosulfan	51.9
96-hour static	silver nitrate	26.6
96-hour flow-through	silver nitrate	22.3

[1]CV—coefficient of variation.
[2]This represents a difference of one exposure concentration.
[3]NAPCP—Sodium pentachlorophenol.
—: Data unavailable.
Note: Data summarized in this table were taken from Appendix A-1.

- **Effluent variability** is caused by changes in the composition of the effluent. Virtually all effluents vary in composition over time.

- **Exposure variability** is caused by changes in flow rates of both effluent and receiving water. There also are variable receiving water parameters that may be independent of flow, such as background toxicant levels, pH, salinity, tides, suspended solids, hardness, dissolved oxygen, and temperature, that can be important in assessing impact.

- **Species sensitivity** differences are caused by the differences in response to toxicants between species.

Each type of variability is discussed below.

Effluent Variability

Effluent variability is an important component in overall variability of water quality impact analyses and should be addressed adequately in permitting (see Chapter 5, Permit Requirements). Effluent variability can be addressed by designing proper sampling and testing procedures. Sampling measurements should be tailored to the toxic effect of concern (i.e., acute or chronic) and the need to design testing that accounts for effluent variability. Chapter 3, Effluent Characterization, describes recommendations for a testing frequency designed to assess variable effluents. Appendix F details suggested sampling procedures.

Appendix A-2 demonstrates the types of effluent variability that may be seen in publicly owned treatment works (POTW) effluents as measured through toxicity testing of the effluents (see Appendix A-2, Tables A-2-1 to A-2-9). The CVs (effluent variability) for POTW effluents are based on acute LC_{50} data that range from 19.6 percent to 42 percent effluent, and for IC_{25} chronic data that range from 52.8 percent to 101.3 percent. Also in Appendix A-2, Tables A-2-10 to A-2-12 show acute and short-term chronic effluent variability data from oil refineries on three species, fathead minnows, *Ceriodaphnia*, and mysids. The CVs associated with this effluent variability data range from 18.7 percent to 54 percent for the acute LC_{50} data, and from 29.8 percent to 59.6 percent for the chronic NOEC data. Data on effluent variability in various types of manufacturing facilities are in Appendix A-2, Tables A-2-13 to A-2-18. Acute toxicity test results show CVs for effluent variability ranging from 20.3 percent to >53.9 percent.

Tables A-2-6 to A-2-9 in Appendix A-2 illustrate the effluent variability of a POTW effluent over the course of a year in which gradual upgrading to full secondary treatment was occurring. Four saltwater short-term chronic toxicity tests were conducted on the POTW's effluent using the sea urchin fertilization test (*Arbacia punctulata*), the red macroalga fertilization test (*Champia parvula*), the mysid 7-day growth, fecundity and survival test (*Mysidopsis bahia*), and the inland silverside 7-day larval growth and survival test (*Menidia beryllina*). The sea urchin and red macroalga tests were conducted daily during each of the four 7-day studies, and provide good examples of the daily variability of the effluent.

These results show that the effluents vary in toxicity and that any one effluent can exhibit significantly varying toxicity to different test species over time. The data also indicate that the effluents were rarely toxic below 10 percent effect concentration and were not toxic below 0.1 percent effect concentration. This information is discussed in Chapter 3, Recommendations for Testing the Toxicity of Effluents section.

Exposure Variability

Exposure variability is a complex factor that can be addressed in two ways. First, the simplest, easiest applied approach is to assume a steady state exposure condition (usually an estimate of presumed "worst case" exposure) using a critical receiving water flow or condition and a typical effluent flow.

A second method is to attempt to estimate or actually measure the variable exposure situation at the discharge site. This requires statistical analysis and some form of dynamic modeling. Chapter 4, Exposure and Wasteload Allocation, describes appropriate exposure assessment procedures for freshwater and saltwater systems.

Species Sensitivity Differences

One of the primary considerations in establishing a toxicity testing requirement for a discharger is requiring a suitable test species. Different species exhibit different sensitivities to toxicants. Often, differences of several orders of magnitude exist for a given individual toxicant between the least sensitive and the most sensitive species. This range varies greatly and can be narrow or wide depending on the individual toxicant involved.

Since the measured toxicity of an effluent will be caused by unknown toxic constituents, the relative sensitivities of various test species also will be unknown. Therefore, proper effluent toxicity analysis requires an assessment of a range of sensitivities of different test species to that effluent. A knowledge of the range is necessary so that the regulatory authority can protect aquatic organisms. The only way to assess the range of sensitivities is to test a number of different species from different taxonomic groups, as in the development of the national ambient water quality criteria.

To provide sufficient information for making permitting decisions, EPA recommends a minimum number of three species, representing three different phyla (e.g., a fish, an invertebrate, and a plant) be used to test an effluent for toxicity. However, in some cases, the optimum number of species may be fewer or more depending upon such factors as how thoroughly the effluent has been characterized, the available receiving water dilution, the use classification and existing uses of the receiving water, as well as other special considerations. For example, if an effluent has been characterized as highly consistent, with little chance of variation due to batch processes, changes in raw materials or changes in treatment efficiency, then the use of the two most sensitive species, or even the one most sensitive species, may be appropriate as determined on a case-by-case basis.

Since whole effluents are complex mixtures of toxicants, generalizations about sensitive and nonsensitive species are difficult to make. For example, one generalization is that trout are considered sensitive organisms requiring high-quality water. However, this generalization may not apply in all cases; trout are very sensitive to oxygen depletion but may be relatively insensitive to

certain toxicants. Another species, *Daphnia magna*, is very sensitive when exposed to many toxicants, but relatively insensitive when exposured to the pesticide endrin. Bluegills are very resistant to metals, particularly copper. Conversely, bluegills are a sensitive test species for organophosphate pesticides.

Figures 1-7 to 1-9 show the differences in species sensitivities to hexavalent chromium, dieldrin, and an effluent from a POTW, respectively [53]. The wide range between sensitivities for the different test species is shown. Comparing the figures shows that the fish, invertebrates, and algae shift relative sensitivities to the effluents/toxicants. The fish are less sensitive to chromium but more sensitive to dieldrin. For the cladocerans, the reverse is true. The results of whole effluent tests using five marine/estuarine short-term chronic test methods also indicate that no species or test method is always the most sensitive. In a total of 13 effluents tested onsite, *Champia parvula* was the most sensitive in 15 percent, *Arbacia punctulata* in 54 percent, mysids in 31 percent and fish in 15 percent of the cases [24].

Analysis of species sensitivity ranges found in the national ambient water quality criteria [1, 2] indicates that if tests are conducted on three particular species (*Daphnia magna, Pimephales promelas*, and *Lepomis macrochirus*), the most sensitive of the three will have an LC_{50} within one order of magnitude of the most sensitive of all species tested [54]. This was found to be true for 71 of the 73 priority pollutants tested with four or more species.

Sometimes, regulatory agencies require testing on representative resident species under the assumption that such tests are needed to assess impact to local biota. EPA considers it unnecessary to test resident species since standard test species have been shown to represent the sensitive range of all ecosystems analyzed [54]. Resident species toxicity testing is strongly discouraged unless it is required by State statute or some other legally binding factor, or it has been determined that a unique resident species would be far more protective of the receiving water than the EPA surrogate species. The use of other representative species should be subjected to strict quality assurance and quality control procedures and should follow rigorous test methodologies that are at least equivalent to EPA methods. Quality assurance procedures should account for the use of the same species, the same life stage and age of individuals, acclimation periods to avoid mortality due to collection, seasonal variations in populations, habitat requirements, health of the species cultured, as well as the use of reference toxicant tests and other standard procedures. To use a resident organism, a facility would have to develop a protocol to culture the organism and to assess intra- and interlaboratory variability. Such testing is more costly, more difficult, and potentially subject to more variability (disease, age, etc.) than standardized testing. In any case, organisms collected directly from the receiving water itself should never be used because existing impairment may mask any toxicity.

Acute-to-Chronic Ratio

The acute-to-chronic ratio (ACR) expresses the relationship between the concentration of whole effluent toxicity or a toxicant causing acute toxicity to a species (expressed as an acute toxicity endpoint such as an LC_{50}) and the concentration of whole effluent toxicity or a toxicant causing chronic toxicity to the same species (expressed as a chronic toxicity endpoint such as an

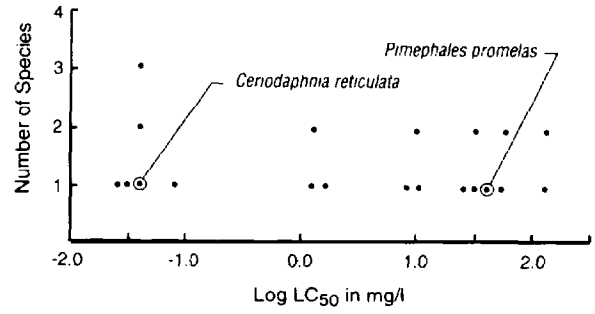


Figure 1-7. Log of LC_{50}s of Freshwater Species Exposed to Hexavalent Chromium

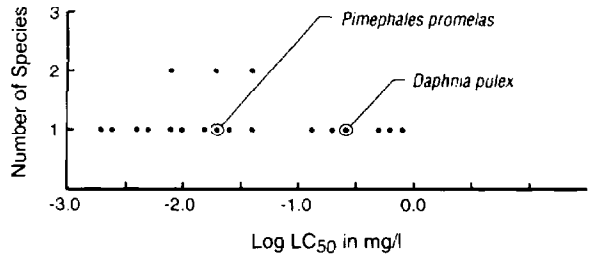


Figure 1-8. Log of LC_{50}s of Freshwater Species Exposed to Dieldrin

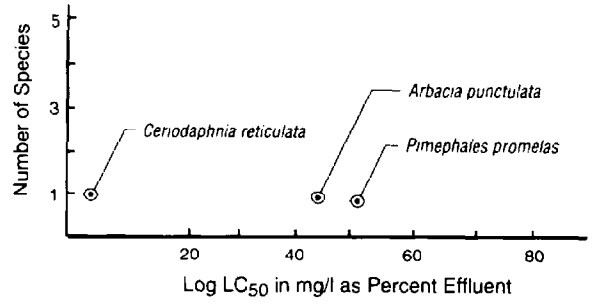


Figure 1-9. Log of LC_{50}s of Freshwater and Saltwater Species Exposed to a POTW Effluent

NOEC or its equivalent, i.e., ACR=ATE/CTE or LC_{50}/NOEC). An ACR is commonly used to extrapolate to a "chronic toxicity" concentration using exposure considerations and available acute toxicity data when chronic toxicity data for the species, chemical, or effluent of concern are unavailable. The ACR should be greater than one, since the ratio compares an acute effect concentration with a chronic effect concentration.

This parameter can be a source of uncertainty in predicting water quality impact because the ACR varies between species for a given chemical and, for any one species, between different toxicants. The latter is a reason why the ACR for a complex effluent may not be a constant. Regardless of this variability, when faced with a limited amount of chronic toxicity data, the regulatory authority

must apply some ACR to an effluent or chemical (or decide to collect more data) when converting wasteload allocations to common terms in the permit limit derivation process described in Chapter 5.

The ACR also may be used in developing chronic toxicity limits where chronic toxicity is not measured directly, in order to minimize testing costs. Likewise, if the toxicity is for the most part manifested in reproduction, growth, etc. (i.e., nonlethal) endpoints, an acute test may not be appropriate for compliance monitoring. **Where acute and chronic toxicity data are available, the ACR should be calculated directly for that specific effluent.**

Data on acute and chronic toxicity for complex effluents from different categories of dischargers (i.e., POTWs, oil refineries, and chemical manufacturers) show that ACRs for whole effluents range from <1.0 to >50.0, with the majority of ACRs falling below 20 (see Appendix A-3). Acute to chronic ratios for oil refinery data from one plant, based on three species ranged from 1.49 to >10.0. Acute to chronic ratios for a variety of chemical manufacturers, based on data from two species ranged from <1.0 to >50.0. Acute to chronic ratios for POTWs based on two species ranged from 1.4 to 16.1 (these data can be found in Appendix A-3). Interestingly, this range of ACRs virtually is identical to ACRs generated on a number of wastewater dischargers in the State of Sao Paulo, Brazil (Appendix A-3, Tables A-3-1 and A-3-2). Although the acute and chronic toxicities measured in Brazil were proportionally higher (more toxic) than those measured in the United States, the ACRs were quite similar (Appendix A-3, Tables A-3-1 to A-3-3).

EPA recommends that regulatory authorities use a measured ACR. In the absence of data to develop an ACR, EPA's data suggests that an ACR of 10 could be used (see Appendix A-3). This represents the upper 90th percentile of all the ACR data in Appendix A-3. Given the protective margin of safety inherent with the use of a critical flow for the calculation of a chronic receiving water waste concentration, an ACR of 10 should provide ample protection against chronic instream impacts.

1.4 BIOLOGICAL CRITERIA/BIOASSESSMENT AND BIOSURVEY APPROACH FOR AQUATIC LIFE PROTECTION

As illustrated in Figure 1-10, ecological integrity is attainable when chemical, physical, and biological integrity occur simultaneously [55]. Biological integrity is a good indicator of overall ecological integrity of aquatic environments because it can provide both a meaningful goal and a useful measure of environmental status that relates directly to the overall integrity of the Nation's waters. **To better protect the biological integrity of aquatic communities, EPA recommends that States begin to develop and implement biological criteria in their water quality standards.** Biological criteria, or "biocriteria," are numerical values or narrative statements that describe the reference biological integrity of aquatic communities inhabiting waters of a given designated aquatic life use. When formally adopted into State standards, biological criteria and aquatic life use designations serve as

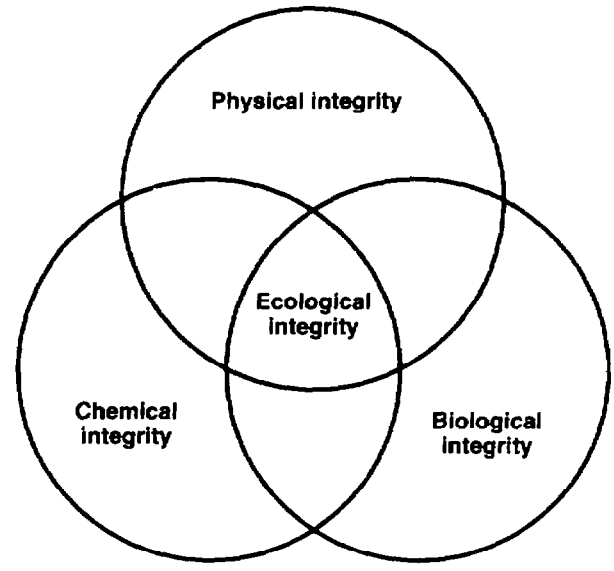


Figure 1-10. The Elements of Ecological Integrity

direct, legal endpoints for determining aquatic life use nonattainment. Per Section 131.11(b)(2) of the Water Quality Standards Regulation (40 *CFR* Part 131), biological criteria can supplement existing chemical-specific criteria and provide an alternative to chemical-specific criteria where such criteria cannot be established. Biological criteria quantitatively are developed by identifying unimpaired or least-impacted reference waters that operationally represent best attainable conditions. Once candidate references are identified, integrated biological surveys (biosurveys) are used to characterize the resident community. Because of the complexity of fully characterizing the biological integrity of an entire aquatic community, State standards should contain biological criteria that consider various components (measures of structure and/or function) of the larger aquatic community.

When biological criteria are incorporated into water quality programs, the biological integrity of surface waters may be directly evaluated and protected. Biological criteria also provide additional benefits by requiring an evaluation of physical integrity and providing a monitoring tool to assess the effectiveness of current chemically based criteria. Table 1-9 summarizes how biological criteria directly and indirectly protect the elements of ecological integrity [55].

1.4.1 Use of Biosurveys and Bioassessments in Water Quality-based Toxics Control

A biological assessment, or "bioassessment," is an evaluation of the biological condition of a waterbody using biological surveys and other direct measurements of resident biota in surface waters. A biological survey, or "biosurvey," consists of collecting, processing, and analyzing representative portions of a resident aquatic community to determine the community structure and function. Biosurveys and bioassessments can be used directly to evaluate the overall biological integrity (structure and/or functional characteristics) of an aquatic community. Deviations from the biological integrity of an aquatic community can be measured directly using bioassessments and biosurveys only when the impacted commu-

Table 1-9. Water Quality Programs That Incorporate Biological Criteria to Protect Elements of Ecological Integrity

Elements of Ecological Integrity	Directly Protects	Indirectly Protects
Chemical Integrity	Chemical-specific criteria (toxics) Whole effluent toxicity (toxics)	Biocriteria (identification of impairment)
Physical Integrity	Criteria for conventionals (pH, tempature, dissolved oxygen)	Biocriteria (habitat evaluation)
Biological Integrity	Biocriteria (biota response in surface water)	Chemical/whole effluent testing (biota response in laboratory)

nity is compared against a predetermined reference condition. Without proper quality controls (i.e., reference conditions), biosurveys tend to underestimate impairment.

Biosurveys assess or detect the aggregate effect of impacts upon an aquatic community where discharges are multiple, complex, and variable and where point, nonpoint, and stormwater discharges are all affecting the biological condition of the receiving water. The resident community integrates the effects of multiple stresses and sources on numerous interactive biological components over time. Because of this, biosurveys necessarily cannot measure the impacts of one particular effluent that is being discharged to the receiving water. Chemical-specific analyses of pollutants known to impact aquatic life and whole effluent toxicity tests are predictive water quality assessment tools used to evaluate biological integrity. At the present time, biological surveys and biological assessments cannot be used as predictive water quality assessment tools.

Biosurveys provide a useful monitor of both aggregate ecological impact and historical trends in the condition of an aquatic ecosystem. Biosurveys can detect aquatic life impacts that other available assessment methods may miss, such as impacts caused by pollutants that are difficult to identify chemically or characterize toxicologically, and impacts from complex or unanticipated exposures. Perhaps most importantly, biosurveys can detect impacts caused by habitat degradation such as channelization, sedimentation, and historical contamination that disrupt the interactive balance among community components.

Biosurvey data should be applied towards:

- Refining use classifications among different types of aquatic systems and within a given type of use category.
- Defining and protecting existing aquatic life uses under State antidegradation policies as required by the water quality standards regulation.
- Classifying outstanding national resource waters.
- Identifying where site-specific criteria modifications may be needed effectively to protect a waterbody.
- Improving use-attainability studies.
- Assessing impacts of certain nonpoint sources and, together with the chemical-specific and whole effluent toxicity approaches, assist in controlling them.
- Monitoring the ecological effects of regulatory action taken under CWA Sections 401, 402, and 301(h).
- Evaluating the effectiveness and documenting the receiving water biological benefits of pollution controls.

1.4.2 Conducting Biosurveys

As is the case with all types of water quality monitoring programs, biosurveys should have clear data quality objectives, utilize consistent laboratory and field methods, and include quality assurance and quality control. Biosurveys should be tailored to the particular type of waterbody being assessed (e.g., wetland, lake, stream, river, or estuary) and should focus on aquatic community components that are representative of the larger ecosystem and that are practical to measure. Biosurveys should be coupled routinely with basic chemical and physical measurements and an objective evaluation of habitat quality.

EPA's Office of Water and several State water quality programs have developed techniques as guidance to support biosurveys and bioassessments [56-62]. The techniques are an excellent supplementary tool to whole effluent toxicity testing and chemical-specific techniques. However, it is important that biosurveys include sampling of as many species at different trophic levels as possible to reveal accurately receiving water community impacts.

Excellent examples of biosurvey/bioassessment data collected and used in concert with ambient or effluent toxicity test data are the site studies described in Boxes 1-3 and 1-4. The toxicity test results and the ambient biosurvey data were based on the recommended minimum of three trophic levels (a fish, invertebrate, and a plant) to give a good overall picture of what was happening in

the receiving water. Recommended methodologies for conducting biosurveys are included in References 56 through 62.

1.5 INTEGRATION OF THE WHOLE EFFLUENT, CHEMICAL-SPECIFIC, AND BIOASSESSMENT APPROACHES

Section 101(a) of the CWA states: "The objective of this Act is to restore and maintain the chemical, physical and biological integrity of the Nation's waters." Taken together, chemical, physical, and biological integrity define the overall ecological integrity of an aquatic ecosystem. Regulatory agencies should strive to fully integrate all three approaches since each has its respective capabilities and limitations. Table 1-10 shows EPA guidance, State implementation, and State application of each approach [55]. The information summarized in Box 1-6, and discussed in detail below, explains how each approach complements the other and why no one of the approaches should be used alone.

A more detailed discussion of the capabilities and limitations of the three approaches is provided below.

1.5.1 Capabilities and Limitations of the Chemical-specific Approach

The principal capabilities of the chemical-specific approach are:

- At present, protection of human health only can be achieved by control of specific chemicals.
- A more complete understanding is available on the toxicology of specific chemicals. EPA acute ambient water quality criteria are based on protecting up to a minimum of eight different organisms including fish, invertebrates, and plants; a minimum of three organisms are used to develop chronic criteria. Considerable information is available in the scientific literature on toxicity caused by specific chemicals.
- Treatment systems are more easily designed to meet chemical requirements because more treatability data are available.
- More information is available on the fate of a pollutant in receiving waters so that the pollutant fate can be conveniently predicted through modeling. Persistence and degradation can be factored into the evaluation.
- Chemical analyses are sometimes less expensive than toxicity testing and biological surveys, if there are only a few toxicants present. This is more pertinent if only chlorine and ammonia are present in an effluent or ambient water.
- This approach allows prediction of ecological impacts before they occur. NPDES permit limits can therefore be developed before an actual ecological impact occurs.

The principal limitations of the chemical-specific approach are:

- All toxicants in complex wastewaters are not known and, therefore, control requirements for all toxicants cannot be set. Toxicological information on these unknown pollutants is often unavailable.
- The bioavailability of the toxicants at the discharge site are typically not assessed, and the interactions between toxicants (e.g., additivity, antagonism) are not measured or accounted for. As a result, the controls may be either under protective or overly protective.
- Direct biological receiving water impact and impairment is not typically measured. There is no way to ascertain directly if the chemical controls adequately are protecting aquatic life.
- Complete measurement of all individual toxicants, particularly where many are present in the mixture, can be expensive. Organic chemicals, in particular, can be costly to measure.

Table 1-10. Process for Implementation of Water Quality Standards

Criteria	EPA Guidance	State Implementation	State Application
Chemical-Specific	Pollutant-specific numeric criteria	State Standards -use designation -numeric criteria -antidegradation	Permit limits monitoring Best management practices Wasteload allocations
Narrative "Free Froms"	Whole effluent toxicity guidance	Water Quality Narrative -no toxic amounts translator	Permit limits monitoring Wasteload allocation Best management practices
Biological	Biosurvey minimum requirement guidance	State Standards -refined use -narrative/numeric criteria -antidegradation	Permit conditions monitoring Best management practices Wasteload allocation

Box 1-6. Components of an Integrated Approach to Water Quality-based Toxics Control

Control Approach	Capabilities	Limitations
Chemical-Specific	-Human health protection -Complete toxicology -Straightforward treatability -Fate understood -Less expensive testing if only a few toxicants are present -Prevents impacts	-Does not consider all toxics present -Bioavailability not measured -Interactions of mixtures (e.g., additivity) unaccounted for -Complete testing can be expensive -Direct biological impairment not measured
Whole effluent toxicity	-Aggregate toxicity -Unknown toxicants addressed -Bioavailability measured -Accurate toxicology -Prevents impacts	-No direct human health protection -Incomplete toxicology (few species may be tested) -No direct treatment -No persistency or sediment coverage -Conditions in ambient may be different -Incomplete knowledge of causative toxicant
Bioassessments	-Measures actual receiving water effects -Historical trend analysis -Assesses quality above standards -Total effect of all sources, including unknown sources	-Critical flow effects not always assessed -Difficult to interpret impacts -Cause of impact not identified -No differentiation of sources -Impact has already occurred -No direct human health protection

1.5.2 Capabilities and Limitations of the Whole Effluent Approach

The principal capabilities of whole effluent techniques are:

- The aggregate toxicity of all constituents in a complex effluent is measured, and toxic effect can be limited by limiting one parameter—whole effluent toxicity.
- Toxicity caused by compounds commonly not analyzed for in chemical tests is detected. Control of the toxicant(s) is not dependent upon established toxicological information that may not yet be available for some pollutants.
- The bioavailability of the toxic constituents is assessed, and the effects of interactions of constituents are measured. Additivity, synergism, and antagonism between compounds in an effluent are addressed implicitly by whole effluent toxicity.
- The toxicity of the effluent or ambient water is measured directly for the species tested.
- This approach allows prediction of ecological impacts before they occur. NPDES permit limits can therefore be developed before an actual ecological impact occurs.

The principal limitations of whole effluent techniques are:

- The approach only measures and controls toxicity to aquatic organisms. It does not protect human health from exposures through ingestion of fish. This is particularly important for carcinogens.
- EPA's water quality criteria are based on a minimum of eight different species for the acute criteria and three different species for the chronic criteria. Effluent aquatic toxicity commonly is measured with only one, two, or three species. For some toxicants a wider sensitivity range (more species) must be tested; particularly where the mode of toxicity action is specific (such as diazinon or some other pesticides).
- There is less knowledge on designing or manipulating treatment systems to treat the parameter toxicity. Investigate tools for identifying causative toxicants only have been recently developed and may not easily identify all causative toxicants. As a result, identification and proper control may be difficult and expensive.
- The whole effluent toxicity test directly measures only the immediate bioavailability of a toxicant; it cannot measure the persistence "downstream" and long-term cumulative toxicity of a compound. Thus, bioaccumulative chemicals necessarily are not assessed or limited. Toxicants can accumulate in sediment to toxic concentrations over a period of time.
- Where there are chemical/physical conditions present (pH changes, hardness changes, solids changes, salinity changes, photolysis, etc.) that act on toxicants in such a way as to

"release" toxicity away from the discharge point, such toxicity may not be measured in the effluent. The opposite of this also is possible; toxicity may degrade rapidly so there is no trace of it away from the point of discharge. For example, the actual pH and temperature in an ambient water may be sufficiently low to preclude toxicity from ammonia whereas the higher pH and temperature of the toxicity test may induce toxicity from ammonia.

- It is not always clear which compound or mixture of compounds is causing toxicity in the mixture. The causative toxicant may be difficult to identify for control.

1.5.3 Capabilities and Limitations of the Bioassessment Approach

The principal capabilities of the bioassessment approach are:

- Biological communities reflect overall ecological integrity. Biosurvey results therefore directly assess the status of a waterbody. The status of a waterbody's biological health may be of direct interest and more meaningful as a measure of a pollution-free environment.

- Biological communities integrate the effects of different pollutant stressors and thus provide a holistic measure of their aggregate impact. Biological assessments also measure stresses over long time periods and can measure historical trends and fluctuating environmental conditions.

- Biosurveys can identify previously unknown sources of impairment and may identify where site-specific chemical criteria are needed. Bioassessments can be useful in characterizing ecological impacts to a waterbody in multiple discharge situations.

- Bioassessments can characterize the ecological value of ambient waters that are in attainment of the standards. As such, bioassessments provide a means to determine compliance with State antidegradation requirements in standards.

The principal limitations of the bioassessment approach are:

- Bioassessments conducted at critical low flow conditions may be difficult to accomplish.

- Biosurvey data cannot fully characterize impairment until after suitable biocriteria are developed. Biosurvey data may not be sufficient to detect impairments without appropriate reference conditions.

- Bioassessments measure integrated impacts over long periods of time. Multiple factors can contribute to measured impacts. However, bioassessments cannot isolate the causative factor leading to the impairment nor predict future impairment.

- Bioassessments measure impact from any source and as such, the data bracketing a discharge used to assess impacts may be influenced by pollutant sources further upstream. Causes of biological impairment may not be assigned readily to any one discharger.

- Bioassessments identify water quality problems after they have occurred; they currently are not predictive of water quality problems. By design, bioassessments are limited in their ability to identify waters that are not impaired.

- The approach only measures biological impairments to aquatic organisms. It does not protect human health from exposures through ingestion of fish.

By using all three approaches, a State will more thoroughly protect aquatic life. The chemical-specific approach provides a high accuracy of analysis of the individual chemical constituents, has been used by regulatory agencies, and is generally lowest in cost because of market availability. However, the level of protection of the chemical-specific approach can be low if toxicants are present in an effluent for which no chemical-specific criteria exists. In addition, some States have adopted very few criteria as a part of their water quality standards. On the other hand, whole effluent toxicity provides a high level of protection by measuring the aggregate effect of all toxicants. It provides accurate toxicology, but it can be higher in cost and has been historically less widely used by regulatory authorities. Bioassessments also provide a coverage of many biological impacts and allow for accurate historical trend analyses. However, bioassessments cost more and data interpretation can be difficult. Therefore, the integrated approach to water quality-based toxics control is essential for a strong toxics control program.

To more fully protect aquatic habitats and provide more comprehensive assessments of aquatic life use nonattainment, **EPA recommends that States fully integrate chemical-specific, whole effluent, and bioassessment approaches into their water quality-based toxics control programs. It is EPA's position that the concept of "independent application" be applied to water quality-based situations. Since each method has unique as well as overlapping attributes, sensitivities, and program applications, no single approach for detecting impact should be considered uniformly superior to any other approach. For example, the inability to detect receiving water impacts using a biosurvey alone is insufficient evidence to waive or relax a permit limit established using either of the other methods. The most protective results from each assessment conducted should be used in the effluent characterization process (see Chapter 3). The results of one assessment technique should not be used to contradict or overrule the results of the other(s).** (For more information see Reference 55.)

Whenever there are discrepancies between the findings of the approaches, regulatory agencies may need to re-examine the findings to determine if simplifications or assumptions may have caused the difference. The State of Ohio found in 60 percent of the sites where they collected bioassessment data, a biological impact occurred when chemical-specific data predicted no impact. The reverse also can occur—biosurveys may not show any impact in a stream whereas effluent data modeled at low flow project an exceedance of a chemical-specific criterion. In this instance, the regulatory authority may need to consider a more detailed monitoring and modeling of chemical fate and transport

(which could include probabilistic modeling) to determine if simplifications in dilution calculations projected higher concentrations than would be expected using the detailed model. The authority also would need to examine concurrently the sampling approach and analysis of the biosurvey data to determine if it appropriately characterized the water. If there was still a difference, then the regulatory authority will need to use the more protective approach as the basis to determine necessary regulatory controls.

1.6 OTHER FACTORS INFLUENCING WATER QUALITY-BASED TOXICS CONTROL

An understanding of the fate and behavior of both single toxicants and whole effluent toxicity after discharge can be important in the application of water quality-based toxics controls. Evaluating the combined effects of interacting toxic discharges also may be important in multiple discharge situations. When evaluating the receiving water behavior of toxicants and toxicity, factors such as toxicity degradation or persistence, and toxicant additivity, antagonism, and synergism are important. Ambient toxicity tests can give some indication of the importance of each of these factors:

- **Toxicity Persistence**—How long and to what extent (in terms of area), does effluent toxicity or the toxicity of a single toxicant persist after discharge? It is not reasonable to assume that in all cases the persistence of both individual toxic chemicals and effluent toxicity is conservative. For two effluents of equal initial toxicity, the aquatic effects of an effluent whose toxicity degrades rapidly will be different from an effluent whose toxicity persists.

- **Additivity, Antagonism, and Synergism**—When toxicants or effluents with toxic properties mix in the receiving water, what is their combined fate and toxic effects?

- **Test Interferences**—This includes pH, temperature, salinity, hardness, and metals.

Each of these factors is discussed below.

1.6.1 Persistence

As soon as an effluent mixes with receiving water its properties begin to change. The rate of change of toxicity in that effluent is a measure of its toxicity persistence or degradation. After mixing, the level of toxicity in the receiving water may either remain relatively constant (until further diluted), increase in toxicity due to transformation, or degrade due to fate processes (photodecomposition, microbial degradation) or compartmentalization processes (particulate adsorption and sediment deposition, volatilization).

One disadvantage of the chemical-specific approach is that the bioavailability of the toxicant after discharge is not measured. Onsite toxicity testing has indicated that the individual toxicants causing toxicity measured at discharge sites tend relatively to be persistent near the point of discharge [23, 31-38]. However, persistence of individual chemicals can be modeled and the persistence of specific toxicants also can be accounted for in making impact predictions and setting controls. A procedure to determine whether or not an effluent's toxicity is persistent has been developed by EPA [63]. The procedure describes the steps required to conduct a laboratory evaluation of the degradation of toxicity in complex effluents that are released to receiving waters by simplistically simulating a water body and discharge. **EPA recommends this procedure be conducted where the interaction of sources of toxicants is critical to establishing controls.**

This simple procedure is performed in a refrigerator-sized environmental chamber in the laboratory using commonly available glassware and shipped effluent samples. Toxicity is measured using conventional acute or short-term chronic toxicity tests. The results are used to generate a toxicity degradation rate for the effluent under representative environmental conditions. The procedure has several applications, including measuring the decay of effluent toxicity in a stream or lake, and identifying the most important fate processes responsible for toxicity decay (which also may be useful in treatability or toxicity identification studies).

Mixing zones designated by State water quality standards, or developed on a case-by-case basis, are typically small enough that toxicity evaluations need only consider near field situations. Continuous discharges continually can introduce toxic pollutants into a receiving water. Although these pollutants can decay over time, this decay will occur downstream or away from the discharge. The receiving water concentrations at the point of discharge continually are being refreshed. In these instances, toxicity can be considered conservative and persistent (nondecaying) in the near field.

However, effluent toxicity can exhibit far field decay. Typical patterns of progressively decreasing downstream toxicity (similar to biochemical oxygen demand decay) have been observed in a number of freshwater situations [23, 31-38]. This is of concern when evaluating the combined toxicity of sources located far apart. If there is reason to suspect that an effluent's toxicity is not persistent, several techniques can be employed to measure changes of toxicity after discharge:

- Testing should be performed during various seasons of the year corresponding to various receiving water flow regimes. The toxicity test itself, when performed with dilution water immediately upstream or from an uncontaminated area nearby, is an analogue of the mixing and fate processes taking place in the receiving water. The types of rapid chemical reactions found in the mixing zone also can be expected to take place to a large extent when effluents and receiving waters are mixed for toxicity tests. The effects on toxicity persistence of varying physical/chemical conditions in the receiving water or in the effluent cannot, however, be accurately predicted from these results.

- Ambient toxicity testing, as detailed in Appendix C, measures the ambient interactions of effluent and receiving water and can be used to assess toxicity persistence.

Toxicity persistence may present a more serious problem in estuarine or lake receiving waters where the toxicity is not flushed away rapidly. In one study, on a POTW effluent being discharged into a small cove off of Narragansett Bay, the decay rate of the effluent was temperature-dependent and was reduced markedly during

the winter. However, persistence of the effluent in the receiving water cove in the winter did present a problem because tidal flushing did not remove the toxicity [39].

For coastal discharges, certain toxic compounds are more often found to cause impacts in marine and estuarine environments [64]. Due to the physical and chemical processes that tend to trap pollutants in estuaries (sedimentation, salinity flux, etc.), the discharge of these compounds, at very low concentrations over a long period of time, may allow them to accumulate to toxic concentrations. For many of these compounds, applicable permit limits may need to be very stringent to avoid chronic toxicity problems due to the persistence of these compounds.

1.6.2 Additivity, Antagonism, and Synergism

Where multiple toxic effluents are discharged to a receiving water, the resultant ambient toxicity is of interest. Since each effluent is composed of individual toxic substances, a mixture of the effluents in a receiving water produces a mixture of these individual pollutants (assuming conservative behavior). The overall ambient toxicity could be equal to the sum of each discharge's toxicity (additivity), less than the sum (antagonism), or greater than the sum (synergism).

Alabaster and Lloyd [65] observed from their data that the combined acutely lethal toxicity to fish and other aquatic organisms is approximately the simple addition of the proportional contribution from each toxicant. The median value of the effect on fish is 0.95 of that predicted; the collective value for sewage effluents, river waters and a few industrial wastes is 0.85. The range for effluents, river wastes, and industrial wastes is 0.4 to 2.8. (Figure 1-11 illustrates the data summary.)

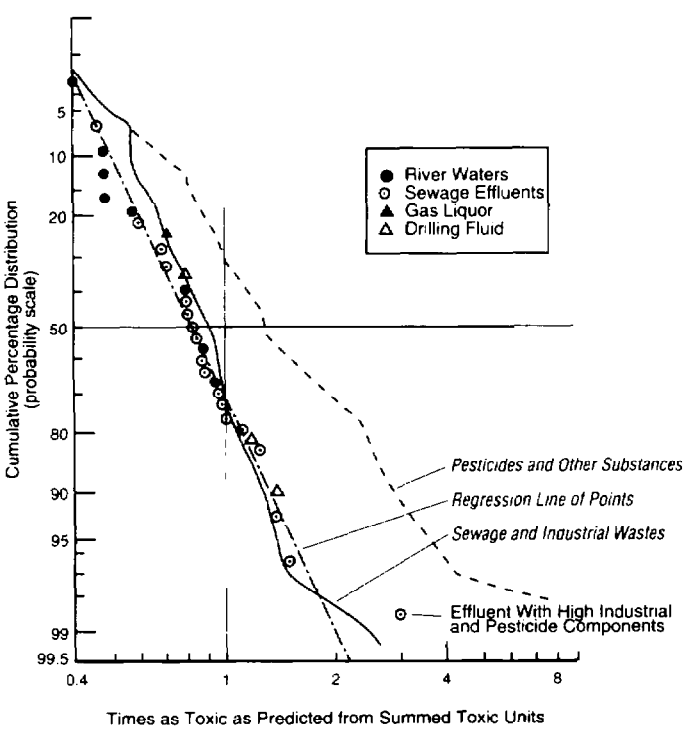


Figure 1-11. Data Summary on Additivity [65]

In relation to chronic toxicity, for the growth of fish, Alabaster and Lloyd [65] conclude:

> ...in the few studies on the growth of fish, the joint effect of toxicants has been consistently less than additive which suggests that as concentrations of toxicants are reduced towards the levels of no effect, their potential for addition is also reduced. There appear to be no marked and consistent differences between the response of species to mixtures of toxicants.

Cases in which one effluent or pollutant parameter (such as total suspended solids) ameliorated the toxicity of another effluent pollutant (antagonism) have been observed. Testing procedures can be designed to measure such interactions. A description of such a procedure is found in "Recommended Multiple-Source Toxicity Test Procedures," Box 3-3, Chapter 3.

Theoretically, under certain conditions, synergism, a greater than additive increase in toxicity upon mixing, can occur. However, field studies of effluent toxicity and laboratory experiments with specific chemicals imply that synergism would be an extremely rare phenomenon. It has not been observed during onsite effluent toxicity studies, and is not considered an important factor in the toxicological assessment of effluents.

In summary, the available information indicates that the combined effects of individual acutely toxic pollutants are from 0.4 to 2.8 times the effects predicted by adding the individual effects. The median combined effect is approximately additive. For this reason, **EPA recommends in the absence of site-specific data that regulatory authorities consider combined acute toxicity to be additive**. Since the data shows no such additivity for chronic toxicity, **EPA recommends that chronic toxicity not be considered as additive.**

1.6.3 Test Interferences

Environmental conditions such as pH, temperature, salinity, hardness, and solids concentration can influence the toxicity test. For example, higher ambient solids concentrations provide more surfaces for toxicants to be adsorbed and can tend to reduce toxicity. In addition, toxicity caused by ammonia is controlled by the ambient pH and temperature. **As a normal part of the whole effluent toxicity testing procedure, it is very important to replicate closely the "worst case" receiving water conditions in the testing conditions.**

There may be a few unusual situations where the pH, temperature, hardness, salinity, and solids requirements of the testing procedures differ greatly from the worst environmental conditions for these parameters. In these situations, the effluent toxicity tests may either over or under predict the toxicity in the ambient receiving water. An example of this is where ammonia is present and the highest expected ambient water temperature is 20°C whereas the chronic toxicity test must be conducted at 25°C. Since a higher temperature causes more ammonia toxicity, the temperature requirements of the test may induce toxicity not found in the ambient water. In such an instance, the regulatory authority must look carefully at the test protocols and all the data collected to determine if the facility is actually contributing to toxicity in the ambient water. A toxicity identification evaluation

may be necessary to make this determination. If this analysis shows a toxicity test result to be artificial due to environmental parameters, then that test should be overridden by subsequent valid toxicity tests conducted.

1.7 HUMAN HEALTH PROTECTION

Impacts on human health due to exposure to waterborne toxicants can occur through three primary exposure routes: contact recreation, drinking water, and the ingestion of contaminated fish and shellfish tissues. Contact recreation may pose potential risks due to dermal absorption and incidental ingestion. Exposure through drinking water is a significant concern but can be mitigated for specific chemicals by applying drinking water criteria. The third exposure route, human consumption of contaminated aquatic life, is of primary concern in this document due to the potentially high concentrations achieved in fish and shellfish tissues from bioconcentration, and because no NPDES permitting controls exist between tissue contamination and human exposure. For these reasons, this document focuses on prevention of contaminated aquatic life from bioconcentration as the principal way to control human exposure to waterborne toxicants.

Currently, the regulation of human health impacts typically are based only upon the control of individual chemicals. EPA human health water quality criteria protect against the consumption of contaminated water and aquatic life. There is no mechanism like the aquatic toxicity test to determine the effect of a chemical mixture like an effluent on human health. EPA is developing, however, a preliminary approach to analyzing effluents for bioaccumulation potential through the use of a whole effluent bioconcentration analysis followed by identification of individual bioconcentratable pollutants [66]. This procedure is described in Chapter 3. Once this method is reviewed (both internally and externally) and finalized, it will provide another way for regulatory authorities to assess bioconcentratable pollutants.

1.7.1 Types of Health Effects

Health effects from toxics are divided into two categories: **nonthreshold** effects, such as carcinogenicity, and threshold effects, such as acute, subacute, or chronic toxicity. Both terms are defined below.

EPA's approach to assessing the risks associated with nonthreshold human carcinogens is different from the approach for threshold toxicants due to the different mechanisms of action thought to be involved. In the case of carcinogens, the Agency assumes that a small number of molecular events can evoke changes in a single cell that can lead to uncontrolled cellular proliferation. This mechanism for carcinogenesis is referred to as "nonthreshold," since there is essentially no level of exposure for such a chemical that does not pose a small, but finite, probability of generating a carcinogenic response. Genotoxic pollutants are presumed to have no threshold level, but incremental risk levels can be determined based on the carcinogenic potency of the chemicals.

Threshold toxicants, on the other hand, are generally treated as if there is an identifiable exposure threshold (both for individuals and populations) below which effects are not observable. Threshold toxicants are chemicals that give rise to toxic endpoints other than cancer because of their effects on the function of various organ systems. Such chemicals are presumed to have safe exposure levels. This characteristic distinguishes threshold endpoints from nonthreshold endpoints. However, it should be noted that chemicals that cause cancer and mutations also commonly evoke other toxic effects (systemic toxicity). In the case of systemic toxicity, compensating and adaptive "defense" mechanisms exist that must be overcome before the toxic endpoint is manifested. For example, there could be a large number of cells performing the same or similar function whose population must be significantly altered before the effect is seen. The individual threshold hypothesis holds that a range of exposures from zero to some finite value can be tolerated by the organisms with essentially no chance of expression of the toxic effect.

Currently, the control of toxicants that bioconcentrate in edible tissues is achieved in the NPDES program by limiting such pollutants individually. There are whole effluent tests that can measure a wastewater's potential to cause carcinogenicity or mutagenicity (e.g., Ames test). However, the application of such data is experimental because of the difficulty in establishing cause/effect relationships between exposure to wastewaters and human health problems. Therefore, at this time EPA recommends regulatory authorities focus on controls for bioconcentratable toxicants on a chemical-by-chemical control basis.

The remaining information regarding regulation of human health impacts is contained in the following chapters: Chapter 2, Water Quality Standards, discusses the development and updating of human health water quality criteria. Chapter 3, Effluent Characterization, discusses the evaluation of effluents for potential human health impacts. Chapter 4, Exposure and Wasteload Allocation, contains information on design conditions and averaging periods. Finally, Chapter 5, Permit Requirements, discusses the derivation of permit limits protective against human health impacts.

CHAPTER 1

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2. WATER QUALITY CRITERIA AND STANDARDS

2.1 INTRODUCTION

The foundation of a water quality-based toxics control program consists of the State water quality standards applicable to the waterbody. The following discussion describes the regulatory and technical considerations for application of water quality standards.

2.1.1 Overview of Water Quality Standards

A water quality standard defines the water quality goals of a water body, or portion thereof, by designating the use or uses to be made of the water, by setting criteria necessary to protect the uses, and by establishing antidegradation policies and implementation procedures that serve to maintain and protect water quality. States adopt water quality standards to protect public health or welfare, enhance the quality of water, and serve the purposes of the Clean Water Act (CWA). "Serve the purposes of the Act" (as defined in Sections 101(a), 101(a)(2), and 303(c) of the Act) means that water quality standards should (1) include provisions for restoring and maintaining chemical, physical, and biological integrity of State waters; (2) provide, wherever attainable, water quality for the protection and propagation of fish, shellfish, and wildlife and recreation in and on the water ("fishable/swimmable"); and (3) consider the use and value of State waters for public water supplies, propagation of fish and wildlife, recreation, agriculture and industrial purposes, and navigation.

The CWA describes various uses of waters that are considered desirable and should be protected. These uses include public water supply, recreation, and propagation of fish and wildlife. The States are free to designate more specific uses (e.g., cold water and warm water aquatic life), or to designate uses not mentioned in the CWA, with the exception that waste transport and assimilation is not an acceptable designated use (see 40 *CFR* 131.10(a)). EPA's regulations emphasize the uses specified in CWA Section 101(a)(2), but do not preclude other beneficial uses and subcategories of uses as determined by the State.

When designating uses, States should give careful consideration to whether uses that will support the "fishable and swimmable" goal of Section 101(a)(2) are attainable. If the State does not designate uses in support of this goal, the State must perform a use attainability analysis under Section 131.10(j) of the standards regulation. States should designate uses for the waterbody that the State determines can be attained in the future. "Attainable uses" are those uses (based on the State's system of water use classification) that can be achieved when effluent limits under CWA Section 301(b)(1)(A) and (B) and Section 306 are implemented for point source discharges and when cost-effective and reasonable best management practices are implemented for nonpoint sources. The Water Quality Standards regulation specifies the conditions under which States may remove uses or establish subcategories of uses. Among these are that the State must provide opportunity for public hearing. In addition, uses that have been attained in the waterbody on or after November 28, 1975, whether or not they are included in the water quality standards, may not be removed unless a use requiring more stringent criteria is added. These uses are the "existing uses" as defined in 40 *CFR* 131.3(e). Also, uses that are attainable, as defined above, may not be removed. Removal of a "fishable/swimmable" use, or adoption of a subcategory of a "fishable/swimmable" use that requires less stringent criteria, requires the State to conduct a use attainability analysis. Technical guidance on conducting use attainability analyses is available from EPA (e.g., Chapter 3 of the *Water Quality Standards Handbook* (1983) [1], and *Technical Support Manual: Waterbody Surveys and Assessments for Conducting Use Attainability Analyses* (1983) [2].

In the Water Quality Standards regulation, Section 131.11 encourages States to adopt both numeric and narrative criteria. Aquatic life criteria should protect against both short-term (acute) and long-term (chronic) effects. Numeric criteria particularly are important where the cause of toxicity is known or for protection against pollutants with potential human health impacts or bioaccumulation potential. Numeric water quality criteria also may be the best way to address nonpoint source pollution problems. Narrative criteria can be the basis for limiting toxicity in waste discharges where a specific pollutant can be identified as causing or contributing to the toxicity but there are no numeric criteria in the State standards or where toxicity cannot be traced to a particular pollutant. Section 131.11(a)(2) requires States to develop implementation procedures that explain how the State will ensure that narrative toxics criteria are met.

EPA's water quality standards regulation requires each State to adopt, as part of its water quality standards, an antidegradation policy consistent with 40 *CFR* 131.12 and to identify the methods it will use for implementing the policy. Activities covered by the antidegradation policy and implementation methods include both point and nonpoint sources of pollution. Section 131.12 effectively sets out a three-tiered approach for the protection of water quality.

"Tier I" (40 *CFR* 131.12(a)(1)) of antidegradation maintains and protects existing uses and the water quality necessary to protect these uses. An existing use can be established by demonstrating that fishing, swimming, or other uses have actually occurred since November 28, 1975, <u>or</u> that the water quality is suitable to allow such uses to occur, whether or not such uses are designated uses for the waterbody in question. (Compare Sections 131.3(e) and 131.3(f) of the existing regulation.) For example, in an area where shellfish are propagating and surviving in a biologically suitable habitat, the shellfish use is existing, whether or not people are harvesting the shellfish. The aquatic life protection use is a broad category requiring further explanation, which may be found in the *Water Quality Standards Handbook*.

"Tier II" (Section 131.12(a)(2)) protects the water quality in waters whose quality is better than that necessary to protect "fishable/swimmable" uses of the waterbody. 40 *CFR* 131.12(a)(2) requires that certain procedures be followed and certain showings be made before lowering water quality in high-quality waters. These showings may be called an "antidegradation review." In no case may water quality on a Tier II waterbody be lowered to the level at which existing uses are impaired. The Tier II protection usually is applied on a parameter-by-parameter basis (called the definitional approach to Tier II). This approach is applied on a case-by-case basis so that, if the level of any parameter is better than water quality standards for that waterbody, then an antidegradation review will be performed for any activity that could reduce the level of that parameter.

Outstanding national resource waters (ONRWs) are provided the highest level of protection under the antidegradation policy (Tier III); no degradation is allowed. ONRWs include the highest-quality waters of the United States. However, the ONRW antidegradation classification also offers special protection for waters of "exceptional ecological significance," i.e., those waterbodies that are important, unique, or sensitive ecologically, but whose water quality, as measured by the traditional parameters such as dissolved oxygen or pH, may not be particularly high. Waters of exceptional ecological significance may also include waters whose characteristics cannot be described adequately by traditional parameters (such as wetlands and estuaries).

States may, at their discretion, adopt certain policies in their standards affecting the application and implementation of standards. For example, policies concerning mixing zones, variances, low-flow exemptions, and schedules of compliance for water quality-based permit limits may be adopted. Although these are areas of State discretion, EPA retains authority to review and approve or disapprove such policies (see 40 *CFR* 131.13). Guidance on these subjects is available from EPA's Office of Water Regulations and Standards, Criteria and Standards Division.

2.1.2 Water Quality Standards and State Toxics Control Programs

Applicable requirements for State adoption of water quality criteria for toxicants vary depending upon the toxicant. The reason for this is that the 1983 water quality standards regulation and the 1987 amendments to the CWA (Pub. L. 100-4) include more specific requirements for the particular toxicants listed in CWA Section 307(a). For regulatory purposes, EPA has translated the 65 compounds and families of compounds listed in Section 307(a) into 126 specific substances that EPA refers to as priority toxic pollutants. The 126 priority toxic pollutants are listed in Appendix A of 40 *CFR* Part 423. Because of the more specific requirements for priority toxic pollutants, it is convenient to organize the requirements applicable to State adoption of criteria for toxicants into three categories:

- Requirements applicable to priority toxic pollutants that have been the subject of CWA Section 304(a)(1) criteria guidance
- Requirements applicable to priority toxic pollutants that have not been the subject of CWA Section 304(a)(1) criteria guidance and
- Requirements applicable to all other toxicants (i.e., nonpriority toxic pollutants).

The criteria requirements applicable to priority toxic pollutants (i.e., the first two categories above), are specified in CWA Section 303(c)(2)(B). On December 2, 1988, EPA sent "Guidance for State Implementation of Water Quality Standards for CWA Section 303(c)(2)(B)" to each of its Regions and to each State water pollution control agency. The guidance contained three options for implementing the new numeric criteria requirements of the Act: (1) adopt Statewide numeric criteria in standards for all those priority toxic pollutants for which EPA has published national criteria; (2) adopt numeric criteria for only those priority toxic pollutants and those stream segments where the discharge or presence of the pollutant could reasonably be expected to interfere with designated uses; or (3) adopt a specific procedure in the standards to "translate" the State's narrative "free from toxics" standard to derived numeric criteria.

The transmittal memorandum for the Section 303(c)(2)(B) national guidance expresses the Office of Water position regarding priority toxic pollutants that may "reasonably be expected" to interfere with designated uses. That memorandum and guidance established a rebuttable presumption that <u>any</u> information indicating that such pollutants are discharged or present in surface waters (now or in the future) is sufficient justification to require adoption or derivation of numerical criteria. The goal is not just to identify pollutants that are already impacting surface waters, but rather to identify pollutants that may be impacting surface waters now, or have the potential to do so in the future. Lack of detailed or widespread monitoring data is not an acceptable basis to omit numerical (or derived numerical) criteria from water quality standards under Options 2 and 3. Even a limited amount of monitoring data indicating the discharge or presence of priority toxic pollutants in surface waters is sufficient basis to conclude that numerical (or derived numerical) criteria are necessary.

Where States select an Option 2 or 3 approach, States must include, as part of the rationale supporting the adopted standards, the information used in determining which priority toxic pollutants require criteria. Where there is uncertainty about the need for criteria for specific priority toxic pollutants, the State should adopt (or derive) criteria for such pollutants so as to err on the side of environmental protection and pollution prevention. This approach is appropriate given the general lack of monitoring data for priority toxic pollutants; it will provide maximum protection to the environment by anticipating, rather than reacting to, water quality problems.

For priority toxic pollutants for which EPA has not issued Section 304(a)(1) criteria guidance, CWA Section 303(c)(2)(B) requires States to adopt criteria based on biological monitoring or assessment methods. The phrase "biological monitoring or assessment methods" includes (1) whole effluent toxicity control methods, (2) biological criteria methods, or (3) other methods based on biological monitoring or assessment. The phrase "biological monitoring or assessment methods" in its broadest sense also includes criteria developed through translator procedures. This broad interpretation of that phrase is consistent with EPA's policy of applying chemical-specific, biological, and whole effluent toxicity methods independently in an integrated toxics control program. It also is consistent with the intent of Congress to expand

State standards programs beyond chemical-specific approaches.

Where EPA has not issued Section 304(a) criteria guidance, but available laboratory toxicity (bioassay) data are sufficient to support derivation of chemical-specific criteria, States should consider deriving and adopting numeric criteria for such priority toxic pollutants. This is particularly important where other components of a State's narrative criterion implementation procedure (e.g., whole effluent toxicity controls or biological criteria) may not ensure full protection of designated uses. For some pollutants, a combination of chemical-specific and other approaches is necessary (e.g., pollutants where bioaccumulation in fish tissue or water consumption by humans is a primary concern).

Criteria requirements applicable to toxicants that are not priority toxic pollutants (i.e., the third category above), are specified in the 1983 water quality standards regulation (see 40 *CFR* 131.11). Under these requirements, States must adopt criteria based on sound scientific rationale that cover sufficient parameters to protect designated uses. Both numeric and narrative criteria are addressed by these requirements.

Numeric criteria are required where such criteria are necessary to protect designated uses. Numeric criteria to protect aquatic life should be developed to address both short-term (acute) and long-term (chronic) effects. Saltwater species, as well as freshwater species, must adequately be protected. Adoption of numeric criteria is particularly important for toxicants known to be impairing surface waters and for toxicants with potential human health impacts (e.g., those with high bioaccumulation potential). Human health should be protected from exposure resulting from consumption of water and fish or other aquatic life (e.g., mussels, crayfish). Numeric water quality criteria also are useful in addressing nonpoint source pollution problems.

In evaluating whether chemical-specific numeric criteria for toxicants are required, States should consider whether other approaches (such as whole effluent toxicity criteria or biological controls) will ensure full protection of designated uses. As mentioned above, a combination of independent approaches may be required in some cases to support the designated uses and comply with the requirements of the water quality standards regulation (e.g., pollutants where bioaccumulation in fish tissue or water consumption by humans is a primary concern).

To supplement numeric criteria for toxicants, all States also have adopted narrative criteria for toxicants. Such narrative criteria are statements that describe the desired water quality goal, such as the following:

> All State waters must, at all times and flows, be free from substances that are toxic to humans or aquatic life.

EPA considers that the narrative criteria apply to all designated uses at all flows unless specified otherwise in a State's water quality standards. EPA also believes that no acutely toxic condition may exist in any State waters regardless of designated use (54 *FR* 23875).

Narrative criteria can be the basis for establishing chemical-specific limits for waste discharges where a specific pollutant can be identified as causing or contributing to the toxicity and the State has not adopted chemical-specific numeric criteria. Narrative criteria also can be the basis for establishing whole effluent toxicity controls required by EPA regulations at 40 *CFR* 122.44(d)(1)(v).

To ensure that narrative criteria for toxicants are attained, the water quality standards regulation requires States to develop implementation procedures (see 40 *CFR* 131.11(a)(2)). Such implementation procedures (Box 2-1) should address all mechanisms used by the State to ensure that narrative criteria are attained. Because implementation of chemical-specific numeric criteria is a key component of State toxics control programs, narrative criteria implementation procedures must describe or reference the State's procedures to implement such chemical-specific numeric criteria (e.g., procedures for establishing chemical-specific permits limits under the NPDES permitting program). Implementation procedures also must address State programs to control whole effluent toxicity and may address programs to implement biological criteria, where such programs have been developed by the State. Implementation procedures therefore serve as umbrella documents that describe how the State's various toxics control programs are integrated to ensure adequate protection for aquatic life and human health and attainment of the narrative toxics criterion. In essence, the procedure should apply the "independent application" principle, which provides for independent evaluations of attainment of a designated use based on chemical-specific, whole effluent toxicity, and biological criteria methods (see Chapter 1, Reference 56).

EPA encourages, and may ultimately require, State implementation procedures to provide for implementation of biological criteria. However, the regulatory basis for requiring whole effluent toxicity controls is clear. EPA regulations at 40 *CFR* 122.44(d)(1)(v) require NPDES permits to contain whole effluent toxicity limits where a permittee has been shown to cause, have the reasonable potential to cause, or contribute to an in-stream excursion of a narrative criterion. Implementation of chemical-specific controls also is required by EPA regulations at 40 *CFR* 122.44(d)(1). State implementation procedures should, at a minimum, specify or reference methods to be used in implementing chemical-specific and whole effluent toxicity-based controls, explain how these methods are integrated, and specify needed application criteria.

In addition to EPA's regulation at 40 *CFR* Part 131, EPA has regulations at 40 *CFR* 122.44 that cover the National Surface Water Toxics Control Program. These regulations intrinsically are linked to the requirements to achieve water quality standards, and specifically address the control of pollutants both with and without numeric criteria. For example, Section 122.44(d)(1)(vi) provides the permitting authority with several options for establishing effluent limits when a State does not have a chemical-specific numeric criteria for a pollutant present in an effluent at a concentration that causes or contributes to a violation of the State's narrative criteria.

2.2 GENERAL CONSIDERATIONS

2.2.1 Magnitude, Duration, and Frequency

As stated earlier, criteria are specifications of water quality designed to ensure protection of the designated use. EPA criteria are

Box 2-1. Components of an Ideal State Implementation Procedure

- Specific, scientifically defensible methods by which the State will implement its narrative toxics standard for all toxicants, including:
  - Methods for chemical-specific criteria, including methods for applying chemical-specific criteria in permits, developing or modifying chemical-specific criteria via a "translator procedure" (defined and discussed below), and calculating site-specific criteria based on local water chemistry or biology
  - Methods for developing and implementing whole effluent toxicity criteria and/or controls
  - Methods for developing and implementing biological criteria.
- Integration of these methods in the State's toxics control program (i.e., how the State will proceed when the specified methods produce conflicting or inconsistent results).
- Application criteria and information that are needed to apply numerical criteria, for example:
  - Methods the State will use to identify thosepollutants to be regulated in a specific discharge
  - An incremental cancer risk level for carcinogens
  - Methods for identifying compliance thresholds inpermits where calculated limits are below detection
  - Methods for selecting appropriate hardness, pH, and temperature variables for criteria expressed as functions
  - Methods or policies controlling the size and in-zone quality of mixing zones
  - Design flows to be used in translating chemical-specific numeric criteria for aquatic life and human health into permit limits
  - Other methods and information that will be needed to apply standards on a case-by-case basis.

developed as national recommendations to assist States in developing their standards and to assist in interpreting narrative standards. EPA criteria or guidance consist of three components:

- Magnitude—How much of a pollutant (or pollutant parameter such as toxicity), expressed as a concentration, is allowable.
- Duration—The period of time (averaging period) over which the instream concentration is averaged for comparison with criteria concentrations. This specification limits the duration of concentrations above the criteria.
- Frequency—How often criteria can be exceeded.

A typical aquatic life water quality criteria statement contains a concentration, averaging period, and return frequency, stated in the following format:

> The procedures described in the *Guidelines for Deriving National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* indicate that, except possibly where a locally important species is very sensitive, (1) aquatic organisms and their uses should not be affected unacceptably if the four-day average concentration of (2) does not exceed (3) µg/L more than once every three years on the average and if the one-hour average concentration does not exceed (4) µg/L more than once every three years on the average.

In this example generic statement, the following terms are inserted at:

(1) — either "freshwater" or "saltwater"

(2) — the name of the pollutant

(3) — the lower of the chronic-effect or residue-based concentrations as the criterion continuous concentration (CCC)

(4) — the acute effect-based criterion maximum concentration (CMC).

Defining water quality criteria with an appropriate duration and frequency of excursions helps to ensure that criteria appropriately are considered in developing wasteload allocations (WLAs), which are then translated into permit requirements. Duration and frequency may be defined in the design stream flow appropriate to the criterion. However, in these cases, the State should provide an evaluation that the selected design stream flow approximates the recommended duration and frequency.

2.2.2 Mixing Zones

It is not always necessary to meet all water quality criteria within the discharge pipe to protect the integrity of the waterbody as a whole. Sometimes it is appropriate to allow for ambient concentrations above the criteria in small areas near outfalls. These areas are called mixing zones. Since these areas of impact, if disproportionately large, could potentially adversely impact the productivity of the waterbody, and have unanticipated ecological consequences, they should be carefully evaluated and appropriately limited in size. As our understanding of pollutant impacts on ecological systems evolves, there may be cases identified where no mixing zone is appropriate.

To ensure mixing zones do not impair the integrity of the waterbody, it should be determined that the mixing zone will not cause lethality to passing organisms and, considering likely pathways of exposure, that there are no significant human health risks. One means to achieve these objectives is to limit the size of the area affected by the mixing zones.

For application of two-number aquatic life criteria, there may be up to two types of mixing zones (Figure 2-1). In the zone immediately surrounding the outfall, neither the acute nor the chronic criterion is met. The acute criterion is met at the edge of this zone. In the next mixing zone, the acute, but not the chronic, criterion is met. The chronic criterion is met at the edge of the second mixing zone.

In the general case, where a State has both acute and chronic aquatic life criteria, as well as human health criteria, independently established mixing zone specifications may apply to each of the three types of criteria. The acute mixing zone may be sized to prevent lethality to passing organisms, the chronic mixing zone sized to protect the ecology of the waterbody as a whole, and the health criteria mixing zone sized to prevent significant human risks. For any particular pollutant from any particular discharge, the magnitude, duration, frequency, and mixing zone associated with each of the three types of criteria will determine which one most limits the allowable discharge.

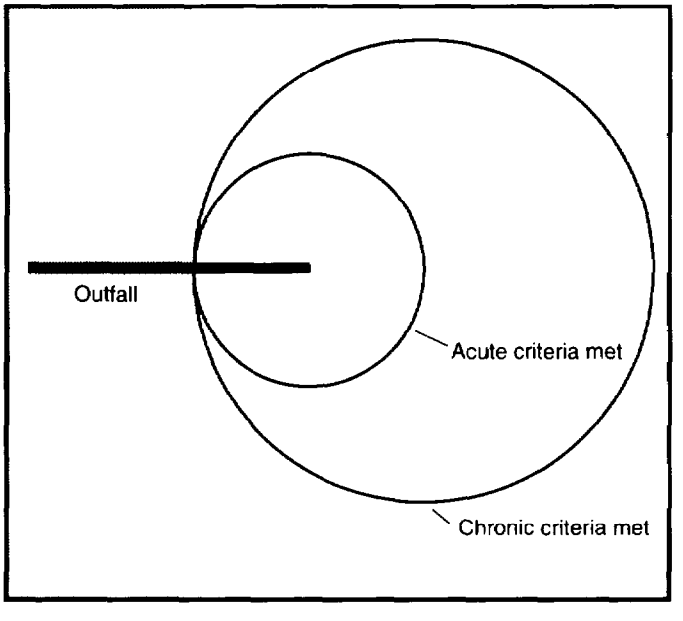

Figure 2-1. Diagram of the Two Parts of the Mixing Zone

Mixing zone allowances will increase the mass loadings of the pollutant to the waterbody, and decrease treatment requirements. They adversely impact immobile species, such as benthic communities, in the immediate vicinity of the outfall. Because of these and other factors, mixing zones must be applied carefully, so as not to impede progress toward the CWA goals of maintaining and improving water quality. EPA recommendations for allowances for mixing zones, and appropriate cautions about their use, are contained in this section.

The CWA allows mixing zones at the discretion of the State [1]. **EPA recommends that States have a definitive statement in their standards on whether or not mixing zones are allowed.** Where mixing zones provisions are part of the State standards, the State should describe the procedures for defining mixing zones.

To determine that a mixing zone is sized appropriately for aquatic life protection, water quality conditions within the mixing zone may be compared to laboratory-measured or predicted toxicity bench marks as follows:

> It is not necessary to meet chronic criteria within the mixing zone, only at the edge of the mixing zone. Conditions within the mixing zone would thus not be adequate to ensure survival, growth, and reproduction of all organisms that might otherwise attempt to reside continuously within the mixing zone.
>
> If acute criteria (CMC derived from 48- to 96-hour exposure tests) are met throughout the mixing zone, no lethality should result from temporary passage through the mixing zone. If acute criteria are exceeded no more than a few minutes in a parcel of water leaving an outfall (as assumed in deriving the Section 4.3.3 options for an outfall velocity of 3 m/sec, and a size of 50 times the discharge length scale), this likewise assures no lethality to passing organisms.
>
> If a full analysis of concentrations and hydraulic residence times within the mixing zone indicates that organisms drifting through the plume along the path of maximum exposure would not be exposed to concentrations exceeding the acute criteria when averaged over the 1-hour (or appropriate site-specific) averaging period for acute criteria, then lethality to swimming or drifting organisms ordinarily should not be expected, even for rather fast-acting toxicants. In many situations, travel time through the acute mixing zone must be less than roughly 15 minutes if a 1-hour average exposure is not to exceed the acute criterion.
>
> Where mixing zone toxicity is evaluated using the probit approach described in the water quality criteria "Bluebook" [3], or using models of toxicant accumula-

tion and action in organisms (described by Mancini [4] or Erickson et al. [5]), the phenomenon of delayed mortality should be taken into account before judging the mixing zone concentrations to be safe.

The above recommendations assume that the effluent is repulsive, such that free-swimming organisms would avoid the mixing zones. While most toxic effluents are repulsive, caution is necessary in evaluating attractive mixing zones of known effluent toxicity, and denial of such mixing zones may well be appropriate. It also is important to ensure that concentration isopleths within any plume will not extend to restrict passage of swimming organisms into tributary streams.

In all cases, the size of the mixing zone and the area within certain concentration isopleths should be evaluated for their effect on the overall biological integrity of the waterbody. If the total area affected by elevated concentrations within all mixing zones combined is small compared to the total area of a waterbody (such as a river segment), then mixing zones are likely to have little effect on the integrity of the waterbody as a whole, provided that they do not impinge on unique or critical habitats. EPA has developed a multistep procedure for evaluating the overall acceptability of mixing zones [6].

For protection of human health, the presence of mixing zones should not result in significant health risks, when evaluated using reasonable assumptions about exposure pathways. Thus, where drinking water contaminants are a concern, mixing zones should not encroach on drinking water intakes. Where fish tissue residues are a concern (either because of measured or predicted residues), mixing zones should not be projected to result in significant health risks to average consumers of fish and shellfish, after considering exposure duration of the affected aquatic organisms in the mixing zone, and the patterns of fisheries use in the area.

While fish tissue contamination tends to be a far-field problem affecting entire waterbodies rather than a narrow-scale problem confined to mixing zones, restricting or eliminating mixing zones for bioaccumulative pollutants may be appropriate under conditions such as the following:

- Mixing zones should be restricted such that they do not encroach on areas often used for fish harvesting particularly of stationary species such as shellfish.
- Mixing zones might be denied where such denial is used as a device to compensate for uncertainties in the protectiveness of the water quality criteria or uncertainties in the assimilative capacity of the waterbody.

2.3 WATER QUALITY CRITERIA FOR AQUATIC LIFE PROTECTION

2.3.1 Development Process for Criteria

The development of national numerical water quality criteria for the protection of aquatic organisms is a complex process that uses information from many areas of aquatic toxicology. (See Reference 7 for a detailed discussion of this process.) After a decision is made that a national criterion is needed for a particular material, all available information concerning toxicity to, and bioaccumulation by, aquatic organisms is collected and reviewed for acceptability. If enough acceptable data for 48- to 96-hour toxicity tests on aquatic animals are available, they are used to derive the acute criterion. If sufficient data on the ratio of acute to chronic toxicity concentrations are available, they are used to derive the chronic or long-term exposure criteria. If justified, one or both of the criteria may be related to another water quality characteristic, such as pH, temperature, or hardness. Separate criteria are developed for freshwaters and saltwaters.

The water quality standards regulation allows States to develop numerical criteria or modify EPA's recommended criteria to account for site-specific or other scientifically defensible factors. In cases where additional toxicological data are needed to modify or develop criteria, the discharger may be required to generate the data. Guidance on modifying national criteria is found in the handbook [1]. When a criterion must be developed for a chemical for which a national criterion has not been established, the regulatory authority should refer to the *Guidelines for Deriving Criteria for Aquatic Life and Human Health* (see 45 *FR* 79341, November 28, 1980, and 50 *FR* 30784, July 29, 1985).

2.3.2 Magnitude for Single Chemicals

Water quality criteria for aquatic life contain two expressions of allowable magnitude: a CMC to protect against acute (short-term) effects and a CCC to protect against chronic (long-term) effects. EPA derives acute criteria from 48- to 96-hour tests of lethality or immobilization. EPA derives chronic criteria from longer-term (often greater than 28-day) tests that measure survival, growth, reproduction, or in some cases, bioconcentration.

Most State standards include numerical criteria for a limited number of individual toxic chemicals. Therefore, evaluation and control of toxic pollutants is based on maintenance of the designated use and often relies on the narrative criterion prohibiting toxic substances in toxic amounts. The adverse effects of concern will depend on the designated use and the chemical. Bioaccumulation of chemicals in aquatic organisms, toxicity to these organisms, the potential for additivity, antagonism, synergism, and persistence of the chemicals may be important. Available information on the toxic effects of the chemical is used when standards do not include specific numerical criteria. Such information can include EPA criteria documents, published literature reports, or studies conducted by the discharger.

As mentioned in Section 2.1.2, water quality-based controls may be based directly on the State's technical determination of what concentration of a specific pollutant meets the State's narrative "free from" toxics criterion. Although EPA water quality standards regulation requires that the State's process for implementing its narrative criterion be described in the State standards, there is no requirement that this concentration be adopted as a numerical criterion in State water quality standards prior to use in developing water quality-based controls and therefore a case-by-case interpretation of the narrative criterion may be necessary.

2.3.3 Magnitude for Whole Effluent Toxicity

Criteria for toxicity in current State standards range from the narrative prohibition (e.g., no discharge of toxic chemicals in toxic amounts) to detailed requirements that specify the test species and the allowable toxicity level. At present, there are no national criteria developed under CWA Section 304(a) for whole effluent toxicity. Acute and chronic toxicity units (TUs) are a mechanism for quantifying instream toxicity using the whole effluent approach. The procedure to implement the narrative criteria using a whole effluent approach should specify the testing procedure, the duration of the tests (acute or chronic), the test species, and the frequency of testing required.

EPA's recommended magnitudes for whole effluent toxicity are as follows (again, two expressions of allowable magnitude are used): a CMC to protect against acute (short-term) effects and a CCC to protect against chronic (long-term) effects. **For acute protection, the CMC should be set at 0.3 acute toxic unit (TU_a) to the most sensitive of at least three test species.**

The selection of test species for testing the effluent is not critical provided species from ecologically diverse taxa are used (e.g., a fish, an invertebrate, and a plant). The factor of 0.3 is used to adjust the typical LC_{50} endpoint of an acute toxicity test (50 percent mortality) to an LC_1 value (virtually no mortality). Specifically, a factor of 0.3 was found to include 91 percent of observed LC_1 to LC_{50} ratios in 496 effluent toxicity tests as illustrated in Figure 2-2. This figure presents effluent toxicity data from many years of toxicity testing of both industrial and municipal effluents by the Environmental Services Division, U.S. EPA Region IV, Athens, Georgia.

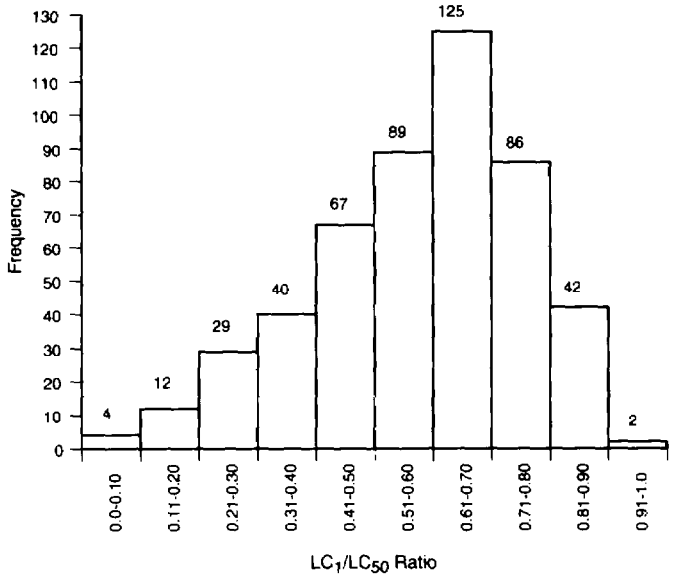

Figure 2-2. LC_1 to LC_{50} Ratios for Effluent Toxicity Tests

For chronic protection, the CCC should be set at 1.0 chronic toxic unit (TU_c) to the most sensitive of at least three test species. The selection of test organisms is as described above. A 1.0 TU_c is applied at the edge of the mixing zone to prevent any chronic toxicity in the receiving water outside the mixing zone.

2.3.4 Duration for Single Chemicals and Whole Effluent Toxicity

The quality of an ambient water typically varies in response to variations of effluent quality, stream flow, and other factors. Organisms in the receiving water are not experiencing constant, steady exposure but rather are experiencing fluctuating exposures, including periods of high concentrations, which may have adverse effects. Thus, EPA's criteria indicate a time period over which exposure is to be averaged, as well as a maximum concentration, thereby limiting the duration of exposure to elevated concentrations.

For acute criteria, EPA recommends an averaging period of 1 hour. That is, to protect against acute effects, the 1-hour average exposure should not exceed the CMC. The 1-hour acute averaging period was derived primarily from data on response time for toxicity to ammonia, a fast-acting toxicant. The 1-hour averaging period is expected to be fully protective for the fastest-acting toxicants, and even more protective for slower-acting toxicants. Scientifically justifiable alternative (site-specific) averaging periods can be derived from (1) data relating toxic response to exposure time, if coupled with considerations of delayed mortality (mortality occurring after exposure has ended), or (2) models of toxicant uptake and action, such as presented by Erickson [5] and Mancini et al. [4].

In practice, 1-day periods are the shortest periods for which WLA modelers and enforcement personnel have adequate data. Attainment of the duration criterion can be ensured by paying particular attention to short-term effluent variability and requiring measures to control variability (e.g., installation of equalization basins) when needed.

For chronic criteria, EPA recommends an averaging period of 4 days. That is, the 4-day average exposure should not exceed the CCC. Different chronic averaging periods could be derived, depending on the nature of the pollutant and the toxic endpoint of concern (e.g., the rate of uptake and accumulation, and the mode of action).

The toxicity tests used to establish the national criteria are conducted using steady exposure to toxicants usually for at least 28 days. The test concentrations do not fluctuate as much as typically occurs instream. As the period of averaging increases, so too does the period of time the exposure concentrations can be above the criterion concentration without exceeding the average. The significant consideration involved in setting duration criteria is how long the exposure concentration can be above the criterion concentration without unacceptably affecting the endpoint of the test (e.g., survival, growth, or reproduction). EPA selected the 4-day averaging period based on the shortest duration in which chronic effects are sometimes observed for certain species and toxicants, and thus should be fully protective even for the fastest-acting toxicants.

2.3.5 Frequency for Single Chemicals and Whole Effluent Toxicity

To predict or ascertain the attainment of criteria it is necessary to specify the allowable frequency for exceeding the criteria. This is because it is statistically impossible to project that criteria will never be exceeded. As ecological communities are naturally subjected to a series of stresses, the allowable frequency of pollutant stress may be set at a value that does not significantly increase the frequency or severity of all stresses combined.

EPA recommends a once in 3-year average frequency for excursions of both acute and chronic criteria. These recommendations apply to both chemical-specific and whole effluent approaches. However, the allowable frequency depends on site-specific factors. To implement alternative frequencies, site-specific factors (see Appendix D) or other data or analyses should be taken into account. In all cases, the recommended frequency applies to actual ambient concentrations, and excludes the influence of measurement imprecision.

EPA established its recommended frequency as part of its *Guidelines for Deriving Criteria,* last issued in 1985 [8]. EPA selected the 3-year return interval with the intent of providing a degree of protection roughly equivalent to a 7Q10 design flow condition, and with some consideration of rates of ecological recovery from a variety of severe stresses. Because of the nature of the ecological recovery studies available, the severity of criteria excursions could not be related rigorously to the resulting ecological impacts. Nevertheless, EPA derives its criteria intending that a single marginal criteria excursion (i.e., a slight excursion over a 1-hour period for acute or over a 4-day period for chronic) would result in little or no ecological effect and require little or no time for recovery. If the frequency of marginal criteria excursions is not high, it can be shown that the frequency of severe stresses, requiring measurable recovery periods, would be extremely small. EPA thus expects the 3-year return interval to provide a very high degree of protection.

Field studies indicate that many discharge situations are affected both by predictable and measurable discharges of toxicants and by unpredictable spills of toxic substances. In most cases, the dischargers were unaware that spills were occurring. These spills are a second source of stress for the community and decrease recovery potential. An aggressive program to minimize, contain, and treat spills should be in place at any plant where the potential for spills exists.

The concentration, duration, and frequency provisions of the criteria are implemented through the development of WLAs and water quality-based effluent limits. As discussed in Chapter 4, the duration and frequency recommendations are implemented directly if a dynamic modeling approach is used to develop WLAs and permit limits. However, if a steady-state approach is used, a design condition is needed for the calculations.

For the protection of aquatic life, the duration and frequency recommendations provided above have been used to develop recommended design flows for steady-state modeling. Chapter 4 discusses these recommended design flows.

Traditionally, most water quality-based permits for point source discharges had been tied to the 7-day, once in 10-year, low-flow conditions. The reason for this is that critical conditions for perennial point source discharges occur, in general, during the low-flow period. Currently, State laws and regulations generally state that water quality standards are applicable to the 7-day, 10-year low-flow or higher flow conditions.

It should be noted that EPA's water quality criteria for aquatic life protection are applicable at all flow conditions, low as well as high. These criteria and their specified duration and frequency, if adopted into or used to interpret State water quality standards, may be used as the basis for total maximum daily load (TMDL) after considering seasonal flow and loading scenarios. The concentration, duration, and frequency provisions of EPA's water quality criteria can be modified to account for site-specific conditions. As States have started using the new two-number water quality criteria for perennial as well as intermittent discharges such as combined sewer overflows, urban runoff, etc., their proper use in the context of the TMDL/WLA process needs to be emphasized.

2.4 WATER QUALITY CRITERIA FOR HUMAN HEALTH PROTECTION

2.4.1 Overview

There are a number of key elements of State water quality standards and implementation procedures relevant to human health protection. States must determine ambient standards for the two primary human exposure routes, fish consumption and drinking water. States must then establish whether mixing zones will apply, and, if so, determine the design conditions.

State standards or their implementation procedures often specify the risk level for carcinogens; methods for identifying compliance thresholds in permits where calculated limits are below detection; and methods for selecting appropriate hardness, pH, and temperature variables for criteria. However, if State standards do not specify these items, then the permitting authority must develop water quality-based effluent limits based upon either an interpretation of the State's water quality standards or EPA's criteria and procedures.

The purpose of the following section is to provide a review of EPA's procedures used to develop assessments of human health effects in developing water quality criteria and reference ambient concentrations. A complete human health effects discussion is included in the (draft) *Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Documents* by EPA's Environmental Criteria and Assessment Office (ECAO). The procedures contained in the ECAO document are used in the development and updating of EPA water quality criteria and may be used in developing reference ambient concentrations (RACs) for those pollutants lacking EPA human health criteria. Although the same procedures are used to develop criteria and RACs, only those values that are subjected to the regulatory process of regional, State, and public comment can be considered "criteria." RACs may be applied as site-specific interpretations of narrative standards and as a basis for permit limits under 40 *CFR* 122.44 (d)(1)(vi).

Procedures also are provided in this chapter to develop values called reference tissue concentrations (RTCs) that can be used in assessing or monitoring fish tissues for unacceptable residues.

2.4.2 Magnitude and Duration

Water quality criteria for human health contain only a single expression of allowable magnitude; a criterion concentration generally to protect against long-term (chronic) human health effects. Currently, national policy and prevailing opinion in the expert community dictate that the duration for human health criteria for carcinogens be derived assuming lifetime exposure, taken to be a 70-year time period. The duration of exposure assumed in deriving criteria for noncarcinogens is more complicated due to a wide variety of endpoints: some developmental (and thus age-specific and perhaps sex-specific), some lifetime, and some, such as organoleptic effects, not duration-related at all. Thus, appropriate durations depend on the individual noncarcinogenic pollutants and the endpoints or adverse effects being considered.

2.4.3 Human Exposure Considerations

A complete human exposure evaluation for toxic pollutants of concern for bioaccumulation would not only encompass estimates of exposures due to fish consumption, but also exposure due to background concentrations and other exposure routes, including recreational and occupational contact, dietary intake from other than fish, inhalation of air, and drinking water. However, the focus of this document is on ingestion of contaminated fish tissue, a direct human exposure route of potentially significant risk. (For the human health sections in this document the term "fish" generally is used to mean both fish and shellfish.) The consumption of contaminated fish tissue is of serious concern since the presence of even extremely low ambient concentrations of bioaccu-mulative pollutants (sublethal to aquatic life) in surface waters, can result in residue concentrations in fish tissue that can pose a human health risk. Other exposure route information should be considered and incorporated in human exposure evaluations to the extent it is available.

Levels of actual human exposures from consuming contaminated fish vary depending upon a number of case-specific consumption factors. These factors include type of fish species consumed, type of fish tissue consumed, tissue lipid content, consumption rate and pattern, and food preparation practices. In addition, depending on the spatial variability in the fishery area, the behavior of the fish species, and the point of application of the RAC or criterion, the average exposure of fish may be only a small fraction of the expected exposure at the point of application of the criterion. If an effluent attracts fish, the average exposure might be greater than the expected exposure.

With shellfish, such as oysters, snails, and mussels, whole body tissue consumption commonly occurs, whereas with fish, muscle tissue and roe are most commonly eaten. This difference in the types of tissues consumed has implications for the amount of available bioaccumulative contaminants likely to be ingested. Whole body shellfish consumption presumably means ingestion of the entire burden of bioaccumulative contaminants. However, with most fish, selective cleaning and removal of internal organs, and sometimes body fat as well, from edible tissues, may result in removal of much of the lipid material in which bioaccumulative contaminants tend to concentrate.

2.4.4 Fish Consumption Values

EPA's human health criteria have assumed a human body weight of 70 kg and the consumption of 0.0065 kg of fish and shellfish per day. Based on data collected in 1973-1974, the national per capita consumption of freshwater and estuarine fish was estimated to average 6.5 g/day. Per capita consumption of all seafood (including marine species) was estimated to average 14.3 g/day. The 95th percentile for consumption of all seafood by individuals over a period of 1 month was estimated to be 42 g/day [9]. The mean lipid content of fish tissue consumed in this study was estimated to be 3.0 percent [10].

Currently, four levels of fish consumption are provided in the EPA guidance manual, *Assessing Human Health Risk from Chemically Contaminated Fish and Shellfish.* These are:

- 6.5 g/day to represent an **estimate of average consumption of fish and shellfish from estuarine and freshwaters** by the entire U.S. population [9]. This fish consumption level is based on the average of both consumers and nonconsumers of fish.

- 20 g/day to represent an **estimate of the average consumption of fish and shellfish from marine, estuarine, and freshwaters** by the U.S. population [11]. This average fish consumption level also includes both consumers and nonconsumers of fish.

- 165 g/day to represent **consumption of fish and shellfish from marine, estuarine, and freshwaters by the 99.9th percentile of the U.S. population** consuming the most fish or seafood [12].

- 180 g/day to represent a "**reasonable worst case**" based on the assumption that some individuals would consume fish at a rate equal to the combined consumption of red meat, poultry, fish, and shellfish in the United States (EPA Risk Assessment Council assumption based on data from the U.S. Department of Agriculture Nationwide Food Consumption Survey of 1977-1978).

EPA currently is updating the national estuarine and freshwater fish and shellfish consumption default values and will provide a range of recommended national consumption values. This range will include mean values appropriate to the population at large, and values appropriate for those individuals who consume a relatively large proportion of fish in their diets (maximally exposed individuals).

Many States use the EPA's 6.5 g/day consumption value. However, some States (e.g., Wisconsin, Louisiana, Illinois, and Arizona) use the above mentioned 20 g/day value. For salt waters Delaware uses another EPA value, 37 g/day [13]. In general, EPA recommends that the consumption values used in deriving RACs from the formulas in this chapter reflect the most current relevant and/or site-specific information available.

2.4.5 Bioaccumulation Considerations for Reference Ambient Concentration Development

The ratio of the contaminant concentrations in fish tissue versus water is termed either the bioconcentration factor (BCF) or the bioaccumulation factor (BAF). Bioconcentration is defined as involving contaminant uptake from water only (not from food). Bioaccumulation is defined as involving contaminant uptake from both water and food. Under laboratory conditions, measurements of tissue/water partitioning generally are considered to involve uptake from water only. On the other hand, both process are likely to apply in the field since the entire food chain is exposed.

Table 2-1 shows the ratio of the BAF to the BCF as a function of the trophic level of the aquatic organism, and the log P (log octanol-water partition coefficient) of the chemical [14]. The BAF/BCF ratio ranges from 1 to 100, with the highest ratios applying to organisms in higher trophic levels, and to chemicals with log P close to 6.5. For chemicals with log P values greater than about 7, there is some uncertainty regarding the degree of bioaccumulation, but generally, trophic level effects appear to decrease due to slow transport kinetics of these chemicals in fish, the growth rate of the fish, and the chemical's relatively low bioavailability.

Care must be taken in assigning the trophic level since certain fish species may inhabit one source area of contaminated food for only a portion of their life. Under such conditions of migration, fish would only receive a small portion of the chemical and never come into equilibrium. In addition, trophic level for a given fish species will vary with life stage and structure of the food chain.

In this document, bioaccumulation considerations are integrated into the RAC equations in Sections 2.4.7 and 2.4.8 by using food chain multipliers (FMs) with the BCF. The bioaccumulation and bioconcentration factors for a chemical are related as follows:

$$BAF = FM \times BCF$$

By incorporating the FM and BCF terms into the RAC equations, bioaccumulation is addressed.

In this process, bioaccumulation considerations are included by incorporating the FM term with the BCF in calculating the RTCs and RACs. In Table 2-1, FM values derived from the work of Thomann [14, 15] are listed according to log P value and trophic level of the organism. **Trophic level 4 organisms are typically the most desirable species for sport fishing and therefore, FMs for trophic level 4 generally should be used in the equations for calculating RTCs and RACs.** In those very rare situations where only lower trophic level organisms are found, e.g., possibly oyster beds, an FM for a lower trophic level may be used in calculating the RTCs and RACs.

Measured BAFs (especially for those chemicals with log P values above 6.5) reported in the literature should be used when available. To use experimentally measured BAFs in calculating the RAC or RTC, the (FM x BCF) term, is replaced by the BAF in the equations in Sections 2.4.7 and 2.4.8. Relatively few BAFs have been measured accurately and reported, and their application to sites other than the specific ecosystem where they were developed is problematic and subject to uncertainty. The option also is available to develop BAFs experimentally, but this will be extremely resource intensive if done on a site-specific basis with all the necessary experimental and quality controls.

Table 2-1. Estimated Food Chain Multipliers

	Trophic Levels		
Log P	2	3	4
3.5	1.0	1.0	1.0
3.6	1.0	1.0	1.0
3.7	1.0	1.0	1.0
3.8	1.0	1.0	1.0
3.9	1.0	1.0	1.0
4.0	1.1	1.0	1.0
4.1	1.1	1.1	1.1
4.2	1.1	1.1	1.1
4.3	1.1	1.1	1.1
4.4	1.2	1.1	1.1
4.5	1.2	1.2	1.2
4.6	1.2	1.3	1.3
4.7	1.3	1.4	1.4
4.8	1.4	1.5	1.6
4.9	1.5	1.8	2.0
5.0	1.6	2.1	2.6
5.1	1.7	2.5	3.2
5.2	1.9	3.0	4.3
5.3	2.2	3.7	5.8
5.4	2.4	4.6	8.0
5.5	2.8	5.9	11
5.6	3.3	7.5	16
5.7	3.9	9.8	23
5.8	4.6	13	33
5.9	5.6	17	47
6.0	6.8	21	67
6.1	8.2	25	75
6.2	10	29	84
6.3	13	34	92
6.4	15	39	98
6.5	19	45	100
≥6.5	19.2*	45*	100*

* These recommended FMs are conservative estimates; FMs for log P values greater than 6.5 may range from the values given to as low as 0.1 for contaminants with very low bioavailability.

2.4.6 Updating Human Health Criteria and Generating RACs Using IRIS

EPA recommends using the most current risk information when updating criteria and generating RACs. The Integrated Risk Information System (IRIS) is an electronic online data base of the U.S. EPA that provides chemical-specific risk information on the relationship between chemical exposure and estimated human health effects [16]. Risk assessment information contained in the IRIS, except as specifically noted, has been reviewed and agreed upon by an interdisciplinary group of scientists representing various program offices within the Agency and represent an Agencywide consensus. Risk assessment information and values are updated monthly and are approved for Agencywide use.

The IRIS is intended to make risk assessment information readily available to those individuals who must perform risk assessments and also to increase consistency among risk assessment/risk management decisions. The IRIS is available to Federal and some State and local environmental agencies through the EPA's electronic MAIL system and also is available to the public through the Public Health Network and TOXNET. Since IRIS is designed to be a publicly available data base, interested parties may submit studies or documents for consideration by the appropriate interdisciplinary review group for chemicals currently on the IRIS or scheduled for review. Information regarding the submission of studies of chemicals may be obtained from the IRIS Information Submission Desk. In addition to chemical-specific summaries of hazard and dose-response assessments, the IRIS contains a series of sections identified by service codes that serve as a user's guide as well as provide background documentation on methodology. Additional information is available from IRIS Users Support: 513/FTS 684-7254.

The IRIS contains two types of quantitative risks values: reference dose (RfD) and the carcinogenic potency estimate or slope factor. The RfD (formerly known as the acceptable daily intake or ADI) is the human health hazard assessment for noncarcinogenic (target organ) effects. The carcinogenic potency estimate (formerly known as $q1^*$) represents the upper bound cancer causing potential resulting from lifetime exposure to a substance. The RfD or the oral carcinogenic potency estimate are used in the derivation of an RAC. Appendix H contains the supporting information for derivation of RfDs.

EPA periodically updates risk assessment information including RfDs, cancer potency estimates, and related information on contaminant effects, and reports the current information on IRIS. Since the IRIS contains the Agency's most recent quantitative risk assessment values, current IRIS values should be used in developing new RACs. **This means that the 1980 human health criteria should be updated with the latest IRIS values.** The procedure for deriving an updated human health water quality criterion would require inserting the current RfD or carcinogenic potency estimate on the IRIS into the appropriate equation in Section 2.4.7 or 2.4.8.

Figure 2-3 shows the procedure for determining an updated criterion or RAC using IRIS data. **If a chemical has both carcinogenic and noncarcinogenic effects, i.e., both a cancer potency estimate and RfD, the carcinogen RAC formula in Section 2.4.8 should be used as it will result in the more stringent RAC of the two.**

2.4.7 Calculating RACs for Noncarcinogens

The RfD is an estimate of the daily exposure to the human population that is likely to be without appreciable risk of causing

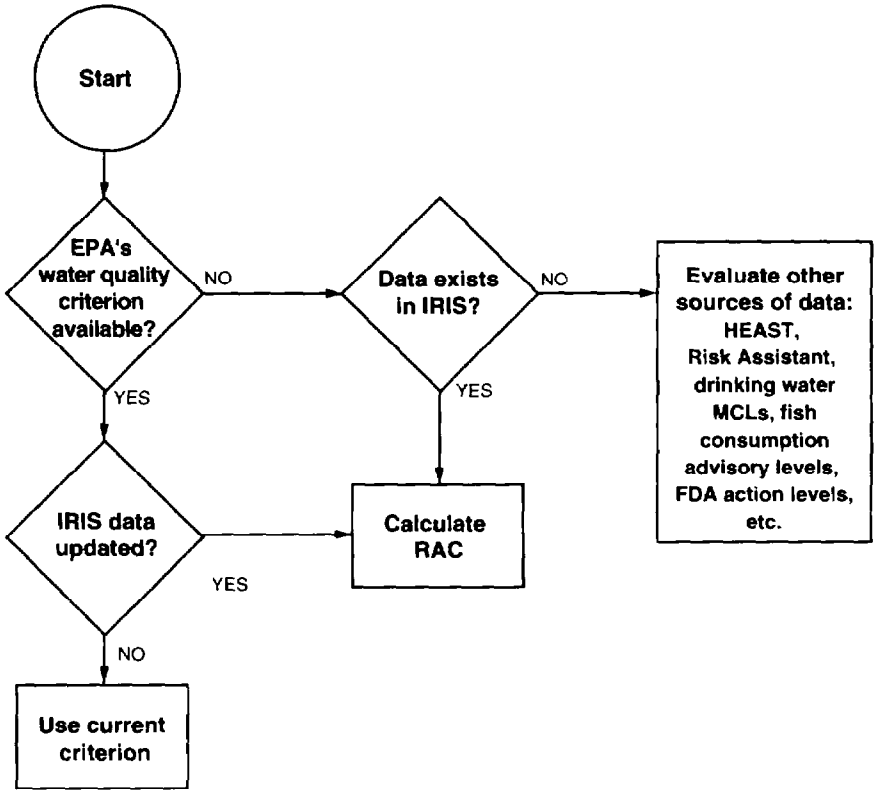

Figure 2-3. Procedure for Revising an EPA Human Health Criterion or Developing a Reference Ambient Concentration

deleterious effects during a lifetime. The RfD is expressed in units of mg toxicant per kg human body weight per day.

RfDs are derived from the "no observed adverse effect level" (NOAEL) or the "lowest observed adverse effect level" (LOAEL) identified from chronic or subchronic human epidemiology studies or animal exposure (mammal LD_{50}) studies. [Note: LOAEL and NOAEL refer to animal and human toxicology and are there fore distinct from the aquatic toxicity terms "no observed effect concentration" (NOEC) and the "lowest observed effect concentration" (LOEC)]. Uncertainty factors are then applied to the NOAEL or LOAEL to account for uncertainties in the data associated with variability among individuals, extrapolation from non-human test species to humans, data on other than long-term exposures, and the use of an LOAEL [17]. An additional uncertainty may be applied to account for significant weakness or gaps in the data base.

The RfD is a threshold below which effects are unlikely to occur. While exposures above the RfD increase the probability of adverse effects, they do not produce a certainty of adverse effects. Similarly, while exposure at or below the RfD reduces the probability, it does not guarantee the absence of effects in all persons. The RfDs contained in the IRIS are values that represent EPA's consensus (and have uncertainty spanning perhaps an order of magnitude).

For noncarcinogenic effects, an updated criterion or an RAC can be derived using the following equation:

$$C \text{ or } RAC\ (mg/l) = \frac{(RfD \times WT) - (DT + IN) \times WT}{WI + [FC \times L \times FM \times BCF]}$$

where

- C = updated water quality criterion (mg/l)
- RAC = reference ambient concentration (mg/l)
- RfD = reference dose (mg toxicant/kg human body weight/day)
- WT = weight of an average human adult (70 kg)
- DT = dietary exposure (other than fish) (mg toxicant/kg body human weight/day)
- IN = inhalation exposure (mg toxicant/kg body human weight/day)
- WI = average human adult water intake (2 liters/day)
- FC = daily fish consumption (kg fish/day)
- L = ratio of lipid fraction of fish tissue consumed to 3 percent
- FM = food chain multiplier (from Table 3-1)
- BCF = bioconcentration factor (mg toxicant/kg fish divided by mg toxicant/l water) for fish with 3 percent lipid.

If the receiving waterbody is not used as a drinking water source, the factor WI can be deleted. Where dietary and/or inhalation exposure values are unknown, these factors may be deleted from the above calculation. For identified noncarcinogenic chemicals without known RfDs, extrapolation procedures can be used to estimate the RfD (see Appendix H).

2.4.8 Calculating RACs for Carcinogens

Any human health criterion for a carcinogen is based on at least three interrelated considerations: potency, exposure, and risk characterization. States may make their own judgments on each of these factors within reasonable scientific bounds, but documentation to support their judgments must be clear and in the public record.

Maximum protection of human health from the potential effects of exposure to carcinogens via contaminated fish would require an RAC of zero. The zero level is based upon the assumption of nonthreshold effects (i.e., no safe level exists below which any increase in exposure does not result in an increase in the risk of cancer) for carcinogens. However, because safety does not require the absence of all risk, a numerical estimate of risk (in µg/l) that corresponds to a given level of risk for a population of a specified size is selected instead. A cancer risk level is defined as the number of new cancers that may result in a population of specified size due to an increase in exposure (e.g., 10^{-6} risk level = 1 additional cancer in a population of 1,000,000). Cancer risk is calculated by multiplying the experimentally derived cancer potency estimate by the concentration of the chemical in the fish and the average daily human consumption of contaminated fish. The risk for a specified population (e.g., 1,000,000 people or 10^{-6}) is then calculated by dividing the risk level by the specific cancer risk. EPA's ambient water quality criteria documents provide risk levels ranging from 10^{-5} to 10^{-7} as examples.

When the cancer potency estimate, or slope factor (formerly known as the q1*), is derived using animal studies, high-dose exposures are extrapolated to low-dose concentrations and adjusted to a lifetime exposure period through the use of a linearized multistage model. The model calculates the upper 95 percent confidence limit of the slope of a straight line that the model postulates to occur at low doses. When based on human (epidemiological) data, the slope factor is based on the observed increase in cancer risk, and is not extrapolated. For deriving RACs for carcinogens, the oral cancer potency estimates or slope factors from the IRIS are used.

It is important to note that cancer potency factors may overestimate actual risk. Such potency estimates are subject to great uncertainty due to two primary factors: (1) adequacy of the cancer data base (i.e., human versus animal data) and (2) limited information regarding the mechanism of cancer causation. The actual risk may be much lower, perhaps as low as zero, particularly for those chemicals for which human carcinogenicity information is lacking. Risk levels of 10^{-5}, 10^{-6}, and 10^{-7} are often used by States as minimal risk levels in interpreting their standards. EPA considers risks to be additive, i.e., the risk from individual chemicals is not necessarily the overall risk from exposure to water. For example, an individual risk level of 10^{-6} may yield a higher overall risk level if multiple carcinogenic chemicals are present.

For carcinogenic effects, the RAC can be determined by using the following equation:

$$C \text{ or } RAC\ (mg/l) = \frac{(RL \times WT)}{q1^* [WI + FC \times L \times (FM \times BCF)]}$$

where

C = updated water quality criterion (mg/l)
RAC = reference ambient concentration (mg/l)
RL = risk level (10^{-x})
WT = weight of an average human adult (70 kg)
q1* = carcinogenic potency factor (kg day/mg)
WI = average human adult water intake (2 liters/day)
FC = daily fish consumption (kg fish/day)
L = ratio of lipid fraction of fish tissue consumed to 3 percent
FM = food chain multiplier (from Table 3-2)
BCF = bioconcentration factor (mg toxicant/kg fish divided by mg toxicant/l water) for fish with 3 percent lipid.

If the receiving waterbody is not used as a drinking water source, the factor WI can be deleted. For identified carcinogenic chemicals without known cancer potency estimate values, extrapolation procedures can be used to estimate the cancer potency.

2.4.9 Deriving Quantitative Risk Assessments in the Absence of IRIS Values

The RfDs or cancer potency estimates comprise the existing dose factors for developing RACs. When IRIS data are unavailable, quantitative risk level information may be developed according to a State's own procedures. Some States have established their own procedures whereby dose factors can be developed based upon extrapolation of acute and/or chronic animal data to concentrations of exposure protective of fish consumption by humans. Where no procedure exists, factors may be based upon extrapolation from mammalian or other data using IRIS documentation or information available from other EPA risk data bases. Also, where no other information or procedure exists, drinking water maximum contaminant levels (MCLs) or Food and Drug Administration (FDA) action levels may be used as guidance in developing numerical estimates.

2.4.10 Deriving Reference Tissue Concentrations for Monitoring Fish Tissue

Where fish tissue evaluations have been used for assessing human health risks, or, perhaps, used for additional routine monitoring where a chemical is below analytical detection limits, the following formulas may be used to calculate an RTC. Readers also should consult EPA's *Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish* [17].

The basic equations for deriving RTC (in mg/kg) use the same parameters as in equations 2.1 and 2.2, where BCF is normalized at 3.0 percent lipid:

For noncarcinogens:

$$\text{RTC (mg/kg)} = \frac{(\text{RFD} \times \text{WT}) - (\text{DT} + \text{IN}) \times \text{WT}}{[\text{WI}/(\text{BCF} \times \text{FM} \times \text{L})] + \text{FC}}$$

For carcinogens:

$$\text{RTC (mg/kg)} = \frac{\text{RL} \times \text{WT}}{\text{q1*}\ [\text{WI}/(\text{BCF} \times \text{FM} \times \text{L}) + \text{FC}]}$$

The above equations should be corrected for site-specific lipid content and bioaccumulation factors where data are available.

Again, some States have established their own procedures whereby RTCs can be developed based upon extrapolation of acute and/or chronic animal data to safe concentrations protective of fish consumption by humans. Where additional risk information is needed, an RTC could be based upon other information such as drinking water MCLs or FDA action levels.

2.5 BIOLOGICAL CRITERIA

As discussed in Chapter 1, to fully protect aquatic habitats and provide more comprehensive assessments of aquatic life use attainment/nonattainment, States are to fully integrate chemical-specific techniques, toxicity testing, biological surveys, and biocriteria into their water quality programs. In particular, the Agency's policy is that States should develop and implement biological criteria in their water quality standards (see Chapter 1, Reference 55).

2.5.1 Regulatory Bases for Biocriteria

The primary statutory basis for EPA's policy that States should develop biocriteria is found in Sections 101(a) and 303(c)(2)(B) of the Water Quality Act of 1987. Section 101(a) of the CWA gives the general authority for biological criteria. It establishes as the objective of the Act the restoration and maintenance of the chemical, physical, and biological integrity of the Nation's waters. To meet this objective, water quality criteria should address biological integrity. Section 101(a) includes the interim water quality goal for the protection and propagation of fish, shellfish, and wildlife.

Section 304 of the Act provides the legal basis for the development of informational criteria, including biological criteria. Specific directives for the development of regulatory biocriteria can be found in Section 303, which requires EPA to develop criteria based on biological assessment methods when numerical criteria are not established.

Once biocriteria formally are adopted into State standards, biocriteria and aquatic life use designations serve as direct, legal endpoints for determining a quality life use attainment/nonattainment. As stated in Section 131.11(b)(2) of the Water Quality Standards Regulation (40 *CFR* Part 131), biocriteria should be used as a supplement to existing chemical-specific criteria and as criteria where such chemical-specific criteria have not been established. States are encouraged to implement and integrate all three approaches (biosurvey, chemical-specific, and toxicity testing methods) into their water quality programs, applying them in combination or independently (providing the most protective of the three methods is used) as site-specific conditions and assessment objectives dictate.

Section 304(a) directs EPA to develop and publish water quality criteria and information on methods for measuring water quality and establishing water quality criteria for toxic pollutants on bases other than pollutant-by-pollutant, including biological monitoring and assessment methods that assess:

- The effects of pollutants on aquatic community components (". . . plankton, fish, shellfish, wildlife, plant life . . .")

and community attributes (". . . biological community diversity, productivity, and stability . . ."); in any body of water.

- Factors necessary " . . . to restore and maintain the chemical, physical, and biological integrity of all navigable waters . . ." for " . . . the protection of shellfish, fish, and wildlife for classes and categories of receiving waters . . . ."

2.5.2 Development and Implementation of Biocriteria

Biocriteria are numerical values or narrative expressions that describe the reference biological integrity of aquatic communities inhabiting unimpaired waters of a designated aquatic life use. The biological communities in these waters represent the best attainable conditions. The reference site conditions then become the basis for developing biocriteria for major surface water types (streams, rivers, lakes, wetlands, estuaries, or marine waters).

Biological criteria support designated aquatic life use classifications for application in State standards. Each State develops its own designated use classification system based on the generic uses cited in the Act (e.g., protection and propagation of fish, shellfish, and wildlife). Designated uses are intentionally general. However, States may develop subcategories within use designations to refine and clarify the use class. Clarification of the use class is particularly helpful when a variety of surface waters with distinct characteristics fit within the same use class, or do not fit well into any category.

For example, subcategories of aquatic life uses may be on the basis of attainable habitat (e.g., cold versus warmwater communities dominates by bass versus catfish). Special uses also may be designated to protect particularly unique, sensitive, or valuable aquatic species, communities, or habitats.

Resident biota integrate multiple impacts over time and can detect impairment from known and unknown causes. Biocriteria can be used to verify improvement in water quality in response to regulatory efforts and detect continuing degradation of waters. They provide a framework for developing improved best management practices for nonpoint source impacts. Numeric criteria can provide effective monitoring criteria for inclusion in permits.

The assessment of the biological integrity should include measures of the structure and function of an aquatic community of species within a specified habitat. Expert knowledge of the system is required for the selection of appropriate biological components and measurement indices. The development and implementation of biological criteria requires:

- Selecting unimpaired (minimal impact) surface waters to use as the reference condition for each designated use

- Measuring the structure and function of aquatic communities in reference surface waters to establish biological criteria

- Establishing a protocol to compare the biological criteria to biota in impacted waters to determine whether impairment has occurred.

These elements serve as an interactive network that is particularly important during early development of biological criteria where rapid accumulation of information is effective for refining both designated uses and developing biological criteria values.

2.6 SEDIMENT CRITERIA

2.6.1 Current Developments in Sediment Criteria

While ambient water quality criteria are playing an important role in assuring a healthy aquatic environment, they alone have not been sufficient to ensure appropriate levels of environmental protection. Sediment contamination, which can involve deposition of toxicants over long periods of time, is responsible for water quality impacts in some areas.

EPA has authority to pursue the development of sediment criteria in streams, lakes, and other waters of the United States under CWA Sections 104 and 304(a)(1) and (2) as follows:

- Section 104(n)(1) authorizes the Administrator to establish national programs that study the effects of pollution, including sedimentation, in estuaries on aquatic life.

- Section 304(a)(1) directs the Administrator to develop and publish criteria for water quality, including information on the factors affecting rates of organic and inorganic sedimentation for varying types of receiving waters.

- Section 304(a)(2) directs the Administrator to develop and publish information on, among other things, "the factors necessary for the protection and propagation of shellfish, fish, and wildlife for classes and categories of receiving waters..."

To the extent that sediment criteria could be developed that address the concerns of the Section 404(b)(1) guidelines for discharges of dredged or fill material under the CWA or the Marine Protection Research, and Sanctuaries Act, they also could be incorporated into those regulations.

2.6.2 Approach to Sediment Criteria Development

Over the past several years, sediment criteria development activities have centered on evaluating and developing the equilibrium partitioning approach for generating sediment criteria. The equilibrium partitioning approach focuses on predicting the chemical interaction between sediments and contaminants. Developing an understanding of the principal factors that influence the sediment/contaminant interactions will allow for predictions to be made as to what concentration of a contaminant benthic and other organisms may be exposed to. Chronic water quality criteria, or possibly other toxicological endpoints can then be used to predict potential biological effects. In addition to the development of sediment criteria, EPA also is working to develop a standardized sediment toxicity test that could be used with or independently of sediment criteria and could be used to assess chronic effects in freshwater and marine water.

Equilibrium partitioning (EqP) sediment quality criteria (SQC) are the EPA's best recommendation of the concentration of a substance in sediment that will not unacceptably affect benthic organisms or their uses.

Methodologies for deriving effects based SQC vary for different classes of compounds. For non-ionic organic chemicals the methodology requires normalization to organic carbon. A methodology for deriving effects based sediment criteria for metal contaminants is under development and is expected to require normalization to acid volatile sulfide. EqP SQC values can be derived for varying degrees of uncertainty and levels of protection thus permitting use for ecosystem protection and remedial programs.

2.6.3 Application of Sediment Criteria

SQC would provide a basis for making more informed decisions on the environmental impacts of contaminated sediments. Existing sediment assessment methodologies are limited in their ability to identify chemicals of concern, responsible parties, degree of contamination, and zones of impact. EPA believes that a comprehensive approach using SQC and biological test methods is preferred in order to make the most informed decisions.

Sediment criteria will be particularly valuable in site monitoring applications where sediment contaminant concentrations are gradually approaching a criteria over time. Sediment criteria also are valuable as a preventative tool to ensure that point and nonpoint sources of contamination are controlled to ensure uncontaminated sediments remain uncontaminated. Also, comparison of field measurements to sediment criteria will be a reliable method for providing early warning of a potential problem. An early warning would provide an opportunity to take corrective action before adverse impacts occur. For the reasons mentioned above it has been identified that SQC are essential to resolving key contaminated sediment and source control issues in the Great Lakes.

Specific Applications

Specific applications of sediment criteria are under development. The primary use of EqP-based sediment criteria will be to assess risks associated with contaminants in sediments. The various offices and programs concerned with contaminated sediment have different regulatory mandates and thus, have different needs and areas for potential application of sediment criteria. Because each regulatory need is different, EqP-based sediment quality criteria designed specifically to meet the needs of one office or program may have to be implemented in different ways to meet the needs of another office or program.

One mode of application of EqP-based numerical SQC would be in a tiered approach. In such an application, when contaminants in sediments exceed the SQC, the sediments would be considered as causing unacceptable impacts. Further testing may or may not be required depending on site-specific conditions and the degree in which a criteria has been violated. (No additional testing would be required in locations where contamination significantly exceeds a criterion. Where sediment contaminant levels are close to a criteria, additional testing may be necessary.) Contaminants in a sediment at concentrations less than the sediment criteria would not be of concern. However, in some cases the sediment could not be considered safe because they may contain other contaminants above safe levels for which no sediment criteria exist. In addition, the synergistic, antagonistic, or additive effects of several contaminants in the sediments may be of concern.

Additional testing in other tiers of an evaluation approach, such as bioassays, could be required to determine if the sediment is safe. It is likely that such testing would incorporate site-specific considerations. Examples of specific applications of sediment criteria after they are developed are as follows:

- Establish permit limits to ensure that uncontaminated sediments remain uncontaminated or sediments already contaminated have an opportunity to cleanse themselves. This would occur only after criteria and the means to tie point sources to sediment deposition are developed.
- Establish target levels for nonpoint source causes of sediment contamination.
- For remediation activities, SQC would be valuable in identifying:
  - Remediation need
  - Spatial extent of remediation area
  - Benefits derived from remediation activities
  - Responsible parties
  - Impacts of depositing contaminated sediments in water environments
  - Success of remediation activities.
- In tiered testing sediment evaluation processes, sediment criteria and biological testing procedures work very well together.

2.6.4 Sediment Criteria Status

Science Advisory Board Review

The Science Advisory Board has completed its review and issued a favorable report on the EqP for assessing sediment quality. The Subcommittee found the EqP "to have major strengths in its foundation in chemical theory, its ease of calculation, and its ability to make use of existing data... The conceptual basis of the approach is supported by the Subcommittee; however, its application at this time is limited."

The Science Advisory Board also identified the need for "a better understanding of the uncertainty around the assumptions inherent in the approach, including assumptions of equilibrium, bioavailability, and kinetics, all critical to the application of the EqP." An uncertainty analysis and a guidance document to assist in the regulatory application of developed criteria are under development and expected to be completed in 1991.

Sediment Criteria Documents and Application Guidance

EPA efforts at producing sediment criteria documents are being directed first toward phenanthrene, fluoranthene, DDT, dieldrin, acenaphthene and endrin. Efforts also are being directed to produce a guidance document, *Application of Sediment Quality Criteria for the Protection of Aquatic Life*, scheduled for release in 1991.

Methodology for Developing Sediment Criteria for Metal Contaminants

EPA is proceeding with a methodology for developing sediment criteria for metal contaminants, with key work focused on identifying and understanding the role of acid volatile sulfides (AVS) in controlling the bioavailability of metal contaminants. A variety of field and laboratory verification studies are underway to add additional support to the methodology. Standard AVS sampling and analytical procedures are under development [18]. Presentation of the metals methodology to the Science Advisory Board for review is scheduled for 1991.

CHAPTER 2
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3. EFFLUENT CHARACTERIZATION

3.1 INTRODUCTION

Once the applicable designated uses and water quality criteria for a waterbody are determined, the effluent must be characterized and the permitting authority must determine the need for permit limits to control the discharge. The purpose of effluent characterization is to determine whether the discharge causes, has the reasonable potential to cause, or contributes to an excursion of numeric or narrative water quality criteria. **Once the permitting authority determines that a discharge causes, has the reasonable potential to cause, or contributes to the excursion of water quality criteria, the permitting authority must develop permit limits that will control the discharge.** At a minimum, the permitting authority must make this determination at each permit reissuance. The effluent characterization procedures described in the following sections apply only to the water quality-based approach, not to end-of-the-pipe technology-based controls.

Although many waterbodies receive discharges from only single point sources, permitting authorities will also occasionally encounter receiving waters where several dischargers are in close proximity. In such situations, the permitting authority may find that each discharger alone does not cause, have the reasonable potential to cause, or contribute to an excursion above water quality criteria. Yet, the dischargers may collectively cause, have the reasonable potential to cause, or contribute to an excursion. **Under these circumstances, limits must be developed for each discharger to protect against collective excursions of applicable water quality standards consistent with the Environmental Protection Agency's (EPA) existing regulations in 40 *CFR* 122.44(d)(1)(ii) for controlling multiple discharges.** The terms "cause," "reasonable potential to cause," and "contribute to" are the terms used in the National Pollutant Discharge Elimination System (NPDES) regulations for conditions under which water quality-based limits are required. Permitting authorities are required to consider each of these concepts when performing effluent characterizations.

This chapter is divided into two parts: Section 3.2, Determining the Need for Permit Limits Without Effluent Data, and Section 3.3, Determining the Need for Permit Limits With Effluent Data. Section 3.3 includes effluent characterization for whole effluent toxicity and for specific chemicals (including those for human health protection) and is based on the cumulative experience gained by EPA, States, publicly owned treatment works (POTWs), and industry when implementing the water quality-based approach to toxics control. The effluent bioconcentration evaluation procedures described in the section on human health are currently draft and are subject to further validation before being used. Until the procedures are fully developed, reviewed, and finalized, permitting authorities should not use them to characterize effluents.

3.1.1 NPDES Regulation Requirements

Effluent characterization is an essential step in determining the need for an NPDES permit limit. NPDES regulations under 40 *CFR* 122.44(d)(1) specify the minimum requirements and general types of analyses necessary for establishing permit limits. Each of these regulations is described below.

40 *CFR* 122.44(d)(1)(ii)

> When determining whether a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above a narrative or numeric criteria within a State water quality standard, the permitting authority shall use procedures which account for existing controls on point and nonpoint sources of pollution, the variability of the pollutant or pollutant parameter in the effluent, the sensitivity of the species to toxicity testing (when evaluating whole effluent toxicity), and where appropriate, the dilution of the effluent in the receiving water.

This regulation requires at a minimum the consideration of each of these elements in determining the need for a limit.

40 *CFR* 122.44(d)(1)(iii)

> When the permitting authority determines, using the procedures in paragraph (d)(1)(ii) of this section, that a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above the allowable ambient concentration of a State numeric criteria within a State water quality standard for an individual pollutant, the permit must contain effluent limits for that pollutant.

Under this regulation, permitting authorities need to investigate for the existence of pollutants in effluents if there is a numeric water quality criterion for that pollutant and to implement limits for those pollutants where necessary.

40 *CFR* 122.44(d)(1)(iv)

> When the permitting authority determines, using the procedures in paragraph (d)(1)(ii) of this section, that a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above the numeric criterion for whole effluent toxicity, the permit must contain effluent limits for whole effluent toxicity.

Under this regulation, permitting authorities need to investigate for the existence of whole effluent toxicity in effluents if there is a numeric water quality criterion for that parameter and to implement whole effluent toxicity limits where necessary.

40 *CFR* 122.44(d)(1)(v)

> Except as provided in this subparagraph, when the permitting authority determines, using the procedures in paragraph (d)(1)(ii) of this section, toxicity testing data, or other information, that a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above a narrative criterion within an applicable State water quality standard, the permit must contain effluent limits for whole effluent toxicity. Limits on whole effluent toxicity are not necessary where the permitting authority demonstrates in the fact sheet or statement of basis of the NPDES permit, using the procedures in paragraph (d)(1)(ii) of this section, that chemical-specific limits for the effluent are sufficient to attain and maintain applicable numeric and narrative State water quality standards.

Under this regulation, permitting authorities need to investigate for the existence of whole effluent toxicity in effluents. If the permitting authority can demonstrate that control of specific chemicals is sufficient to control toxicity to the point of achieving compliance with the water quality criteria, then chemical-specific permit limits alone will be sufficient to comply with the regulation.

40 *CFR* 122.44(d)(1)(vi)

> Where a State has not established a water quality criterion for a specific chemical pollutant that is present in an effluent at a concentration that causes, has the reasonable potential to cause, or contributes to an excursion above a narrative criterion within an applicable State water quality standard, the permitting authority must establish effluent limits using one or more of the following [three] options: ....

Under this regulation, permitting authorities need to investigate for the existence of specific chemicals in effluents for which the State has not adopted numeric criteria, but which may be contributing to aquatic toxicity or impairment of human health. Narrative criteria apply when numeric criteria do not protect all the designated or existing uses. For example, the narrative criteria need to be used to protect human health if a State has only adopted a numeric criteria for protecting aquatic life. Conversely, the narrative criteria need to be used to protect aquatic life if a State has only adopted a numeric criteria for protecting human health. Once the permitting authority determines that one or more specific chemicals in an effluent must be controlled, the authorities can use EPA's national criteria, develop their own criteria, or control the pollutant through use of an indicator pollutant, as provided in subparagraph (d)(1)(vi). In any case, the permitting authority will need to characterize the effluent in a manner consistent with the selected approach for controlling the pollutant.

3.1.2 Background for Toxic Effects Assessments on Aquatic Life and Human Health

Aquatic toxicity effects can be characterized by conducting a general assessment of the effluent, or by measuring effluent toxicity or concentrations of individual chemicals and comparing these measurements to the expected exposure concentrations in the receiving water. The "receiving water concentration" (RWC) is the measured or projected exposure concentration of a toxicant or the parameter toxicity (when dealing with the whole effluent toxicity) in the receiving water after mixing. The RWC is calculated at the edge of a mixing zone if such a zone is allowed by a State's water quality standards.

As with aquatic life protection, there are two possible approaches to characterizing effluents for human health effects: chemical-by-chemical and whole effluent. However, only the chemical-by-chemical approach currently is practical for assessing and controlling human health impacts. Appendix G discusses developing procedures for assessing human health impacts from whole effluents.

A fundamental principle in the development of water quality-based controls is that the RWC must be less than the criteria that comprise or characterize the water quality standards. With individual toxicants (or the parameter toxicity), the potential for toxicity in the receiving water is minimized where the RWC is less than the criterion continuous concentration (CCC), the criterion maximum concentration (CMC), and the reference ambient concentration (RAC). Toxicity becomes maximized where the RWC exceeds these criteria. **Therefore, to prevent impacts to aquatic life or human health, the RWC of the parameter effluent toxicity or an individual toxicant (based on allowable dilution for the criterion) must be less than the most limiting of the applicable criterion, as indicated below.** (The RAC as used throughout this chapter incorporates EPA human health criteria and State standards as well.)

RWC < CCC (chronic aquatic life)
RWC < CMC (acute aquatic life)
RWC < RAC (human health)

The water quality analyst will use the same basic components in the above-described relationship (i.e., critical receiving water flows, ambient criteria values, measures of effluent quality) for both effluent characterization and wasteload allocation (WLA) development, albeit from different perspectives. In the case of effluent characterization, the objective is to project receiving water concentrations based upon existing effluent quality to determine whether or not an excursion above ambient criteria occurs, or has the reasonable potential to occur. In developing WLAs, on the other hand, the objective is to fix the RWC at the desired criteria level and determine an allowable effluent loading that will not cause excursions above the criteria.

Recommendations for projecting the RWC are described within this chapter. Chapter 4, Exposure Assessment and Wasteload Allocation, provides recommendations for determining allowable effluent loadings to achieve established ambient criteria and for calculating WLAs for establishing permit limits. The procedures described within Chapter 4 can also be used to calculate the dilution for analyses within Chapter 3. Chapter 5, Permit Requirements, describes the actual calculation of permit limits after effluent characterization and loadings, as well as WLAs, are complete.

3.1.3 General Considerations in Effluent Characterization

There are two possible ways to characterize an effluent to determine the need for effluent limits for the protection of aquatic life and human health. First, an assessment may be made without generating effluent data; second, an assessment may be conducted after effluent data have been generated. Regulatory authorities must determine whether a discharge causes, has the "reasonable potential" to cause, or contributes to an excursion above an applicable narrative or numeric water quality criterion. An analysis of "reasonable potential" determines an effluent's capability to cause such excursions.

In determining the need for a permit limit for whole effluent toxicity or for an individual toxicant, the regulatory authority is required to consider, at a minimum, existing controls on point and nonpoint sources of pollution, the variability of the pollutant or pollutant parameter in the effluent, the sensitivity of the involved species to toxicity testing (for whole effluent), and, where appropriate, the dilution of the effluent in the receiving water (40 *CFR* 122.44(d)(ii)).

The regulatory authority is also required by NPDES regulations to consider whether technology-based limits are sufficient to maintain State water quality standards. There are two possibilities that will need to be assessed. First, if the limits based on appropriate treatment technology have already been specified in a previous permit, and if the facility is operating at the required level, then historical effluent and receiving water information can be used. Second, if the facility has yet to achieve the required technology performance (best available technology or best conventional technology), the regulatory authority will need to assess the technology-based limit for reasonable potential for causing or contributing to an excursion above the water quality standard.

In addition, the regulatory authority should consider all other available data and information pertaining to the discharger to assist in making an informed judgment. Where both effluent testing data and important other factors exist, the regulatory authority will need to exercise discretion in the determination of the need for a limit. **The authority should employ the principle of "independent application" of the data and information that characterizes the effluent.** In other words, effluent data alone, showing toxicity at the RWC, may be adequate to demonstrate the need for a limit for toxicity or for individual toxicants. Likewise, other factors may form an adequate basis for determining that limits are necessary. For example, where available dilution is low and monitoring information shows that toxic pollutants are frequently discharged at concentrations that have caused toxicity when discharged from similar facilities, the permitting authority may reason that a whole effluent toxicity limit is necessary even without whole effluent toxicity data from the specific facility. In all cases, the decision must be based upon consideration of factors cited in 40 *CFR* 122.44(d)(1)(ii). The regulatory authority will need to prioritize, on a case-by-case basis, the importance of all data and information used in making a determination. To assist in case-by-case determinations, recommended guidelines for characterizing an effluent for the need for a permit limit for whole effluent toxicity or individual toxicants are discussed below and summarized in Boxes 3-1 through 3-3.

Box 3-1. Determining "Reasonable Potential" for Excursions Above Ambient Criteria Using Factors Other than Facility-specific Effluent Monitoring Data

When determining the "reasonable potential" of a discharge to cause an excursion above a State water quality standard, the regulatory authority must consider all the factors listed in 40 *CFR* 122.44(d)(1)(ii). Examples of the types of information relating to these factors are listed below.

Existing controls on point and nonpoint sources of pollution

- Industry type: Primary, secondary, raw materials used, products produced, best management practices, control equipment, treatment efficiency, etc.
- Publicly owned treatment work type: Pretreatment, industrial loadings, number of taps, unit processes, treatment efficiencies, chlorination/ammonia problems, etc.

Variability of the pollutant or pollutant parameter in the effluent

- Compliance history
- Existing chemical data from discharge monitoring reports and applications.

Sensitivity of the species to toxicity testing

- Adopted State water quality criteria, or EPA criteria
- Any available in-stream survey data **applied under independent application of water quality standards**
- Receiving water type and designated/existing uses

Dilution of the effluent in the receiving water

- Dilution calculations

3.2 DETERMINING THE NEED FOR PERMIT LIMITS WITHOUT EFFLUENT MONITORING DATA FOR A SPECIFIC FACILITY

If the regulatory authority so chooses, or if the circumstances dictate, the authority may decide to develop and impose a permit limit for whole effluent toxicity or for individual toxicants without facility-specific effluent monitoring data, or prior to the generation of effluent data. Water quality-based permit limits can be set for a single toxicant or for whole effluent toxicity based on the available dilution and the water quality criterion or the State standard in the absence of facility specific effluent monitoring data. However, in doing so, the regulatory authority must satisfy all the requirements of 40 *CFR* 122.44(d)(1)(ii).

When determining whether or not a discharge causes, has the reasonable potential to cause, or contributes to an excursion of a numeric or narrative water quality criterion for individual toxicants or for toxicity, the regulatory authority can use a variety of factors and information where facility-specific effluent monitoring data are unavailable. These factors also should be considered with available effluent monitoring data. Some of these factors are the following:

- **Dilution**—Toxic impact is directly related to available dilution for the effluent. Dilution is related to the receiving stream flow and the size of the discharge. The lower the available dilution, the higher the potential for toxic effect. If an effluent's concentration at the edge of a mixing zone in a receiving water is expected to reach 1 percent or higher during critical or worst-case design periods, then such an effluent may require a toxicity limit (see discussion in Section 3.3.3). Assessment of the amount of stream dilution available should be made at the conditions required by the water quality standards or, if not specified in the standards, at the harmonic mean flow and the 7Q10 flow. Figure 3-3 (Pg. 57) shows that, whereas a majority of NPDES permittees nationwide discharge to areas during annual mean flow ranging in dilution from 100 to 1,000, the majority of dischargers fall into the 1 to 10 dilution range during low-flow conditions.

- **Type of industry**—Although dischargers should be individually characterized because toxicity problems are site-specific, the primary industrial categories should be of principal toxicity concern. EPA's treatment technology data base generally suggests that secondary industrial categories may have less potential for toxicity than primary industries. However, based on experience, it is virtually impossible to generalize the toxicity of effluents with any certainty. If two plants produce the same type of product, one effluent may be toxic while the other may not be toxic due to the type and efficiency of the treatment applied, general materials handling practices, and the functional target of the compound(s) being produced.

- **Type of POTW**—POTWs with loadings from indirect dischargers (particularly primary industries) may be candidates for toxicity limits. However, absence of industrial input does not guarantee an absence of POTW discharge toxicity problems. For example, commercial pesticide applicators often discharge to POTWs, resulting in pesticide concentrations in the POTW's effluent. Household disposal of pesticides, detergents, or other toxics may have a similar effect. The types of industrial users, their product lines, their raw materials, their potential and actual discharges, and their control equipment should be evaluated. POTWs should also be characterized for the possibility of chlorine and ammonia problems.

- **Existing data on toxic pollutants**—Discharge monitoring reports (DMRs) and data from NPDES permit application forms 2C and 2A may provide some indication of the presence of toxicants. The presence or absence of the 126 "priority pollutants" may or may not be an indication of the presence or absence of toxicity. There are thousands of "nonpriority" toxicants that may cause effluent toxicity. Also, combinations of several toxicants can produce ambient toxicity where the individual toxicants would not. EPA regulations at 40 *CFR* 122.21(j) require POTWs with design flows equal to or greater than 1 MGD and POTWs with approved pretreatment programs, or POTWs required to develop a pretreatment program, to submit the results of whole effluent toxicity tests with their permit applications. These regulations also provide discretion to the permitting authority to request such data from other POTWs at the time of permit application.

- **History of compliance problems and toxic impact**—Regulatory authorities may consider particular dischargers that have had difficulty complying with limits on toxicants or that have a history of known toxicity impacts as probable priority candidates for effluent toxicity limits.

- **Type of receiving water and designated use**—Regulatory authorities may compile data on water quality. Examples of available data include fish advisories or bans, reports of fish kills, State lists of priority waterbodies, and State lists of waters that are not meeting water quality standards. Regulatory authorities should use this information as a means of identifying point sources that discharge to impaired waterbodies and that thus may be contributing to this impairment. One source of this information is the lists of waters generated by states to comply with Section 304(l) regulations at 40 *CFR* 130.10(d)(6); 50 *FR* 23897-98, June 2, 1989:

    1) Waters where fishing or shellfish bans and/or advisories are currently in effect or are anticipated;

    2) Waters where there have been repeated fish kills or where abnormalities (cancers, lesions, tumors, etc.) have been observed in fish or other aquatic life during the last ten years;

    3) Waters where there are restrictions on water sports or recreational contact;

    4) Waters identified by the state in its most recent state section 305(b) report as either "partially achieving" or "not achieving" designated uses;

5) Waters identified by the states under section 303(d) of the Clean Water Act as waters needing water quality-based controls;

6) Waters identified by the state as priority water bodies;

7) Waters where ambient data indicate potential or actual excursions of water quality criteria due to toxic pollutants from an industry classified as a primary industry in Appendix A of 40 CFR Part 122;

8) Waters for which effluent toxicity test results indicate possible or actual excursions of state water quality standards, including narrative "free from" water quality criteria or EPA water quality criteria where state criteria are not available;

9) Waters with primary industrial major dischargers where dilution analyses indicate exceedances of state narrative or numeric water quality criteria (or EPA water quality criteria where state standards are not available) fortoxic pollutants, ammonia, or chlorine;

10) Waters with POTW dischargers requiring local pretreatment programs where dilution analyses indicate exceedances of state water quality criteria (or EPA water quality criteria where state water quality criteria are not available) for toxic pollutants, ammonia, or chlorine;

11) Waters with facilities not included in the previous two categories such as major POTWs, and industrial minor dischargers where dilution analyses indicate exceedances of numeric or narrative state water quality criteria (or EPA water quality criteria where state water quality criteria are not available) for toxic pollutants, ammonia, or chlorine;

12) Water classified for uses that will not support the "fishable/swimmable" goals of the Clean Water Act;

13) Waters where ambient toxicity or adverse water quality conditions have been reported by local, state, EPA or other Federal Agencies, the private sector, public interest groups, or universities;

14) Waters identified by the state as impaired in its most recent Clean Lake Assessments conducted under 314 of the Clean Water Act; and

15) Surface waters impaired by pollutants from hazardous waste sites on the National Priority List prepared under section 105(8)(A) of CERCLA.

16) Waters judged to be impaired as a result of a bioassessment/biosurvey.

The presence of a combination of these factors, such as low available dilution, high-quality receiving water, poor compliance record, and clustered industrial and municipal discharges, could constitute a high priority for effluent limits.

Regardless, the regulatory authority, if it chooses to impose an effluent limit after conducting an effluent assessment without facility-specific monitoring data, will need to provide adequate justification for the limit in its permit development rationale or in its permit fact sheet. A clear and logical rationale for the need for the limit covering all of the regulatory points will be necessary to defend the limit should it be challenged. In justification of a limit, **EPA recommends that the more information the authority can acquire to support the limit, the better a position the authority will be in to defend the limit if necessary.** In such a case, the regulatory authority may well benefit from the collection of effluent monitoring data prior to establishing the limit.

If the regulatory authority, after evaluating all available information on the effluent, in the absence of effluent monitoring data, is not able to decide whether the discharge causes, has the reasonable potential to cause, or contributes to, an excursion above a numeric or narrative criterion for whole effluent toxicity or for individual toxicants, the authority should require whole effluent toxicity or chemical-specific testing to gather further evidence. In such a case, the regulatory authority can require the monitoring prior to permit issuance, if sufficient time exists, or it may require the testing as a condition of the issued/reissued permit.

Under these circumstances, the regulatory authority may find it protective of water quality to include a permit reopener for the imposition of an effluent limit should the effluent testing establish that the discharge causes, has the reasonable potential to cause, or contributes to excursion above a water quality criteria. A discussion of these options is provided later in this chapter.

3.3 DETERMINING THE NEED FOR PERMIT LIMITS WITH EFFLUENT MONITORING DATA

3.3.1 General Considerations

When characterizing an effluent for the need for a whole effluent toxicity limit, and/or an individual toxicant limit, the regulatory authority should use any available effluent monitoring data, together with any information like that discussed under Section 3.2 above, as the basis for a decision. The regulatory authority may already have effluent toxicity data available from previous monitoring, or it may decide to require the permittee to generate effluent monitoring data prior to permit issuance or as a condition of the issued permit. EPA regulations at 40 *CFR* 122.21(j) require POTWs with design flows equal to or greater than 1 MGD and POTWs with approved pretreatment programs, or POTWs required to develop a pretreatment program, to submit the results of whole effluent toxicity tests with their permit applications. These regulations also provide discretion to the permitting authority to request such data from additional POTWs at the time of permit application.

In the instance where the permittee is required to generate data in advance, data collection should begin 12 to 18 months in advance of permit development to allow adequate time for conducting toxicity tests and chemical analyses. The type of data, including toxicity testing data, should be specified by the regulatory authority at the outset so that decisions on permit actions will not be delayed. **EPA recommends monitoring data be generated on effluent toxicity prior to permit limit development for the following reasons: (1) the presence or absence of effluent toxicity can be more clearly established or refuted and (2) where toxicity is shown, effluent variability can be more clearly defined.** Several basic factors that should be considered in generating effluent monitoring data are discussed below.

3.3.2 Addressing Uncertainty in Effluent Characterization by Generating Effluent Monitoring Data

All toxic effects testing and exposure assessment parameters, for both effluent toxicity and individual chemicals, have some degree of uncertainty associated with them. The more limited the amount of test data available, the larger the uncertainty. The least amount of uncertainty of an effluent's impact on the receiving water exists where (1) a complete data base is available on the effects of acute and chronic toxicity on many indigenous species, (2) there is a clear understanding of ecosystem species composition and functional processes, and (3) actual measured exposure concentrations are available for all chemicals during seasonal changes and dilution situations. The uncertainty associated with such an ideal situation would be minimal. However, generation of these data can be very resource intensive.

An example of uncertainty that results from limited monitoring data is if a regulatory authority has only one piece of effluent data (e.g., an LC_{50} of 50 percent) for a facility. Effluent variability in such a case, given the range of effluent toxicity variability seen in other effluents, may range between 20 percent and 100 percent (see Appendix A). It is impossible to determine from one piece of monitoring data where in this range the effluent variability really falls. More monitoring data would need to be generated to determine the actual variability of this effluent and reduce this source of uncertainty.

To better characterize the effects of effluent variability and reduce uncertainty in the process of deciding whether to require an effluent limit, EPA has developed the statistical approach described below and in Box 3-2. This approach combines knowledge of effluent variability as estimated by a coefficient of variation with the uncertainty due to a limited number of data to project an estimated maximum concentration for the effluent. The estimated maximum concentration is calculated as the upper bound of the expected lognormal distribution of effluent concentrations at a high confidence level. The projected effluent concentration after consideration of dilution can then be compared to an appropriate water quality criterion to determine the potential for exceeding that criterion and the need for an effluent limit.

The statistical approach has two parts. The first is a characterization of the highest measured effluent concentration based on the desired confidence level. The relationship that describes this is the following:

$$p_n = (1 - \text{confidence level})^{1/n}$$

where p_n is the percentile represented by the highest concentration in the data and n is the number of samples. The following are some examples of this relationship at a 99 percent confidence level:

- The largest value of 5 samples is greater than the 40 percentile
- The largest value of 10 samples is greater than the 63 percentile
- The largest value of 20 samples is greater than the 79 percentile
- The largest value of 100 samples is greater than the 96 percentile.

The second part of the statistical approach is a relationship between the percentile described above and the selected upper bound of the lognormal effluent distribution. EPA's effluent data base suggests that the lognormal distribution well characterizes effluent concentrations (see Appendix E). For example, if five samples were collected (which represents a 40th percentile), the coefficient of variation is 0.6, and the desired upper bound of the effluent distribution is the 99th percentile, then the two percentiles can be related using the coefficient of variation (CV) as shown below:

$$\frac{C_{99}}{C_{40}} = \frac{\exp(2.326\sigma - 0.5\sigma^2)}{\exp(-0.258\sigma - 0.5\sigma^2)} = 4.2$$

where $\sigma^2 = \ln(CV^2+1)$ and 2.326 and -0.258 are the normal distribution values for the 99th and 40th percentiles, respectively. The use of the 99th percentile is for illustrative purposes here. Although it does represent a measure of the upper bound of an effluent distribution, other percentiles could be selected by a regulatory agency. The relationship shown above can be calculated for other percentiles and CVs by replacing the values in the equation.

Tables 3-1 and 3-2 show the combined effects of both parts for a 99-percent confidence level and upper bounds of the 99th and 95th percentiles, respectively. The factors shown in the tables are multiplied by the highest concentration in an effluent sample to estimate the maximum expected concentration.

This procedure can be used for both single and multiple discharges to the same receiving waterbody. This is accomplished for multiple dischargers by summing the projected RWCs for the pollutant or pollutant parameter of concern from each individual discharger, and comparing it to the water quality standard. This involves an assumption of conservative additivity of the pollutant after discharge, which may not accurately reflect the true behavior of the toxicant. To overcome this, and to further refine the proportional contribution of each discharger and the resultant limits, the permitting authority should supplement this evaluation with multiple source WLA modeling and/or ambient water concentration monitoring.

Box 3-2. Determining "Reasonable Potential" for Excursions Above Ambient Criteria Using Effluent Data Only

EPA recommends finding that a permittee has "reasonable potential" to exceed a receiving water quality standard if it cannot be demonstrated with a high confidence level that the upper bound of the lognormal distribution of effluent concentrations is below the receiving water criteria at specified low-flow conditions.

Step 1 Determine the number of total observations ("*n*") for a particular set of effluent data (concentrations or toxic units [TUs]), and determine the highest value from that data set.

Step 2 Determine the coefficient of variation for the data set. For a data set where $n<10$, the coefficient of variation (CV) is estimated to equal 0.6, or the CV is calculated from data obtained from a discharger. For a data set where $n>10$, the CV is calculated as standard deviation/mean (see Figure 3-1). For less than 10 items of data, the uncertainty in the CV is too large to calculate a standard deviation or mean with sufficient confidence.

Step 3 Determine the appropriate ratio from Table 3-1 or 3-2.

Step 4 Multiply the highest value from a data set by the value from Table 3-1 or 3-2. Use this value with the appropriate dilution to project a maximum receiving water concentration (RWC).

Step 5 Compare the projected maximum RWC to the applicable standard (criteria maximum concentration, criteria continuous concentration [CCC], or reference ambient concentration). EPA recommends that permitting authorities find reasonable potential when the projected RWC is greater than an ambient criterion.

Example

Consider the following results of toxicity measurements of an effluent that is being characterized: 5 TU_c, 2 TU_c, 9 TU_c, and 6 TU_c. Assume that the effluent is diluted to 2 percent at the edge of the mixing zone. Further assume that the CV is 0.6, the upper bound of the effluent distribution is the 99th percentile, and the confidence level is 99 percent.

Step 1 There are four samples, and the maximum value of the sample results is 9 TU_c.

Step 2 The value of the CV is 0.6.

Step 3 The value of the ratio for four pieces of data and a CV of 0.6 is 4.7.

Step 4 The value that exceeds the 99th percentile of the distribution (ratio times x_{max}) after dilution is calculated as:

$$[9\ TU_c \times 4.7 \times 0.02] = 0.85\ TU_c.$$

Step 5 0.85 TU_c is less than the ambient criteria concentration of 1.0 TU_c. There is no reasonable potential for this effluent to cause an excursion above the CCC.

3.3.3 Effluent Characterization for Whole Effluent Toxicity

Once an effluent has been selected for whole effluent toxicity characterization after consideration of the factors discussed above, the regulatory authority should require toxicity testing in accordance with appropriate site-specific considerations and the recommendations discussed below. In the past 5 years, significant additional experience has been gained in generating effluent toxicity data upon which to make decisions as to whether or not an effluent will cause toxic effects in the receiving water in both freshwater and marine environments.

General Considerations and Assumptions

EPA has revised its initial effluent toxicity data generation recommendations based on three observations made over the last 5 years:

1) Only rarely have effluents discharged by NPDES permittees been observed to have LC_{50}s less than 1.0 percent or no observed effect concentrations (NOECs) less than 0.1 percent. However, there is always a chance that an effluent could be toxic at such low effluent concentrations.

Table 3-1. Reasonable Potential Multiplying Factors: 99% Confidence Level and 99% Probability Basis

Number of	Coefficient of Variation																			
Samples	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0
1	1.6	2.5	3.9	6.0	9.0	13.2	18.9	26.5	36.2	48.3	63.3	81.4	102.8	128.0	157.1	190.3	227.8	269.9	316.7	368.3
2	1.4	2.0	2.9	4.0	5.5	7.4	9.8	12.7	16.1	20.2	24.9	30.3	36.3	43.0	50.4	58.4	67.2	76.6	86.7	97.5
3	1.4	1.9	2.5	3.3	4.4	5.6	7.2	8.9	11.0	13.4	16.0	19.0	22.2	25.7	29.4	33.5	37.7	42.3	47.0	52.0
4	1.3	1.7	2.3	2.9	3.8	4.7	5.9	7.2	8.7	10.3	12.2	14.2	16.3	18.6	21.0	23.6	26.3	29.1	32.1	35.1
5	1.3	1.7	2.1	2.7	3.4	4.2	5.1	6.2	7.3	8.6	10.0	11.5	13.1	14.8	16.6	18.4	20.4	22.4	24.5	26.6
6	1.3	1.6	2.0	2.5	3.1	3.8	4.6	5.5	6.4	7.5	8.6	9.8	11.1	12.4	13.8	15.3	16.8	18.3	19.9	21.5
7	1.3	1.6	2.0	2.4	2.9	3.6	4.2	5.0	5.8	6.7	7.7	8.7	9.7	10.8	12.0	13.1	14.4	15.6	16.9	18.2
8	1.2	1.5	1.9	2.3	2.8	3.3	3.9	4.6	5.3	6.1	6.9	7.8	8.7	9.6	10.6	11.6	12.6	13.6	14.7	15.8
9	1.2	1.5	1.8	2.2	2.7	3.2	3.7	4.3	5.0	5.7	6.4	7.1	7.9	8.7	9.6	10.4	11.3	12.2	13.1	14.0
10	1.2	1.5	1.8	2.2	2.6	3.0	3.5	4.1	4.7	5.3	5.9	6.6	7.3	8.0	8.8	9.5	10.3	11.0	11.8	12.6
11	1.2	1.5	1.8	2.1	2.5	2.9	3.4	3.9	4.4	5.0	5.6	6.2	6.8	7.4	8.1	8.8	9.4	10.1	10.8	11.5
12	1.2	1.4	1.7	2.0	2.4	2.8	3.2	3.7	4.2	4.7	5.2	5.8	6.4	7.0	7.5	8.1	8.8	9.4	10.0	10.6
13	1.2	1.4	1.7	2.0	2.3	2.7	3.1	3.6	4.0	4.5	5.0	5.5	6.0	6.5	7.1	7.6	8.2	8.7	9.3	9.9
14	1.2	1.4	1.7	2.0	2.3	2.6	3.0	3.4	3.9	4.3	4.8	5.2	5.7	6.2	6.7	7.2	7.7	8.2	8.7	9.2
15	1.2	1.4	1.6	1.9	2.2	2.6	2.9	3.3	3.7	4.1	4.6	5.0	5.4	5.9	6.4	6.8	7.3	7.7	8.2	8.7
16	1.2	1.4	1.6	1.9	2.2	2.5	2.9	3.2	3.6	4.0	4.4	4.8	5.2	5.6	6.1	6.5	6.9	7.3	7.8	8.2
17	1.2	1.4	1.6	1.9	2.1	2.5	2.8	3.1	3.5	3.8	4.2	4.6	5.0	5.4	5.8	6.2	6.6	7.0	7.4	7.8
18	1.2	1.4	1.6	1.8	2.1	2.4	2.7	3.0	3.4	3.7	4.1	4.4	4.8	5.2	5.6	5.9	6.3	6.7	7.0	7.4
19	1.2	1.4	1.6	1.8	2.1	2.4	2.7	3.0	3.3	3.6	4.0	4.3	4.6	5.0	5.3	5.7	6.0	6.4	6.7	7.1
20	1.2	1.3	1.6	1.8	2.0	2.3	2.6	2.9	3.2	3.5	3.8	4.2	4.5	4.8	5.2	5.5	5.8	6.1	6.5	6.8

Table 3-2. Reasonable Potential Multiplying Factors: 95% Confidence Level and 95% Probability Basis

Number of	Coefficient of Variation																			
Samples	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0
1	1.4	1.9	2.6	3.6	4.7	6.2	8.0	10.1	12.6	15.5	18.7	22.3	26.4	30.8	35.6	40.7	46.2	52.1	58.4	64.9
2	1.3	1.6	2.0	2.5	3.1	3.8	4.6	5.4	6.4	7.4	8.5	9.7	10.9	12.2	13.6	15.0	16.4	17.9	19.5	21.1
3	1.2	1.5	1.8	2.1	2.5	3.0	3.5	4.0	4.6	5.2	5.8	6.5	7.2	7.9	8.6	9.3	10.0	10.8	11.5	12.3
4	1.2	1.4	1.7	1.9	2.2	2.6	2.9	3.3	3.7	4.2	4.6	5.0	5.5	6.0	6.4	6.9	7.4	7.8	8.3	8.8
5	1.2	1.4	1.6	1.8	2.1	2.3	2.6	2.9	3.2	3.6	3.9	4.2	4.5	4.9	5.2	5.6	5.9	6.2	6.6	6.9
6	1.1	1.3	1.5	1.7	1.9	2.1	2.4	2.6	2.9	3.1	3.4	3.7	3.9	4.2	4.5	4.7	5.0	5.2	5.5	5.7
7	1.1	1.3	1.4	1.6	1.8	2.0	2.2	2.4	2.6	2.8	3.1	3.3	3.5	3.7	3.9	4.1	4.3	4.5	4.7	4.9
8	1.1	1.3	1.4	1.6	1.7	1.9	2.1	2.3	2.4	2.6	2.8	3.0	3.2	3.3	3.5	3.7	3.9	4.0	4.2	4.3
9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1	3.2	3.4	3.5	3.6	3.8	3.9
10	1.1	1.2	1.3	1.5	1.6	1.7	1.9	2.0	2.2	2.3	2.4	2.6	2.7	2.8	3.0	3.1	3.2	3.3	3.4	3.6
11	1.1	1.2	1.3	1.4	1.6	1.7	1.8	1.9	2.1	2.2	2.3	2.4	2.5	2.7	2.8	2.9	3.0	3.1	3.2	3.3
12	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	3.0	3.0
13	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.5	2.6	2.7	2.8	2.9
14	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.3	2.4	2.5	2.6	2.6	2.7
15	1.1	1.2	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.8	1.9	2.0	2.1	2.2	2.2	2.3	2.4	2.4	2.5	2.5
16	1.1	1.1	1.2	1.3	1.4	1.5	1.6	1.6	1.7	1.8	1.9	1.9	2.0	2.1	2.1	2.2	2.3	2.3	2.4	2.4
17	1.1	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.2	2.2	2.3	2.3
18	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.6	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.1	2.2	2.2
19	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.5	1.6	1.6	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.0	2.1	2.1
20	1.1	1.1	1.2	1.2	1.3	1.4	1.4	1.5	1.5	1.6	1.7	1.7	1.8	1.8	1.8	1.9	1.9	2.0	2.0	2.0

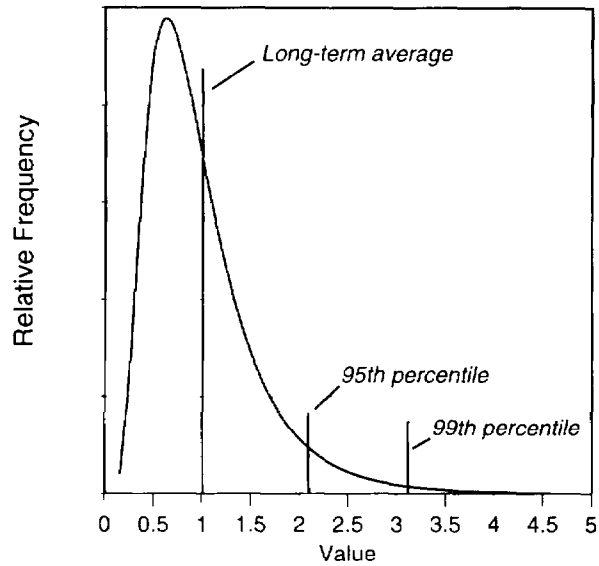


Figure 3-1a. Frequency Distribution of Values for a Lognormal Distribution with a Mean of 1.0 and a Coefficient of Variation of 0.6

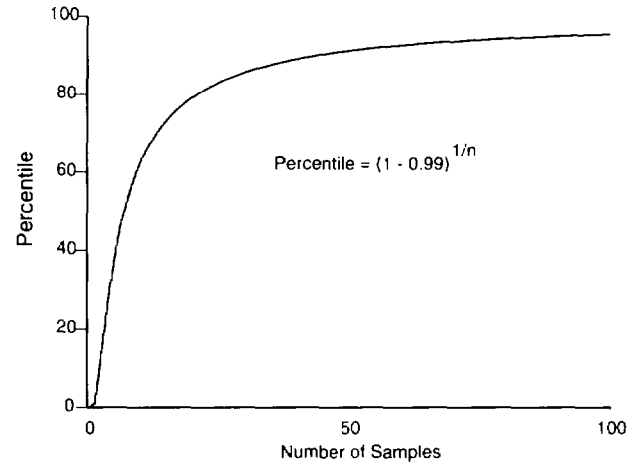


Figure 3-1c. Relationship Between the Largest Value of n Samples and the Percentile It Exceeds with 99 Percent Confidence

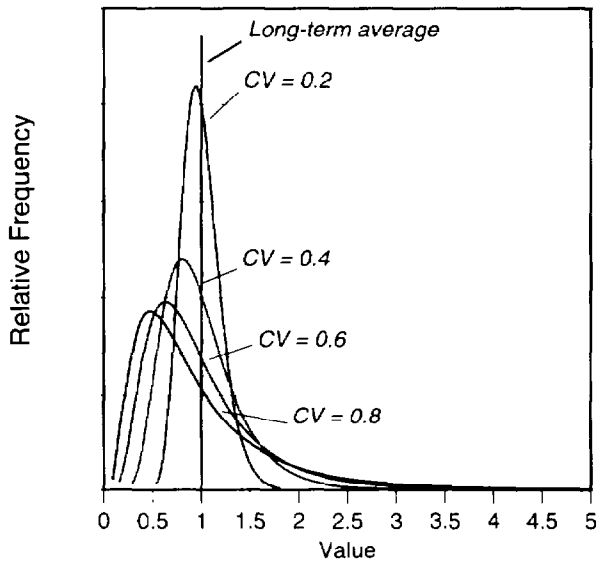


Figure 3-1b. Comparison of Relative Frequencies of Lognormal Distributions with a Mean of 1.0 for Different Coefficients of Variation

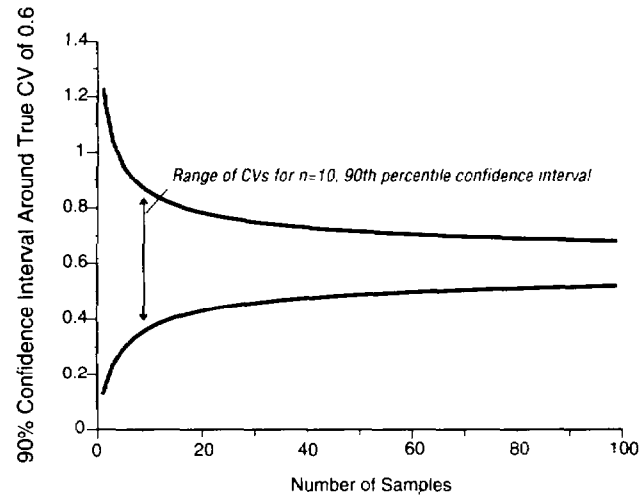
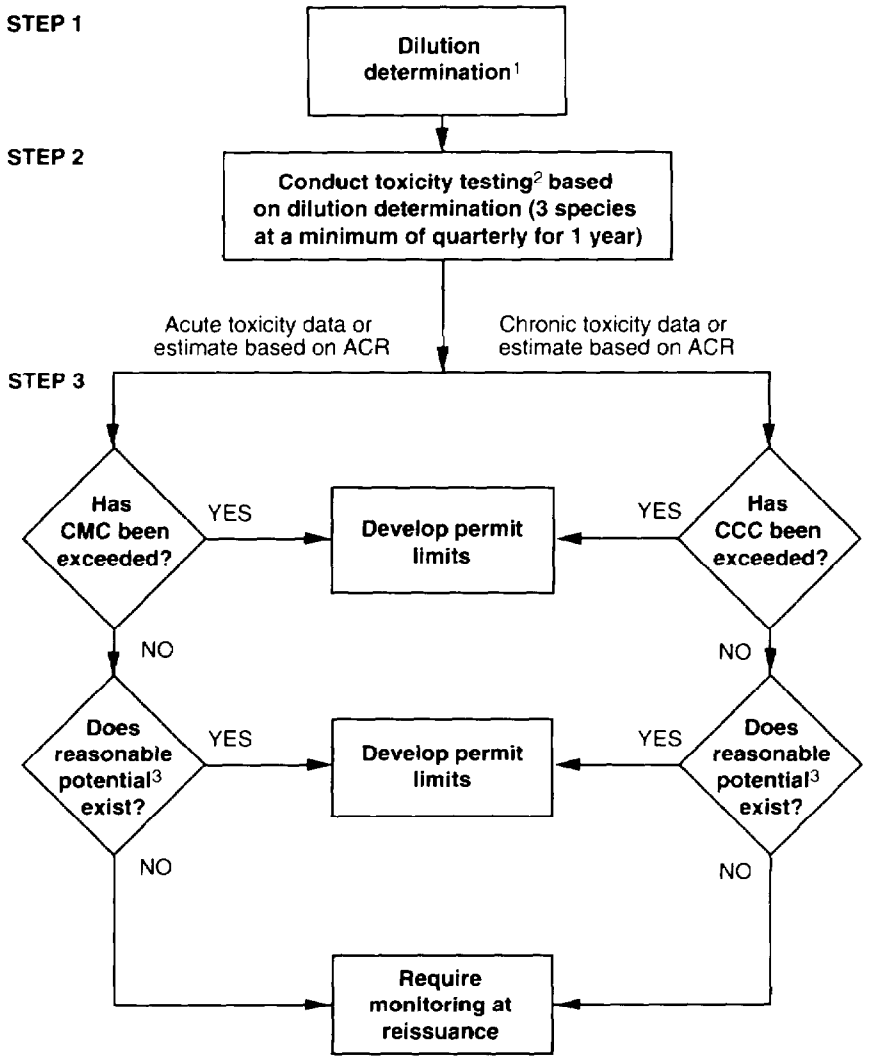


Figure 3-1d. Example of 90 Percent Confidence Intervals Around Coefficient of Variation Estimates for Numbers of Samples

2) With the exception of a small number of "outliers" for which confirmation is not possible, acute-to-chronic ratios (ACRs) above 20 for effluents discharged by NPDES permittees have not been observed by EPA. The majority of observed ACRs are very seldom above 10. However, higher ACRs may be found for selected facilities.

3) The use of the three commonly used freshwater species and of three of the five commonly used marine organisms has generally been sufficient to measure any effluent's toxicity for the purposes of projecting effluent toxicity impact and making regulatory decisions.

Figure 3-2 is a flow chart of EPA's recommendations for data generation for three different dilution scenarios. It is divided into three basic steps: determining initial dilution, developing toxicity testing procedures, and developing decision criteria for permit limit. There are certain basic assumptions built into this flow chart. The basic principle used in making decisions is to compare available dilution to known or projected toxic effect concentrations in order to place an effluent into one of three categories:



Notes:

[1]Dilution determinations should be performed for critical flows and any applicable mixing zones.

[2]Toxicity testing recommendations

a. Dilution > 1000:1: acute testing, check CMC only.

b. 100:1 < Dilution < 1000:1: acute or chronic testing, check CMC and CCC with data or ACR.

c. Dilution < 100:1: conduct chronic testing, check CCC with data and CMC using acute data or ACR.

[3]Reasonable potential: Use procedures in Box 3-3.

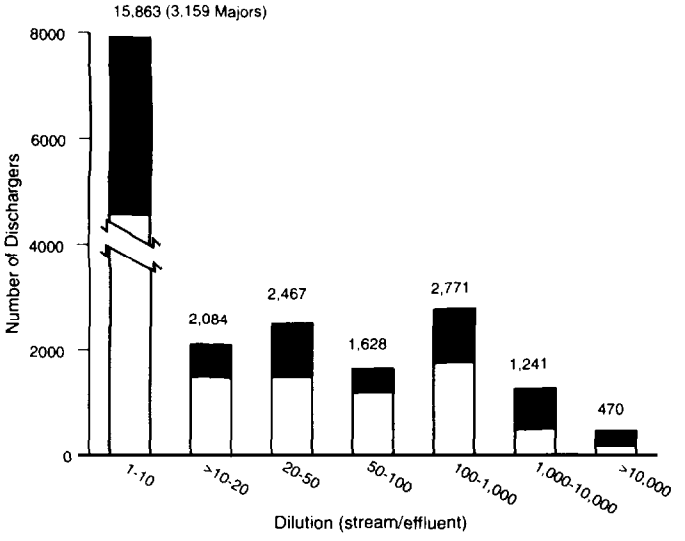
Figure 3-2. Effluent Characterization for Whole Effluent Toxicity

1) The effluent causes or contributes to an excursion of a numeric or narrative water quality criterion and the permit requires a limit on toxicity.

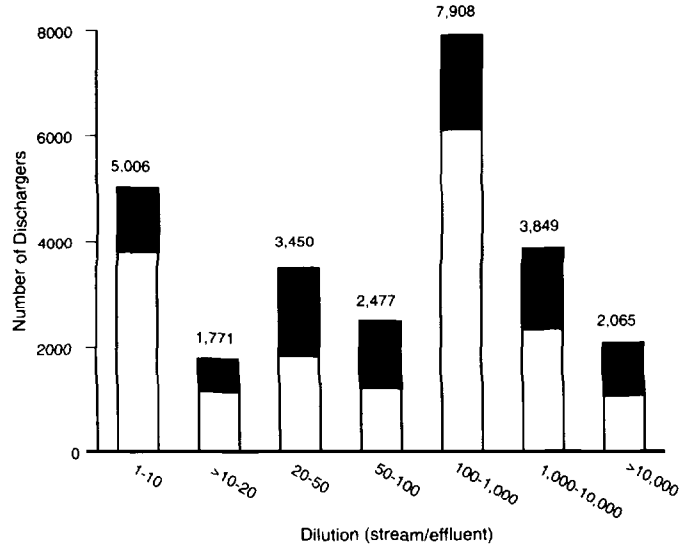
2) The effluent has a reasonable potential of causing or contributing to an excursion of a numeric or narrative water quality criterion and a limit is required.

3) The effluent has a very low probability of causing or contributing to an excursion of a water quality standard and no limit is required.

This categorization is accomplished by using dilution estimates in the first step and the results of the toxicity tests in the next steps. In addition, all these impact estimates assume discharge at critical conditions and imposition of any applicable mixing zone requirements. Therefore, a conservative assumption is used to determine whether or not an impact is projected to occur. Estimates of possible toxic impact are made assuming that the effluent is most toxic to the most sensitive species or lifestage at the time of lowest available dilution.



(a) At Low Flow (7Q10)



(b) At Annual Mean Flow

Figure 3-3. National Distribution of NPDES Dilution Conditions at 7Q10 and at Annual Mean Flow

The changes to the EPA's data generation recommendations eliminate the application of multiple sets of safety margins that was proposed in the 1985 version of this document. Rather, general observations on effluent toxicity described above now allow regulatory authorities to tighten the bounds of the initial dilution categorization, eliminate the species sensitivity uncertainty factor and target LC_{50}s of 1 percent and NOECs of 0.1 percent as the most extreme toxicity measurements that can normally be expected for the vast majority of effluents discharged by NPDES permittees for acute and chronic toxicity, respectively. The observation of toxicity was based on multiple dilution tests. The same observation may not hold for toxicity measured with single dilution tests (pass/fail). As reflected in Chapter 1, single dilution toxicity tests are much more variable than multiple dilution tests. **Therefore, the use of single concentration toxicity tests is strongly discouraged for this data generation process.**

Since the new data generation requirements are much less expensive than the previous requirements, tiered testing (less expensive, single-concentration, initial screening followed by increasingly expensive definitive data generation, using multiconcentration tests, as described in the September 1985 version of the technical support document) is unnecessary. However, **elimination of the requirement to conduct toxicity testing on the basis of projections using dilution alone is not recommended.** Although EPA's data review suggests that an LC_{50} of 1 percent and an NOEC of 0.1 percent are the lower bounds on effluent toxicity, there may be other effluents that are presently unmeasured that are more toxic. Testing data are always desirable for fully characterizing discharges of concern.

Steps in Whole Effluent Characterization Process

The following is a detailed description of the major steps presented in Figure 3-2 and the rationale behind each.

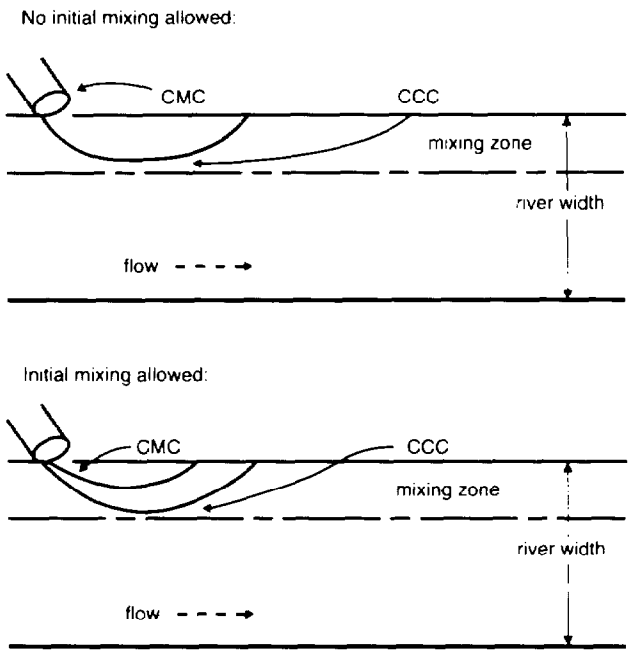
Step 1: Dilution Determination

The initial step is to determine the dilution of the effluent at the edge of the mixing zone, assuming the State allows mixing zones. Figure 3-4 shows a schematic representation of typical mixing zone requirements for both acute and chronic toxicity. Calculating the dilution at the edges of mixing zones for site-specific situations can be complicated. Modeling can be employed using either steady-state or dynamic approaches to calculate the dilution (see Chapter 4). However, for complex situations, such as marine and estuarine waters or lakes, dye studies (or other techniques used to assess mixing zones) may still be required.

Some State water quality standards do not allow the use of mixing in the control of acute toxicity. For these States, acute toxicity is often limited at the end of the pipe. Permit limits derived to enforce such requirements would be considered "water quality-based" because they would be based upon an ambient criterion (as opposed to an arbitrary test endpoint). Regardless, both chronic and acute toxicity must be assessed in these situations.

Step 2: Toxicity Testing Procedures

Where toxicity tests are required in order to make decisions regarding appropriate next steps in a screening protocol, **EPA recommends as a minimum that three species (for example, a vertebrate, an invertebrate, and a plant) be tested quarterly for a minimum of 1 year.** As discussed in Chapter 1, the use of three species is strongly recommended. Experience indicates that marine algae can be a highly sensitive test species for some effluents. Using a surrogate species of the plant kingdom adds another trophic level to the testing regimen. For both freshwater and marine situations, the use of three species is more protective than two species since a wider range of species sensitivity can be measured. EPA is continuing to develop toxicity test methods using additional organisms including plants. In addition, EPA has revised the test for *Selenastnum*, which has improved the test precision.



where

$CMC = 0.3\ TU_a$

$CCC = 1.0\ TU_c$

Figure 3-4. Schematic Representation of Mixing Zone Areas Where the CMC and CCC Apply

EPA recommends against selecting a "most sensitive" species for toxicity testing. For one organism to consistently be the most sensitive in a battery of toxicity tests, two conditions must occur: (1) the toxicants causing toxicity must remain the same, and (2) the ratios of the toxicants in the effluent (if more than one) must remain the same. Based on EPA's experience at the Duluth research laboratory, neither of these conditions is likely to occur. For example, the causes of effluent toxicity in POTWs can vary on a seasonal basis. Toxicity in the summer can be caused by pesticides to which invertebrates are most sensitive. However, the winter toxicity could be caused by ammonia to which fathead minnows will respond most sensitively. The most sensitive species for an effluent actually may not exist and at best is difficult to identify.

Conducting toxicity tests using three species quarterly for 1 year is recommended to adequately assess the variability of toxicity observed in effluents. Below this minimum, the chances of missing toxic events increase. The toxicity test result for the most sensitive of the tested species is considered to be the measured toxicity for a particular effluent sample.

The data generation recommendations in Figure 3-2 represent minimum testing requirements. Since uncertainty regarding whether or not an effluent causes toxic impact is reduced with more data, **EPA recommends that this test frequency be increased where necessary to adequately assess effluent variability.** If less frequent testing is required in the permit, it is preferable to use three species tested less frequently than to test the effluent more frequently with only a single species whose sensitivity to the effluent is not well characterized.

EPA recommends that a discharger conduct <u>acute</u> toxicity testing if the dilution of the effluent is greater than 1000:1 at the edge of the mixing zone [3]. Such a discharger would be considered a low priority for chronic toxicity testing. The rationale for this is that the effluent concentration would be below 0.1 percent at the edge of the mixing zone and thus incapable of causing an excursion above the CCC. A worst case NOEC of 0.1 percent translates into 1,000 TU_c, which would result in a concentration of less than 1.0 TU_c at the edge of the mixing zone for this dilution category. The test results would be compared to the CMC after consideration of any allowable mixing.

EPA recommends that a discharger conduct either <u>acute or chronic</u> toxicity testing if the dilution of the effluent falls between 100:1 and 1,000:1 at the edge of the mixing zone. Effluents have been shown to be both acutely and chronically toxic within this range of receiving water dilution. Under worst-case scenarios, LC_{50}s of 1.0 percent and ACRs of 10 will result in excursions above both the CCC and CMC at the edge of the regulatory mixing zone.

Although either acute or chronic testing can be required within this dilution range, acute testing would be more appropriate at the higher end of this dilution range (1,000:1 or 0.1 percent). At the lower end of this dilution range (100:1 or 1.0 percent), chronic tests may be more appropriate. Where other factors are equal, chronic testing may be preferable since the interim results in a chronic test gives data on acute toxicity as well. The acute endpoint data can then be used to compare directly to the CMC without the need for an ACR.

Whichever type of toxicity test (either acute or chronic) is specified, the results from that test should be compared to the criterion associated with that type of test. For example, a chronic test would be compared to the CCC. Comparisons to the other criteria can be made by using the ACR or additional data generated to convert a chronic test result to an acute endpoint and vice versa. For example, a chronic NOEC of 5 percent effluent (or 20 TU_c) represents an acute LC_{50} of 50 percent (or 2 TU_a) at an ACR of 10.

EPA recommends that a discharger conduct chronic toxicity testing if the dilution of the effluent falls below 100:1 at the edge of the mixing zone. The rationale for this recommendation is that chronic toxicity has been observed in some effluents down to the 1.0 percent effect concentration. Therefore, chronic toxicity tests, although somewhat more expensive to conduct, should be used directly in order to make decisions about toxic impact.

There is a potential for acute toxicity within this dilution range, although this is less likely as the 100:1 dilution level is approached. Thus, the recommended screening protocol shown in Figure 3-2 includes a determination of whether excursions above the CMC are projected [4]. This analysis may be performed by assuming an ACR, applying this value to the chronic toxicity testing data, and allowing for any allowable initial mixing. Alternatively, the regulatory authority may use the interim results in the chronic test to calculate the acute toxicity.

Both the chronic and acute toxicity test data would be compared to their respective criterion. The chronic test results would be compared to the CCC, and the acute results, regardless of how calculated, would be compared to the CMC.

Step 3: Decision Criteria for Permit Limit Development

Once the toxicity data have been generated for a discharger, the regulatory authority must decide whether or not the results show that the permittee causes, has the reasonable potential to cause, or contributes to an excursion of an applicable numeric or narrative water quality criterion and therefore needs to limit effluent toxicity. To do this, these data should be used to project receiving water concentrations, which are then compared to the CCC and CMC. One of four outcomes will be reached when following the screening protocol shown in Figure 3-2:

1) Excursion Above CMC or CCC—Where any one data point shows an excursion above the State's numeric or narrative criterion for the parameter toxicity, EPA regulations require a permit limit be set for whole effluent toxicity (40 *CFR* 122.44(d)(1)(iv or v)), unless limits on a specific chemical will allow the narrative water quality criterion to be attained or maintained. In the absence of a State numeric criterion for the parameter toxicity, **EPA recommends that 1.0 TU_c and 0.3 TU_a be used as the CCC and CMC, respectively.** The decision to develop permit limits based upon an excursion above either the CMC or CCC will lead to protection against both acute and chronic toxicity if the permit derivation procedures in Chapter 5 are used to set effluent limits.

2) Reasonable Potential for Excursion Above CMC or CCC—**EPA believes that "reasonable potential" is shown where an effluent is projected to cause an excursion above the CCC or CMC. This projection is based upon a statistical analysis of available data that accounts for limited sample size and effluent variability.** EPA's detailed recommendations for making a statistical determination based upon effluent monitoring data alone are shown in Box 3-2. Where a regulatory authority finds that test results alone indicate a "reasonable potential" to cause an excursion above a State water quality criterion in accordance with 40 *CFR* 122.44(d)(1)(ii), a permit limit must be developed.

   A regulatory authority may select an alternative approach for assessing reasonable potential. For example, an authority may opt to use a stochastic dilution model that incorporates both ambient dilution and effluent variability for determining reasonable potential. Such an approach is analogous to the statistical approach shown in Box 3-2. Whatever approach selected by the authority, it must use all the factors that account for all the factors listed in 40 *CFR* 122.44(d)(1)(ii).

   In some cases the statistical analysis of the effluent data may not actually project an excursion above the CMC or CCC but may be close. Under such conditions, reasonable potential determinations will include an element of judgment on the part of the regulatory authority. Other factors will need to be considered and given appropriate weight in the decisionmaking process, including value of waterbody (e.g., high-use fishery), relative proximity to the CCC or CMC, existing controls on point and nonpoint sources, information on effluent variability, compliance history of the facility, and type of treatment facility. These factors are summarized in Box 3-2 and are discussed in detail in Section 3.1. **EPA recommends regulatory authorities establish a written policy and procedure for making determinations of "reasonable potential" under these circumstances.**

3) No Reasonable Potential for Excursions Above CMC or CCC—In these situations, **EPA recommends that the toxicity tests recommended above be repeated at a frequency of at least once every 5 years as a part of the permit application.** Such testing is required for certain POTWs under 40 *CFR* 122.21(j).

4) Inadequate Information—Where a regulatory authority has inadequate information to determine reasonable potential for an excursion of a numeric or narrative water quality criterion, there may still be a basis for concern on the part of the authority. The permit should contain whole effluent toxicity monitoring requirements and a reopener clause. This clause would require reopening of the permit and establishment of a limit based upon any test results, or other new factors, which substantiate that the effluent causes, has the reasonable potential of causing, or contributes to an excursion above the CCC or CMC.

3.3.4 Use of Toxicity Testing in Multiple-source Discharge Situations

Where more than one discharge to the same receiving waterbody contributes, or has the reasonable potential to contribute to an excursion of water quality standards, permit limits must be developed for each individual discharger on that waterbody. For the regulatory authority to make this assessment, additional testing may be needed to provide the authority with the information necessary to assess the relative impact of each source. For purposes of this discussion, a multiple-source discharge situation is defined as a situation where impact zones overlap, or where ambient receiving water concentrations of a pollutant are elevated due to upstream discharges. In multiple-source discharge situations, additivity, antagonism, and persistence of toxicity can be of concern. To collect additional data, the permit authority should employ the toxicity testing procedures for multiple dischargers described in Box 3-3. In addition, ambient toxicity testing, as described below, could be used.

Assuming that screening has been conducted that reveals the need for permit limits, two options for controlling the discharges exist. The first option is for the permit authority to regulate each source separately using the procedures for individual point sources. In this option, the permitting authority would require use of upstream ambient water as a diluent in the toxicity test so as to be able to evaluate the contributions of upstream sources of toxicity. A second option is to treat each discharge as an interactive component of a whole system. In this option, the permit writer would determine a total maximum daily load for the receiving waterbody and develop individual wasteload allocations for each discharger using the procedures discussed in Chapter 4.

Box 3-3. Recommend Multiple-source Toxicity Testing Procedures

Tests

Where the combined effluents make up 1 percent or greater of the receiving waters, conduct chronic toxicity tests following the testing procedures described in Section 3.3.3.

Where the combined effluents make up less than 1 percent of the receiving waters, conduct acute toxicity tests following the testing procedures described in Section 3.3.3 (see Figure 3-2) to determine if any of the effluents are exhibiting toxicity.

An additional data requirement is the assessment of relative and absolute toxicity of each source so that appropriate permit conditions can be set for individual dischargers. The following procedure is suggested.

1) Conduct one set of toxicity tests on the effluents using a control of reconstituted or uncontaminated dilution water. The set of tests will give an absolute toxicity measurement of the effluent.

2) Run a parallel set of toxicity tests on the effluent using dilution water taken directly upstream from the point of discharge or, for estuarine waters, from an area outside of the immediate discharge impact zone (this will have to be determined by a dye study). This dilution water may be contaminated with upstream effluents or other toxicant sources. The purpose of this test is to project toxic impact of the effluent after it is mixed at its point of discharge. This is a relative effluent toxicity measurement. The relative testing procedure could result in a change in the standard concentration-effect curve generated by the testing. The dilution water for the relative toxicity test may cause significant mortality, growth, or reproductive effects at the lower effluent concentrations (including the 100 percent diluent control concentration) if the diluent from the receiving water is toxic (from an upstream discharge). Such mortality does not invalidate the test. Instead, analysis of toxicity trends resulting from the relative toxicity tests can be used to assess the effluent's toxicity in relation to other sources and ambient receiving water conditions. However, a control dilution water with no toxicity must be used for quality assurance and determination of absolute toxicity of the effluent.

3) Conduct ambient toxicity tests to (a) determine whether or not the effluent has a measurable toxicity after mixing, (b) measure persistence of toxicity from all sources contributing to receiving water toxicity, and (c) determine combined toxicity resulting from the mixing of multiple, point, and nonpoint sources of toxicity. See Appendix C for a discussion of ambient toxicity testing procedures.

The ambient testing can be required of each discharger and conducted during low-flow or worst-case design periods.

Frequency for Ambient Testing

All testing should be conducted simultaneously by each discharger, if possible. At a minimum, the tests should be conducted concurrently starting within a short time period (1 to 2 days). Repeated ambient toxicity analyses will be desirable when variable effluents are involved. Effluent toxicity data showing variability can be used to assess what frequency will be most applicable. The level of repetition for variability analysis should be similar to that used in effluent variability analyses.

Other Considerations

Dye studies of effluent dispersion for rivers, lakes, reservoirs, and estuaries are strongly recommended. This allows analysis of effluent concentration at the selected sampling stations above and below the discharge points.

The procedures suggested in this multiple source section are based on actual multiple source site investigations conducted under the Complex Effluent Toxicity Testing Program. Site reports from that study can be used to obtain further description of the toxicity testing procedures used to analyze multiple source toxic impact [1, 2].

3.3.5 Ambient Toxicity Testing

Ambient toxicity testing also is useful in screening receiving water bodies for existing toxic conditions. The procedure described in Appendix C uses short-term chronic toxicity tests to measure the toxicity of samples of receiving water taken above, at, and below outfalls. It can be used in freshwater, marine, and estuarine systems. The procedure must be conducted during an appropriate low-flow or worst-case design period.

The utility of the ambient toxicity screening approach is that actual receiving water toxicity is directly measured. No extrapolation from exposure or ACR is needed. Further, impact from multiple source discharge situations, which may not be apparent from individual discharger data, is identified. Finally, the technique can provide an assessment of the persistence of effluent toxicity.

3.3.6 Special Considerations for Discharges to Marine and Estuarine Environments

Special problems are encountered when assessing and controlling impacts of toxic pollutants discharged to marine and estuarine waterbodies. These special problems include the following:

- Determining the physical characteristics of estuaries and the complex mixing and effluent dilution situations for RWCs of effluents.
- Generating toxicity data on nonsaline effluents that discharge to brackish or saline waters and establishing cause-effect relationships on that basis.
- Assessing exposure and controlling impacts from persistent toxicants accumulating in fish and shellfish tissues and in sediments. These factors are particularly important in estuaries and near coastal waters because of high use of estuaries as breeding and fishing areas for important commercial seafood supplies and recreational fishing, and because many estuaries and near coastal waters act as sinks for pollutants that accumulate in sediments.

Where these special problems are encountered, additional information may need to be gathered to better quantify dilution, to determine metals partitioning, and to identify potential interferences in whole effluent toxicity tests.

To characterize the type of whole effluent toxicity that is most relevant for a particular discharge to marine and estuarine waters, the following questions should be considered [5]:

- What is the salinity of the receiving water, and is this important in terms of the State standards?
- What is the appropriate test organism to require for toxicity testing under differing salinity conditions?

The answers to these questions will enable the permitting authority to determine what type of toxicity testing is most suitable for effluent characterization and whole effluent toxicity control.

For most marine and estuarine discharges the choice of test species and dilution water should be made based on the characteristics of the receiving water at the critical conditions for flow, mixing, and salinity. Foremost in this determination should be the salinity of the receiving water and, to a lesser extent, the salinity of the effluent itself.

The primary objective of whole effluent toxicity tests is to identify sources of toxicity that can potentially cause an excursion of a State's narrative or numeric water quality criteria. For this reason, the toxicity tests should reflect the natural conditions of the receiving water so to be able to measure any effluent characteristic that could contribute to ambient toxicity. The marine toxicity test methods identify 1,000 mg/l as the point at which salinity begins to exert an effect on freshwater species. **As a general rule, EPA recommends that freshwater organisms be used when the receiving water salinity is less than 1,000 mg/l, and that marine organisms be used when the receiving water salinity equals or exceeds 1,000 mg/l.**

Saline Effluent Discharges to Saltwater

The dissolved salts in the effluent are pollutants. These salts may or may not be the same as those present in the receiving water. Also, the proportion of dissolved salts in the effluent may be different from that of the salts in the receiving water. In this case, the toxicity test needs to be able to determine if these salts contribute to ambient toxicity. For this reason, marine organisms are needed.

Saline Effluent Discharged to Freshwater

In this case, the dissolved salts in the effluent is a pollutant that does not exist in the receiving water. The toxicity test needs to determine whether the dissolved salts can be one of the toxicants that contribute to ambient toxicity. For this reason, freshwater organisms are needed.

Freshwater Effluent Discharged to Saltwater

In this instance, the lack of dissolved salts in the effluent can cause an apparent toxic effect to the marine organisms in the toxicity test. However, in contrast to the instances presented above, the toxicity test does not need to be able to measure this effect because a lack of salts is not a pollutant. The marine toxicity test methods account for this by requiring that the salinity of the effluent be adjusted to approximate the salinity of the receiving water. As an alternative to using a marine organism, a freshwater organism can be used if the test is being conducted only on a 100-percent effluent sample and if State water quality standards do not require that a marine organism be used.

3.3.7 Using a Chemical-specific Limit to Control Toxicity

EPA regulations at 40 *CFR* 122.44(d)(1)(v) provide that limits on whole effluent toxicity are not necessary where the permitting authority demonstrates in the fact sheet or statement of basis of the NPDES permit that chemical-specific limits for the effluent are sufficient to attain and maintain applicable numeric and narrative State water quality criteria. To make this demonstration that chemical-specific limits are sufficient, additional effluent information will be needed. **EPA recommends that the discharger conduct a toxicity identification evaluation to identify the causative agent(s) in the effluent.** Where the permitting authority determines that the demonstration required by 40 *CFR* 122.44(d)(1)(v) has been made, limits on whole effluent toxicity

need not be imposed. Effluent limits on the controlling chemical with concurrent whole effluent monitoring will be sufficient. Where subsequent whole effluent toxicity testing reveals the presence of toxicity in the effluent, the above process will need to be repeated, or alternatively a whole effluent toxicity limit will be needed. If continued toxicity testing shows that additional chemical-specific effluent limits are insufficient to control whole effluent toxicity, then toxicity limits may be the only practical way to control toxicity.

3.3.8 Effluent Characterization for Specific Chemicals

The previous section discussed effluent characterization for whole effluent toxicity. This section will describe EPA's recommendations for data generation to determine whether or not permit limits are needed to control specific chemical pollutants in effluents. While many of the same principles apply when developing chemical-specific limits, there are some differences based upon regulatory and analytical considerations.

Characterization of impacts due to specific chemicals do not require a determination of the type of testing as is required for whole effluent toxicity because there is generally only one type of test for specific chemicals. However, there are some antecedent steps that are unique to effluent characterization for specific chemicals: determination of the chemicals of concern and determination of acceptable ambient levels (RAC, CMC, or CCC) for these pollutants.

Steps for Chemical-specific Effluent Characterization Process

Figure 3-5 illustrates EPA's recommendations for determining whether or not permit limits need to be developed according to an evaluation of a limited data set. The following discussion corresponds to the various activities shown in Figure 3-5. (Refer to the human health discussion in Section 3.3.9 for additional details on procedures to characterize the bioconcentration potential of effluents.)

Step 1: Identify the Pollutants of Concern

This process should begin with an examination of existing data to determine the presence of specific toxicants for which criteria, standards, or other toxicity data are available. Sources of data include the following:

- Permit application forms, DMRs, permit compliance systems (PCS), and permit files
- Pretreatment industrial surveys
- STORET for ambient monitoring data
- SARA Title III Toxic Chemical Release Inventory
- Industrial effluent guidelines development documents
- The Treatability Manual [6]
- Effluent bioconcentration assessment (see Section 3.3.9).

Data on specific chemicals that are typically submitted with NPDES application forms will consist of a limited number of analytical test results for many of the reported parameters. Where the regulatory authority has reason to believe that additional data for key parameters of concern are needed in order to adequately characterize the effluent, this information should be requested as a part of the application or, in some cases, through the use of Section 308 letters. **It is recommended that 8 to 12 samples be analyzed for key parameters of concern.** In some cases, special analytical protocols will need to be specified in order to gather all appropriate information.

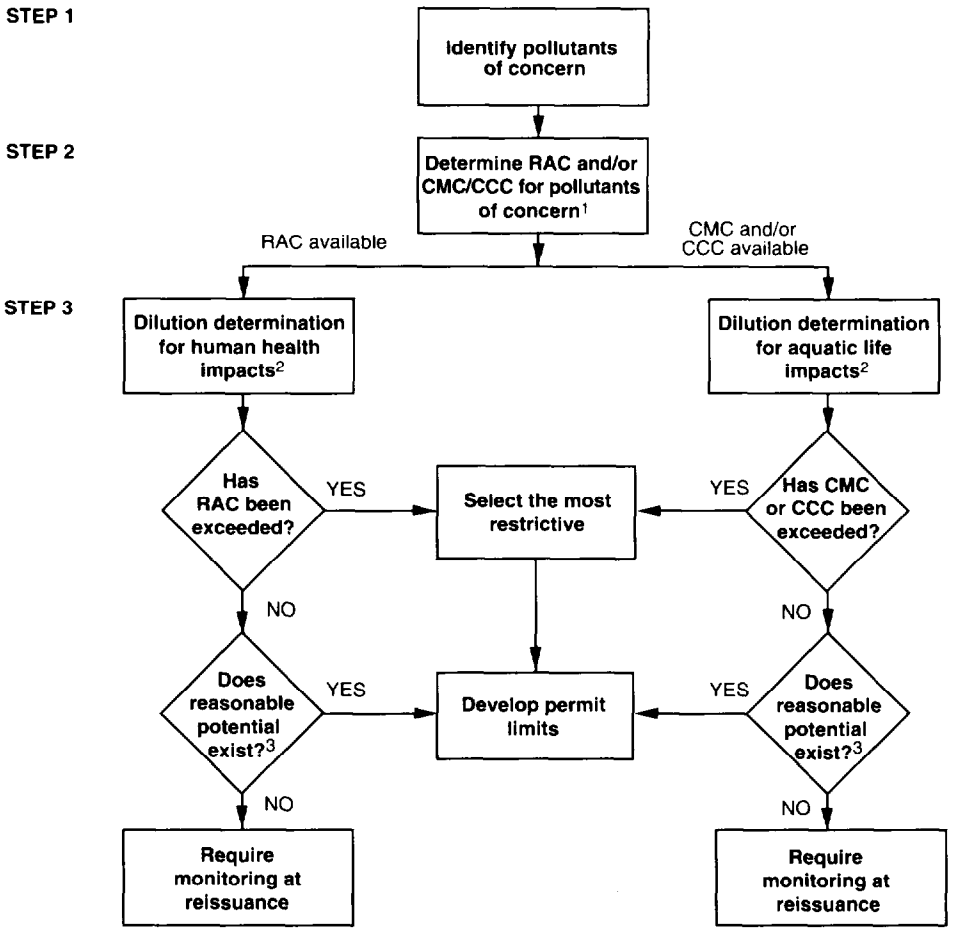
Step 2: Determine the Basis for Establishing RACs, CMCs, and CCCs for the Pollutants of Concern

The second step is to identify the appropriate water quality standard, including designated or existing use, and criteria for use. Ideally, the State water quality standards include aquatic life and human health criteria for the pollutants of concern. If a State does not have a numeric water quality criterion for the pollutant of concern, then one of three options for using the narrative criterion may be used (40 *CFR* 122.44(d)(1)(vi)) to determine whether a discharge causes, has the reasonable potential to cause, or contributes to an excursion above a narrative criteria because of an individual pollutant. Although the provisions of 40 *CFR* 122.44(d)(1)(vi) are presented in the regulation in the context of permit limit development, these same considerations should be applied in characterizing effluents in order to determine whether limits are necessary. The options available are as follows:

- **Option A** allows the regulatory authority to establish limits using a "calculated numeric water quality criterion" that the regulatory authority demonstrates will attain and maintain applicable narrative water quality criteria and fully protect the designated use. This option allows the regulatory authority to use any criterion that protects aquatic life and human health. This option also allows the use of site-specific factors, including local human consumption rates of aquatic foods, the State's determination of an appropriate risk level, and any other current data that may be available.

- **Option B** allows the regulatory authority to establish effluent limits using EPA's Water Quality Criteria guidance documents, if EPA has published a criteria document for the pollutant supplemented where necessary by other relevant information. As discussed earlier, EPA criteria documents provide a comprehensive summary of available data on the effects of a pollutant.

- **Option C** may be used to develop limits for a pollutant of concern based on an indicator parameter under limited circumstances. An example of an indicator parameter is total toxic organics (TTO); effluent limits on TTO are useful where an effluent contains organic compounds. However, use of this option must be justified to show that controls on one pollutant control one or more other pollutants to a level that will attain and maintain applicable State narrative water quality criteria and will protect aquatic life and human health (see 40 *CFR* 122.44(d)(1)(vi)(C)). Use of this option is restricted by regulation to those instances where it can be demonstrated that controls on indicator pollutants serve to control the toxicant of concern. Using Option A or Option B is a more direct and perhaps more defensible approach.



Notes:

[1] RAC and/or CMC/CCC: Use State numeric criterion or interpret State narrative criterion using one of three options specified under 40 *CFR* 122.44(d).

[2] Dilution determination: Perform for critical flow and for any applicable mixing zones for aquatic life and human health protection procedures, respectively.

[3] Reasonable potential: Use procedures in Boxes 3-2 and 3-4.

Figure 3-5. Effluent Characterization for Specific Chemicals

Step 3: Dilution Determination

The third step is to calculate the effluent dilution at the edge of the mixing zone. The pertinent factors for consideration here are the same as were previously presented for whole effluent toxicity with one difference: there are two levels of dilution analysis for chemical data. The first level is to use simple fate models based on a dilution analysis and comparison with the RAC, CMC, or CCC. The second level of analysis is to use more complex fate models, including dynamic models to estimate persistence, and may be applied to lakes, rivers, estuaries, and coastal systems using a desktop calculator or microcomputer. EPA has supported development of a second level of analysis that estimates point source wasteload allocations and nonpoint source allocations and predicts the resulting pollutant concentrations in receiving waters [7].

Step 4: Decision Criteria for Permit Limit Development

After this dilution analysis has been performed, the projected RWC is compared to the RAC, CMC, or CCC (either the State numeric criteria or an interpretation of the narrative criteria as described earlier). Whereas analysis of aquatic impacts should include evaluations with respect to both the CCC and the CMC, analysis of human health impacts will only involve comparisons with the RAC. The four possible outcomes discussed above in the triggers for permit limit development discussion in Section 3.3.3 also apply here:

- Excursion above the RAC, CMC, or CCC
- Reasonable potential for excursion above the RAC, CMC, or CCC

- No reasonable potential for excursion above the RAC, CMC, CCC

- Inadequate information.

If these evaluations project excursions or the reasonable potential to cause or contribute to an excursion above the RAC, CMC, or CCC, then a permit limit is required (40 *CFR* 122.44(d)(1)(iii)). The statistical approach shown in Box 3-2 or an analogous approach developed by a regulatory authority can be used to determine the reasonable potential. Effluents that are shown not to cause or that have a reasonable potential to cause or contribute to an excursion above an RAC, CMC, or CCC should be reevaluated at permit reissuance.

Where chemical-specific test results do not show a reasonable potential but indicate a basis for concern after consideration of the other factors discussed in Section 3.2, or if there were inadequate information to make a decision, the permit should contain chemical testing requirements and a reopener clause. This clause would require reopening of the permit and establishment of a limit based upon any test results that show effluent toxicity at levels that cause or have a reasonable potential to cause or contribute to an excursion above the RAC, CCC, or CMC.

3.3.9 Effluent Characterization for Bioconcentratable Pollutants

The previous section discussed how to characterize effects of specific chemicals, including those that may threaten human health, to determine whether or not a discharge causes, has the reasonable potential to cause, or contributes to excursions above an water quality criterion. The primary disadvantage of this approach is that it does not identify all effluent chemicals of potential concern for human health. To help address this gap, EPA is developing a procedure for identifying pollutants with the propensity to bioconcentrate in fish tissue. This procedure is presently in draft form and should not be used for establishing NPDES permit limits until EPA releases the final document on the procedure. This section describes the outline of this procedure.

The overall approach illustrated in Figure 3-6 is a seven-step procedure that starts with collecting samples and ends with developing permit effluent limits. The effluent characterization step unique to this approach lies in Step 3. There are two alternatives under this step: fish tissue residue and effluent assessment. An analytical chemistry laboratory with residue chemistry and gas chromatograph/mass spectometer (GC/MS) capability is needed to conduct the analytical methods for both alternatives. A summary of the alternatives follows:

- Tissue Residue Alternative: This alternative measures the concentrations of organic bioconcentratable chemicals in tissue samples of indigenous organisms from the receiving water. This analysis involves the collection of fish or shellfish samples, the extraction of the organic chemicals from the tissue and the analysis of these extracts with GC/MS to identify and quantify the bioconcentratable contaminants. The procedure provides recommendations to sort the results of this screening analysis in order to determine which of the contaminants pose a hazard and require regulatory action. The approach recommends that the identity of those contaminants then be confirmed prior to taking subsequent action.

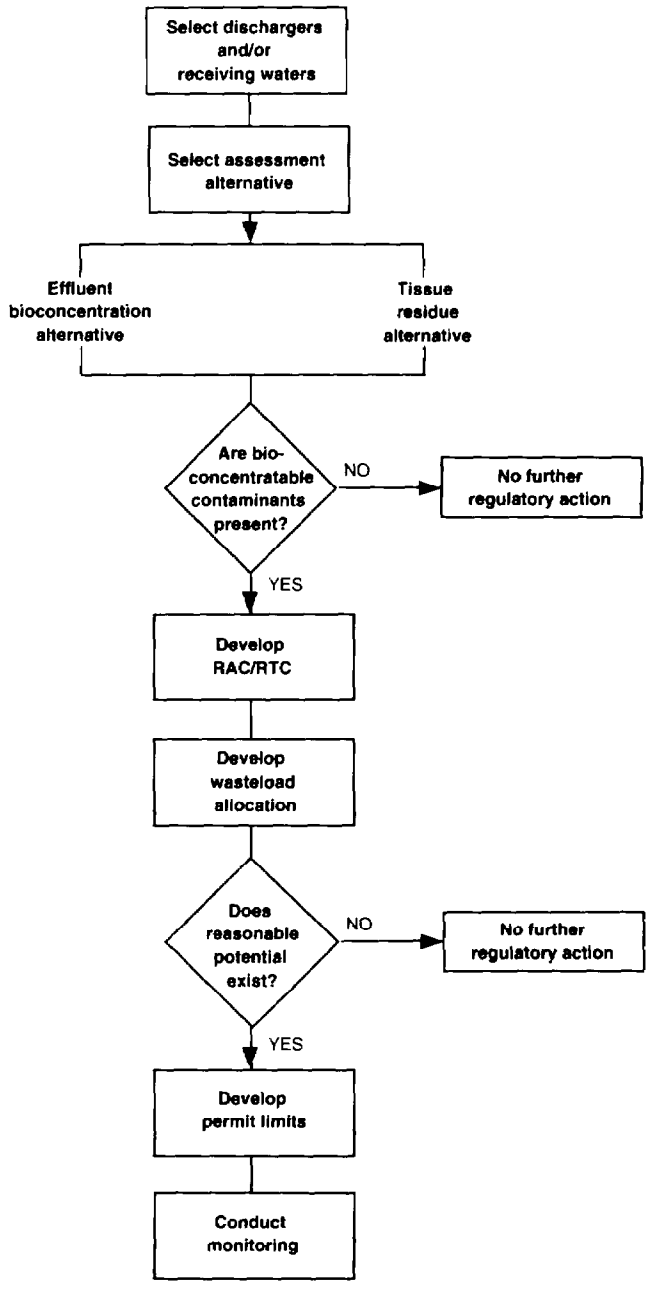


Figure 3-6. Procedure for Assessment and Control of Bioconcentratable Contaminants in Surface Waters

- Effluent Alternative: This alternative measures the concentrations of organic bioconcentratable chemicals in effluent samples from point source dischargers. This analysis involves the collection of effluent samples, the extraction of the organic chemicals from the effluent sample, and the separation of the chemicals that have characteristics known to result in bioconcentration from the other chemical components of the effluent sample. This separation is achieved by way of an analytical chemistry methodology called high-

pressure liquid chromotography (HPLC). The HPLC also separates (fractionates) an effluent sample into three subsamples or "fractions." These three fractions contain chemicals with increasing potential to bioconcentrate, with the third fraction containing those chemicals with the highest bioconcentration rates. Following HPLC fractionation, each fraction is then analyzed with GC/MS to identify and quantify the bioconcentratable contaminants. The effluent procedure also provides recommendations to sort the results of the initial screening analysis to determine which of the contaminants pose a hazard and require subsequent regulatory action. The approach then recommends that the identity of those contaminants then be confirmed prior to taking further regulatory action.

While both of the assessment alternatives described above may be used for a given discharger, generally one of these alternatives may be preferred by the regulatory authority. The regulatory authority would select the assessment approach based on the available site- and facility-specific information and the objectives of the application.

Although the approach provides a means to identify chemicals that can bioconcentrate, it does not identify all bioconcentratable chemicals. Chemicals that bioconcentrate include many organic compounds, and a small number of metals (e.g., mercury and selenium) and organometals (e.g., tributyltin). The new approach is limited to nonpolar organic chemicals that produce measurable chemical residues in aquatic organisms or that have log octanol-water partition coefficients greater than 3.5.

3.3.10 Analytical Considerations for Chemicals

Analysis of discharges for toxic substances requires special quality control procedures beyond those necessary for conventional parameters. Toxicants can occur in trace concentrations and are frequently volatile or otherwise unstable. An EPA publication entitled, *Test Methods—Technical Additions to Methods for Chemical Analysis of Water and Wastes* [8], contains sampling and handling procedures recommended by EPA for a number of toxic and conventional parameters. Additional methods for analyses for toxicants are described in Standard Methods of Water and Wastewater Analyses (ASTM, 17th edition, 1989, or most recent edition) and 40 CFR Part 136. Chapter 5 discusses detection limits and sampling requirements.

CHAPTER 3
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4. EXPOSURE AND WASTELOAD ALLOCATION

4.1 INTRODUCTION

At this point in the toxics control process, a water quality problem has been identified. Screening analyses may have been done to assess the extent of toxicity, or a wasteload allocation (WLA) based on an existing total maximum daily load (TMDL) may already have been established. A TMDL is the sum of the individual WLAs for point sources and load allocations (LAs) for nonpoint sources of pollution and natural background sources, tributaries, or adjacent segments. WLAs represent that portion of a TMDL that is established to limit the amount of pollutants from existing and future point sources so that surface water quality is protected at all flow conditions.

The TMDL process uses water quality analyses to predict water quality conditions and pollutant concentrations. Limits on wastewater pollutant loads are set and nonpoint source allocations are established so that predicted receiving water concentrations do not exceed water quality criteria. TMDLs and WLAs/LAs should be established at levels necessary to attain and maintain the applicable narrative and numerical water quality standards, with seasonal variations and a margin of safety that takes into account any lack of knowledge concerning the relationship between point and nonpoint source loadings and water quality. Determination of WLAs/LAs and TMDLs should take into account critical conditions for stream flow, loading, and water quality parameters. Conditions that will protect the receiving water have been determined from State numeric or narrative water quality criteria.

This chapter is divided into sections that explain the steps that precede establishment of a WLA and then the methods and tools (models) that can be used to determine the WLA. Section 4.2 briefly discusses TMDLs and how they relate to waters identified as requiring a water quality-based approach for toxics control. The section also discusses different WLA schemes. Sections 4.3 and 4.4 discuss mixing zones, areas described as allocated impact zones where acute and chronic water quality criteria may be exceeded. Section 4.3 provides background information on mixing zones and discusses EPA's mixing zone policy and how this policy affects the allowable toxic load that can be discharged from a point source. State mixing zone dimensions and the determination of mixing zone boundaries are also discussed.

Section 4.4 discusses mixing zone analyses for situations in which the discharge does not mix completely with the receiving water within a short distance. Included in Section 4.4 are discussions of outfall designs that maximize initial dilution in the mixing zone, critical design periods for mixing zone analyses, and methods to analyze and model near-field and far-field mixing.

Section 4.5 discusses the calculations of the WLA and LA and the types of EPA-recommended mathematical models available to determine WLAs in completely mixed situations for both aquatic life and human health. The WLA models listed in Section 4.5 can be used to predict ambient concentrations and to calculate the effluent quality required to meet the criteria and protect designated and existing uses of the receiving water. The data requirements of each of these models are also described so that the effluent characterization procedures described in Chapter 3 can be designed to support the specific types of WLA modeling selected by the regulator. Section 4.6 discusses human health considerations and how to determine WLAs for human health toxicants.

EPA is currently working on methods to develop sediment criteria. Once developed, point source discharges could be further limited to prevent accumulation of pollutants in the bed sediment; such accumulation impairs beneficial uses. Although the criteria are not yet available for this document, they will be addressed in future documents. In the meantime, some of the models discussed in Section 4.5 are capable of simulating interactions between the water column and sediment and between toxic transport and transformation in the sediment. EPA is encouraging the States to consider the role of sediments in WLA.

4.2 TOTAL MAXIMUM DAILY LOADS AND WASTELOAD ALLOCATIONS

4.2.1 Total Maximum Daily Loads

The Federal Clean Water Act (CWA), under Section 303(d), requires the establishment of TMDLs for "water quality limited" stream segments. In such segments, water quality does not meet applicable water quality standards and/or is not expected to meet applicable water quality standards even after the application of the technology-based effluent limitations. A TMDL includes a determination of the amount of a pollutant, or property of a pollutant, from point, nonpoint, and natural background sources, including a margin of safety, that may be discharged to a water quality-limited waterbody. Any loading above this loading capacity risks violating water quality standards. TMDLs can be expressed in terms of chemical mass per unit of time, by toxicity, or by other appropriate measures. Permits should be issued based on TMDLs where available.

The establishment of a TMDL for a particular waterbody is dependent on the location of point sources, available dilution, water quality standards, nonpoint source contributions, background conditions, and instream pollutant reactions and effluent toxicity. All of these factors can affect the allowable mass of the pollutant in the waterbody. Thus, two issues must be determined in conjunction with the establishment of the TMDL: (1) the definition of upstream and downstream boundaries of the waterbody for which the TMDL is being determined, and (2) the definition of critical conditions. For the following discussion, the waterbody boundaries are delineated as the portion of the waterbody be-

tween the pollutant source (whether point source or nonpoint source) that is farthest upstream and the downstream point at which water quality has recovered to the background quality found above the pollutant source that is farthest upstream. The delineation of critical conditions for stream flow, loading, and water quality parameters may be specific to the type of waterbody and is discussed in Section 4.4.

TMDLs are established based on water quality criteria pertinent to the designated and existing uses for the waterbody in question. TMDLs are traditionally calculated using State water quality standards as applied to a specific waterbody. Such a fitting of the TMDL to desired water quality criteria requires information concerning the distribution of loadings within the waterbody, namely, the locations and relative contributions of pollutant-specific loadings from point, nonpoint, and background sources during all flow conditions (40 *CFR* 130.2(f)). Low-flow TMDLs, by themselves, will not be adequate in situations where nonpoint source loadings (LAs) during high or intermediate flow conditions cause excursions above water quality standards (40 *CFR* 130.2(f)).

The loading capacity of TMDLs have been determined in many ways, but the most common method is to find the pollutant loading that will attain and maintain applicable water quality criteria. For example, in the Tualatin River Basin in Oregon, loading capacity was determined by multiplying stream flow in critical flow periods by the pollutant water quality standard [1]. Another method of determining a loading capacity is by quantifying instream toxicity. This method was used in developing a TMDL for the Amelia River in Florida [2].

The allowable TMDL is defined as the sum of the individual WLAs and LAs; a margin of safety can be included with the two types of allocations to ensure that allocated loads, regardless of source, would not produce an excursion above water quality standards. The WLAs are those portions of the TMDL assigned to point sources; the LAs are those portions of the TMDL assigned to the sum of all nonpoint sources and background sources (40 *CFR* 130.2(f)). The background sources represent loadings to the specified waterbody or stream segment that come from sources outside the defined segment. For example, loadings from regions upstream of the segment and estimated atmospheric deposition of the pollutant would constitute background sources. Sediments that are highly contaminated from upstream discharges or historical discharges might also act as a source of toxicants and contribute to the background levels; these sediments also may be part of the nonpoint sources.

The TMDL represents a mass loading that may occur over a given time period to attain and maintain water quality standards. As a result, the design flows under which the TMDL is determined can significantly alter its value. This phenomenon results in a somewhat unusual dichotomy. The design flows for aquatic life protection most applicable to point source loadings (WLAs) usually involve low-flow events (e.g., 7Q10) because the volumes associated with the point sources generally do not decrease with decreased stream flow. As a result, the highest concentrations associated with specific point source loads would be expected under low flow conditions. Conversely, elevated nonpoint source pollutant loadings (i.e., urban, agricultural) generally correspond to storm events. In fact, agricultural and urban runoff are often minimal or nonexistent in the absence of precipitation (i.e., nonexistent under low-flow drought conditions).

The TMDL is a composite of the allowable loads associated with point sources and nonpoint sources within the defined boundaries of the waterbody segment and the background loadings to that segment from upstream and from in-place sediments. Therefore, the TMDL should be evaluated under conditions that reflect worst-case (critical) conditions for both point and nonpoint source loadings (i.e., low-flow drought and high flow conditions). Determination of the TMDL under these two scenarios would identify the lower of the two loading capacities of the waterbody. This lower capacity is necessary to protect the waterbody in question.

In the case of design flows for human health protection, the harmonic mean flow is recommended as the basis for TMDLs for carcinogens. Design flows for human health protection should consider worst-case conditions for both point and nonpoint source loadings under this flow condition (see Section 4.6).

In many cases, LAs for nonpoint sources are difficult to assess because the information needed to describe the runoff associated with the high-flow storm events does not exist. This lack of information is due to the high variability of the events. Because of the importance of estimating the nonpoint contributions to the waterbody, site-specific models may be required to estimate nonpoint source loadings. Even then, detailed models are difficult to calibrate with accuracy without intensive monitoring studies, and simplistic correlations between loadings and rainfall can be, by their statistical nature, unreliable for estimating low-frequency events (e.g., worst 10-year storm). The uncertainties associated with nonpoint source loadings and background sources require that the TMDL be determined with a sufficient margin of safety to allow for significant variability in nonpoint source loadings.

CWA Section 303(d) and EPA regulations (40 *CFR* Parts 35 and 130, January 11, 1985) require that TMDLs contain a margin of safety "which takes into account any lack of knowledge concerning the relationship between effluent limitations and water quality." The margin of safety is to take into account any uncertainties related to development of the water quality-based control, including any uncertainties in pollutant loadings, ambient conditions, and the model analysis. The size of the required margin of safety can, of course, be reduced by collecting additional information, which reduces the amount of uncertainty. The margin of safety can be provided for in the TMDL process by one of the following:

- Reserving a portion of the loading capacity to a separate margin of safety.
- Including a margin of safety within the individual WLAs for point sources and within the LAs for nonpoint sources and background sources.

Most TMDLs are developed using the second approach, most often through the use of conservative design conditions.

In addition, all WLAs, LAs, and TMDLs must meet the State antidegradation provisions developed prusuant to the Water Quality Standards Regulation (Section 131.12 of 40 *CFR* Part 131,

November 8, 1983). This regulation establishes explicit procedures that must be followed prior to lowering existing water quality to a level that still supports the Section 101(a)(2) "fishable/swimmable" goal of the Act. WLAs, LAs, and TMDLs that allow such a decline in water quality cannot be established unless the applicable public participation and intergovern-mental review requirements of the antigradation provisions have been met and all existing uses are fully maintained and protected.

4.2.2 Wasteload Allocation Schemes

WLAs for water quality-based toxics permits must be set in accordance with EPA regulations [3, 4]. EPA has developed a number of WLA guidance documents to assist regulatory authorities in developing TMDLs and WLAs. The EPA Office of Water Regulations and Standards, Assessment and Watershed Protection Division, maintains the latest listing of all WLA guidance documents. Toxic WLA guidance documents are currently available for rivers and streams [5], lakes and reservoirs [6], and estuaries [7]. Guidance for the determination of critical design conditions for steady-state modeling of rivers and streams also is available [8].

Table 4-1 lists 19 allocation schemes that may be used by the States to develop WLAs. This is not intended to be a complete list of approaches; regulatory authorities may use any reasonable allocation scheme that meets the antidegradation provisions and other requirements of State water quality standards [3].

The most commonly used allocation methods have been equal percent removal, equal effluent concentrations, and a hybrid method. The equal percent removal approach can be applied in two ways: the overall removal efficiencies of each pollutant source must be equal, or the incremental removal efficiencies must be equal. The equal effluent concentration approach also can be applied in two acceptable ways—equal final concentrations or equal incremental concentration reductions. This method is similar to the equal percent removal method if influent concentrations at all sources are approximately the same. However, if one point source has substantially higher influent levels, requiring equal effluent concentrations will result in higher overall treatment levels for that source than the equal percent removal approach.

The final commonly used method of allocating wasteloads is a hybrid method in which the criteria for waste reduction may not be the same for each point source. One facility may be allowed to operate unchanged, while another may be required to provide the entire load reduction. More often, a proportionality rule that requires the percent removal to be proportional to the input loading can be assigned. In these cases, larger sources would be required to achieve higher overall removals.

4.3 INCOMPLETELY MIXED, DISCHARGE RECEIVING WATER SITUATIONS

Mixing zones are areas where an effluent discharge undergoes initial dilution and are extended to cover the secondary mixing in the ambient waterbody. A mixing zone is an allocated impact zone where acute and chronic water quality criteria can be exceeded as long as a number of protections are maintained, including freedom from the following:

- Materials in concentrations that settle to form objectionable deposits
- Floating debris, oil, scum, and other matter in concentrations that form nuisances

Table 4-1. Wasteload Allocation Methods [9]

1. Equal percent removal (equal percent treatment)
2. Equal effluent concentrations
3. Equal total mass discharge per day
4. Equal mass discharge per capita per day
5. Equal reduction of raw load (pounds per day)
6. Equal ambient mean annual quality (mg/l)
7. Equal cost per pound of pollutant removed
8. Equal treatment cost per unit of production
9. Equal mass discharged per unit of raw material used
10. Equal mass discharged per unit of production

11a. Percent removal proportional to raw load per day

11b. Larger facilities to achieve higher removal rates

12. Percent removal proportional to community effective income

13a. Effluent charges (dollars per pound, etc.)

13b. Effluent charge above some load limit

14. Seasonal limits based on cost-effectiveness analysis
15. Minimum total treatment cost
16. Best availability technology (BAT) (industry) plus some level for municipal inputs
17. Assimilative capacity divided to require an "equal effort among all dischargers"

18a. Municipal: treatment level proportional to plant size

18b. Industrial: equal percent between best practicable technology (BPT) and BAT, i.e., Allowable wasteload allocation:

$$(WLA) = BPT - \frac{x}{100}(BPT - BAT)$$

19. Industrial discharges given different treatment levels for different stream flows and seasons. For example, a plant might not be allowed to discharge when stream flow is below a certain value, but below another value, the plant would be required to use a higher level of treatment than BPT. Finally, when stream flow is above an upper value, the plant would be required to treat to a level comparable to BPT.

- Substances in concentrations that produce objectionable color, odor, taste, or turbidity

- Substances in concentrations that produce undesirable aquatic life or result in a dominance of nuisance species.

Acutely toxic conditions are defined as those lethal to aquatic organisms that may pass through the mixing zone. As discussed in Chapter 2, the underlying assumption for allowing a mixing zone is that a small area of concentrations in excess of acute and chronic criteria, but below acutely toxic releases, can exist without causing adverse effects to the overall waterbody. The State regulatory agency can decide to allow or deny a mixing zone on a site-specific basis. For a mixing zone to be permitted, the discharger should prove to the State regulatory agency that all State requirements for a mixing zone are met.

When wastewater is discharged into a waterbody, its transport may be divided into two stages with distinctive mixing characteristics. Mixing and dilution in the first stage are determined by the initial momentum and buoyancy of the discharge. This initial contact with the receiving water is where the concentration of the effluent will be its greatest in the water column. The design of the discharge outfall should provide ample momentum to dilute the concentrations in the immediate contact area as quickly as possible.

The second stage of mixing covers a more extensive area in which the effect of initial momentum and buoyancy is diminished and the waste is mixed primarily by ambient turbulence. In large rivers or estuaries, this second-stage mixing area may extend for miles before uniformly mixed conditions are attained. In some instances, such as larger lakes or coastal bays, completely mixed conditions are never reached in the waterbody. The general definition for a completely mixed condition is when no measurable difference in the concentration of the pollutant (e.g., does not vary by more than 5 percent) exists across any transect of the waterbody.

This section provides background information on the policy of mixing zones and the means to characterize them for use in WLAs (Section 4.5). The first subsection discusses the concerns that must be addressed when the boundaries and restrictions of a mixing zone are determined. The second subsection discusses the guidelines for preventing lethal conditions in the mixing zone.

4.3.1 Determination of Mixing Zone Boundaries

Allowable mixing zone characteristics should be established to ensure the following:

- Mixing zones do not impair the integrity of the waterbody as a whole.

- There is no lethality to organisms passing through the mixing zone.

- There are no significant health risks, considering likely pathways of exposure (see Section 2.2.2).

The Water Quality Criteria—1972 [10] recommends that mixing zone characteristics be defined on a case-by-case basis after it has been determined that the assimilative capacity of the receiving system can safely accommodate the discharge. This assessment should take into consideration the physical, chemical, and biological characteristics of the discharge and the receiving system; the life history and behavior of organisms in the receiving system; and the desired uses of the waters. Nearly all States require such an analysis before they allow a mixing zone [11]. Further, mixing zones should not be permitted where they may endanger critical areas (e.g., drinking water supplies, recreational areas, breeding grounds, areas with sensitive biota).

EPA has developed a holistic approach to determine whether a mixing zone is tolerable [12]. The method considers all the impacts to the waterbody and all the impacts that the drop in water quality will have on the surrounding ecosystem and waterbody uses. It is a multistep data collection and analysis procedure that is particularly sensitive to overlapping mixing zones. It includes the identification of all upstream and downstream waterbodies and the ecological and cultural data pertaining to them; the collection of data on all present and future discharges to the waterbody; the assessment of relative environmental value and level of protection needed for the waterbody; and, finally, the allocation of environmental impact for a discharge applicant. Because of the difficulty in collecting the data necessary for this procedure and the general lack of agreement concerning relative values, this method will be difficult to implement in full. However, the method does serve as a guide on how to proceed in allocating a mixing zone.

Most States allow mixing zones as a policy issue, but provide spatial dimensions to limit the areal extent of the mixing zones. The mixing zones are then allowed (or not allowed) after case-by-case determinations. State regulations dealing with streams and rivers generally limit mixing zone widths, cross-sectional areas, and flow volumes and allow lengths to be determined on a case-by-case basis. For lakes, estuaries, and coastal waters, dimensions are usually specified by surface area, width, cross-sectional area, and volume.

Where a mixing zone is allowed, water quality standards are met at the edge of that regulatory mixing zone during design flow conditions and generally, (1) provide a continuous zone of passage that meets water quality criteria for free-swimming and drifting organisms and (2) prevent impairment of critical resource areas. Individual State mixing zone dimensions are designed to limit the impact of a mixing zone on the waterbody. Furthermore, EPA's review of State WLAs should evaluate whether assumptions of complete or incomplete mixing are appropriate based on available data.

In river systems, reservoirs, lakes, estuaries, and coastal waters, zones of passage are defined as continuous water routes of such volume, area, and quality as to allow passage of free-swimming and drifting organisms so that no significant effects are produced on their populations. Transport of a variety of organisms in river water and by tidal movements in estuaries is biologically important in a number of ways: food is carried to the sessile filter

feeders and other nonmobile organisms, spatial distribution of organisms and reinforcement of weakened populations are enhanced, and embryos and larvae of some fish species develop while drifting [11]. Anadromous and catadromous species must be able to reach suitable spawning areas. Their young (and in some cases the adults) must be assured a return route to their growing and living areas. Many species make migrations for spawning and other purposes. Barriers or blocks that prevent or interfere with these types of essential transport and movement can be created by water with inadequate chemical or physical quality.

As explained above, a State regulatory agency may decide to deny a mixing zone in a site-specific case. For example, denial should be considered when bioaccumulative pollutants are in the discharge. The potential for a pollutant to bioaccumulate in living organisms is measured by (1) the bioconcentration factor (BCF), which is chemical-specific and describes the degree to which an organism or tissue can acquire a higher contaminant concentration than its environment (e.g., surface water); (2) the duration of exposure; and (3) the concentration of the chemical of interest. While any BCF value greater than 1 indicates that bioaccumulation potential exists, bioaccumulation potential is generally not considered to be significant unless the BCF exceeds 100 or more. Thus, a chemical that is discharged to a receiving stream, resulting in low concentrations, and that has a low BCF value will not create a bioaccumulation hazard. Conversely, a chemical that is discharged to a receiving stream, resulting in a low concentration but having a high BCF value, may cause in a bioaccumulation hazard. Also, some chemicals of relatively low toxicity, such as zinc, will bioconcentrate in fish without harmful effects resulting from human consumption.

Another example of when a regulator should consider prohibiting a mixing zone is in situations where an effluent is known to attract biota. In such cases, provision of a continuous zone of passage around the mixing area will not serve the purpose of protecting aquatic life. A review of the technical literature on avoidance/attraction behavior revealed that the majority of toxicants elicited an avoidance or neutral response at low concentrations [13]. However, some chemicals did elicit an attractive response, but the data were not sufficient to support any predictive methods. Temperature can be an attractive force and may counter an avoidance response to a pollutant, resulting in attraction to the toxicant discharge. Innate behavior such as migration may also supersede an avoidance response and cause fish to incur a significant exposure.

4.3.2 Minimizing the Size of Mixing Zones

Concentrations above the chronic criteria are likely to prevent sensitive taxa from taking up long-term residence in the mixing zone. In this regard, benthic organisms and territorial organisms are likely to be of greatest concern. The higher the concentrations occurring within an isopleth, the more taxa are likely to be excluded, thereby affecting the structure and function of the ecological community. It is thus important to minimize the overall size of the mixing zone and the size of elevated concentration isopleths within the mixing zone.

4.3.3 Prevention of Lethality to Passing Organisms

The *Water Quality Standards Handbook* [14] indicates that whether to establish a mixing zone policy is a matter of State discretion, but that any State policy allowing for mixing zones must be consistent with the CWA and is subject to approval of the Regional Administrator. The handbook provides additional discussion regarding the basis for a State mixing zone policy.

Lethality is a function of the magnitude of pollutant concentrations and the duration an organism is exposed to those concentrations. Requirements for wastewater plumes that tend to attract aquatic life should incorporate measures to reduce the toxicity (e.g., via pretreatment, dilution) to minimize lethality or any irreversible toxic effects on aquatic life.

EPA's water quality criteria provide guidance on the magnitude and duration of pollutant concentrations causing lethality. The criterion maximum concentration (CMC) is used as a means to prevent lethality or other acute effects. As explained in Appendix D, the CMC is a toxicity level and should not be confused with an LC_{50} level. The CMC is defined as one-half of the final acute value for specific toxicants and 0.3 acute toxic unit (TU_a) for effluent toxicity (see Chapter 2). The CMC describes the condition under which lethality will not occur if the duration of the exposure to the CMC level is less than 1 hour. The CMC for whole effluent toxicity is intended to prevent lethality or acute effects in the aquatic biota. The CMC for individual toxicants prevents acute effects in all but a small percentage of the tested species. Thus, the areal extent and concentration isopleths of the mixing zone must be such that the 1-hour average exposure of organisms passing through the mixing zone is less than the CMC. The organism must be able to pass through quickly or flee the high-concentration area. The objective of developing water quality recommendations for mixing zones is to provide time-exposure histories that produce negligible or no measurable effects on populations of critical species in the receiving system.

Lethality to passing organisms can be prevented in the mixing zone in one of four ways. The first method is to prohibit concentrations in excess of the CMC in the pipe itself, as measured directly at the end of the pipe. As an example, the CMC should be met in the pipe whenever a continuous discharge is made to an intermittent stream. The second approach is to require that the CMC be met within a very short distance from the outfall during chronic design-flow conditions for receiving waters (see Section 4.4.2).

If the second alternative is selected, hydraulic investigations and calculations indicate that the use of a high-velocity discharge with an initial velocity of 3 meters per second, or more, together with a mixing zone spatial limitation of 50 times the discharge length scale in any direction, should ensure that the CMC is met within a few minutes under practically all conditions. The discharge length scale is defined as the square root of the cross-sectional area of any discharge pipe.

A third alternative (applicable to any waterbody) is not to use a high-velocity discharge. Rather the discharger should provide

data to the State regulatory agency showing that the most restrictive of the following conditions are met for each outfall:

- The CMC should be met within 10 percent of the distance from the edge of the outfall structure to the edge of the regulatory mixing zone in any spatial direction.

- The CMC should be met within a distance of 50 times the discharge length scale in any spatial direction. In the case of a multiport diffuser, this requirement must be met for each port using the appropriate discharge length scale of that port. This restriction will ensure a dilution factor of at least 10 within this distance under all possible circumstances, including situations of severe bottom interaction, surface interaction, or lateral merging.

- The CMC should be met within a distance of five times the local water depth in any horizontal direction from any discharge outlet. The local water depth is defined as the natural water depth (existing prior to the installation of the discharge outlet) prevailing under mixing zone design conditions (e.g., low flow for rivers). This restriction will prevent locating the discharge in very shallow environments or very close to shore, which would result in significant surface and bottom concentrations.

A fourth alternative (applicable to any waterbody) is for the discharger to provide data to the State regulatory agency showing that a drifting organism would not be exposed to 1-hour average concentrations exceeding the CMC, or would not receive harmful exposure when evaluated by other valid toxicological analysis, as discussed in Section 2.2.2. Such data should be collected during environmental conditions that replicate critical conditions.

For the third and fourth alternatives, examples of such data include monitoring studies, except for those situations where collecting chemical samples to develop monitoring data would be impractical, such as at deep outfalls in oceans, lakes, or embayments. Other types of data could include field tracer studies using dye, current meters, other tracer materials, or detailed analytical calculations, such as modeling estimations of concentration or dilution isopleths.

The Water Quality Criteria—1972 [11] outlines a method, applicable to the fourth alternative, to determine whether a mixing zone is tolerable for a free-swimming or drifting organism. The method incorporates mortality rates (based on toxicity studies for the pollutant of concern and a representative organism) along with the concentration isopleths of the mixing zone and the length of time the organism may spend in each isopleth. The intent of the method is to prevent the actual time of exposure from exceeding the exposure time required to elicit an effect [10]:

$$\Sigma \frac{T(n)}{ET(X) \text{ at } C(n)} \leq 1$$

where T(n) is the exposure time an organism is in isopleth n, and ET(X) is the "effect time." That is, ET(X) is the exposure time required to produce an effect (including a delayed effect) in X percent of organisms exposed to a concentration equal to C(n), the concentration in isopleth n. ET(X) is experimentally determined; the effect is usually mortality. If the summation of ratios of exposure time to effect time is less than 1, then the percent effect will not occur.

4.3.4 Prevention of Bioaccumulation Problems for Human Health

States are not required to allow mixing zones. Where unsafe fish tissue levels or other evidence indicates a lack of assimilative capacity in a particular waterbody for a bioaccumulative pollutant, care should be taken in calculating discharge limits for this pollutant or the additivity of multiple pollutants. In particular, relaxing discharge limits because of the provision of a mixing zone may not be appropriate in this situation.

4.4 MIXING ZONE ANALYSES

Proper design of a mixing zone study for a particular waterbody requires estimation of the distance from the outfall to the point where the effluent mixes completely with the receiving water. The boundary is usually defined as the location where the concentrations across a transect of the waterbody differ by less than 5 percent. The boundary can be determined based on the results of a tracer study or the use of mixing zone models. Both procedures, along with simple order-of-magnitude dilution calculations, are discussed in the following subsections.

If the distance to complete mixing is insignificant, then mixing zone modeling is not necessary and the fate and transport models described in Section 4.5 can be used to perform the WLA. **It is important to remember that the assumption of complete mixing is not a conservative assumption for toxic discharges; an assumption of minimal mixing is the conservative approach.** If completely mixed conditions do not occur within a short distance of the outfall, the WLA study should rely on mixing zone monitoring and modeling. Just as in the case of completely mixed models, mixing zone analysis can be performed using both steady-state and dynamic techniques. State requirements regarding the mixing zone will determine how water quality criteria are used in the TMDL.

This section is divided into five subsections. The first discusses recommendations for outfall designs and means to maximize initial dilution. The second provides a brief description of the four major waterbody types and the critical design period when mixing zone analysis should be performed for each. The third provides a brief description of tracer studies and how they may be used to define a mixing zone. The fourth and fifth subsections discuss simplified methods and sophisticated models to predict the two stages of mixing (i.e., discharge-induced and ambient-induced mixing). For a detailed explanation of the mechanisms involved in estimating both stages of mixing, two references are recommended, Holley and Jirka [15] and Fischer et al. [16]. Although the models presented in Sections 4.4.4 and 4.4.5 simplify the mixing process, the assessor should have an understanding of the basic physical concepts governing mixing to use these

models appropriately. (The U.S. EPA Center for Exposure Assessment Modeling [CEAM] in Athens, Georgia, provides an overview course that teaches the basics of mixing and how the basics should be used for water quality management.)

It is important to note that the mixing zone models presented here attempt to predict the dispersion and dilution of the effluent plume. They do not attempt to predict any removal or transformation of the pollutants. In the near field, dispersion and dilution caused by discharge-induced mixing and then ambient-induced mixing will be the major cause of toxicity reduction. If incomplete mixing persists downstream (such as in the case of shore hugging plumes), then some far-field processes will become important. Some of the models described in Section 4.5 that have sophisticated hydrodynamic simulation routines coupled with fate simulation routines may be used for these far-field, incomplete mixing analyses.

4.4.1 General Recommendations for Outfall Design

An important factor in maximizing the initial dilution of an effluent is the design of the effluent outfall. There are three major types of outfall designs: surface discharge from free flows in a pipe or canal, single-port submerged discharge, and multiport submerged discharge. The last type is often referred to as multiport diffusers. Of the three, the surface discharge type is the least favorable for toxic discharges since it offers the least initial mixing. In particular, surface discharges at the shoreline of a waterbody usually have an impact along the shoreline when there is significant cross-flow and thus yield high surface concentrations.

Submerged discharges offer more flexibility in meeting the design goals for toxic discharges. Submerged discharges may be in the form of a single pipe outlet or of multiport discharges (diffusers) giving rise to one or several submerged discharge jets. A typical diffuser section is illustrated in Figure 4-1. Submerged discharges allow the effluent to be directed at different angles to the ambient flow to maximize the initial dilution. Diffusers are particularly effective in counteracting the buoyancy of the effluent. However, submerged multiport discharges are only feasible in waterbodies that are of sufficient depth and are not subjected to periodic dredging or to considerable scour or deposition.

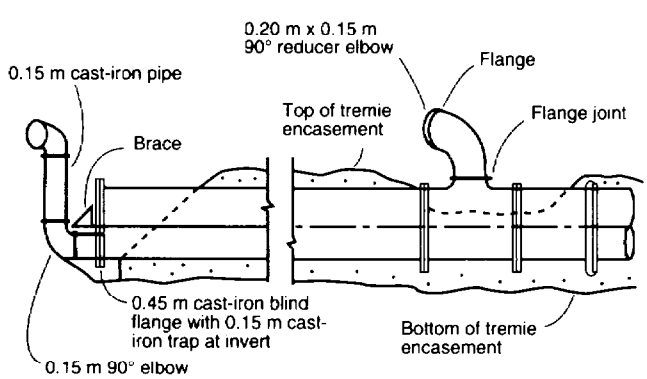

Figure 4-1. A Typical Diffuser Section [17]

Many of the complexities of submerged diffusers have been summarized by Jirka [18], Holley and Jirka [15], and Roberts et al. [19, 20, 21]. Submerged discharges should be designed to avoid direct surface impingement and bottom attachment of the submerged jet or jets. Surface and bottom impacts should be evaluated at critical design conditions (low flow or high stratification) and at off-design conditions (higher flow or lower stratification) to ensure the best placement and design of the diffuser. Diffusers provide more dilution than single outlets, but the alignment of the diffuser with the receiving water flow direction influences how much dilution will be provided. If the outlet structure is directed parallel to the direction of flow, dilution under high ambient velocities (off-design conditions) may be lower than under low velocities (critical design conditions).

In rivers, the preferred arrangement for a submerged discharge is to direct the outlet into the current flow direction or vertically upward. To deal with the reversing currents of estuaries and coastal bays, the preferred arrangements for offshore discharges are parallel diffuser alignment (tee diffuser) and perpendicular diffuser alignment (staged diffuser) [18]. In lakes and reservoirs, the preferred arrangement for a negatively buoyant discharge is to direct the diffuser vertically upward. A positively buoyant, vertically directed jet could penetrate stratification, so the preference for this type of discharge is to orient the diffuser at a slight angle above the horizontal. For ocean outfalls, initial dilution is improved by longer (perpendicular to the shoreline) and deeper diffusers. Further, the ports of the diffuser should be sufficiently separated to minimize merging of the separate plumes [22].

4.4.2 Critical Design Periods for Waterbodies

This section provides a brief description of the four major waterbody types and defines the critical design periods that should be used when performing mixing zone analyses in each of these waterbody types. Appendix D provides a further discussion on the appropriate selection of design periods.

1) Rivers and Run-of-River Reservoirs

Rivers and run-of-river reservoirs are waterbodies that have a persistent throughflow in the downstream direction and do not exhibit significant natural density stratification. Recommendations for hydrologically based and biologically based design flows for completely mixed, steady-state modeling of rivers are described in Appendix D of this document. The biologically based design flows are determined using the averaging periods and frequencies specified in water quality criteria [8]. Also, the hydrologically based flows 1Q10 and 7Q10 for the CMC and CCC, respectively, have been used traditionally and may continue to be used for steady-state modeling. Run-of-river reservoirs with residence times less than 20 days at critical conditions also should be analyzed using biologically or hydrologically based design flows (see below). Regulated rivers may have a minimum flow in excess of these toxicological flows. In such cases, the minimum flow should be used in TMDL modeling.

2) Lakes and Reservoirs

This receiving water category encompasses lakes and reservoirs with residence times in excess of 20 days at critical conditions

[23]. Seasonal variations in the water level, wind speed and direction, and seasonal solar radiation should be determined to define the critical period [23]. In the case of long and narrow reservoirs, areas above the plunge point (i.e., areas where no stream-like flow is present and waters are mixed or stratified by density) can be analyzed as rivers. The areas below can be analyzed as reservoirs. Since effluent density relative to the ambient water can vary over seasons, no one season or stratification condition can be selected as the most critical dilution situation for all cases. In general, all four seasons should be analyzed to determine the most critical periods for mixing zone analyses. All seasonal analyses should assume an ambient velocity of zero unless persistent currents have been documented. Special attention should be given to periods of rising water level since pollutants can move back into coves and accumulate under these conditions. Location of discharges in coves and dead-end embayments should be prevented whenever possible.

3) Estuaries and Coastal Bays

This receiving water category encompasses estuaries, which are defined as having a main channel reversing flow, and coastal bays, which are defined as having significant two-dimensional flow in the horizontal directions. For both waterbodies, the critical design conditions recommended here are based on astronomical, not meteorological, tides.

Determining the nature and extent of the discharge plume is complicated in marine systems by such conditions as differences in tides, riverine input, wind intensity and direction, and thermal and saline stratification. Because of the tidal nature of the estuaries and coastal systems and their complex circulation patterns, dilution of discharges cannot be determined simply by calculating the discharge rate and the rate of receiving water flow (i.e., the design flow). For example, tidal frequency and amplitude vary significantly in different coastal regions of the United States. Furthermore, tidal influences at any specific location have daily and monthly cycles. These and additional factors require that direct, empirical steps be taken to ensure that basic dilution characteristics of a discharge to salt water are determined.

In estuaries without stratification, the critical dilution condition includes a combination of low-water slack at spring tide for the estuary and design low flow for riverine inflow. In estuaries with stratification, a site-specific analysis of a period of minimum stratification and a period of maximum stratification, both at low-water slack, should be made to evaluate which one results in the lowest dilution. In general, minimum stratification is associated with low river inflows and large tidal ranges (spring tide), whereas maximum stratification is associated with high river inflows and low tidal ranges (neap tide).

After either stratified or unstratified estuaries are evaluated at critical design conditions, an off-design condition should be checked. The off-design condition (e.g., higher flow or lower stratification) recommended for both cases is the period of maximum velocity during a tidal cycle. This off-design condition results in greater dilution than the design condition, but it causes the maximal extension of the plume. Extension of the plume into critical resource areas may cause more water quality problems than the high-concentration, low-dilution situation.

Recommendations for a critical design for coastal bays are the same as for stratified estuaries. The period of maximum stratification must be compared with the period of minimum stratification in order to select the worst case. The off-design condition of maximum tidal velocity should also be evaluated to predict the worst-case extent of the plume.

4) Oceans

Critical design periods for ocean analyses are described in two separate documents, the Section 301(h) *Technical Support Document* [22] and the Section 301(h) document, *Initial Mixing Characteristics of Municipal Ocean Discharges* [24]. The following subsection contains a summary from these documents. Like discharges to estuaries, discharges to ocean waters are subject to two-dimensional horizontal flows. Oceanic critical design periods must include periods with maximum thermal stratification, or density stratification. These periods shorten the distance of vertical diffusion that occurs in the zone of initial dilution. Thus, during these periods it is difficult to achieve the recommended 100-to-1 dilution that is to occur before the plume begins a predominantly horizontal flow as compared to vertical flow. Periods when discharge characteristics, oceanographic conditions (spring tide and neap tide currents), wet and dry weather periods, biological conditions, or water quality conditions that indicate that water quality standards are likely to be exceeded should also be noted. The 10th percentile value from the cumulative frequency of each parameter should be used to define the period of minimal dilution.

4.4.3 General Recommendations for Tracer Studies

A tracer or dye study can be used to determine the areal extent of mixing in a waterbody, the boundary where the effluent has completely mixed with the ambient water, and the dilution that results from the mixing. Analysis of the mixing zone with a dye study that is supplemented with modeling should be performed at flow conditions that approach critical flow. Some of those design conditions are summarized above in the subsections dealing with specific waterbodies. Once the critical design condition has been selected for a waterbody, dye studies can be performed to provide data on the dimensions and dilution of the wastewater plume during this critical period. Tracer studies other than dye studies (e.g., chloride, lithium) can be performed for cases in which the receiving water is amenable to such tests.

For WLA studies in which a discharge is already in operation, tracer studies can be used to determine specific concentration isopleths in the mixing zone that reflect both discharge-induced and ambient-induced mixing. The isopleth concentrations, with effluent toxic concentrations, should be superimposed over a map of the various resource zones of the waterbody. The map will illustrate whether the State's mixing zone dimensions are exceeded, whether the required zone of passage is provided, and whether the plume avoids critical resource areas. The WLA can then be calculated to provide the appropriate zone of passage and to prevent detrimental impacts on spawning grounds, nurseries, water supply intakes, bathing areas, and other important resource areas.

Obviously, if the outfall is not yet in operation, it is impossible to determine discharge-induced mixing by tracer studies. Tracer

studies can be used in these situations to determine characteristics of the ambient mixing. For ambient mixing studies, the tracer release can be either instantaneous or continuous. Instantaneous releases are used frequently to measure longitudinal dispersion, but can also be used to determine lateral mixing in rivers [15] and lateral and vertical mixing in estuaries, bays, reservoirs, and lakes. For waterbodies with significant flow velocities, continuous releases of tracer are normally used to determine lateral and vertical mixing coefficients. Continuous releases can also be used to determine three-dimensional concentration isopleths for steady-state conditions. The tracer study must be made at critical design conditions in order to use the results directly for WLAs. If a tracer study for ambient mixing is conducted at near-to-design conditions, the observed data can be used to determine dimensionless mixing coefficients. These coefficients can then be extrapolated to critical conditions using hydraulic parameters [15]. A tracer study at near-to-critical conditions also can be used to determine the computer model required to predict critical-condition mixing and provide the coefficients needed for that TMDL model.

A number of references provide information concerning the design, conduct, and analysis of tracer studies for mixing analyses. *Techniques of Water-Resources Investigations of the USGS* provides the best overview of how to conduct tracer studies [25, 26, 27]. The fluorescent dyes (usually Rhodamine WT), measuring equipment, fluorometers, field and laboratory procedures, and calculation methods are all discussed. The procedures essentially consist of adding dye to the waterbody and recording concentrations of the dye at various stations at specific time intervals. Examples of tracer studies for river systems are presented in Fischer [28]; Kisiel [29]; Holley and Jirka [15]; and Yotsukura, Fisher, and Sayre [30]. Examples of tracer studies in tidal systems are presented in Wilson, Cobb, and Yotsukura [31] and Hetling and O'Connell [32], both of which are studies of the Potomac River estuary; Baily [33], a study of Suisun Bay in California; Fischer [34], a study of Bolinas Lagoon, a coastal bay in Marin County, California; and Crocker et al. [35], a study of Corpus Christi Bay, Texas. Methods to perform a tracer study in a reservoir are provided in Johnson [36].

The dye study recommended for obtaining a quick saltwater dilution assessment is one in which Rhodamine WT dye is administered to a discharge and monitored in the receiving waters for not less than 24 hours. The basic goal of this study is to determine the near-field nature of the effluent dilution, not the steady-state or far-field dilution. The environmental and discharge conditions selected for the study should be those that would elicit "worst-case" conditions (i.e., highest ambient concentrations in the receiving water). These include low wind, neap tide (tide of minimum range occurring during the 1st and 3rd quarters of the moon), plume trapping by density stratification, low rainfall and low riverine input, and, if possible, high effluent discharge.

The dye should be administered to the effluent before discharge to the receiving water in proportion to effluent flow rate. Dye should be maintained at a concentration in the effluent sufficient to permit detection of the dilution ratio of interest when the amount and variability of background fluorescence in the receiving water are taken into account. Measurements of dye concentration are made using a fluorometer and should be corrected for water temperature.

A survey of background fluorescence and its variability in the anticipated mixing zone must be conducted just prior to the beginning of the study in order to permit correction of fluorescence data and to determine the dye concentration required in the effluent. Since Rhodamine WT dye is bleached by free chlorine, a preliminary study of the degree of dye bleaching by the effluent should precede the study for chlorinated discharges to avoid underestimation of the extent of the mixing zone. Dye concentrations should be surveyed for two successive slack tides, and for any other conditions that could lead to concentration maxima. Surveys should extend from the point of discharge to a distance at which the effluent dilution ratio of interest is attained. The dye fluorescence at this point should be at least twice the variability in background fluorescence.

EPA has completed two TMDL studies to test the procedures outlined in the previous version of this document. Both studies used dye to determine the mixing zone and the dilution within it. The first study was performed on the Amelia River, an estuarine system in Florida [2]; the second was performed on the Greenwich Cove, an embayment of Narragansett Bay in Rhode Island [37]. In both studies, Rhodamine WT dye was introduced continuously into the effluent and numerous stations were set up to measure the spatial and temporal distribution of the dye. Both studies are good examples of how to perform a dye study in complex tidal systems.

4.4.4 Discharge-induced Mixing

The first stage of mixing is controlled by discharge jet momentum and buoyancy of the effluent (see Figure 4-2). This stage generally covers most of the regulatory or near-field mixing zone. It is particularly important in lakes and reservoirs and slow moving rivers since ambient mixing in those waterbodies is minimal.

In shallow environments, it is important to determine whether near-field instabilities occur. These instabilities, associated with surface and bottom interaction and localized recirculation cells extending over the entire water depth, can cause buildup of effluent concentrations by obstructing the effluent jet flow. There are no simple means to estimate dilution in these cases. Criteria for these instabilities and specialized predictive models have been developed to address these problems [13].

In the absence of near-field instabilities, horizontal or nearly horizontal discharges will create a clearly defined jet in the water column that will initially occupy only a small fraction of the available water depth. The following equations and models are designed to describe mixing under stable near-field conditions.

1) Use of a Simplistic Screening Equation

A minimum estimate of the initial dilution available in the vicinity of a discharge can be made using the following equation derived from information in Holley and Jirka (1986) [15]:

$$S = 0.3 \frac{x}{d}$$

where

S = flux-averaged dilution
x = distance from outlet
d = diameter of outlet.

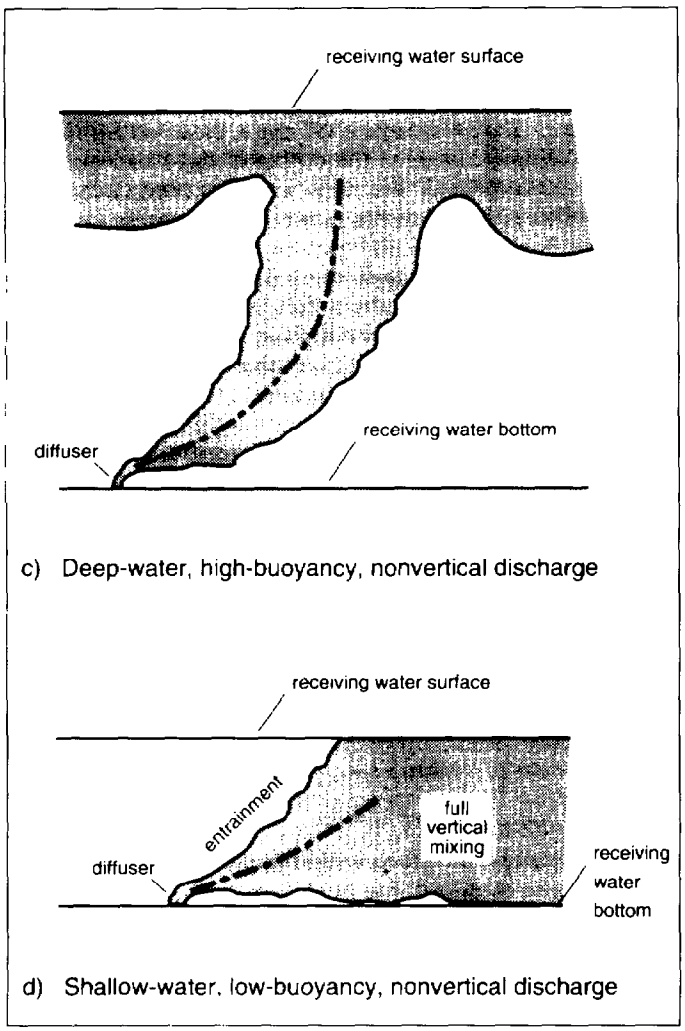

Figure 4-2. Example of Discharge-Induced Mixing [7]

The coefficient 0.3 represents the average of two values derived from the literature, 0.28 [16] and 0.32 [38].

The equation provides a minimum estimate of mixing because it is based on the assumptions that outlet velocity is zero and the discharge is neutrally buoyant. Dilution may be underestimated for partially full pipes because the equation assumes a fully flowing pipe. The equation can be used in inverse form to solve for the discharge x at which a desired solution—for example, that corresponding to the CMC—has been achieved. The equation is valid only close to the discharge, up to a distance corresponding to several (two to three) water depths. At longer distances, other factors are of increasing importance in jet mixing and must be included.

Mixing graphs that include the effects of discharge buoyancy, ambient velocity, and stratification can be found in Holley and Jirka [15], Fischer et al. [16], and Wright [39]. They are useful to account for these other initial dilution factors and can aid in determining whether criteria will be met at the edge of the regulatory mixing zone.

2) Use of Detailed Computer Models

More detailed design data for the mixing zone can be obtained from the use of computer models based on integral jet techniques. It is important to note that most models represent an idealization of actual field conditions and must be used with caution to ensure that the underlying model assumptions hold for the site-specific situation being modeled. In general, these buoyant jet models require the following input data: discharge depth, effluent flow rates, density of effluent, density gradients in receiving water, ambient current speed and direction, and outfall characteristics (port size, spacing, and orientation). Model output includes the dimensions of the plume at each integration step, time of travel to points along the plume centerline, and the average dilution at each point.

Described below are six mixing zone models that are available through EPA. All of the models require a user who is well versed in mixing concepts and the data necessary to run the models. The first model, CORMIX [40, 41], may be the most useful to regulators since it is an expert system that guides the user in selecting an appropriate modeling strategy for rivers or estuaries. It is available from the National Technical Information Service (NTIS), and user support is available from the U.S. EPA CEAM. The other models were developed and designed for ocean discharges. All but one can be used on rivers, lakes, and estuaries with appropriate input modifications; UPLUME is restricted to stagnant water environments where the ambient water current velocity is zero (e.g., lakes, reservoirs).

These five models were designed for submerged discharges in oceans. They all report dilution, and all terminate execution when the vertical ascent of the plume is zero (e.g., when the plume reaches the surface or when plume density is equal to ambient density in some stratified systems). With the exception of CORMIX1, they all assume that there is a "deep" receiving stream (i.e., no bottom interference). They too are available from NTIS, and user support is provided by the U.S. EPA Hatfield Marine Science Center in Newport, Oregon [24]. These five models have been modified such that the user inputs the data into a universal data format that allows the user to apply any of the five models with only minor input changes.

- CORMIX is a series of software elements for the analysis and design of a submerged buoyant or nonbuoyant discharge containing conventional or toxic pollutants and entering into stratified or unstratified watercourses, with emphasis on the geometry and dilution characteristics of the initial mixing zone. Subsystem CORMIX1 deals with single-port discharges, and subsystem CORMIX2 addresses multiport diffusers. The system operates on microcomputers with the MS-DOS operating system. CORMIX1 can summarize dilution characteristics of the proposed design, flag undesirable designs, give dilution characteristics at specified boundaries (i.e., legal and toxic mixing zones) and recommend design alterations to improve dilution characteristics. The CORMIX1 program guides the user, based on the user's input, to

appropriate analyses of design conditions and mixing zone dimensions.

- UPLUME is an initial dilution model that can be used for stagnant waterbodies, such as lakes and reservoirs, where the ambient currents can be assumed to be zero. The model simulates a submerged single-port discharge. The bouyancy between the effluent and ambient water can be accounted for, and the discharge can be given a vertical angle. UPLUME calculates flux-averaged dilutions and, for one output option, a centerline dilution.

- UOUTPLM can be used in flowing and stagnant waterbodies. The user specifies the current speed of the ambient water, and this speed is assumed to be constant with depth. The model simulates a submerged single-port discharge. Buoyancy between the effluent and ambient water can be modeled, as well as the discharge vertical angle. The ambient current is assumed to be perpendicular to the diffuser.

- UMERGE is a model that can also be used for both flowing and stagnant waters. It has capabilities that UOUTPLM does not have: it considers multiple submerged ports, and the user can specify arbitrary ambient current speed variations with depth. The ports are assumed to be equally spaced. The model accounts for adjacent plume interferences over the course of the plume trajectory and in the subsequent dilution calculation. Positive buoyancy is accounted for, and the discharge vertical angle can be modified. The ambient current is assumed to be perpendicular to the diffuser.

- UDKHDEN is a three-dimensional model that can be used for flowing and stagnant waterbodies. It has all the capabilities of UMERGE plus the ability to simulate instances where the ambient current flow is not perpendicular to the diffuser.

- ULINE models a vertical slot jet discharge into a flowing waterbody. The discharge angle is assumed to be perpendicular to ambient current. The ambient current may vary with depth, and the axis of the diffuser may range from parallel to perpendicular to the ambient current. The buoyancy of the effluent can also be modeled.

An evaluation and comparison of all these models can be found in the *Technical Guidance Manual for Performing Wasteload Allocations—Book 3, Estuaries* [7].

4.4.5 Ambient-Induced Mixing

The equations for discharge-induced mixing can be used to predict concentrations in the regulatory mixing zone where strong jet mixing predominates over ambient mixing. Beyond this point, the mixing is controlled by ambient turbulence. Thus, ambient mixing models must be used to predict the pollutant concentration distributions up to the stage of complete lateral mixing to provide boundary conditions for the completely mixed fate and transport models described in Section 4.5. This information also may be needed to estimate concentrations encountered at important resource areas or at subsequent downstream dischargers.

If there is no discharge-induced vertical mixing associated with the jet action of the discharge, then mixing over the depth of the waterbody must be accomplished by ambient mixing. For a neutrally buoyant, soluble effluent discharged with low velocity at the surface or at the bed of a stream, the flow distance required to achieve complete vertical mixing is on the order of 50 to 100 times the depth of water in that portion of the channel where the effluent is discharged [42]. For a discharge that is either lighter (positively buoyant) or heavier (negatively buoyant) than the ambient water, but still has no excess momentum, the flow distance for mixing over the depth will be greater. In the normal case with a high-velocity jet designed to prevent lethality in the mixing zone, mixing over the depth will be accomplished primarily by jet action, and the distance required for this vertical mixing will be much shorter.

In general, ambient mixing must also accomplish mixing over the width of a waterbody to bring the effluent to the completely mixed condition. For situations where the width of the zone that is mixed by the discharge-induced mixing is much smaller than the width of the river, the flow distance (X_m) required to achieve the completely mixed condition may be estimated from an equation of the form [16]:

$$X_m = \frac{mW^2u}{D_y}$$

where

- W = width of the river
- u = flow velocity for the critical design flow
- D_y = lateral dispersion coefficient as discussed below
- m = a parameter whose value depends on the degree of uniformity used to define "complete mixing" and on the transverse location of the outfall in the stream.

If completely mixed conditions are defined as a 5-percent variation in concentration across the stream width, the value of m would be approximately 0.1 for a discharge near the center of river flow (not the center of river width) and approximately 0.4 for a discharge near the edge of the river. If, because of other uncertainties, a 25-percent variation across the width is accepted as being completely mixed, then the corresponding values for m would be approximately 0.06 for a discharge near the center of river flow and approximately 0.24 for a discharge near the edge of the river. For a very small stream, X_m may be only a few hundred feet; for medium and large streams, X_m is normally several miles to several tens of miles.

The lateral dispersion coefficient (D_y) for most rivers can be calculated with the following equation [16]:

$$D_y = 0.6\ du^* \pm 50\%$$

where

- d = water depth at design flow
- u^* = shear velocity.

The coefficient (0.6) can vary from 0.3 to above 1.0 depending on the type and degree of irregularity of the channel cross-sections. The more straight and uniform the flow, the lower the

value; the more irregular the flow (resulting from curves, sidewall interference, etc.), the higher the value. Values approaching and exceeding 1.0 are normally associated with significant channel meandering [42]. The following equation for shear velocity should be used [16]:

$$u^* = (gds)^{1/2}$$

where

- g = acceleration due to gravity
- s = slope of the channel
- d = water depth.

For diffusers that initially spread the discharge across a significant part of the river width or for cases where the discharge-induced mixing causes mixing across a significant part of the river width, the values of m and X_m can be smaller than the ones indicated here. For distances greater than X_m, the models for completely mixed effluents discussed in Section 4.5 can be used to calculate concentrations at these distances. For shorter distances, maximum concentrations can be much greater than those predicted by "completely mixed" models and should be estimated using the following equation:

$$C_x = \frac{C_e Q_e W}{Q_s(\pi D_y X/u)^{1/2}}$$

where

- C_x = maximum pollutant concentration distance x from the outlet
- C_e = effluent concentration
- Q_e = design effluent flow
- Q_s = design stream flow
- D_y = lateral dispersion coefficient
- X = distance from the outlet
- W = stream width
- u = flow velocity for the design flow.

It should be noted that this estimate of C_x is a worst-case prediction since the equation assumes no significant discharge-induced mixing and a neutrally buoyant effluent. A more accurate way to predict concentrations within this second stage of mixing is to use the methods of Yotsukura and Sayre [42]. To use this approach, however, the value of D_y and pollutant concentrations after discharge-induced mixing must be known from tracer studies and/or from the use of one of the discharge-induced models.

The PSY model can be used to predict ambient mixing in shallow, freshwater streams where water depth is small in proportion to the width. PSY is a steady-state, two-dimensional plume model that predicts dilution of a surface discharge into a shallow receiving water where the plume attaches to both bottom and nearshore [43]. Uniform vertical mixing is assumed to occur at the point of discharge.

Ambient mixing is minor for lakes and reservoirs because flow velocity is assumed to be minimal and mixing is accomplished by means of the discharge momentum and buoyancy. For estuaries that are completely mixed with regard to salinity, the equations presented above can be used to estimate concentrations between the outlet and the point of complete mixing with a slight modification of shear velocity. The above equations will be applicable to only unstratified estuaries since the time required to mix across the estuary must be significantly less than the time required for the effluent to pass out of the unstratified part of the estuary, the time required for the effluent to pass into a segment of greatly changed cross-section, or the time required for the substance to decay. When the above equations for estuaries are used, the velocity of the design flow should include the velocity associated with the inflow of freshwater as well as the tidal velocity; thus u_t, which is based on an average total velocity; is substituted for u in the equations and shear velocity becomes

$$u^* = 0.10\ u_t.$$

The CORMIX expert system model can also be used to obtain predictions for the ambient-induced mixing. In addition to the routines for discharge-induced mixing, this model also includes predictive elements that apply to ambient mixing in riverine, lake, or coastal situations.

4.5 COMPLETELY MIXED DISCHARGE RECEIVING WATER SITUATIONS

At the present time, most States and EPA Regions use steady-state models that assume the wastewater is completely mixed with the receiving waters in order to calculate WLAs for contaminants. This approach is appropriate for conventional contaminants where critical environmental effects are expected to occur far downstream from the source. WLAs for toxic chemicals require a different approach, however, because critical environmental conditions occur near the discharge before complete mixing with the receiving water occurs. Consequently, mixing analyses should be performed because many of these toxicants can exert maximal toxicity in a variety of regions spanning from the discharge point to significant distances downstream.

If complete mixing occurs near the discharge point, such as in effluent-dominated receiving streams, then steady-state models may be used to calculate TMDLs. Recent EPA developments in the identification of critical design flows based on toxicological concerns provide for better use of steady-state models in calculating toxic WLAs. However, if complete mixing does not occur near the discharge point and the effluent plume is discernible downriver, then modeling techniques that can simulate and predict mixing conditions are more appropriate. The mixing zone models presented in the previous section may be used to define the mixing zone. However, they only determine the dispersion and dilution of the effluent and do not account for chemical or biological processes in the mixing zone. TMDL models are available that can simulate mixing processes and predict areas of maximal concentrations in the receiving stream based on chemical, biological, and physical processes.

4.5.1 Wasteload Modeling Techniques

1) Steady-State Modeling Techniques

A steady-state model requires single, constant inputs for effluent flow, effluent concentration, background receiving water concentration (RWC), receiving water flow, and meteorological conditions (e.g., temperature). The frequency and duration of ambient concentrations predicted with a steady-state model must be assumed to equal the frequency and duration of the critical receiv-

ing water conditions used in the model. The variability in effluent flows and concentrations also affects RWCs, but these effects cannot be predicted with constant inputs. Steady-state models can be improved for toxic WLAs by means of the following:

- Using design flows that will ensure criteria compliance at the appropriate duration and frequency.

- Calculating both acute and chronic WLAs.

EPA is encouraging the States to adopt two-number aquatic life water quality criteria and is using them in WLA studies. Ambient water quality criteria have been established for numerous toxic pollutants. These criteria specify an acute concentration (CMC) and a chronic concentration (criteria continuous concentration, or CCC) for each toxicant, as well as durations and frequencies of exposure for the two concentration levels. The design flows used in steady-state modeling should be reflective of the CCC and CMC durations and frequencies. The duration of the design flow is based on the maximum exposure time that will prevent acute and chronic effects. The duration of flow is assumed to apply to the duration of the allowable effluent concentration or load. For example, if the flow used is a 7-day average value, the allowable load is considered to be a 7-day average. The return frequency is based on the number of years required for biological population recovery after criteria have been exceeded. Appendix D describes the toxicological basis for selecting receiving stream design flows for steady-state modeling and recommends specific design flows for CCC and CMC calculation of TMDLs for rivers and streams.

In summary, there are two types of design flows, hydrologically based and biologically based. The hydrologically based design flows are those traditionally used by the States, in which the 7Q10 flow is used as the CCC design flow and the 1Q10 is used as the CMC design flow. The biologically based method uses the 1-day, 3-year duration-frequency for determining the CMC design flow and the 4-day, 3-year duration-frequency for determining the CCC design flow. Consequently, the biologically based design flows are based on specific toxicological effects of a pollutant and biological recovery times from localized stresses [6]. The advantages of both types, as well as how they may be calculated, also are described in Appendix D.

A 4-day, 3-year biological design flow does not equate to a 4Q3 hydrological design flow. EPA has determined that a 4Q3 design flow would result in an excessive number of water quality criteria exceedances. As explained in Appendix D, a hydrologically based 7Q10 will, for most streams, be similar to a biologically based 4-day, 3-year design flow.

At the present time, there are no recommended toxicological flows for steady-state modeling of lakes, reservoirs, or estuaries. The design conditions recommended for these waterbodies in Section 4.4.2 are based on hydrological and meteorological conditions rather than on toxicological duration and frequency data. These conditions should be used until further guidance is provided.

Another improvement in steady-state toxics modeling can be realized by performing two separate WLAs, one for the CMC and one for the CCC. Steady-state WLA models should be used to calculate the allowable effluent load that will meet the CMC at the acute design flow and the allowable load that will meet the CCC at the chronic design flow. Calculation of these values will enable the permit writer to calculate the more limiting long-term average (LTA) for the treatment system and develop permit limits protective of both WLAs (see Chapter 5).

In addition to stream design flow, steady-state models require design temperature, pH, alkalinity, and hardness, depending on the pollutants modeled at site-specific conditions. To determine stream design temperature, pH, alkalinity, and hardness, a program called DESCON was developed. (See Appendix D for additional information.) DESCON is a computer program that estimates design conditions for WLA modeling. These conditions are based on maintaining a desired limit on the frequency of water quality excursions in a receiving water. DESCON considers the effect that daily fluctuations in stream flow and water quality conditions, such as temperature and pH, have on the variability of the capability of a receiving water to accept pollutant loadings. It specifically accounts for the within-year correlations observed between such variables as stream flow, temperature, pH, alkalinity, hardness, and dissolved oxygen. DESCON determines design conditions using a four-step process (see Figure 4-3):

1) A long-term record of observed stream flows and pertinent water quality data are assembled or synthesized.

2) The maximum allowable pollutant load that the receiving water can accept without causing a water quality excursion is computed for each day of this record.

3) This synthesized record of allowable loads is searched for the critical load, i.e., the load whose frequency of not being exceeded matches the desired water quality excursion frequency.

4) Design conditions are then derived from receiving water conditions realized during the period of record when the computed allowable load was closest to the critical load.

DESCON provides the same advantages as continuous simulation by considering the joint occurrences of stream flow and other water quality parameters as observed in the historical record. In addition, it is more computationally efficient; it contains a facility for extracting and analyzing flow and water quality data from STORET; it can use both the extreme value and the biologically based methods of calculating of water quality excursions; and it is specifically designed to handle such pollutants as ammonia, heavy metals, pentachlorophenol, and biochemical oxygen demand (BOD) for which water quality criteria are functions of such design condition variables as temperature, pH, alkalinity, hardness, and dissolved oxygen. The main limitations of DESCON are that it requires at least 10 years of historical daily flow data and it can only analyze a single discharger, edge-of-mixing zone situations (or a simplified Streeter-Phelps dissolved oxygen response for BOD).

2) Dynamic Modeling Techniques

Steady-state modeling considers only a single condition; effluent flow and loading are assumed to be constant. The impact of receiving water flow variability on the duration for which and frequency with which criteria are exceeded is implicitly included

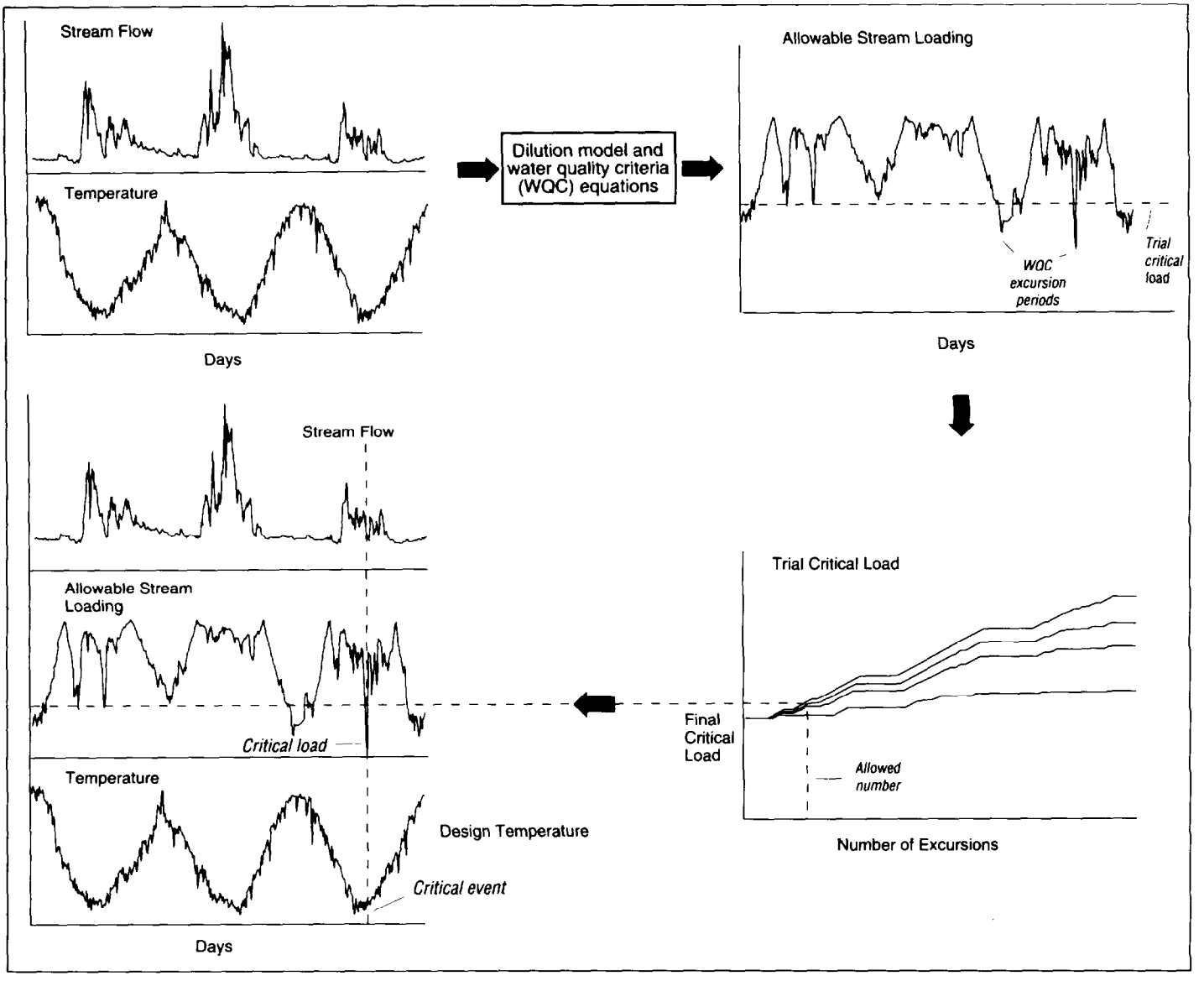

Figure 4-3. Computational Scheme for Deriving Design Conditions

in the design conditions if these conditions reflect the desired toxicological effects regime. Dynamic modeling techniques explicitly predict the effects of receiving water and effluent flow and of concentration variability. The three dynamic modeling techniques recommended by EPA for WLAs are continuous simulation, Monte Carlo simulation, and lognormal probability modeling. These methods calculate a probability distribution for RWCs rather than a single, worst-case concentration based on critical conditions. Prediction of complete probability distributions allows the risk inherent in alternative treatment strategies to be directly quantified.

The use of probability distributions in place of worst-case conditions has been accepted practice for years in water resource engineering, where it was found to produce more cost-effective design of bridge openings, channel capacities, floodplain zoning, and water supply systems. The same cost-effectiveness can be realized for pollution controls if probability analyses are used.

The dynamic modeling techniques have an additional advantage over steady-state modeling in that they determine the entire effluent concentration frequency distribution required to produce the desired frequency of criteria compliance. Maximum daily and monthly average permit limits can be obtained directly from the effluent LTA concentration and coefficient of variation (CV) that characterize this distribution. Generally, steady-state modeling has been used to calculate only a chronic WLA. Steady-state modeling generates a single allowable effluent value and no information about effluent variability. If the steady-state model is used to calculate both acute and chronic wasteloads, limited information will be provided and the entire effluent distribution will not be predicted. Steady-state WLA values can be more difficult to use in permits and enforcement because of the variable nature of the receiving waterbody and the effluent. The outcome of probabilistic modeling can be used to ensure that permit limits are determined based on best probability estimates of RWCs rather than a single, worst-case condition. As a result, maximum daily and monthly average permit limits, based on compliance

with water quality criteria over a 3-year period, can be obtained directly from the probability distribution.

Continuous Simulation Models. As shown in Figure 4-4, a continuous simulation model uses daily effluent flows (Q_e) and concentration data (C_e) with daily receiving water flow (Q_s) and background concentration data (C_s) to calculate downstream RWCs [44]. The model predicts these concentrations in chronological order with the same time sequence as the input variables (C_b versus time). The daily RWCs can then be ranked from the lowest to the highest without regard to time sequence. A probability plot can be constructed from these ranked values, and the occurrence frequency of any 1-day concentration of interest can be determined (C_b versus frequency). Running average concentrations for 4 days (i.e., the chronic design flow), or for any other averaging period, also can be computed from the daily concentrations (Figure 4-5).

The probability plot generated by the continuous simulation model using existing effluent data will indicate whether criteria are predicted to be exceeded more frequently than desired. Appendix D discusses how to select the appropriate allowed frequency of excursions based on the biological recovery period required for a specific waterbody. If recurrence intervals of 10 or 20 years are desired, at least 30 years of flow data should be available to provide a sufficient record to estimate the probability of such rare events. Of the 30 years of required flow data, at least 20 to 25 years should be continuous daily data, with the remaining years represented with only intermittent data. The data should be examined to verify that the receiving stream has not undergone significant hydrological modification. The data also should be examined to determine if there were any long-term changes due to technology-based treatment or periodic changes due to industrial or municipal plant closings or expansions. The same data requirements are also true for the lognormal probabilistic and Monte Carlo methods. However, except for the continuous simulation models, other nonsteady-state models in this section

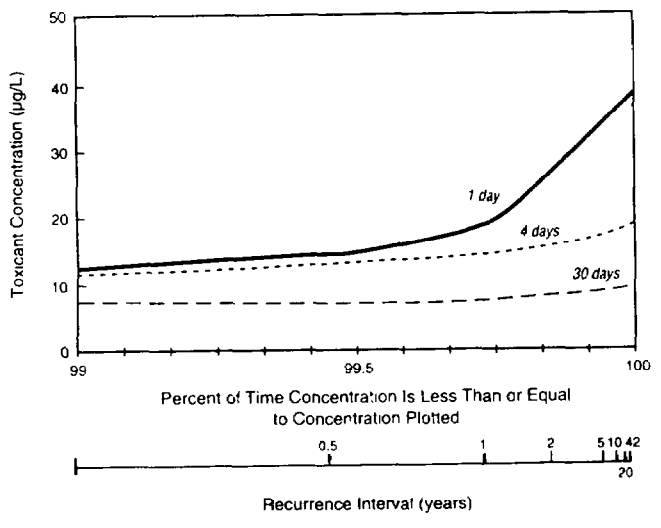

Figure 4-4. Frequency of Occurrence of Concentrations in Receiving Waters and Recurrence Intervals Generated by a Continuous Simulation Model

cannot be used to account for the duration and frequency provision of the two-number water quality criteria. Users are cautioned about the specific limitations of some of the dynamic models included here. Continuous simulation models have the following advantages compared to steady-state formulations:

- The frequency and duration of toxicant concentrations in a receiving water can be predicted.
- The cross-correlation and interaction of time-varying pH, flow, temperature, pollutant discharges, and other parameters are incorporated.
- The effect that the serial correlation of daily flows and other parameters has on the persistence of criteria excursions is incorporated.
- Long-term stream flow records for ungauged rivers using precipitation and evapotranspiration data can be synthesized.
- Long simulation times can prevent the initial conditions used in the model from affecting the calibration of fate and transport processes.

Unlike steady-state models, continuous simulation models require significantly more data to apply, to calibrate, and/or to verify a specific problem and require that input information for the application of the model be time-series data. Also, the model results need manipulation to calculate the effluent LTA concentration and CV for use in developing effluent limits.

Monte Carlo Simulation Models. Monte Carlo simulation combines probabilistic and deterministic analyses since it uses a fate and transport mathematical model with statistically described inputs. Monte Carlo simulations have been the most frequently used approach in stochastic water quality studies [45-51]. The probability distributions of effluent flow, effluent concentration, and other model input must be defined using the appropriate duration for comparison to the CMC and CCC. If 1-day average RWCs must be predicted for CMC comparisons, probability distributions of daily model input data are needed for Monte Carlo simulation. If 4-day average concentrations must be predicted for CCC comparisons, the probability distributions of 4-day average input data are required. The computer selects input values from these distributions using a random generating function. The fate and transport model is repetitively run for a large number of randomly selected input data sets. The result is a simulated sequence of RWCs. These concentrations do not follow the temporal sequence that is calculated with the continuous simulation model, but they can be ranked in order of magnitude and used to form a frequency distribution. Monte Carlo analyses can be used with steady-state or continuous simulation models [52].

The approach for calculating the allowable pollutant load distribution using Monte Carlo simulation is the same as that described for the continuous simulation model. The advantages of Monte Carlo simulation are the following:

- It can predict the frequency and duration of toxicant concentrations in a receiving water.

- It can be used with steady-state or continuous simulation models that include fate processes for specific pollutants.
- It can be used with steady-state or continuous simulation models that include transport processes for rivers, lakes, and estuaries.
- It can be used with steady-state or continuous simulation models that are designed for single or multiple pollutant source analyses.
- It does not require time series data.
- It does not require model input data to follow a specific statistical distribution or function.
- It can incorporate the cross-correlation and interaction of time-varying pH, flow, temperature, pollutant discharges, and other parameters if the analysis is developed separately for each season and the results are combined.

The primary disadvantages of Monte Carlo simulation are that it requires more input, calibration, and verification data than do steady-state models, and the model results need manipulation to calculate the effluent LTA concentration and CV to develop effluent limits.

Lognormal Probabilistic Dilution Model. Without resorting to the continuous simulation method of computing RWCs in temporal sequence, this probabilistic method uses the lognormal probability distributions of the input variables to calculate probability distributions of output variables [53]. As a result, the method requires only the relevant statistical parameters of the input variables (medians and coefficients of variation) rather than the actual time series data needed for continuous simulation. If 1-day average RWCs must be predicted for comparisons with the CMC, lognormal probability distributions of daily input data are needed. If 4-day average concentrations must be predicted, the lognormal probability distributions of 4-day average input data are required. Because this probabilistic model cannot, as yet, incorporate fate and transport processes, it can be used to predict the concentration of a substance only after complete mixing and before degradation or transformation significantly alters the concentration.

The lognormal probabilistic dilution model has the following advantages:

- It can predict the frequency and duration of toxicant concentrations in riverine environments.
- It does not require time series data.
- It can incorporate the cross-correlation and interaction of time-varying pH, flow, temperature, pollutant discharges, and other parameters if the analysis is developed separately for each season and the results are combined.

The lognormal probability dilution model has the following disadvantages:

- It requires more input than a steady-state model.

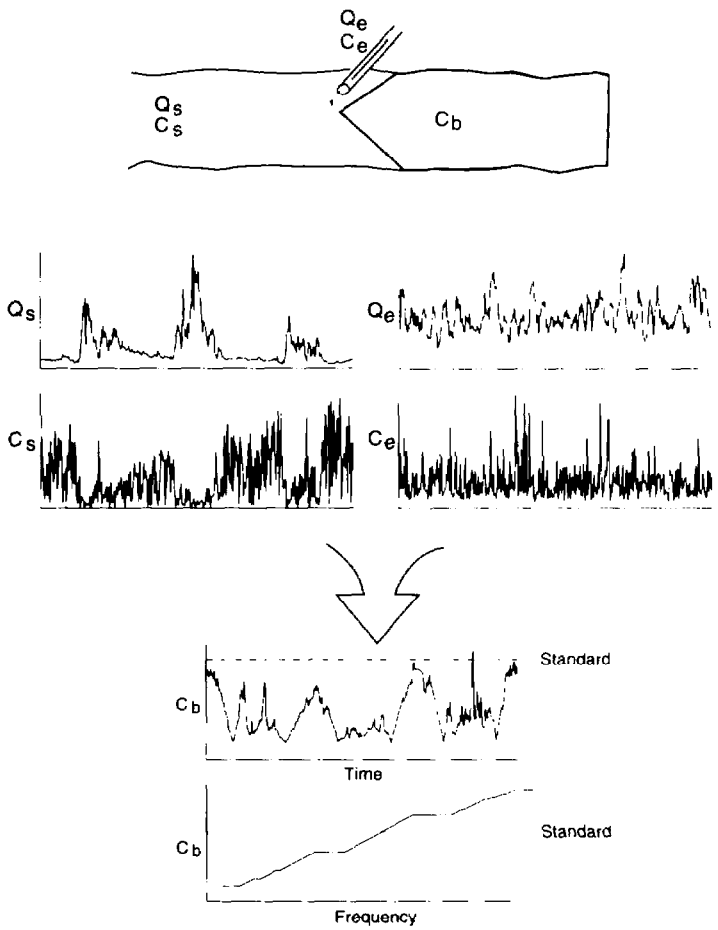

Figure 4-5. Concentration Frequency Curves

- It does not include instream fate processes.
- It applies only to rivers and streams.
- It analyzes multiple pollutant sources inaccurately.
- It requires model input data to be lognormally distributed.

4.5.2 Calculating the Allowable Effluent Concentration Distribution and the Return Period

Information concerning effluent concentration means and variabilities can be obtained from data bases on existing treatment plants and from development documents for specific industrial point source categories. This information is available from the Industrial Technology Division of the Office of Water Regulations and Standards. These effluent data can be used with dynamic models to determine what the effluent concentration distribution must be to meet water quality standards. Two possible approaches can be taken to determine this distribution regardless of the type of dynamic modeling technique (i.e., continuous, Monte Carlo, or lognormal probabilistic). One approach is based on the simplifying assumption that treatment will change only the mag-

nitude of effluent concentrations; no changes are assumed to occur in effluent flows or in the relative variability of effluent concentrations. With these assumptions, no additional model runs are needed to determine the allowable distribution for effluent concentrations. The other approach assumes that the required effluent concentration distribution is the same as the existing distribution except that it is reduced in magnitude by whichever is greater—the percentage necessary for the 1-day average concentrations to meet the CMC, or the 4-day average concentrations to meet the CCC at the desired recurrence interval. Chapter 5 includes details on how permit limits are derived from the mean and coefficient of variation of effluent concentrations determined from this analysis.

The second approach for determining the allowable effluent concentration distribution is based on the assumption that effluent concentrations after treatment will not have the same CV as concentrations before treatment. Studies have documented that advanced secondary treatment increases the CV of BOD and total suspended solids concentrations compared to secondary treatment. Where feasible, investigations should be conducted to evaluate how treatment processes for heavy metals, organic chemicals, and effluent toxicity will change the variability of these constituents. The development documents mentioned above also provide some variability data for treatment processes. To account for a change in variability, an alternative approach should be used to determine the allowable effluent distribution. Iterative model runs can be performed using different concentration means with the effluent "future treatment" variance until a mean is found that meets the criteria at the desired recurrence intervals. These iterative model runs require stochastic generation of effluent input data since daily effluent concentrations will not be available for the hypothetical treatment schemes. The required "future treatment" mean and CV of effluent concentration can then be used to set permit limits (see Chapter 5).

EPA's Office of Water Regulations and Standards developed an interactive preprocessor for DYNTOX that automatically creates input for continuous simulation models, randomly selects the sets of input data required for Monte Carlo simulations, and performs the numerical integration calculation for the lognormal probabilistic model. DYNTOX is available from the EPA CEAM, Environmental Research Laboratory (ERL) [54]. If the observed data base is fairly complete but missing a few points, a linear interpolation scheme is used to fill in the missing data. If data are scarce, a lag-one Markov method is used to generate daily data stochastically. The lag-one Markov method uses the mean, standard deviation, and daily correlation coefficient of the observed data to create random sequences of data having the same statistical properties. The interactive program is written in FORTRAN and is available for use on mainframe or IBM PC-compatible computers.

Two common methods exist to calculate the return period for a given concentration from probabilistic modeling: the **percentile method** and the **extrema method**. The percentile method used by DYNTOX ranks a listing of all individual daily concentrations. The return period for a concentration is then calculated based on the percentile occurrence. In the extrema method, only annual extrema values are used in the ranking. The return periods calculated from these two methods are equally valid statistical representations. When using the percentile method, results express an average return period and multiple occurrences within any year. The extrema method describes the return period for an annual extreme and includes only the extreme of multiple occurrences within a year.

4.5.3 General Recommendations for Model Selection

The reliability of the predictions from any of the modeling techniques depends on the accuracy of the data used in the analysis. The minimum data required for model input include receiving water flow, effluent flow, effluent concentrations, and background concentrations. In many locations, stream flow data should be sufficient for both steady-state and dynamic models. At least 30 years of flow data should be available if excursions of the CMC and CCC must be evaluated at rare frequency of once in 10 or 20 years. Measurements of effluent toxicity or individual toxicity can be much more limited.

If only a few toxicant or effluent toxicity measurements are available, steady-state assessments should be used. Modeling also should be limited to steady-state procedures if a daily receiving water flow record is not available; however, in effluent-dominated situations, critical flow may be used to characterize the receiving stream. Appendix D describes how to select appropriate design flows if State regulations do not require a specific design flow for river WLAs. Fate and transport models or dilution calculations can be used for individual toxicants. At the present time, only dilution calculations or first-order decay equations are recommended for effluent toxicity analyses. Chapter 1 discusses the conservative/additive assumption for toxicity.

If adequate receiving water flow and effluent concentration data are available to estimate frequency distributions, one of the dynamic modeling techniques should be used to develop more cost-effective treatment requirements. If the effluent data exhibit significant seasonal differences or batch process trends, the continuous simulation approach may be the easiest dynamic modeling method to use. The best results will, of course, be obtained if daily effluent flows and concentrations are available for model input for an entire year. The lag-one Markov technique can be used to generate daily effluent data for the entire simulation as long as adequate measurements for the site-specific facility (or a similar one) are available to estimate a day-to-day correlation coefficient and to determine when seasonal or batch process changes in effluent quality occur.

If adequate receiving water flow and effluent concentration data are available and if effluent data exhibit no seasonal or batch process trends, lognormal and Monte Carlo methods may be easier and require less computer time than the continuous simulation approach.

4.5.4 Specific Model Recommendations

The following section recommends models for toxicity and individual toxicants for each type of receiving water—rivers, lakes, and estuaries. Detailed guidelines on the use of fate and transport models of individual toxicants are included in the toxic TMDL guidance available from the Monitoring Branch of EPA's Office of Water Regulations and Standards [5, 6, 7] and Office of Research and Development [55]. These manuals describe in detail the

transport and transformation processes involved in water quality modeling. Transport processes include the dispersion and advection of a contaminant once it enters the receiving stream; its volatilization from the water; and its sorption to suspended sediment, eventual settling, and possible resuspension and diffusion from the sediment. Transformation processes include the oxidation, hydrolysis, photolysis, biodegradation, and bioaccumulation of the chemical.

Most water quality models were developed with an emphasis on the dynamics in the water column and the eventual water column concentrations. Several models, including some of those listed below (EXAMS-II, WASP4) are now capable of simulating water column-sediment interactions (resuspension, settling, and diffusion), however, additional work needs to be completed on the mechanisms of sediment-water column exchange before the models can be validated for predictive applications involving sediments. With the advent of sediment criteria in the next few years, it will be necessary to use models that predict concentrations in both receiving water and bed sediment. This will be of particular importance in areas where the sediments are contaminated to the point at which they act as the source of a pollutant to the water column. Table 4-2 lists and summarizes models that may be used for predicting the fate and transport of toxicants and that are supported by the EPA CEAM [56]. All the models, plus two bioaccumulation models, briefly are described below.

- DYNTOX [54] is a WLA model that uses a probabilistic dilution technique to estimate receiving water chemical concentrations or whole effluent toxicity fractions. The model considers dilution and net first-order loss, but not sorption and benthic exchange. The net loss rate must be determined empirically on a case-by-case basis and cannot be extrapolated to different conditions of flow, temperature, solids, pH, or light.

- EXAMS-II [57] is a compartment model that can be used as either a steady-state or quasi-dynamic model designed for evaluation of the behavior of synthetic organic chemicals in aquatic ecosystems. It simulates a toxic chemical and its transformation products using second-order kinetics for all significant organic chemical reactions. EXAMS-II does not simulate the solids with which the chemical interacts. The concentration of solids must be user-specified for each compartment. The model accounts for sorbed chemical transport based on solids concentrations and specified transport fields. Sediment exchanges with the water column include pore-water advection, pore-water diffusion, and solids mixing. The last describes a net steady-state exchange associated with solids that is proportional to pore-water diffusion.

- WASP4 [58] is a generalized modeling framework for contaminant fate in surface waters. Based on the flexible compartment modeling approach, WASP4 can be applied in one, two, or three dimensions, given the transport of fluxes between segments. WASP4 can read output files from the link-node hydrodynamic model DYNHYD4, which predicts unsteady flow rates in unstratified rivers and estuaries, given variable tides, wind, and inflow. TOXI4, a subset of WASP4, simulates up to three interacting toxic chemicals and up to three sediment size fractions in the bed and overlying waters. First- or second-order kinetics can be used for all significant organic chemical reactions. Sediment exchanges include pore-water advection, pore-water diffusion, and deposition/scour. Net sedimentation and burial rates can be specified or calculated. The output can be used with the two bioaccumulation models FGETS and FCM2, which are described below.

- HSPF [59] simulates watershed hydrology and water quality for both conventional and toxic organic pollutants. HSPF incorporates the watershed-scale ARM and NPS models into a basin-scale analysis framework that includes transport and transformation in one-dimensional stream channels. The simulation provides a time history of the runoff flow rate, sediment load, and nutrient and pesticide concentrations, along with a time history of water quantity and quality at any point in a watershed. HSPF simulates three sediment types (sand, silt, and clay) in addition to specific

Table 4-2. Toxicant Fate and Transport Models

Model	Environment	Time Domain	Spatial Domain	Chemical
DYNTOX	river	dynamic	far field, 1-dimensional	organic, metal
EXAMS-II	lake, river, estuary	steady-state, quasi-dynamic	far field, 3-dimensional	organic
WASP4	lake, river, estuary	steady-state, dynamic	far field, 3-dimensional	organic, metal
HSPF	river	dynamic	far field 1-dimensional	organic, metal
SARAH2	river	steady-state	treatment plant, near field, 2-dimensional	organic
MINTEQA2	lake, river, estuary	steady-state	—	metal

organic chemicals and transformation products of those chemicals. The reaction and transfer processes included are hydrolysis, oxidation, photolysis, biodegradation, volatilization, and sorption. Sorption is modeled as a first-order kinetic process in which a desorption rate and an equilibrium partition coefficient for each of the three solid types must be specified. Resuspension and settling of silts and clays (cohesive solids) are defined in terms of shear stress at the sediment-water interface. For sands, the system's capacity to transport sand at a particular flow is calculated and resuspension or settling is defined by the difference between the sand in suspension and the calculated capacity. Sediment exchanges with surficial benthic sediments are modeled as sorption/desorption and deposition/scour. Underlying sediment and pore water are not modeled.

- SARAH2 [60] is a steady-state, near-field model for calculating acceptable concentrations of hazardous organic chemicals discharged to land disposal or wastewater treatment facilities. Acceptable leachate or treated industrial waste discharge constituent concentrations are estimated by a "back calculation" procedure starting from chemical safety criteria in surface water, drinking water, or fish. For steady or batch waste streams, SARAH2 considers the following concentration reductions: dilution and loss during treatment, initial Gaussian mixing at the edge of a stream, lateral and longitudinal diffusion in the mixing zone, sorption, volatilization, hydrolysis, and bioaccumulation in fish. The user must specify appropriate concentrations for protection of the aquatic community and of humans exposed through consumption of fish and water. The benthic community is not presently considered. Treatment loss is handled empirically. SARAH2 contains data sets for three disposal-watershed scenarios that can be easily modified and employed. The model is designed for screening analysis and contains numerous assumptions that should be verified before the model is used in actual cases.

- MINTEQA2 is an equilibrium metals speciation model for dilute aqueous systems [61]. It does not have any transport and transformation processes and must be run with one of the above models. It can be used to calculate the mass distribution at equilibrium among dissolved, absorbed, and solid phases and the species distribution within each phase. MINTEQA2 contains a chemical component data set for major ions commonly found in aqueous systems (e.g., Ca, Fe, and S), trace metals/metalloids of pollution interest (e.g., Cd, Cr, Ni, Pb, and Zn), and organic ligands of significant affinity for metal complexation. The model can be used to calculate the concentrations of adsorbed metals via any of seven different adsorption algorithms.

- FGETS is a toxicokinetic model that simulates the bioaccumulation of nonpolar organic chemicals by fish from both water and food [62]. Both of these routes of exchange are modeled as diffusion processes that depend upon physicochemical properties of the pollutant and morphological/physiological characteristics of the fish. FGETS contains a moderately sized data base of allometric relationships for gill morphology with which it can simulate the direct gill/water exchange of organic chemicals for essentially any fish species, assuming certain default values. FGETS also contains a limited data base of physiological/morphological relationships that are used to set parameters for food exchange. In addition to simulating bioaccumulation of organic toxicants, FGETS can calculate time to death from chemicals whose mode of action is narcosis. This calculation is based on the existence of a single, lethal, internal chemical activity for such chemicals. The concentrations of toxic chemical to which the food chain is exposed may be specified by the user or may be taken directly from the values calculated by the exposure concentration model WASP4. Thus FGETS may be executed as a separate model or as a postprocessor to WASP4.

- FCM2 is a generalized model of the uptake and elimination of toxic chemicals by aquatic organisms [63]. It generates a mass balance calculation in which the rates of uptake and elimination are related to the bioenergetic parameters of the species. A linear food chain or a food web may be specified. Fish tissue concentrations are calculated as a function of time and age for each species included. Exposure to the toxic chemical in food is based on a consumption rate and predator-prey relationships that are specified as a function of age. Exposure to the toxic chemical in water is functionally related to the respiration rate. Steady-state concentrations also may be calculated. The concentrations of the toxic chemical to which the food chain is exposed may be specified by the user or may be taken directly from the values calculated by the exposure concentration model WASP4. Thus FCM2 may be executed as a separate model or as a postprocessor to WASP4. Migratory species, as well as nonmigratory species, may be considered. Separate nonmigratory food chains may be specified, and the migratory species is exposed sequentially to each food chain based on its seasonal movements.

4.5.5 Effluent Toxicity Modeling

To apply the steady-state, continuous simulation, or probabilistic methods to effluent toxicity modeling, the percent effluent measurements should be converted to toxic units (TUs). As discussed in Chapters 1, 2, and 3, it is necessary to convert toxicity to units that can be directly related to mass. When comparing toxicity among chemicals, the relationship between toxicity and concentration is inverse; chemicals that have toxic effects at low concentrations have a greater "toxicity" than chemicals that have toxic effects at higher concentrations. The modeling of toxic effluents is based on mass balance principles; therefore, toxicity needs to be in units that increase when the percent of the effluent of the receiving stream increases. Thus, a TU is the reciprocal of the dilution that produces the test endpoint, i.e., acute toxicity endpoint (ATE) or chronic toxicity endpoint (CTE). An acute toxic unit (TU_a) is the reciprocal of an ATE. A chronic toxic unit (TU_c) is the reciprocal of a CTE. The TMDL must ensure that the CMC and the CCC are met in the receiving water at the desired duration and frequency. The CMC for toxicity is recommended as 0.3 TU_a. This is a value that should prevent lethality unless the duration of exposure exceeds 1 hour.

The CCC for toxicity measured with chronic tests is recommended as the following:

$$CCC = 1.0\ TU_c.$$

The first step in the TMDL process is to calculate the allowable acute effluent toxicity that meets the CMC in the receiving water at the duration and frequency discussed in Appendix D.

The next step in the TMDL process is to calculate the allowable chronic effluent toxicity that meets the CCC in the receiving water at the duration and frequency discussed in Appendix D. To compare the allowable acute toxicity value to the allowable chronic toxicity value, the numbers must be converted to the same units as follows:

$$TU_a = (ACR)(TU_c)$$

where the acute-to-chronic ratio (ACR) is determined from tests on the effluent. It is important that the ACR used for TMDL purposes be based on actual data and not be assumed to be 10 or 20, as in the screening procedure (Chapter 3). The value of this ratio will influence whether the acute or chronic TMDL is more stringent and is used to calculate the permit limit using the methods described in Chapter 5.

At the present time, the fate of effluent toxicity in a receiving water is not fully understood. Even if a decay rate for toxicity can be measured on a given day in a site-specific situation, there is no way as yet to know how this rate is affected by temperature, pH, or other environmental conditions. There is also no way to know how this rate may change when new treatment is installed. Instream measurements of toxicity should be made at least once per season to identify any time-varying trends in site-specific fate processes. These monitored decay rates can then be used in steady-state or continuous simulation fate and transport models to predict receiving water toxicity, assuming that the rates will not change with future treatment.

Without specific information concerning the persistence of toxicity, it is recommended that effluent toxicity be limited to dilution estimates and that toxicity be assumed to be additive and conservative. Toxicity is expected to be additive even when the toxicity of one effluent affects selected biota while the toxicity of a downstream discharge affects different biota. For rivers and run-of-river reservoirs with a detention time of less than 20 days, the following dilution equation should be used, assuming completely mixed conditions:

$$C = \frac{C_s Q_s + C_e Q_e}{Q_e + Q_s}$$

where

- C = downstream concentration (TU_c or TU_a)
- C_s = upstream concentration (TU_c or TU_a)
- Q_s = upstream flow (cfs)
- C_e = effluent concentration (TU_c or TU_a) and
- Q_e = effluent flow (cfs).

For multiple dischargers, this equation must be applied sequentially to find the concentration as a function of distance downstream. The equation can be used for a steady-state analysis if Q_s is set equal to the design flow, Q_e is set equal to the historical plant flow, and C_e is calculated to meet the CMC and CCC. This equation can also be used with the continuous simulation, lognormal probabilistic, or Monte Carlo methods. For these dynamic analyses, a series of C_e, Q_e, C_s, and Q_s values would be used.

If instream toxicity measurements are available and a first-order decay rate for toxicity can be estimated, the following equation should be used:

$$C = C_o e^{-K(x/u)}$$

where

- C = downstream concentration (TU_c or TU_a)
- C_o = concentration after the point source discharge has mixed completely with the river (TU_c or TU_a)
- x = distance downstream of complete mix point
- u = velocity of river
- K = measured decay rate.

Additional statistical approaches are available that might provide better statistical fits to the available data. However, these models are somewhat more limited than the example provided above.

The same equations used for toxicity analyses in **rivers** can also be used in steady-state, continuous simulation, or probabilistic analysis of long, narrow, shallow impoundments with high inflow velocities. **Wider, deeper lakes** require more complicated analyses since prolonged detention times (>20 days) and stratification exert a significant impact on water quality. The prolonged detention times make it essential that receiving water measurements of toxicity be available to estimate decay factors. These measurements should be made at least once per season to identify any time-varying trends in toxicity fate processes. Steady-state or continuous simulation fate and transport models for lakes can then be run with monitored decay rates for toxicity. A simple steady-state analysis can be performed using the following equations [64]:

$$T_w = V/Q$$
$$C = C_{in}/(1+T_w K)$$

where

- T_w = mean hydraulic residence time
- V = lake volume at design conditions
- Q = mean total inflow rate at design conditions
- C = steady-state lake concentration (TU_c or TU_a)
- C_{in} = steady-state inflow concentration (TU_c or TU_a)
- K = first-order decay rate.

If effluent is discharged into a stratified lake and mixes only with the hypolimnion or epilimnion, the volume of the layer should be used only to calculate mean hydraulic residence time (T_w). The mean total inflow rate (Q) and the inflow concentration (C_{in}) should be calculated as the sum of all sources to the lake, including point source, nonpoint source, and tributary inputs.

Dilution calculations for effluent toxicity discharges to an **estuary** are complicated by the oscillatory motion of the tides and possible stratification of the estuary. The prolonged detention times make it essential that field measurements of toxicity be available to estimate decay factors. These measurements should be made at least once per season to identify any time-varying trends in toxicity rate processes. Steady-state or continuous simulation fate and transport models for estuaries can then be run with monitored decay rates for toxicity. A simple steady-state analysis can be performed using the following equations for each nonconservative pollutant entering from the river at the head of an estuary [64]:

$$C_i = C_{i-1} \frac{(f_i)}{(f_{i-1})} B_i$$

where

$$B_i = \frac{r_i}{1 - (1-r_i)e^{-kt}}$$

r_i = exchange ratio for segment i as defined by modified tidal prism method
t = flushing time
f_i = fraction of freshwater in segment i
C_i = nonconservative pollutant concentration in segment i (TU_a or TU_c)
k = decay rate of pollutant.

The following equations should be used for each nonconservative pollutant entering along the side of an estuary:

For segments downstream of outfall:

$$C_i = C_o \prod_{i=1}^{n} \frac{f_i}{f_o} \frac{r_i}{1 - (1-r_i)e^{-kt}}$$

For segments upstream of outfall:

$$C_i = C_o \prod_{i=1}^{n} \frac{S_i}{S_o} \frac{r_i}{1 - (1-r_i)e^{-kt}}$$

where

C_i = nonconservative pollutant mean concentration in segment i (TU_c or TU_a)
C_o = nonconservative pollutant mean concentration in segment of discharge
r_i = exchange ratio for segment i as defined by the modified tidal prism method
n = number of segment away from outfall
f_i = fraction of freshwater in segment i
f_o = fraction of freshwater in segment with discharge
S_i = salinity in segment i
S_o = salinity in segment of discharge
k = decay rate
t = flushing time.

The details of how to calculate exchange ratios and flushing times for estuaries are included in Part 2 of EPA's water quality assessment manual [64]. This manual also describes how to perform these calculations for stratified estuaries using a two-dimensional box model analysis.

4.6 HUMAN HEALTH

4.6.1 Human Health Considerations

Human exposure to pollutants should be evaluated as completely as available information will allow. Exposure information is used in calculating the human health reference ambient concentration (RAC) from the formulas in Chapter 2, Water Quality Standards. This information should be used to estimate exposures due to fish consumption and drinking water ingestion, background concentrations, and other exposure routes, such as recreational, occupational, drinking water, dietary (other than fish), and inhalation. Factors in the formulas for which information is not available can be omitted from the calculation. If States choose, bioaccumulation factors also can be modified.

4.6.2 Determining the TMDL Based on Human Health Toxicants

TMDLs are typically necessary only where mixing is allowed. Mixing zones are used at the discretion of the States. If a State does not allow a mixing zone or the assumption of complete mixing, then the RAC is applied at the end of pipe and no TMDL determination is typically necessary.

With persistent or bioconcentratable pollutants, special mixing zone considerations apply. Bioconcentratable pollutant criteria exceedances within the mixing zone can potentially result in tissue contamination of organisms directly or indirectly through contamination of bed sediments with subsequent incorporation into the food chain. For discharge situations with incomplete mixing (e.g., large rivers, lakes, estuaries, oceans), States need to carefully consider whether mixing zones for persistent or bioconcentratable pollutants are appropriate. Where a mixing zone is allowed, one TMDL should be calculated to achieve the RAC or criterion selected above [65]. Because most human health criteria are chronic only, a TMDL to protect against acute effects will usually not be needed, although EPA's Office of Drinking Water does have acute criteria for some pollutants.

For the purpose of the following discussion, use of simple, steady-state dilution models is assumed. However, these models may be inappropriate for certain situations where sediments serve as a sink for bioconcentratable pollutants and where additional factors need to be considered. Dynamic models, where available, are useful tools for accounting for an array of variables that may have an impact on the fate of bioconcentratable pollutants in the food chain. These models may be used by States for surface waters in appropriate instances.

In simple situations, the TMDL is determined from the RAC and the design flow of the receiving water. In more complicated situations, e.g., where mixing is not rapid or where lakes or estuaries are involved, a spatial averaging scale must be chosen. Selection of the spatial scale must be consistent with reasonable assumptions about the behavior of aquatic organisms and the target human population.

In some cases, it may be necessary to apply the chronic human health criterion within a mixing zone if it is reasonable to assume that the bioconcentrating aquatic organisms have little mobility, thus spending most of their time within the mixing zone; and the target human population consistently consumes fish from the mixing zone (over a 70-year lifetime, for carcinogenic risks).

The procedure for developing TMDLs/WLAs generally requires determining values for the following parameters, based upon water quality considerations: (1) the duration of the averaging period applicable to the WLA; (2) design considerations, e.g., flow; (3) the discharge (WLA) concentration that will result in meeting the ambient water quality criterion during the design condition; and (4) the allowable probability (or frequency) of the discharge's exceeding the WLA, averaged over the appropriate

duration. The technical basis for setting these values is discussed in the following sections.

1) Averaging Periods

The duration of the averaging period for the WLA should be selected to be consistent with the assumptions used to derive the water quality criteria. Two categories of pollutants should be recognized: carcinogens and noncarcinogens.

The human health criteria for carcinogens are derived assuming lifetime exposure. The upper-bound risk is directly proportional to the lifetime arithmetic mean dose. The criteria thus apply to the ambient water concentrations averaged over a 70-year period.

The duration of exposure assumed in deriving criteria for noncarcinogens may be ambiguous, particularly where a criterion is derived from animal studies. Furthermore, the duration may be highly variable, ranging as high as 20 to 30 years for cadmium.

2) Dilution Design Conditions

a) Carcinogens: River and Stream Discharge Situations

In well-mixed situations, the RWC, C, is determined by the pollutant load, W (mass/time), and the combined receiving water plus effluent flow, Q, such that, C = W/Q.

The long-term harmonic mean flow is recommended as the design flow for carcinogens. The recommendation of long-term harmonic mean flow has been derived from the definition of the human health criteria (HHC) for carcinogenic pollutants. The adverse impact of carcinogenic pollutants is estimated in terms of receptors (human) lifetime intakes. To be within the acceptable level of life-time body-burden of any carcinogen, such intakes should not exceed the HHC during the average life-time of the receptor. A life-time for exposure to carcinogenic pollutants is defined as 70 years, or approximately 365 (days/year) multiplied by 70 years.

The HHC for carcinogenic pollutants can be numerically expressed as:

$$HHC = C\ (design) = (C_1 + C_2 + C_3 + \text{-----} + C_n)/n$$

where
n = (365 days/year) x 70 years
C = concentrations

Based on an assumption of a constant daily load from a treatment facility, the fully mixed instream concentration will go up or down inversely with the ups and downs of receiving water flows. Therefore, instream concentration is a function of, and inversely proportional to, the streamflow downstream of the discharge. Using this concept, 1/Q can be substituted for C, as follows:

$$1/Q\ (design) = (1/Q_1 + 1/Q_2 + 1/Q_3 + \text{-----} + 1/Q_n)/n.$$

The stream design flow (Q design) can then be shown as follows:

$$Q\ (design) = n/(1/Q_1 + 1/Q_2 + 1/Q_3 + \text{-----} + 1/Q_n)$$

The harmonic mean is expressed as follows:

$$Q\ (design) = n/\sum_{i=1}^{n} (1/Q_i)$$

where
n = the number of recorded flows.

The harmonic mean is always less than the arithmetic mean. The harmonic mean is the appropriate design flow for determining long-term exposures using steady-state modeling of effluents. The arithmetic mean flow is not appropriate as the design flow since it overstates the dilution available. Extreme value statistics (such as 7Q10 or 30Q5) are also not appropriate since they have no consistent relationship with the long-term mean dilution. However, for situations involving seasonably variable effluent discharge rates, hold-and-release treatment systems, and effluent-dominated sites, the harmonic mean may not be appropriate. In these cases, the effluent load and downstream flow are not independent (i.e., they are correlated). Modeling techniques that can calculate an average daily concentration over a long period of time are more appropriate to determine the long-term exposure in these cases.

The harmonic mean flow may be estimated by any of several methods [8], assuming that flows are approximately lognormally distributed:

$$Q_{hm} = \frac{Q_{gm}^2}{Q_{am}}$$

where
Q_{gm} is the geometric mean flow
Q_{am} is the arithmetic mean flow.

For U.S. Geological Survey flow records, summaries of the statistical parameters needed to estimate the harmonic mean can be quickly obtained from STORET, through a user-friendly procedure for permit writers, as described in Appendix D.

WQAB DFLOW is a software package available for computation of harmonic mean flow. The DFLOW program (as discussed below and described in Appendix D) should be used with data that are not lognormally distributed.

To develop some quantitative sense of how a long-term harmonic mean flow of any stream compares with its 7Q10 flow, the Assessment and Watershed Protection Division and the Risk Reduction Engineering Laboratory at Cincinnati, Ohio, analyzed flow records of 60 streams selected at random throughout the United States. These are the same stream flow records that had been analyzed for stream design flow condition for aquatic life protection as listed in EPA guidance [8]. Based on the long-term harmonic flow and 7-day, 10-year low-flow estimates for these 60 streams, the long-term harmonic mean flows of all 60 streams were equal to or greater than two times the 7Q10 low flow. Fifty-four of the streams' harmonic mean flows were equal to or greater than 2.5 times their 7Q10 low flows. Finally, 40 of the 60 streams' harmonic mean flows were equal to or greater than 3.5 times the 7Q10.

Based on the above observations, permit authorities may choose a multiplication factor of 3 x 7Q10 to estimate stream design flow for human health protection for carcinogenic pollutants. How-

ever, it is recommended that the harmonic mean flow be calculated directly from the historical daily flow record, if possible. Alternatively, the following equation might be used to estimate harmonic mean flow [66]:

$$Q_{hm} = [1.194 * (Q_{am})^{0.473}] * [(7Q10)^{0.552}],\ r^2 = 0.99.$$

In this equation, Q_{am} and 7Q10 are estimated using the U.S. Geological Survey computer program, FLOSTAT.

b) Noncarcinogens: River and Stream Discharge Situations

The choice of average period represents a level-of-protection consideration inherent in the risk management decision to be made by the permitting agency. If a short-term duration of exposure is chosen (i.e., 90 days or less), design flows may be appropriately based on extreme value statistics. Because the effects from noncarcinogens are more often associated with shortened exposures, EPA suggests the use of 30Q5. However, in the comparisons of flows for smaller rivers (i.e., low flow of 50 cfs), the 30Q5 flow was, on the average, only 1.1 times that of the 7Q10. For larger rivers (i.e., low flow of 600 cfs), the factor was, on the average, 1.4 times. **If the effects from certain noncarcinogens are manifested after a lifetime of exposure, then a harmonic mean flow may be appropriate.**

3) Point of Application of the Criteria

The point at which the chronic criteria are to be met in the receiving water may be fixed by existing State standards or may be determined by considerations for managing individual and aggregate risks. The several possibilities include the following:

- Where State standards allow no mixing zone and no spatial averaging, the criterion would be met at the end of the pipe.
- Where State standards specify that the criterion must be met at the end of the mixing zone, the criterion would be applied at that point.
- Where State standards allow consideration of spatial averaging, the criterion may be met as an average within a specified area, as appropriate for the individual and aggregate risk scenarios underlying the application.

CHAPTER 4

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5. PERMIT REQUIREMENTS

5.1 INTRODUCTION

As the final step in the "standards-to-permits" process, development of permit requirements is often the culmination of the activities discussed in the preceding chapters. This chapter describes the basic principles of effluent variability and permit limit derivation and provides recommendations for deriving limits from various types of wasteload allocation outputs such that water quality standards are protected. It also addresses important considerations in the expression of limits and other types of permit requirements, including toxicity reduction evaluations. The first portion of the chapter deals principally with aquatic life protection. Permitting for protection of human health is found in Section 5.4.4.

5.1.1 Regulatory Requirements

There are both mandatory and discretionary elements associated with the development of water quality-based permit limits to control toxic pollutants and toxicity. The mandatory elements are described in the revisions to the National Pollutant Discharge Elimination System (NPDES) Surface Water Toxics Control Program regulations (54 *FR* 23868, June 2, 1989). The regulations at 40 *CFR* 122.44(d)(1) require that regulatory authorities first determine whether a discharge causes, has the reasonable potential to cause, or contributes to an excursion above water quality standards (narrative or numeric). In making these determinations, regulatory authorities must use a procedure that accounts for effluent variability, existing controls on point and nonpoint sources of pollution, available dilution, and (when using toxicity testing) species sensitivity. Each of these regulations were previously discussed in Chapter 3.

There is a degree of flexibility in the specific procedures a regulatory authority uses in determining whether an excursion occurs or is reasonably expected to occur and in the weight given to the various factors in conducting the evaluation of a specific discharger. The Environmental Protection Agency's (EPA) guidance for making these determinations is contained in the recommendations in Chapter 3.

There are also several EPA policies that reflect these regulatory requirements, including the "National Policy for the Development of Water Quality-Based Limits for Toxic Pollutants" (Appendix B-2) and EPA's "Whole Effluent Toxicity Permitting Principles and Enforcement Strategy," (Appendix B-4). This strategy states that "all major permits and minors of concern must be evaluated for potential or known toxicity (chronic or acute if more limiting)." In addition, the strategy states that "[f]inal whole effluent toxicity limits must be included in permits where necessary to ensure that State Water Quality Standards are met. These limits must properly account for effluent variability, available dilution, and species sensitivity."

There is an element of judgment inherent in the specific permit limit derivation procedures used for an individual discharger once a decision has been made to develop a specific type of limit. Case-specific considerations will usually dictate the most appropriate approach to be taken in individual situations. Nevertheless, the various assumptions used in the permit limit development process should be consistent with the assumptions and principles inherent in the effluent characterization and exposure assessment steps preceding permit limit development. **The permit limit derivation procedure used by the permitting authority should be fully enforceable and should adequately account for effluent variability, consider available receiving water dilution, protect against acute and chronic impacts, account for compliance monitoring sampling frequency, and protect the wasteload allocation (WLA) and ultimately water quality standards. To accomplish these objectives, EPA recommends that permitting authorities use the statistical permit limit derivation procedure discussed in Section 5.4 with the outputs from either steady state or the dynamic wasteload allocation modeling.**

5.2 BASIC PRINCIPLES OF EFFLUENT VARIABILITY

An understanding of the basic principles of effluent variability is central to water quality-based permitting. Many of the concepts are the same as those considered in the development of technology-based limits. However, the process for applying the principles is substantially different, as explained below.

5.2.1 Variations in Effluent Quality

Effluent quality and quantity vary over time in terms of volumes discharged and constituent concentrations. Variations occur due to a number of factors, including changes in human activity over a 24-hour period for publicly owned treatment works (POTWs), changes in production cycles for industries, variation in responses of wastewater treatment systems to influent changes, variation in treatment system performance, and changes in climate. Very few effluents remain constant over long periods of time. Even in industries that operate continuous processes, variations in the quality of raw materials and activities, such as back-washing of filters, cause peaks in effluent constituent concentrations and volumes.

If effluent data for a particular pollutant or pollutant parameter for a typical POTW are plotted against time, the daily concentration variations can be seen (see Figure 5-1, left-hand graphs). This behavior can be described by constructing frequency-concentration plots of the same data (see Figure 5-1, right-hand graphs).

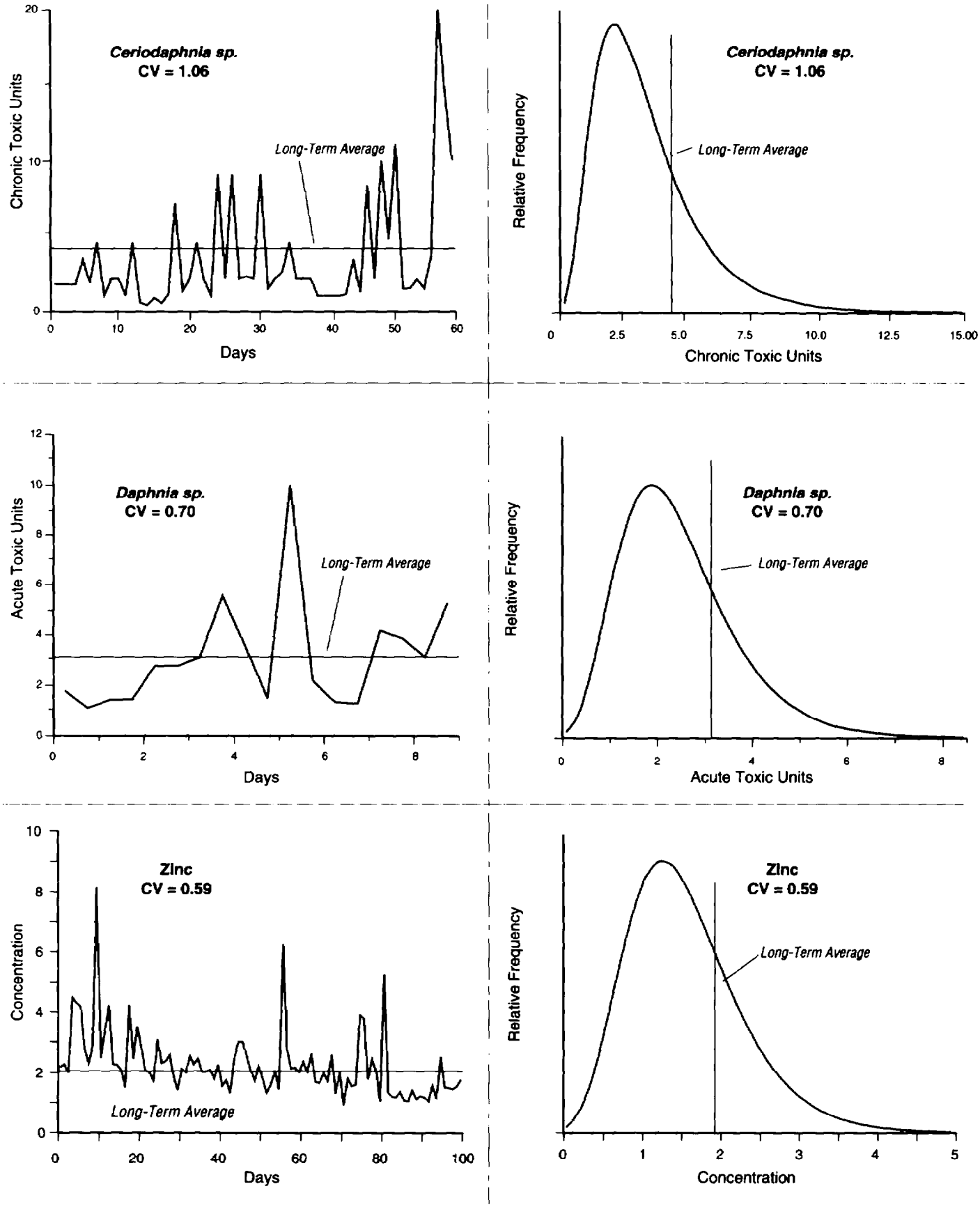

Figure 5-1. Data Relative Frequency Distributions for *Ceriodaphnia* Toxicity, *Daphnia* Toxicity, and Zinc Concentrations for Three Different Effluents

5.2.2 Statistical Parameters and Relationship to Permit Limits

Based upon the shape of the curve of a frequency-concentration plot, the data can be described in terms of a particular type of statistical distribution. The choices for statistical distributions include normal (bell-shaped), lognormal (positively skewed), or other variations on the lognormal distribution. From the vast amount of data that EPA has examined, it is reasonable to assume (unless specific data show otherwise) that treated effluent data follow a **lognormal** distribution. This is because effluent values are non-negative and treatment efficiency at the low end of the concentration scale is limited, while effluent concentrations may vary widely at the high end of the scale, reflecting various degrees of treatment system performance and loadings. These factors combine to produce the characteristically positively skewed appearance of the lognormal curve when data are plotted in a frequency histogram. Appendix E discusses the basis for concluding that effluent data are typically lognormally distributed, as well as recommendations for handling data sets from treatment plants that follow some other type of distribution.

Effluent data from any treatment system may be described using standard descriptive statistics, such as the mean concentration of the pollutant or pollutant parameter (i.e., the long-term average [LTA] and the coefficient of variation [CV]). The CV is a standard statistical measure of the relative variations of a distribution or set of data, defined as the ratio of the standard deviation to the mean. Using a statistical model, such as the lognormal, an entire distribution of values can be projected from limited data, and limits can be set at a specified probability of occurrence. Figure 5-1 shows the frequency-concentration curve and the relative positions of the concentrations corresponding to the mean for the data.

All permit limits, whether technology-based or water quality-based, are set at the upper bounds of acceptable performance. The purpose of a permit limit is to specify an upper bound of acceptable effluent quality. For technology-based requirements, the limits are based on proper operation of a treatment system. For water quality-based requirements, the limits are based on maintaining the effluent quality at a level that will comply with water quality standards, even during critical conditions in the receiving water. These requirements are determined by the WLA. The WLA dictates the required effluent quality which defines the desired level of treatment plant performance or target LTA.

In the development of technology-based effluent limits guidelines, the operating records of various wastewater treatment facilities for a particular category of discharger are examined. Based on the effluent data for the treatment facilities, a composite mean or LTA value for the parameter is determined. This LTA value, with relevant estimates of variability, is then used to derive effluent limit guidelines, which lead directly to permit limits.

In contrast, the process operates in reverse for water quality-based permit limits. The WLA, determined from water quality standards, defines the appropriate discharge level, which in turn determines the requisite target LTA for the treatment facility in order to meet that WLA. Permit limits may then be derived from this targeted LTA and CV. Figure 5-2 illustrates the relationship among the various statistical parameters. As these figures show, highly variable effluents require a much lower targeted LTA to meet the WLA and account for the variability that occurs in effluent concentration above the LTA.

It is extremely important to recognize that the various statistical principles and relationships discussed above operate in any dis-

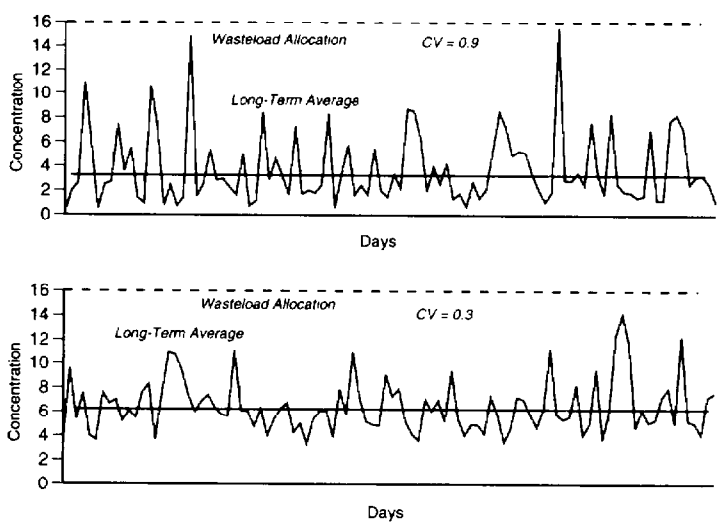

Figure 5-2a. Relationship Between a Single Wasteload Allocation and Two Long-Term Averages for Different Coefficients of Variation

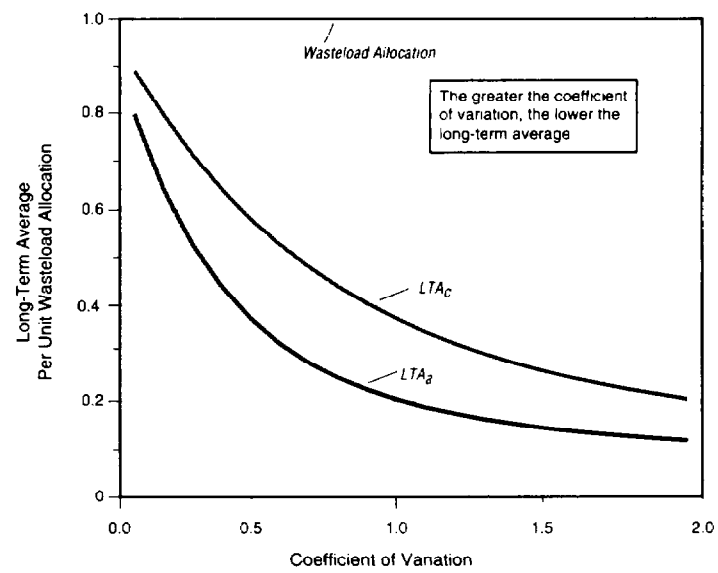

Figure 5-2b. Long-Term Average Per Unit Wasteload Allocation as a Function of the Coefficient of Variation

charge situation—whether or not they are specifically recognized or accounted for. Where a permit limit derivation procedure does not address these principles specifically, the permit writer will be implicitly assuming that there are enough conservative assumptions built into other steps in the process (e.g., water quality models, "buffer" between permit limits and actual operating conditions) to ensure that there will be no reasonable potential for excursions above water quality standards.

5.2.3 Expression of Permit Limits

The NPDES regulations at 40 *CFR* 122.45(d) require that all permit limits be expressed, unless impracticable, as both average monthly and maximum daily values for all discharges other than POTWs and as average weekly and average monthly limits for POTWs. The **maximum daily** permit limit (MDL) is the highest allowable discharge measured during a calendar day or 24-hour period representing a calendar day. The **average monthly** permit limit (AML) is the highest allowable value for the average of daily discharges obtained over a calendar month. The **average weekly** permit limit (AWL) is the highest allowable value for the average of daily discharges obtained over a calendar week.

EPA believes that a maximum daily permit limit can be directly used to express an effluent limit for all toxic pollutants or pollutant parameters except chronic whole effluent toxicity. The typical toxicity test used to measure chronic toxicity consists of samples collected from at least 3 different days over a 7-day period. Therefore, the test does not measure toxicity in any given 24-hour period or calendar day, but rather measures toxicity over a 7-day period. The toxicity could be caused by any one sample or a combination of samples. To address this situation, **EPA recommends that the permit contain a notation indicating that when chronic toxicity tests are required in a permit, the MDL should be interpreted as signifying the maximum test result for the month.**

Additionally, in lieu of an AWL for POTWs, EPA recommends establishing an MDL (or a maximum test result for chronic toxicity) for toxic pollutants and pollutant parameters in water quality permitting. This is appropriate for at least two reasons. First, the basis for the 7-day average for POTWs derives from the secondary treatment requirements. This basis is not related to the need for assuring achievement of water quality standards. Second, a 7-day average, which could comprise up to seven or more daily samples, could average out peak toxic concentrations and therefore the discharge's potential for causing acute toxic effects would be missed. A MDL, which is measured by a grab sample, would be toxicologically protective of potential acute toxicity impacts.

5.3 ENSURING CONSISTENCY WITH THE WASTELOAD ALLOCATION

The WLA provides a definition of effluent quality that is necessary to meet the water quality standards of the receiving water. The WLA is based on ambient criteria and the exposure of the resident aquatic community or humans to toxic conditions. Once a WLA has been developed, accounting for all appropriate considerations, a water quality-based permit limit may be derived to enforce the WLA. The method used to derive the permit limits must be consistent with the nature of the WLA.

The WLA addresses variability in effluent quality. For example, a WLA for human health pollutants is typically expressed as a single level of receiving water quality necessary to provide protection against long-term or chronic effects. On the other hand, a WLA for toxic pollutants affecting aquatic life (with corresponding duration and frequency requirements) should describe levels necessary to provide protection against both short-term and long-term effects.

5.3.1 Statistical Considerations of WLAs

Direct use of a WLA as a permit limit creates a significant risk that the WLA will be enforced incorrectly, since effluent variability and the probability basis for the limit are not considered specifically. For example, the use of a steady state WLA typically establishes a level of effluent quality with the assumption that it is a value never to be exceeded. The same value used directly as a permit limit could allow the WLA to be exceeded without observing permit violations if compliance monitoring was infrequent. Confusion can also result in translating a longer duration WLA requirement (e.g., for chronic protection) into maximum daily and average monthly permit limits. The permit writer must ensure that permit limits are derived to implement a WLA requirement correctly. Potential problem areas are as follows:

- The WLA must be enforced in a regulatory context by translating it into MDLs and AMLs; then and only then, will compliance monitoring associated with permit limits allow the regulatory authority to determine whether or not such permit limits are violated.
- The WLA that assumes that the discharge is steady state (i.e., not changing over time) requires a limit derivation assumption regarding how the effluent may vary.
- MDLs and AMLs average monthly limits must be developed so that they are consistent with each other and mandate the required level of wastewater treatment facility performance.
- If the acute WLA is used alone directly as the MDL, the limit will not necessarily be protective against chronic effects. If the acute WLA is used alone directly as the AML, the limit can allow excursions above the WLA within each month.
- If the chronic WLA is used alone as an MDL, the limit will be protective against acute and chronic effects but at the expense of being overly stringent. If the chronic WLA is used alone as the AML, the limit may be protective against acute and chronic effects depending upon effluent variability.

The objective is to establish permit limits that result in the effluent meeting the WLA under normal operating conditions virtually all the time. It is not possible to guarantee, through permit limits, that a WLA will never be exceeded. It is possible, however, using the recommended permit limit derivation procedures, to account for extreme values and to establish low probabilities of exceedence

of the WLA in conformance with the duration and frequency requirements of the water quality standards. This is not to suggest that permit writers should assume a probability of exceedence of the WLA, but rather, that they should develop limits that will make an exceedance a very small likelihood.

Since effluents are variable and permit limits are developed based on a low probability of exceedence, the permit limits should consider effluent variability and ensure that the requisite loading from the WLA is not exceeded under normal conditions. In effect then, the limits must "force" treatment plant performance, which, after considering acceptable effluent variability, will only have a low statistical probability of exceeding the WLA and will achieve the desired loadings.

Figure 5-3 shows a number of important aspects of the relationships among the various statistical parameters. In this illustration, the most limiting LTA (after comparing the LTAs derived from both acute and chronic WLAs) has been chosen for the chronic limiting condition. The more restrictive LTA will automatically meet both WLA requirements. If the effluent "fingerprint" for this LTA (and associated CV) is projected, it can be seen that the distribution of daily effluent values will not exceed the acute or chronic wasteload allocations for unacceptable periods of time. The duration and frequency requirements of the acute and chronic criteria for the pollutant or pollutant parameter will not be exceeded. This figure also illustrates permit limits derived from the more limiting LTA. (Note that for the scenario depicted in Figure 5-3, the MDL is lower than the acute WLA and the average monthly limit is lower than the chronic WLA. This scenario will occur when a 99-percent probability basis is used to calculate the LTA and a 95-percent probability basis is used to calculate the permit limits from the lower of the acute and chronic LTA. For other probability assumptions, these relationships will differ.)

5.3.2 Types of Water Quality Models and Model Outputs

Each of the two major types of water quality models, steady-state and dynamic, and their WLA outputs have specific implications

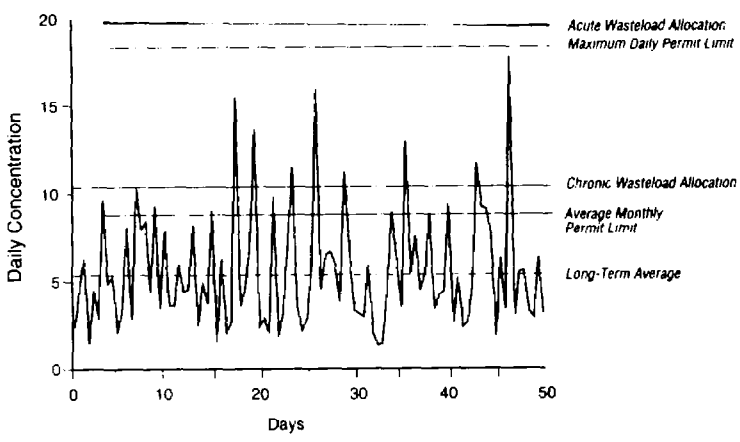

Figure 5-3. Relationship Between Daily Concnetrations, Long-Term Average, Wasteload Allocations, and Permit Limits

for the subsequent permit limit development process. These implications are discussed in detail below. **EPA recommends that steady-state WLA analyses generally be used by permitting authorities in most cases and especially where few or no whole effluent toxicity or specific chemical measurements are available, or where daily receiving water flow records are not available.** Two-value, steady-state models, although potentially more protective than necessary, can provide toxicologically protective results and are relatively simple to use. **If adequate receiving water flow and effluent concentration data are available to estimate frequency distributions, EPA recommends that one of the dynamic WLA modeling techniques be used to derive WLAs that will more exactly maintain water quality standards.**

Steady-State Modeling

Traditional single-value or two-value steady-state WLA models calculate WLAs at critical conditions, which are usually combinations of worst-case assumptions of flow, effluent, and environmental effects. For example, a steady-state model for ammonia considers the maximum effluent discharge to occur on the day of lowest river flow, highest upstream concentration, highest pH, and highest temperature. Each condition by itself has a low probability of occurrence; the combination of conditions may rarely or never occur. Permit limits derived from a steady-state WLA model will be protective of water quality standards at the critical conditions and for all environmental conditions less than critical. However, such permit limits may be more stringent than necessary to meet the return frequency requirements of the water quality criterion for the pollutant of concern.

On the other hand, a steady-state model approach may involve simplifying assumptions for other factors, such as ambient background concentrations of a toxicant, multiple source discharges of a toxicant, number of pollutants causing toxicity, incorrect effluent variability assumptions, and infrequent compliance monitoring. The effect of these types of factors, especially if unaccounted for in the WLA determination, can reduce the level of protectiveness provided by the critical condition assumptions of the steady-state model approach. Therefore, when using a steady-state WLA model, the permitting authority should be aware of the different assumptions and factors involved and should consider these assumptions and factors adequately consideration when developing permit limits.

In general, steady-state analyses tend to be more conservative than dynamic models because they rely on worst case assumptions. Thus, permit limits derived from these outputs will generally be lower than limits derived from dynamic models.

a) Single Value From a Steady-State Analysis

Some single-value, steady-state modeling has been used to calculate only chronic WLAs. These models produce a single effluent loading value and no information about effluent variability. Single value WLAs are typically based upon older State water quality standards that do not specify levels for both acute and chronic protection but only include one level of protection. Such outputs also would be found where a model is based upon protection of human health, since only a single long-term ambient value is of concern.

b) Two Values from Steady-State Analysis

Steady-state modeling for protection of aquatic life can specify two sets of calculations—one for protection against acute effects and one for protection against chronic effects. These models must use water quality criteria specifying two levels of protection. In addition, these models include considerations of mixing zones when developing WLAs to afford two levels of protection. Like the single-value, steady-state models, these models do not produce any information about acceptable effluent variability and may require additional calculations to be translated into permit limits.

For complex discharge situations (i.e., multiple dischargers or complex environmental factors needing consideration), water quality models and associated WLAs are typically developed by specialized water quality analysts in the regulatory authority. However, the permit writer is often required to develop a water quality model and WLA prior to permit limit derivation. In the latter situation, water quality modeling usually consists of simple steady-state dilution models using worst-case assumptions.

Dynamic Modeling

Dynamic models use estimates of effluent variability and the variability of receiving water assimilation factors to develop effluent requirements in terms of concentration and variability. The outputs from dynamic models can be used to base permit limits on probability estimates of receiving water concentrations rather than worst-case conditions. The advantages and disadvantages of various types of dynamic models are provided in Chapter 4.

In general, dynamic models account for the daily variations of and relationships between flow, effluent, and environmental conditions and therefore directly determine the actual probability that a water quality standards exceedence will occur. Because of this, dynamic models can be used to develop WLAs that maintain the water quality standards exactly at the return frequency requirements of the standards. Since this return frequency is usually one event in 3 years, WLAs developed by dynamic models are typically higher than those developed by steady-state models.

A targeted long-term average performance level and coefficient of variation can be derived from each type of dynamic model output, but some of the outputs require some additional manipulation of the data to develop the LTA and the CV. These parameters are also the starting point for the statistical permit limit derivation procedures discussed in the next section. **Continuous Simulation** models offer an array of effluent data that require further manipulation to develop an LTA and a CV. Both **Monte Carlo** and **Lognormal Probabilistic** models produce an LTA and CV, which can be used directly in developing permit limits. Chapter 4 details the different dynamic models. Specific instructions for the use of dynamic models are available in the references listed at the end of Chapter 4.

5.4 PERMIT LIMIT DERIVATION

There are a number of different approaches currently being used by permitting authorities to develop water quality-based limits for toxic pollutants and toxicity. Differences in approaches are often attributable to the need for consistency between permit limit derivation procedures and the assumptions inherent in various types of water quality models and WLA outputs. In addition, permitting authorities also are constrained by legal requirements and policy decisions that may apply to a given permitting situation. In some instances, however, permitting procedures have been adopted without careful consideration of the toxicological principles involved or the advantages and disadvantages of the procedure.

To avoid this problem, EPA recommends that the statistical permit limit derivation procedure described in this chapter be used for the derivation of both chemical-specific and whole effluent toxicity limits for NPDES permits. The type of WLA chosen from which to derive the limits is a matter of case-by-case application, as determined by the permitting authority. Although there are advantages and disadvantages associated with each of the procedures, EPA believes that the statistical derivation procedures will result in the most defensible and protective water quality-based permit limits for both specific chemicals and whole effluent toxicity.

The following section explains EPA's recommended permitting procedures and highlights advantages and disadvantages of various other approaches. With this information, permitting authorities will be better informed when deciding on the most appropriate permit limit derivation approach. For example, permitting authorities may decide to derive water quality-based permit limits for all dischargers using a steady-state WLA model as a baseline limit determination. If time and resources are available or if the discharger itself takes the initiative (after approval by the regulatory authority), dynamic modeling could be conducted to further refine the WLA from which final permit limits would be derived. Box 5-1 presents example permit limit calculations for each of the principal types of WLA outputs discussed in Section 5.4.1. Permit limits derived from dynamic modeling are usually higher than those based upon steady-state modeling. The difference is reflected in Box 5-1 and has been observed in actual applications [1, 2, 3]. In addition, the case studies in Chapter 7 illustrate how water quality-based permit limits are derived and compare the results of limits derived from steady state and dynamic wasteload allocations.

5.4.1 EPA Recommendations for Permitting for Aquatic Life Protection

Permit Limit Derivation from Two-Value, Steady-State Outputs for Acute and Chronic Protection

A number of WLAs have two results: acute and chronic requirements. These types of allocations will be developed more often as States begin to adopt water quality standards that provide both acute and chronic protection for aquatic life. These WLA outputs need to be translated into MDLs and AMLs. The following methodology is designed to derive permit limits for specific chemicals as well as whole effluent toxicity to achieve these WLAs.

- A treatment performance level (LTA and CV) that will allow the effluent to meet the WLA requirement is calculated.

Box 5-1. Sample Calculations of Permit Limits for Whole Effluent Toxicity from Different Wasteload Allocation Data

Available Data	Two Value wasteload allocation	Dynamic model output	Single wasteload allocation
Wasteload Allocation (WLA)	----	----	14.3
Acute Wasteload Allocation (WLAa)	2.60	----	----
Chronic Wasteload Allocation (WLAc)	14.3	----	----
Acute-Chronic Ratio	4.62	----	----
Coefficient of Variation (CV)	0.8	0.8	0.8
Number of Samples per Month (n)	4	4	4
Long Term Average (LTA)	----	9.44	----

From two-value steady state wasteload allocation

$WLA_{a,c} = WLA_a \bullet ACR = 2.60 \bullet 4.62 = 12.0$

$LTA_c = WLA_c \bullet e\,[0.5\sigma_4^2 - 2.326\sigma_4] = 14.3 \bullet 0.440$ (from Table 5-1) $= 6.29$

$LTA_{a,c} = WLA_{a,c} \bullet e\,[0.5\sigma^2 - 2.326\sigma] = 12.0 \bullet 0.249$

(from Table 5-1) $= 2.99$

$MDL = LTA_{a,c} \bullet e\,[2.326\sigma - 0.5\sigma^2] = 2.99 \bullet 4.01$ (from Table 5-2) $= 12.0$

$AML = LTA_{a,c} \bullet e\,[2.326\sigma_n - 0.5\sigma_n^2] = 2.99 \bullet 2.27$ (from Table 5-2) $= 6.79$

From dynamic model output

$MDL = LTA_c \bullet e\,[2.326\sigma - 0.5\sigma^2] = 9.44 \bullet 4.01$ (from Table 5-2) $= 37.9$

$AML = LTA_c \bullet e\,[2.326\sigma_n - 0.5\sigma_n^2] = 9.44 \bullet 2.27$ (from Table 5-2) $= 21.4$

From single wasteload allocation

Option 1

$LTA = WLA \bullet e\,[0.5\sigma^2 - 2.326\sigma] = 14.3 \bullet 0.440$ (from Table 5-1) $= 6.29$

$MDL = LTA \bullet e\,[2.326\sigma - 0.5\sigma^2] = 6.29 \bullet 4.01$ (from Table 5-2) $= 25.2$

$AML = LTA \bullet e\,[2.326\sigma_n - 0.5\sigma_n^2] = 6.29 \bullet 2.27$ (from Table 5-2) $= 14.3$

Option 2

$MDL = WLA = 14.3$

$AML = MDL/2 = 7.15$

Note: All calculations use the 99th percentile z statistic for calculation of long-term averages and permit limits.

Where two requirements are specified based on different duration periods, two performance levels are calculated (Box 5-2, Step 2).

- For whole effluent toxicity only, the acute WLA is converted into an equivalent chronic WLA by multiplying the acute WLA by an acute-to-chronic ratio (ACR). This ratio should optimally be based on effluent data, but also can be estimated as 10, based on the information presented in Chapter 1 and Appendix A.
- Permit limits are then derived directly from whichever performance level is more protective (Box 5-2, Steps 3 and 4).

Figure 5-4 presents a flow chart summarizing the various steps in this procedure. In addition, the equations used in Box 5-2 are based on the lognormal distribution, which is explained in more detail in Appendix E. The principal advantages of this procedure are described below.

- This procedure provides a mechanism for setting permit limits that will be toxicologically protective. A steady-state WLA uses a single value to reflect the effluent loading and thus is an inherent assumption that the actual effluent will not exceed the calculated loading value. If the WLA is simply adopted as the permit limit, the possibility exists for exceedance of the WLA due to effluent variability. Clearly, however, effluents are variable. Therefore, permit limits are established using a value corresponding to a percentile of the selected probability distribution of the effluent (e.g., 95th or 99th percentile).
- It allows comparison of two independent WLAs (acute and chronic) to determine which is more limiting for a discharge. The WLA output provides two numbers for protection against two types of toxic effects, each based upon different mixing conditions for different durations. Acute effects are limited based upon 1-hour exposures at critical conditions, close to the point of discharge, or where necessary, at the end of the pipe. Chronic effects are limited based on 4-day exposures after mixing at critical conditions. These requirements yield different effluent treatment requirements that cannot be compared to each other without calculating the LTA performance level the plant would need to maintain in order to meet each requirement. Without this comparison (or in the absence of procedures that address this comparison), the WLA representing the more critical condition cannot be determined. A treatment system will only need to be designed to meet one level of

Box 5-2. Calculating Permit Limits Based on Two-Value Wasteload Allocation

To set maximum daily and average monthly permit limits based on acute and chronic wasteload allocations, use the following four steps:

1. Convert the acute wasteload allocation to chronic toxic units. Skip to Step 2 for chemical-specific limits.
2. Calculate the long-term average wasteload that will satisfy the acute and chronic wasteload allocations.
3. Determine the lower (more limiting) of the two long-term averages.
4. Calculate the maximum daily and average monthly permit limits using the lower (more limiting) long-term average.

Term	Meaning
CV	Coefficient of variation
σ	Standard deviation
$WLA_{a,c}$	Acute wasteload allocation in chronic toxic units
WLA_a	Acute wasteload allocation in acute toxic units
WLA_c	Chronic wasteload allocation in chronic toxic units
LTA_{ac}	Acute long-term average wasteload in chronic units
LTA_c	Chronic long-term average wasteload
TU_a	Acute toxic units
TU_c	Chronic toxic units
ACR	Acute-to-chronic ratio
MDL	Maximum daily limit
AML	Average monthly limit
z	z statistic

Step 1 *(for whole effluent toxicity only)*

$$WLA_{ac}\ (in\ TU_c) = WLA_a\ (in\ TU_a) \bullet ACR$$

Step 2 *(start here for chemical specific limits)*

$$LTA_{a,c} = WLA_{a,c} \bullet e^{[0.5\sigma^2 - z\sigma]}$$

where $\sigma^2 = \ln(CV^2+1)$
z = 1.645 for 95th percentile probability basis, and
z = 2.326 for 99th percentile probability basis

$$LTA_c = WLA_c \bullet e^{[0.5\sigma_4^2 - z\sigma_4]}$$

where $\sigma_4^2 = \ln(CV^2/4 + 1)$
z = 1.645 for 95th percentile probability basis, and
z = 2.326 for 99th percentile probability basis

Step 3

$$LTA = \min(LTA_c, LTA_{a,c})$$

Step 4

$$MDL = LTA \bullet e^{[z\sigma - 0.5\sigma^2]}$$

where $\sigma^2 = \ln(CV^2+1)$
z = 1.645 for 95th percentile probability basis, and
z = 2.326 for 99th percentile probability basis

$$AML = LTA \bullet e^{[z\sigma_n - 0.5\sigma_n^2]}$$

where $\sigma_n^2 = \ln(CV^2/n + 1)$
z = 1.645 for 95th percentile probability basis, and
z = 2.326 for 99th percentile probability basis

*Full details of this procedure are found in Appendix E.

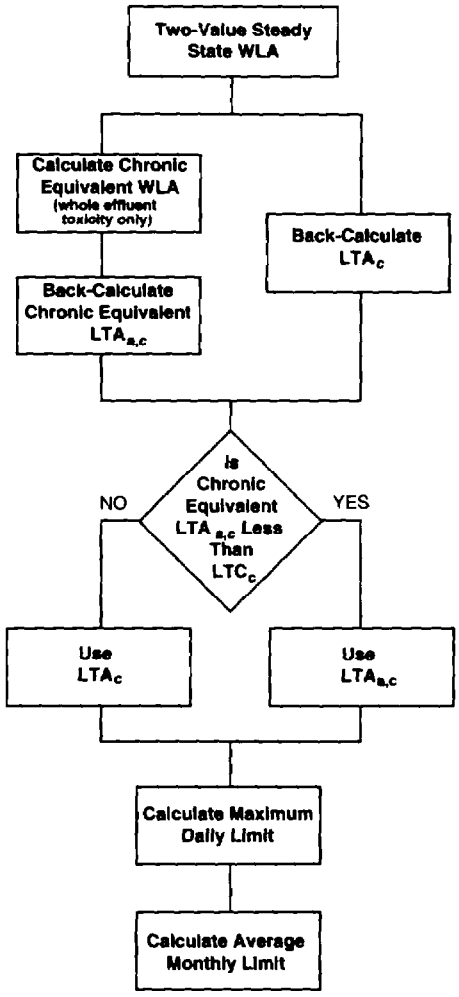

Figure 5-4. Flowchart for Calculating Permit Limits From Two-Value, Steady-State Wasteload Allocation for Aquatic Life Protection

treatment for effluent toxicity—treatment needed to control the most limiting toxic effect.

- The actual number of samples can be factored into permit limit derivation procedures. The procedure provides the means to accurately determine the AML based on the number of observations that will be taken.

The principal disadvantages of this approach are:

- Some permit writers have indicated that additional mathematical calculations associated with these procedures increase the burden for the permit writer and add what is perceived to be an unnecessary step.
- The use of a steady-state WLA may result in permit limits that are more conservative due to the assumption of critical conditions. However, these limits are still protective of water quality criteria. The level of conservatism may be necessary in those instances where limited data prevent a more precise evaluation of a WLA.

This procedure provides a toxicologically sound approach. To help the permit writer, EPA has developed tables (see Tables 5-1 and 5-2) to be used to quickly determine the necessary values. In addition, some permit authorities have developed their own computer programs to readily compute the necessary information from the appropriate inputs.

Permit Limit Derivation From Dynamic Model Outputs

The least ambiguous and most exact way that a WLA for specific chemicals or for whole effluent toxicity can be specified by using dynamic modeling from which the WLA is expressed as a required effluent performance in terms of the LTA and CV of the daily values. When a WLA is expressed as such, there is no confusion about assumptions used and the translation to permit limits. A permit writer can readily design permit limits to achieve the WLA objectives. The types of dynamic exposure analyses that yield a WLA in terms of required performance are the continuous simulation, Monte Carlo, and lognormal probabilities analyses. Chapter 4 provides a general discussion of these models. Guidance manuals for developing WLAs are listed in the references at the end of Chapter 4. Once the WLA is determined, the permit limit derivation procedure which can be used for both whole effluent toxicity and specific chemicals, is as follows:

- The WLA is first developed by iteratively running the dynamic model with successively lower LTAs until the model shows compliance with the water quality standards.
- The effluent LTA and CV must then be calculated from the model effluent inputs used to show compliance with the water quality standards. This step is only necessary for the Monte Carlo and continuous simulation methods.
- The permit limit derivation procedures described in Box 5-2, Step 4 are used to derive MDLs and AMLs from the required effluent LTA and CV. Unlike these procedures for steady-state WLAs, there is only a single LTA that provides both acute and chronic protection, and, therefore, the comparison step indicated in Figure 5-4 and Box 5-2 is unnecessary.

The principal advantages of this procedure are:

- It provides a mechanism for computing permit limits that are toxicologically protective. As with the procedure summarized below for two-value, steady-state WLA outputs, the permit limit derivation procedures used with this type of output consider effluent variability and derive permit limits from a single limiting LTA and CV.
- Actual number of samples is factored into permit limit derivation procedures. This procedure has the same elements as discussed for the statistical procedures in Option 2 below.
- Dynamic modeling determines an LTA that will be adequately protective of the WLA, which relies on actual flow data thereby reducing the need to rely on worst case critical flow condition assumptions.

Table 5-1. Back Calculations of Long-Term Average

CV	WLA Multipliers $e^{[0.5\,\sigma^2 - z\sigma]}$ 95th Percentile	WLA Multipliers $e^{[0.5\,\sigma^2 - z\sigma]}$ 99th Percentile
0.1	0.853	0.797
0.2	0.736	0.643
0.3	0.644	0.527
0.4	0.571	0.440
0.5	0.514	0.373
0.6	0.468	0.321
0.7	0.432	0.281
0.8	0.403	0.249
0.9	0.379	0.224
1.0	0.360	0.204
1.1	0.344	0.187
1.2	0.330	0.174
1.3	0.319	0.162
1.4	0.310	0.153
1.5	0.302	0.144
1.6	0.296	0.137
1.7	0.290	0.131
1.8	0.285	0.126
1.9	0.281	0.121
2.0	0.277	0.117

Acute

$$LTA_{a,c} = WLA_{a,c} \cdot e^{[0.5\,\sigma^2 - z\sigma]}$$

where $\sigma^2 = ln\,[CV^2 + 1]$,
z = 1.645 for 95th percentile occurrence probability, and
z = 2.326 for 99th percentile occurrence probability

Chronic
(4-day average)

$$LTA_c = WLA_c \cdot e^{[0.5\,\sigma_4^2 - z\,\sigma_4]}$$

where $\sigma_4^2 = ln\,[CV^2/4 + 1]$,
z = 1.645 for 95th percentile occurrence probability, and
z = 2.326 for 99th percentile occurrence probability

CV	WLA Multipliers $e^{[0.5\,\sigma_4^2 - z\,\sigma_4]}$ 95th Percentile	WLA Multipliers $e^{[0.5\,\sigma_4^2 - z\,\sigma_4]}$ 99th Percentile
0.1	0.922	0.891
0.2	0.853	0.797
0.3	0.791	0.715
0.4	0.736	0.643
0.5	0.687	0.581
0.6	0.644	0.527
0.7	0.606	0.481
0.8	0.571	0.440
0.9	0.541	0.404
1.0	0.514	0.373
1.1	0.490	0.345
1.2	0.468	0.321
1.3	0.449	0.300
1.4	0.432	0.281
1.5	0.417	0.264
1.6	0.403	0.249
1.7	0.390	0.236
1.8	0.379	0.224
1.9	0.369	0.214
2.0	0.360	0.204

The principal disadvantages of this procedure are:

- Necessary data for effluent variability and receiving water flows may be unavailable, which prevents the use of this approach.
- The amount of staff resources needed to explain how the limits were developed and to conduct the WLA also is a concern. The permit documentation (i.e., fact sheet) will need to clearly explain the basis for the LTA and CV and this can be resource intensive.

Permit Limit Derivation From Single, Steady-State Model Output

Some State water quality criteria and the corresponding WLAs are reported as a single value from which to define an acceptable level of effluent quality. For example, "copper concentration must not exceed 0.75 milligrams per liter (mg/l) instream." Steady-state analyses assume that the effluent is constant and, therefore, the WLA value will never be exceeded. This presents a problem in deriving permit limits because permit limits need to consider effluent variability.

Table 5-2. Calculation of Permit Limits

CV	LTA multipliers $e^{[z\sigma - 0.5\sigma^2]}$ 95th Percentile	LTA multipliers $e^{[z\sigma - 0.5\sigma^2]}$ 99th Percentile
0.1	1.17	1.25
0.2	1.36	1.55
0.3	1.55	1.90
0.4	1.75	2.27
0.5	1.95	2.68
0.6	2.13	3.11
0.7	2.31	3.56
0.8	2.48	4.01
0.9	2.64	4.46
1.0	2.78	4.90
1.1	2.91	5.34
1.2	3.03	5.76
1.3	3.13	6.17
1.4	3.23	6.56
1.5	3.31	6.93
1.6	3.38	7.29
1.7	3.45	7.63
1.8	3.51	7.95
1.9	3.56	8.26
2.0	3.60	8.55

Maximum Daily Limit

$$MDL = LTA \bullet e^{[z\sigma - 0.5\sigma^2]}$$

where $\sigma^2 = ln[CV^2 + 1]$,
z = 1.645 for 95th percentile occurrence probability, and
z = 2.326 for 99th percentile occurrence probability

Average Monthly Limit

$$AML = LTA \bullet e^{[z\sigma_n - 0.5\sigma_n^2]}$$

where $\sigma_n^2 = ln[CV^2/n + 1]$,
z = 1.645 for 95th percentile,
z = 2.326 for 99th percentile, and
n = number of samples/month

CV	LTA Multipliers $e^{[z\sigma_n - 0.5\sigma_n^2]}$ 95th Percentile n=1	n=2	n=4	n=10	n=30	99th Percentile n=1	n=2	n=4	n=10	n=30
0.1	1.17	1.12	1.08	1.06	1.03	1.25	1.18	1.12	1.08	1.04
0.2	1.36	1.25	1.17	1.12	1.06	1.55	1.37	1.25	1.16	1.09
0.3	1.55	1.38	1.26	1.18	1.09	1.90	1.59	1.40	1.24	1.13
0.4	1.75	1.52	1.36	1.25	1.12	2.27	1.83	1.55	1.33	1.18
0.5	1.95	1.66	1.45	1.31	1.16	2.68	2.09	1.72	1.42	1.23
0.6	2.13	1.80	1.55	1.38	1.19	3.11	2.37	1.90	1.52	1.28
0.7	2.31	1.94	1.65	1.45	1.22	3.56	2.66	2.08	1.62	1.33
0.8	2.48	2.07	1.75	1.52	1.26	4.01	2.96	2.27	1.73	1.39
0.9	2.64	2.20	1.85	1.59	1.29	4.46	3.28	2.48	1.84	1.44
1.0	2.78	2.33	1.95	1.66	1.33	4.90	3.59	2.68	1.96	1.50
1.1	2.91	2.45	2.04	1.73	1.36	5.34	3.91	2.90	2.07	1.56
1.2	3.03	2.56	2.13	1.80	1.39	5.76	4.23	3.11	2.19	1.62
1.3	3.13	2.67	2.23	1.87	1.43	6.17	4.55	3.34	2.32	1.68
1.4	3.23	2.77	2.31	1.94	1.47	6.56	4.86	3.56	2.45	1.74
1.5	3.31	2.86	2.40	2.00	1.50	6.93	5.17	3.78	2.58	1.80
1.6	3.38	2.95	2.48	2.07	1.54	7.29	5.47	4.01	2.71	1.87
1.7	3.45	3.03	2.56	2.14	1.57	7.63	5.77	4.23	2.84	1.93
1.8	3.51	3.10	2.64	2.20	1.61	7.95	6.06	4.46	2.98	2.00
1.9	3.56	3.17	2.71	2.27	1.64	8.26	6.34	4.68	3.12	2.07
2.0	3.60	3.23	2.78	2.33	1.68	8.55	6.61	4.90	3.26	2.14

The proper enforcement of this type of WLA depends on the parameter limited. For nutrients and biochemical oxygen demand (BOD), the WLA value generally has been used as the average daily permit limit. However, the impact associated with toxic pollutants is more time dependent, as reflected in the 4-day average duration for the criteria continuous concentration (CCC) (see Chapter 2). Where there is only one water quality criterion and therefore only one WLA, permit limits can be developed using the following procedure:

- Consider the single WLA to be the chronic WLA and derive an chronic LTA for this WLA using the procedures in Box 5-2 (Step 2, Part 2).
- Derive MDLs and AMLs using the procedures in Box 5-2 (Step 4).

The principal advantages and disadvantages of this procedure are similar to those for the two-value permit limit derivation method discussed previously except that it does not examine two WLAs.

5.4.2 Other Approaches to Permitting for Aquatic Life

Other approaches for translating WLA outputs into permit limits have been used by some permitting authorities. These methods may combine elements of the statistical procedures discussed earlier with specific technical and policy requirements of the permitting authority to derive limits that may be protective of water quality and consistent with the requirements of the WLA. Such approaches may use simplified statistical procedures.

For example, some permitting authorities assume a value for the CV and an acute to chronic ratio above which the chronic WLA will always be more limiting. Where such simplifying assumptions are used, the need to compare LTAs derived from acute and chronic steady-state models is unnecessary. Similarly, for assumed values for n, CV, and exceedence probability, the various equations shown in Box 5-2 can be simplified further, such that the AML will always be a constant fraction of the MDL.

These approaches allow the permit writer to rapidly and easily translate the results of WLAs into permit limits. However, the permit writer clearly should understand the underlying procedures and carefully explain the basis for the chosen assumption. Appropriate State or regional guidance documents also should be referenced.

Another approach used by some permit authorities involves the direct use of the WLA as a permit limit. This approach sometimes involves the following steps:

- The WLA value for toxic pollutants is used as the MDL.
- In the absence of other information, permit writers typically divide the MDL by 1.5 or 2.0 to derive an AML (depending on the expected range of variability).

The principal advantage of this approach is that it is very straightforward to implement and requires minimal resources. The disadvantage of this option is that the average monthly limits must be derived without any information about the variability of the effluent parameter; therefore, the permit writer cannot be sure that these procedures are protective of water quality criteria. Conversely, limits derived from this approach may be overly stringent and subject to challenge.

The direct application of both the acute and chronic WLAs as permit limits is another approach that has been used. The WLA developed for protection against chronic effects becomes the average monthly limit and the acute WLA becomes the MDL. **EPA discourages the use of this approach.** Since effluent variability has not been specifically addressed with this approach, compliance with the monthly average (30-day) effluent limit during critical conditions could exceed the chronic (4-day) WLA. Whether standards are violated with excessive frequency under such conditions would depend upon whether the conditions represented by the worst-case assumptions of the model also were occurring at the same time. By contrast, compliance with limits that were developed using statistical procedures have a low chance of leading to WLA excursions before effluent variability is accounted for in deriving the limits (see Figure 5-3).

Another permitting approach is to use a narrative "no toxicity" limit that is measured using a toxicity testing method that employs only a control and a single exposure at the receiving water concentration (RWC). This is sometimes referred to as a "pass/fail" toxicity test. Although these tests can be less expensive than full dilution series testing, they provide no knowledge as to the extent of toxicity present during the test and therefore no data concerning the seriousness of the impact or the amount of toxicity reduction necessary. The death of a single test animal can occur at any concentration level beyond the lethality threshold for the test organism; therefore, such a test is much less powerful from a statistical standpoint. In addition, it is not possible to determine dose-response relationships for the test organisms without using multiple effluent concentrations. Dose-response curves are useful in determining quality assurance of the tests and in defining threshold dosages for regulatory purposes. Because the drawbacks of the approach generally outweigh the benefits, **EPA recommends that whole effluent toxicity limits be established using a statistical derivation procedure that adequately accounts for effluent variability and that monitoring for compliance with whole effluent toxicity limits be conducted using a full dilution series.**

When setting a whole effluent toxicity limit to protect against acute effects, some permitting authorities use an end-of-pipe approach. Typically, these limits are established as an LC_{50}>100-percent effluent at the end of the pipe. These limits are routinely set without any consideration as to the fate of the effluent and the concentrations of toxicant(s) after the discharge enters the receiving water. Limits derived in this way are not water quality-based limits and suffer from significant deficiencies since the toxicity of a pollutant depends mostly upon concentration, duration of exposure, and repetitiveness of the exposure. This is especially true in effluent dominated waters. For example, an effluent that has an LC_{50}=100 percent contains enough toxicity to be lethal to up to 50 percent of the test organisms. If the effluent is discharged to a low-flow receiving waterbody that provides no more than a threefold dilution at the critical flow, significant mortality can occur in the receiving water. Furthermore, such a limit could not assure protection against chronic effects in the receiving waterbody. Chronic effects could occur if the dilution in the receiving water multiplied by the acute to chronic ratio is greater than 100 percent. Therefore, in effluent dominated situations, limits set using this approach may be severely underprotective. In contrast, whole effluent toxicity limits set using this approach in very high receiving water flow conditions may be overly restrictive. **Because of these problems, EPA recommends that all whole effluent toxicity limits be set as water quality-based limits and that to do so, the statistical permit limit derivation procedures discussed in Section 5.4.1 be followed.**

5.4.3 Special Permitting Requirements

Water quality-based permit limit development for discharges to marine and estuarine waters follows the same basic steps as the water quality-based approach for freshwater discharges. There are some differences in the water quality criteria used as the basis for protection, the designation of mixing zones, and the water quality models used to develop WLAs; however these differences are addressed in the WLA. (See discussions of these elements in previous chapters.) In addition, there are some special regulatory considerations associated with these types of dischargers, including special reviews of permits with such programs as the Coastal Zone Management Program. Some discharges also require an Ocean Discharge Criteria Evaluation under Section 403(c) of the Clean Water Act (CWA).

5.4.4 EPA Recommendations for Permitting for Human Health Protection

Permit development to protect against certain routes of exposure is another key consideration. Ingesting contaminated fish and shellfish is a toxic chemical exposure route of serious potential

human health concern for which there is no intervening treatment process, unlike the drinking water route of exposure. Effluent limits designed to meet aquatic life criteria for individual toxicants and whole effluent toxicity are not necessarily protective of toxic pollutant residue formation in fish or shellfish tissue.

Developing permit limits for pollutants affecting human health is somewhat different from setting limits for other pollutants because the exposure period is generally longer than 1 month, and can be up to 70 years, and the average exposure rather than the maximum exposure is usually of concern. Because compliance with permit limits is normally determined on a daily or monthly basis, it is necessary to set human health permit limits that meet a given WLA for every month. If the procedures described previously for aquatic life protection were used for developing permit limits for human health pollutants, both MDLs and AMLs would exceed the WLA necessary to meet criteria concentrations. Thus, even if a facility was discharging in compliance with permit limits calculated using these procedures, it would be possible to constantly exceed the WLA. This approach clearly is unacceptable. In addition, the statistical derivation procedure is not applicable to exposure periods more than 30 days. Therefore, the recommended approach for setting water quality-based limits for human health protection with statistical procedures is as follows:

- Set the AML equal to the WLA
- Calculate the MDL based on effluent variability and the number of samples per month using the multipliers provided in Table 5-3.

This approach ensures that the instream criteria will be met over the long-term and provides a defensible method for calculating a MDL. Both an MDL (weekly average limit for POTWs) and a monthly average limit are required by EPA regulations, unless impracticable (40 *CFR* 122.45(d)) and are applicable for human health protection. The MDL sets an upper bound on effluent values used to determine the monthly average and provides a measure of effluent compliance during operational periods between monthly sampling.

5.5 SPECIAL CONSIDERATIONS IN USE OF STATISTICAL PERMIT LIMIT DERIVATION TECHNIQUES

The following discussion summarizes the effect of changes in the various statistical parameters on the permit limits that are derived. An understanding of these relationships is important for the permit writer. Additional considerations of each of these parameters with respect to the statistical methods for permit limit derivation also are discussed below.

5.5.1 Effect of Changes of Statistical Parameters on Permit Limits

- **Effect of changes in CV on derivation of LTA from WLA:** As the CV increases, the LTA decreases; and conversely, as the CV decreases, the LTA increases (see Figure 5-5).

  Reason: The LTA must be lower relative to the WLA to account for the extreme values observed with high CVs. An LTA with a zero CV equals the WLA.

- **Effect of changes in CV on derivation of permit limits for a fixed probability basis:** As the CV increases, the permit limits increase (become less stringent); and conversely, as the CV decreases, the permit limits decrease (become more stringent; see Figure 5-6).

  Reason: A higher value for the permit limit is produced for the same LTAs as the CV increases in order to allow for fluctuations about the mean. Following the steps in Box 5-2 to derive the LTA will account for such fluctuations.

- **Effect of changes in number of monthly samples on permit limits:** As the value for "n" (number of observations) increases in the average monthly permit limit derivation equations, the average monthly permit limit decreases to a certain point. The effect on the average monthly limit is minimal for values of n greater than approximately 10. Conversely, as the value for "n" decreases, the AML increases until n=1, at which point the AML equals the MDL (see Figure 5-7).

  Reason: As n increases, the probability distribution of the n-day average values becomes less variable (narrower) around the LTA. Therefore, the 95th or 99th percentile value for an n-day average decreases in absolute value as n increases. (See additional discussion in Section 5.5.3.)

- Effect **of changes in probability basis for permit limits:** As the probability basis for the permit limits expressed in percentiles (e.g., 95 percent and 99 percent) increases, the value for the permit limits increases (becomes less stringent). The converse is true as the probability basis decreases (see Figure 5-6).

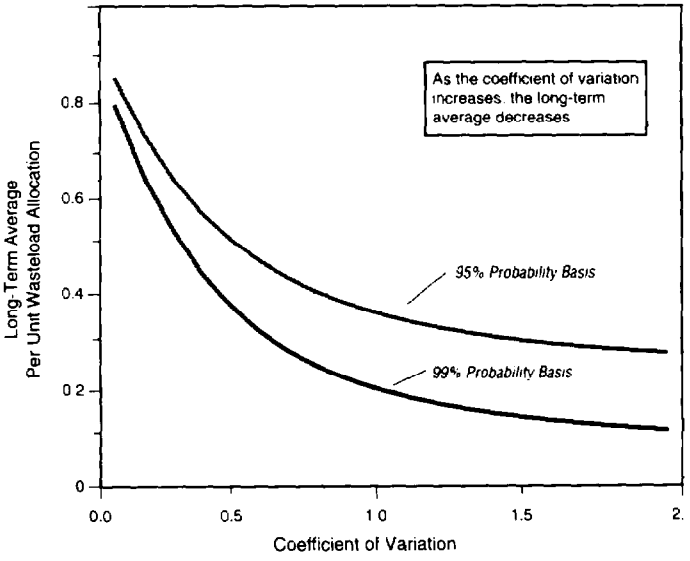

Figure 5-5. Long-Term Average as a Function of the Coefficient of Variation

Reason: There is a higher probability that any randomly chosen effluent sample will be in compliance with its permit limits, if those limits are statistically designed to be greater than a high percentage (e.g., 99 percent) of all possible values for a given LTA and CV.

The overall combination of the coefficient of variation, number of samples, and the assumed probability basis for calculating the LTA from the WLA, and the most limiting LTA, has different effects on the derived limits depending upon the selection made for each. To help illustrate the combined effect of these factors, Figure 5-8 illustrates how the CV, number of samples and probability basis affect the derivation of the AML. Figure 5-9 illustrates the combined effect of the CV and the probability basis on the derivation of the MDL.

5.5.2 Coefficient of Variation

Use of the statistical method of permit limit derivation requires an estimate of the CV of the distribution of the daily measurements of the parameter after the plant complies with the requirements.

Table 5-3. Multipliers for Calculating Maximum Daily Permit Limits From Average Monthly Permit Limits

To obtain the maximum daily permit limit (MDL) for a bioconcentratable pollutant, multiply the average monthly permit limit (AML) (the wasteload allocation) by the appropriate value in the following table.

Each value in the table is the ratio of the MDL to the AML as calculated by the following relationship derived from Step 4 of the statistically based permit limit calculation procedure.

$$\frac{MDL}{AML} = \frac{\exp\,[z_m\sigma - 0.5\sigma^2]}{\exp\,[z_a\sigma_n - 0.5\sigma_n^2]}$$

where

$\sigma_n^2 = \ln(CV^2/n + 1)$
$\sigma^2 = \ln(CV^2 + 1)$
CV = the coefficient of variation of the effluent concentration
n = the number of samples per month
z_m = the percentile exceedance probability for the MDL
z_a = the percentile exceedance probability for the AML.

Ratio Between Maximum Daily and Average Monthly Permit Limits

	Maximum = 99th percentile Average = 95th percentile					Maximum = 99th percentile Average = 99th percentile				
CV	n=1	n=2	n=4	n=8	n=30	n=1	n=2	n=4	n=8	n=30
0.1	1.07	1.13	1.16	1.18	1.22	1.00	1.07	1.12	1.16	1.20
0.2	1.14	1.25	1.33	1.39	1.46	1.00	1.13	1.24	1.32	1.43
0.3	1.22	1.37	1.50	1.60	1.74	1.00	1.19	1.36	1.49	1.67
0.4	1.30	1.50	1.67	1.82	2.02	1.00	1.24	1.46	1.66	1.92
0.5	1.38	1.622	1.84	2.04	2.32	1.00	1.28	1.56	1.81	2.18
0.6	1.46	1.73	2.01	2.25	2.62	1.00	1.31	1.64	1.95	2.43
0.7	1.54	1.84	2.16	2.45	2.91	1.00	1.34	1.71	2.08	2.67
0.8	1.61	1.94	2.29	2.64	3.19	1.00	1.35	1.76	2.19	2.89
0.9	1.69	2.03	2.41	2.81	3.45	1.00	1.36	1.80	2.27	3.09
1.0	1.76	2.11	2.52	2.96	3.70	1.00	1.37	1.83	2.34	3.27
1.1	1.83	2.18	2.62	3.09	3.93	1.00	1.37	1.84	2.39	3.43
1.2	1.90	2.25	2.70	3.20	4.13	1.00	1.36	1.85	2.43	3.56
1.3	1.97	2.31	2.77	3.30	4.31	1.00	1.36	1.85	2.45	3.68
1.4	2.03	2.37	2.83	3.39	4.47	1.00	1.35	1.84	2.46	3.77
1.5	2.09	2.42	2.89	3.46	4.62	1.00	1.34	1.83	2.46	3.84
1.6	2.15	2.42	2.89	3.46	4.62	1.00	1.33	1.82	2.46	3.90
1.7	2.21	2.52	2.98	3.57	4.85	1.00	1.32	1.80	2.45	3.94
1.8	2.27	2.56	3.01	3.61	4.94	1.00	1.31	1.78	2.43	3.97
1.9	2.32	2.60	3.05	3.65	5.02	1.00	1.30	1.76	2.41	3.99
2.0	2.37	2.64	3.07	3.67	5.09	1.00	1.29	1.74	2.38	4.00

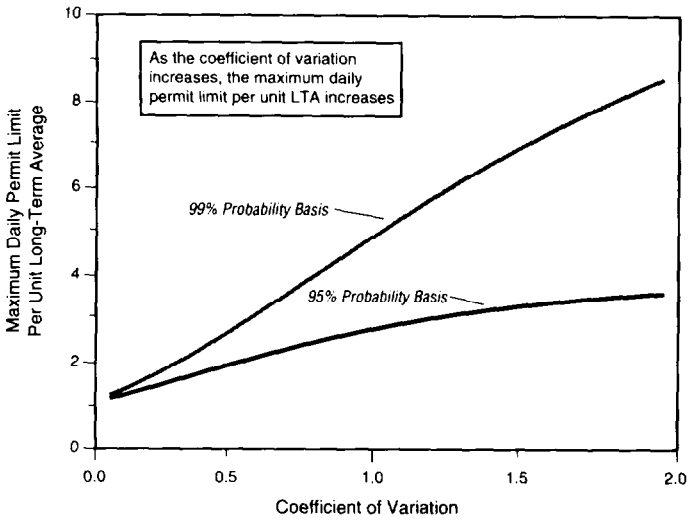

Figure 5-6. Maximum Daily Permit Limit as a Function of the Coefficient of Variation

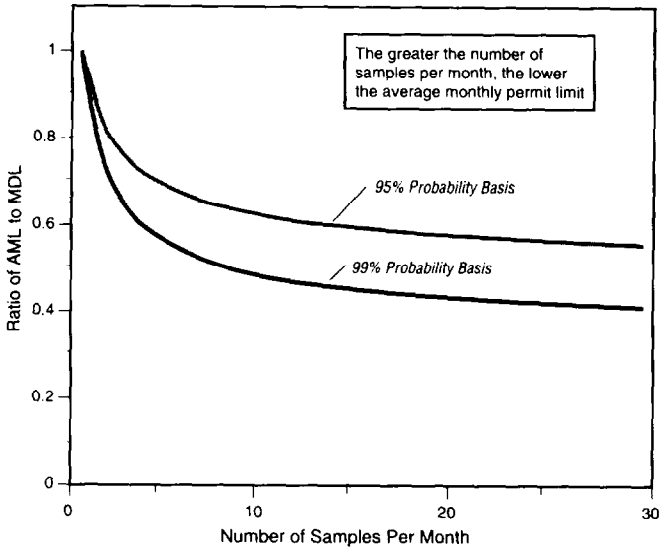

Figure 5-7. Relationship Between Average Monthly Permit Limits and Number of Samples Per Month

If variability is mostly related to production, current data may be used to estimate the CV. If future variability is expected to be substantially different, the CV must be estimated. Discharges of toxic pollutants are generally more variable than discharges of conventional pollutants. It is important to use the best estimate of the CV that can be reasonably achieved. As explained in Chapter 3, EPA's review of the uncertainty associated with effluent variability suggests that a minimum of 10 samples is needed to reasonably quantify the CV.

One concern with respect to using an appropriate CV in the statistical limit derivation procedures is that CVs of regulated systems may be quite different from nonregulated systems. In other words, after permit limits are in place and the permittee is operating to achieve the requisite limits, the variability associated with the parameter of concern may change considerably. Where the permit writer has reason to believe that the CV of the regulated system may behave differently from the nonregulated system (e.g., where changes in the treatment facility are planned), information concerning effluent concentration means and variability can be obtained from effluent guideline documents for individual chemical parameters.

Variability associated with effluent levels of both individual chemicals and whole effluent toxicity is difficult to predict for any individual situation. However, it is important to recognize that failure to assign any CV to an individual toxicant or the parameter toxicity involves an implicit assumption that there is no effluent variability present. Based upon analyses of a wide variety of data from various types of plants, **EPA recommends a value of 0.6 as a default CV, if the regulatory authority does not have more accurate information on the CV for the pollutant or pollutant parameter.** Permit limits are usually not extremely sensitive to small changes in the CV. The value of 0.6 is typical of the range of variability of effluents measured by EPA (see Appendix A) and represents a reasonable degree of relative variability. However, wherever possible, it is recommended that data on effluent variability for the pollutant of concern be collected to define a CV rather than selecting a default value.

5.5.3 Number of Samples

The statistically based method for permit limit derivation results in an MDL that does not depend on monitoring frequency. However, the AML decreases as the monitoring frequency increases, and a greater number for "n" is inserted in the relevant equations. Some permit writers are concerned with this outcome because facilities with more frequent sampling requirements appear to receive more stringent permit limits than those with less frequent monthly sampling requirements.

The AML decreases as the number of monthly samples increases because an average of 10 samples, for example, is closer to the LTA than an average based on 4 samples. This phenomenon makes AMLs based on 10 samples appear to be more stringent than the monthly limit based on 4 samples. However, the stringency of these procedures is constant across monitoring frequencies because the probability basis and the targeted LTA performance are the same regardless of the number of samples taken. Thus, a permittee performing according to the LTA and variability associated with the wasteload allocation will, in fact, meet either of these AMLs when taking the corresponding number of monthly samples.

For water quality-based permitting, effluent quality is determined by the underlying distribution of daily values, which is determined by the LTA associated with a particular WLA and by the CV of the effluent concentrations. Increasing or decreasing monitoring frequency does not affect this underlying distribution or treatment performance, which should, at a minimum, be targeted to comply with the values dictated by the WLA. **Therefore, it is recommended that the actual planned frequency of monitoring normally be used to determine the value of n for calculating the AML. However, in situations where monitoring frequency is once per month or less, a higher value for n must be assumed for AML derivation purposes.** This is particularly applicable for addressing situations such as where a single criterion is applied at the end of the pipe and a single monthly sample

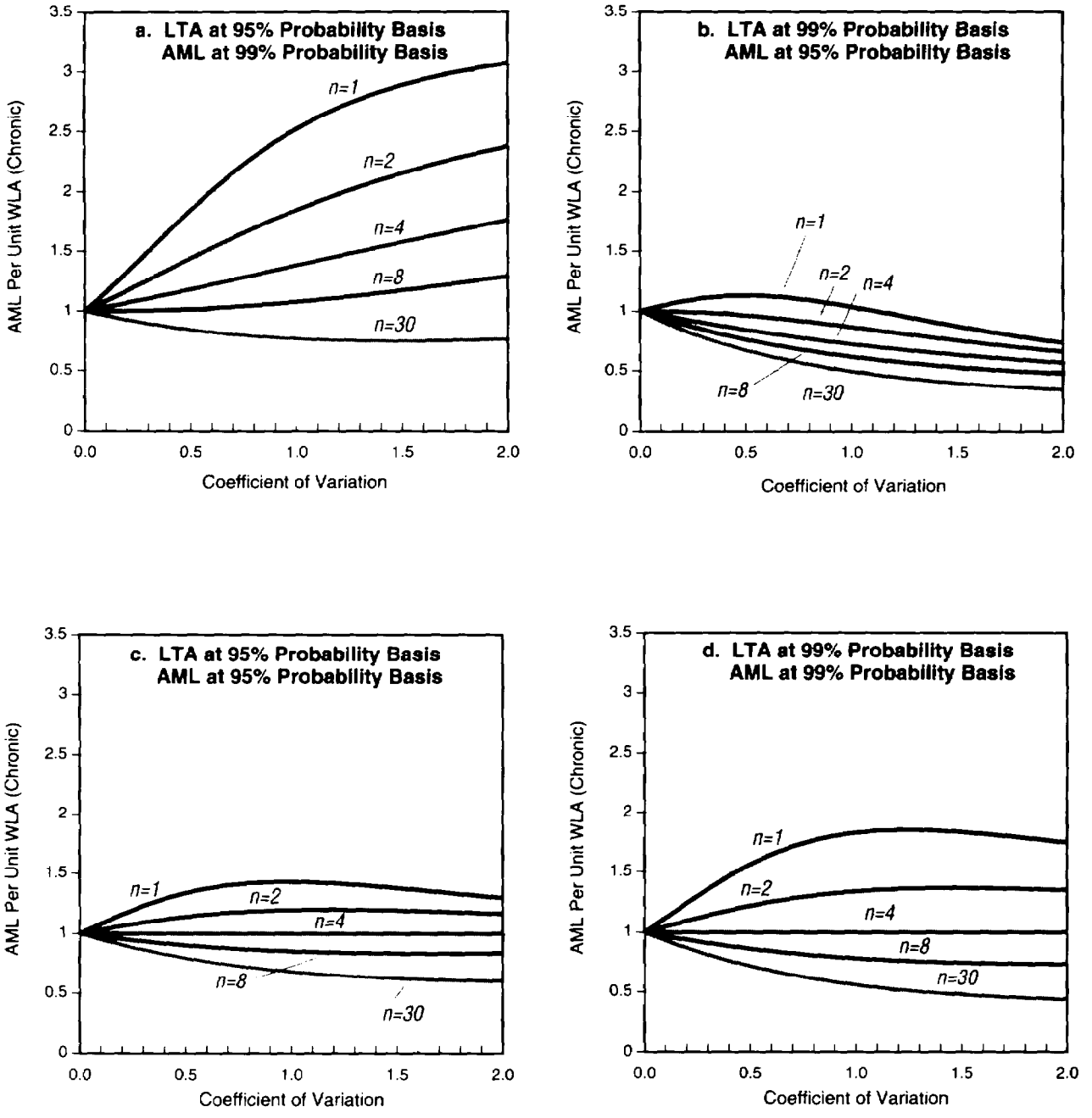

Figure 5-8. Effect of Coefficient of Variation on Average Monthly Limits

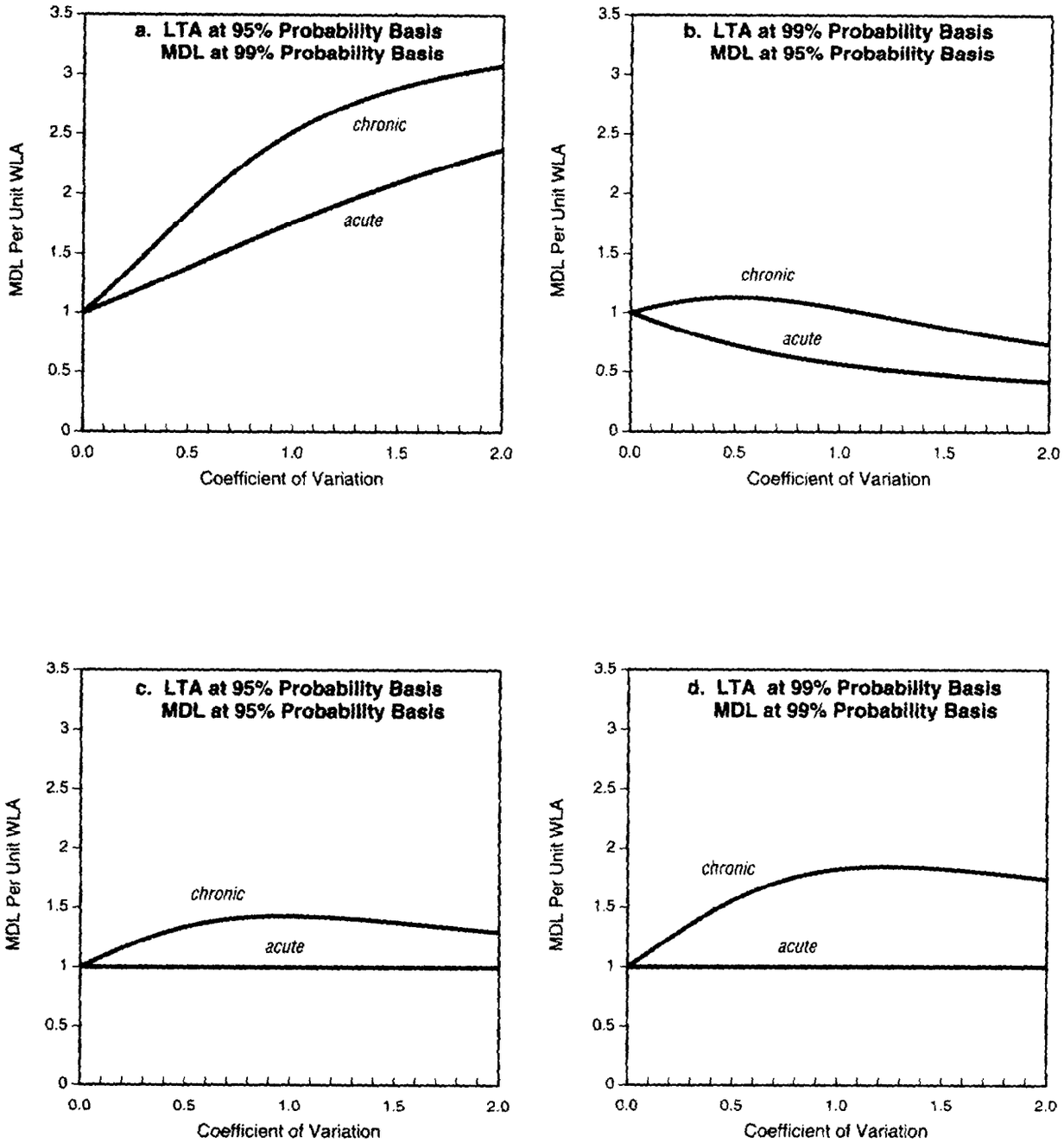

Figure 5-9. Effect of Coefficient of Variation on Maximum Daily Limits

is contemplated for compliance monitoring purposes, or where monitoring frequency is only quarterly. In this case, both the average monthly and the MDL would exceed the criterion. (For example, for a CCC of 1.0 chronic toxic unit [TU_C] applied as a WLA at the end of the pipe, both the MDL and AML would be 1.6 TU_C; assuming CV=0.6, n=1, and a 99-percent probability basis.) A discharger could thus comply with the permit limit but routinely exceed the criterion. **Under these circumstances, the statistical procedure should be employed using an assumed number of samples of at least <u>four</u> for the AML derivation.**

5.5.4 Probability Basis

Selection of the probability basis for use in the equations in Boxes 5-1 and 5-2 is a permitting authority decision necessary for establishing statistically derived permit limits. **Where a permitting authority does not have specific guidance for the probability basis, EPA recommends the following:**

For calculation of the LTAs from the WLAs (Box 5-2):

- Both acute and chronic WLA—.01 probability (99th percentile level).

For calculation of permit limits from the most limiting LTA (Box 5-1):

- MDL—.01 probability basis (99th percentile level)
- AML—.05 probability basis (95th percentile level).

The probability levels for deriving permit limits have been used historically in connection with development of the effluent limits guidelines and have been upheld in legal challenges to the guidelines [4]. It is important to note that these levels are statistical probabilities used as the basis for developing limits. The goal in establishing these levels is to allow the regulatory agency to distinguish between adequately operated wastewater treatment plants with normal variability from poorly operated treatment plants and to protect water quality criteria.

The level for the calculation of the LTA from the WLA is based upon EPA's interpretation of the steady state model used to develop the WLA. EPA considers the WLA to produce an effluent condition that should never be exceeded whenever the critical design conditions occur. To characterize this effluent condition, EPA uses the 99th percentile concentration from the upper tail of the effluent probabilistic distribution curve. The selection of this value is one which can have a significant influence on the level of conservatism in the permit limits. Permit authorities should consider Figures 5-8 and 5-9 to understand the effect of this decision along with other decisions on the AMLs and MDLs.

5.6 PERMIT DOCUMENTATION

The fact sheet and supporting documentation accompanying the permit must clearly explain the basis and the rationale for the permit limits. When the permit is in the draft stage, the supporting documentation will serve to explain the rationale and assumptions used in deriving the limits to the permittee and the general public in order to allow public comment on the draft permit. When the permit is issued, the administrative record for the facility (particularly the fact sheet) will be the primary support for defending the permit in administrative appeals including evidentiary hearings. This information also will serve to alert compliance/enforcement personnel to any special considerations that were addressed at the time of permit issuance. In addition, the accompanying documentation will be extremely important during permit reissuance and will assist the permit writer in developing a revised permit.

In 40 *CFR* Part 124.56, a fact sheet containing "[a]ny calculations or other necessary explanation of the derivation of specific effluent limitations" for many draft permits is required. Accordingly, the WLAs along with the required LTA and CV used and the calculations deriving them must be included or referenced in the fact sheet. The permit limit derivation method used must also be explained in the permit documentation. Where a permitting authority develops a standardized and simplified method for permit limit development as discussed in Section 5.4.2, the permitting authority may not need to document all of the underlying assumptions in the fact sheet, provided that the fact sheet references a written permit limit development protocol. Any other guidance used must also be cited.

5.7 EXPRESSING LIMITS AND DEVELOPING MONITORING REQUIREMENTS

Limits must be expressed clearly in the NPDES permit so that they clearly are enforceable and unambiguous. Chapter 6 discusses compliance monitoring and enforcement problems that can result from improperly expressed limits. All limits, both chemical-specific and whole effluent, should appear in Part 1 of the permit. Special considerations in the use of both chemical-specific and whole effluent toxicity limits are discussed below.

5.7.1 Mass-based Effluent Limits

Mass-based effluent limits are required by NPDES regulations at 40 *CFR* 122.45(f). The regulation requires that all pollutants limited in NPDES permits have limits, standards, or prohibitions expressed in terms of mass with three exceptions, including one for pollutants that cannot be expressed appropriately by mass. Examples of such pollutants are pH, temperature, radiation, and whole effluent toxicity. Mass limitations in terms of pounds per day or kilograms per day can be calculated for all chemical-specific toxics such as chlorine or chromium. Mass-based limits should be calculated using concentration limits at critical flows. For example, a permit limit of 10 mg/l of cadmium discharged at an average rate of 1 million gallons per day also would contain a limit of 38 kilograms/day of cadmium.

Mass-based limits are particularly important for control of bioconcentratable pollutants. Concentration-based limits will not adequately control discharges of these pollutants if the effluent concentrations are below detection levels. For these pollutants, controlling mass loadings to the receiving water is critical for preventing adverse environmental impacts.

However, mass-based effluent limits alone may not assure attainment of water quality standards in waters with low dilution. In

these waters, the quantity of effluent discharged has a strong effect on the instream dilution and therefore upon the RWC. At the extreme case of a stream that is 100 percent effluent, it is the effluent concentration rather than the effluent mass discharge that dictates the instream concentration. Therefore, **EPA recommends that permit limits on both mass and concentration be specified for effluents discharging into waters with less than 100 fold dilution to ensure attainment of water quality standards.**

5.7.2 Energy Conservation

Water quality-based permit limits by themselves do not provide any incentive to dischargers to reduce wastewater flows. The reverse is true; a more dilute effluent means water quality-based limits are more easily achieved. However, increased flow translates into increased power consumption for treatment facilities. Significant power usage stems from pumping and mixing of volumes of wastewater in treatment systems. If the volume of wastewater can be reduced, power consumption can be reduced and less fossil fuel burned. Such reductions can be expected to result in concomitant decreases in air pollution.

Therefore, EPA recommends that flow reductions and energy savings be specifically encouraged where appropriate (usually in dilutions greater than 100:1) by allowing water quality-based permit limits to be mass-based and by allowing concentration-based limits to vary in accordance with flow reduction requirements. The permit also could include an energy savings analysis subject to approval by the permitting authority.

5.7.3 Considerations in the Use of Chemical-specific Limits

Metals

Another common problem encountered in expressing permit limits occurs for metals. Some water quality standards express numeric criteria for metals in terms of the dissolved or acid soluble phase of the metal. NPDES regulations at 40 *CFR* 122.45(c) require permit limitations for metals to be expressed in terms of total recoverable metal unless (1) an effluent guideline requires the use of another form, (2) technology-based limits are established on a case-by-case basis, or (3) the approved analytical method measures only the dissolved form.

Where State water quality standards are expressed directly as total or total recoverable metals, the permit limit can be established directly. Where the water quality standards are expressed as dissolved or acid soluble metal, the permit writer will need to reconcile the different expressions of metals when establishing the permit limits. Some State water quality standards implementation policies or procedures provide the requirements for this conversion. In instances where a State has no policy or procedure, the permit writer can take one of four approaches. First, the permit writer could assume no difference between the dissolved or acid soluble phases and the total recoverable phase. This is the most stringent approach and would be most appropriate in waters with low solids, where the discharged form of the metal was mostly in the dissolved phase, or where data to use the other options are unavailable. Second, the permit writer could develop a site-specific relationship between the phases of metals by developing a relationship through review of information on instream metal concentrations. This approach requires concurrent sampling of both metal phases during periods reflective of the environmental conditions used to determine the WLA. Third, the permit writer could use a relationship developed by EPA from national data; this relationship is described in the national guidance for determining WLAs for toxic metals in rivers. This relationship requires knowledge of instream concentrations of total suspended solids at the environmental conditions used to determine the WLA. Fourth, the permit writer could use a geochemical model, such as the equilibrium metal speciation model MINTEQA2 (see Chapter 4). However, the input data requirement of this model are equivalent to collecting site-specific data under Option 2. These options will be expressed in more detail in subsequent guidance issued by EPA.

Update: The Agency has issued "Interim Guidance on Interpretation and Implementation Aquatic Life Criteria for Metals." See the update notice in front of this document for availability.

Detection Level Limits

A commonly encountered problem is the expression of calculated limits for specific chemicals where the concentration of the limit is below the analytical detection level for the pollutant of concern. This is particularly true for pollutants that are toxic in extremely low concentrations or that bioaccumulate.

The recommended approach for these situations is to include in Part 1 of the permit the appropriate permit limit derived from the water quality model and the WLA for the parameter of concern, regardless of the proximity of the limit to the analytical detection level. The limit also should contain an accompanying requirement indicating the specific analytical method that should be used for purposes of compliance monitoring. The requirement should indicate that any sample is analyzed in accordance with the specified method and found to be below the compliance level will be deemed to be in compliance with the permit limit unless other monitoring information (as discussed below) indicates a violation. Sample results reported at or above the compliance level should be reported as observed whereas samples below the compliance level should be reported as less than this level.

The level of compliance cited in the permit must be clearly defined and quantified. **For most NPDES permitting situations, EPA recommends that the compliance level be defined in the permit as the minimum level (ML). The ML is the level at which the entire analytical system gives recognizable mass spectra and acceptable calibration points.** This level corresponds to the lowest point at which the calibration curve is determined based on analyses for the pollutant of concern in a reagent water. The ML has been applied in determinations of pollutant measurements by gas chromatography combined with mass spectrometry. The concept of a minimum level recently was used in developing the Organic Chemicals, Plastics, and Synthetic Fibers effluent guidelines [5].

The minimum level is not equivalent to the method detection level, which is defined in 40 *CFR* Part 136 Appendix B as the minimum concentration of a substance that can be measured and reported with 99-percent confidence that the analyte concentration is greater than zero and is determined from the analysis of a sample in a given matrix containing the analyte. EPA is not recommending use of the method detection level because quantitation at the method detection level is not as precise as at

the ML. It is not similar to the practical quantitation limit (PQL), which is typically set as a specific (and sometimes arbitrary) multiple of the method detection level. Because the PQL has no one definition, EPA is not recommending its use in NPDES permitting. Nor is it similar to other terms such as the limit of detection, limit of quantitation, estimated quantitation limit, or instrument detection limit.

The permitting authority may choose to specify another level at which compliance determinations are made. Where the permitting authority so chooses, the authority must be assured that the level is quantifiable, defensible, and close as possible to the permit level.

Where water quality-based limits below analytical detection levels are placed in permits, EPA recommends that special conditions also be included in the permit to help ensure that the limits are being met and that excursions above water quality standards are not occurring. Examples of such special conditions include fish tissue collection and analyses, limits and/or monitoring requirements on internal waste streams, and limits and/or monitoring for surrogate parameters. This information can be used to help support reopening the permit to establish more stringent effluent limits if necessary.

5.7.4 Considerations in the Use of Whole Effluent Toxicity Limits

Test Methods

NPDES regulations at 40 *CFR* 122.44(i)(1)(iv) require that methods approved under 40 *CFR* Part 136 be used for compliance monitoring, and in the absence of an approved method, the permit must specify the method to be used. The permit should also carefully consider any other case-specific aspects of the whole effluent toxicity test method that should be designated in the permit. Such aspects as the dilutions at which testing will be conducted, the different species to be used, the specific endpoints, the statistical procedures for analyzing the data, quality assurance, and other factors should be clearly stated as a permit condition to assure that the whole effluent toxicity testing that is performed to ascertain compliance with a limit or monitoring requirement is the test procedure the regulatory authority desires. In some instances, promulgated methodologies allow significant flexibility and choice in how the method is actually conducted. A simple reference to the methodology in the permit may not result in the test being conducted as intended.

Units of Expression and Detection Levels

The permit limit for toxicity itself and the detection levels, or sensitivity levels, associated with the various types of toxicity tests determine the type of monitoring requirement, which should be specified with the limit. It is a misconception to think, for example, that only acute toxicity tests should be used where the WLA for acute protection is used to derive the more limiting LTA or should always be used to monitor for the MDL. It is a similar misconception to think that only chronic tests should be used where chronic LTA is limiting or should always be used to monitor for the average monthly limit. The MDLs and AMLs are derived from the more limiting of the two LTAs. Therefore, either acute or chronic tests might apply to a given situation depending upon the test detection levels or test sensitivity.

For example, a limit of 5 TU_c (no observed effect concentration [NOEC] of 20 percent or greater) would require chronic toxicity testing where the ACR is 20 for that effluent. An acute test would not be sensitive enough to measure effluent toxicity in this instance, since 5 TU_c would be equivalent to 0.25 TU_a. Conversely, if the ACR was 2, then an acute test could be used because 5 TU_c would be equal to 2.5 TUa. Generally, there is no reason to mix two types of monitoring requirements for the same limit when limits are derived from the most limiting LTA. Doing so will confuse the results and complicate assessments of average monthly limits where sampling frequency is greater than once per month.

The acute toxicity test, when using an LC_{50} as the test endpoint, has an upper sensitivity level of 100-percent effluent, or 1.0 TU_a. If less than 50 percent of the test organisms die at 100-percent effluent an LC_{50} cannot be determined from the test data, and the true LC_{50} value for the effluent cannot be measured. In this situation, an acute test could still be used for compliance monitoring purposes but the endpoint would need to be changed to a greater level of sensitivity. The endpoint could be specified in terms of "no statistically significant difference in acute toxicity between 100 percent effluent sample and the control." This is the most sensitive application of an acute test and could be used for monitoring compliance with a limit that, because of lack of available dilution, applies the EPA recommended acute criterion of 0.3 TU_a at the end of the pipe.

However, these tests would not accurately quantify any level of chronic toxicity present. For chronic testing, an effluent with an NOEC of greater than 100 percent presents a similar test sensitivity problem. An effluent with an NOEC of greater than 100 percent contains less than 1.0 TU_c and would meet the EPA recommended chronic criterion for toxicity at the edge of the mixing zone, if dilution were available, as well as at the end of the pipe if no dilution were available.

Description of Limits

When toxicity limits are used, additional description of the limit is required. The limit should be stated in Part 1 as "effluent toxicity" in the parameter column with "maximum TUs," "minimum ATE [acute toxicity endpoint]," or "minimum NOEC" in parentheses underneath. The numerical values should be placed in the appropriate concentration column followed by TU or a percent sign. A footnote should direct the reader to Part 3 for specific requirements on how to conduct the tests. The description in Part 3 should accomplish the following:

- Explain how the limit is expressed (e.g., the limit is the minimum ATE expressed as percent effluent or the limit is the maximum TU_a)
- Specify the test species and the test methods for compliance monitoring purposes
- Describe any special reporting or followup requirements (e.g., requirements to conduct a toxicity reduction evaluation).

The language in Part 3 should be modified as needed to suit the situation. The following example language is provided only for purposes of illustration:

- "The effluent toxicity limit contained in Part 1 is the allowable chronic toxicity to the most sensitive of three test species. It is expressed as the allowable NOEC in percent effluent. The required test species and the procedures to follow are described in *Short Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms*, EPA/600/4-89/001, March 1989."
- "The permittee shall conduct monitoring of effluent toxicity once per month. One 24-hour composite sample shall be collected and tested within 24 hours of collection. Results shall be reported as the NOEC. Any test that does not meet quality control requirements as described in the above referenced methods shall be repeated using a freshly collected sample as soon as practicable."

5.7.5 Selection of Monitoring Frequencies

There is no fixed guidance on establishment of monitoring frequencies. The decision on the monitoring frequency is case-specific and needs to consider a number of factors, including those listed below:

- Type of treatment process, including retention time
- Environmental significance and nature of the pollutant or pollutant parameter
- Cost of monitoring relative to the discharger's capabilities and benefit obtained
- Compliance history
- Number of monthly samples used in developing the permit limit
- Effluent variability.

Based upon an array of data analyzed for both individual chemicals and whole effluent toxicity, and independent of other considerations, EPA has observed that ideally 10 or more samples per month provides the greatest statistical likelihood that the average of the various monthly values will approach the true monthly LTA value. In practice, however, selection of monitoring frequencies will need to consider the previously mentioned factors and arrive at a reasonable compromise of the appropriate considerations.

5.7.6 Analytical Variability

Permits require monitoring to establish whether a facility is discharging at a level that complies with the permit limits. All monitoring includes analytical variability. The true concentration in a sample can be higher or lower than the measured one due to this variability; however, there is no way to predict which way it will go.

Historically, EPA has not directly considered analytical variability from monitoring methods when establishing permit limits. If the upper bound of the analytical variability was added to the limit, there would be a higher potential that the permit limit would fail to protect the wasteload allocation. This would not be consistent with 40 *CFR* 122.44(d)(1). On the other hand, if the lower bound of the analytical uncertainty was subtracted from the limit, there would be better assurance that the limit achieved the WLA. This approach could be overly conservative given the other factors used to develop permit limits. EPA believes that its recommended approach provides a balance between these two extremes.

5.7.7 Antibacksliding

CWA Section 402(o) establishes express statutory language prohibiting the relaxation of permit limits based on water quality. Under the statute, relaxation of water quality-based limits is permissible only if either the requirements of Sections 402(o)(2) or 303(d)(4) are met. These two provisions constitute independent exceptions to the prohibition against relaxation of permit limits. If either is met, relaxation is permissible.

Relaxation of Water Quality-based Limits Under Section303(d)(4)

Section 402(o)(1) prohibits the establishment of less stringent water quality-based effluent limitations "except in compliance with Section 303(d)(4)." Section 303(d)(4) has two parts: Paragraph (A), which applies to "nonattainment waters" and Paragraph (B), which applies to "attainment waters."

- Nonattainment waters: Section 303(d)(4)(A) allows establishment of less stringent water quality-based effluent limitations in a permit for discharge into a nonattainment water only if (1) the existing permit limitation must have been based on a total maximum daily load (TMDL) or other WLA established under Section 303, and (2) attainment of water quality standards must be assured.
- Attainment waters: Section 303(d)(4)(B) allows establishment of less stringent water quality-based effluent limitations in a permit for discharge into an attained water as long as the revised permit limit is consistent with a State's antidegradation policy. This is not restricted to limits based on a TMDL or WLA.

Relaxation of Water Quality-based Limits Under Section 402

Section 402(o)(2) also outlines exceptions to the general prohibition against establishment of less stringent water quality-based permit limits in a permit. Under Section 402(o)(2), the establishment of less stringent limits based on water quality may be allowed where:

1) There have been material and substantial alterations or additions to the permitted facility which justify this relaxation.
2) Good cause exists due to events beyond the permittee's control (e.g., acts of God) and for which there is no reasonably available remedy.
3) The permittee has installed and properly operated and maintained required treatment facilities but still has been unable to meet the permit limitations (relaxation may only be allowed to the treatment levels actually achieved).

4) New information (other than revised regulations, guidance, or test methods) justifies relaxation of water quality-based permit limitations.

   This last exception applies to water quality-based permit limitations only where the revised limitations result in a net reduction in pollutant loadings and are not the result of another discharger's elimination or substantial reduction of its discharge for reasons unrelated to water quality (e.g., operation termination).

Although Paragraph 402(o)(2) lists two additional exceptions, one for technical mistakes and mistakes of law and one for permit modifications or variances, the statute provides that these exceptions do not apply to water quality-based effluent limitations. As a result, these exceptions do not provide a basis for relaxing water quality-based limitations.

Relaxation of Water Quality-Based Permit Conditions or Standards

The provisions in Section 402(o) discussed previously only address the relaxation of effluent limits based on water quality. The relaxation of other permit conditions or standards based on water quality are governed by EPA's existing antibacksliding regulations at 40 *CFR* 122.44(l)(1). Under these regulations when a permit is renewed or reissued, interim effluent limitations, standards, or conditions must be at least as stringent as the final effluent limitations, standards, or conditions in the previous permit "unless the circumstances on which the previous permit was based have materially and substantially changed since the time the permit was issued and would constitute cause for permit modification...". In other words, unless cause for permit modification is present, relaxed conditions or standards are not permissible. EPA regulations setting forth cause for permit modification can be found at 40 *CFR* 122.62.

Restrictions of Backsliding

Even if any of the backsliding exceptions outlined in the statute or regulations are applicable and met, Section 402(o)(3) acts as a floor and restricts the extent to which water quality-based permit limitations may be relaxed. Paragraph (o)(3) prohibits the relaxation of water quality-based permit limitations in all cases if there will be a violation of applicable effluent limitation guidelines or water quality standards, including antidegradation requirements. This requirement affirms existing provisions of the CWA that require permit limits, standards, and conditions to ensure compliance with applicable technology-based limits and water quality standards.

5.8 TOXICITY REDUCTION EVALUATIONS

Where monitoring indicates unacceptable effluent toxicity, one principal mechanism for bringing a discharger into compliance with a water quality-based whole effluent toxicity requirement is a toxicity reduction evaluation (TRE) [6]. The purpose of a TRE is to investigate the causes and to identify corrective actions for difficult effluent toxicity problems. The permitting authority may require that the permittee conduct a TRE in those cases where the discharger is unable to explain adequately and immediately correct exceedances of a whole effluent toxicity permit limit or requirement.

A TRE is a site-specific study conducted in a stepwise process to narrow the search for effective control measures for effluent toxicity. TREs are designed to identify the causative agents of effluent toxicity, isolate the sources of the toxicity, evaluate the effectiveness of toxicity control options, and then confirm the reduction in effluent toxicity. The ultimate objective of a TRE is for the discharger to achieve the limits or permit requirements for effluent toxicity contained in the permit and thereby attain the water quality standards for receiving waters.

The requirement for a permittee to conduct a TRE may be written into the special conditions section of a permit, which contains whole effluent toxicity limits. In some cases, the permit issuing authority may also use other legally binding mechanisms, including Section 308 letters, Administrative Orders, or Consent Decrees, to require a TRE.

5.8.1 TRE Guidance Documents

To assist permittees in conducting TREs and achieving compliance with whole effluent toxicity limits, EPA has developed a series of three guidance documents [6, 7, 8]:

1) *Generalized Methodology for Conducting Industrial Toxicity Reduction Evaluations* (EPA/600/2-88/070)
2) *Toxicity Reduction Evaluation Protocol for Municipal Wastewater Treatment Plants* (EPA/600/2-88/062)
3) *Methods for Aquatic Toxicity Identification Evaluations:*

   Phase 1 Toxicity Characterization Procedures (EPA/600/3-88/034)

   Phase 2 Toxicity Identification Procedures (EPA/600/3-88/035)

   Phase 3 Toxicity Confirmation Procedures (EPA/600/3-88/036).

These guidance documents describe the methods and procedures for conducting TREs and Toxicity Identification Evaluations (TIEs). They are based on the results of EPA's continuing efforts in TRE methods research and case study applications. Separate TRE guidance has been developed for industrial dischargers and municipal wastewater treatment plants to better address the circumstances of each type of facility. Procedures for the characterization, identification, and confirmation of the causative agents of effluent acute toxicity have been developed and are described in a three-phased TIE methods manual. These TIE methods are applicable to both industrial and municipal effluents and are an integral part of the protocols for TREs described in the industrial and municipal TRE guidance documents. TIE methods using chronic toxicity tests for identifying toxicants will soon be developed and available in a draft guidance document.

5.8.2 Recommended Approach for Conducting TREs

To ensure the successful completion of a TRE, the guidance documents recommend a systematic, stepwise approach that

eliminates the possible causes or sources of toxicity until a solution or control method is determined. The guidance documents discourage "playing hunches" or implementing extensive control measures solely on the basis of unsubstantiated conclusions (e.g., selecting and implementing a treatment plant upgrade without adequate information). Experience shows that unnecessary delays and expenditures in achieving the objective of the evaluation are avoided by building a sound scientific and engineering basis for selection of a control method. This can best be done by the logical interpretation of the information and data collected in a systematic approach to a TRE. The causes or control methods identified should then go through a confirmation stage. This is especially important in cases where the control method selected requires the construction of additional treatment. A flow chart, generalized from the guidance documents, for this approach to TREs is presented in Figure 5-10. The steps in this flow chart are summarized in the following discussion.

Determination of TRE Objectives and Development of the TRE Plan

Obviously, the success of any study is dependent on a clear understanding of what is to be achieved and how these objectives are to be demonstrated and measured. Typically, TRE objectives are set by the regulatory authority in terms of a toxicity test endpoint (ATE or chronic toxicity endpoint [CTE]) in order to meet a limit or permit condition. TRE plans should be submitted by the discharger as soon as possible. In some cases, this could be 30 to 60 days following notification that a TRE is required. In other instances, this period could be longer. These plans are important for ensuring that the TRE objectives are well understood and that the TRE to be conducted is thorough and represents a reasonable effort to achieve the required reduction in effluent toxicity. An implementation schedule should also be developed describing the timeframe for completion of the specific components of the TRE plan by the required TRE completion date. This schedule should be submitted for review in conjunction with the TRE plan. **EPA recommends that the TRE schedule should be set or approved by the regulatory agency**. Approval of the schedule and the completion date should not imply approval of the TRE plan itself or the procedures and methods outlined in the plan. Instead, the TRE plan should only be reviewed and any comments provided to the permittee as needed.

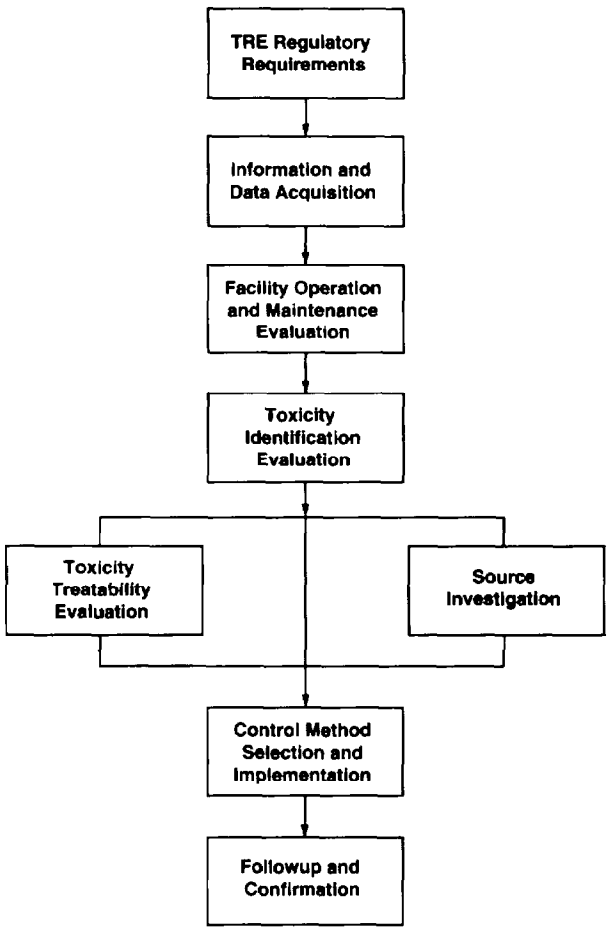

Figure 5-10. Generalized TRE Flow Chart

To assist in this review, Box 5-3 provides evaluation criteria for TRE plans. The permitting authority should review the TRE plan and inform the discharger of any apparent shortcomings or potential problems. The TRE should not be delayed pending completion of the review of the plan. The specified completion date for the TRE must still be met and the permittee should be expected to begin steps to investigate and alleviate the effluent toxicity as soon as possible following notification that a TRE is required. During the course of the TRE, the regulatory agency should provide oversight, as time permits, to make the TRE as effective as possible.

Evaluation of Existing Site-specific Information

The next step involves the collection of any information and analytical data relevant to the effluent toxicity. The permittee should begin collecting and evaluating this information as soon as possible following notification that a TRE is required. In some cases, this step may be conducted concurrently with accelerated toxicity testing as part of the development of a TRE plan. For an industrial discharger, this part of the evaluation would include information such as plant and process information, influent and effluent physical and chemical monitoring data, effluent toxicity data, and material use. For a POTW, additional information, such as industrial waste survey applications, local limits compliance reports, and monitoring data, should be collected. This information is used to supplement the data generated in the later steps of the TRE and may be useful at that stage to point to potential sources or treatment options.

Evaluation of Facility Operations and Maintenance Practices

This part of the evaluation is performed in order to ascertain whether the facility is consistently well operated and whether the effluent toxicity is the result of periodic treatment plant upsets, bypass, or some other operational deficiency that may be causing or contributing to the effluent toxicity. This part of the TRE should be initiated immediately after notification that a TRE is required. Alternatively, the permittee may begin to conduct this step at the same time that any accelerated toxicity testing is required. At both municipal and industrial facilities, this step would involve the evaluation of "housekeeping," treatment system operation, and chemical use. In some cases, best management practices (BMPs)

may be identified, which would improve operations and effluent quality. However, the effectiveness of BMPs in reducing effluent toxicity should be carefully confirmed, and it will usually be necessary to test a number of samples and perhaps to conduct Phase 1 of the TIE to develop this level of certainty. The results of this evaluation may lead to preliminary strategies for source reduction and pollution prevention, including spill or leak prevention, improvements in material handling and disposal practices, or substitution or re-use of a compound known to be highly toxic.

Toxicity Identification Evaluation

TIE procedures are performed in three phases: characterization, identification, and confirmation [7]. In each phase, aquatic organism toxicity tests are used to track toxicity at each step of the procedure. In most cases, these are abbreviated or shortened toxicity tests. In the toxicity characterization phase, the general nature of the causative agents of effluent toxicity or toxicants is determined. This is done by conducting a battery of tests to characterize the physical/chemical characteristics of the toxicity: solubility, volatility, decomposability, complexibility, filterability, and sorbability. This information can then be used to decide which chemical analytical methods will to use in Phase 2 or it can be used to design treatability studies.

The results of Phase 1 also may be used to provide additional confirmation of the effectiveness of any BMP that was implemented in the previous step of the TRE to reduce the effluent toxicity. This would require conducting at least one Phase 1 analysis prior to implementation of the BMP (i.e., any source control method implemented as a result of the evaluation of facility operation and maintenance). The results of this analysis would then be compared with Phase 1 results from samples taken after BMP implementation.

Box 5-3. Evaluation Criteria for TRE Plans

- Are the objectives or targets of the TRE stated clearly and accurately?
- Are the schedule and milestones for accomplishing the tasks described in the study plan?
- Are the final TRE report, progress reports, and meetings with the regulatory authority included as part of the schedule?
- Are the approaches or methods to be used described to the extent possible prior to beginning the TRE?
- Has available EPA guidance been used in designing the TRE and developing the TRE plan (or if other methods are proposed, are these sufficiently documented)?
- Does the TRE plan specify what results and data are to be included in the interim and final reports?
- Does the TRE plan provide for arrangements for any inspections or visits to the facility or laboratory that are determined to be necessary by the regulatory authority?
- Are the toxicity test methods and endpoints to be used described or referenced?
- Does the approach described build on previous results and proceed by narrowing down the possibilities in a logical progression?
- Does the plan provide for all test results to be analyzed and used to focus on the most effective approach for any subsequent source investigations, treatability studies, and control method evaluations?
- Are optimization of existing plant/treatment operations and spill control programs part of the initial steps of the TRE?
- Does the TRE plan allow a sufficient amount of time and appropriate level of effort for each of the components of the study plan?
- Does the TIE use broad characterization steps and consider quantitative and qualitative effluent variability?
- Is toxicity tracked with aquatic organism toxicity tests throughout the analyses?
- Is the choice of toxicity tests for the TRE logical and will correlations be conducted if the species used are different from those used for routine biomonitoring?
- Is the laboratory analytical capability and the expertise of the investigator broad enough to conduct the various components of the evaluation?

In Phase 2 of the TIE, the results of Phase 1 are built upon, and the TIE proceeds to chemical analyses designed to identify the specific chemicals causing effluent toxicity. In Phase 3, the identified toxicants are confirmed using a number of procedures, including correlation of toxicity with chemical concentration, spiking experiments, toxicity mass balance, and additional test species and their symptoms.

The current version of the TIE methods uses acute toxicity tests to characterize and identify the toxicants. In some cases, these methods may also be used for TREs where the objective is to reduce chronic toxicity. In order for these methods to be applicable, however, there must be some measurable acute toxicity in the effluent samples that are to be characterized in Phase 1 and analyzed in Phase 2. If this approach is used, the appropriate chronic toxicity test, as specified in the TRE objectives and permit requirements, should then be used in the Phase 3 confirmation procedures. This will confirm that the toxicant(s) identified using acute tests in Phases 1 and 2, are indeed causing the whole effluent chronic toxicity, which must be reduced.

It is possible to use the methods and procedures described in the other components of the overall TRE with either acute or chronic toxicity tests. The fact that the previous version of the EPA TIE methods use acute toxicity tests should not be construed to mean that TREs cannot be required or conducted for the reduction of chronic toxicity. These methods provide additional tools to assist permittees in the reduction of whole effluent chronic toxicity. Phase 1 procedures that use chronic toxicity tests will soon be available in draft EPA guidance. These TIE methods are applicable to freshwater discharges to either saltwater or freshwater receiving waters. The use of these methods for saltwater receiving waters may require their adaption for use with marine test species or, preferably, an initial correlation of the recommended freshwater TIE test species to the marine species used for monitoring.

Source Investigation

Based on the results of the TIE, a decision is made on whether to conduct treatability studies on the final effluent and/or conduct a source investigation. A source investigation is most readily performed when the specific toxicants have been identified and influent samples can be analyzed for the presence of these compounds or when potential source streams can be selected for chemical analysis (based on the results of the initial data acquisition step). However, in some cases where the specific causative agents of effluent toxicity have not been identified in the TIE, it may be possible to conduct a source investigation by "treating" influent samples in bench-scale models of the facility treatment plant, measuring the toxicity of the treated sample and then tracking this toxicity to its source.

Source investigations will lead to control methods, such as chemical substitution, process modification, treatment of process or influent streams (pretreatment), and possible elimination of the process. For POTWs, source investigations may lead to the development of local limits or to the requirement that an indirect discharger evaluate and control their effluent so as to reduce its toxicity and prevent passthrough at the POTW. The implementation of source control methods can effectively reduce effluent toxicity and also can avoid any cross-media transfer of pollutants to air or sludge, which may occur as a result of end of pipe treatment. Types of source control methods that have proven to be effective in reducing effluent toxicity are improvements in facility housekeeping, chemical substitution, process optimization, reclamation/re-use, and pretreatment.

Toxicity Treatability Evaluation

Toxicity treatability evaluations are conducted to identify possible treatment methods that can effectively reduce effluent toxicity and may involve modifications or additions to the existing system. Treatability studies generally use the same type of information on the nature of the chemicals to be removed as is generated by Phase 1 of the TIE. These treatability tests should be conducted on a bench-scale initially and then a pilot scale prior to construction of additional treatment or substantial modification of the existing plant. The use of these bench- and pilot-scale tests, coupled with aquatic organism toxicity tests, should be used to confirm the effectiveness of the treatment option. Confirmation of the results of treatability studies is equally important as it is for the TIE. Skipping this confirmation step is an invitation for unwarranted expense.

Toxicity Control Method Selection and Implementation

After the investigative steps of the TRE are completed, it is not unusual for a number of possible control options to have been identified. At this point, a site specific selection must be made by the discharger based on the technical and economic feasibility of the various alternatives. Following this selection, the toxicity control method is implemented or a compliance plan is submitted if construction of additional treatment requires a substantial amount of time.

Followup and Confirmation

After the control method is implemented and the final TRE report is submitted, the permitting agency should direct the permittee to conduct followup monitoring to confirm that the reduction in effluent toxicity is attained and maintained. Normally, this monitoring should follow an accelerated schedule, weekly or biweekly toxicity tests, for a period of 2 to 3 months to confirm the effectiveness of the controls implemented and the continued attainment of the TRE objective. This followup monitoring should use the same species as were specified for routine toxicity testing in the permit. The test endpoints of these toxicity tests should be the same as those which were calculated by the water quality-based permit limit derivation procedure used when the permit was issued. Once the discharger has demonstrated the successful completion of the TRE, the permitting agency should direct the discharger to return to the routine permit monitoring schedule.

5.8.3 Circumstances Warranting a TRE

It is the responsibility of the permitting authority to determine if the permit limits and/or the State water quality criteria have been threatened or violated and to notify the permittee if a TRE is required. It is appropriate for the permitting authority to require additional toxicity testing following the initial exceedance or violation. This additional testing may precede notification that a TRE will be required or it may be considered as the initial part of the

TRE and be conducted simultaneously with TRE plan development and the evaluation of other existing site-specific information.

It is important to recognize that the purpose of this additional toxicity testing is to determine the continued presence or absence of effluent toxicity and the magnitude of that toxicity. This information can then be used to determine the continued compliance or noncompliance with the limit or permit conditions for effluent toxicity. These tests do not serve to verify or confirm the initial test results from an earlier sample. Instead, the permit authority shall use the results of these tests to determine if a TRE or some other action is the appropriate response to the initial occurrence of toxicity.

If the permit has a limit for whole effluent toxicity, then generally, the permit should not include any specific conditions for accelerated toxicity testing or for triggering a TRE or some other action (e.g., exceedances in two consecutive tests or exceedances in any three out of five tests). CWA Section 309 requires that any single violation of a permit limit may be subject to enforcement. The EPA *Compliance Monitoring and Enforcement Strategy for Toxics Control* (January 19, 1989, Appendix B-4) states that, "Each exceedance of a directly enforceable whole effluent toxicity limit is of concern to the regulatory agency and therefore qualifies as meeting the VRAC [violation review action criterion] requiring professional review." Accelerated monitoring should only be used to assist in this professional review to determine what, if any, enforcement response is necessary, including the need for the permittee to conduct a TRE. It will be necessary for the Region or State regulatory authority to determine this on a case-by-case basis. This must be done in a manner consistent with the priorities established in their respective toxics control strategies and permitting procedures.

In situations where it is determined that accelerated testing is appropriate, a maximum of weekly tests for a minimum period of 2 months is recommended. This would result in eight tests, plus the routine monitoring toxicity test that initially indicated the exceedence or violation, for a total of nine tests in the series. As a practical approach for determining if a TRE is an appropriate response, **EPA recommends if toxicity is repeatedly or periodically present at levels above the effluent limits more than 20 percent of the time, a TRE should be required.** With toxicity present at this rate, the TRE protocols will be useful.

In most cases, any one additional exceedance (beyond the initial routine monitoring toxicity test result) in the accelerated toxicity tests could result in notification of the permittee that a TRE is required. Exceptions to this guideline might include cases where the permittee is able to adequately demonstrate that the cause of the exceedances is known and corrective actions have been immediately implemented or cases where additional test quality assurance/quality control (QA/QC) is necessary or desirable. The submittal of QC fact sheets for self-biomonitoring (e.g., Appendix B-2) should always be recommended to avoid QA/QC problems.

If the test results indicate that toxicity is not consistently or repeatedly present in the test series, previous discharge monitoring reports (DMRs) should be examined to ascertain if a recurrent problem exists. If the problem is recurrent, a TRE should be required, and the TRE plan should explain how the design of the evaluation will address this periodic or recurrent effluent toxicity problem. In these cases, more elaborate sampling design and influent or process stream monitoring may be needed. It should be expected that TREs conducted under these circumstances will probably require a more flexible schedule and perhaps additional time before the required completion date.

If the accelerated testing and previous DMRs show the continued absence of effluent toxicity, then the initial exceedance would be considered an episodic event and a TRE should not be required. A TRE is not an appropriate response to a single, episodic effluent toxicity event (e.g., a spill or a plant upset). By conducting accelerated testing following a violation or exceedance of a permit condition, unnecessary TREs can be avoided. Similarly, conducting accelerated testing as part of the initial steps of a TRE will allow for the TRE to be ended in its very early stages if the toxicity is immediately controlled or determined to be episodic or nonrecurrent. By following the TRE guidance and incorporating accelerated testing into the TRE, unnecessary analyses and expense can be avoided.

It also is important to note that for the practical purposes of conducting a TRE (as opposed to the purpose of determining if a TRE should be required or not), the magnitude of the effluent toxicity needed to conduct a TRE may be less than the magnitude or level set as the permit limit or permit monitoring condition. This is because if the limit or monitoring condition is water quality-based then some amount of dilution will usually be incorporated in determining the unacceptable level of effluent toxicity. In some cases, it may be possible for the TRE procedures to be carried out even if the toxicity does not actually exceed this permitted level. This will be the case as long as the effluent toxicity is periodically or consistently present in measurable amounts in samples of 100-percent effluent.

It also is reasonable for a discharger to initiate a TRE prior to the establishment of a permit limit for toxicity if unacceptable levels of toxicity are found in the effluent through routine monitoring or through inspection and compliance sampling by the regulatory authority. Under these circumstances the regulatory authority will need to identify what constitutes unacceptable levels of toxicity since this will not be defined by a permit limit (see Chapter 3 on determining the reasonable potential for excursions of water quality standards). It also is not unreasonable for the discharger to voluntarily initiate a TRE under these circumstances.

5.8.4 Mechanisms for Requiring TREs

There are a number of mechanisms that can be used to require a TRE. In most cases, the TRE should be required by a Section 308 letter or by an enforcement action, such as a Section 309 Administrative Order or a Consent Decree. The permittee should receive notification from the permit authority of what response is required. This enables the permit authority to assess whether a TRE is the appropriate action to pursue. If effluent toxicity reappears following the successful completion of a TRE, then the permit authority should be able to review this type of situation to determine if an additional TRE is appropriate or if some other action is required. In general, when the permit is issued with whole effluent toxicity limits in Part 1 of the permit, TRE requirements should be used where necessary to bring the permittee into compliance with those limits. Box 5-4 provides example lan-

guage for effluent toxicity limits, developed as part of the Whole Effluent Toxicity Basic Permitting Principles and Enforcement Strategy (Appendix B-4).

Box 5-5 presents sample language for use in requiring TREs by a Section 308 letter or a Section 309 Order. This sample language, especially the reporting dates, should be tailored to fit the specific permittee. The completion date should be specified on a case-by-case basis. Factors to consider in setting this completion date include the type of facility, the variability of the effluent, and the previous compliance history. In order to conduct a TRE, reasonable timeframes are 6 to 18 months for an industrial discharger and 12 to 24 months for a municipal wastewater treatment plant. For POTWs, it may take longer to conduct a TRE due to lengthy government contracting procedures, large sewer collection systems, and less influent constituent control. It should be recognized that extensions to these initial timeframes may be granted if the progress reports demonstrate that this is warranted. In situations where reductions in chemical concentrations to meet chemical-specific limits are needed as well as reductions in effluent toxicity, the timeframes may be adjusted to enable those efforts to proceed simultaneously.

Box 5-4. Model Permit Language for Effluent Toxicity Limits

Part 1.A. Final Effluent Limits and Monitoring Requirements

During the period beginning on the effective date of this permit and lasting until the expiration date, the permittee is authorized to discharge in accordance with the following limits and monitoring requirements from the following outfall(s): 001.

Effluent Characteristic		Discharge Limit Concentration		Monitoring Requirement	
Reporting Code/Units	Parameter	Daily Maximum	Monthly Average	Measurement Frequency	Sample Type
—TU_c	Toxicity	10.0	5.0	x/month	composite

The permittee shall use the toxicity testing and data assessment procedures described in Part 3.B of this permit.

Box 5-5. Example Language for Requiring Toxicity Reduction Evaluations

The discharger shall demonstrate that effluent toxicity-based permit limits described in Part 1.A. of the permit are being attained and maintained through the application of all reasonable treatment and/or source control measures. Upon identifying noncompliance with those limits the discharger shall initiate corrective actions according to the following schedule:

	Task	Deadline
1.	Take all reasonable measures necessary to reduce toxicity immediately.	Within 24 hours
2.	Submit a plan and schedule to attain continued compliance with the effluent toxicity-based permit limits in Part I.A.,where source of toxicity is known, if immediate compliance is not attained.	Within 30 days
3.	Submit a TRE study plan detailing the toxicity eduction procedures to be employed where source is unknown and toxicity cannot be immediately controlled through operational changes. EPA's Toxicity Reduction Procedures, Phases 1, 2, and 3 (EPA-600/3-88/034, 035, and 036) and TRE protocol for POTWs (EPA-600/2-88/062) shall be the basis for this plan and schedule.	Within 45 days

Box 5-5. Example Language for Requiring Toxicity Reduction Evaluations (continued)

4.	Initiate TRE plan.	Within 45 days
5.	Comply with approved TRE schedule.	Immediately upon approval
6.	Submit results of the TRE, including summary of findings, corrective actions required, and data generated.	Per approved schedule
7.	Implement TRE controls as described in the final report.	On due date of final report per approved schedule
8.	Complete TRE implementation to meet permit limits and conditions.	Per approved schedule, but in no case later than XX months from initial noncompliance.

CHAPTER 5
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6. COMPLIANCE MONITORING AND ENFORCEMENT

6.1 INTRODUCTION

Once a water quality-based permit containing limitations and conditions to control effluent quality is issued, the permittee is responsible for attaining, monitoring, and maintaining compliance with the requirements of that National Pollutant Discharge Elimination System (NPDES) permit. Failure to comply with any requirements stated in the permit is a violation of the Clean Water Act (CWA).

The Environmental Protection Agency (EPA) and authorized State agencies are responsible for tracking compliance with and enforcing NPDES permit requirements in the enforcement of the CWA. Section 308 of the CWA and equivalent State statutes enable the regulatory agency to verify compliance with permit conditions (including water quality-based toxics limitations and compliance schedules) by authorizing the agency to impose on permittees requirements for sampling and analysis, record-keeping, and reporting. Section 308 also authorizes access by EPA or State agencies to facilities and records for verifying compliance with permit conditions. All records associated with monitoring must be maintained by the facility and available for a 3-year inspection period in conformance with 40 *CFR* Part 122.41.

The CWA establishes the authority to enforce water quality-based permit conditions. The ability to enforce water quality-based permit conditions, however, relies on well-written, clearly stated permits. The enforcement official must be familiar with the process by which permit requirements were derived, including the procedures used to determine the wasteload allocation based on applicable water quality standards and the procedures used to derive limitations from the wasteload allocation.

6.2 PERMIT REQUIREMENTS

The conditions that are to be included in NPDES permits are described in 40 *CFR* Part 122 Subpart C. In general, permits include effluent limitations, schedules of compliance, and accompanying reporting requirements. Permits should prescribe the self-monitoring procedures, frequency of analysis, sampling location and procedures, acceptable or required analytical techniques, and frequency of reporting. Permits often require that analytical methods referenced in 40 *CFR* 136 be used for analysis, but may specify methodology not included in Part 136 for pollutants with no approved methods or where the approved method is inappropriate for a particular permit limitation. Permits should define any effluent limitations and explain specific procedures for calculating averages of data if different from arithmetic averaging. Permits should identify what information must be retained by the permittee, and what data must be submitted to EPA or the State. Results from self-monitoring required by the permit are reported on discharge monitoring reports (DMRs) that generally are submitted monthly. Sampling and analysis that is done more frequently than required by the permit must be included in the DMR.

6.3 COMPLIANCE MONITORING

Since most of the routine information gathered in compliance monitoring results from permittee self-monitoring, quality assurance (QA) is as important as compliance with limits. It is essential that permittees develop and adhere to a QA plan consistent with the required monitoring and analyses. The permittee is responsible for maintaining data to demonstrate compliance with QA procedures established in the test methodology or as specified in the permit.

The regulatory agency generally has three ways of determining compliance with an NPDES permit and assuring adequate QA: self-monitoring reports, DMR/QA results, and inspections. Each of these methods is discussed below.

6.3.1 Self-monitoring Reports

Self-monitoring reports provide much of the compliance data used by the regulatory authority in the review of permittee compliance. These reports include DMRs and reports of progress on compliance schedules. DMRs contain information on the sampling method, frequency and location, and analytical results of permittee self-monitoring. These data and data from progress reports on major schedule milestones must be entered into the Permit Compliance System (PCS), a computerized data base, by the State or EPA [1]. When the required data are entered into the system, PCS will automatically "flag" violations of permit limitations, compliance schedules, and reporting requirements.

In order to detect any problems with the quality of the sample analysis, it is often desirable to obtain QA information with the self-monitoring data. For this reason, several States and Regions have developed additional QA forms to accompany permittee self-monitoring reports. This additional information may be required through the permit or through a Section 308 order. The QA data are compared to a reference QA data sheet that can be completed by the regulatory authority to indicate acceptable ranges of values for the required protocol. Appendix B-5 provides an example of a reference QA data sheet for a whole effluent toxicity test. Once completed, this QA data sheet can be included in the compliance file for quick reference by compliance personnel.

It is important to note that poor QA is a violation if the permit explicitly specifies adequate QA or references an acceptable protocol with corresponding QA procedures. It also is important to note that the signatory's certification of effluent data certifies

compliance with the specified protocols. Any problems with QA should be reported at the time of DMR submission and the testing repeated.

6.3.2 Discharge Monitoring Report/Quality Assurance (DMR/QA)

The DMR/QA program evaluates a permittee's ability to analyze and report accurate data. This program is intended to improve overall laboratory analytical performance for self-monitoring data. Authority for requiring participation is granted in CWA Section 308. In the DMR/QA program, permittees are required to analyze "blind" samples with constituents and concentrations that can be found in their industrial or municipal wastewaters. The permittees' results are compared to the known content of the sample, and an evaluation of the reported data is sent to the permittees. Permittees are expected to use the same personnel and methods employed for reporting NPDES data to analyze the samples. Permittees are required to follow the instructions for reporting results and include a signed certification statement in accordance with 40 CFR 122.22.

Regulatory agencies conduct followup investigations to address poor or incomplete DMR/QA results, failure to participate, or late submittal of DMR/QA results. DMR/QA performance results are compiled annually.

In the past, only chemical-specific analyses were tested in the DMR/QA program. The Environmental Monitoring and Support Laboratory (EMSL) in Cincinnati has developed a reference toxicant DMR/QA sample for permittees with whole effluent toxicity monitoring requirements. National implementation is occurring in 1991.

6.3.3 Inspections

Inspections are conducted by the regulatory authority or its contractors to address specific violations or problems and to verify permittee compliance with permit conditions and QA procedures. Inspections may include reviewing records, inspecting treatment facilities, assessing progress with compliance schedules, evaluating laboratory facilities and performance, and collecting samples for analysis or "splitting" samples taken by the permittee for concurrent analyses. EPA has defined several types of inspections based on the tasks that are included in the *NPDES Compliance Inspection Manual* [2]. Because regulatory authorities are expected to inspect all major permittees annually regardless of compliance status, nonsampling inspections (which are generally less resource-intensive) are encouraged for routine evaluation of permittee performance. However, sampling inspections are still encouraged to address permitting and enforcement priorities. For that reason, the regulatory agency must have the full capability to assess effluent compliance through inhouse resources or contract support.

Inspections that focus on toxics control can provide useful information for water quality assessment and permit reissuance in addition to compliance data. Procedures for inspecting facilities with toxicity testing requirements and measuring effluent toxicity are detailed in the *NPDES Compliance Inspection Manual,* Chapter 7 [2].

6.4 VIOLATION REVIEW

Review of permittee self-monitoring data to determine appropriate enforcement response generally involves a two-tiered review. The first tier is a preliminary review for timely, complete data that indicates compliance with permit requirements. Minor violations of requirements are often handled through informal phone calls or warning letters that do not require extensive review or oversight. As violations increase in magnitude, duration, or frequency, they generally are assigned to personnel who are responsible for the second-tier review (determining what enforcement action, if any, is appropriate). The guidelines for this process are presented in the Enforcement Management System (EMS) [3], but the basic concepts of responsible compliance tracking of water quality-based requirements are discussed below. Section 6.5 discusses the enforcement decision process.

When the initial review of effluent monitoring data indicates that unacceptable analytical methods were used by a permittee or its contract laboratory, the results should be assigned for review by personnel qualified to determine the significance of the results. If the monitoring is insufficient to determine compliance with effluent limitations, a warning letter or Section 308 letter requiring that the tests be repeated using acceptable procedures would be an appropriate response.

Tracking a permit or Section 308 letter that contains "monitor only" requirements requires both a compliance review (e.g., to determine if results of acceptable quality were submitted on time), and an action review (e.g., to determine if the permit should be modified or re-issued to include a limitation). This second review should be assigned to personnel who are qualified to make this regulatory decision.

In addition to the guidelines for reviewing monitoring data in the absence of a specific effluent limitation, EPA also has recommended a criterion for determining which effluent violations must be assigned for review by a professional who will determine if a formal enforcement action is needed, or if a phone call, warning letter, or Section 308 letter is more appropriate. These criteria are known as the Violation Review Action Criteria and are listed in the EMS.

In the case of a whole effluent toxicity limitation, any violation must be reviewed by a qualified professional responsible for the enforcement decision. EPA makes this recommendation to ensure that adequate attention is given to QA and to ensure that additional testing is required if permitted testing frequency is less than once per month.

In the case of a violation of a chemical-specific permit limitation, EPA recommends that monthly average limitation violations be reviewed by a professional for potential enforcement response whenever two or more violations occur in a 6-month period. Seven-day average and daily maximum violations should likewise be reviewed if a minimum of two or four, respectively, occur during the course of 1 month. Although there is no delineation between technology-based versus water quality-based limitations in these Violation Review Action Criteria, Regions and States may wish to adopt a criteria of "any violation" for all water quality-

based, chemical-specific limitations as these criteria are solely to determine the level of review and do not prescribe enforcement action.

6.5 ENFORCEMENT

Effective enforcement of toxic controls depends upon clearly expressed requirements in NPDES permits. These controls are generally in the form of numeric limits on specific toxic chemicals or whole effluent toxicity and schedules to initiate construction or other compliance measures.

Exceeding a permit limitation is a violation subject to enforcement. Some members of the regulated community have expressed concerns that single violations of stringent water quality-based limitations will result in unreasonable enforcement actions. EPA's guidance outlines a systematic review of all violations to determine the appropriate level of response. This guidance generally suggests an informal response for minor or infrequent violations, escalating to formal enforcement and perhaps penalties for more frequent and environmentally harmful violations.

In evaluating appropriate response to violations, EPA's "Enforcement Response Guide" of the EMS should be used for guidelines on the minimum acceptable response [3].

Further guidance on addressing violations of whole effluent toxicity limitations in particular is presented in the Compliance Monitoring and Enforcement Strategy for Toxics Control [4] (see Appendix B-4). This strategy expects that all available avenues to compliance will be explored by the permittee, that the treatment facility is designed, constructed, maintained, and operated to achieve all water quality-based, chemical-specific or best available technology/secondary treatment limitations, that chemical or process substitutions have been attempted and pretreatment explored, and that, in the case of publicly owned treatment works (POTWs), pretreatment program requirements and local limits have been established and enforced. The strategy further expects that the permittee will pursue a Toxicity Reduction Evaluation (TRE) as discussed in Chapter 5 in compliance with enforcement requirements or under its own initiative. If all of these expectations have been met and the facility is unsuccessful in identifying the cause, source, or treatability of toxicity despite making good-faith efforts to do so, the strategy allows for relief from civil penalties. The underlying responsibility to achieve compliance with the permit limitation remains in effect.

Some members of the regulated community have requested EPA and several State agencies to define more clearly enforcement discretion with respect to violations of whole effluent toxicity limitations. To define enforcement discretion would in effect make it no longer discretionary. Furthermore, the purpose of such guidance would be questionable as individual enforcement responses by EPA and the States are open to review by the public and the courts. In lieu of such additional guidance on enforcement discretion, it is recommended that Regions and States adhere to the principles presented in the EMS, the strategy, and in this document.

EPA also has developed a policy [5] on the assessment of appropriate civil penalties in both administrative and civil judicial actions in response to any CWA violation. This policy bases the penalty amount on the seriousness of the violation, the economic benefit enjoyed as a result of delayed compliance, any history of such violations, any good-faith efforts to comply, and the violator's ability to pay. In no instance can this calculated penalty exceed the statutory maximum penalties defined in CWA Section 309.

If any violation occurs, the permittee has the responsibility of informing the regulatory agency. If the violation potentially endangers health or the environment, the violation must be verbally reported to the regulated agency within 24 hours and the permittee must submit a noncompliance report within 5 days of violation detection. If there is no danger to health or the environment, the written report must be submitted at the time monitoring reports are submitted. These reports must include a description of the violation, its cause, the period of noncompliance, and if the noncompliance has not been corrected, the anticipated time when compliance will be achieved.

As with other NPDES permit limitation violations, violation of a water quality-based toxics limit should prompt immediate action on the part of the permittee. Permittee response should include evaluation of the cause of the violation, correction of operational deficiencies or improvement of treatment efficiency, and any other initial steps necessary to resolve the violation and mitigate the environmental effects. These immediate investigatory and corrective steps also should provide information that may be used in developing a compliance schedule if the violation is not resolved quickly.

When a water quality-based toxicity limit is violated, the regulatory agency may require additional monitoring to determine the frequency and duration of the violation. If the permit limit is not met quickly through improved housekeeping, operation, or raw waste control (e.g., POTW enforcement of pretreatment requirements, or chemical substitution by industries), requiring a TRE as discussed in Chapter 5 may be appropriate. Where toxicity-based limitations are in effect, the enforcement response must require expeditious compliance with the limit.

Available enforcement mechanisms include Section 308 orders, Section 309 Administrative Orders, Administrative Penalty Orders with Administrative Orders, or judicial action. Enforcement action must be tailored to the specific violation and type of remedial action required. Enforcement actions must be worded carefully so that they clearly are understood, easily tracked, and expeditiously enforced.

Violating limitations of pollutants at concentrations that pose a threat to human health should receive immediate enforcement attention to prompt rapid resolution of the noncompliance. The regulatory agency should consider the pollutant concentration, exposure route, and whether or not the pollutant exhibits a threshold response in determining if a schedule may be allowed. Immediate injunctive relief (such as a temporary restraining order or preliminary injunction) should be sought when necessary to protect public water supplies and fish and shellfish areas from imminent or substantial impairment.

6.6 REPORTING OF VIOLATIONS

The regulatory authority is responsible for reporting to the public on permittees in violation. Reporting requirements for the Quarterly Noncompliance Report (QNCR) of major permittees in violation of their NPDES permits are established in 40 *CFR* 123.45. Reporting of violations of water quality-based monitoring, limitations, schedules, and reporting requirements by major facilities must be consistent with 40 *CFR* 123.45. Violations of permit or enforcement order conditions by major permittees must be reported as follows [6]:

- Effluent violations (chemical-specific and whole effluent toxicity) must be reported on the QNCR if the violation has the potential to have caused a water quality problem (40 *CFR* 123.45(a)(2)(iii)(A)(1)).

- Chemical-specific toxic permit limit violations must be reported on the QNCR if two or more monthly average measurements in a 6-month period exceed the limit by a factor of 1.2 for a Group I parameter or 1.4 for a Group II parameter as defined in the Regulation, or if four or more monthly average measurements in a 6-month period exceed the limit by any amount (40 *CFR* 123.45(a)(2)(ii)(C)). Any violation during the quarter of an interim monthly average chemical-specific toxic limit established in an administrative order or court order/consent decree must be reported on the QNCR (40 *CFR* 123.45(a)(2)(ii)(A)). (Note: Whole effluent toxicity is not characterized as a Group I or Group II parameter, and as such, must be evaluated on a professional judgement basis under 40 *CFR* 123.45(a)(2)(iii)(A)(1).)

- Compliance schedule milestones that are not met within 90 days of the scheduled date must be reported on the QNCR (40 *CFR* 123.45(a)(2)(ii)(B)).

- Failure to submit a report within 30 days of the due date must be reported on the QNCR (40 *CFR* 123.45(a)(2)(ii)(D)).

CHAPTER 6
REFERENCES

1. Jensen, L.J. *Permit Compliance System (PCS) Policy Statement.*
2. *NPDES Compliance Inspection Manual,* May 1988.
3. Enforcement Management System for the National Pollutant Discharge Elimination System, September 1986.
4. Hanmer, R.W. 1989. *Whole Effluent Toxicity Basic Permitting Principles and Enforcement Strategy.*
5. Jensen, L.J. 1986. *Clean Water Act Penalty Policy for Civil Settlement Negotiations.*
6. Hanmer, R.W. 1986. *Guidance for Preparation of Quarterly and Semi-Annual Noncompliance Reports.*

7. CASE EXAMPLES

7.1 INTRODUCTION

This chapter presents examples of the development of water quality-based discharge limits to illustrate the integration of the guidance of the previous chapters. There are three examples: an industrial discharge with ample dilution, a publicly owned treatment works (POTW) with moderate dilution, and the combination of an industrial facility and a POTW discharge to the same reach.

7.2 CASE 1: INDUSTRIAL DISCHARGE

The first example is the Jaybird Corporation, a metal finishing firm. The NPDES permit for the facility is about to expire, and the corporation has submitted an application for a new permit. The example shows the steps that a permitting authority would take to determine if a water quality-based effluent limit is necessary and then to establish such a limit. The example also illustrates when best available technology (BAT) limits are applied instead of water quality-based limits, the use of human health criteria, and the variations in the limits derived by different wasteload allocation methods.

7.2.1 General Site Description and Information

The Jaybird Corporation facility discharges into the Locapunct River. The river is approximately 60 miles long and its banks are occupied by small towns separated by woodland and farmland. The river is classified by the State in the water quality standards as having designated uses of a fish habitat, primary contact recreation, and a drinking water supply. For these uses, the State has adopted the federal water quality criteria into the water quality standards to protect aquatic life and human health. The State standards also includes a narrative criterion of "no toxics in toxic amounts" for other toxic materials.

Water quality monitoring indicates some infrequent excursions above water quality criterion for copper and nickel. These pollutants have been found in measurable quantities in the effluents of several facilities.

The Jaybird Corporation is a metal finishing facility that specializes in copper plating of lead shells for a nearby military installation. As a metal finisher, the Jaybird Corporation is relatively small with a discharge of 0.034 cfs (0.022 mgd). The effluent at the Jaybird Corporation is treated by precipitation and settles before discharge through a multiport diffuser. The corporation is subject to BAT and best practicable technology (BPT) effluent limits for the metal finishing industry.

7.2.2 Effluent Characterization for Specific Chemicals

The permitting authority has adopted a procedure in which pollutants concentrations in each facility are evaluated for the potential to cause, have the reasonable potential to cause, or contribute to an excursion of the water quality standards. The authority used the effluent characterization process for specific chemicals described in Chapter 3 in this evaluation. In general, the procedures are designed to determine which pollutants are of concern and which require effluent limits.

Step 1: Identify Pollutants of Concern

Data were obtained from a number of sources to identify and quantify the pollutants of concern in the Jaybird Corporation effluent:

- Effluent chemical concentrations were taken from the Permit Application Form 2C, Discharge Monitoring Reports (DMRs), EPA's Permit Compliance System (PCS), and permit files.
- EPA's STORET data base was used to obtain U.S. Geological Survey flow data and ambient monitoring data for the river.
- BAT limits for the metal finishing industry were obtained from 40 *CFR* 433 Subpart A.

The permitting authority noticed in review of these data that the information in Form 2C replicated the information in the DMRs, and therefore decided to use the DMR data as the primary basis for characterizing the effluent. These data for toxicants DMRs are shown in Table 7-1. For those parameters currently not covered by the permit, Form 2C data indicated that pollutant concentrations were below detection limits. The permitting authority requested information from the facility showing the detection levels used; these levels were consistent with the detection levels listed in the National Pollutant Discharge Elimination System (NPDES) regulations at 40 *CFR* 136.

The effluent from the Jaybird Corporation is regulated by the Metal Finishing Point Source Category effluent guidelines at 40 *CFR* 433 Subpart A. These guidelines regulate the following toxic pollutants: cadmium, chromium, copper, cyanide, lead, nickel, silver, zinc, and total toxic organics.

Although these parameters were regulated at the Jaybird Corporation, the only toxic pollutants evident in the discharge were lead, copper, and nickel. The facility's treatment system reduced concentrations of other pollutants to below detection.

Step 2: Determine the RAC, CMC, and CCC for Pollutants of Concern

The State has adopted numeric water quality criteria for acute toxicity (criterion maximum concentration [CMC]), chronic toxicity (criterion continuous concentration [CCC]), and protection of human health (reference ambient concentration [RAC]). The water quality standards present the CMC and CCC criteria as equations based on ambient hardness concentrations. The standards require that the 85th percentile lowest hardness be used. This value is 100 mg/l as $CaCO_3$ for the Locapunct River.

Table 7-1. Effluent Data for the Jaybird Corporation

n	Copper µg/l	Lead µg/l	Nickel µg/l	Toxicity TU_c
1	1,317	187	223	5
2	1,092	230	261	10
3	1,073	258	464	5
4	1,059	423	341	20
5	1,072	227	369	
6	1,677	275	1,058	
7	2,664	364	199	
8	1,058	170	259	
9	3,439	259	437	
10	6,596	264	773	
11	1,211	267	300	
12	1,082	175	356	
Mean	1,945	258	420	10
SD	1,650	74	252	7.1
CV	0.8	0.3	0.6	0.7
Max	6,596	423	1,058	20
Min	1,058	170	199	5
N	12	12	12	4

Source: DMR data for chemicals; 308 request for whole effluent toxicity.
Notes:
Metals reported as total recoverable metals; toxicity reported in chronic toxic units (100/NOEC).
The permittee did not use a geometric dilution series for the toxicity tests. The results are the highest toxic units for any of the test organisms used.

The aquatic toxicity criteria for metals in the standards are expressed as the acid soluble form of the metal. The State has adopted a ratio to express the acid soluble form of metals as the total recoverable form for the purposes of developing NPDES permit limits. This ratio is based on historical data that the State has collected for rivers in the basin where the Locapunct lies. The values of the ratio are 0.35 for lead, 0.70 for copper, and 0.85 for nickel. The standards consider the criteria for human health protection to be in the total recoverable form of the metal.

Based on the hardness and acid soluble-to-total recoverable ratios, the applicable state water quality criteria are the following:

Pollutant	CCC (µg/l)	CMC (µg/l)	RAC (µg/l)
Lead	9.1	235	50
Copper	17.1	25.7	NA
Nickel	188	1,647	13.4

Step 3: Determine Dilution for Aquatic Life and Human Health Impacts

The State water quality standards require that compliance with water quality criteria be achieved at the edge of the mixing zone. The standards specify the minimum dilution at which the criteria apply. These are the 7Q10 flow for the CCC, the 1Q10 flow for the CMC, and the harmonic mean flow for human health criteria (RAC). The U.S. Geological Survey operates a gaging station on the river; the flow statistics were calculated using the data from this station:

- Harmonic mean flow = 38.0 cfs
- 7Q10 flow = 13.0 cfs
- 1Q10 flow = 10.1 cfs.

The facility provided a study of the outfall that showed that the multiport diffuser quickly achieved complete mixing across the width of the river. Dilution at the edge of the mixing zone could therefore be characterized by the complete mixing equation:

$$C = (C_{em}Q_e + C_sQ_s)/(Q_e + Q_s)$$

where

C = the receiving water concentration

C_{em} = the maximum effluent concentration

Q_e = the effluent flow

C_s = the receiving water background concentration

Q_s = the appropriate receiving water flow.

Step 4: Determine Reasonable Potential for Excursions

To determine if the facility discharge was expected to cause or have the reasonable potential to cause the CMC, CCC, or RAC to be exceeded in the receiving water, the maximum receiving water concentration of each pollutant was first compared to the appropriate receiving water criterion. If the criteria were exceeded, then this was considered evidence that a water quality-based limitation must be developed.

Maximum expected concentrations were calculated using the average effluent flow, maximum effluent concentrations, background receiving water concentrations, and the relevant receiving water flow: the 1Q10 for the CMC, the 7Q10 for the CCC, or the harmonic mean for the RAC. The background receiving water concentrations for total recoverable metals were obtained from STORET data:

Lead	1.6 µg/l
Copper	4.8 µg/l
Nickel	13.2 µg/l

The maximum effluent concentration was estimated using the statistical approach in Chapter 3. There were 12 concentrations of each metal reported in the DMRs. For lead, these concentrations had a maximum value of 423 µg/l, an arithmetic mean of 258 µg/l, an arithmetic standard deviation of 74, and an arithmetic coefficient of variation of 74/258, or 0.3. This coefficient of variation and the number of observations determined which multiplier was selected from Table 3-1. In this case, the multiplier value for 12 observations and a CV of 0.3 was interpolated from the values for 12 observations and CVs of 0.2 and 0.4. The 99th percentile multiplier was estimated to be 1.7. Similar calculations were conducted for copper (multiplier of 2.8) and nickel (multiplier of 3.7).

The receiving water concentration for lead for comparison with the CCC was calculated using data from Table 7-1:

$$C = \frac{[(1.7 \times 423\ \mu g/l \times 0.034\ cfs) + (1.6\ \mu g/l \times 13\ cfs)]}{(0.034\ cfs + 13\ cfs)}$$

$$= 3.5\ \mu g/l$$

where

13 cfs	=	the receiving water flow at 7Q10
0.034 cfs	=	the mean effluent flow
423 µg/l	=	the maximum effluent concentration
1.7	=	the statistical effluent multiplier to estimate the 99th percentile concentration
1.6 µg/l	=	the background receiving water concentration.

The value of the calculated receiving water concentration, 3.5 µg/l, was less than the chronic water quality standard of 9.1 µg/l for lead, and therefore there is no reasonable potential for the CCC to be exceeded.

Using the effluent data presented in Table 7-1, the receiving water concentration is compared to the CMC as:

$$C = \frac{[(1.7 \times 423\ \mu g/l \times 0.034\ cfs) + (1.6\ \mu g/l \times 10.1\ cfs)]}{(0.034\ cfs + 10.1\ cfs)}$$

$$= 4.0\ \mu g/l$$

where 10.1 is the receiving water 1Q10 flow and the other values are identical to those for the CCC comparison. The resulting concentration of 4.0 µg/l was less than the acute standard of 234 µg/l for lead. There is no reasonable potential for the CMC to be exceeded.

For human health criterion evaluation, the receiving water concentration for compared to the RAC was calculated as:

$$C = \frac{[(1.7 \times 423\ \mu g/l \times 0.034\ cfs) + (1.6\ \mu g/l \times 38\ cfs)]}{(0.034\ cfs + 38\ cfs)}$$

$$= 2.2\ \mu g/l$$

where 38 cfs is the harmonic mean flow and other values are the same as above. This value was less than the human heath criteria value of 50 µg/l for lead, so there is no reasonable potential for the RAC to be exceeded.

Similar calculations were done for copper and nickel:

	Criterion (µg/l)	Receiving Water Concentration (µg/l)
Copper		
CCC	17.1	22.0
CMC	25.7	26.9
Nickel		
CCC	188	15.9
CMC	1,647	16.6
RAC	13.4	14.1

The effluent characterization showed the reasonable potential for excursions above the CCC for copper and above the RAC for nickel. Therefore, permit limits are necessary for these two pollutants.

7.2.3 Effluent Characterization for Whole Effluent Toxicity

Whole effluent toxicity also was evaluated since there was a potential for excursions above the narrative water quality criterion due to the combination of effluent toxicants with other toxicants in the receiving water and in the effluent but below the detection level. The procedures used below follow those presented schematically in Figure 3-2, Chapter 3.

Step 1: Dilution Determination

The initial dilution determination was used to establish the types of toxicity tests that are conducted to characterize the effluent. The dilution at the low-flow characteristics for the facility is the following:

At the 7Q10, dilution = (0.034 cfs + 13 cfs)/0.034 cfs
= 383

At the 1Q10, dilution = (0.034 cfs + 10.1 cfs)/0.034 cfs
= 298.

Step 2: Conduct Toxicity Testing

EPA recommends that a discharger having a dilution between 100 and 1,000 be required to conduct either chronic or acute toxicity testing. The permitting authority decided to require chronic testing but required the permittee to report the test results at the 48-hour endpoint so that acute toxicity could be measured. One year before the permit was due to expire, the permitting authority requested, under the authority of the Clean Water Act (CWA) Section 308, that the permittee test his effluent for toxicity to provide effluent information in order to write the next NPDES permit. In this case, the permitting authority specified that the discharger submit quarterly chronic toxicity data for 1 year using the EPA toxicity tests for *Selenastrum, Ceriodaphnia,* and *Pimephales*. The permitting authority also specified that upstream ambient water be used as the diluent in the tests so as to allow the tests to measure additive effects from ambient toxics. In response to the Section 308 request, the discharger submitted the whole effluent toxicity data shown in Table 7-1.

Step 3: Determine Reasonable Potential for Excursions

The State interprets its narrative criteria for whole effluent toxicity to require that the technical support document recommendations of 0.3 TU_a and 1.0 TU_c be used as numeric values for acute and chronic toxicity, respectively. In accordance with the State standards, the CMC applies under the 1Q10 flow and the CCC applies under the 7Q10 flow.

The determination of exceedance of the CMC or the CCC was simplified by the way in which the tests were conducted. Since the upstream ambient water was used as a diluent, the test results

already include an assessment of contributions from background toxicity. Therefore, the upstream receiving water concentration was set to zero.

The maximum effluent concentration was again estimated by using the statistical approach in Chapter 3. As shown in Table 7-1, there were four observations of whole effluent toxicity. Based on the guidance of Box 3-4, these are insufficient to determine the CV accurately; therefore, the default CV of 0.6 was used. The effluent multiplier of 4.7 was obtained from Table 3-1 using the number of observations, the CV, and the 99-percent probability basis.

The receiving water concentration for chronic toxicity for comparison with the CCC was calculated using data from Table 7-1:

$$C = \frac{(4.7 \times 20\ TU_c \times 0.034\ cfs) + (0\ TU_c \times 13\ cfs)]}{(0.034\ cfs + 13\ cfs)}$$
$$= 0.25\ TU_c$$

where

13 cfs	=	the receiving water flow at 7Q10
0.034 cfs	=	the mean effluent flow
4.7	=	the statistical effluent multiplier
20 TU_c	=	the maximum effluent concentration.

The value of the calculated receiving water concentration, 0.25 TU_c, was less than the chronic water quality standard of 1.0 TU_c, and therefore there is no reasonable potential for the CCC to be exceeded.

To calculate the receiving water concentration for acute toxicity, the permitting authority first converted the chronic toxicity data into equivalent acute toxicity units by applying the acute-to-chronic ratio (ACR) of 5 obtained from the monitoring data. The receiving water concentration for acute toxicity was then calculated:

$$C = \frac{[(4.7 \times 20\ TU_c / 5\ ACR \times 0.034\ cfs) + (0\ TU_c \times 10.1\ cfs)]}{(0.034\ cfs + 10.1\ cfs)}$$
$$= 0.06\ TU_a$$

where 10.1 cfs is the receiving water flow at 1Q10, 5 is the acute to chronic ratio, and the other values are the same as above. The calculated value of 0.06 TU_a is below the criterion of 0.3 TU_a; therefore, there is no reasonable potential for the CMC to be exceeded. Since there was no reasonable potential for exceedances above either the acute or chronic criterion, permit limits were not developed for whole effluent toxicity.

7.2.4 Determine Wasteload Allocations

The wasteload allocation (WLA) was used to determine the level of effluent concentration that would comply with water quality standards in the receiving waters. A WLA will only be determined for those parameters that have a reasonable potential to cause exceedances of water quality standards. Therefore, WLAs were determined for copper and nickel. Since there was no reasonable potential for excursions above the CMC or CCC for nickel, only the WLA for human health was calculated.

To determine WLAs, the numeric criteria in the water quality standards and background concentrations were used to calculate effluent concentrations that would result in compliance with those standards. The calculation of WLAs used receiving water flows that were appropriate to each standard: chronic WLAs were calculated using the 7Q10 flow, acute WLAs were calculated using the 1Q10 flow, and human health WLAs were calculated using the harmonic mean flow. Since the effluent was mixed rapidly by the multiport diffuser, the complete mix equation was used:

$$WLA = [WQC \times (Q_e + Q_s) - Q_s C_s]/Q_e$$

where

Q_e	=	the effluent flow
Q_s	=	the receiving water flow
C_s	=	the background receiving water concentration
WQC	=	the water quality criterion.

The chronic and acute WLA for copper were calculated at the 7Q10 and 1Q10 flows, respectively:

$$WLA_c = [17.1\ \mu g/l \times (0.034\ cfs + 13\ cfs) - 13\ cfs \times 4.8\ \mu g/l] / 0.034\ cfs$$
$$= 4{,}720\ \mu g/l$$

$$WLA_a = [25.7\ \mu g/l \times (0.034\ cfs + 10.1\ cfs) - 10.1\ cfs \times 4.8\ \mu g/l] / 0.034\ cfs$$
$$= 6{,}234\ \mu g/l.$$

The human health WLA for nickel was calculated at the harmonic mean flow:

$$WLA_h = [13.4\ \mu g/l \times (0.034\ cfs + 38\ cfs) - 38\ cfs \times 13.2\ \mu g/l / 0.034\ cfs$$
$$= 237\ \mu g/l.$$

7.2.5 Develop Permit Limits

Permit limits were developed using a steady-state, two-value WLA model as described in Box 5-2, Chapter 5. Values for constants were obtained from Table 5-2, Chapter 5.

Step 1: Calculate LTA (note: this is Step 2 in Box 5-2)

The chronic long-term average (LTA) for copper was calculated using the following formula:

$$LTA_c = WLA \times \exp[0.5\,\sigma^2 - z\,\sigma]$$
$$= 4{,}720\ \mu g/l \times 0.440$$
$$= 2{,}077\ \mu g/l$$

where values of $\exp[0.5\,\sigma^2 - z\,\sigma\sigma]$ are presented in Table 5-1 (see Chapter 5). The CV of 0.8 was used, and following the

guidance of Section 5.5.4, the z value for the 99th occurrence probability was used.

The acute LTA for copper was calculated, again using the 99th percentile occurrence probability values from Table 5-1 as the multiplier:

$$LTA_a = 6{,}234\ \mu g/l \times 0.249$$
$$= 1{,}552\ \mu g/l.$$

The LTA for nickel human health permitting is considered to be the same as the WLA because the 70-year averaging period is used for human health evaluations (see Section 5.4.4). The LTA is calculated as:

$$LTA_h = WLA_h$$
$$= 237\ \mu g/l.$$

Step 2: Determine the More Limiting LTA

The limiting LTA for each pollutant was the minimum of the chronic, acute and human health LTA. The limiting LTA value was used in the next step to calculate maximum daily limits and average monthly limits. The limiting LTA for copper was found to be the acute LTA (1,552 µg/l) and the limiting LTA for nickel was found to be the human health LTA (237 µg/l).

Step 3: Calculate Maximum Daily and Average Monthly Limits

The maximum daily limit (MDL) for copper was calculated using the expression:

$$MDL = LTA \times \exp[z\sigma - 0.5\sigma^2]$$
$$= 1{,}552\ \mu g/l \times 4.01$$
$$= 6{,}224\ \mu g/l$$

where the appropriate value for $\exp[z\sigma - 0.5\sigma^2]$ was taken from Table 5-2 using the row with the CV for copper (0.8) and the column for the 99th percentile probability basis.

The average monthly limit (AML) for copper was calculated using the expression:

$$AML = LTA \times \exp[z\sigma_n - 0.5\sigma_n^2]$$
$$= 1{,}552\ \mu g/l \times 1.75$$
$$= 2{,}716\ \mu g/l$$

where the value for $\exp[z\sigma_n - 0.5\sigma_n^2]$ was taken from Table 5-2 and, for this case, the number of samples per month was four. Following the recommendations in Section 5.5.4, the z value for the 95th percentile probability basis was used.

The effluent limits for nickel were determined by using the recommendations in Section 5.4.4, Chapter 5. The AML was considered to be identical to the WLA_h whereas the MDL was calculated from the AML by using the appropriate multiplier factor in Table 5-3. With a CV of 0.6, four samples per month for sampling, and a 99th percentile used for the MDL, the factor is 1.64:

$$MDL = AML \times 1.64$$
$$= 237\ \mu g/l \times 1.64$$
$$= 389\ \mu g/l.$$

7.2.6 Determining and Expressing the Controlling Effluent Limits

The NPDES regulations require that effluent limits require treatment characteristic of the appropriate treatment technology and also achieve water quality standards. If water quality-based limits are more stringent than BAT limits, then the water quality-based limits become the basis for the effluent limits. Conversely, if the treatment technology (BAT) limits are more stringent, then they become the basis of the limits.

The comparison between the water quality-based and technology-based effluent limits are shown below. The more stringent limits are different for different pollutants: for nickel, water quality-based limits are more stringent whereas for copper, the BAT limits are the more stringent.

		Copper	Nickel
Water quality	MDL	6,224	389
	AML	2,716	237
BAT	MDL	3,380	3,980
	AML	2,070	2,380
Limit to use	MDL	3,380	389
	AML	2,070	237

In accordance with NPDES regulations, the effluent limits were expressed in the permit as mass (pounds per day) by multiplying the concentrations above by the effluent flow of 0.034 cfs and the conversion factor of 5.394:

	Copper (lb/d)	Nickel (lb/d)
MDL	0.62	0.071
AML	0.38	0.043

7.2.7 Comparing Different Limit Development Methods

Permit limits for copper also were developed using a Monte Carlo simulation in order to compare the results to the permit limits derived from the two-value, steady-state model. A Monte Carlo simulation was used to generate receiving water concentrations to determine the effluent LTA for each of the pollutants such that the water criteria are achieved at the required frequency in the water quality standards.

Monte Carlo simulation used the same completely mixed dilution equation as was used for the steady state calculation:

$$C = (Q_e C_e + Q_s C_s)/(Q_e + Q_s)$$

where C is the receiving water concentration (in µg/l); C_e and C_s are the effluent concentration and the background concentration of the receiving water, respectively (in µg/l); and Q_e and Q_s and effluent and receiving water flows, respectively (in cfs). Effluent flows were held constant at the mean effluent flow, and river flows were read from a computer file containing 60 years of daily flow data provided by the U.S. Geological Survey. The effluent concentrations were characterized by a lognormally distributed random variate. The random variate had a coefficient of variation that matched the CV of the pollutant in the effluent.

The Monte Carlo simulation was run using 22,276 iterations. Once 22,276 receiving water concentrations had been calculated, receiving water concentrations were sorted, highest first. The 20th value (corresponding to the maximum concentration expected for 1 day in 3 years) was compared with the appropriate criterion. The 1-day in 3-year return frequency is recommended by EPA for criteria (see Chapter 2). If this value was higher than the criterion, the effluent LTA was reduced, and a new set of 22,276 numbers was generated. When the receiving water concentration of the 20th value was just under the water quality criterion (and the 19th value was just over the same value), then the LTA effluent concentration generating these results was sufficient to achieve the water quality criterion; this LTA was then used in permit limit determinations.

For chronic criteria, 4-day average concentrations were generated by taking the 4-day running average of modeled daily concentrations. The recurrence concentration was calculated in the same way as the 1-day calculations described in the previous paragraph. Calculations were not made for the human health criterion.

The permit limits were calculated according to the procedures given in Box 5-3. Each LTA was multiplied by the 99th percentile multiplier from Table 5-3 for the MDL, and by the 95th percentile multiplier from Table 5-3 for the AML. For the AML, the same number of samples were used for the steady state and Monte Carlo permit limits (n=4). Thus, the resulting permit limits are directly comparable. The results of the Monte Carlo simulation for copper compared to the steady state calculations in units of micrograms/liter are shown below:

	Maximum Daily	Average Monthly
Monte Carlo	8,618	3,761
Steady State	6,224	2,716

7.3 CASE 2: POTW DISCHARGE

The second example is of a fictitious POTW that discharges to the same reach as the Jaybird Corporation. The NPDES permit for this facility also is up for reissuance. The example highlights the use of background receiving water concentrations, and demonstrates the differences between industrial and POTW permit limits. In developing permit limits for the POTW in this example, the potential impacts from the Jaybird Corporation discharge were considered in the use of background receiving water concentrations. The interrelationships between the two facilities are discussed explicitly in Section 7.4.

7.3.1 General Site Description and Information

The Locapunct River receives discharges from a POTW serving the city of Auburn, a small city of about 10,000 people. The POTW treats a mixture of household and industrial waste with an activated sludge process. The mean effluent flow from the POTW is 1.23 cfs. The POTW has no pretreatment program, but the municipality generally is aware of the small industries that are indirect dischargers because of research conducted by a local university. Generally, the plant is well operated.

7.3.2 Effluent Characterization for Specific Chemicals

The permitting authority's approach for determining which pollutants cause, have the reasonable potential to cause, or contribute to excursions above water quality standards applies to POTWs as well as industries. The authority used the procedures described for the Jaybird Corporation in the evaluation of the Auburn POTW.

Step 1: Identify Pollutants of Concern

At the time of the last permit issuance, there was evidence of a number of toxic pollutants in the POTW's effluent, including copper, chlorine, and ammonia. These pollutants had monitoring requirements in the previous permit. Because there were metals in the effluent and, due to the industries discharging into the POTW sewer system, the permitting authority requested the POTW to conduct a complete priority pollutant scan of the effluent. The data received following the Section 308 letter request indicated that the concentrations of all priority pollutants except copper were below detection limits. The POTW's primary toxic pollutants of concern were copper, chlorine, and ammonia (see Table 7-2).

Step 2: Determine RAC, CMC, or CCC for Pollutants of Concern

As described in the example of the industrial discharge, the water quality standards include numeric criteria for copper. The State also has adopted a numeric criterion for ammonia that is a function of the river 85th percentile pH and temperature; these values are 8.25°C and 25°C, respectively. Finally, the State interprets its narrative criterion of "no toxics in toxic amounts" to require use of the federal water quality criteria in the absence of a numeric state criterion. As a result, the permitting authority uses the federal criteria for chlorine. The applicable water quality criteria for the river are as follows:

	CCC (µg/l)	CMC (µg/l)
Copper	17.1	25.7
Chlorine	11	19
Ammonia	540	4,000

Table 7-2. Effluent Data for the Auburn POTW

n	Copper µg/l	Chlorine µg/l	Ammonia µg/l	Toxicity TU_c
1	268	185	11,009	2
2	115	301	13,025	1
3	228	881	12,201	1
4	59	372	24,548	2
5	53	245	9,700	
6	213	244	15,645	
7	68	123	21,358	
8	200	343	3,976	
9	262	153	22,307	
10	519	448	7,427	
11	53	1,022	11,834	
12	474	347	8,430	
13	115	130	4,382	
14	259	128	9,330	
15	404	271	6,137	
16	57	451	6,448	
17	101	701	37,772	
18	187	582	14,307	
19	103	178	16,848	
20	76	436	28,205	
21	198	347	12,119	
22	265	475	11,778	
23	60	153	3,109	
24	112	268	4,474	
Mean	185	366	13,182	1.5
SD	133	235	8,491	0.6
CV	0.7	0.6	0.6	0.4
Max	519	1,022	37,772	2
Min	52.6	123	3,109	1

Source: DMR data for chemicals; 308 request for whole effluent toxicity.
Notes:
Metals as total recoverable; toxicity in toxic units (100/NOEC).
The results are the highest toxic units for any of the test organisms used.

Step 3: Determine Dilution for Aquatic Life and Human Health Impacts

The State water quality standards requires that compliance with water quality criteria be achieved at the edge of the mixing zone. The standards specify the minimum dilution at which the criteria apply. These are the 7Q10 flow for the CCC, the 1Q10 flow for the CMC, and the harmonic mean flow for human health criteria (RAC). The U.S. Geological Survey operates a gaging station on the river. The flow statistics were calculated using the data from this station:

- Harmonic mean flow = 38.0 cfs
- 7Q10 flow = 13.0 cfs
- 1Q10 flow = 10.1 cfs.

The POTW is located at a bend of the river where mixing is rapid. Therefore, the permitting authority used the complete mixing equation to calculate the receiving water concentrations. This is the same equation used for the industrial example.

Step 4: Determine Reasonable Potential for Excursions

The determination of possible exceedances in the CMC or CCC was based on a calculation of the maximum receiving water concentration of each pollutant, followed by a comparison to the appropriate receiving water criterion. The calculation of the maximum receiving water concentrations were made using the statistical estimate of the 99th percentile concentration of each pollutant in the effluent, the same flow used in the industrial example, and considered background receiving water concentrations of:

Copper	4.8 µg/l
Chlorine	0 µg/l
Ammonia	120 µg/l.

The maximum effluent concentration was estimated using the statistical approach in Chapter 3. There were 24 concentrations of each chemical reported in the DMRs. For copper, these concentrations had a maximum value of 519 µg/l, an arithmetic mean of 185 µg/l, an arithmetic standard deviation of 133, and an arithmetic coefficient of variation of 133/185, or 0.7. The multiplier was calculated to be 2.4 based on the CV of 0.7, 24 observations, and a 99-percent confidence level (see Section 3.3.2). Similar calculations were conducted for chlorine (multiplier of 2.2) and ammonia (multiplier of 2.2).

The receiving water concentrations for each pollutant were calculated. An example calculation for the comparison of copper to the CCC is shown below:

$$C = \frac{[(2.4 \times 519\ \mu g/l \times 1.23\ cfs) + (4.8\ \mu g/l \times 13\ cfs)]}{(1.23\ cfs + 13\ cfs)}$$

$$= 112\ \mu g/l$$

where

519 µg/l	=	the maximum measured effluent concentration
2.4	=	the statistical multiplier
1.23 cfs	=	the average effluent flow
4.8 µg/l	=	the upstream receiving water concentration
13 cfs	=	the 7Q10 flow.

The maximum receiving water concentrations for comparison to applicable standards for all pollutants were calculated to be:

	Criterion (µg/l)	Receiving Water Concentration (µg/l)
Copper		
CCC	17.1	112
CMC	25.7	140
Chlorine		
CCC	11	194
CMC	19	244
Ammonia		
CCC	540	7,292
CMC	4,000	9,128

The effluent characterization showed the reasonable potential for excursions above the CCC and CMC for copper, chlorine, and ammonia. Therefore, permit limits were developed for these pollutants.

7.3.3 Effluent Characterization for Whole Effluent Toxicity

Step 1: Dilution Determination

The initial dilution determination was used to establish the types of toxicity tests that must be conducted to characterize the effluent. The dilution at the low flow characteristics for the facility is the following:

At the 7Q10, dilution = (1.23 cfs + 13 cfs)/1.23 cfs
= 11.6

At the 1Q10, dilution = (1.23 cfs + 10.1 cfs)/1.23 cfs
= 9.2.

Step 2: Conduct Toxicity Testing

EPA recommends that a discharger having a dilution less than 100 be required to conduct chronic testing. The permitting authority requested through a Section 308 letter that the POTW provide quarterly chronic toxicity data for the year prior to permit reissuance. Tests using *Selenastrum, Ceriodaphnia,* and *Pimephales* were required. The permitting authority also required the permittee to report the test results at the 48-hour endpoint so that acute toxicity also could be measured. Table 7-2 summarizes the results of the whole effluent toxicity testing.

Step 3: Determine Reasonable Potential for Excursions

As explained in the industrial example, the State interprets its narrative criteria for whole effluent toxicity to require that the technical support document recommendations of 0.3 TU_a and 1.0 TU_c be used as numeric values for acute and chronic toxicity, respectively. In accordance with the State standards, the CMC applies under the 1Q10 flow and the CCC applies under the 7Q10 flow.

The reasonable potential determination of exceedance of the CMC or the CCC was conducted in the same way as described in the industrial example. Upstream ambient water was used as a diluent to assess contributions directly from background toxicity; therefore, the upstream receiving water concentration was set to zero. The maximum effluent concentration was again estimated by using the statistical approach in Chapter 3. For the same reasons as were expressed in the industrial example, a multiplier of 4.7 was used.

The receiving water concentration for chronic toxicity for comparison with the CCC was calculated using data from Table 7-2:

$$C = \frac{(4.7 \times 2\ TU_c \times 1.23\ cfs) + (0\ TU_c \times 13\ cfs)}{(1.23\ cfs + 13\ cfs)}$$
$$= 0.8\ TU_c$$

where

13 cfs = the receiving water flow at 7Q10
1.23 cfs = the mean effluent flow
4.7 = the statistical effluent multiplier
4 TU_c = the maximum effluent concentration.

The value of the calculated receiving water concentration, 0.8 TU_c, is less than the chronic water quality standard of 1.0 TU_c, and therefore there is no reasonable potential for the CCC to be exceeded.

To calculate the receiving water concentration for acute toxicity, the permitting authority first converted the chronic toxicity data into equivalent acute toxicity units by applying the ACR of 2 obtained from the monitoring data. The receiving water concentration for acute toxicity was then calculated:

$$C = \frac{[(4.7 \times 2\ TU_c / 2\ ACR \times 1.23\ cfs) + (0\ TU_c \times 10.1\ cfs)]}{(1.23\ cfs + 10.1\ cfs)}$$
$$= 0.5\ TU_a$$

where 10.1 cfs is the receiving water flow at 1Q10, 2 is the acute to chronic ratio, and the other values are the same as above. The calculated value of 0.5 TU_a is greater than the criterion of 0.3 TU_a. Therefore, there is reasonable potential for the CMC to be exceeded and permit limits were developed for whole effluent toxicity.

7.3.4 Determine Wasteload Allocations

WLAs for chemicals and whole effluent toxicity were determined using information on the available dilution at the edge of the mixing zone. The calculation of WLA using the steady-state model was described in Section 7.2.4. The WLAs for the POTW using the equation discussed in Section 7.2.4 are:

	Toxicity (TU)	Copper (µg/l)	Chlorine (µg/l)	Ammonia (µg/l)
WLA_a	2.8	197	175	35,860
WLA_c	11.6	147	127	4,979

7.3.5 Develop Permit Limits

The permit limit development process described in Box 5-2, Chapter 5 was applied to all pollutants. This process is identical to that explained in Section 7.2.5 except that (1) the WLA for acute toxicity needs to be expressed in equivalent chronic toxic units by multiplying by the ACR of 2, and (2) daily sampling of chlorine is required in the permit. The calculated LTA and permit limits are:

	Toxicity TU_c	Copper (µg/l)	Chlorine (µg/l)	Ammonia (µg/l)
LTA_a	1.8	55.4	56.2	11,511
LTA_c	6.1	70.7	66.9	2,625
MDL	5.6	197	175	8,162
AML	2.8	91	87	4,067

7.3.6 Determining and Expressing the Controlling Effluent Limit

The treatment technology for POTWs is secondary treatment and is characterized by effluent limits for biochemical oxygen demand, total suspended solids, and pH. There are no BAT limits for toxics for POTWs, so there was no need to compare these water quality-based limits with other limits to determine which were more stringent.

The permitting authority decided to use acute toxicity tests rather than chronic tests to measure compliance with the toxicity effluent limits. The appropriate effluent limits in terms of TU_a were calculated by dividing the above calculation for TU_c by the ACR of 2 that was obtained from effluent monitoring.

In accordance with NPDES regulations, the effluent limits for chemicals were expressed in the permit as mass (pounds per day) by multiplying the concentrations above by the effluent flow of 1.23 cfs and the conversion factor of 5.394. Because there is no equivalent mass based unit for toxicity, toxicity mass limits are impractical under the regulation.

	Toxicity TU_a	Copper (lb/d)	Chlorine (lb/d)	Ammonia (lb/d)
MDL	2.8	1.31	1.16	54.2
AML	1.4	0.64	0.58	27.0

7.3.7 Comparing Different Limit Development Methods

Permit limits also were developed using a Monte Carlo simulation to compare the results to the steady-state permit limits. A Monte Carlo simulation was used to generate receiving water concentrations for determining the appropriate LTA for each of the pollutants. The methodology for the Monte Carlo simulation is presented in Section 7.2.7. The results for this case are presented below.

MDLs in TU_a and µg/l

	Toxicity	Copper	Chlorine	Ammonia
Monte Carlo	3.9	264	249	9,657
Steady State	2.8	197	175	8,162

AMLs in TU_a and µg/l

	Toxicity	Copper	Chlorine	Ammonia
Monte Carlo	2.7	171	170	6,614
Steady State	1.4	91	87	4,067

7.4 CASE 3: MULTIPLE DISCHARGES INTO THE SAME REACH

Permit development for water quality-based toxics control has been illustrated for two single dischargers. This process increases in complexity in cases of multiple dischargers into a reach. The development of permit limits for multiple dischargers is based on the degradation in water quality resulting from the combined discharges, the development of total maximum daily loads (TMDLs) for the river reach before generating WLAs, and the allocation of discharges to each discharger. The following example describes the permit development process when two dischargers release effluent into the same reach of a river. The dischargers are the Jaybird manufacturing plant described in Case 1 and the Auburn POTW described in Case 2. These facilities discharge into the Locapunct River, whose flow characteristics previously were described.

7.4.1 Effluent Characterization

The major differences in the effluent characterization for one facility and for multiple facilities is to identify those pollutants that are common to more than one facility, and to determine whether the combined discharges cause or are likely to cause water quality standards excursions.

Step 1: Identify Pollutants of Concern

Based on the data in Form 2C, the DMRs from the Jaybird Corporation and the data in the DMRs and Section 308 request from the Auburn POTW, the permitting authority found two contaminants common to both discharges: copper and whole effluent toxicity. Lead and nickel were found to be a problem at the Jaybird Corporation, but since there were no complicating discharges from the POTW, it was dealt with as a pollutant only at the metal finishing facility. Similarly, chlorine and ammonia were discharged solely by the POTW, so it was not necessary to provide effluent limits for the metal finishing facility for these chemicals.

Step 2: Determine the CMC and CCC for Pollutants of Concern

The numerical standards adopted by the State already have been presented. The relevant values for copper and whole effluent toxicity are:

	CCC	CMC
Copper	17.1 µg/l	25.7 µg/l
Toxicity	1.0 TU_c	0.3 TU_a

Step 3: Determine Dilution for Aquatic Life and Human Health Impacts

Since this example is concerned with potential excursions above standards resulting from the collective discharge of two dischargers, the calculation of dilution includes the combined effluent flow from both facilities. The combined dilution can be characterized by the complete mixing equation:

$$C = (C_{e1}Q_{e1} + C_{e2}Q_{e2} + C_sQ_s)/(Q_{e1} + Q_{e2} + Q_s)$$

where

Q_{e1} and Q_{e2} = the flows of the two facilities
C_{e1} and C_{e2} = the effluent concentrations of the two facilities
C_s = the upstream receiving water concentration
Q_s = the receiving water flow.

Step 4: Determine Reasonable Potential for Excursions

To determine if the CMC or CCC were exceeded as a result of the combined discharges into the river, the receiving water concentration of each pollutant was calculated and compared to the appropriate criterion. The receiving water concentration calculation was based on the maximum value of the effluent concentrations (obtained from effluent data and multiplied by the appropriate statistical factor), average effluent flows, background receiving water concentrations, and appropriate river flows. All this information has been presented previously in the separate examples. The following results were obtained:

	Criterion (µg/l)	Receiving Water Concentration (µg/l)
Copper		
CCC	17.1	156
CMC	25.7	194
Toxicity		
CCC	1.0	0.57
CMC	0.3	0.45

These calculations demonstrated exceedances of the copper CCC and CMC criteria and the toxicity CMC criterion. Permit limits were required.

7.4.2 TMDLs and WLAs

WLAs were calculated to develop permit limits. WLAs for each discharger and chemical were based on calculated TMDLs, the total load to the Locapunct River that would not result in water quality standards exceedances. TMDLs are comprised of a load allocation for nonpoint sources, WLAs for point sources, and, if required by the State, a reserve capacity. TMDLs are further described in Section 4.2, Chapter 4.

Step 1: Calculate TMDL

The first step in developing individual WLAs for the two dischargers was to develop TMDLs for each pollutant of concern. TMDLs were developed in the same way as an individual WLA with the total load of a pollutant from the two dischargers being considered as a single discharge.

The calculation of TMDLs used the following formula:

$$TMDL = WQS \times (Q_t + Q_s)$$

where

WQS = the water quality standard

Q_t = the combined flow of both effluents

Q_s = the appropriate receiving water flow.

The acute copper TMDL was calculated by using the data presented in the previous two examples as:

$$TMDL = 25.7\ \mu g/l \times (0.034\ cfs + 1.23\ cfs + 10.1\ cfs)$$
$$= 292\ \mu g\text{-}cfs/l$$

where

25.7 µg/l = the CMC

0.034 cfs and

1.23 cfs = the average effluent flows

10.1 = the 1Q10.

Similar calculations were made for chronic copper and acute toxicity. A TMDL was not calculated for chronic toxicity because the information presented in Chapter 1 indicates that chronic toxicity does not demonstrate additivity. The results are summarized below.

	Total Maximum Daily Loads	
	Chronic	Acute
Copper (µg-cfs/l)	244	292
Toxicity (TU_a-cfs/l)	NA	3.4

Step 2: Develop WLAs

The State had adopted an approach into the water quality management plan that described how WLAs were to be calculated. The approach required that existing upstream concentrations be used to determine the load allocation part of the TMDL and that 10 percent of the TMDL had to be reserved and unavailable for allocation. The remainder of the TMDL could be apportioned to point sources in the WLA.

The permitting authority decided to allocate the wasteloads based on the proportion of the existing load of each parameter that was attributed to each of the existing discharges. Based on the information shown in Tables 7-1 and 7-2 and the average effluent flows, the pollutant loads from each facility are shown below.

	Auburn POTW		Jaybird Corporation	
Parameter	Load	Proportion	Load	Proportion
Copper (µg-cfs/l)	227.6	0.77	66.1	0.23
Toxicity (TU_a-cfs)	1.23	0.90	0.14	0.10

Individual WLAs were then determined using the following equation:

$$WLA = (TMDL - LA - 10\%\ TMDL) \times proportion/Q_e$$

where the chronic TMDL was used to determine the chronic WLA, and the acute TMDL was used to determine the acute WLA for each facility. The WLAs for each pollutant and for each facility are presented on the following page.

Jaybird	Acute WLA		Chronic WLA	
Copper (µg/l)	134	1,450	98.4	1,063
Toxicity (TU_a)	2.2	9.0	NA	NA

7.4.3 Permit Limit Development

Once the WLAs had been determined, permit limit development proceeded as in the previous examples. LTAs were calculated from the WLAs, and the limiting LTA was selected for calculating permit limits. For the metal finisher, where BAT limits were more restrictive than the water quality-based limits, the BAT limits applied. For the POTW, permit limits for toxic materials were required only to prevent exceedances of water quality standards. This process is summarized below.

Step 1: Calculate LTAs

The LTA was calculated for each discharger and pollutant as described in Step 2, Box 5-2, Chapter 5; the LTAs are shown below.

	Acute LTA		Chronic LTA	
Parameter	POTW	Jaybird	POTW	Jaybird
Copper (µg/l)	37.7	361	47.3	468
Toxicity (TU_a)	0.71	2.9	NA	NA

Step 2: Determine the More Lmiting LTA

The minimum LTA was used to calculate MDLs and AMLs. The acute LTA was the lower LTA for both pollutants.

Step 3: Calculate the Maximum Daily and Average Monthly Limits

The MDL and AML were calculated as described in Box 5-2, Chapter 5:

	Average Monthly Limit		Maximum Daily Limit	
Parameter	POTW	Jaybird	POTW	Jaybird
Copper (µg/l)	62	632	134	1,448
Toxicity (TU_a)	1.1	4.5	2.2	9.0

Step 4: Express the Limits

The final step is to compare the water quality-based limits to the BAT limits to ensure that the more restrictive of the two are used, and to express the copper limits in terms of mass. The copper water quality-based limits for Jaybird Corporation are lower than the BAT ones (see Section 7.2.6). Therefore, the water quality-based limits are required by the permit. In addition, the limits are lower than those calculated when only one of the facilities were considered. The final permit limits are listed below.

	Average Monthly Limit		Maximum Daily Limit	
Parameter	POTW	Jaybird	POTW	Jaybird
Copper (lb/d)	0.41	0.12	0.89	0.27
Toxicity (TU_a)	1.1	4.5	2.2	9.0

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* *This is not a comprehensive index. Only topics of importance are highlighted.*

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Appendix A-1

Toxicity Test Precision Data

Marine/Estuarine Short-Term Chronic Toxicity Tests

SHEEPSHEAD MINNOW (*Cyprinodon variegatus*)

Seven-day Larval Survival and Growth Test
Single Laboratory Precision Data

Table A-1-1. Single laboratory precision of test performed in 40 fathoms artificial seawater, using larvae from fish maintained and spawned in 40 fathoms artificial seawater, using copper as the reference toxicant [1].

Test Number	NOEC (mg/l)	IC_{25} (mg/l)	IC_{50} (mg/l)	Most Sensitive Endpoint
1	0.05	0.1133	0.1523	S
2	<0.05*	0.0543	0.0975	G
3	<0.05*	0.0418	0.0714	G
4	0.05	0.0632	0.0908	S
5	<0.05*	0.0577	0.0998	S
6	0.05	0.0483	0.1325	G
7	0.05	0.0796	0.1597	G
8	0.05	0.1235	0.2364	G
n:	5	8	8	
Mean:	0.05	0.0727	0.1300	
CV(%):	NA	41.82	40.77	

* The lowest concentration tested was 0.05 mg./l

NOEC Range: >0.05* - 0.05 mg/l.

Copper concentrations in Tests 1-6 were 0.050, 0.10, 0.20, 0.40, and 0.80 mg/l and Tests 7-8 were 0.025, 0.050, 0.10, 0.20, and 0.40 mg/l.

Prepared by Florence Kessler, TAI, Cincinnati, OH, January 11, 1990 (ICp Program, version 1.1b).

Table A-1-2. Single laboratory precision of test performed in 40 fathoms artificial seawater, using larvae from fish maintained and spawned in 40 fathoms artificial seawater, using sodium dodecyl sulfate (SDS) as the reference toxicant [1].

Test Number	NOEC (mg/l)	IC_{25} (mg/l)	IC_{50} (mg/l)	Most Sensitive Endpoint
1	1.0	1.2799	1.5598	S
2	1.0	1.4087	1.8835	S
3	1.0	2.3051	2.8367	S
4	0.5	1.9855	2.6237	G
5	1.0	1.1901	1.4267	S
6	0.5	1.1041	1.4264	G
n:	6	6	6	
Mean:	0.8	1.5456	1.9595	
CV(%):	NA	31.44	31.82	

NOEC Range: 0.5 - 1.0 mg/l (this represents a difference of one exposure concentration).

SDS concentrations in Tests 1-2 were 1.0, 1.9, 3.9, 7.7, and 15.5 mg/l and in Tests 3-6 were 0.20, 0.50, 1.0, 1.9, and 3.9 mg/l.

Prepared by Florence Kessler, TAI, Cincinnati, OH, January 11, 1990 (ICp Program, version 1.1b).

Table A-1-3. Single laboratory precision of test performed in natural seawater, using larvae from fish maintained and spawned in natural seawater, using copper as the reference toxicant [1].

Test Number	NOEC (mg/l)	IC_{25} (mg/l)	IC_{50} (mg/l)	Most Sensitive Endpoint
1	125	320.3	437.5	S
2	31	182.3	323.0	G
3	125	333.4	483.4	S
4	125	228.4	343.8	S
5	125	437.5	NC*	S
n:	5	5	4	
Mean:	106.2	300.4	396.9	
CV(%):	NA	33.0	19.2	

* No linear interpolation estimate could be calculated from the data, since none of the group response means were less than 50 percent of the control response mean.

NOEC Range: 31 - 125 mg/l (this represents a difference of two exposure concentrations).

Prepared by Elise Torello, SAIC, Narragansett, RI, and Margarete Heber, EPA, Washington, DC, February 1990 (ICp Program, version 1.1b).

Table A-1-4. Single laboratory precision of test performed in natural seawater, using larvae from fish maintained and spawned in natural seawater, using sodium dodecyl sulfate (SDS) as the reference toxicant [1].

Test Number	NOEC (mg/l)	IC_{25} (mg/l)	IC_{50} (mg/l)	Most Sensitive Endpoint
1	2.5	2.9	3.6	S
2	1.3	NC[1]	NC[2]	G
3	1.3	1.9	2.4	S
4	1.3	2.4	NC[2]	G
5	1.3	1.5	1.8	S
n:	5	4	3	
Mean:	1.5	2.2	2.6	
CV(%):	NA	27.6	35.3	

NOEC Range: 1.3 - 2.5 mg/l (this represents a difference of one exposure concentration).

[1] No linear interpolation estimate could be calculated from the data, since none of the group response means were less than 75 percent of the control response mean.

[2] No linear interpolation estimate could be calculated from the data, since none of the group response means were less than 50 percent of the control response mean.

Prepared by Elise Torello, SAIC, Narragansett, RI, and Margarete Heber, EPA, and Washington, DC, February 1990 (ICp Program, version 1.1b).

SHEEPSHEAD MINNOW (*Cyprinodon variegatus*)

Seven-day Larval Survival and Growth Test
Interlaboratory Precision Data

Table A-1-5. Interlaboratory precision of test using an industrial effluent as the reference toxicant [1].

	Test Number	Most Sensitive Endpoint NOEC (%)	IC_{25} (%)	IC_{50} (%)
Laboratory A				
	1	3.2 (S,G)	7.4 (S)	7.4 (G)
	2	3.2 (S,G)	7.6 (S)	14.3 (G)
Laboratory B				
	1	3.2 (S,G)	5.7 (G)	9.7 (G)
	2	3.2 (S,G)	5.7 (G)	8.8 (G)
Laboratory C				
	1	1.0 (S)	4.7 (S)	7.2 (S)
Laboratory D				
	1	3.2 (S,G)	7.4 (G)	24.7 (G)
	2	1.0 (G)	5.2 (S)	7.2 (S)
n:		7	7	7
Mean:		2.6	5.5	11.3
CV(%):		NA	44.2	56.9

NOEC Range: 1.0 - 3.2 percent (this represents a difference of one exposure concentration).

Prepared by Elise Torello, SAIC, Narragansett, RI, and Margarete Heber, EPA, and Washington, DC, February (ICp Program, version 1.1b).

SHEEPSHEAD MINNOW (*Cyprinodon variegatus*)

Embryo-larval Survival and Teratogenicity Test
Single Laboratory Precision Data

Table A-1-6. Single laboratory precision of test performed in HW Marinemix artificial seawater, using embryos from fish maintained and spawned in HW Marinemix artificial seawater, using copper as the reference toxicant [1].

Test Number	EC_1 (ug/l)	EC_5 (ug/l)	EC_{10} (ug/l)	EC_{50} (ug/l)	NOEC (ug/l)
1	173	189	198	234	240
2	*	*	*	*	240
3	*	*	*	*	240
4	182	197	206	240	240
5	171	187	197	234	240
6	*	*	*	*	<200
	*	*	*	*	220
	195	203	208	226	220
n:	4	4	4	4	7
Mean:	180	194	202	233	234
CV(%):	6.1	3.8	2.8	2.5	NA

* Data do not fit the Probit model.

NOEC Range: 200 - 240 (this represents a difference of two exposure concentrations).

SHEEPSHEAD MINNOW (*Cyprinodon variegatus*) (continued)

Embryo-larval Survival and Teratogenicity Test
Single Laboratory Precision Data

Table A-1-7. Single laboratory precision of test performed in HW Marinemix artificial seawater, using embryos from fish maintained and spawned in HW Marinemix artificial seawater, using sodium dodecyl sulfate (SDS) as the reference toxicant [1].

Test Number	EC_1 (mg/l)	EC_5 (mg/l)	EC_{10} (mg/l)	EC_{50} (mg/l)	NOEC (mg/l)
1	1.7	2.0	2.2	3.1	2.0
2	*	*	*	*	4.0
3	0.4	0.7	0.9	2.5	2.0
4	1.9	2.2	2.4	3.3	2.0
5	1.3	1.7	1.9	3.0	2.0
n:	4	4	4	4	5
Mean:	1.3	1.6	1.9	2.9	2.4
CV(%):	51.2	41.6	35.0	11.7	NA

* Data do not fit the Probit model.

NOEC Range: 2.0 - 4.0 ug/l (this represents a difference of one exposure concentration).

INLAND SILVERSIDE (*Menidia beryllina*)

Seven-day Larval Survival and Growth Test Single Laboratory Precision Data

Table A-1-8. Single laboratory precision of the inland silverside (*Menidia beryllina*) larval survival and growth test performed in natural seawater, using larvae from fish maintained and spawned in natural seawater, using copper as the reference toxicant [1].

Test Number	NOEC (ug/l)	IC_{25} (ug/l)	IC_{50} (ug/l)	Most Sensitive Endpoint
1	63	96.2	148.6	S
2	125	207.2	NC*	S
3	63	218.9	493.4	G
4	125	177.5	241.4	S
5	31	350.1	479.8	G
n:	5	5	4	
Mean:	81.4	209.9	340.8	
CV(%):	NA	43.7	50.7	

* No linear interpolation estimate could be calculated from the data, since none of the group response means were less than 50 percent of the control response mean.

NOEC Range: 31 - 125 ug/l (this represents a difference of two exposure concentrations).

Prepared by Elise Torello, SAIC, Narragansett, RI, and Margarete Heber, EPA, and Washington, DC, February 1990 (ICp Program, version 1.1b).

Table A-1-9. Single laboratory precision of the inland silverside (*Menidia beryllina*) larval survival and growth test performed in natural seawater, using larvae from fish maintained and spawned in natural seawater, using sodium dodecyl sulfate (SDS) as the reference toxicant [1].

Test Number	NOEC (mg/l)	IC_{25} (mg/l)	IC_{50} (mg/l)	Most Sensitive Endpoint
1	1.3	0.3	1.7	S
2	1.3	1.6	1.9	S
3	1.3	1.5	1.9	S
4	1.3	1.5	1.9	S
5	1.3	1.6	2.2	S
n:	5	5	5	
Mean:	1.3	1.3	1.9	
CV(%):	NA	43.2	9.4	

NOEC Range: 1.3 mg/l.

Prepared by Elise Torello, SAIC, Narragansett, RI, and Margarete Heber, EPA, and Washington, DC, February 1990 (ICp Program, version 1.1b).

MYSID (*Mysidopsis bahia*)

Seven-day Survival, Growth, and Fedundity Test Single Laboratory Precision Data

Table A-1-10. Single laboratory precision of the mysid (*Mysidopsis bahia*) survival, growth and fecundity test performed in natural seawater, using juveniles from mysids cultured and maintained in natural seawater, using copper as the reference toxicant [1].

Test Number	NOEC (ug/l)	IC_{25} (ug/l)	IC_{50} (ug/l)	Most Sensitive Endpoint
1	63	96.1	NC*	S
2	125	138.3	175.5	S
3	125	156.3	187.5	S
4	125	143.0	179.9	S
5	125	157.7	200.3	S
n:	5	5	4	
Mean:	112.6	138.3	185.8	
CV(%):	NA	18.0	5.8	

* No linear interpolation estimate could be calculated from the data, since none of the group response means were less than 50 percent of the control response mean.

NOEC Range: 63 - 125 ug/l (this represents a difference of two exposure concentrations).

Prepared by Elise Torello, SAIC, Narragansett, RI, and Margarete Heber, EPA, and Washington, DC, February 1990 (ICp Program, version 1.1b).

Table A-1-11. Single laboratory precision of the mysid (*Mysidopsis bahia*) survival, growth, and fecundity test performed in natural seawater, using juveniles from mysids cultured and maintained in natural seawater, using sodium dodecyl sulfate (SDS) as the reference toxicant [1].

Test Number	NOEC (mg/l)	IC_{25} (mg/l)	IC_{50} (mg/l)	Most Sensitive Endpoint
1	2.5	4.5	NC[2]	S
2	<0.3	NC[1]	NC[2]	S
3	<0.6	NC[1]	NC[2]	S
4	5.0	7.8	NC[2]	S
5	2.5	3.6	4.6	S
6	5.0	7.0	9.3	S
n:	4	4	2	
Mean:	3.8	5.7	6.9	
CV(%):	NA	35.0	47.8	

[1]No linear interpolation estimate could be calculated from the data, since none of the group response means were less than 75 percent of the control response mean.

[2]No linear interpolation estimate could be calculated from the data, since none of the group response means were less than 50 percent of the control response mean.

NOEC Range: <0.3 - 5.0 mg/l (this represents a difference of four exposure concentrations).

Prepared by Elise Torello, SAIC, Narragansett, RI, and Margarete Heber, EPA, and Washington, DC, February 1990 (ICp Program, version 1.1b).

SEA URCHIN (*Arbacia punctulata*)

Fertilization Test Single Laboratory Precision Data

Table A-1-12. Single laboratory precision of the sea urchin (*Arbacia punctulata*) fertilization test performed in natural seawater, using gametes from sea urchins maintained and spawned in artificial seawater (40 Fathoms), using copper as the reference toxicant [1].

Test Number	NOEC (ug/l)	IC_{25} (ug/l)	IC_{50} (ug/l)
1	5.0	8.92	29.07
2	12.5	26.35	38.96
3	<6.2	11.30	23.93
4	6.2	34.28	61.75
5	12.5	36.67	75.14
n:	4	5	5
Mean:	9.0	23.51	45.77
CV(%):	NA	54.60	47.87

NOEC Range: <5.0 - 12.5 ug/l (this represents a difference of one exposure concentration).

Copper concentrations in Test 1 were 2.5, 5.0, 10.0, 20.0, and 40.0 ug/l and in Tests 2-5 were 6.25, 12.5, 25.0, 50.0, and 100.0 ug/l.

Prepared by Florence Kessler, TAI, Cincinnati, OH, January 11, 1990 (ICp Program, version 1.1b).

Table A-1-13. Single laboratory precision of the sea urchin (*Arbacia punctulata*) fertilization test performed in natural seawater, using gametes from sea urchins maintained and spawned in artificial seawater (40 Fathoms), using sodium dodecyl sulfate (SDS) as the reference toxicant [1].

Test Number	NOEC (mg/l)	IC_{25} (mg/l)	IC_{50} (mg/l)
1	<0.9	1.11	1.76
2	0.9	1.27	1.79
3	1.8	2.26	2.87
4	0.9	1.90	2.69
5	1.8	2.11	2.78
n:	4	5	5
Mean:	1.4	1.73	2.38
CV(%):	NA	29.7	23.3

NOEC Range: 1.2 - 3.3 mg/l (this represents a difference of one exposure concentration).

SDS concentrations for all tests were 0.9, 1.8, 3.6, 7.2, and 14.4 mg/l.

Prepared by Florence Kessler, TAI, Cincinnati, OH, January 11, 1990 (ICp Program, version 1.1b).

Table A-1-14. Single laboratory precision of the sea urchin (*Arbacia punctulata*) fertilization test performed in natural seawater, using gametes from sea urchins maintained and spawned in natural seawater, using copper as the reference toxicant [1].

Test Number	NOEC (ug/l)	IC_{25} (ug/l)	IC_{50} (ug/l)
1	12.2	14.2	18.4
2	12.2	32.4	50.8
3	24.4	30.3	46.3
4	<6.1	26.2	34.1
5	6.1	11.2	17.2
n:	4	5	5
Mean:	13.7	22.8	29.9
CV(%):	NA	41.9	48.2

NOEC Range: <6.1 - 24.4 ug/l (this represents a difference of two exposure concentrations).

Prepared by Elise Torello, SAIC, Narragansett, RI, and Margarete Heber, EPA, and Washington, DC, February 1990 (ICp Program, version 1.1b).

Table A-1-15. Single laboratory precision of the sea urchin (*Arbacia punctulata*) fertilization test performed in natural seawater, using gametes from sea urchins maintained and spawned in natural seawater, using sodium dodecyl sulfate (SDS) as the reference toxicant [1].

Test Number	NOEC (ug/l)	IC_{25} (ug/l)	IC_{50} (ug/l)
1	1.8	2.3	2.7
2	1.8	3.9	5.1
3	1.8	2.3	2.9
4	0.9	2.1	2.6
5	1.8	2.3	2.7
n:	5	5	5
Mean:	1.6	2.58	3.2
CV(%):	NA	28.7	33.3

NOEC Range: 0.9 - 1.8 mg/l (this represents a difference of one exposure concentration).

Prepared by Elise Torello, SAIC, Narragansett, RI, and Margarete Heber, EPA, and Washington, DC, February 1990 (ICp Program, version 1.1b).

RED MACROALGAE (*Champia parvula*)

Reproduction Test Single Laboratory Precision Data

Table A-1-16. Single laboratory precision of the red macroalga (*Champia parvula*) reproduction test performed in 50/50 natural seawater and GP-2 artificial seawater. Copper is the reference toxicant [1].

Test Number	NOEC (ug/l)	IC_{25} (ug/l)	IC_{50} (ug/l)
1	1.0	1.67	2.35
2	1.0	1.50	1.99
3	1.0	0.69	1.53
4	1.0	0.98	1.78
5	0.5	0.38	0.76
6	0.5	0.38	0.75
n:	6	6	6
Mean:	0.83	0.93	1.5
CV(%):	NA	59.6	43.7

NOEC Range: 0.5 - 1.0 ug/l (this represents a difference of one exposure concentration).

Prepared by Elise Torello, SAIC, Narragansett, RI, and Margarete Heber, EPA, and Washington, DC, February 1990 (ICp Program, version 1.1b).

Table A-1-17. Single laboratory precision of the red macroalga (*Champia parvula*) reproduction test performed in 50/50 natural seawater and GP-2 artificial seawater. Sodium dodecyl sulfate (SDS) is the reference toxicant [1] (personal communication with G. Thursby, SAIC, Narragansett, RI).

Test Number	NOEC (mg/l)	IC_{25} (mg/l)	IC_{50} (mg/l)
1	<0.80	0.6	0.3
2	0.48	0.7	0.6
3	<0.48	0.4	0.2
4	<0.48	0.2	0.4
5	0.26	0.2	0.5
6	0.09	0.1	0.3
7	0.16	0.2	0.3
8	0.09	0.1	0.2
9	<0.29	0.3	0.4
n:	5	9	9
Mean:	0.22	0.31	0.36
CV(%):	NA	69.0	37.0

NOEC Range: 0.09 - 0.48 mg/l (this represents a difference of two exposure concentrations).

Prepared by Elise Torello, SAIC, Narragansett, RI, and Margarete Heber, EPA, and Washington, DC, February 1990 (ICp Program, version 1.1b).

Table A-1-18. Single laboratory precision testing of the red macroalga (*Champia parvula*) reproduction test in natural seawater (30 $^{o}/_{oo}$ salinity). The reference toxicants used were copper sulfate (Cu)[1,2] and sodium dodecyl sulfate (SDS)[2,3] [7].

	Cu (ug/l)			SDS (mg/l)		
Test	NOEC	IC_{25}	IC_{50}	NOEC	IC_{25}	IC_{50}
1	1.00	2.62	4.02	0.60	0.05	0.50
2	0.50	0.71	1.66	0.60	0.48	0.81
3	0.50	2.83	3.55	0.30	0.69	0.89
4	0.50	0.99	4.15	0.15	0.60	0.81
n:	4	4	4	4	4	4
Mean:	0.63	1.79	3.35	0.41	0.46	0.75
CV(%):	NA	61.09	34.45	NA	62.29	22.92

[1]Copper concentrations were 0.5, 1.0, 2.5, 5.0, 7.5, and 10 ug/l. Concentrations of Cu were made from a 100 ug/ml $CuSO_4$ standard obtained from Inorganic Ventures, Inc., Brick, NJ.

[2]All tests were conducted at 23 ± 1°C in natural seawater with irradiance set at 40 $uE/m^2/s$.

[3]SDS concentrations were 0.0375, 0.075, 0.15, 0.30, 0.60, and 1.20 mg/l. Concentrations of SDS were made from a 44.64 ± 3.33 mg/ml standard obtained from U.S. EPA-EMSL, Cincinnati, OH.

Prepared by Steven H. Ward and Glen Thursby, EPA, Narragansett, RI (ICp Program, version 1.1b).

Fresh Water Short-Term Chronic Toxicity Tests

FATHEAD MINNOW (*Pimephales promelas*)

Seven-day Larval Survival and Growth Test and Embryo-larval Survival and Teratogenicity Test Single Laboratory Precision Data

Table A-1-19. Single laboratory precision of the fathead minnow (*Pimephales promelas*) embryo-larval survival and teratogenicity test performed in using Diquat as the reference toxicant [2].

Test Number	LC_1 (mg/l)
1	0.58
2	2.31
3	1.50
4	1.71
5	1.43
n:	5
Mean:	1.51
CV(%):	41.3

Table A-1-20. Single laboratory precision of the fathead minnow (*Pimephales promelas*) embryo-larval survival and teratogenicity test performed in using cadmium chloride as the reference toxicant [2].

Test Number	LC_1 (mg/l)	NOEC (mg/l)
1	0.014	0.012
2	0.006	0.012
3	0.005	0.013
4	0.003	0.011
5	0.006	0.012
n:	5	5
Mean:	0.0068	0.012
CV(%):	62	NA

NOEC Range: 0.011 - 0.013 mg/l (this represents a difference of one exposure concentration).

FATHEAD MINNOW (*Pimephales promelas*)

Seven-day Larval Survival and Growth Test
Single Laboratory Precision Data

Table A-1-21. Single laboratory precision of the fathead minnow (*Pimephales promelas*) larval survival and growth test performed in using NAPCP as the reference toxicant [2].

Test Number	NOEC* (ug/l)
1	256
2	128
3	256
4	128
5	128
n:	5
Mean:	179.2
CV(%):	NA

*Raw data unavailable, IC_{25} and IC_{50} values could not be calculated.

NOEC Range: 128 - 256 ug/l (this represents a difference of one exposure concentration).

Table A-1-22. Results of the performance evaluation for contract laboratories conducted for the California Regional Water Quality Control Board. All tests were conducted using potassium chromate (expressed as Cr^{+6}) and testing the fathead minnow (*Pimephales promelas*) in the 7-day subchronic tests [3].

Lab	Water	Food	Age	X Control Weight	Ctrl. n	IC_{25} (CI) (mg/l as Cr^{+6})	NOEC Endpoint	IC_{50} (CI) (mg/l as Cr^{+6})
1	Tap[1]	2X	≤24	0.590	3	3.7 (2.3-4.7)	3 G	5.4 (4.5-8.3)
2	MHRW	2X	≤24	0.623	3[2]	1.6[3] (1.4-2.0)	<3 G	3.3 (2.8-4.0)
3	MHRW	3X	≤24	0.274[4]	4	2.2[3] (1.7-3.1)	<3 G	4.7 (3.9-5.6)
4	Tap[5]	3X	≤24	0.670	2	4.1 (2.3-5.0)	6 G	6.6 (5.0-8.4)
5	MHRW	--[6]	≤24	0.773	4	1.3[3] (1.2-1.5)	<3 G	.6[3] (2.5-3.3)
6	MHRW	3X	y≤24	0.635	2	7.1 (2.0-8.2)	6 G	9.9 (8.5-11)
7	MHRW	3X	≤24	0.390	3	4.5 (3.5-5.4)	3 G	7.4 (6.6-8.1)
8	Well[7]	2X	≤24	0.346	5	2.5[3] (1.9-3.3)	<3 G	8.1 (6.4-15)
9	MHRW	3X	≤24	0.415	4	6.6 (5.3-7.6)	6 G	9.2 (8.4-10)
10	MHRW	3X	≤24	0.255	2	4.6 (4.1-5.9)	3 G	7.8[8] (5.2-12)
Mean:						5.1		6.9
CV (%):						27		31

[1] Moderately hard tap water.

[2] Control with three replicates and all concentrations with two replicates.

[3] Value is extrapolated and is not included in coefficient of variation calculation.

[4] Weight measurements made with questionable techniques.

[5] Dechlorinated Lake Ontario tap water.

[6] Not reported.

[7] Well water mixed with spring water, moderately hard.

[8] Value may be skewed as middle concentration had 45 percent survival but no weights reported.

Seven-day Larval Survival and Growth Test

Interlaboratory Precision Data

Table A-1-23. Interlaboratory precision data of the fathead minnow (*Pimephales promelas*) 7-day larval survival and growth test. Combined frequency distribution for survival NOECs for all participating laboratories [2].

	NOEC Frequency (%) Distribution					
	Tests with 2 Reps			Tests with 4 Reps		
Sample	Median	±1(a)	>2(b)	Median	± 1(a)	>2(b)
Sodium Pentachlorophenate [1]	35	53	12	57	29	14
Sodium Pentachlorophenate [2]	42	42	16	56	44	0
Potassium Dichromate [1]	47	47	6	75	25	0
Potassium Dichromate [2]	41	41	18	50	50	0
Refinery Effluent 301	26	68	6	78	22	0
Refinery Effluent 401	37	53	10	56	44	0
Utility Waste 501	56	33	11	56	33	11

[1] Percent of values with one concentration intervals of the median.

[2] Percent of values within two or more concentrations intervals of the median.

Table A-1-24. Interlaboratory precision data of the fathead minnow (*Pimephales promelas*) 7-day larval survival and growth test. Combined frequency distribution for weight NOECs for all participating laboratories [2].

	NOEC Frequency (%) Distribution					
	Tests with 2 Reps			Tests with 4 Reps		
Sample	Median	±1(a)	>2(b)	Median	± 1(a)	>2(b)
Sodium Pentachlorophenate [1]	59	41	0	57	43	0
Sodium Pentachlorophenate [2]	37	63	0	22	45	33
Potassium Dichromate [1]	35	47	18	88	0	12
Potassium Dichromate [2]	12	47	41	63	25	12
Refinery Effluent 301	35	53	12	75	25	0
Refinery Effluent 401	37	47	16	33	56	11
Utility Waste 501	11	61	28	33	56	11

[1] Percent of values with one concentration intervals of the median.

[2] Percent of values within two or more concentrations intervals of the median.

CERIODAPHNIA (*Ceriodaphnia dubia*)

Seven-day Reproduction Test

Single Laboratory Precision Data

Table A-1-25. Single laboratory precision of (*Ceriodaphnia dubia*) reproduction test performed in using sodium pentachlorophenol as the reference toxicant [2].

Test Number	NOEC (mg/l)	IC_{25} (mg/l)	IC_{50} (mg/l)
19	0.30	0.3754	0.4508
46A	0.20	0.0938	0.2608
46B	0.20	0.2213	0.2897
49	0.20	0.2303	0.2912
55	0.20	0.2306	0.3177
56	0.10	0.1345	0.1744
57	0.20	0.2241	0.2827
n:	7	7	7
Mean:	0.20	0.2157	0.2953
CV(%):	NA	41.1	27.9

NOEC Range: 0.25 - 0.30 mg/l (these values all fell within the same concentration range).
Prepared by Florence Kessler, TAI, Cincinnati, OH, January 11, 1990 (ICp Program, version 1.1b).

Table A-1-26. Single laboratory precision, from six discrete laboratories, of the (*Ceriodaphnia dubia*) reproduction test performed using sodium chloride (NaCl) as the reference toxicant. Tests were conducted in 1989 [4].

Laboratory	Test Number	NOEC (mg/l)	IC_{25} (mg/l)	IC_{50} (mg/l)
A	1	0.50^R	0.61	0.77
	2	1.00^S	1.00	1.34
	3	1.00^R	0.81	1.32
	4	1.00^R	0.67	1.28
	5	1.00^R	1.19	1.47
	6	0.50^R	1.06	1.38
n:		6	6	6
Mean:		0.83	0.89	1.26
CV(%):		NA	25.83	19.73
B	1	1.00^R	1.28	1.63
	2	1.00^S	1.01	1.51
	3	0.50^S	0.69	0.88
	4	0.50^S	0.81	1.16
	5	1.00^R	1.31	1.84
	6	1.00^R	1.12	1.57
n:		6	6	6
Mean:		0.83	1.04	1.43
CV(%):		NA	24.11	24.37
C	1	1.00^S	1.23	1.49
	2	0.50^S	0.46	1.02
	3	1.00^S	1.25	1.50
	4	0.50^R	1.13	1.44
	5	1.00^S	1.22	1.49
	6	1.00^S	1.21	1.51
n:		6	6	6
Mean:		0.83	1.13	1.41
CV(%):		NA	16.54	13.62
D	1	0.50^R	0.58	0.84
	2	0.25^R	0.30	0.60
	3	1.00^S	0.84	1.22
	4	1.00^S	1.04	1.38
	5	1.00^S	1.04	1.37
	6	0.50^R	0.76	1.14
n:		6	6	6
Mean:		0.71	0.76	1.08
CV(%):		NA	37.55	28.56
E	1	1.00^S	0.44	0.74
	2	1.00^S	1.04	1.37
	3	1.00^S	1.06	1.37
	4	1.00^S	1.13	1.42
	5	1.00^S	1.13	1.42
	6	1.00^S	1.19	1.46
n:		6	6	6
Mean:		1.00	1.00	1.30
CV(%):		NA	27.96	21.20
F	1	0.50^R	0.61	1.13
	2	0.50^R	0.63	1.20
	3	0.50^S	0.66	0.83
	4	0.50^S	0.65	0.81
	5	0.50^R	0.74	1.04
	6	0.50^R	0.50	0.73
n:		6	6	6
Mean:		0.50	0.63	0.95
CV(%):		NA	12.40	19.32

R = Reproduction was the most sensitive endpoint.
S = Survival was the most sensitive endpoint.
Prepared by William Peltier, EPA, Region IV, November 28, 1990 (ICp Program, version 1.1b).

CERIODAPHNIA (*Ceriodaphnia dubia*)

Seven-day Larval Reproduction Test Interlaboratory Precision Data

Table A-1-27. Interlaboratory precision of (*Ceriodaphnia dubia*) reproduction test, using sodium chloride (NaCl) as the reference toxicant. The single lab precision data are presented in the preceding table [4].

Laboratory	NOEC (mg/l)	IC_{25} (mg/l)	IC_{50} (mg/l)
A	0.83	0.89	1.26
B	0.83	1.04	1.43
C	0.83	1.13	1.41
D	0.71	0.76	1.09
E	1.00	1.00	1.30
F	0.50	0.63	0.95
n:	6	6	6
Mean:	0.80	0.91	1.24
CV(%):	NA	20.53	15.17

Prepared by William Peltier, EPA, Region IV, November 28, 1990 (ICp Program, version 1.1b).

Table A-1-28 Interlaboratory precision of (*Ceriodaphnia dubia*) reproduction test, using an industrial effluent as the reference toxicant and sodium chloride (NaCl) as a reference toxicant. Tests were conducted in May 1987 [3].

Lab	Effluent		Reference Toxicant	
	IC_{50} (%)	IC_{25} (%)	IC_{50} (%)l	IC_{25} (%)
A	6.20	4.9	33.0	21.8
B	8.40	6.2	38.8	30.8
D	7.69	5.8	36.3	29.4
E	6.34	5.0	36.6	28.0
F	4.00	1.2	8.1*	1.21*
J	2.84	1.9	35.1	25.2
K	6.89	5.3	18.4	13.2
M	5.70	1.9	38.1	31.0
N	7.43	5.9	27.8	10.4
O	0.04*	0.02*	35.1	27.3
n:	9	9	9	9
Mean:	6.17	3.4	32.8	24.1
CV(%):	29	67	21	31

*Values were excluded from mean calculations because they fell outside of ± 2 standard deviations. For this reason, these values are considered statistical outliers and, according to EPA's toxicity methods guidance [2] on reference toxicant control charts, are excluded.

Table A-1-29. Results of the performance evaluation for contract laboratories conducted for the California Regional Water Quality Control Board. All tests were conducted using sodium chloride and testing *Ceriodaphnia dubia* in the 7-day chronic tests [3].

Lab	Water	Food	Age	X Young/ Control	IC_{25} (Cl) (g/l NaCl)	NOEC Endpt
1	Tap[1]	YCT/Algae	0-4;<24	17.80.20[2]	(0.14-0.35)	<0.25 R
2	Hard W[3]	TF/Algae	0-4	26.51.3	(0.78-1.7)	1.0 R
3	DMW[4]	YCT/Algae	0-6	24.90.21[2]	(0.17-0.54)	<0.25 R
4	Tap[5]	YCT	0-4	17.20.49	(0.35-1.0)	0.5 R
5	HRW	YCT	0-4;<24	19.80.42	(0.20-1.1)	0.5 R
6	Surface[6]	YCT/Algae	0-6	14.80.90	(0.66-1.1)	0.25 R
7	MHRW	YCT/Algae	4-8	17.20.56	(0.24-0.64)	0.25 R
8	MHRW	YCT	<24	16.80.21[2]	(0.11-0.32)	0.25 R
9	MHRW	YCT	0-4	12.80.71	(0.56-0.81)	0.50 R
10	DMW[4]	YAT/Algae	0-4	31.50.91	(0.45-1.1)	1.0 R
Mean:				0.76		
CV(%):				40		

[1] Moderately hard tap water.
[2] Dose response curve limited.
[3] Hard well water.
[4] Ten percent diluted mineral water.
[5] Dechlorinated Lake Ontario tap water.
[6] Briones reservoir water.
R = Reproductive endpoint

MHRW = Moderately hard reconstituted water
HRW = Hard reconstituted water
WW = Well water
YCT = Yeast-Cerophyl-Trout chow
YAT = Yeast-Alfalfa-Trout chow
TF = Trout food suspension
Algae = *Selenastrum capricornutum*

CERIODAPHNIA (Ceriodaphnia dubia) (continued)

Seven-day Larval Reproduction Test Interlaboratory Precision Data

Table A-1-30. Interlaboratory precision data for *Ceriodaphnia dubia* summarized for eight materials, including reference toxicants and effluents [5].

	Test Material	Mean IC_{50}	CV %	Mean IC_{25}	CV %
1	Sodium chloride	1.34	29.9	1.00	34.3
2	Industrial	3.6	83.3	3.2	78.1
3	Sodium chloride	0.96	57.4	0.90	44.4
4	Pulp & Paper	60.0	28.3	47.3	27.0
5	Potassium dichromate	35.8	30.8	23.4	32.7
6	Pulp & Paper	70.2	7.5	55.7	12.2
7	Potassium dichromate	53.2	25.9	29.3	46.8
8	Industrial	69.8	37.0	67.3	36.7
n:			8		8
Mean:			37.5		39.0
Standard Deviation:			23.0		19.1

SELENASTRUM CAPRICORNUTUM

Growth Test

Single Laboratory Precision Data

Table A-1-31. Single laboratory precision of (*Selenastrum capricornutum*) growth test performed in using cadmium as the reference toxicant [2].

Test Number	EC_{50} (g/l)	Control Variation (%CV)
1	2.3	4.8
2	2.4	9.6
3	2.3	5.5
4	2.8	13.3
5	2.6	4.4
6	2.1	8.2
7	2.1	14.4
8	2.1	7.1
9	2.6	11.9
10	2.4	5.0
11	2.7	36.4*
12	2.4	77.8*
n=10		
Mean:	2.37	8.42
CV(%):	10.2	44.1

*Outlier values are excluded from mean because they fell outside of a QA control table for these reference toxicants.

Note: Sodium chloride concentrations were 1, 2, 4, 8, and 16 g/l in all tests.

Prepared by Dr. Cornelius Weber, EPA, Cincinatti, OH, March 15, 1991.

APPENDIX A-2

EFFLUENT VARIABILITY DATA

Table A-2-1. Percent mortality in 100 percent collected 1989 by grab method (personal communication W. Peltier, EPA, Athens, GA). Results indicate variability over 24 hours and differences in species sensitivity over time. Tests were conducted according to methods described in Reference 6.

Date	Time	% Mortality in 100% Effluent		
		P. promelas	*D. pulex*	*C. dubia*
3/07/89	1230	0	15	100
3/07/89	1830	0	85	100
3/08/89	0030	0	65	100
3/08/89	0630	0	30	80
3/20/89	1230	0	0	100
3/20/89	1830	0	100	100
3/21/89	0030	0	95	100
3/21/89	0630	0	70	100
6/19/89	1230	0	5	100
6/19/89	1830	0	40	100
6/20/89	0030	0	100	100
6/20/89	0630	0	100	100
7/25/89	1230	0	0	100
7/25/89	1830	0	100	100
7/26/89	0030	0	100	100
7/26/89	0630	0	55	100

Table A-2-2. LC_{50}s for a POTW effluent over 17 months. All tests were conducted using *Ceriodaphnia dubia* and tests were run for 48 hours. All tests were conducted according to the methods described in Reference 6. Dates with roman numeral notation mean that more than one sample was collected at different times over a short interval (1 to 2 days). (Data source: [8].)

Sample Date	48 hours LC_{50} (%)
08/23/86-I	71
03/09/87-I	71
05/02/87-I	35
05/03/87-I	65
05/04/87-I	71
05/23/87-I	71
05/23/87-II	71
05/23/87-III	61
06/27/87-I	36
06/27/87-II	41
06/27/87-III	18
09/22/87-I	71
12/18/87-I	87
01/05/88-I	68
01/05/88-II	63
Mean LC_{50} :	60.0
CV (%):	31.1
n:	15

Table A-2-3. LC_{50}s for a POTW effluent over 7 months. All tests were conducted using *Ceriodaphnia dubia* and tests were run for 48 hours. All tests were conducted according to the methods described in Reference 6. Dates with roman numeral notation mean that more than one sample was collected at different times over a short interval (1 to 2 days). (Data source: [8].)

Sample Date	48 hours LC_{50} (%)
10/06/87-I	71
10/06/87-II	71
10/06/87-III	71
10/30/87-I	87
12/03/87-I	61
12/03/87-II	35
01/12/88-I	61
01/13/88-I	58
02/03/88-IX	50
02/03/88-X	50
03/03/88-III	87
03/03/88-IV	81
03/23/88-I	25
03/23/88-II	35
04/28/88-I	50
04/28/88-II	55
05/17/88-I	61
05/17/88-II	35
Mean LC_{50} :	58.0
CV (%):	31.4
n:	18

Table A-2-4. LC_{50}s for a POTW effluent over 12 months. Tests were conducted using either *Ceriodaphnia dubia* or fathead minnows or both. *Ceriodaphnia* tests were conducted for 48 hours while fathead minnow tests were 96 hours. Both the 48-hour and 96-hour fathead minnow results are shown in order to evaluate how the LC_{50}s for the two species compare. All tests were conducted according to the methods described in Reference 6. Dates with roman numeral notation mean that more than one sample was collected at different times over a short interval (1 to 2 days). (Data source: [8].)

Sample Date	LC_{50} (%)		
	C. dubia	*P. promelas*	
	48 hours	48 hours	96 hours
03/16/88-I	62	35	25
06/09/88-I	18	–*	–*
09/08/88-I	68	>100	>100
10/04/88-I	61	–*	–*
10/04/88-II	63	–*	–*
12/14/88-I	70	58	34
12/14/88-II	17	60	41
02/17/89-I	35	61	39
02/17/89-II	35	61	37
03/22/89-I	35	81	64
03/22/89-II	47	61	40
Mean LC_{50}:	46	59.6	40.0
CV (%):	42	22.4	29.7
n:	11	7	7

* Data not available.

Note: Greater than (>) values were excluded from the mean LC_{50} calculation.

Table A-2-5. LC_{50}s for a POTW effluent over 4 months. Tests were conducted using either *Ceriodaphnia dubia* or fathead minnows or both. *Ceriodaphnia* tests were conducted for 48 hours while fathead minnow tests were 96 hours. Both the 48-hour and 96-hour fathead minnow results are shown in order to evaluate how the LC_{50}s for the two species compare. All tests were conducted according to the methods described in Reference 6. Dates with roman numeral notation mean that more than one sample was collected at different times over a short interval (1 to 2 days). (Data source: [8].)

Sample Date	LC_{50} (%)		
	C. dubia	*P. promelas*	
	48 hours	48 hours	96 hours
09/01/88-I	2.1	>100	77
11/15/88-I	92	67	37
11/16/88-I	61	>100	100
11/30/88-II	>100	>100	33
11/30/88-III	95	>100	>100
12/08/88-I	100	87	54
12/08/88-II	>100	87	53
12/13/88-I	90	>100	77
12/13/88-II	87	85	51
01/10/89-I	75	58	–*
01/10/89-II	61	41	–*
01/19/89-I	100	88	68
01/19/89-II	87	84	69
01/25/89-I	>100	87	64
01/25/89-II	95	85	56
01/31/89-I	90	70	60
01/31/89-II	63	70	60
Mean:	78.4	75.8	61.3
CV (%):	33.1	19.6	27.7
n:	14	12	14

*Not obtained.

Note: Greater than (>) values were not included in the mean LC_{50} calculation.

Table A-2-6. NOECs for a POTW effluent conducted 20 times over 1 year. All tests were conducted using *Champia parvula* according to methods described in Reference 1. All effluent samples were 24-hour composites collected post-chlorination. (personnal communication—Glen Thursby, SAIC, Narragansett, RI).

Test Date	% Effluent		
	IC_{25}	IC_{50}	NOEC
12/09/85	0.65	1.23	1.25
12/10/85	0.38	0.76	1.25
12/11/85	0.69	1.50	2.50
12/12/85	0.41	0.82	1.25
12/13/85	3.09	4.12	5.00
12/15/85	2.16	4.09	5.00
07/16/86	2.99	4.33	5.00
07/17/86	3.59	4.68	5.00
07/18/86	.44	4.76	5.00
07/19/86	.47	3.41	5.00
07/20/86	.24	3.98	7.50
07/21/86	.11	3.20	5.00
07/22/86	.84	5.19	5.00
9/09/86	.07	3.02	2.50
09/10/86	.17	4.13	7.50
09/11/86	.73	3.62	7.50
09/12/86	.57	1.89	1.25
09/14/86	.25	1.76	2.50
n:	18	18	18
Mean:	2.2	3.1	4.2
CV (%):	52.8	46.8	NA

Table A-2-8. NOECs for a POTW effluent over 1 year. All tests used *Mysidopsis bahia* according to methods described in Reference 1. All effluent samples were 24-hour composites collected post-chlorination. (Data source: ERL-Narragansett, RI.)

Test Date	% Effluent		
	IC_{25}	IC_{50}	NOEC
12/09 - 12/16/85	1.78(G)	2.93(G)	1.0
07/16 - 07/23/86	2.75(R)	6.3(S)	3.2
09/09 - 09/16/86	0.69(R)	20.1(S)	10.0
11/11 - 11/18/86	0.66(R)	0.99(R)	3.2
Mean:	1.47	7.58	4.4
CV (%):	68.0	113.8	NA
n:	4	4	4

R-Reproductive endpoint

S-Survival endpoint

G-Growth endpoint

Table A-2-7. NOECs for a POTW effluent over 1 year. All tests used *Arbacia punctulata* according to methods described in Reference 1. All effluent samples were 24-hour composites collected post-chlorination. (Data source: ERL-Narragansett, RI.)

Test Date	% Effluent		
	IC_{25}	IC_{50}	NOEC
12/09/85	1.09	1.71	0.65
12/10/85	1.41	2.84	0.65
12/11/85	0.75	1.09	0.65
12/12/85	3.28	4.06	1.30
12/13/85	2.65	5.32	2.50
12/14/85	1.11	1.60	0.65
12/15/85	1.29	1.84	0.65
07/16/86	0.17	0.35	<0.30
07/17/86	0.21	0.46	<0.30
07/18/86	0.63	0.86	<0.30
07/19/86	1.09	1.68	<0.30
07/20/86	0.54	1.13	<0.30
07/21/86	0.40	0.58	<0.30
07/22/86	0.40	0.56	<0.30
09/09/86	0.31	0.41	<0.30
09/11/86	0.47	0.79	<0.60
09/12/86	0.21	0.48	<0.20
09/13/86	3.30	5.42	1.30
09/14/86	0.23	0.35	<0.20
09/15/86	0.10	0.15	<0.20
11/11/86	0.27	0.54	1.30
11/13/86	0.88	1.48	0.30
11/14/86	0.82	1.61	0.60
11/15/86	0.34	0.56	<0.30
Mean:	0.91	1.49	0.95
CV (%):	101.3	96.9	NA
n:	24	24	11

Note: Less than (<) values were excluded from CV and mean NOEC calculations.

Table A-2-9. NOECs for a POTW effluent over 1 year. All tests used *Menidia beryllina* according to methods described in Reference 1. All effluent samples were 24-hour composites collected post-chlorination. (Data source: ERL-Narragansett, RI.)

Test Date	% Effluent		
	IC_{25}	IC_{50}	NOEC
12/09 - 12/16/85	15.4	21.3	10.0
07/16 - 07/23/86	15.2	21.0	10.0
09/09 - 09/16/86	14.2	20.1	10.0
11/11 - 11/18/86	NC	NC	10.0
Mean:	14.9	20.8	10.0
CV (%):	4.3	3.0	NA
n:	3	3	4

NC - Value is not calculable.

Table A-2-10. LC_{50}s for a refinery effluent over 14 months. Tests were conducted using either *Ceriodaphnia dubia* or fathead minnows *Pimephales promelas* or both. *Ceriodaphnia* tests were conducted for 48 hours while fathead minnow tests were 96 hours. Both the 48-hour and 96-hour fathead minnow results are shown in order to evaluate how the LC_{50}s for the two species compare. All tests were conducted according to the methods described in Reference 6. Dates with roman numeral notation mean that more than one sample was collected at different times over a short interval (1 to 2 days). (Data source: [8].)

Sample Date	LC_{50} (%)		
	C. dubia	*P. promelas*	
	48 hours	48 hours	96 hours
12/01/87	15	35	16
01/05/88	35	36	19
02/09/88-I	35	35	<12
02/09/88-I	35	35	<12
03/02/88-I	17	–*	–*
03/02/88-II	<12	38	–*
03/24/88-I	35	35	–*
05/06/88-I	35	–*	–*
07/14/88-I	55	61	25
07/28/88-I	37	35	22
07/28/88-II	28	31	<25
09/29/88-I	41	39	25
12/01/88-I	75	56	34
12/07/88-I	18	67	13
01/27/89-I	100	61	37
01/27/89-II	71	60	25
03/23/89-I	58	54	20
Mean LC_{50}:	43	45	24
CV (%):	54	28	32
n:	16	15	10

* Data not available.

Note: Less than values excluded from mean LC_{50} calculations.

Table A-2-11. LC_{50}s for a refinery effluent conducted over 6 months using fathead minnows (*Pimephales promelas*), *Ceriodaphnia dubia*, and mysids (*Mysidopsis bahia*), according to methods described in Reference 6. (Data source: Dorn, 1989.)

Test Date	LC_{50} (% Effluent)		
	C. dubia	*P. promelas*	*M. bahia*
1/24/86	–	26.6	–
2/26/86	65.0	24.5	–
3/05/86	50.9	–	–
3/12/86	39.3	36.6	–
3/19/86	66.5	40.5	–
4/02/86	65.4	32.8	–
4/09/86	69.8	34.2	–
4/17/86	71.2	37.2	–
4/23/86	71.8	35.9	38.0
5/14/86	82.0	38.7	35.8
5/28/86	65.4	22.0	–
6/11/86	82.0	–	24.7
Mean NOEC:	66.3	32.9	32.8
CV (%):	18.7	19.5	21.6
n:	11	10	3

Table A-2-12. NOECs for a refinery effluent conducted over 6 months using fathead minnows (*Pimephales promelas*), *Ceriodaphnia dubia*, and mysids (*Mysidopsis bahia*), according to methods described in References 1 and 2. (Data source: Dorn, 1989.)

Test Date	LC_{50} (% Effluent)		
	C. dubia	*P. promelas*	*M. bahia*
1/24/86	–	14.1	–
2/26/86	10.1	7.1	–
3/05/86	5.6	–	–
3/12/86	10.1	14.1	–
3/19/86	10.1	14.1	–
4/02/86	18.0	14.1	–
4/09/86	10.1	14.1	–
4/17/86	10.1	7.1	–
4/23/86	10.1	7.1	24.0
5/14/86	31.7	14.1	24.0
5/28/86	18.0	7.1	–
6/11/86	31.7	–	13.4
Mean NOEC:	15.1	11.3	20.5
CV (%):	59.6	31.9	29.8
n:	11	10	3

Table A-2-13. LC_{50}s for a manufacturing effluent conducted over 2 ears. All tests were conducted using *Daphnia magna* according to methods described in Reference 6. (Data source: [8].)

Test Date	LC_{50} (% Effluent)
1982 (1st quarter)	56
1982 (4th quarter)	90
1982 (4th quarter)	70
1983 (3rd quarter)	69
1983 (3rd quarter)	36
1983 (3rd quarter)	36
1983 (3rd quarter)	32
1983 (3rd quarter)	< 18
1983 (3rd quarter)	28
1983 (3rd quarter)	67
1983 (3rd quarter)	< 10
1983 (4th quarter)	46
1983 (4th quarter)	75
1983 (4th quarter)	78
1983 (4th quarter)	24
1983 (4th quarter)	26
1983 (4th quarter)	32
1983 (4th quarter)	19
Mean LC_{50}:	45.1 ± 24.3
CV (%):	53.9
n:	18

Note: Less than (<) values were excluded from the mean LC_{50} calculations.

Table A-2-14. LC_{50}s for a manufacturing effluent conducted over 8 years. All tests were conducted using *Pimephales promelas* according to methods described in Reference 6. (Data source: [8].)

Test Date	LC_{50} (% Effluent)
1979 (1st quarter)	72.0
1979 (1st quarter)	62.0
1979 (1st quarter)	52.0
1979 (3rd quarter)	39.0
1981 (2nd quarter)	64.0
1981 (4th quarter)	70.0
1982 (2nd quarter)	44.0
1982 (2nd quarter)	66.0
1985 (1st quarter)	59.6
1985 (4th quarter)	>100.0
1986 (2nd quarter)	49.2
1986 (2nd quarter)	63.8
1986 (2nd quarter)	50.0
1986 (3rd quarter)	75.7
1986 (3rd quarter)	80.0
1986 (3rd quarter)	79.0
1986 (4th quarter)	71.0
Mean LC_{50}:	64.5 ± 15.1
CV (%):	23.5
n:	17

Note: Greater than (>) values were excluded from the mean LC_{50} calculations.

Table A-2-15. LC_{50}s for a manufacturing effluent conducted over 5 years. All tests were conducted using *Pimephales promelas* according to methods described in Reference 6. (Data source: [8].)

Test Date	LC_{50} (% Effluent)
1980 (1st quarter)	18.0
1980 (2nd quarter)	11.0
1980 (3rd quarter)	32.0
1980 (4th quarter)	16.0
1981 (1st quarter)	32.0
1981 (2nd quarter)	23.0
1981 (3rd quarter)	17.0
1981 (4th quarter)	46.0
1982 (1st quarter)	9.0
1982 (2nd quarter)	32.0
1982 (3rd quarter)	28.0
1982 (4th quarter)	52.0
1983 (1st quarter)	34.0
1983 (2nd quarter)	33.0
1983 (3rd quarter)	20.0
1983 (4th quarter)	43.0
1984 (1st quarter)	45.0
1984 (2nd quarter)	19.0
1984 (3rd quarter)	61.0
1984 (4th quarter)	20.0
Mean LC_{50}:	29.6 ± 14.2
CV (%):	47.9
n:	20

Table A-2-16. LC_{50}s for a manufacturing effluent conducted over 5 years. All tests were conducted using *Daphnia magna* according to methods described in Reference 6. (Data source: [8].)

Test Date	LC_{50} (% Effluent)
1981 (2nd quarter)	100.0
1981 (3rd quarter)	>100.0
1982 (3rd quarter)	>100.0
1984 (4th quarter)	80.0
1985 (1st quarter)	75.0
1986 (1st quarter)	25.0
1986 (2nd quarter)	82.0
1987 (1st quarter)	75.0
1987 (1st quarter)	24.0
1987 (1st quarter)	>100.0
1987 (1st quarter)	>100.0
Mean LC_{50}:	65.9 ± 29.5
CV (%):	44.8
n:	11

Note: Greater than (>) values were excluded from the mean LC_{50} calculations.

Table A-2-17. LC_{50}s for a manufacturing effluent conducted over 7 years. All tests were conducted using *Daphnia pulex* according to methods described in Reference 6. (Data source: [8].)

Test Date	LC_{50} (% Effluent)
1980 (1st quarter)	55.0
1980 (4th quarter)	33.0
1981 (1st quarter)	60.0
1981 (1st quarter)	24.0
1981 (1st quarter)	>100.0
1981 (2nd quarter)	>100.0
1981 (3rd quarter)	>100.0
1982 (3rd quarter)	>100.0
1986 (3rd quarter)	>100.0
1986 (3rd quarter)	>100.0
Mean LC_{50}:	43.0 ± 17.3
CV (%):	40.2
n:	10

Note: Greater than (>) values were excluded from the mean LC_{50} calculations.

Table A-2-18. LC_{50}s for a manufacturing effluent conducted over 3 months. All tests were conducted using *Daphnia magna* according to methods described in Reference 6. (Data source: [8].)

Test Date	LC_{50} (% Effluent)
1982 (4th quarter)	>100.0
1982 (4th quarter)	81.0
1982 (4th quarter)	57.0
1982 (4th quarter)	61.0
1982 (4th quarter)	87.0
1982 (4th quarter)	90.0
1982 (4th quarter)	90.0
1982 (4th quarter)	>100.0
1982 (4th quarter)	>100.0
1982 (4th quarter)	54.0
1982 (4th quarter)	74.0
1982 (4th quarter)	>100.0
Mean LC_{50}:	74.3 ± 15.1
CV (%):	20.3
n:	12

Note: Greater than (>) values were excluded from the mean LC_{50} calculations.

Appendix A-3

Acute-to-Chronic Ratio Data

Table A-3-1. Example of Acute-to-Chronic Ratios

Oil Refinery[1]

	Fathead Minnow	*Ceriodaphnia*	*Mysids*
	1.89	9.09	1.58
	3.47	3.89	1.49
	2.60	6.58	1.84
	2.87	3.63	
	2.33	6.91	
	2.43	7.05	
	5.26	7.11	
	5.08	3.63	
	2.74	2.59	
	3.11	5.5	
	5.1	4.4	
		>10.0	
		> 7.1	
		> 3.3	
		> 2.0	
		> 3.0	
		2.8	
		5.4[2]	
Mean ACR:	3.3	5.3	1.64
n:	11	13	3
Range:	1.89-5.26	2.59->10.0	1.49-1.84

[1] Personal communication P. Dorn.

[2] Personal communication M.L.C. Ramos and E. Bertoletti (Sao Paulo, Brazil).

Note: Greater than (>) values were excluded from mean calculations.

Table A-3-2. Examples of Acute-to-Chronic Ratios

Chemical Manufacturers

	Fathead Minnow	*Ceriodaphnia*
	0.17	> 1.0
	0.07	> 1.0
	8.4	>10.0
	7.6	>50.0
	>3.0	> 2.9
	3.9	> 1.4
	>3.0	1.4
	1.8	1.4
		3.9
		2.8
		> 2.0
		> 4.0
		4.0
		1.4
		5.5
		1.8
		> 3.3
		> 3.3
		> 3.3
		1.4
		> 2.0
		5.5
		1.5
		1.4
		5.0
		>10.0
		> 2.0
		> 3.3
		3.1[1]
		14.0[1]
		4.3[1]
		2.5[1]
		1.8[1]
		5.5[1]
		5.4[1]
Mean ACR:	3.7	3.7[2]
n:	6	20
Range:	0.07 - 8.4	1.4 - >50

[1] Personal communication M.L.L.C. and E. Bertoletti (Sao Paulo, Brazil).

[2] Greater than (>) values were excluded from the mean calculation.

Table A-3-3. Example of Acute-to-Chronic Ratios

POTWs

	Fathead Minnow	*Ceriodaphnia*
	2.9	1.4
	6.1	5.5
	1.5	> 1.0
	13.0	> 1.0
	1.8	> 1.0
	2.6	1.8
	9.3	1.4
	> 1.0	2.0
	> 3.0	2.4
	5.3	3.0
	3.3	3.0
	5.4	5.5
	> 3.0	4.9
	3.0	> 2.0
		> 8.0
		> 2.0
		> 1.0
		> 3.3
		> 2.0
		4.4
		16.1
		> 4.0
		> 3.3
		>10.0
		2.6
		5.7
		2.8
		>10.0
		> 2.0
		1.4
		2.6
		> 3.3
		1.8
		5.5
		1.5
		> 3.3
		5.5
Mean ACR:	4.9	3.8*
n:	11	21
Range:	1.5 - 9.3	1.4 - 16.1

* Greater than (>) values were excluded from mean calculations.

APPENDIX A

REFERENCES

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2. Weber, C.I. et. al., eds. 1989. Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, 2d ed. EPA 600/4-89/001. Office of Research and Development, Cincinnati, OH.

3. Norberg-King, T.J. Memorandum: Summary of Effluent Toxicity Data for the Technical Support Document for Water Quality-based Toxics Control, Chapters 2 and 3. April 11, 1989. U.S. EPA, Environmental Research Laboratory, Duluth, MN, to M.A. Heber, U.S. EPA, Enforcement Division, Washington, DC. Memorandum: Technical Support Document for Water Quality-based Toxics Control Data: Fathead Minnow Round Robin Data Analyzed to Obtain the IC_{25}s. May 6, 1990. U.S. EPA, Environmental Research Laboratory, Duluth, MN, to M.A. Heber, U.S. EPA, Enforcement Division, Washington, DC.

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8. Norberg-King, T.J. May 4, 1989. Memorandum: Additional Data for the Technical Support Document for Water Quality-based Toxics Control, Chapters 2 and 3. U.S. EPA, Environmental Research Laboratory, Duluth, MN, to M.A. Heber, U.S. EPA, Enforcement Division, Washington, DC.

Appendix B-1

Summary of Clean Water Act Provisions

CLEAN WATER ACT (33 U.S.C. 1251 SEQ.)

Statutory Authority for the Use of Toxicity Testing and Whole Effluent Toxicity Limitations in NPDES Permits:

Over the years, a developmental process has occurred regarding the use of biological techniques to assess effluent discharges and set permit limits. The acquisition of data and the development of new techniques has contributed to the refinement of toxicity testing methods, thus enabling EPA to more fully act in accordance with its mandates to implement statutory requirements relating to the attainment and maintenance of water quality.

Toxicity testing of Whole Effluents and Whole Effluent toxicity limitations in National Pollutant Discharge Elimination System (NPDES) permits are essential components in the control of the discharge of toxic pollutants to the nation's waters. The use of toxicity testing and Whole Effluent toxicity limitation in the NPDES program is clearly authorized by the Clean Water Act (CWA).

Relevant provision of the CWA that provide the statutory authority for using toxicity testing and Whole Effluent toxicity limitations include the following:

- Section 101(a) sets forth not only the goal of restoring and maintaining the "chemical, physical, and biological integrity of the Nation's waters" (emphasis added), but also in Section 101(a)(3) the national policy of prohibiting the "discharge of toxic pollutants in toxic amounts" (emphasis added).
- As defined at Section 502(15), biological monitoring means that "determination of the effects on aquatic life, including accumulation of pollutants in tissue, in receiving waters due to the discharge of pollutants (A) by techniques and procedures, including sampling of organisms representative of appropriate levels of the food chain appropriate to the volume and the physical, chemical, and biological characteristics of the effluent, and (B) at appropriate frequencies and locations."
- Section 304(a)(8) requires EPA to develop information on methods, including biological monitoring and assessment methods, to establish and measure water quality criteria for toxic pollutants on bases other than pollutant by pollutant criteria.
- Section 303(c)(2)(B) states, "Nothing in this section shall be construed to limit or delay the use of effluent limitations or other permit conditions based on or involving biological monitoring or assessment methods..." (emphasis added).
- Section 302(a) provides the authority to establish water quality-based effluent limitations on discharges that interfere with the attainment or maintenance of that water quality which shall assure protection of public health, public water supplies, and the protection and propagation of a balance population of shellfish, fish and wildlife, among other uses. The effluent limitations established must reasonably be expected to contribute to attainment or maintenance of such water quality.
- Under Section 301(b)(1)(C) and Section 402, all NPDES permits must comply with any more stringent limitations necessary to meet applicable water quality standards, whether numeric or narrative.
- CWA Section 308(a) and Section 402 provide authority to EPA or the Sate to require that NPDES permittees/applicants use biological monitoring methods and provide chemical, toxicity, and instream biological data when necessary for the establishment of effluent limits, the detection of violations, or the assurance of compliance with water quality standards.
- Section 510 provides the authority for states to adopt or enforce any standards or effluent limitations for the discharge of pollutants only on the condition that such limitations or standards are no less stringent than those in effect under the CWA.

Appendix B-2

Policies for Toxics Control

[OW-FRL-2533-1]

Development of Water Quality-Based Permit Limitations for Toxic Pollutants; National Policy

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has issued a national policy statement entitled "Policy for the Development of Water Quality-Based Permit Limitations for Toxic Pollutants." This policy addresses the technical approach for assessing and controlling the discharge of toxic substances to the Nation's waters through the National Pollutant Discharge Elimination System (NPDES) permit program.

FOR FURTHER INFORMATION CONTACT: Bruce Newton or Rick Brandes, Permits Division (EN-336), Office of Water Enforcement and Permits, U.S. Environmental Protection Agency, Washington, D.C. 20460, 426-7010.

SUPPLEMENTARY INFORMATION: As the water pollution control effort in the United States progresses and the "traditional" pollutants (oxygen demanding and eutrophying materials) become sufficiently treated to protect water quality, attention is shifting towards pollutants that impact water quality through toxic effects. Compared with the traditional pollutants, regulation of toxic pollutants is considerably more difficult. The difficulties include (1) the great number of toxic chemicals that may potentially be discharged to receiving waters and the difficulties in their analysis; (2) the changes in the toxic effects of a chemical resulting from reactions with the matrix of constituents in which it exists; and (3) the inability to predict the effects of exposure to combinations of chemicals.

To overcome some of these problems, EPA and the States have begun to use aquatic toxicity tests and various human health assessment techniques to complement chemical analyses of effluents and receiving water samples. Because these techniques or their application to effluent testing are new, EPA and the States have been cautious in their use. Based on EPA's evaluation of these techniques and the experiences of several States, EPA is now recommeding the use of biological techniques as a complement to chemical-specific analyses to assess effluent discharges and express permit limitations. EPA has issued these recommendations through a statement of policy and is developing a technical guidance document to help implement the policy.

The complete test of the national policy statement follows:

Policy for the Development of Water Quality-Based Permit Limitations for Toxic Pollutants

Statement of policy

To control pollutants beyond Best Available Technology Economically Achievable (BAT), secondary treatment, and other Clean Water Act technology-based requirements in order to meet water quality standards, the Environmental Protection Agency (EPA) will use an integrated strategy consisting of both biological and chemical methods to address toxic and nonconventional pollutants from industrial and municipal sources. Where State standards contain numerical criteria for toxic pollutants, National Pollutant Discharge Elimination System (NPDES) permits will contain limits as necessary to assure compliance with these standards. In addition to enforcing specific numerical criteria, EPA and the States will use biological techniques and available data on chemical effects to assess toxicity impacts and human health hazards based on the general standard of "no toxic materials in toxic amounts."

EPA, in its oversight role, will work with States to ensure that these techniques are used wherever appropriate. Under section 308 and section 402 of the Clean Water Act (the Act), EPA or the State may require NPDES permit applicants to provide chemical, toxicity, and instream biological data necessary to assure compliance with standards. Data requirements may be determined on a case-by-case basis in consultation with the State and the discharger.

Where violations of water quality standards are identified or projected, the State will be expected to develop water quality-based effluent limits for inclusion in any issued permit. Where necessary, EPA will develop these limits in consultation with the State. Where there is a significant likelihood of toxic effects to biota in the receiving water, EPA and the States may impose permit limits on effluent toxicity and may require an NPDES permittee to conduct a toxicity reduction evaluation. Where toxic effects are present but there is a significant likelihood that compliance with technology-based requirements will sufficiently mitigate the effects, EPA and the States may require chemical and toxicity testing after installation of treatment and may reopen the permit to incorporate additional limitations if needed to meet water quality standards. (Toxicity data, which are considered "new information" in accordance with 40 CFR 122.62(a)(2), could constitute cause for permit modification where necessary.)

To carry out this policy, EPA Regional Administrators will assure that each Region has the capability to conduct water quality assessments using both biological and chemical methods and provide technical assistance to the States.

Background

The Clean Water Act establishes two principal bases for effluent limitations. First, existing dischargers are required to meet technology-based effluent limitations that reflect the best controls available considering economic impacts. New source dischargers must meet the best demonstrated technology-based controls. Second, where necessary, additional requirements are imposed to assure attainment and maintenance of water quality standards established by the States and approved by EPA. In establishing or reviewing NPDES permit limits, EPA must ensure that the limits will result in the attainment of water quality standards and protect designated water uses, including an adequate margin of safety.

For toxic and nonconventional pollutants it may be difficult in some situations to determine attainment or nonattainment of water quality standards and set appropriate limits because of complex chemical interactions which affect the fate and ultimate impact of toxic substances in the receiving water. In many cases, all potentially toxic pollutants cannot be identified by chemical methods. In such situations, it is more feasible to examine the whole effluent toxicity and instream impacts using biological methods rather than attempt to identify all toxic pollutants, determine the effects of each pollutant individually, and then attempt to assess their collective effect.

The scientific basis for using biological techniques has advanced significantly in recent years. There is now a general consensus that an evaluation of effluent toxicity, when adequately related to instream conditions, can provide a valid indication of receiving system impacts. This information can be useful in developing regulatory requirements to protect aquatic life, especially when data from toxicity testing are analyzed in conjunction with chemical and ecological data. Generic human health effects methods, such as the Ames mutagenicity test, and structure-activity relationship techniques are showing promise and should be used to identify potential hazards. However, pollutant-specific techniques are the best way to evaluate and control human health hazards at this time.

Biological testing of effluents is an important aspect of the water quality-based approach for controlling toxic pollutants. Effluent toxicity data in conjunction with other data can be used to establish control priorities, assess compliance with State water quality standards, and set permit limitations to achieve those standards. All States have water quality standards which include narrative statements prohibiting the discharge of toxic materials in toxic amounts. A few State standards have criteria more specific than narrative criteria (for example, numerical criteria for specific toxic pollutants or a toxicity criterion to achieve designated uses). In States where numerical criteria are not specified, a judgment by the regulatory authority is required to set quantitative water quality-based limits on chemicals and effluent toxicity to assure

compliance with water quality standards.

Note.—Section 308 of the Act and corresponding State statutes authorize EPA and the States to require of the owner/operator any information reasonably required to determine permit limits and to determine compliance with standards or permit limits. Biological methods are specifically mentioned. Toxicity permit limits are authorized under Section 301 and 402 and supported by Section 101.

Application

This policy applies to EPA and the States. The policy addresses the use of chemical and biological methods for assuring that effluent discharges are regulated in accordance with Federal and State requirements. This policy was prepared, in part, in response to concerns raised by litigants to the Consolidated Permit Regulations (see FR 52079, November 18, 1982). Use of these methods for developing water quality standards and trend monitoring are discussed elsewhere (see 48 FR 51400, November 8, 1983 and *Basic Water Monitoring Program* EPA-440/9-76-025). This policy is part of EPA's water quality-based control program and does not supersede other regulations, policy, and guidance regarding use attainability, site-specific criteria modification, wasteload allocation, and water quality management.

Implementation

State Role

The control of toxic substances to protect water quality must be done in the context of the Federal-State partnership. EPA will work cooperatively with the States in identifying potential water quality standards violations, assembling relevant data, developing appropriate testing requirements, determining whether standards are being violated, and defining appropriate permit limits.

Note.—Under sections 303 and 401 of the Act, States are given primary responsibility for developing water quality standards and limits to meet those standards. EPA's role is to review the State standards and limits and develop revised or additional standards or limits as needed to meet the requirements of the Act.

Integration of Approaches

The type of testing that is most appropriate for assessing water quality impacts depends on the type of effluent and discharge situation. EPA recommends that an integrated approach, including both biological and chemical techniques, be used to assess and control water quality. The principal advantages of chemical-specific techniques are that (1) chemical analyses are usually less expensive than biological measurements in simple cases; (2) treatment systems are more easily designed to meet chemical requirements than toxicity requirements; and (3) human health hazards and bioaccumulative pollutants can best be addressed at this time by chemical-specific analysis. The principal advantages of biological techniques are that (1) the effects of complex discharges of many known and unknown constituents can be measured only by biological analyses; (2) bioavailability of pollutants after discharge is best measured by toxicity testing; and (3) pollutants for which there are inadequate chemical analytical methods or criteria can be addressed.

Pollutant-specific chemical analysis techniques should be used where discharges contain few, well-quantified pollutants and the interactions and effects of the pollutants are known. In addition, pollutant-specific techniques should be used where health hazards are a concern or bioaccumulation is suspected. Biological techniques should be used where effluents are complex or where the combined effects of multiple discharges are of concern. EPA recognizes that in many cases both types of analysis must be used.

Testing Requirements

Requirements for dischargers to collect information to assess attainment or nonattainment of State water quality standards will be imposed only in selected cases where the potential for nonattainment of water quality standards exists. Where water quality problems are suspected but there is a strong indication that complying with BCT/BAT will sufficiently mitigate the impacts, EPA recommends that applicable permits include testing requirements effective after BCT/BAT compliance and reopener clauses allowing reevaluation of the discharge.

The chemical, physical, and biological testing to be conducted by individual dischargers should be determined on a case-by-case basis. In making this determination, many factors must be considered, including the degree of impact, the complexity and variability of the discharge, the water body type and hydrology, the potential for human health impact, the amount of existing data, the level of certainty desired in the water quality assessment, other sources of pollutants, and the ecology of the receiving water. The specific data needed to measure the effect that a discharger has on the receiving water will vary according to these and other factors.

An assessment of water quality should, to the extent practicable, include other point and nonpoint sources of pollutants if the sources may be contributing to the impacts. Special attention should be focused on Publicly Owned Treatment Works (POTW's) with a significant contribution of industrial waste-water. Recent studies have indicated that such POTW's are often significant sources of toxic materials. When developing monitoring requirements, interpreting data, and determining limitations, permit engineers should work closely with water quality staff at both the State and Federal levels.

A discharger may be required to provide data upon request under section 308 of the Act, or such a requirement may be included in its NPDES permit. The development of a final assessment may require several iterations of data collection. Where potential problems are identified, EPA or the State may require monitoring to determine whether more information is needed concerning water quality effects.

Use of Data

Chemical, physical, and biological data will be used to determine whether, after compliance with BCT/BAT requirements, there will be violations of State water quality standards resulting from the discharge(s). The narrative prohibition of toxic materials in toxic amounts contained in all State standards is the basis for this determination taking into account the designated use for the receiving water. For example, discharges to waters classified for propagation of cold water fish should be evaluated in relation to acute and chronic effects on cold water organisms, potential spawning areas, and effluent dispersion.

Setting Permit Limitations

Where violations of water quality standards exist or are projected, the State and EPA will determine pollution control requirements that will attain the receiving water designated use. Where effluent toxicity is an appropriate control parameter, permit limits on effluent toxicity should be developed. In such cases, EPA may also require a permittee to conduct a toxicity reduction evaluation. A toxicity reduction evaluation is an investigation conducted within a plant or municipal system to isolate the sources of effluent toxicity, specific causative pollutants if possible, and determine the effectiveness of pollution control options in reducing the effluent toxicity. If specific chemicals are identified as the cause of the water

quality standards violation, these individual pollutants should be limited. If a toxicity reduction evaluation demonstrates that limiting an indicator parameter will ensure attainment of the water quality-based effluent toxicity requirement, limits on the indicator parameter should be considered in lieu of limits on effluent toxicity. Such indicator limits are not limits on causative pollutants but limits demonstrated to result in a specific toxicity reduction.

Monitoring

Where pollution control requirements are expressed in terms of a chemical or toxicological parameter, compliance monitoring must include monitoring for that parameter. If an indicator parameter is used based on the results of a toxicity reduction evaluation, periodic toxicity testing may be required to confirm the adequacy of the indicator. Where biological data were used to develop a water quality assessment or where the potential for water quality standards violations exist, biological monitoring (including instream monitoring) may be required to ensure continuing compliance with water quality standards.

EPA believes that the intelligent application of an integrated strategy using both biological and chemical techniques for water quality assessment will facilitate the development of appropriate controls and the attainment of water quality standards. EPA looks forward to working with the States in a spirit of cooperation to further refine these techniques.

Policy signed February 3, 1984 by Jack E. Ravan, Assistant administrator for Water.

Dated: February 16, 1984.

Jack E. Ravan,

Assistant Administrator for Water

[FR Doc. 84-6445 Filed 3-8-84; 8:45 am]

BILLING CODE 6560-50-M

Appendix B-3

Regulations for Toxics Control

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 21 1989

OFFICE OF WATER

MEMORANDUM

SUBJECT: New Regulations Governing Water Quality-Based Permitting in the NPDES Permitting Program

FROM: James R. Elder, Director
Office of Water Enforcement and Permits

TO: Water Management Division Directors
Regions I - X

On May 26, 1989 the Deputy Administrator signed regulations that implement section 304(l) of the CWA. The regulations became effective upon his signature and were published in the Federal Register on June 2, 1989 (54 Fed. Reg. 23868). This rulemaking also clarified and reinforced EPA's existing regulations governing water quality-based permitting. The purpose of this memorandum is to describe the significance of these clarifications to EPA's baseline water quality-based permitting regulations.

CHANGES TO 40 C.F.R. PART 122

Section 122.44 covers the establishment of limitations, standards, and other permit conditions in NPDES permits. Subsection (d) covers water quality standards and state requirements. Prior to the promulgation of these new regulations the subsection was non-specific, requiring only that NPDES permits be issued with requirements more stringent than promulgated effluent guidelines as necessary to achieve water quality standards. We have strengthened considerably the requirements of §122.44(d). The new language is very specific and requires water quality-based permit limits for specific toxicants and whole effluent toxicity where necessary to achieve state water quality standards. The following is a section-by-section description of the new requirements.

1. §122.44(d)(1)(i)

This new paragraph provides that all pollutants that cause, have the reasonable potential to cause, or contribute to an excursion above a water quality standard must be controlled to achieve all applicable water quality standards, including narrative water quality criteria. We added this paragraph so that our regulations would reflect EPA's approach to water quality-based permitting.

2. §122.44(d)(1)(ii)

Subparagraph (ii) of the new regulations requires the states to use valid procedures to determine whether a discharge causes, has the reasonable potential to cause, or contributes to an excursion above a water quality standard. These procedures must account for existing controls on point and nonpoint sources of pollution, the variability of the pollutant in the effluent, the sensitivity of the test species (when evaluating whole effluent toxicity), and where allowed by state water quality standards, the dilution of the effluent in the receiving water. The purpose of this new regulation is to require the states to use technically valid procedures when determining whether a discharge is exceeding a numeric or narrative water quality criterion. When the permitting authority determines, using these procedures, that a discharge causes, has the reasonable potential to cause, or contributes to an excursion above a water quality criterion, that permit must include one or more water quality-based effluent limits established under subparagraphs (iii) - (vi). Subparagraphs (iii) and (iv) deal with water quality-based limitations where the state has numeric water quality criteria; subparagraphs (v) and (vi) deal with a state's narrative water quaity criteria.

3. §122.44(d)(1)(iii)

This paragraph requires NPDES permits to include effluent limitations for every individual pollutant that causes, has the reasonable potential to cause, or contributes to an excursion above a numeric water quality criterion. Thus, when a state has adopted a water quality criterion for an individual pollutant and the state determines under subparagraph (ii) that an effluent limit is necessary, subparagraph (iii) requires an effluent limit for that individual pollutant.

4. §122.44(d)(1)(iv)

Subparagraph (iv) requires effluent limitations on whole effluent toxicity when a discharge is exceeding a state numeric criteria for whole effluent toxicity. This paragraph is applied

where a state has adopted a numeric criterion for whole effluent toxicity (e.g. a discharge must achieve an LC50 of 50% or higher).

5. §122.44(d)(1)(v)

When the state determines that a discharge exceeds a narrative water quality criterion, subparagraph (v) requires effluent limitations on whole effluent toxicity. If, however, chemical-specific effluent limitations are demonstrated to be sufficient to achieve all applicable water quality standards, then subparagraph (v) allows the permitting authority to forego a limitation on whole effluent toxicity. It may be necessary for you to work with an individual state to ensure that they have the necessary protocols to support whole effluent toxicity limits.

6. §122.44(d)(1)(vi)

Where an actual or projected excursion above a narrative water quality criterion is attributable to a particular pollutant, but the state has not adopted a water quality criterion for the pollutant of concern, this new regulation requires water quality-based effluent limitations which will control the pollutant of concern. Subparagraph (vi) establishes three options for developing such limitations. Under these options, a state may: 1) calculate a numeric criterion for the pollutant; 2) use EPA's water quality criterion for the pollutant of concern; or 3) establish effluent limits on an indicator parameter.

By an indicator parameter we mean a pollutant or pollutant parameter for which control of this indicator will result in control of the pollutant of concern. For example, it may be shown that a more stringent control on total suspended solids will reduce discharge of a metal to a level which achieves the water quality standard. Subparagraph (vi) also sets out four provisions which must be met to allow the use of an indicator:

1) The permit must identify which pollutants are intended to be controlled by a limit on the indicator parameter.

2) The fact sheet must set forth the basis for the limit, including a finding that compliance with the limit will result in controls on the pollutant of concern that are sufficient to achieve the water quality standard.

3) The permit must require all monitoring necessary to show continued compliance with water quality standards.

4) The permit must contain a reopener clause allowing for changes in the permit as needed to achieve water quality standards.

A state's narrative water quality criterion serves as the legal basis for establishing such effluent limits.

7. §122.44(d)(1)(vii)

Subparagraph (vii) requires that all water quality-based effluent limitations adhere to two fundamental principles: 1) the effluent limitations must be derived from and comply with all applicable water quality standards; and 2) the effluent limitations are consistent with the assumptions and requirements of an applicable wasteload allocation (WLA) if a WLA is available for the pollutant.

CHANGES TO 40 C.F.R. PART 123

We amended the permit objection regulations at 40 C.F.R. §123.44 to reflect the amendments to §122.44(d)(1). Under §123.44(c)(8) EPA may now object to a state-issued permit if the permit does not meet the requirements of §122.44(d)(1). Thus, if a state does not use technically sound procedures for evaluating the need for water quality-based effluent limitations then EPA may object to the permit. Also, if a state fails to include chemical-specific or whole effluent toxicity limitations in a permit as required by paragraphs (iii) - (vi), then EPA may object to the permit. Finally, if a water quality based effluent limitation is not derived according to the principles in subparagraph (vii) then EPA may object to the permit.

If a state's surface water toxics control program is not adequate to implement these requirements, the new regulations at 40 C.F.R. §123.63 expand EPA's criteria for withdrawing a state's NPDES program. Under the new regulations (§123.63(a)(5)), EPA may withdraw a state's NPDES program if the state fails to develop an adequate regulatory program for developing water quality-based effluent limitations. In November 1987, Headquarters provided procedural and technical guidance to the Regions on conducting state toxics control program reviews to assess the adequacy of state water quality-based control programs. This guidance sets guidelines for assessing whether or not a state's regulations, policies, and technical guidance constitute an adequate program.

The significance of these additions to Part 123 is twofold. First, the Regions must issue permits which comply with these requirements and must work with the NPDES states to insure they also issue permits which comply with these regulations. If the states do not issue permits consistent with Part 123, the Region must veto insufficient permits and work with the states to

reissue the permits with water quality-based effluent limitations which achieve water quality standards. The specific requirements in §122.44(d) are structured in a way that implements EPA's Policy for the Development of Water Quality-Based Permit Limitations for Toxic Pollutants (49 Fed. Reg. 9016 March 9, 1984). Second, Regions will need to look closely at each state's surface water toxics control program to ensure that the state's regulations, policies and technical guidance result in the consistent and comprehensive development of NPDES permits which achieve the state's water quality standards. Where this does not occur, each Region should work with the state to rectify the problem and, after these negotiations and where necessary, investigate the possibility of withdrawing the NPDES program.

I hope these regulations will assist you in developing water quality-based effluent limits and will support your efforts to implement surface water toxics control programs. If you have questions or need more information about these requirements, please contact Cynthia Dougherty at FTS 475-9545 or have your staff contact Rick Brandes at FTS 475-9537.

cc: Permits Branch Chiefs, Regions I - X
Martha Prothro, OWRS

ENVIRONMENTAL PROTECTION AGENCY

[FRL-3557-6]

40 CFR Parts 122, 123 and 130

National Pollutant Discharge Elimination System; Surface Water Toxics Control Program

AGENCY: Environmental Protection Agency.

ACTION: Final Rule.

SUMMARY: Today's action amends Parts 122, 123, and 130 of EPA's regulations. The regulations clarify EPA's surface water toxics control program, and incorporate section 308(a) of the Water Quality Act of 1987 into EPA's toxics control program. Section 308(a) of the Water Quality Act added section 304(l) to the Clean Water Act (hereafter referred to as section 304(l)). Section 304(l) requires the states to identify those waters that are adversely affected by toxic, conventional, and nonconventional pollutants, and requires the states to prepare individual control strategies that will control point source discharges of toxic pollutants. The states must submit lists of waters and individual control strategies to EPA for review, and if EPA disapproves a state's decision with respect to a list or an individual control strategy, then EPA must implement the requirements of section 304(l) in cooperation with the state. EPA and the states must accomplish the tasks in section 304(l) according to an ambitious series of deadlines. Today's regulations will strengthen State and Federal controls over discharges to toxic pollutants, and will assist EPA and the states in satisfying the requirements of section 304(l) of the CWA.

EFFECTIVE DATE: These regulations shall be effective on May 26, 1989 at 1:00 p.m. Eastern Daylight Savings Time. In accordance with 40 CFR 23.2, EPA hereby specifies that these regulations shall be considered final agency action for purposes of judicial review at 1:00 p.m. Eastern Daylight Savings Time on May 26, 1989.

FOR FURTHER INFORMATION CONTACT: Paul Connor, Program Development Branch, Office of Water Enforcement and Permits, (EN-336), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 475-9537, or Judith Leckrone, Assessment and Watershed Protection Division, Office of Water Regulations and Standards, (WH-553), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, (202) 382-7056. The Public record for this regulation is available at the EPA library, M2904, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

1. The authority citation for Part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 *et seq.*

2. Section 122.2 is amended by adding in alphabetical order a new definition as follows:

§ 122.2 Definitions.

* * * * *

Whole effluent toxicity means the aggregate toxic effect of an effluent measured directly by a toxicity test.

3. Paragraph (d)(1) of § 122.44 is revised to read as follows:

§ 122.44 Establishing limitations, standards, and other permit conditions (applicable to State NPDES programs, see § 123.25).

* * * * *

(d) * * *

(1) Achieve water quality standards established under section 303 of the CWA, including State narrative criteria for water quality.

(i) Limitations must control all pollutants or pollutant parameters (either conventional, nonconventional, or toxic pollutants) which the Director determines are or may be discharged at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any State water quality standard, including State narrative criteria for water quality.

(ii) When determining whether a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above a narrative or numeric criteria within a State water quality standard, the permitting authority shall use procedures which account for existing controls on point and nonpoint sources of pollution, the variability of the pollutant or pollutant parameter in the effluent, the sensitivity of the species to toxicity testing (when evaluating whole effluent toxicity), and where appropriate, the dilution of the effluent in the receiving water.

(iii) When the permitting authority determines, using the procedures in paragraph (d)(1)(ii) of this section, that a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above the allowable ambient concentration of a State numeric criteria within a State water quality standard for an individual pollutant, the permit must contain effluent limits for that pollutant.

(iv) When the permitting authority determines, using the procedures in paragraph (d)(1)(ii) of this section, that a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above the numeric criterion for whole effluent toxicity, the permit must contain effluent limits for whole effluent toxicity.

(v) Except as provided in this subparagraph, when the permitting authority determines, using the procedures in paragraph (d)(1)(ii) of this section, toxicity testing data, or other information, that a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above a narrative criterion within an applicable State water quality standard, the permit must contain effluent limits for whole effluent toxicity. Limits on whole effluent toxicity are not necessary where the permitting authority demonstrates in the fact sheet or statement of basis of the NPDES permit, using the procedures in paragraph (d)(1)(ii) of this section, that chemical-specific limits for the effluent are sufficient to attain and maintain applicable numeric and narrative State water quality standards.

(vi) Where a State has not established a water quality criterion for a specific chemical pollutant that is present in an effluent at a concentration that causes, has the reasonable potential to cause, or contributes to an excursion above a narrative criterion within an applicable State water quality standard, the permitting authority must establish effluent limits using one or more of the following options:

(A) Establish effluent limits using a calculated numeric water quality criterion for the pollutant which the permitting authority demonstrates will attain and maintain applicable narrative water quality criteria and will fully protect the designated use. Such a criterion may be derived using a proposed State criterion, or an explicit State policy or regulation interpreting its narrative water quality criterion, supplemented with other relevant information which may include: EPA's Water Quality Standards Handbook, October 1983, risk assessment data, exposure data, information about the pollutant from the Food and Drug Administration, and current EPA criteria documents; or

(B) Establish effluent limits on a case-by-case basis, using EPA's water quality criteria, published under section 307(a) of the CWA, supplemented where necessary by other relevant information; or

(C) Establish effluent limitations on an indicator parameter for the pollutant of concern, provided:

(*1*) The permit identifies which pollutants are intended to be controlled by the use of the effluent limitation;

(*2*) The fact sheet required by § 124.56 sets forth the basis for the limit, including a finding that compliance with the effluent limit on the indicator parameter will result in controls on the pollutant of concern which are sufficient to attain and maintain applicable water quality standards;

(*3*) The permit requires all effluent and ambient monitoring necessary to show that during the term of the permit the limit on the indicator parameter continues to attain and maintain applicable water quality standards; and

(*4*) The permit contains a reopener clause allowing the permitting authority to modify or revoke and reissue the permit if the limits on the indicator parameter no longer attain and maintain applicable water quality standards.

(vii) When developing water quality-based effluent limits under this paragraph the permitting authority shall ensure that:

(A) The level of water quality to be achieved by limits on point sources established under this paragraph is derived from, and complies with all applicable water quality standards; and

(B) Effluent limits developed to protect a narrative water quality criterion, a numeric water quality criterion, or both, are consistent with the assumptions and requirements of any available wasteload allocation for the

discharge prepared by the State and approved by EPA pursuant to 40 CFR 130.7.

* * * * *

4. The title of paragraph (e) of § 122.44 is revised to read as follows:

* * * * *

(e) *Technology-based controls for toxic pollutants.* * * *

PART 123—STATE PROGRAM REQUIREMENTS

1. The authority citation for Part 123 continues to read as follows:

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

2. Section 123.44 is amended by adding paragraph (c)(8) to read as follows:

§ 123.44 EPA review of and objections to State permits.

* * * * *

(c) * * *

(8) The effluent limits of a permit fail to satisfy the requirements of 40 CFR 122.44(d).

* * * * *

3. In § 123.46 paragraph (a) is revised and paragraphs (c), (d), (e) and (f) are added, as follows:

§ 123.46 Individual control strategies.

(a) Not later than February 4, 1989, each State shall submit to the Regional Administrator for review, approval, and implementation an individual control strategy for each point source identified by the State pursuant to section 304(l)(1)(C) of the Act which will produce a reduction in the discharge of toxic pollutants from the point sources identified under section 304(l)(1)(C) through the establishment of effluent limitations under section 402 of the CWA and water quality standards under section 303(c)(2)(B) of the CWA, which reduction is sufficient, in combination with existing controls on point and nonpoint sources of pollution, to achieve the applicable water quality standard as soon as possible, but not later than three years after the date of the establishment of such strategy.

* * * * *

(c) For the purposes of this section the term individual control strategy, as set forth in section 304(l) of the CWA, means a final NPDES permit with supporting documentation showing that effluent limits are consistent with an approved wasteload allocation, or other documentation which shows that applicable water quality standards will be met not later than three years after the individual control strategy is established. Where a State is unable to issue a final permit on or before February 4, 1989, an individual control strategy may be a draft permit with an attached schedule (provided the State meets the schedule for issuing the final permit) indicating that the permit will be issued on or before February 4, 1990. If a point source is subject to section 304(l)(1)(C) of the CWA and is also subject to an on-site response action under sections 104 or 106 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), (42 U.S.C. 9601 et seq.), an individual control strategy may be the decision document (which incorporates the applicable or relevant and appropriate requirements under the CWA) prepared under sections 104 or 106 of CERCLA to address the release or threatened release of hazardous substances to the environment.

(d) A petition submitted pursuant to section 304(l)(3) of the CWA must be submitted to the appropriate Regional Administrator. Petitions must identify a waterbody in sufficient detail so that EPA is able to determine the location and boundaries of the waterbody. The petition must also identify the list or lists for which the waterbody qualifies, and the petition must explain why the waterbody satisfies the criteria for listing under CWA section 304(l) and 40 CFR 130.10(d)(6).

(e) If the Regional Administrator disapproves one or more individual control strategies, or if a State fails to provide adequate public notice and an opportunity to comment on the ICSs, then, not later than June 4, 1989, the Regional Administrator shall give a notice of approval or disapproval of the individual control strategies submitted by each State pursuant to this section as follows:

(1) The notice of approval or disapproval given under this paragraph shall include the following:

(i) The name and address of the EPA office that reviews the State's submittals.

(ii) A brief description of the section 304(l) process.

(iii) A list of ICSs disapproved under this section and a finding that the ICSs will not meet all applicable review criteria under this section and section 304(l) of the CWA.

(iv) If the Regional Administrator determines that a State did not provide adequate public notice and an opportunity to comment on the waters, point sources, or ICSs prepared pursuant to section 304(l), or if the Regional Administrator chooses to exercise his or her discretion, a list of the ICSs approved under this section, and a finding that the ICSs satisfy all applicable review criteria.

(v) The location where interested persons may examine EPA's records of *approval and disapproval.*

(vi) The name, address, and telephone number of the person at the Regional Office from whom interested persons may obtain more information.

(vii) Notice that written petitions or comments are due within 120 days.

(2) The Regional Administrator shall provide the notice of approval or disapproval given under this paragraph to the appropriate State Director. The Regional Administrator shall publish a notice of availability, in a daily or weekly newspaper with State-wide *circulation or in the Federal Register, for* the notice of approval or disapproval. The Regional Administrator shall also provide written notice to each discharger identified under section 304(l)(1)(C), that EPA has listed the discharger under section 304(l)(1)(C).

(3) As soon as practicable but not later than June 4, 1990, the Regional Offices shall issue a response to petitions or comments received under section 304(l). The response to comments shall be given in the same manner as the notice described in paragraph (e) of this section except for the following changes:

(i) The lists of ICSs reflecting any changes made pursuant to comments or petitions received.

(ii) A brief description of the subsequent steps in the section 304(l) process.

(f) EPA shall review, and approve or disapprove, the individual control strategies prepared under section 304(l) of the CWA, using the applicable criteria set forth in section 304(l) of the CWA, and in 40 CFR Part 122, including § 122.44(d). At any time after the Regional Administrator disapproves an ICS (or conditionally aproves a draft permit as an ICS), the Regional Office may submit a written notification to the State that the Regional Office intends to issue the ICS. Upon mailing the notification, and notwithstanding any other regulation, exclusive authority to issue the permit passes to EPA.

4. Section 123.63 is amended by adding paragraph (a)(5) to read as follows:

§ 123.63 Criteria for withdrawal of state programs.

(a) * * *

(5) Where the State fails to develop an adequate regulatory program for developing water quality-based effluent limits in NPDES permits.

APPENDIX B-4

WHOLE EFFLUENT TOXICITY PERMITTING PRINCIPLES AND ENFORCEMENT STRATEGY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
January 25, 1989

OFFICE OF WATER

MEMORANDUM

SUBJECT: Whole Effluent Toxicity Basic Permitting Principles and Enforcement Strategy

Rebecca Hanmer

FROM: Rebecca W. Hanmer, Acting Assistant Administrator
Office of Water

TO: Regional Administrators

Since the issuance of the "Policy for the Development of Water Quality-based Permit Limitations for Toxic Pollutants" in March of 1984, the Agency has been moving forward to provide technical documentation to support the integrated approach of using both chemical and biological methods to ensure the protection of water quality. The Technical Support Document for Water Quality-based Toxics Control (September, 1985) and the Permit Writer's Guide to Water Quality-based Permitting for Toxic Pollutants (July, 1987) have been instrumental in the initial implementation of the Policy. The Policy and supporting documents, however, did not result in consistent approaches to permitting and enforcement of toxicity controls nationally. When the 1984 Policy was issued, the Agency did not have a great deal of experience in the use of whole effluent toxicity limitations and testing to ensure protection of water quality. We now have more than four years of experience and are ready to effectively use this experience in order to improve national consistency in permitting and enforcement.

In order to increase consistency in water quality-based toxicity permitting, I am issuing the attached Basic Permitting Principles for Whole Effluent Toxicity (Attachment 1) as a standard with which water quality-based permits should conform. A workgroup of Regional and State permitting, enforcement, and legal representatives developed these minimum acceptable requirements for toxicity permitting based upon national experience. These principles are consistent with the toxics control approach addressed in the proposed Section 304(l) regulation. Regions should use these principles when reviewing draft State permits. If the final Section 304(l) regulations include changes in this area, we will update these principles as necessary. Expanded guidance on the use of these principles will be sent out shortly by James Elder, Director of the Office of

Water Enforcement and Permits. This expanded guidance will include sample permit language and permitting/enforcement scenarios.

Concurrent with this issuance of the Basic Permitting Principles, I am issuing the Compliance Monitoring and Enforcement Strategy for Toxics Control (Attachment 2). This Strategy was developed by a workgroup of Regional and State enforcement representatives and has undergone an extensive comment period. The Strategy presents the Agency's position on the integration of toxicity control into the existing National Pollutant Discharge Elimination System (NPDES) compliance and enforcement program. It delineates the responsibilities of the permitted community and the regulatory authority. The Strategy describes our current efforts in compliance tracking and quality assurance of self-monitoring data from the permittees. It defines criteria for review and reporting of toxicity violations and describes the types of enforcement options available for the resolution of permit violations.

In order to assist you in the management of whole effluent toxicity permitting, the items discussed above will join the 1984 Policy as Appendices to the revised Technical Support Document for Water Quality-based Toxics Control. To summarize, these materials are the Basic Permitting Principles, sample permit language, the concepts illustrated through the permitting and enforcement scenarios, and the Enforcement Strategy. I hope these additions will provide the needed framework to integrate the control of toxicity into the overall NPDES permitting program.

I encourage you and your staff to discuss these documents and the 1984 Policy with your States to further their efforts in the implementation of EPA's toxics control initiative.

If you have any questions on the attached materials, please contact James Elder, Director of the Office of Water Enforcement and Permits, at (FTS/202) 475-8488.

Attachments

cc: ASWIPCA
Water Management Division Directors

BASIC PERMITTING PRINCIPLES FOR WHOLE EFFLUENT TOXICITY

1. Permits must be protective of water quality.

   a. At a minimum, all major permits and minors of concern must be evaluated for potential or known toxicity (chronic or acute if more limiting).

   b. Final whole effluent toxicity limits must be included in permits where necessary to ensure that State Water Quality Standards are met. These limits must properly account for effluent variability, available dilution, and species sensitivity.

2. Permits must be written to avoid ambiguity and ensure enforceability.

   a. Whole effluent toxicity limits must appear in Part I of the permit with other effluent limitations.

   b. Permits contain generic re-opener clauses which are sufficient to provide permitting authorities the means to re-open, modify, or reissue the permit where necessary. Re-opener clauses covering effluent toxicity will not be included in the Special Conditions section of the permit where they imply that limit revision will occur based on permittee inability to meet the limit. Only schedules or other special requirements will be added to the permit.

   c. If the permit includes provisions to increase monitoring frequency subsequent to a violation, it must be clear that the additional tests only determine the continued compliance status with the limit; they are <u>not</u> to verify the original test results.

   d. Toxicity testing species and protocols will be accurately referenced/cited in the permit.

3. Where not in compliance with a whole effluent toxicity limit, permittees must be compelled to come into compliance with the limit as soon as possible.

   a. Compliance dates must be specified.

   b. Permits can contain requirements for corrective actions, such as Toxicity Reduction Evaluations (TREs), but corrective actions cannot be delayed pending EPA/State approval of a plan for the corrective actions, unless State regulations require prior approval. Automatic corrective actions subsequent to the effective date of a final whole-effluent toxicity limit will not be included in the permit.

Explanation of the Basic Permitting Principles

The Basic Permitting Principles present the minimum acceptable requirements for whole-effluent toxicity permitting. They begin with a statement of the goal of whole-effluent toxicity limitations and requirements: the protection of water quality as established through State numeric and narrative Water Quality Standards. The first principle builds on the Technical Support Document procedures and the draft Section 304(l) rule requirements for determining potential to violate Water Quality Standards. It requires the same factors be considered in setting whole-effluent toxicity based permits limits as are used to determine potential Water Quality Standards violations. It defines the universe of permittees that should be evaluated for potential violation of Water Quality Standards, and therefore possible whole-effluent limits, as all majors and minors of concern.

The second permitting principle provides basic guidelines for avoiding ambiguities that may surface in permits. Whole-effluent toxicity limits should be listed in Part I of the permit and should be derived and expressed in the same manner as any other water quality-based limitations (i.e., Maximum Daily and Average Monthly limits as required by Section 122.45(d)).

In addition, special re-opener clauses are generally not necessary, and may mistakenly imply that permits may be re-opened to revise whole-effluent limits that are violated. This is not to imply that special re-opener clauses are never appropriate. They may be appropriate in permits issued to facilities that currently have no known potential to violate a Water Quality Standard; in these cases, the permitting authority may wish to stress its authority to re-open the permit to add a whole-effluent limit in the event monitoring detects toxicity.

Several permittees have mistakenly proposed to conduct additional monitoring subsequent to a violation to "verify" their results. It is not possible to verify results with a subsequent test whether a new sample or a split-sample which has been stored (and therefore contains fewer volatiles) is used. For this reason, any additional monitoring required in response to a violation must be clearly identified as establishing continuing compliance status, not verification of the original violation.

The second principle also deals with the specification of test species and protocol. Clearly setting out the requirements for toxicity testing and analysis is best done by accurately referencing EPA's most recent test methods and approved equivalent State methods. In this way, requirements which have been published can be required in full, and further advances in technology and science may be incorporated without lengthy permit revisions.

The third and final permitting principle reinforces the responsibility of the permittee to seek timely compliance with the requirements of its NPDES permit. Once corrective actions have been identified in a TRE, permittees cannot be allowed to delay corrective actions necessary to comply with water quality-based whole effluent toxicity limitations pending Agency review and approval of voluminous reports or plans. Any delay on the part of the permittee or its contractors/agents is the responsibility of the permittee.

The final principle was written in recognition of the fact that a full-blown TRE may not be necessary to return a permittee to compliance in all cases, particularly subsequent to an initial TRE. As a permittee gains experience and knowledge of the operational influences on toxicity, TREs will become less important in the day to day control of toxicity and will only be required when necessary on a case-specific basis.

Background to the Compliance Monitoring and Enforcement Strategy for Toxics Control

The Compliance Monitoring and Enforcement Strategy for Toxics Control sets forth the Agency's strategy for tracking compliance with and enforcing whole-effluent toxicity monitoring requirements, limitations, schedules and reporting requirements.

The Strategy delineates the respective responsibilities of permittees and permitting authorities to protect water quality through the control of whole-effluent toxicity. It establishes criteria for the review of compliance data and the quarterly reporting of violations to Headquarters and the public. The Strategy discusses the integration of whole-effluent toxicity control into our existing inspection and quality assurance efforts. It provides guidelines on the enforcement of whole-effluent toxicity requirements.

The Strategy also addresses the concern many permittees share as they face the prospect of new requirements in their permit - the fear of indiscriminate penalty assessment for violations that they are unable to control. The Strategy recognizes enforcement discretion as a means of dealing fairly with permittees that are doing everything feasible to protect water quality. As indicated in the Strategy, this discretion deals solely with the assessment of civil penalties, however, and is not an alternative to existing procedures for establishing relief from State Water Quality Standards. The Strategy focuses on the responsibility of the Agency and authorized States to require compliance with Water Quality Standards and thereby ensure protection of existing water resources.

COMPLIANCE MONITORING AND ENFORCEMENT STRATEGY FOR TOXICS CONTROL

I. Background

Issuance of NPDES permits now emphasizes the control of toxic pollutants, by integrating technology and water quality-based permit limitations, best management practices for toxic discharges, sludge requirements, and revisions to the pretreatment implementation requirements. These requirements affect all major permittees and those minor permittees whose discharges may contribute to impairment of the designated use for the receiving stream. The goal of permitting is to eliminate toxicity in receiving waters that results from industrial and municipal discharges.

Major industrial and municipal permits will routinely contain water quality-based limits for toxic pollutants and in many cases whole effluent toxicity derived from numerical and narrative water quality standards. The quality standards to establish NPDES permit limits are discussed in the "Policy for the Development of Water Quality-based Permit Limits for Toxic Pollutants," 49FR 9016, March 9, 1984. The Technical Support Document for Water Quality-based Toxics Control, EPA #440/44-85032, September, 1985 and the Permit Writer's Guide to Water Quality-based Permitting for Toxic Pollutants, Office of Water, May, 1987, provide guidance for interpreting numerical and narrative standards and developing permit limits.

The Water Quality Act (WQA) of 1987 (PL 100-4, February 4, 1987) further directs EPA and the States to identify waters that require controls for toxic pollutants and develop individual control strategies including permit limits to achieve control of toxics. The WQA established deadlines, for individual control strategies (February 4, 1989) and for compliance with the toxic control permit requirements (February 4, 1992). This Strategy will support the additional compliance monitoring, tracking, evaluation, and enforcement of the whole effluent toxicity controls that will be needed to meet the requirements of the WQA and EPA's policy for water quality-based permitting.

It is the goal of the Strategy to assure compliance with permit toxicity limits and conditions through compliance inspections, compliance reviews, and enforcement. Water quality-based limits may include both chemical specific and whole effluent toxicity limits. Previous enforcement guidance (e.g., Enforcement Management System for the National Pollutant Discharge Elimination System, September, 1986; National Guidance for Oversight of NPDES Programs, May, 1987; Guidance for Preparation of Quarterly and Semi-Annual Noncompliance Reports, March, 1986) has dealt with

chemical-specific water quality-based limits. This Strategy will focus on whole effluent toxicity limits. Such toxicity limits may appear in permits, administrative orders, or judicial orders.

II. Strategy Principles

This strategy is based on four principles:

1) Permittees are responsible for attaining, monitoring, and maintaining permit compliance and for the quality of their data.

2) Regulators will evaluate self-monitoring data quality to ensure program integrity.

3) Regulators will assess compliance through inspections, audits, discharger data reviews, and other independent monitoring or review activities.

4) Regulators will enforce effluent limits and compliance schedules to eliminate toxicity.

III. Primary Implementation Activities

In order to implement this Strategy fully, the following activities are being initiated:

A. Immediate development

1. The NPDES Compliance Inspection Manual was revised in May 1988 to include procedures for performing chronic toxicity tests and evaluating toxicity reduction evaluations. An inspector training module was also developed in August 1988 to support inspections for whole effluent toxicity.

2. The Permit Compliance System (the national NPDES data base) was modified to allow inclusion of toxicity limitations and compliance schedules associated with toxicity reduction evaluations. The PCS Steering Committee will review standard data elements and determine if further modifications are necessary.

3. Compliance review factors (e.g., Technical Review Criteria and significant noncompliance definitions) are being proposed to evaluate violations and appropriate response.

4. A Quality Assurance Fact Sheet has been developed (Attached) to review the quality of toxicity test results submitted by permittees.

5. The Enforcement Response Guide in the Enforcement Management System will be revised to cover the use of administrative penalties and other responses to violations of toxicity controls in permits. At least four types of permit conditions are being examined: (1) whole-effluent toxicity monitoring (sampling and analysis), (2) whole effluent toxicity-based permit limits, (3) schedules to conduct a TRE and achieve compliance with water quality-based limits, and (4) reporting requirments.

B. Begin development in Spring 1989

With the assistance of the Office of Enforcement and Compliance Monitoring (OECM), special remedies and model forms will be developed to address violations of toxicity permit limits (i.e., model consent decrees, model complaints, revised penalty policy, model litigation reports, etc.)

IV. <u>Scope and Implementation of Strategy</u>

A. Compliance Tracking and Review

1. Compliance Tracking

The Permits Compliance System (PCS) will be used as the primary system for tracking limits and monitoring compliance with the conditions in NPDES permits. Many new codes for toxicity testing have already been entered into PCS. During FY 89, headquarters will provide additional guidance to Regions and States on PCS coding to update existing documentation. The Water Enforcement Data Base (WENDB) requirements as described in the PCS Policy Statement already require States and Regions to begin incorporating toxicity limits and monitoring information into PCS.

In addition to guidance on the use of PCS, Headquarters has prepared guidance in the form of Basic Permitting Principles for Regions and States that will provide greater uniformity nationally on approaches to toxicity permitting. One of the major problems in the tracking and enforcement of toxicity limits is that they differ greatly from State-to-State and Region-to-Region. The Permits Division and Enforcement Division in cooperation with the PCS Steering Committee will establish standard codes for permit limits and procedures for reporting toxicity results based on this guidance.

Whole effluent toxicity self-monitoring data should undergo an appropriate quality review. (See attached checklist for suggested toxicity review factors.) All violations of permit limits for toxics control should be reviewed by a professional qualified to assess the noncompliance. Regions and States should designate appropriate staff.

2. Compliance Review

Any violation of a whole effluent toxicity limit is of concern to the regulatory agency and should receive an immediate professional review. In terms of the Enforcement Management System (EMS), any whole effluent violation will have a violation review action criterion (VRAC) of 1.0. However, the appropriate initial enforcement response may be to require additional monitoring and then rapidly escalate the response to formal enforcement if the noncompliance persists. Where whole effluent toxicity is based on a pass-fail permit limitation, any failure should be immediately targeted for compliance inspection. In some instances, assessment of the compliance status will be required through issuance of Section 308 letters and 309(a) orders to require further toxicity testing.

Monitoring data which is submitted to fulfill a toxicity monitoring requirement in permits that do not contain an independently enforceable whole-effluent toxicity limitation should also receive immediate professional review.

The burden for testing and biomonitoring is on the permittee; however, in some instances, Regions and States may choose to respond to violations through sampling or performance audit inspections. When an inspection conducted in response to a violation identifies noncompliance, the Region or State should initiate a formal enforcement action with a compliance schedule, unless remedial action is already required in the permit.

B. Inspections

EPA/State compliance inspections of all major permittees on an annual basis will be maintained. For all facilities with water quality-based toxic limits, such inspections should include an appropriate toxic component (numerical and/or whole effluent review). Overall the NPDES inspection and data quality activities for toxics control should receive greater emphasis than in the present inspection strategy.

1. Regional/State Capability

The EPA's "Policy for the Development of Water Quality-based Permit Limits for Toxic Pollutants" (March 9, 1984 Federal Register) states that EPA Regional Administrators will assure that each Region has the full capability to conduct water quality assessments using both biological and chemical methods and provide technical assistance to the States. Such capability should also be maintained for compliance biomonitoring inspections and toxics sampling inspections. This capability should include both inspection and laboratory capability.

2. Use of Nonsampling Inspections

Nonsampling inspections as either compliance evaluations (CEIs) or performance audits (PAIs) can be used to assess permittee self-monitoring data involving whole effluent toxicity limits, TREs, and for prioritization of sampling inspections.* As resources permit, PAIs should be used to verify biomonitoring capabilities of permittees and contractors that provide toxicity testing self-monitoring data.

3. Quality Assurance

All States are encouraged to develop the capability for acute and chronic toxicity tests with at least one fish and one invertebrate species for freshwater and saltwater if appropriate. NPDES States should develop the full capability to assess compliance with the permit conditions they establish.

EPA and NPDES States will assess permittee data quality and require that permittees develop quality assurance plans. Quality assurance plans must be available for examination. The plan should include methods and procedures for toxicity testing and chemical analysis; collection, culture, maintenance, and disease control procedures for test organisms; and quality assurance practices. The

* Due to resource considerations, it is expected that sampling inspections will be limited to Regional/State priorities in enforcement and permitting. Routine use of CEIs and PAIs should provide the required coverage.

permittee should also have available quality control charts, calibration records, raw test data, and culture records.

In conjunction with the QA plans, EPA will evaluate permittee laboratory performance on EPA and/or State approved methods. This evaluation is an essential part of the laboratory audit process. EPA will rely on inspections and other quality assurance measures to maintain data quality. However, States may prefer to implement a laboratory certification program consistent with their regulatory authorities. Predetermined limits of data acceptability will need to be established for each test condition (acute/chronic), species-by-species.

C. Toxicity Reduction Evaluations (TREs)

TREs are systematic investigations required of permittees which combine whole effluent and/or chemical specific testing for toxicity identification and characterization in a planned sequence to expeditiously locate the source(s) of toxicity and evaluate the effectiveness of pollution control actions and/or inplant modifications toward attaining compliance with a permit limit. The requirement for a TRE is usually based on a finding of whole effluent toxicity as defined in the permit. A plan with an implementation schedule is then developed to achieve compliance. Investigative approaches include causative agent identification and toxicity treatability.

1. Requiring TRE Plans

TRE's can be triggered: 1) whenever there is a violation of a toxicity limit that prompts enforcement action or 2) from a permit condition that calls for a toxicity elimination plan within a specified time whenever toxicity is found. The enforcement action such as a 309(a) administrative order or State equivalent, or judicial action then directs the permittee to take prescribed steps according to a compliance schedule to eliminate the toxicity. This schedule should be incorporated into the permit, an administrative order, or judicial order and compliance with the schedule should be tracked through PCS.

2. Compliance Determination Followup

Compliance status must be assessed following the accomplishment of a TRE plan using the most efficient and effective methods available. These methods include site visits, self-monitoring, and inspections.

Careful attention to quality assurance will assist in minimizing the regulatory burden. The method of compliance assessment should be determined on a case-by-case basis.

D. Enforcing Toxic Control Permit Conditions

Enforcement of toxic controls in permits depends upon a clear requirement and the process to resolve the noncompliance. In addition to directly enforceable whole effluent limits (acute and chronic, including absolute pass-fail limits), permits have contained several other types of toxic control conditions: 1) "free from" provisions, 2) schedules to initiate corrective actions (such as TREs) when toxicity is present, and/or 3) schedules to achieve compliance where a limit is not currently attained. Additional requirements or schedules may be developed through 308 letters, but the specific milestones should be incorporated into the permit, administrative order or State equivalent mechanism, or judicial order to ensure they are enforceable.

1. The Quarterly Noncompliance Report (QNCR)

Violations of permit conditions are tracked and reported as follows:

a. Effluent Violations

Each exceedance of a directly enforceable whole effluent toxicity limit is of concern to the regulatory agency and, therefore, qualifies as meeting the VRAC requiring professional review (see section IV.A.2.).

These violations must be reported on the QNCR if the violation is determined through professional review to have the potential to have caused a water quality impact.

All QNCR-reportable permit effluent violations are considered significant noncompliance (SNC).

b. Schedule Violations

Compliance schedules to meet new toxic controls should be expeditious. Milestones should be established to evaluate progress routinely and minimize delays. These milestones should be tracked and any slippage of 90 days or more must be reported on the QNCR.

The following milestones are considered SNC when 90 days or more overdue: submit plan/schedule to conduct TRE, initiate TRE, submit test results, submit implementation plan/schedule (if appropriate), start construction, end construction, and attain compliance with permit.

c. Reporting/Other Violations

Violation of other toxic control requirements (including reports) will be reported using criteria that are applied to comparable NPDES permit conditions. For example, failure to submit a report within 30 days after the due date or submittal of an inaccurate or inadequate report will be reportable noncompliance (on the QNCR).

Only failure to submit toxicity limit self-monitoring reports or final TRE progress reports indicating compliance will be SNC when 30 days or more overdue.

Resolution (bringing into compliance) of all three types of permit violations (effluent, schedule, and reporting/other) will be through timely and appropriate enforcement that is consistent with EPA Oversight Guidance. Administering agencies are expected to bring violators back into compliance or take formal enforcement action against facilities that appear on the QNCR and are in SNC; otherwise, after two or more quarters the facility must be listed on the Exceptions List.

2. Approaches to Enforcement of Effluent Limitations

In the case of noncompliance with whole effluent toxicity limitations, any formal enforcement action will be tailored to the specific violation and remedial actions required. In some instances, a Toxicity Reduction Evaluation (TRE) may be appropriate. However, where directly enforceable toxicity-based limits are used, the TRE is <u>not</u> an acceptable enforcement response to toxicity noncompliance if it requires only additional monitoring without a requirement to determine appropriate remedial actions and ultimately compliance with the limit.

If the Regions or States use administrative enforcement for violations of toxic requirements, such actions should require compliance by a date certain, according to a set schedule, and an

administrative penalty should be considered.[1] Failure to comply with an Administrative Order schedule within 90 days indicates a schedule delay that may affect the final compliance date and a judicial referral is the normal response. In instances where toxicity has been measured in areas with potential impacts on human health (e.g., public water supplies, fish/shellfish areas, etc.), regions and states should presume in favor of judicial action and seek immediate injunctive relief (such as temporary restraining order or preliminary injunction).

In a few highly unusual cases where the permittee has implemented an exhaustive TRE plan[2], applied appropriate influent and effluent controls[3], maintained continued compliance with all other effluent limits, compliance schedules, monitoring, and other permit requirements, but is still unable to attain or maintain compliance with the toxicity-based limits, special technical evaluation may be warranted and civil penalty relief granted. Solutions in these cases could be pursued jointly with expertise from EPA and/or the States as well as the permittee.

Some permittees may be required to perform a second TRE subsequent to implementation of remedial action. An example of the appropriate use of a subsequent TRE is for the correction of new violations of whole effluent limitations following a period of

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[1]Federal Administrative penalty orders must be linked to violations of underlying permit requirements and schedules.

[2]See Methods for Aquatic Toxicity Identification Evaluations, Phase I, Toxicity Characterization Procedures, EPA-600/3-88/035, Table 1. An exhaustive TRE plan covers three areas: causative agent identification/toxicity treatability; influent/effluent control; and attainment of continued compliance. A listing of EPA protocols for TREs can be found in Section V (pages 11 and 12).

[3]For industrial permittees, the facility must be well-operated to achieve all water quality-based, chemical specific, or BAT limits, exhibit proper O & M and effective BMPs, and control toxics through appropriate chemical substitution and treatment. For POTW permittees, the facility must be well-operated to achieve all water quality-based, chemical specific, or secondary limits as appropriate, adequately implement its approved pretreatment program, develop local limits to control toxicity, and implement additional treatment.

sustained compliance (6 months or greater in duration) indicating a different problem from that addressed in the initial TRE.

3. Enforcement of Compliance Schedule and Reporting Requirements

In a number of instances, the primary requirements in the permits to address toxicity will be schedules for adoption and implementation of biomonitoring plans, or submission of reports verifying TREs or other similar reporting requirements. Regions and States should consider any failure (1) to conduct self-monitoring according to EPA and State requirements, (2) to meet TRE schedules within 90 days, or (3) to submit reports within 30 days of the specified deadline as SNC. Such violations should receive equivalent enforcement follow-up as outlined above.

4. Use of Administrative Orders With Penalties

In addition to the formal enforcement actions to require remedial actions, Regions and States should presume that penalty AO's or State equivalents can be issued for underlying permit violations in which a formal enforcement action is appropriate. Headquarters will also provide Regions and States with guidance and examples as to how the current CWA penalty policy can be adjusted.

5. Enforcement Models and Special Remedies

OWEP and OECM will develop standard pleadings and language for remedial activities and compliance milestones to assist Regions and States in addressing violations of toxicity or water quality-based permit limits. Products will include model litigation reports, model complaints and consent decrees, and revised penalty policy or penalty algorithm and should be completed in early FY 1989.

V. Summary of Principal Activities and Products

A. Compliance Tracking and Review guidance

1. PCS Coding Guidance - May, 1987; revision 2nd Quarter 1989

2. Review Criteria for Self-monitoring Data (draft attached)

B. Inspections and Quality Assurance

1. Revised NPDES Compliance Inspection Manual - May 1988.

2. Quality Assurance Guidance - 3rd Quarter FY 1989.

3. Biomonitoring Inspection Training Module - August 1988.

4. Additions of a reference toxicant to DMRQA program - (to be determined)

C. Toxics Enforcement

1. Administrative and Civil Penalty Guidance - 4th Quarter FY 1989

2. Model Pleadings and Complaints - 2nd Quarter 1989

3. EMS Revision - 2nd Quarter FY 1989

D. Permitting Consistency

1. Basic Permitting Principles - 2nd Quarter FY 1989

E. Toxicity Reduction Evaluations

1. Generalized Methology for Conducting Industrial Toxicity Reduction Evaluations - 2nd Quarter FY 1989

2. Toxicity Reduction Evaluation Protocol for Municipal Wastewater Treatment Plants - 2nd Quarter FY 1989

3. Methods for Aquatic Toxicity Indentification Evaluations

a. Phase I. Toxicity Characterization Procedures, EPA-600/3-88/034- September 1988

b. Phase II. Toxicity Identification Procedures, EPA-600/3-88/035- 2nd Quarter 1989

c. Phase III. Toxicity Confirmation Procedures- EPA-600/3-88/036 - 2nd Quarter FY 1989

APPENDIX B-5

QUALITY CONTROL FACT SHEETS

Attachment

Quality Control Fact Sheet for Self-Biomonitoring Acute/Chronic Toxicity Test Data

Permit No._____

Facility Name _____

Facility Location _____

Laboratory Investigator _____

Permit Requirements

Sampling Location _____ Type of Sample _____

Limit _____ Test Duration _____

Type of Test _____ Test Organism Age _____

Test Results

$LC_{50}/EC_{50}/NOEC/IC_{25}$ _____ 95 Percent Confidence Interval _____

Quality Control Summary

Date of Sample _____ Dates of Test _____

Control Mortality _____% Control Mean Dry Weight _____

Temperature maintained within ±2°C of test temperature? Yes _____ No _____

Dissolved oxygen levels always greater than 40 percent saturation? Yes _____ No _____

Loading factor for all exposure chambers less than or equal to maximum allowed for the test type and temperature? Yes _____ No _____

Do the test results indicate a direct relationship between effluent concentration and response of the test organism (i.e., more deaths occur at the highest effluent concentrations)? Yes _____ No _____

APPENDIX B-6

CASE DECISIONS ON WHOLE EFFLUENT TOXICITY

CASE SUMMARY

Natural Resources Defense Council, Inc. v. EPA, 859 F.2d 156 (D.C. Cir. 1988).

This consolidated case, which arose from EPA's promulgation of various National Pollutant Discharge Elimination System regulations, addresses a multitude of issues. The following paragraphs note issues particularly relevant to this document.

- The Court held that EPA has the authority to express permit limitations in terms of toxicity as long as the limits reflect the appropriate requirements of the Clean Water Act (CWA), as provided in 40 *CFR* 125.3(c)(4). The Court concluded that although toxicity appears to be an attribute of pollutants rather than a pollutant itself, the CWA (by means of the broad definition of "pollutant" in section 502(6)) authorizes the use of toxicity to regulate effluents.
- Industry asked the Court to address several other issues related to setting toxicity limitations (whether EPA failed to demonstrate the existence of a reliable methodology for setting toxicity limits and whether EPA's use of toxicity to set water quality-based limitations to meet "narrative" State water quality standards represents an impermissible trespass on the State's right to set water quality standards). However, the Court did not regard these issues to be adequately developed ("ripe") for review in this case.
- The Court disagreed with industry's assertions that EPA's 1984 policy statement ("Development of Water Quality-Based Permit Limitations for Toxic Pollutants: National Policy," 49 *Federal Register* 9016 [March 9, 1984]) and draft Technical Support Document ("TSD") were "rules" requiring notice and comment under the Administrative Procedure Act, 5 USC 553. The Court noted that informal rulemaking regarding 40 *CFR* 125.3(c)(4), which was pending between 1980 and 1984, did not limit Agency information gathering to the issuance of new or revised notices of proposed rulemaking, and the two documents did not have independent legal value. (In other words, the EPA national policy and the TSD were not binding norms but general statements of policy/guidance.)
- Industry also challenged EPA's refusal to provide an affirmative upset defense to noncompliance with water quality-based limits. The Court indicated that the CWA does not expressly allow such an upset defense, and, upon considering the Act's structure and legislative history, it could discern no congressional intent to provide for the defense in water quality permitting. Significantly, in reaching this position, the Court relied heavily upon the language and legislative history of CWA Section 301(b)(1)(C), by which Congress clearly did not relate compliance with water quality-based limitations to the capabilities of technology. In the Court's view, "Congress had a deep respect for the sanctity of water quality standards and a firm conviction of the need for technology-forcing measures." 895 F.2d at 208-09. However, the Court concluded that EPA had acted arbitrarily in dismissing the defense as impracticable, and directed EPA to conduct further proceedings on the issue.
- Finally, the Court rejected challenges to EPA's regulations governing State public participation requirements and penalty levels. In deciding these issues, the Court noted Congressional desire for nationally uniform effluent limitations as reflected in the legislative history of the 1972 CWA. The Court stated:

  Uniformity is indeed a recurrent theme in the Act, a direct manifestation of concern that the permit program be standardized to avoid the "industrial equivalent of forum shopping" and the creation of "pollution havens" by migration of dischargers to areas having lower pollution standards (859 F.2d at 174 [footnotes omitted] and see accompanying footnotes 17-20 citing various provisions of the legislative history of the 1972 CWA).

Appendix C

Ambient Toxicity Testing and Data Analysis

Ambient Toxicity Analysis

Ambient toxicity testing procedures are useful where measurement of toxicity levels after discharge is important in the assessment of toxic effluent impact. This is particularly true where impact is caused by the presence of multiple point sources. The purpose of this testing is to provide an analysis of toxicity levels instream from whatever sources of toxicity are affecting the receiving water.

Procedures

The basic ambient toxicity testing procedure is to expose test organisms to receiving water samples taken from selected sampling stations above, at, and below the discharge point(s). Since effluent concentrations after discharge are often relatively low, chronic toxicity tests should be conducted so that the tests are sensitive enough for the purpose.

The methods available for chronic testing of sufficiently short duration are limited. Two organisms for which short-term chronic toxicity tests are available are *Pimephales promelas* and *Ceriodaphnia* sp.

The following procedures are used:

- Select instream sampling stations based on the mixing characteristics involved in the specific discharge situation.
- Collect a daily grab sample or a daily composite sample of receiving water from each station.
- Use a renewal testing method to expose test organisms to the daily samples collected at each station. Use an appropriate number of replicates (10 for *Ceriodaphnia*) for each sampling station. No dilution series is required where screening is the primary goal.
- Conduct testing at a low-flow period, although it is not necessary to conduct the tests at the critical low-flow period. Testing is best when relatively stable flow occurs during the test period.
- Record the results of the testing in the format shown in Table C-1. The survival of the test organisms and the effect on their growth or reproduction are used as endpoints. Figure C-1 plots the results in graphic form so that the pattern of ambient toxicity can be observed.

Table C-1. Young Production and Percent Survival of *Ceriodaphnia* in Ambient Toxicity Tests at Ottawa River, Lima, Ohio

Station	Station Description	River Mile	Young Female	SD	Final Survival	Daily Survival 1	2	3	4	5	6	7
1	Above Lima	46.0	15.5	8.0	90	100	100	100	90	90	90	90
2	Above STP	37.7	14.1	2.1	0	100	100	100	100	90	10	0
3	Below STP	37.4	0	-	0	100	100	10	0	0	0	0
3A	Midway between STP and refinery	37.3	0	-	0	100	100	10	0	0	0	0
3B	Above refinery	37.1	0.4	-	0	90	90	40	0	0	0	0
4	Above chemical plant	36.9	7.5	3.6	10	100	100	100	100	100	50	10
4A	Below chemical plant	36.3	11.1	4.6	30	100	100	100	100	100	40	30
5	Shawnee Bridge	36.4	5.7	4.0	0	90	90	90	90	90	60	0
6	Route 117	32.5	12.6	3.8	10	100	100	100	100	100	100	10
7	Allentown	28.8	16.8	6.1	100	100	100	100	100	100	100	100
8	Rimer	16.0	17.4	9.5	100	90	90	90	90	90	80	80
8A	"Boonie" Station	8.0	25.0	3.3	100	100	100	100	100	100	100	100
9	Kalida	1.0	25.6	5.5	100	100	100	100	100	100	100	100

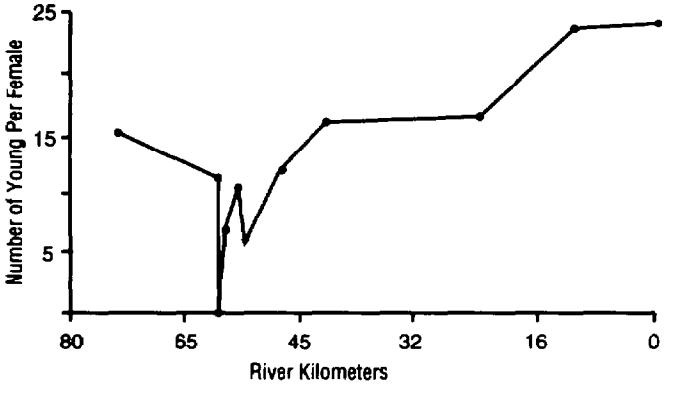

Figure C-1. *Ceriodaphnia* Young Production in Water from Various Stream Stations on the Ottawa River, Lima, Ohio

Selecting Sampling Stations

The selection of sampling stations is determined by the characteristics of the site. When determining stations, consider the following factors:

- Mixing and flow—The mixing characteristics of the discharge site are useful to determine the placement of sampling stations. Knowledge of concentration isopleths allows the regulatory authority to place stations at locations instream that correspond to concentrations measured in the dilution series in the effluent tests. For example, where effluent testing shows the effluent no observed effect concentration is 10 percent, an instream station should be placed where dilution is estimated to create a 10-percent instream waste concentration. In this way, the size of a toxic plume can be measured. Sampling stations should be placed where the effluents exist at relatively constant and relatively specific concentrations. Test at specific low-flow conditions, if possible. Presence of tributaries or other sources of dilution will influence positions and numbers of stations. Where smaller tributaries have several point sources on them, treat the tributary as a point source. Obvious nonpoint source areas also should be used to set stations.
- Existing biological data—Where biosurvey data are available, sampling station location should be influenced by the more obvious trends in impact. In particular, control stations and recovery stations can be determined by biosurvey data.
- Single point sources—Single point source situations should be bracketed with an above station, an immediate mixing station, several intermediate stations corresponding to different instream concentrations, and a recovery station. Of course, a control station should be established.
- Presence of other point sources—Multiple point source situations require the placement of more stations between discharge points. Each source should be bracketed by sampling stations.

There are four areas or zones that can be recognized when establishing the sampling stations for ambient toxicity testing:

Zone 1—An upstream zone before the effluent enters

Zone 2—A zone of mixing

Zone 3—A zone after mixing and before additional dilution water enters

Zone 4—A zone where additional dilution occurs either from effluents or tributaries.

All possible combinations of occurrences are not practical to discuss but must be sorted out for each site. Some generalizations are important to mention:

- Any upstream sources of contaminants, such as other discharges, will confound the individual effects of a downstream discharge. For example, Zone 3 of the downstream discharge may occur in Zone 4 of an upstream discharge. This does not invalidate the measurement of ambient toxicity. It only makes it difficult to attribute amounts of response to each individual discharge. Response to the instream mixture is what is measured.
- Careful location of sampling stations in Zone 3 is critical. Zone 3 is the only place where toxicity decay rates of any one discharger can be measured and then only if there are no upstream discharges, or if there are, only if that upstream effluent is stable in that reach.
- In Zone 4, not only is degradation of the effluent toxicity occurring, but there is dilution of it by other effluents and tributaries. Depending on the site circumstances, one may not be able to learn anything about the ambient toxicity characteristics of the effluent of concern in this zone.
- To emphasize, what can be measured in each zone depends on the above considerations. In the more complex situation, only an estimate of ambient toxicity at each station can be obtained. No information about one effluent's toxicity decay rate will be available where several toxic effluents mix. In the most simple situation of one discharge and no dilution downstream for a long distance, Zone 3 will be large enough to get a good measure of toxicity decay.

Analysis of Ambient Toxicity Measurement

- When used in screening, the ambient toxicity data can identify areas in receiving waters where ambient toxicity exists instream. Attributing such impact to specific point sources (particularly where several sources discharge) may require effluent toxicity testing.
- Except when used for screening purposes, ambient toxicity measurements must be interpreted with effluent toxicity test data if conclusions are to be drawn concerning changes in toxic effect after discharge. The same species must be used in both the ambient and the effluent toxicity tests.
- When analyzing the data, the performance of the animals at each station downstream is compared to that of the animals exposed to receiving water without the effluent of concern in it but containing all other upstream additions. The result is an integration of effects from all contaminants and components and represents not only the toxicity of the effluent of concern but also the interactions of it with other effluents.
- Where the downstream stations show toxic effect at the concentrations measured as toxic in the effluent toxicity tests, effluent toxicity can be considered to be occurring instream, after discharge.
- Where the toxic effect decreases from station to station downstream in the absence of further dilution, the effluent toxicity is degrading. If the decay rate is rapid (e.g., no toxicity at the closest instream station to the discharge point), the effluent has a nonpersistent toxicity. Where the decay rate is more gradual, toxicity is more persistent. The rate of decay of toxicity together with mixing data allows the regulatory authority to approximate a receiving water toxicity impact area. That impact area can then be compared to the appropriate State water quality standards when establishing control requirements.
- In some cases, ambient toxicity may increase in relation to effluent toxicity measurements. Either upstream sources of toxicity exist or some factor in the receiving water is reacting with the effluent to increase its toxicity. Again, the pattern and magnitude of change in toxicity should be analyzed. Differences in toxicity levels between stations will reveal what is happening to the effluent as it is mixed instream and interacts with the constituents of the receiving water.
- Trend analysis in the raw test data is important when interpreting ambient toxicity data. As used in this context, trend analysis means observing toxic effect as it occurs in the test itself and relating it to what is occurring instream (plug flow, intermittent discharge, peak toxicity of effluents). Using time-of-travel data or receiving water flow rates and patterns, observe effects on the test organisms from day to day. There may be a pattern of mortality that can be linked to discharge events. For example, in the table the data indicate late mortality at downstream stations on Days 6 and 7. Flow rates for the river in this example correlated this mortality to the downstream movement of a toxic slug illegally discharged upstream.

Appendix D

Duration and Frequency

DURATION AND FREQUENCY

As discussed on pages 7 through 13 of the *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* [1], the format used to express water quality criteria for aquatic life should take into account toxicological and practical realities. Because of variation in the flows of the effluent and the upstream receiving water as well as variation in the concentrations of pollutants in the effluent and in the upstream receiving water, a simple format, such as specifying a concentration that must not be exceeded at any time or place, is not realistic. Furthermore, such a simple format does not take into account the fact that aquatic organisms can tolerate higher concentrations of pollutants for short periods of time than they can tolerate throughout a complete life cycle. The format that was selected for expressing water quality criteria for aquatic life consists of recommendations concerning concentrations, durations of averaging periods, and average frequencies of allowed excursions. Use of this concentration-duration-frequency format allows water quality criteria for aquatic life to be adequately protective without being as overprotective as would be necessary if criteria were expressed using a simpler format. In addition, this format can be applied directly to hydrological data and to the flow of, and concentrations of pollutants in, effluents using both dynamic and steady-state modeling [2, 3].

In aquatic life criteria for both individual chemicals and Whole Effluents, the recommended concentrations are the criterion maximum concentration (CMC) and the criterion continuous concentration (CCC). For individual chemicals the CMC and CCC are derived using the procedures described by Stephan et al. [1]. As described in Chapter 3 of this TSD, the CMC and CCC for Whole Effluents can be specified generically in terms of toxic units. Alternatively, for a particular effluent the CMC is specified in terms of an acute toxicity endpoint (ATE), which is either an LC_{50} or an EC_{50}, and the CCC is specified in terms of a chronic toxicity endpoint (CTE), which is either a no observed effect concentration (NOEC) or an IC_{xx}, if the LC_{50}, EC_{50}, NOEC, and IC_{xx}, were obtained from appropriate toxicity tests conducted on the effluent with sensitive species.

The CCC is intended to be the highest concentration that could be maintained indefinitely in a receiving water without causing an unacceptable effect on the aquatic community or its uses. Any concentration above the CCC, if maintained indefinitely, is expected to cause an unacceptable effect. Due to the four sources of variation mentioned above, the concentration in the receiving water will not be constant. Because organisms can tolerate higher concentrations for short periods of time, it is expected that the concentration of a pollutant in a body of water can exceed the CCC without causing an unacceptable effect if (a) the magnitudes and the durations of exceedances are appropriately limited and (b) there are compensating periods of time during which the concentration is below the CCC. These goals are accomplished by specifying a duration of an averaging period over which the average concentration should not exceed the CCC. For example, if the concentration is twice the CCC for one-half the specified averaging period, it must be zero for the rest of the averaging period if the average concentration is not to exceed the CCC. Thus, both the magnitude and duration of an exceedance are limited and there must be a compensating period of time during the averaging period when the concentration is below the CCC. Because exceedences are defined to be due to usual variation, most exceedences will be small, with larger exceedances becoming increasingly rare [1, 2].

Although an exceedance is defined to occur whenever the instantaneous concentration is above the CCC, an excursion is defined to occur only when the average concentration over the duration of the averaging period is above the CCC. It is expected that excursions can occur without causing unacceptable effects if (a) the frequency of such excursions is appropriately limited and (b) all other average concentrations are below the CCC. The recommended average frequency of allowed excursions is intended to appropriately limit the frequency of excursions. Because excursions are the highest average concentrations that occurred due to usual variation, all other average concentrations will be less than the CCC. As for exceedances, excursions that are defined to be due to usual variation will be small, with larger excursions becoming increasingly rare. The duration of the averaging period is intended to limit the impact of exceedances, whereas the average frequency of allowed excursions is intended to limit the impact of excursions. (Note: The words "exceedance" and "excursion" are used slightly differently here than in References 1 and 2.)

Although spills can impact aquatic communities, they are not considered exceedances or excursions because they are not part of the usual variation in the concentrations of pollutants in receiving water. In the Complex Effluent Toxicity Testing Program, eight field studies were conducted to evaluate the use of toxicity tests to diagnose the cause of biological impact. Ambient toxicity measurements were taken over a 7-day period.

During two of these studies [4, 5] spills of pollutants resulted in acute toxicity. This suggests that the impacts caused by spills might be as important as impacts caused by variation in the compositions and flows of the effluent and the receiving water.

The primary purpose of this appendix is to present the rationale for the recommendations of the U.S. EPA concerning duration and frequency in national water quality criteria for aquatic life. The recommended duration is based on data from laboratory toxicity tests, whereas the recommended frequency is based on field data. With the concurrence of the U.S. EPA, States may adopt site-specific criteria, rather than national criteria, in their State standards. Such site-specific criteria may include not only site-specific concentrations, but also site-specific, and possibly pollutant-specific, durations of averaging periods and average frequencies of allowed excursions. If adequate justification is provided, site-specific and/or pollutant-specific concentrations, durations, and frequencies may be higher or lower than those given in national water quality criteria for aquatic life. A secondary purpose of this appendix is to discuss rationales that might be used as a basis for selecting alternative durations of averaging periods and average frequencies of allowed excursions.

Duration

In order for this concentration-duration-frequency format to allow water quality criteria for aquatic life to be adequately protective without being unnecessarily overprotective, the duration of the averaging period must allow some exceedances above the CCC without allowing unacceptable effects. Thus, the averaging period must appropriately limit the magnitude and duration of exceedances and provide compensating periods of time during which the concentration is below the CCC.

Even though only a few tests have compared the effects of a constant concentration with the effects of the same average concentration resulting from a fluctuating concentration, nearly all the available comparisons have shown that substantial fluctuations result in increased adverse effects [6-16]. Thus, the duration of the averaging period must be shorter than the duration of the chronic tests on which the CCC is based so that the averaging period does not allow substantially more adverse effect than would have been caused by a continuous exposure to the same average concentration. Life-cycle tests with species such as mysids and daphnids and early life-stage tests with warmwater fishes usually last for 20 to 30 days, whereas life-cycle tests with *Ceriodaphnids* usually last for 7 days. If the duration of the averaging period is too short, however, it will not allow any meaningful exceedances and will, in effect, defeat the purpose of the concept of the averaging period. For example, because few effluents are monitored more often than once a day, an averaging period of 24 hours would effectively mean that for most effluents each individual sample that was above the CCC would be considered an excursion.

For the following reasons, a 4-day averaging period is recommended for application of the CCC in aquatic-life criteria for both individual pollutants and Whole Effluents:

- It is substantially shorter than the 20- to 30-day duration of most chronic tests and is somewhat shorter than the 7-day duration of the *Ceriodaphnia* life-cycle test.
- The results of some chronic tests apparently are due to an acute effect on a sensitive life stage that occurs at some time during the test, rather than being caused by either long-term stress or long-term accumulation of the test material in the organisms. Horning and Neiheisel [17] documented one such situation, and others are probably the cause of at least some of the acute-chronic ratios that are not much greater than unity.
- For both endrin and fenvalerate, Jarvinen et al. [18] found that a 72-hour exposure caused about the same amount of effect on the growth of fathead minnows in early life-stage tests as did a 30-day exposure to the same concentration.
- In some life-cycle tests on effluents with Ceriodaphnids, concentrations of effluents that were a factor of 1.8 greater than the CCC caused unacceptable effects in 4 or 5 days [5, 19, 20].
- It is not so short as to effectively defeat the purpose of the concept of the averaging period.

As discussed below, other averaging periods might be acceptable on a site-specific or pollutant-specific basis.

Just as the concept of exceedances can be applied to the CCC, it also can be applied to the CMC. As with the CCC, the CMC averaging period should be substantially less than the lengths of the tests on which the CMC is based, i.e., substantially less than 48 to 96 hours. Because 4- to 8-hour LC_{50}s are about the same as the 96-hour LC_{50} for some materials [21-27], the duration of the averaging period for the CMC should be less than 4 hours. One hour is probably an appropriate duration of the averaging period for the CMC because concentrations of some materials that are only a factor of two higher than the 96-hour LC_{50} cause death in one to three hours [25]. Even when organisms do not die within the first hour or so, it is not known how many organisms might have died due to the delayed effects of the short exposure [28-31]. If the 1-hour average does not exceed the CMC, it is unlikely that the concentration of the pollutant in the receiving water can fluctuate rapidly enough during the hour to cause additional adverse effect. Thus, it seems inappropriate to apply the CMC to instantaneous concentrations.

With adequate justification, the CMC and/or CCC averaging periods may be increased or decreased on a site-specific or pollutant-specific basis. A possible site-specific justification for increasing the duration of the CCC averaging period would be that the variation in the concentration of the pollutant in the receiving water is low. Where variation is demonstrated to be consistently low, a longer CMC averaging would be acceptable because the magnitudes and durations of exceedances above the CCC would be limited. A possible pollutant-specific justification for a longer averaging period would be that the LC_{50} decreases substantially as the length of the exposure increases. For example, an 8-hour averaging period might be justified for the CMC if it were shown that 24-hour exposures of a variety of sensitive species resulted in 96-hour LC_{50}s that were substantially above the 96-hour LC_{50}s obtained from continuous exposure to a constant concentration for 96 hours.

In some situations the duration of the averaging period does not have to be stated explicitly because one can be implicitly defined using an uptake rate and a depuration rate. For example, if it is known that a specific concentration of a pollutant in the whole body or in a particular tissue of an important aquatic species will result in an unacceptable effect on the survival, growth, and/or reproduction of that species, and if applicable that species or tissue, the only additional information needed to allow calculation of an excessively high estimate of the total maximum daily load from the record of daily flows is the allowed frequency of exceedances of the concentration in the aquatic species. Thus, this approach can be used whenever the following are available:

- A record of daily flows of the body of water, preferably for more than 10 years
- A maximum acceptable concentration in the whole body or in a particular tissue of an aquatic species
- Uptake and depuration rates that are applicable to that pollutant in the whole body or tissue of that species
- An allowed frequency of exceedances of the maximum acceptable concentration.

This approach is likely to be especially useful when an exposure causes delayed effects that are considered unacceptable. For example, it might be found in a test that no fish die during a 2-day exposure of rainbow trout to a pollutant but 50 percent of the fish die within 4 weeks of being transferred to clean water, whereas no comparable control fish die. If values are available for the concentration of the pollutant in the fish at the end of the 2-day exposure and for the uptake and depuration rates, these data could be used with a flow record for a river to determine how often a specified constant daily input of the pollutant to the river would have resulted in exceedances of this concentration and therefore the death of rainbow trout.

Regardless of what averaging periods are used, exact calculation of the number of excursions would require continuous monitoring of the concentration in the receiving water, which is not feasible in most cases. A valid alternative would be to use a statistically designed monitoring program and a statistical interpretation of the measured concentrations. The 1-hour averaging period for the CMC would imply that the samples analyzed should be 1-hour composites; the 4-day averaging period would imply that concentrations in all samples obtained within any 4-day period should be averaged, preferably using a time-weighted average. If information is available concerning the discharge pattern of a particular effluent, it might be possible to design a monitoring program that is specifically appropriate for that effluent.

Unless critical species are especially sensitive to particular toxicants, most excursions of criteria should have minor impacts on aquatic communities. However, whereas excursions above the CCC will probably reduce growth and reproduction, excursions above the CMC will probably cause death and other severe acute effects. In addition, special care should be exercised when many outfalls exist in a small segment of a receiving water, because if low flow causes an excursion for one discharge, that same low flow will probably also cause excursions for other discharges at the same time. Several "minor" excursions might thus add up to a "major" one.

Frequency

The purpose of the average frequency of allowed excursions is to provide an appropriate average period of time during which the aquatic community can recover from the effect of an excursion and then function normally for a period of time before the next excursion. The average frequency is intended to ensure that the community is not constantly recovering from effects caused by excursions of aquatic-life criteria. Because most regulated discharges are to flowing water (lotic) systems, this discussion will emphasize discharges to rivers and streams rather than to lakes, ponds, reservoirs, and estuaries.

General Considerations for Setting Frequency with Which Excursions of Criteria May Occur

Not long ago ecological communities were thought to be largely in equilibrium and their structure and function determined primarily by internal interactions between species, such as competition and predation. Communities were considered to be analogous to "super-organisms," with close parallels to organisms in their response to stress and in "health." Current understanding is that external factors, including disturbances, often play a major role in the structure of communities [32, 33]. The frequency of disturbance affects a community not only by decreasing the fitness of component species, but also by causing a natural selection of species or phenotypes having characteristics that allow them to tolerate or even thrive under the disturbance regime. Natural disturbances such as floods and droughts are common in lotic systems [32] and vary in intensity not only between headwater streams and large rivers, but also between similar sized lotic communities in different climatic regions. Rather than requiring more time to recover from the effects of additional anthropogenic disturbances, lotic communities with high natural background disturbance frequencies are actually predisposed to recover more rapidly because only species that are able to recolonize and reproduce quickly, or perhaps to avoid disturbances, can persist there [34-37]. This does not imply that they also are more resistant to novel anthropogenic disturbances with which they have had no previous evolutionary experience; it only implies that they are predisposed to recover quickly once the disturbance is gone. The question then is how frequently can aquatic communities experience these additional disturbances (excursions of criteria) without being unacceptably affected.

In an extensive review of the published literature, Niemi et al. [38] reviewed the published literature and identified more than 150 case studies of freshwater systems in which some aspect of recovery from the impact of a disturbance was reported. A case study was used only if the disturbance caused a death or displacement of organisms. This restriction was necessary because it was rarely possible to determine if an event was outside the normal intensity range (a common alternate definition of disturbance), mainly because it is usually difficult to define the normal intensity range. It also permitted the inclusion of natural as well as anthropogenic events. Approximately 80 percent of these systems were lotic, and the remainder were lentic (lakes and ponds). The impacts were due to such disturbances as persistent and nonpersistent chemicals, logging, flooding, channelization, dredging, and drought. Reported endpoints for recovery were sparse for phytoplankton, periphyton, and macrophytes, but were numerous for macroinvertebrates and fishes. Because more than one recovery endpoint was reported for most studies, the number of endpoints greatly exceeded the number of case studies. For short-term (nonpersistent) disturbances, approximately 85 percent of all macroinvertebrate endpoints indicated recovery in less than 2 years. Macroinvertebrate biomass, density, and taxonomic richness recovered in less than 1 year for approximately 95 percent of reported endpoints. Dipterans (flies, mosquitos, midges, etc.), which generally have short generation times or high dispersal ability, recovered most rapidly, whereas stoneflies and caddisflies recovered least rapidly. Fishes recovered in 2 years or less for over 85 percent of reported endpoints. However, as discussed below, important exceptions did occur.

Most excursions of criteria will be minor and their impacts will therefore be difficult to detect. Although most disturbances in the above case studies caused more severe impacts than most criteria excursions are expected to

cause, CMC excursions will result in death of some organisms. These data indicate that as a general rule, the purpose of the average frequency of allowed excursions will be achieved if the frequency is set at once every 3 years on the average. Excursions of the CCC are more difficult to evaluate because nonlethal excursions could not be evaluated from the data used by Niemi et al. [38]. It is reasonable to expect, however, that cumulative effects from too frequent excursion of the CCC also will result in unacceptable degradation of lotic communities.

Considerations for Proposing Site-specific Increases or Decreases in the Average Frequency of Allowed Excursions

Although an average frequency of one criterion excursion every 3 years should usually be protective of lotic communities, more frequent excursions might be acceptable in certain situations. Sedell et al. [39] have shown that lotic systems with refugia (areas of refuge) such as well-developed riparian zones, connected flood plains and meanders, snags, etc., recover more rapidly from disturbances than segments without such refugia, because organisms are better able to avoid disturbances and return or repopulate. However, many of these refugia are likely to be most restricted and vulnerable during the low-flow periods when criteria excursions also are most likely to occur. Evidence of action to preserve refugia, particularly during low-flow periods, or to create or restore them, might be grounds for demonstrating that an excursion frequency of more than once every 3 years on the average is acceptable. Schlosser [36] found that lower-order (i.e., headwater) streams, because of their natural high variability, contain communities consisting of species that have short life cycles and/or high dispersal ability and can recover from major disturbances in a year or even less. Thus, many lower-order streams, particularly those for which refugia are available, may be able to tolerate somewhat higher excursion frequencies, unless other considerations are important. For example, discharges to lower-order streams sometimes constitute a large fraction of the stream flow for most of the year.

Although lower-order streams are naturally highly variable and can therefore tolerate higher disturbance frequencies, the converse is true for higher-order lotic streams for at least two partially related reasons: (1) segments with tributaries draining a large watershed will be buffered from the effects of localized droughts in a portion of the watershed, and will therefore experience a less severe natural disturbance regime, and (2) organisms inhabiting these segments will therefore not be adapted to disturbances that are as frequent or severe as those in lower-order segments. Fish in particular will be larger and have longer generation times in larger streams and rivers. Consequently, it will take longer for these populations to reproduce and regain predisturbance densities and size class distributions. Schlosser [36] suggests that, based on such life-history characteristics, fish communities in larger rivers might take 20 to 25 years to re-establish the predisturbance age and size structure of their component populations after a severe disturbance such as a major drought or spill.

Extreme cases in which recovery has taken much longer than 3 years usually involve spills of persistent chemicals or severe habitat modification, such as stream channelization or clear-cutting of a watershed [38]. If the chemical contaminant is not widespread, recovery is limited primarily by the rate of disappearance of the chemical rather than by strictly ecological processes. Widespread contamination can affect recovery by increasing the distance over which recolonizers must travel. Watershed clear-cutting reduces the input of organic matter that provides the food base of streams in forested watersheds and also provides woody debris and snags that serve as refugia. Channelization and dredging reduce the in-stream habitat diversity and thereby decrease refugia. In addition to these anthropogenic disturbances, multiple excursions during a drought, due to low-flow conditions, can result in a severe cumulative impact on sensitive species even if the individual excursions are small. Special measures, such as plant shutdowns, might be required in extreme cases. Finally, severe chemical spills, which cannot be regulated but which will occur in any highly industrialized river segment, will affect aquatic life over a large area. If maintenance of long-lived fish species in these segments is desired, recovery periods up to 25 years may be necessary.

Based on the above considerations, recovery periods longer than 3 years may be necessary after multiple minor excursions or after a single major excursion or spill during a low-flow period in medium-to-large rivers, and up to 25 years where long-lived fish species are to be protected. Even longer times may be necessary as the size of the affected area or the persistence of the pollutant increases.

Calculation of Design Conditions

The use of aquatic-life criteria for developing water quality-based permit limits and for designing waste treatment facilities requires the selection of an appropriate wasteload allocation model. Dynamic models are preferred for the application of aquatic-life criteria in order to make best use of the specified concentrations, durations, and frequencies. If dynamic models cannot be used, then an alternative is steady-state modeling. Because steady-state modeling is based on various simplifying assumptions, it is less complex, and might be less realistic, than dynamic modeling.

An important step in the application of steady-state modeling to streams is calculating the design flow. The procedures outlined in the EPA document *Technical Guidance Manual for Performing Waste Load Allocation, Book 6, Design Conditions: Chapter 1, Steam Design Flow for Steady-State Modeling.* (U.S. EPA 1986) are recommended for calculating design flows for rivers and streams. States may use other methods so long as the methods are technically defensible. The document discusses and recommends two methods for determining design flows, the hydrologically based method and the biologically based method, and the flows that should be used for the CCC and CMC for both methods.

The hydrologically based design flow method is presently used by many States. It is based on selecting and identifying an extreme value, e.g., the 7Q10 flow. The underlying assumption of this method is that the design flow will occur X number of times in Y years. Thus, this method limits the number of years in which one or more excursions below the design flow can occur. The method has two advantages: (1) the log-Pearson Type III flow estimating technique or other extreme value analytical techniques that are used to calculate flow statistics from daily flow data are consistent with past engineering and statistical practice, and (2) the U.S. Geological Survey provides technical support for this method. The disadvantage of this method is that it is essentially independent of biological considerations. Design flows calculated using this method might allow more or fewer excursions than once every 3 years on the average. In addition, it is difficult to use site-specific durations and frequencies with this method. For toxic wasteload allocation studies in which the hydrologically based method is used, EPA recommends the use of the 1Q10 flow as the design flow for the CMC and the 7Q10 as the design flow for the CCC.

The biologically based design flow method was developed by the U.S. EPA Office of Research and Development and directly uses the averaging periods and frequencies specified in the aquatic-life water quality criteria for individual pollutants and Whole Effluents for determining design flows. The method is an empirical iterative convergence procedure that includes the calculation of harmonic means of the flow to determine the total number of excursions. The method makes exact use of whatever duration and frequency are specified for the CMC and CCC. These might be 1 day and 3 years for the CMC and 4 days and 3 years for the CCC or site-specific durations and frequencies.

The two methods were used on approximately 60 different rivers to compare the hydrologically based 1Q10 and 7Q10 design flows with the biologically based 1-day/3-year and 4-day/3-year design flows. For most of the rivers the hydrologically based design flows resulted in more than the allowed number of excursions. For some of the rivers, the 1Q10 and 7Q10 allowed substantially more or fewer excursions than the intended number of excursions. Because the biologically based method calculates the design flow directly from the national or site-specific duration and frequency, it always provides the maximum allowed number of excursions and never provides more excursions than allowed.

EPA provides software tools to calculate both types of design flows via the STORET environment on its NCC-IBM mainframe. Biologically based design flows can be calculated using the program DFLOW [40]. The hydrologically based design flows can be calculated using FLOSTAT or DFLOW; the latter uses a simplified version of the log-Pearson Type III method. Both programs access the STORET Flow file that contains daily flow records for U.S. Geological Survey gaging stations. They are easy to use and the user simply needs to know

the identification number of the gaging station. To obtain further information on the STORET environment and the programs, contact:

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Office of Water Regulations and Standards (WH-553)
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The methods described above use daily flow data to determine design flow, but they do not consider any other physical or chemical condition that might affect toxicity. EPA has prepared a supplementary method and a software tool named DESCON that incorporate such supplemental water quality parameters as temperature, pH, alkalinity, hardness, and dissolved oxygen to determine design conditions. Note that DESCON takes into account such things as effluent variability, which DFLOW does not take into account. The method and software are described in two documents available from the Assessment and Watershed Protection Division of the Office of Water Regulations and Standards—*Technical Guidance on Supplementary Stream Design Conditions for Steady State Modeling* [3] and *DESCON Users Manual* [40].

The supplementary method is consistent with the hydrologically and biologically based methods described above. It simply extends them to include other conditions besides streamflow. The advantage of considering multiple conditions is that the worst-case conditions necessary to protect water quality criteria might not occur when the streamflow is low; e.g., low DO or high temperatures might occur at times other than when the flow is low.

This supplementary method can be used for five pollutant categories with the physical-chemical parameters described above. The pollutant categories are general toxicant, ammonia, heavy metals (Cd, Cr^{+3}, Cu, Pb, Ni, Zn), pentachlorophenol, and ultimate oxygen demand.

The software tool to facilitate this method is called DESCON. It is on EPA's IBM mainframe and is available through the STORET environment. DESCON accesses the STORET flow file for the daily flow record and the water quality file for data on the physical-chemical parameters. Options are available to the user if the area of concern has no flow record or if no water quality data are available.

APPENDIX D
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Appendix E

Lognormal Distribution and Permit Limit Derivations

LOGNORMAL DISTRIBUTION AND PERMIT LIMIT DERIVATIONS

Introduction

This appendix provides supporting information for the statistical methodology used in permit limit calculations. The methodology described in this appendix applies to many types of data including data that are used to develop both technology-based and water quality-based permit limits. The appendix is divided into two sections. The first section gives an overview of permit limits: the derivation of water quality-based limits and the consistency among different permit limits. The second section describes the statistical methodology for the normal distribution, the lognormal distribution, the delta-lognormal distribution, methods of checking distributional assumptions, and correlation. This section also provides guidance on the application of each distribution to permit limits. Tables E-1, E-2, and E-3 at the end of the appendix summarize the permit limit calculations. This appendix describes the statistical methodology for three distributions that are often used in determining permit limits. Other distributions can be used, and this topic is discussed in the subsection, Other Distributions.

Section 1: Overview of Permit Limits

Two types of permit limits are contained in the effluent guidelines regulations: daily maximum limits and monthly average limits. The daily maximum permit limit is the maximum allowable value for any daily sample. The daily maximum limits are usually based on the 99th percentile of the distribution of daily measurements. The monthly average permit limit is the maximum allowable value for the average of all daily samples obtained during 1 month. Monthly average limits are in most cases based on the 95th percentile of the distribution of averages of daily values.

The following two subsections discuss the derivation of water quality-based limits and the consistency among different permit limits.

Derivation of Water Quality-based Limits

Water quality-based limits are derived from the required treatment system performance necessary to comply with the wasteload allocation (WLA). Technology-based effluent limits are derived from treatment system performance. The mathematical expressions for water quality-based limits are the same as those for technology-based effluent limits; the major difference is that the means and standard deviations in those expressions are derived from the WLA. This topic is discussed in Chapter 5.

Consistency Among Different Permit Limits

The current Technical Support Document for Water Quality-based Toxics Control (TSD) procedures provide consistency among different permit limits. The stringency of permit limits is independent of monitoring frequency and is determined entirely by the WLA and permit limit derivation procedures. The daily maximum limit is constant regardless of monitoring frequency. The numerical value of the monthly average limit decreases as monitoring frequency increases only because averages become less variable as the number of values included in the average increases. For example, an average based on 10 samples is less variable than an average based on 4 samples. This phenomenon makes monthly average permit limits based on 10 samples **appear** to be more stringent than the monthly limit based on 4 samples. A permittee performing according to the WLA specifications will in fact be equally capable of meeting either of these monthly average limits when taking the corresponding number of samples. The stringency of the TSD procedures, accordingly, is **constant** across monitoring frequencies.

Section 2: Statistical Methodology

The statistical procedures that are used in permit limit development involve fitting distributions to effluent data. The estimated upper percentiles of the distributions form the basis of the limits. This section describes the statistical methodology applied to permit limits in the following subsections: the normal distribution, the lognormal distribution, the delta-lognormal distribution, methods of checking distributional assumptions, and correlation. Before discussing these topics several definitions are made for notation, assumptions, coefficients of variation, and variability factors.

Notation

In the calculations in this appendix, natural logarithms (i.e., logarithms to the base e), denoted by ln(x), are used. The calculations can be modified to use logarithms to the base 10 by replacing $\log_{10}(x)$ for ln(x) in the formulas.

Assumptions

The distribution fitting methods assume that the daily measurements are independent, uncorrelated observations.

The fundamental assumptions underlying the discussion on calculating limits are:

- Daily pollutant measurements are approximately lognormally distributed for values above the detection limit
- Maximum n-day monthly averages for $n \leq 10$ are approximately lognormally distributed above the detection limit
- Maximum n-day monthly averages for $n > 10$ are normally distributed.

Recommendation of the use of the lognormal distribution for daily pollutant measurements is based on practical rather than theoretical consideration. Usually environmental data sets possess the basic lognormal characteristics of positive values and positive skewness. In addition, the lognormal distribution is flexible enough to model a range of nearly symmetric data. Furthermore, in comparison to other positive valued, positively skewed distributions that could be used to model environmental data, the lognormal is relatively easy to use.

When lognormal data are log transformed, the properties of the normal distribution apply to the transformed data. The section on statistical methodology describes the properties of the normal distribution and its relationship to the lognormal distribution. The delta-lognormal distribution is a generalization of the lognormal distribution and may be used to model data that are a mixture of non-detect measurements with measurements that are lognormally distributed. In delta-lognormal procedures, nondetect values are weighted in proportion to their occurrence in the data.

In determining permit limits based on averages (e.g., monthly average permit limits), a distribution should be used that approximates the distribution of an average of pollutant measurements. The lognormal distribution can be used for approximating the distribution of averages for small sample sizes where the individual measurements are approximately lognormally distributed. For larger sample sizes, a powerful statistical result, called the Central Limit Theorem, provides theoretical support for determining limits based on averages of individual measurements. According to the Central Limit Theorem, when the sample size n is large enough, the average of the n sample values will be approximately normally distributed regardless of the distribution of the individual measurements. The section on statistical methodology provides procedures and guidance for calculating averages for both small and large samples sizes where the individual measurements are lognormally distributed.

The shape of the observed data is the key factor in evaluating a distributional model. For environmental data the lognormal distribution is usually appropriate. The critical question in a given situation is how well a particular distribution models the shape of observed data. Although the lognormal does not provide an exact fit in all cases, it usually provides an appropriate and functional fit to observed environmental data. Graphical displays and goodness-of-fit tests, as described in the subsection, Other Distributions, may be used as a guide in verifying assumptions and selecting a distribution.

Coefficients of Variation

The coefficient of variation (denoted by "CV") is the ratio of the standard deviation to the mean. Thus, the CV is a dimensionless measure of the relative variability of a distribution. Estimates of the CV can be used when the actual CV cannot be calculated or if the available data sets for calculating the CV are small. In such cases, different values for the CV should be used in the permit calculations to assess the effect of the CV on the final permit limit. Typical values of the CV for effluent data usually range from 0.2 to 1.2. The CV is a measure of the relative variation in observed data. In many cases, changes in the CV will have little impact on the final permit limit. In assessing the sensitivity of the permit limit to the CV, the calculations may include CV = 0.6 as a conservative estimate (assumes relatively high variability). If the final permit values vary greatly with different CV values either of two approaches may be used. The first approach is to use a conservative estimate of the CV that assumes relatively high variability (e.g., CV = 0.6) in the final permit limit. The second approach is to collect additional data to obtain a more definitive value for the CV.

Variability Factors

An important component of the process used by the Environmental Protection Agency (EPA) for developing technology-based limits are variability factors. The variability factor is the ratio of a large concentration level of a pollutant to the average level determined from that particular plant. The ratio expresses the relationship between the average treatment performance level and large values that would be expected to occur only on rare occasions in a well-designed and operated treatment system. Such factors are useful in situations where little data are available to characterize the long-term performance of a plant.

In cases where only a small number of observations are available from a plant, EPA has been reluctant to estimate a variability factor. In the Organic Chemicals, Plastics, and Synthetic Fibers (OCPSF) rulemaking [1], a minimum of seven daily observations from a plant, with at least three of the seven above the detection limit, was established for calculation of a plant level priority pollutant variability factor. However, EPA has not established a minimum number of observations required for calculating variability factors for all pollutants in all industries.

The calculations for variability factors for the daily maximum and the monthly average are included in the discussion of the different distributions below.

Normal Distribution

The normal distribution plays a central role in the methods described in this appendix. In most cases, the normal distribution is not an appropriate model for individual pollutant measurements; however, the normal distribution is related to the lognormal distribution that is used to establish many permit limits. In most cases, the simple logarithmic transformation of effluent and water quality data results in data distributions that are normally distributed. Such data are referred to as being lognormally distributed. When lognormal data are log transformed, the properties of the normal distribution apply to the transformed data. Since the normal and lognormal distributions are related in a straightforward manner, the methods of analysis for normal and lognormal data also are easily related. The normal distribution is described below and is followed by a discussion of the lognormal distribution and its relationship to the normal distribution.

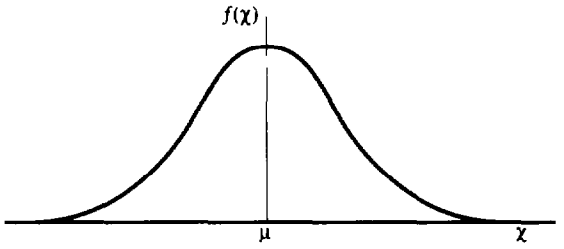

Figure E-1. Normal Probability Distribution

The normal probability distribution is encountered in a number of applications. The bell-shaped curve of the normal distribution is shown above in Figure E-1. Excellent introductions and reviews of the normal distribution are found in numerous statistical, engineering, and scientific texts, as for example in Reference 2. Only a brief review is given here.

A sample of independent observations, denoted by $x_1, x_2, \ldots, x_k$, from a normally distributed population can be used to estimate the mean, μ, and variance, σ^2, according to the formulas below:

$$\begin{aligned}
\hat{\mu} &= \text{estimated mean} \\
&= \Sigma[x_i] / k,\ 1 \le i \le k \\
\hat{\sigma}^2 &= \text{estimated variance} \\
&= \Sigma[(x_i - \hat{\mu})^2] / (k - 1),\ 1 \le i \le k \\
\hat{\sigma} &= \text{estimated standard deviation} \\
&= (\hat{\sigma}^2)^{1/2} \\
\hat{cv} &= \text{estimated coefficient of variation} \\
&= \hat{\sigma} / \hat{\mu}
\end{aligned}$$

The characteristics of the normal distribution are the range is defined for positive and negative values, and the frequency curve is bell-shaped and symmetric about the mean. In most cases, the normal distribution is not an appropriate model for the distribution of individual pollutant measurements. Environmental data rarely are symmetric, which is a fundamental property of the normal distribution. In addition, the normal distribution is defined over a range that includes negative values while pollutant measurements are restricted to nonnegative values. Thus, fitting a data set to a normal distribution allows for the possibility, however small, of observing negative values. The lognormal distribution, or any positive valued distribution, is not defined for negative values and thus avoids assigning any probability to negative values.

Daily Maximum Permit Limits Based on the Normal Distribution

For data sets which have the characteristics of the normal distribution, the daily maximum permit limits can be calculated. The upper percentile daily maximum permit limits for the normal distribution are calculated using the quantity z_p, the standardized Z-score for the pth percentile of the standardized normal distribution (i.e., normal distribution with mean = 0, and variance = 1). For example, the Z-score for the 95th percentile is 1.645. Z-scores are listed in tables for the normal distribution (in most statistical textbooks and references). The pth percentile daily maximum limit is estimated by:

$$\begin{aligned}
\hat{X}_{.p} &= \text{pth percentile daily maximum limit} \\
&= \hat{\mu} + z_p\, \hat{\sigma}.
\end{aligned}$$

For example:

$\hat{X}_{.95}$ = 95th percentile daily maximum limit
= $\hat{\mu} + 1.645\ \hat{\sigma}$
$\hat{X}_{.99}$ = 99th percentile daily maximum limit
= $\hat{\mu} + 2.326\ \hat{\sigma}$

Note:

$Z_{95} = 1.645$
$Z_{99} = 2.326$

The daily variability factors (denoted by VF_1) are estimated by:

Daily maximum 95th percentile $VF_1 = \hat{X}_{.95} / \hat{\mu}$

Daily maximum 99th percentile $VF_1 = \hat{X}_{.99} / \hat{\mu}$

Monthly Average Permit Limits Based on the Normal Distribution

The normal distribution can be used to model the averages of the individual measurements for a wide range of circumstances. Although the normal distribution usually is not an appropriate model for individual pollutant measurements, the averages of those individual measurements can often be modeled by the normal distribution. This subsection explains the theory behind using the normal distribution for averages and provides the general formulas.

A powerful statistical result, called the Central Limit Theorem, provides theoretical support for determining limits based on averages of individual measurements. According to the Central Limit Theorem, when the sample size n is large enough, the average of the n sample values will be approximately normally distributed regardless of the distribution of the individual measurements. In determining permit limits, the calculations incorporate the number of samples that will be required for monitoring purposes during the specified time period (usually a month). For the purposes of permit writing, monitoring sample sizes greater than 10 are recommended to be sufficiently "large enough" to assume the sample average is approximately normally distributed. The above formulas can be modified for finding the estimated mean and variance for the average from a sample of size n (e.g., for 14-day monthly average, n = 14 samples during the month for monitoring purposes). The parameters μ_n and σ_n^2 denote the mean and variance, respectively, of the distribution of the average of n values. The estimates of the n-day average and the variance of the n-day average are denoted by $\hat{\mu}_n$ and $\hat{\sigma}_n^2$, respectively.

$\hat{\mu}$ = estimated mean of distribution of X
$\hat{\sigma}^2$ = estimated variance of distribution of X
$\hat{\mu}_n$ = mean of distribution of the n-day monthly average
= $\hat{\mu}$
$\hat{\sigma}_n^2$ = variance of distribution of the n-day monthly average
= $\hat{\sigma}^2 / n$
$\hat{\sigma}_n$ = standard deviation
= $(\hat{\sigma}_n^2)^{1/2}$
$\hat{cv}_n$ = coefficient of variation
= $\hat{\sigma}_n / \hat{\mu}_n$.

The upper percentile limits are:

$$\hat{X}_{.p} = \text{pth percentile n-day monthly average limit}$$
$$= \hat{\mu}_n + z_p \hat{\sigma}_n$$

where z_p is the pth percentage point of the standard normal distribution.

For example:

$$\hat{X}_{.95} = \text{95th percentile n-day monthly average limit}$$
$$= \hat{\mu}_n + 1.645\ \hat{\sigma}_n$$
$$\hat{X}_{.99} = \text{99th percentile n-day monthly average limit}$$
$$= \hat{\mu}_n + 2.326\ \hat{\sigma}_n$$

Note:

$$Z_{95} = 1.645$$
$$Z_{99} = 2.326.$$

The monthly average variability factors (denoted by VF_n) are estimated by:

Monthly average 95th percentile $VF_n = \hat{X}_{.95} / \hat{\mu}$

Monthly average 99th percentile $VF_n = \hat{X}_{.99} / \hat{\mu}$

The above discussion of the normal distribution can be modified for data from the lognormal distribution. The next subsection explains the modifications.

Lognormal Distribution

Experience has shown that daily pollutant discharges are generally lognormally distributed. The distributional fit of the data varies somewhat from application to application, but not enough to alter the conclusion that effluent pollutant discharges are generally lognormally distributed. Ambient water quality data also are often lognormally distributed. Figure E-2 displays the positively skewed shape of the lognormal distribution.

The distribution fitting methods assume that the daily measurements are independent, uncorrelated observations. Although, in general, this assumption is not satisfied exactly, the lognormal distribution has been used in the effluent guidelines program primarily because it consistently provides a reasonably good fit to observed effluent data distributions. Figure E-3 shows the lognormal distribution applied to data used in the development of the OCPSF effluent guidelines regulation [1].

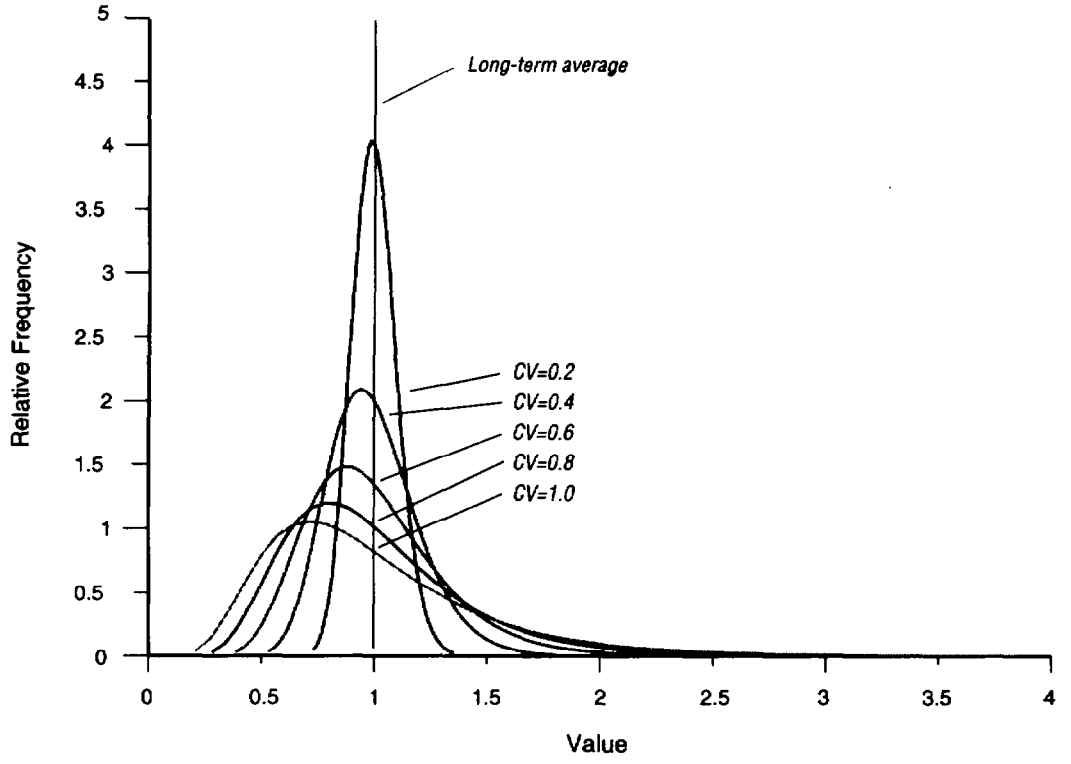

Figure E-2. Examples of Lognormal Densities

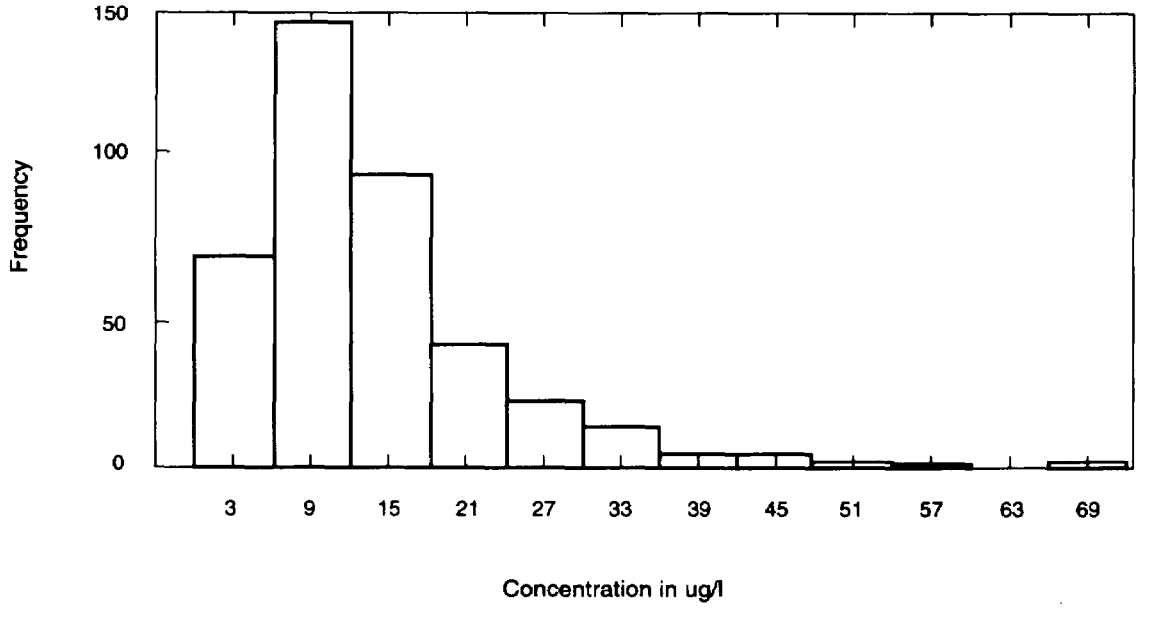

Figure E-3. BOD Frequency Distribution - Plant C

The logarithmic transformation of the random variable X, Y = ln(X) results in a random variable Y that is normally distributed. Therefore, the analysis procedures for analyzing lognormal data are similar to those for the normal distribution. The mean and variance from the normal distribution of the random variable Y are σ_y, and $\hat{\sigma}_y^2$ respectively. These parameters can be estimated by:

$$\hat{\mu}_y = \Sigma(y_i) / k$$

and

$$\hat{\sigma}_y^2 = \Sigma[(y_i - \hat{\mu})^2] / (k - 1), \text{ respectively}$$

where

$$y_i = \ln(x_i) \text{ for } i=1,2,\ldots k.$$

When data are lognormally distributed, these values from the normal distribution can then be used to calculate the mean, variance, and coefficient of variation for the random variable X that is lognormally distributed. The mean, variance, and coefficient of variation of the random variable X may be estimated by $\hat{E}(X)$, $\hat{V}(X)$, and $c\hat{v}(X)$, respectively.

$$\begin{aligned}
\hat{E}(X) &= \text{daily average} \\
&= \exp(\hat{\mu}_y + \hat{\sigma}_y^2 / 2) \\
\hat{V}(X) &= \text{variance} \\
&= \exp(2\hat{\mu}_y + \hat{\sigma}_y^2)[\exp(\hat{\sigma}_y^2) - 1] \\
c\hat{v}(X) &= \text{coefficient of variation} \\
&= [\exp(\hat{\sigma}_y^2) - 1]^{1/2}.
\end{aligned}$$

Daily Maximum Permit Limits Based on the Lognormal Distribution

The upper percentile limits for the random variable X (which is lognormally distributed) are:

$$\begin{aligned}
\hat{X}_{.p} &= \text{pth percentile daily maximum limit} \\
&= \exp[\hat{\mu}_y + z_p \hat{\sigma}_y^2]
\end{aligned}$$

where z_p is the pth percentage point of the standard normal distribution.

For example:

$$\begin{aligned}
\hat{X}_{.95} &= \text{95th percentile daily maximum limit} \\
&= \exp[\hat{\mu}_y + 1.645\,\hat{\sigma}_y] \\
\hat{X}_{.99} &= \text{99th percentile daily maximum limit} \\
&= \exp[\hat{\mu}_y + 2.326\,\hat{\sigma}_y].
\end{aligned}$$

Note:

$$\begin{aligned}
Z_{95} &= 1.645 \\
Z_{99} &= 2.326.
\end{aligned}$$

The daily maximum variability factors (denoted by VF_1) are estimated by:

Daily maximum 95th percentile $VF_1 = \hat{X}_{.95} / \hat{E}(X)$

Daily maximum 99th percentile $VF_1 = \hat{X}_{.99} / \hat{E}(X)$.

Monthly Average Permit Limits Based on the Lognormal Distribution

This subsection contains the formulas required to approximate the distribution of the average of a small number of lognormally distributed values with another lognormal distribution. Although, the Central Limit Theorem holds that the average of a sample of independent measurements is normally distributed provided that the number of measurements, n, is sufficiently large, the minimum value for n required in specific cases may vary considerably. In cases where the individual values are lognormally distributed, the minimum required for the average to be normally distributed may be quite large. As a consequence, the distribution of the average of a small number of lognormally distributed values may be better approximated by another, related lognormal distribution [3]. For sample sizes larger than 10 when the data are lognormally distributed, it is recommended that the calculations given in Table E-3 should be used. For the purposes of permit writing, monitoring sample sizes of 10 or less are recommended to be "small enough" to assume the sample average is approximately lognormally distributed. The mean, variance, and coefficient of variation of the distribution of the average of n daily values are $\hat{\mu}_n$, $\hat{\sigma}_n^2$, and $\hat{cv}$, estimated by:

$$\hat{\sigma}_n^2 = \text{variance}$$
$$= \ln\{\hat{V}(X) / [n[\hat{E}(X)]^2] + 1\}$$
$$\hat{\mu}_n = \text{n-day monthly average}$$
$$= \ln(\hat{E}(X)) - 0.5\,\hat{\sigma}_n^2$$
$$\hat{\sigma}_n = \text{standard deviation}$$
$$= (\hat{\sigma}_n^2)^{1/2}$$
$$\hat{cv}_n = \text{coefficient of variation}$$
$$= [\exp(\hat{\sigma}_n^2) - 1]^{1/2}$$

where

$$\hat{E}(X) = \exp(\hat{\mu}_y + \hat{\sigma}_y^2 / 2)$$
$$\hat{V}(X) = \exp(2\,\hat{\mu}_y + \hat{\sigma}_y^2)\,[\exp(\hat{\sigma}_y^2) - 1].$$

The upper percentile limits of the maximum n-day monthly average are:

$$\hat{X}_{.p} = \text{pth percentile n-day monthly average limit}$$
$$= \exp[\hat{\mu}_n + z_p\,\hat{\sigma}_n]$$

where z_p is the pth percentage point of the standard normal distribution.

For example:

$$\hat{X}_{.95} = \text{95th percentile n-day monthly average limit}$$
$$= \exp[\hat{\mu}_n + 1.645\,\hat{\sigma}_n]$$
$$\hat{X}_{.99} = \text{99th percentile n-day monthly average limit}$$
$$= \exp[\hat{\mu}_n + 2.326\,\hat{\sigma}_n]$$

Note:

$$Z_{95} = 1.645$$
$$Z_{99} = 2.326.$$

The variability factors are:

Monthly average 95th percentile $VF_n = \hat{X}_{.95} / \hat{\mu}_n$
Monthly average 99th percentile $VF_n = \hat{X}_{.99} / \hat{\mu}_n$.

Delta-Lognormal Distribution

The delta-lognormal distribution is a generalization of the lognormal distribution. The delta-lognormal distribution may be used when the data contain a mixture of nondetect values and values above the detection limit and can be used to model nondetects in water quality-based limits. In delta-lognormal procedures, nondetect values are weighted in proportion to their occurrence in the data. The values above the detection limit are assumed to be lognormally distributed values. The delta-lognormal distribution can be used in setting daily maximum limits and for setting limits on monthly averages with the recommended number of monitoring samples being 10 or less.

The delta-lognormal distribution models data as the combination of two distributions: the lognormal distribution and a distribution with discrete probability of obtaining observations at or below the detection limit. The lognormal distribution models the observations above the detection limit. The nondetect values are modeled by the distribution with discrete probability of obtaining observations at or below the detection limit. The organic priority pollutant data set shown in Figure E-4 contains a number of observations that were reported as "nondetect." These detection limit measurements are observations that are censored at the detection limit and are represented by the left-most bar in the histogram. Data sets of this form are fairly typical of organic chemicals in wastewater. The delta-lognormal distribution often provides an appropriate and computationally convenient model for analyzing such data.

The estimation procedure for the delta-lognormal distribution assumes that a certain proportion, δ, of values are at the detection limit, which is denoted by D. (The estimation procedure when D = 0 is detailed in Reference 4. These values set to D are observations that can only by quantified as nondetect (ND) at some minimum level. This minimum level is the detection limit as established by the laboratory performing the chemical analysis.

Let $x_1, x_2, \ldots, x_r, x_{r+1}, \ldots, x_k$ denote a random sample of size k, with r observations recorded as nondetects, and k-r observations greater than the detection limit. The k-r positive observations are assumed to follow a lognormal distribution. The entire data set is assumed to follow the delta-lognormal distribution with censoring point equal to the detection limit D. Let $\hat{\mu}_y$ and $\hat{\sigma}_y^2$ be the sample mean and variance of the distribution of the logarithmic transformation Y = ln(X) of the observations greater than the detection limit. Let $\hat{\delta}$ be the sample proportion of nondetects. Then the estimates of the mean and variance of the delta-lognormal distribution are estimated by:

$$\hat{E}(X^*) = \text{daily average}$$
$$= \hat{\delta} D + (1 - \hat{\delta}) \exp(\hat{\mu}_y + 0.5\, \hat{\sigma}_y^2)$$
$$\hat{V}(X^*) = \text{variance}$$
$$= (1 - \hat{\delta}) \exp(2\, \hat{\mu}_y + \hat{\sigma}_y^2) [\exp(\hat{\sigma}_y^2) - (1 - \hat{\delta})] + \hat{\delta} (1 - \hat{\delta}) D [D - 2 \exp(\hat{\mu}_y + 0.5\, \hat{\sigma}_y^2)]$$
$$\hat{cv}(X^*) = \text{coefficient of variation}$$
$$= [\hat{V}(X^*)]^{1/2} / \hat{E}(X^*)$$

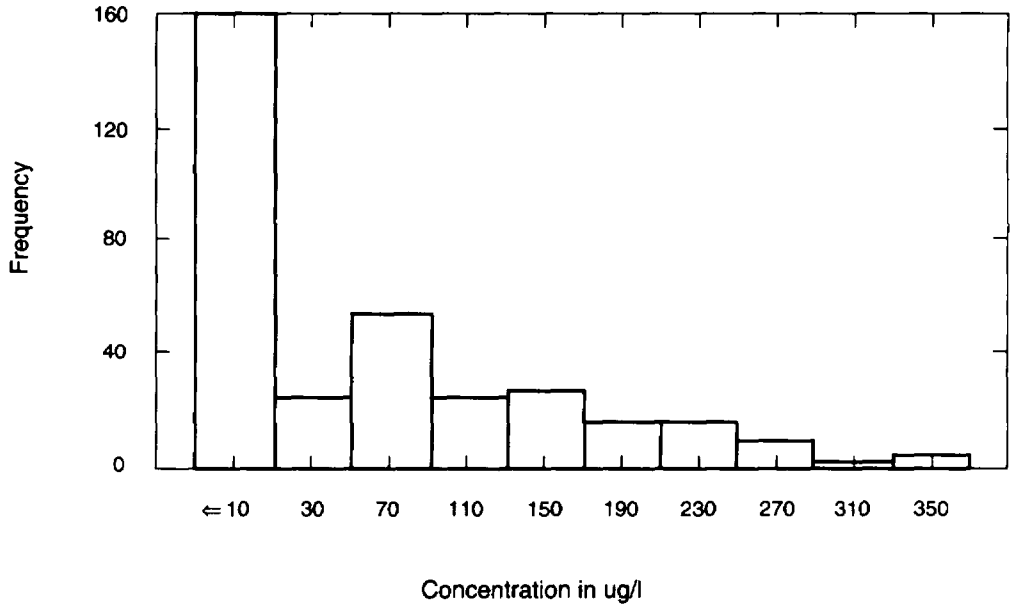

Figure E-4. Organic Priority Pollutant Frequency Distribution—Plant B

where

k = number of samples
D = detection limit
r = number of nondetect values in sample
$k\text{-}r$ = number of values greater than the detection limit
$y_i = \ln(x_i)$ $\quad r+1 \le i \le k, \quad r < k$
$\hat{\mu}_y = \Sigma(y_i) / (k - r)$ $\quad r+1 \le i \le k, \quad r < k$
$\hat{\sigma}_y^2 = \Sigma(y_i - \hat{\mu}_y)^2 / (k - r - 1)$ $\quad r+1 \le i \le k, \quad r < k$
$\delta = r / k$

Daily Maximum Permit Limits Based on the Delta-Lognormal Distribution

The 95th and 99th upper percentile limits for the random variable X (which is delta-lognormally distributed) are given by the following formulas:

The estimated 95th percentile daily maximum limit is:

$$\hat{X}_{.95*} = \begin{cases} D & \delta \ge 0.95 \\ \max\left[D, \exp(\hat{\mu}_y + z^* \hat{\sigma}_y^2\right] & \delta < 0.95 \end{cases}$$

where

$$z^* = \Phi^{-1}[(0.99 - \delta) / (1 - \delta)].$$

The estimated 99th percentile daily maximum limit is:

$$\hat{X}_{.99*} = \begin{cases} D & \delta \ge 0.99 \\ \max\left[D, \exp(\hat{\mu}_y + z^* \hat{\sigma}_y)\right] & \delta < 0.99 \end{cases}$$

where

$$z^* = \Phi^{-1}[(0.99 - \delta) / (1 - \delta)].$$

$\Phi^{-1}[\ ]$ is the mathematical notation for Z-scores. For example, when $\delta = 0$, then the corresponding value is

$\Phi^{-1}[.99] = Z_{99} = 2.326$. Values of $\Phi^{-1}[\ ]$ are available from tables of the normal distribution (available in most statistical textbooks and references).

The variability factors (denoted by VF) are estimated by:

Daily maximum 95th percentile VF = $\hat{X}_{.95} / \hat{E}(X)$
Daily maximum 99th percentile VF = $\hat{X}_{.99} / \hat{E}(X)$.

Delta-Lognormal Distribution of Averages

The derivation of the formulas for the averages computationally is difficult and beyond the scope of this appendix. However, the formulas for n-day averages are included in Table E-2. The derivation of 4-day monthly averages using the delta-lognormal distribution is available in Appendix VII-F of the Development Document for the OCPSF regulation [1]. For the purpose of permit writing, it is recommended that data sets of greater than 10 samples be assumed to fit the normal distribution and the averages be calculated using the formulas given in Table E-3.

Checking Distributional Assumptions

Two methods of checking distributional assumptions are goodness-of-fit and probability plots. When checking distributional assumptions, the sample size must be large enough. Small sample sizes may lead to erroneous conclusions.

Goodness-of-Fit Tests

In some cases, statistical goodness-of-fit tests may indicate that a particular distribution provides a reasonable fit to a data set of pollutant measurements. Such cases should be evaluated carefully to verify that the frequency curve for the data also show the shape characteristic of the distribution.

Probability Plots

Use of probability plots is one method of determining whether a normal distribution is appropriate for modeling a population using only a limited set of measurements. The set of measurements should have at least 20 observations [5]. Consider an independent sample of size k, labeled $x_1, x_2, \ldots, x_k$. Let $u_1, u_2, \ldots, u_k$ be the ordered sample of x-values in ascending order in which $u_1 \leq u_2 \leq, \ldots, \leq u_k$. Now for each u_i, find z_i from the normal table (in any statistical reference or textbook) such that $P[Z \leq z_i] = i/(k+1)$ and plot each pair (z_i, u_i) on linear graph paper (or use a computer graphics software package). If the data are from a normal distribution, they will fall approximately along a straight line.

This same method can be adapted to check the assumption of lognormality. Log-probability plots are similar to probability plots used for the normal distribution. To construct a log-probability plot, set $y_i = \ln(x_i)$ for $i=1,2,\ldots,k$ and then prepare a probability plot for the y_i, first by ordering the data as described in the previous section. If the data are from a lognormal distribution, they will fall approximately along a straight line, as illustrated by Figure E-5.

Other Distributions

If the probability plots or the log-probability plots show serious deviation from straight lines, other distributions should be considered. Nonparametric methods, which do not require the assumption that the data follow a particular distributional form, are often useful for this type of data. Further details are available in many statistical references (e.g., Reference 6).

Correlation

Up to this point, we have assumed that all the observed pollutant levels are independent, i.e., uncorrelated with one another. This subsection is not intended to address correlation between observed pollutant levels and plant operating factors that influence and control treatment performance.

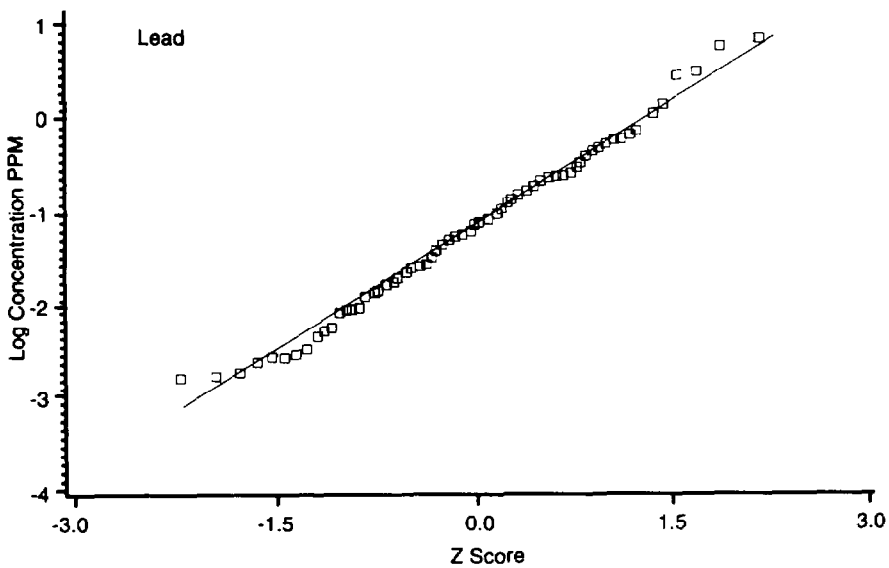

Figure E-5. Example of a Log-Probability Plot with a Normal Distribution

In the case of the monthly average limit derivation, the assumption that observed pollutant levels are independent can be quite important. If the effluent levels are correlated, the actual monthly average limit can be substantially higher than that derived from the analysis based on the independence assumption. However, correlation has essentially no effect on the calculated daily permit limits. This sub-section provides guidance on determining when levels may be correlated, and adjusting the sample size.

A major factor that determines whether effluent levels are highly correlated is the retention time of the wastewater treatment system. If the retention time is large relative to the time between effluent samples, then those samples will tend to be correlated with each other in most cases. In municipal systems, for example, the retention time is frequently a matter of days, and sampling is often conducted on a daily basis. The effluent levels, consequently, may be substantially correlated. However, in many industrial systems, for instance a physical/chemical treatment system for electroplating wastewaters, the treatment system retention time is relatively short 4 to 8 hours. Daily effluent levels from these kinds of systems are generally uncorrelated, i.e., statistically independent. These general patterns are the same irrespective of the kind of pollutant in question. Significant correlation between observed pollutant levels, when present, should be factored into monthly average permit limits.

Several different methods can be used to account for correlation in determining limits. One general approach involves time series modeling. Another possible approach is to use a direct computation of the covariance among the observed data to adjust the variance of the average used in determining the limit. Help in adjusting the sample size for correlation is available from the OW Statistics Section (phone number [202] 382-5397).

Table E-1. Daily Maximum Permit Limit Calculations

The daily maximum permit limit is usually the 99th upper percentile value of the pollutant distribution. In certain cases the 95th percentile value may be allowable. The following gives the formulas:

<u>WITH ALL MEASUREMENTS > DETECTION LIMIT</u> (based on lognormal distribution)

$\hat{X}_{.95}$ = 95th percentile daily maximum limit

$= \exp[\hat{\mu}_y + 1.645\ \hat{\sigma}_y]$

$\hat{X}_{.99}$ = 99th percentile daily maximum limit

$= \exp[\hat{\mu}_y + 2.326\ \hat{\sigma}_y]$

where

x_i = daily pollutant measurement i

y_i = $\ln(x_i)$

k = sample size of data set

$\hat{\mu}_y = \Sigma(y_i) / k \qquad 1 \le i \le k$

$\hat{\sigma}_y^2 = \Sigma[(y_i - \hat{\mu}_y)^2] / (k - 1) \quad 1 \le i \le k$

$\hat{E}(X) = \exp(\hat{\mu}_y + 0.5\ \hat{\sigma}_y^2)$

$\hat{V}(X) = \exp(2\ \hat{\mu}_y + \hat{\sigma}_y^2)\ [\exp(\hat{\sigma}_y^2) - 1]$

$\hat{cv}(X) = [\exp(\hat{\sigma}_y^2) - 1]^{1/2}$

Table E-1. Daily Maximum Permit Limit Calculations (continued)

<u>WITH SOME MEASUREMENTS < DETECTION LIMIT</u> (based on delta-lognormal distribution)

$\hat{X}_{.95}$ = 95th percentile daily maximum limit

$$\hat{X}_{.95} = \begin{cases} D & \delta \geq 0.95 \\ \max[D, \exp(\hat{\mu}_y + z^* \hat{\sigma}_y)] & \delta < 0.95 \end{cases}$$

with $z^* = \Phi^{-1}[(0.95 - \delta) / (1 - \delta)]$

$\hat{X}_{.99}$ = 99th percentile daily maximum limit

$$\hat{X}_{.99} = \begin{cases} D & \delta \geq 0.99 \\ \max[D, \exp(\hat{\mu}_y + z^* \hat{\sigma}_y)] & \delta < 0.99 \end{cases}$$

with $z^* = \Phi^{-1}[(0.99 - \delta) / (1 - \delta)]$

where

x_i	=	daily pollutant measurement i	
k	=	sample size of data set	
D	=	detection limit (as established by the laboratory)	
r	=	number of nondetects	($x_1, x_2, \ldots, x_r$ are $\leq D$)
$k - r$	=	number of detects	($x_{r+1}, x_{r+2}, \ldots, x_k$ are $> D$)
y_i	=	$\ln(x_i)$	for $r+1 \leq i \leq k$
δ	=	r / k	
$\hat{\mu}_y$	=	$\Sigma(y_i) / (k - r)$	$r+1 \leq i \leq k$ (exclude values $\leq D$ from sum)
$\hat{\sigma}_y^2$	=	$\Sigma[(y_i - \hat{\mu}_y)^2] / (k - r - 1)$	$r+1 \leq i \leq k$

$$\hat{E}(X^*) = \delta D + (1 - \delta) \exp(\hat{\mu}_y + 0.5\, \hat{\sigma}_y^2)$$

$$\hat{V}(X^*) = (1 - \delta)\exp(2\, \hat{\mu}_y + \hat{\sigma}_y^2)\, [\exp(\hat{\sigma}_y^2) - (1 - \delta)] + \delta\, (1 - \delta) D[D - 2 \exp(\hat{\mu}_y + 0.5\, \hat{\sigma}_y^2)]$$

Table E-2. Monthly Average Permit Limit Calculations for Ten Samples or Less

The monthly average permit limit is usually based on the estimates of the 95th percentile of the distribution of the average of the daily effluent values. For sample sizes less than or equal to 10, the data are assumed to be lognormally distributed (or delta-lognormally distributed if the data includes nondetects).

<u>ALL MEASUREMENTS > DETECTION LIMIT</u> (based on lognormal distribution)

$\hat{X}_{.95}$ = 95th percentile n-day monthly average limit

$= \exp[\hat{\mu}_n + 1.645\ \hat{\sigma}_n]$

$\hat{X}_{.99}$ = 99th percentile n-day monthly average limit

$= \exp[\hat{\mu}_n + 2.326\ \hat{\sigma}_n]$

where

x_i = daily pollutant measurement i

$y_i = \ln(x_i)$

k = sample size of data set

$\hat{\mu}_y = \Sigma(y_i) / k \qquad 1 \le i \le k$

$\hat{\sigma}_y^2 = \Sigma[(y_i - \hat{\mu}_y)^2] / (k - 1) \qquad 1 \le i \le k$

$\hat{E}(X) = \exp(\hat{\mu}_y + 0.5\ \hat{\sigma}_y^2)$

$\hat{V}(X) = \exp(2\ \hat{\mu}_y + \hat{\sigma}_y^2)[\exp(\hat{\sigma}_y^2) - 1]$

$\hat{\sigma}_n^2 = \ln\{\hat{V}(X) / (n[\hat{E}(X)]^2) + 1\}$

$\hat{\mu}_n = \ln(\hat{E}(X)) - 0.5\ \hat{\sigma}_n^2$

$\hat{cv}_n = [\exp(\hat{\sigma}_n^2) - 1]^{1/2}$

Table E-2. Monthly Average Permit Limit Calculations for Ten Samples or Less (continued)

SOME MEASUREMENTS < DETECTION LIMIT (based on delta-lognormal distribution)

$\hat{X}_{.95}$ = 95th percentile n-day monthly average limit

$$\hat{X}_{.95} = \begin{cases} D & \hat{\delta} \geq 0.95 \\ \max[D, \exp(\hat{\mu}_n + z^* \hat{\sigma}_n)] & \hat{\delta} < 0.95 \end{cases}$$

with $z^* = \Phi^{-1}[(0.95 - \hat{\delta}) / (1 - \hat{\delta})]$.

$\hat{X}_{.99}$ = 99th percentile n-day monthly average limit

$$\hat{X}_{.99} = \begin{cases} D & \hat{\delta} \geq 0.99 \\ \max[D, \exp(\hat{\mu}_n + z^* \hat{\sigma}_n)] & \hat{\delta} < 0.99 \end{cases}$$

with $z^* = \Phi^{-1}[(0.99 - \hat{\delta}) / (1 - \hat{\delta})]$

where

x_i	=	daily pollutant measurement i	
k	=	sample size of data set	
D	=	detection limit (as established by the laboratory)	
r	=	number of nondetects	($x_1, x_2, \ldots, x_r$ are $\leq D$)
$k - r$	=	number of detects	($x_{r+1}, x_{r+2}, \ldots, x_k$ are $> D$)
y_i	=	$\ln(x_i)$	for $r+1 \leq i \leq k$
$\hat{\delta}$	=	r / k	
$\hat{\mu}_y$	=	$\Sigma(y_i) / (k - r)$	$r+1 \leq i \leq k$ (exclude values $\leq D$ from sum)
$\hat{\sigma}_y^2$	=	$\Sigma[(y_i - \hat{\mu}_y)^2] / (k - r - 1)$	$r+1 \leq i \leq k$

$$\hat{E}(X^*) = \hat{\delta} D + (1 - \hat{\delta}) \exp(\hat{\mu}_y + 0.5\hat{\sigma}_y^2)$$

$$\hat{V}(X^*) = (1 - \hat{\delta}) \exp(2 \hat{\mu}_y + \hat{\sigma}_y^2) [\exp(\hat{\sigma}_y^2) - (1 - \hat{\delta})] + \hat{\delta} (1 - \hat{\delta}) D[D - 2 \exp(\hat{\mu}_y + 0.5 \hat{\sigma}_y^2)]$$

$$\hat{\sigma}_n^2 = \ln\{(1 - \hat{\delta}^n) [1 + A + B + C]\}$$

with

$$A = \hat{V}(X^*) / [n(\hat{E}(X^*) - \hat{\delta}^n D)^2]$$

$$B = -[\hat{\delta}^n D^2 (1 - \hat{\delta}^n)] / (\hat{E}(X^*) - \hat{\delta}^n D)^2$$

$$C = (2 \hat{\delta}^n D) / (\hat{E}(X^*) - \hat{\delta}^n D)$$

$$\hat{\mu}_n = \ln[(\hat{E}(X^*) - \hat{\delta}^n D) / (1 - \hat{\delta}^n)] - 0.5 \hat{\sigma}_n^2$$

Table E-3. Monthly Average Permit Limit Calculations for More Than Ten Samples

The monthly average permit limit usually is based on the estimates of the 95th percentile of the distribution of the average of the daily effluent values. These daily values are assumed to be lognormally distributed. For sample sizes larger than 10, the averages (represented by the random variable X_n) are assumed to be normally distributed.

$\hat{X}_{.95}$ = 95th percentile n-day monthly average limit

$= \hat{E}(X_n) + 1.645\,[\hat{V}(X_n)]^{1/2}$

$\hat{X}_{.99}$ = 99th percentile n-day monthly average limit

$= \hat{E}(X_n) + 2.326\,[\hat{V}(X_n)]^{1/2}$

where

x_i = daily pollutant measurement i

y_i = $\ln\,(x_i)$

k = sample size of data set

$\hat{\mu}y = \Sigma(y_i) / k, \qquad 1 \le i \le k$

$\hat{\sigma}_y^2 = \Sigma[(y_i - \hat{\mu}_y)^2] / (k - 1) \qquad 1 \le i \le k$

$\hat{E}(X) = \exp(\hat{\mu}_y + 0.5\,\hat{\sigma}_y^2)$

$\hat{V}(X) = \exp(2\,\hat{\mu}_y + \hat{\sigma}_y^2)\,[\exp(\hat{\sigma}_y^2) - 1]$

$\hat{E}(X_n) = E(X)$

$\hat{V}(X_n) = \hat{V}(X) / n$

$c\hat{v}(X_n) = \hat{V}(X_n)^{1/2} / (X_n)$

APPENDIX E
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APPENDIX F

SAMPLING

SAMPLING

The objective of an effluent or instream sampling program is to obtain a sample (or samples) from which a representative measure of the parameters of interest can be obtained. Unfortunately, many of the industrial and municipal National Pollutant Discharge Elimination System sampling protocols presently in use are carryovers from schemes used for calculating loadings of nutrients and oxygen-demanding substances, or were developed to evaluate treatment plant operational efficiency. Sampling for individual toxicants and particularly for effluent toxicity can require more specific (and thus different) sampling procedures.

Wastewater variability is an important consideration in selecting the method and frequency of sampling for both chemical analysis and toxicity testing. Industrial waste characteristics have been shown to vary in frequency, intensity, and duration [1]. As noted by Bender [2], the sources of effluent variability include both random and systematic components that influence both daily and annual characteristics of waste discharges. Although toxic pollutant loading may be of primary concern in assessing human health impact or bioaccumulation, loading may be of lesser importance in toxicity assessment than frequency, intensity, and duration of peak toxic discharge. Sampling must be tailored to measure the type of toxicity of importance for that discharge: either long-term (chronic) impact, which is a more constant effect, or short-term (acute) impact, which is more variable and subject to peaks of intensity.

There are several chemical parameters for which continuous analysis is possible. These include pH, temperature, dissolved oxygen, and other parameters involving instantaneous measurement. All other types of measurement involve some time period over which the analysis is conducted. Toxicity tests require an exposure period. Chemical tests require sample preparation and analysis. There is no continuous analysis method for toxicity.

It should be noted that although it is difficult to design a representative sampling program for toxicity analysis, the problems are of no greater magnitude than similar problems associated with obtaining a representative sample for conventional pollutants.

Sampling Methods

Continuous Flow Samples

For toxicity testing, the test organisms may be exposed to serial dilutions of a sample continuously pumped from the effluent pipe or ditch. In the case of effluents, if optimum accuracy is desired, then the ratio of effluent flow to test chamber volume can be scaled to simulate the time-varying concentration at the mixing zone boundary.

Although flowthrough methods can provide a realistic simulation of time-varying exposure, they are relatively expensive and are usually conducted on site. Therefore, flowthrough methods may only be practical where the goals of the analysis of impact require this type of testing or where treatment costs are sufficiently high that this type of analysis can be required. A flowthrough exposure method is not a continuous analysis because only one result or data point is obtained at the end of the test. However, the continuous exposure does provide some measure of time-varying exposure effects.

Discrete Samples

Grab or flow composited sampling provide a discrete sample for chemical analysis or toxicity testing. Static or renewal toxicity tests using discrete samples result in exposure of test organisms to a constant effluent composition over the period of the tests, or for the period between renewals.

If discrete samples are collected during peaks of effluent toxicity then constant concentration exposure static tests provide a measure of maximum effect.

Depending on the duration of a peak and the compositing period, composited samples may not be useful for examining toxicity peaks because the compositing process tends to dilute the peaks. Composited samples are

usually appropriate for chronic tests where peak toxicity of short duration is of less concern. The averaging effect of compositing may be misleading when testing for acute toxicity.

Grab samples must be collected at sufficiently frequent intervals to provide a high probability of sampling daily peaks. Fortunately static toxicity tests are relatively inexpensive and can be done on shipped samples; thus, it may be cost effective to conduct individual tests on a series of grab samples collected over a 24-hour period.

Sampling Frequency

Nonrandom effluent variability, resulting from batch processing, variable loadings, etc., is often known or can be determined. Therefore, the first step in designing a sampling program for chemical analysis or toxicity testing is to select the annual sampling frequency based on available site-specific operational information. This is important in selecting sampling periods for both continuous flow and discrete sampling methods.

If discrete sampling methods (grabs or composites) are used, then random variations between and within days for each sampling period must be considered. It is important to recognize the tradeoff between the long-term (between days) frequency and short-term (within days) frequency of sample collection and analysis for toxics. At present, the permit requirements for sampling and analyzing chemical parameters are site specific and generally involve a single grab or 24-hour composite sample collected at daily, weekly, or monthly intervals. Unfortunately, a sampling scheme involving a single daily grab or a 24-hour composite sample can conceal the presence of those daily extreme values that may be of importance. To optimize sampling cost and effectiveness, it may be desirable to reduce long-term frequency so that daily frequency can be increased.

For example, a weekly grab or composite involves 52 analyses per year. It may be more efficient to reduce the annual frequency to monthly or bimonthly, but collect and analyze four or eight grabs daily. Either scheme (12 x 4 or 6 x 8) would involve 48 analyses per year versus 52 for the weekly single sample approach. Assuming that daily toxic events of environmentally significant intensity and duration would not be masked by short-term composites, it might be more efficient to collect eight samples each composited over a 3-hour interval.

If costs or other constraints prohibit satisfactory daily and annual replication of sampling, then a level of uncertainty must be introduced into the calculations used to evaluate waste toxicity (see Section 3, Table 3-1).

Box F-1 presents EPA's recommendations on sampling methods.

Box F-1. Recommendations

The initial sampling design step should involve stratification of sampling periods to account for nonrandom sources of variation (e.g., batch processing). The second step includes selection of the frequency and the method of sampling to be conducted within each sampling period. Depending on site-specific considerations, several options are available.

- Flowthrough Methods — Ideally, for both acute and chronic effluent toxicity tests, the exposure of biota should simulate the time-varying concentration at a predetermined point in the receiving water. For regulatory purposes, the critical point is often the edge of the mixing zone where the waste should exhibit neither acute nor chronic toxicity. Therefore, if warranted by site-specific factors, it is recommended that test biota be exposed to a continuously collected flowthrough sample of serially diluted effluent. If no systematic annual variations (e.g., batch processing) are known or suspected, flowthrough testing can be conducted at a minimum of quarterly intervals for at least 1 year.
- Grab Sample Methods — Grab samples are recommended for chemical analyses and for acute and chronic toxicity tests where site conditions (such as wastewaters that are known to have relatively constant composition) do not require use of continuous flow methods. Grab samples of effluent or receiving water may be used for static or renewal acute toxicity tests, which may be conducted onsite or at a remote lab. The design of a toxics grab-sampling program must take into account the tradeoff between long-term and short-term sampling intensity. Where there is no ponding of wastes or retention time is insufficient for thorough mixing, it is important to collect or analyze a sufficient number of samples to provide a measure of daily spikes. Therefore, to minimize analytical costs where daily fluctuations are known or suspected, the annual sampling frequency should be reduced in favor of more intensive daily sampling. It is recommended that on an annual cycle, grab sampling and analysis include a minimum of four to six daily grabs collected monthly. An option could include the use of short-term (4-hour) composites rather than grabs. If site-specific data are available to indicate that treatment system retention time is adequate to minimize daily variations, then the daily replicates may be omitted in favor of more frequent annual sampling (e.g., weekly or semimonthly rather than monthly). If, to minimize costs in screening tests, only single samples are collected at infrequent intervals (e.g., quarterly) an uncertainty factor for variability should be used in the toxicity evaluation (see Section 3).
- Composite Sample Methods — If static or renewal methods are used for evaluation of toxicity, it is recommended that 24-hour, continuous-flow composite samples be collected. Considerations of annual frequency are the same as those for grab samples.

APPENDIX F

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APPENDIX G

THE DEVELOPMENT OF A BIOLOGICAL INDICATOR APPROACH TO WATER QUALITY-BASED HUMAN HEALTH TOXICS CONTROL

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Current Approach

With one exception (New Jersey), the chemical-specific approach to protecting human health is currently the only method used to regulate human health toxicants in effluents. The chemical-specific approach identifies the individual chemicals in an effluent and regulates them based upon health risk assessment information for each individual chemical. Where data are available for such human health toxicants, the chemical-specific approach can be used to develop permit limits.

However, the complex characteristics of effluent mixtures limit the effectiveness of the single-chemical approach. When used as the sole basis for identifying effluents of human health concern, the chemical-specific approach can overlook wastewaters potentially toxic to humans for the following reasons:

1. Analytical methods may not be sensitive enough to detect extremely small quantities of chemicals which may exert their effects on human health after a long latency period.
2. Human health data are limited or lacking for many of the §307(a) "priority" pollutants. Moreover, the number of human health toxicants discharged far exceeds the "priority" pollutants list.
3. The various chemical constituents of an effluent may resulting in synergistic, additive or antagonistic chemical effects.

As a result of these limitations, biological indicator tests have been developed for human health impact effluent screening, including both in vitro and in vivo tests. Though not yet widely implemented, biological indicator test results can be important supplements to a chemical-by-chemical effluent characterization.

Short-term biological indicator tests for human health impact screening are based on cellular-level responses, indicating whether the substances being tested are biologically active, and providing some measure of that activity. While these tests do not quantify the degree of toxicity to humans, they can be used to identify effluents with potential human health impacts, and regulatory priority-setting and targeting of dischargers for further chemical-specific analyses. Research is currently underway within EPA and in the private sector to evaluate various biological indicator test batteries for whole effluent analysis.

Biological Indicator Tests

Biological indicator tests include in vitro (test tube) and in vivo (whole animal) tests which can help form the first tiers of a single chemical evaluation process. A battery of simple biological tests can be used to test for the major types of effects which are underlying causes of potential health impact, since each biological test measures a different type of response. The results of these tests can be used to decide whether more definitive (and more resource-intensive) testing is needed to identify actual problem pollutants.

Test results can serve as triggers to additional chemical-specific analysis or more sophisticated definitive biological tests. Where results of these screening tools indicate potential health hazards, further characterization of the effluents, and regulation based upon toxicological data and/or chemical structure-activity relationships can proceed. If an effluent is extremely variable in other parameters, screening assays should be repeated periodically to ensure that potentially hazardous discharges are detected. Two types of biological indicator tests are discussed below: tests for non-threshold (no safe level exists) chemicals and tests for threshold (a safe level is presumed to exist) chemicals.

Genotoxicity Tests for Non-Threshold Chemicals

Genotoxicity is the ability of a substance to damage an organism's genetic material (its DNA). Certain positively-charged compounds tend to bind to DNA and may lead to permanent changes in the genetic information. Such damage to the DNA of reproductive (germ) cells can impair reproductive ability or can produce a change in the DNA structure that could be passed on to offspring as a heritable mutation. Alterations in the DNA of somatic cells can result in cancer or other diseases.

Interpretation of genotoxicity test results assumes that DNA damage in nonhuman cells may be predictive of latent diseases in humans such as genetic disorders, birth defects, and cancer. EPA believes that genotoxicity tests for point mutations, numerical and structural chromosome aberrations, DNA damage/repair and in vitro transformation provide supportive evidence of carcinogenicity [U.S. EPA, 1979 and 1987c]. In addition, wastewater mutagenicity tests could be used to detect genotoxic activity which can adversely affect aquatic biota [Black, et. al., 1980]. Several short-term assays have been developed which can assess genotoxic effects (discussed below).

For example, a correlation has been established between animal carcinogens and positive mutagenic responses in the Ames Test. The Ames test is often used to assess point mutation effects. The original correlation study revealed that 90% of tested carcinogens were detected as mutagens, while 87% of noncarcinogens were identified as nonmutagens. Other studies have determined that between 77% and 91% of tested carcinogens produce positive responses in the Ames test. The Ames Test has been used in over 2,000 laboratories worldwide for drug and food additive screening, product development, and environmental testing [New Jersey DEP, 1983].

To assess clastogenic effects (chromosomal breakage) either the mammalian sister chromatid exchange test or a mammalian cell chromosomal aberrations test can be conducted. Both of these tests typically use Chinese hamster ovary cell cultures and involve cytologic examination after exposure to determine if chromosomal effects are evident. The Organization of Economic Cooperation Development (OECD) test methodology is recommended [OECD]. EPA's Office of Toxic Substances and Office of Pesticides Programs also have published test methods [U.S. EPA 1982a and 1982b] that are consistent with the OECD tests.

Most effluent samples need special preparation (for example, concentration) to produce a measurable biological indicator test response for human health effects. When samples are concentrated, the response is calculated in terms of the pre-concentration sample. In addition, for genotoxicity tests, because many chemicals are not actively mutagenic in humans until they enter the body and are metabolized, many in vitro tests are supplemented with extracts from mammalian livers which act as a source of enzymes. The extract enzymes act to mimic metabolic activation of procarcinogens and promutagens in humans, providing a more realistic picture of potential effects [U.S. EPA, 1979].

A number of genetic toxicity assay batteries have been suggested in order to address the many potential effects produced by nonthreshold chemicals (for which no safe level exists) [U.S. EPA, 1979; Lave and Omenn; Environment Canada]. In addition to providing assays that detect different endpoints, a battery of tests can also be structured to minimize effort at the screening level while supplying more definitive data for samples failing the initial tier of testing. Positive results can lead to further effluent characterization, including priority and other pollutant chemical analyses, or mutagenicity testing of specific processes or effluent fractions. Another approach would be to evaluate the effects of various treatment or waste segregation techniques on mutagenicity [McGeorge, et. al., 1985].

Many of the proposed test batteries utilize the Ames Assay as a screening level test because of its relatively high degree of sensitivity (i.e. a high percentage of carcinogens are Ames positive) and specificity (i.e. a high percentage of noncarcinogens are Ames negative) [Tennant, et. al., 1987]. One study of 28 selected industrial discharges revealed that 11 of the 28, or 39%, produced positive results using the Ames Test (described below). Other test endpoints frequently covered in the initial tier of testing include mammalian cell chromosomal effects, mammalian gene mutation and microbial and mammalian cell DNA damage.

Results of a recent National Toxicology Program project suggest that combinations of four of the most commonly used short-term tests covering these endpoints did not show significant differences in individual

concordance with rodent carcinogenicity results for pure chemicals [Tennant, et. al., 1987]. This suggests that if a sample causes only one type of endpoint as measured by several screening level tests, its potential to cause human health effects should not be disregarded.

To assess the potential carcinogen hazard, subsequent tests focusing on effluent-induced malignant changes in mammalian cells in vitro can be conducted. Higher levels of testing may include in vivo rodent testing or the Medaka (fish) tumor assay, for example. It should be noted that under existing guidelines, in vivo mammalian tumor assays are necessary to establish a material as a possible human carcinogen. Results from short term tests alone are considered as inadequate to establish human carcinogenicity [U.S. EPA, 1986c]. Guidelines for risk assessment of individual compounds are covered in U.S. EPA, 1986b and 1987c.

In vivo tests on complex mixtures are extremely complicated and expensive given the variability intrinsic to effluents. As a result, it is recommended that after each tier of biological indicator testing, the cost of further refining the weight of evidence for carcinogenesis or mutagenesis be balanced against the cost of conducting a causative agent identification evaluation. Given the identity of the substance leading to positive results in short term in vitro tests, it should not be necessary to generate in vivo dose-response data for risk characterization if these data are already available in the literature for the specific chemical.

In addition, causative agent identification studies may be unnecessary if information on the physical and/or chemical characteristics of the toxicant is obtained. Such information may provide clues to appropriate effluent treatment technologies needed to reduce effluent mutagenicity.

In weighing the need for more definitive biological assays against causative agent evaluation, the frequency (i.e., how often the effluent tests positive) and intensity (e.g., revertants/liter) of the effluent's mutagenicity must be considered. As a default assumption, a high dose of a carcinogen received over a short period of time is equivalent to a low dose spread over a life-time [U.S. EPA, 1986c]. While effluents which are highly variable in their mutagenicity are of concern, they will be more difficult and costly to deal with in subsequent phases of study.

Accordingly, the initial tier of qualitative tests for human health effects assessment can be relatively inexpensive, rapid, and have a low rate of false negative results. Subsequent tests can be designed to increase confidence in the predictive nature of the results. Additional levels of testing may also provide diagnostic information on the characteristics of the causative agent(s) in the effluent.

Subsequent tiers of testing should focus on a more concise assessment of risk. Such an assessment can be used to delineate hazard type; in effect, to separate germ cell mutations (heritable genetic risk) from carcinogen risk. Thus, to assess heritable mutation, subsequent testing should focus on mammalian germ cells, ultimately tested in vivo [U.S. EPA, 1986b]. To assess potential carcinogen hazard, subsequent tests focusing on effluent-induced malignant changes in in vitro mammalian systems should be conducted. Ultimately, testing must result in a dose-response assessment to be used with an exposure assessment in characterizing risk [U.S. EPA, 1987a].

EPA's Region V (Chicago), New Jersey, and Environment Canada have been conducting mutagenicity testing at selected facilities. In Region V Ames test results are used to suggest the need for more intensive chemical-specific analyses of the effluent. New Jersey has incorporated a prohibition against discharging mutagenic compounds in amounts that are mutagenic into its "New Jersey Administrative Code" [N.J.S.A. Section 7:9-4.5 (a)4, May 1985].

For both types of endpoints (genotoxicity and carcinogenesis), hazard identification should be followed by quantitative risk assessment which includes assessment of dose response (requiring in vivo data) and human exposure. Human exposure assessment typically considers the composition and size of the population exposed and the types, magnitude, frequency and duration of exposures [U.S. EPA, 1986d].

Evaluation of Effluent Genotoxicity Screening Results

Control of human health hazards depends upon assessment of both the toxicological properties of the pollutants and the level of exposure. The permit authority should review the results of a human health toxicant

effluent screening program and establish the actions triggered by each level of potential risk indicated. For example, a discharger with either a high exposure risk or a high effects risk might automatically be required to conduct a detailed assessment or institute controls. A medium risk in both exposure and effects might require further review of the data and a case-specific decision about whether to require additional assessment. A medium effects risk and a low exposure risk might indicate the need for limited testing to ensure that the low is really indicative of the risk. Low risk in both exposure and effects should receive low priority for further assessment. The bioconcentration evaluation procedures can be used to aid in defining exposure risk, as well as determining receiving water concentration.

One possible tool for evaluating results of biological indicator effluent screening is the "relative potency approach," a concept used rather widely in radiation biology and chemical pharmacology. The relative potency of an effluent is the dose of a reference agent needed to produce an effect of a given magnitude in a particular bioassay, divided by the dose of the effluent needed to produce the same magnitude of the same effect in the same bioassay. A predictive battery of several short-term biological tests, when standardized to a reference agent, could provide a rank or comparative estimate of the hazard posed by an effluent in the context of measures of other known hazards [Glass, 1988]. It should be recognized that this approach does not consider exposure through bioaccumulation.

When screening has indicated a high potential for health hazard, further assessment should be required. A chemical-specific approach is recommended to evaluate and regulate the discharge constituents. The first half of this process involves characterizing the composition of the effluent. Typically, only a small fraction of the total organic carbon (TOC) can be accounted for as individual chemicals. Therefore, effort should be placed on identifying constituents through means other than chemical analysis, such as through a detailed process evaluation and/or toxicant characterization evaluation.

A process evaluation is a study in which components in the wastewater are determined from an analysis of feedstocks, manufacturing processes, products, by-products, and pollution control in place. The result is a list of compounds or classes of compounds with a high probability of being present in the wastewater. Chemical analysis can also be conducted for not only the priority pollutants but also nonpriority pollutant peaks and bioconcentratable chemicals [EPA/600/XX-XX]. IRIS and SAR can be used to determine the likelihood that a given compound is causing positive results in the bioassay. The toxicant characterization evaluation can provide information on the physical/chemical nature of the chemical producing positive bioassay results.

Summary of Current Biological Indicator Tests for Non-Threshold Human Health Toxicants

The following tests are currently in use or under development for assessing carcinogenicity or mutagenicity:

- Salmonella typhimurium Assay (Ames Test) [U.S. EPA, 1985 and 1983]

  Background: Strains of Salmonella requiring the amino acid, histidine, are exposed to a solvent extract of the effluent. Tests are performed with and without added rat liver enzyme for activation of indirect mutagens. The bacteria are grown on histidine-free medium; colony formation indicates the effluent contains mutagenic compounds capable of genetically altering the bacteria.

  Endpoint: Gene mutation; response measured in revertant colonies/L effluent.

  Advantages: Test is rapid, relatively inexpensive. The Ames Test has been shown to have broad application for the assessment of the mutagenic activity of a diversity of industrial effluent types [McGeorge, et. al., 1985]. Test sensitivity and specificity are documented [Ashby and Tennant, 1988].

Disadvantages: Requires metabolic activation and several different strains of Salmonella to detect a broad range of compounds, requires extrapolation from prokaryot, use of effluent extract may exclude certain types of compounds, epigenetic carcinogens not detected.

Cost: Approximately $1200 [Lave and Omenn, 1986]

- Escherichia coli SOS Assay (SOS Chromotest) [Quillardet, et.al., 1985].

  Background: All cells contain an "SOS" enzymatic system for detecting and correcting errors in their genetic material. A strain of E. coli has been genetically engineered so that DNA damage ultimately results in production of an enzyme which reacts with test reagents to form a blue color. Bacteria are exposed to effluent or an extract of the effluent, with or without added rat liver enzyme for activation indirect mutagens. The intensity of color produced indicates the extent to which the effluent contains mutagenic compounds capable of damaging bacterial DNA.

  Endpoint: DNA damage; response measured as the change in optical density.

  Advantages: Simple kit commercially available, test requires <8 hrs to perform, relatively inexpensive. Test sensitivity, specificity documented [Quillardet, et.al., 1985].

  Disadvantages: Requires metabolic activation, extrapolation from prokaryot, use of effluent extract may exclude certain types of compounds, epigenetic carcinogens not detected, measurement of effect must be referenced to known genotoxic compound.

  Cost: ??

- Sister-Chromatid Exchange Assay (SCE) [Eckl, et. al., 1987]

  Background: Sister chromatid exchange occurs when damaged DNA is replicated during cell division. Recent advances allow the use of cultured rat hepatocytes in detecting SCE formation, thus precluding the need to add rat liver enzyme for metabolic activation. Hepatocyte exposure to the sample is effected by using filter sterilized effluent in preparing the cell culture medium. Exposed cells are lysed and genetic material fixed in order to count SCEs.

  Endpoint: DNA damage; response measured in SCE per chromosome/L effluent.

  Advantages: Test is rapid, relatively inexpensive, does not require metabolic activation (therefore more realistic). Uses mammalian cells, therefore results more readily applicable to humans.

  Disadvantages: Sensitivity, specificity not well documented, test more complex relative to prokaryotic systems, filter sterilization may remove some genotoxic compounds from the sample, epigenetic carcinogens not detected.

  Cost: $5000 [Jirtle, 1989]

- HGPRT Assay with Chinese Hamster Ovary Cells (HGPRT/CHO) [Hsie, et. al., 1981]

  Background: Strains of Chinese Hamster Ovary cells in culture are exposed to the effluent or an extract of the effluent, with or without added rat liver enzyme. Mutagen interactions with certain sections of the DNA make the cell resistant to toxicants like 6-thioguanine. Cell survival is used to indicate both cytotoxicity (cell death) and genetic mutations resulting from effluent components.

  Endpoint: Gene mutation; response measured in % survival/L.

  Advantages: Test is rapid and uses a mammalian system.

  Disadvantages: Sensitivity, specificity not well documented, use of effluent extract may exclude certain types of compounds, epigenetic carcinogens not detected, requires metabolic activation.

  Cost: $6500

- Medaka Tumor Assay [U.S. EPA, 1988; U.S. EPA, 1989b.]

  Background: Larval fish are exposed to nonlethal concentrations of effluent for one month, this period is followed by a 5-month grow out period in clean water. At six months, fish are sacrificed and submitted for histopathological studies.

  Endpoint: Tumor formation, response measured in frequency of tumors at a given site/effluent concentration.

  Advantages: Use of whole effluent, whole organism, oncogenic endpoint

Disadvantages: Carcinogen levels in unconcentrated effluent may not be high enough to produce tumors at a detectable frequency in exposed populations, effluent must not be toxic to Medaka, requires extrapolation from non-mammalian system, relatively expensive, length of test, endpoint requires pathologist experienced in fish cancers, method still in developmental stages.

Cost: $20,000 [Johnson, 1989].

Other Human Health Effects

Toxicants present in effluents may produce a variety of effects in humans besides genotoxicity or carcinogenicity via exposure through ingestion of water and/or contaminated fish and shellfish. Potential health effects could include suppression of the immune system, neurotoxicity, specific organ toxicity, or developmental toxicity. These effects occur after exposure above a presumed safe (threshold) level and are referred to as "systemic."

Formerly, the only means to assess systemic effects was by using subchronic toxicity procedures designed to determine the effects that may occur with repeated exposure over a part of the average life span of an experimental animal. However, such studies are expensive ($100,000 and over) and beyond the cost constraints for most effluent analyses. As an alternative, a number of short-term in vitro tests utilizing mammalian cells have been developed [U.S. EPA, 1978; Wilson, 1978; Kimmel, et. al., 1982; Brown and Fabro, 1982; Borenfreund and Puerner, 1985]. Test endpoints include cytotoxicity, effects on cell growth, division, structure, metabolism and function, alterations in enzyme activities, and metabolite formation.

As with the nonthreshhold assays previously discussed, these in vitro assays only serve to qualify potential human health hazards. In the case of positive in vitro results, tests on intact mammals can be pursued in order to confirm screening test findings and establish a dose-response relationship. Alternatively, causative agent evaluations resulting in either the identity of the toxicant or toxicity treatability data may be pursued.

Current Limitations of the Biological Regulatory Approach

At present, the use of biological indicator tests as a regulatory tool is limited for a number of reasons. First, biological indicator information must be linked to human exposure to wastewater components. To date, no definitive mechanism exists for interpreting the human health hazard implications of the biological test results. While many in vitro (i.e. test tube) human health assays provide data about cellular changes relative to the dose delivered to the target tissue, they do not provide the information necessary to correlate environmental exposure to target tissue dose or cellular change to ultimate human health effects (e.g., cancer). The higher animal testing necessary to quantify the dose-response relationship (or "potency" of the effluent) would be extremely costly.

Second, as with aquatic organism toxicity tests, a human health hazard test must be capable of dealing with intra- and interspecies sensitivity variability. This concern is particularly relevant for those effluents containing chemicals which only become carcinogenic upon metabolism by mammalian systems (i.e. procarcinogens). The use of cultured human liver cells (hepatocytes), currently being tested, would eliminate the need for interspecies extrapolation.

Finally, whole effluent testing to assess potential human health impacts presents several unique practical problems such as the continual change in composition typical for most effluents, the need to concentrate samples to obtain a dose-response curve, and the need to compensate for or eliminate interferences from cytotoxic (toxic to cells) components of the effluent. Only those components which occur in the relatively nonvolatile, nonpolar organic fraction of the effluent sample are conventionally measured. [Anderson-Carnahan, article in preparation].

Until additional research resolves these difficulties, biological indicator tests will be most useful as screening tools, with actual regulation of effluents posing potential health hazards likely to remain on a chemical-by-chemical basis.

APPENDIX G

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Appendix H

Reference Dose (RfD): Description and Use in Health Risk Assessments

Reference Dose (RfD) Description and Use in Health Risk Assessments (Revised 02/10/88)

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REFERENCE DOSE (RFD): DESCRIPTION AND USE IN HEALTH RISK ASSESSMENTS

Introduction

This concept paper describes the U.S. Environmental Protection Agency's (U.S. EPA) principal approach to and rationale for assessing risk for health effects other than cancer and gene mutations from chronic chemical exposure. By outlining principles and concepts that guide EPA risk assessment for such systemic effects the paper complements the new risk assessment guidelines (U.S. EPA, 1987), which describe the Agency's approach to risk assessment in other areas, specifically carcinogenicity, mutagenicity, developmental toxicity, exposure, and chemical mixtures. (In this document the term "systemic toxicity" refers to an effect other than carcinogenicity or mutagenicity induced by a toxic chemical.)

Background and Summary

Chemicals that give rise to toxic endpoints other than cancer and gene mutations are often referred to as "systemic toxicants" because of their effects on the function of various organ systems. In addition, chemicals that cause cancer and gene mutations also commonly evoke other toxic effects (i.e., systemic toxicity). Based on our understanding of homeostatic and adaptive mechanisms, systemic toxicity is treated as if there is an identifiable exposure threshold (both for the individual and for populations) below which there are no observable adverse effects. This characteristic distinguishes systemic endpoints from carcinogenic and mutagenic endpoints, which are often treated as nonthreshold processes.

Systemic effects have traditionally been evaluated using such terms as "acceptable daily intake (ADI)," "safety factor (SF)," and "margin of safety (MOS)," concepts that are associated with certain limitations described below. The U.S. EPA established the Reference Dose (RfD) Work Group to address these concerns.

In preparing this report, the RfD Work Group has drawn on traditional report on risk assessment (NRC, 1983), to more fully articulate the use of noncancer, nonmutagenic experimental data in reaching regulatory decisions about the significance of exposures to chemicals. In the process, the Work Group has coined less value-laden terminology -- "reference dose (RfD)," "uncertainty factor (UF)"; "margin of exposure (MOE)"; and "regulatory dose (RgD)" -- to clarify and distinguish between aspects of risk assessment and risk management. These concepts are currently in general use in many parts of U.S. EPA.

Traditional Approach to Assessing Systemic Toxicity

The U.S. EPA's approach to assessing the risks associated with systemic toxicity is different from its approach to assessing the risks associated with carcinogenicity, because of the different mechanisms of action thought to be involved in the two cases. In the case of carcinogens, the Agency assumes that a small number of molecular events can evoke changes in a single cell that can lead to uncontrolled cellular proliferation. This mechanism for carcinogenesis is referred to as "nonthreshold," since there is theoretically no level of exposure for such a chemical that does not pose a small, but finite, probability of generating a carcinogenic response. In the case of systemic toxicity, however, organic homeostatic, compensating, and adaptive mechanisms exist that must be overcome before a toxic endpoint is manifested. For example, there could be a large number of cells performing the same or similar function whose population must be significantly depleted before the effect is seen.

The threshold concept is important in the regulatory context. The individual threshold hypothesis holds that a range of exposures from zero to some finite value can be tolerated by the organism with essentially no chance of expression of the toxic effect. Further, it is often prudent to focus on the most sensitive members of the population; therefore, regulatory efforts are generally made to keep exposures below the population threshold, which is defined as the lowest of the thresholds of the individuals within a population.

Description of the Traditional Approach

In many cases, risk decisions on systemic toxicity have been made by the Agency using the concept of the "acceptable daily intake (ADI)" derived from an experimentally determined "no-observed-adverse-effect level (NOAEL)." The ADI is commonly defined as the amount of a chemical to which a person can be exposed on a daily basis over an extended period of time (usually a lifetime) without suffering a deleterious effect. The ADI concept has often been used as a tool in reaching risk management decisions (e.g., establishing allowable levels of contaminants in foodstuffs and water.)

A NOAEL is an experimentally determined dose at which there was no statistically or biologically significant indication of the toxic effect of concern. In an experiment with several NOAELs, the regulatory focus is normally on the highest one, leading to the common usage of the term NOAEL as the highest experimentally determined dose without a statistically or biologically significant adverse effect. The NOAEL for the critical toxic effect is sometimes referred to simply as the NOEL. This usage, however, invites ambiguity in that there may be observable effects that are not of toxicological significance (i.e., they are not "adverse"). For the sake of precision, this document uses the term NOAEL to mean the highest NOAEL in an experiment. In cases in which a NOAEL has not been demonstrated experimentally, the term "lowest-observed-adverse-effect level (LOAEL)" is used.

Once the critical study demonstrating the toxic effect of concern has been identified, the selection of the NOAEL results from an objective examination of the data available on the chemical in question. The ADI is then derived by dividing the appropriate NOAEL by a safety factor (SF), as follows:

$$\text{ADI (human dose)} = \text{NOAEL (experimental dose)}/\text{SF} \qquad \text{(Equation 1)}$$

Generally, the SF consists of multiples of 10, each factor representing a specific area of uncertainty inherent in the available data. For example, a factor of 10 may be introduced to account for the possible differences in responsiveness between humans and animals in prolonged exposure studies. A second factor of 10 may be used to account for variation in susceptibility among individuals in the human population. The resultant SF of 100 has been judged to be appropriate for many chemicals. For other chemicals, with databases that are less complete (for example, those for which only the results of subchronic studies are available), an additional factor of 10 (leading to a SF of 1000) might be judged to be more appropriate. For certain other chemicals, based on well-characterized responses in sensitive humans (as in the effect of fluoride on human teeth), an SF as small as 1 might be selected.

While the original selection of SFs appears to have been rather arbitrary (Lehman and Fitzhugh, 1954), subsequent analysis of data (Dourson and Stara, 1983) lends theoretical (and in some instances experimental) support for their selection. Further, some scientists, but not all, within the EPA interpret the absence of widespread effects in the exposed human populations as evidence of the adequacy of the SFs traditionally employed.

Some Difficulties in Utilizing the Traditional Approach

Scientific Issues

While the traditional approach has performed well over the years and the Agency has sought to be consistent in its application, observers have identified scientific shortcomings of the approach. Examples include the following:

a. Too narrow a focus on the NOAEL means that information on the shape of the dose-response curve is ignored. Such data could be important in estimating levels of concern for public safety.

b. As scientific knowledge increases and the correlation of precursor effects (e.g., enzyme induction) with toxicity becomes known, questions about the selection of the appropriate "adverse effect" arise.

c. Guidelines have not been developed to take into account the fact that some studies have used larger (smaller) numbers of animals and, hence, are generally more (less) reliable than other studies.

These and other "scientific issues" are not susceptible to immediate resolution, since the database needed is not yet sufficiently developed or analyzed. U.S. EPA work groups are presently considering these issues.

Management-related Issues

The use of the term "safety factor" - The term "safety factor" suggests, perhaps inadvertently, the notion of absolute safety (i.e., absence of risk). While there is a conceptual basis for believing in the existence of a threshold and "absolute safety" associated with certain chemicals, in the majority of cases a firm experimental basis for this notion does not exist.

The implication that any exposure in excess of the ADI is "unacceptable" and that any exposure less than the ADI is "acceptable" or "safe" - In practice, the ADI is viewed by many (including risk managers) as an "acceptable" level of exposure, and, by inference, any exposure greater than the ADI is seen as "unacceptable." This strict demarcation between what is "acceptable" and what is "unacceptable" is contrary to the views of most toxicologists, who typically interpret the ADI as a relatively crude estimate of a level of chronic exposure which is not likely to result in adverse effects to humans. The ADI is generally viewed by risk assessors as a "soft" estimate, whose bounds of uncertainty can span an order of magnitude. That is, within reasonable limits, while exposures somewhat higher than the ADI are associated with increased probability of adverse effects, that probability is not a certainty. Similarly, while the ADI is seen as a level at which the probability of adverse effects is low, the absence of all risk to all people cannot be assured at this level.

Possible limitations imposed on risk management decisions - Awareness of the "softness" of the ADI estimate, as discussed above, argues for careful case-by-case consideration of the toxicological implications of individual situation, so that ADIs are not given a degree of significance that is scientifically unwarranted. In addition, the ADI is only one factor in a risk management decision and should not be used to the exclusion of other relevant factors.

Development of different ADIs by different programs - In addition to occasionally selecting different critical toxic effects, Agency scientists have reflected their best scientific judgments in the final ADI by adopting factors different from the standard factors listed in Table 1. For example, if the toxic endpoint for a chemical in experimental animals is the same as that which has been established for a related chemical in humans at similar doses, one could argue for an SF of less than the traditional 100. On the other hand, if the total toxicologic data base is incomplete, one could argue that an additional SF should be included, both as a matter of prudent public policy and as an incentive to others to generate the appropriate data.

Such practices, as employed by a number of scientists in different programs/agencies, exercising their best scientific judgment, have in some cases resulted in different ADIs for the same chemical. The fact that different ADIs were generated (for example, by adopting different SFs) can be a source of considerable confusion when the ADIs are used exclusively in risk management decisionmaking. The existence of different ADIs need not imply that any of them is more "wrong"--or "right"--than the rest. It is more nearly a reflection of the honest difference in scientific judgment.

However, on occasion, these differences in judgment of the scientific data, can be interpreted as differences in the management of the risk. As a result, scientists may be inappropriately impugned, and/or perfectly justifiable risk management decisions may be tainted by charges of "tampering with the science." This unfortunate state of affairs arises, at least in part, from treating the ADI as an absolute measure of safety.

EPA Assessment of Risks Associated with Systemic Toxicity

The U.S. EPA approach to analyzing systemic toxicity data follow the general format set forth by NRC in its description of the risk assessment process (NRC, 1983). The determination of the presence of risk and its potential magnitude is made during the risk assessment process, which consists of hazard identification, dose-response assessment, exposure assessment, and risk characterization. Having been apprised by the risk assessor that a potential risk exists, the risk manager considers control options available under existing statutes and other relevant non-risk factors (e.g., benefits to be gained and costs to be incurred). All of these considerations go into the determination of the regulatory decision (Figure 1).

Table 1. Guidelines for the Use of Uncertainty Factors in Deriving Reference Doses and Modifying Factors

Standard Uncertainty Factors (UFs):

Use a 10-fold factor when extrapolating from valid experimental results in studies using prolonged exposure to average healthy humans. This factor is intended to account for the variation in sensitivity among the members of the human population and is referenced as "10H".

Use an additional 10-fold factor when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. This factor is intended to account for the uncertainty involved in extrapolating from animal data to humans and is referenced as "10A".

Use an additional 10-fold factor when extrapolating from less than chronic results on experimental animals when there are no useful long-term human data. This factor is intended to account for the uncertainty involved in extrapolating from less than chronic NOAELs to chronic NOAELs and is referenced as "10S".

Use an additional 10-fold factor when deriving an RfD from a LOAEL, instead of a NOAEL. This factor is intended to account for the uncertainty involved in extrapolating from LOAELs to NOAELs and is referenced as "10L".

Modifying Factor (MF):

Use professional judgment to determine the MF, which is an additional uncertainty factor that is greater than zero and less than or equal to 10. The magnitude of the MF depends upon the professional assessment of scientific uncertainties of the study and data base not explicitly treated above; e.g., the completeness of the overall data base and the number of species tested. The default value for the MF is 1.

*Source: Adapted from Dourson and Stara, 1983

Hazard Identification

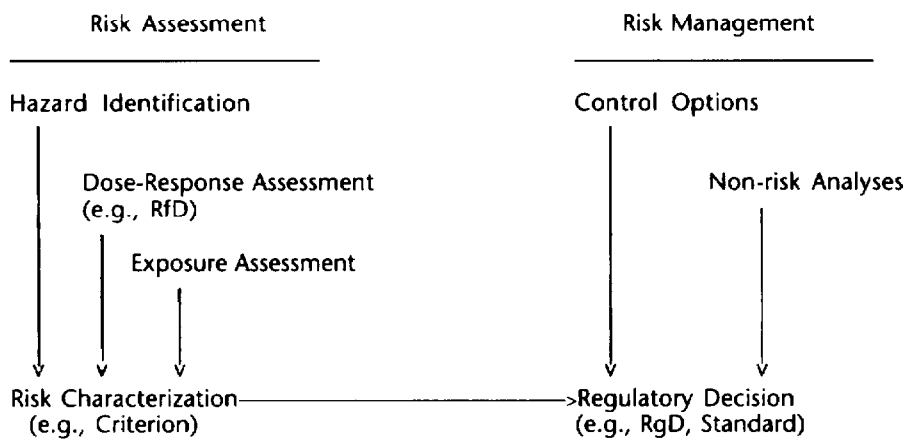
Evidence

Type of effect - Exposure to a given chemical, depending on the dose employed, may result in a variety of toxic effects. These may range from gross effects, such as death, to more subtle biochemical, physiologic, or pathologic changes. In assessments of the risk posed by a chemical, the toxic endpoints from all available studies are considered, although primary attention usually is given to the effect (the "critical effect") exhibiting the lowest NOAEL. In the case of chemicals with limited data bases, additional toxicity testing may be necessary before an assessment can be made.

Principal studies - Principal studies are those that contribute most significantly to the qualitative assessment of whether or not a particular chemical is potentially a systemic toxicant in humans. In addition, they may be

Figure 1.

Conceptual Framework for Risk Assessment and Risk Management*



*Source: Adapted from NRC, 1983

used in the quantitative dose-response assessment phase of the risk assessment. These studies are of two types: studies of human populations (epidemiologic investigations) and studies using laboratory animals.

1. Epidemiologic studies - Human data are often useful in qualitatively establishing the presence of an adverse effect in exposed human populations. When there is information on the exposure level associated with an appropriate endpoint, epidemiologic studies can also provide the basis for a quantitative dose-response assessment. The presence of such data obviates the necessity of extrapolating from animals to humans; therefore, human studies, when available, are given first priority, with animal toxicity studies serving to complement them.

   In epidemiologic studies, confounding factors that are recognized can be controlled and measured, within limits. Case reports and acute exposures resulting in severe effects provide support for the choice of critical toxic effect, but they are often of limited utility in establishing a quantitative relationship between environmental exposures and anticipated effects. Available human studies on ingestion are usually of this nature. Cohort studies and clinical studies may contain exposure-response information that can be used in estimating effect levels, but the method of establishing exposure must be evaluated for validity and applicability.

2. Animal studies - For most chemicals, there is a lack of appropriate information on effects in humans. In such cases, the principal studies are drawn from experiments conducted on nonhuman mammals, most often the rat, mouse, rabbit, guinea pig, hamster, dog, or monkey.

Supporting studies - These studies provide supportive, rather than definitive, information and can include data from a wide variety of sources. For example, metabolic and other pharmacokinetics studies can provide insights into the mechanism of action of a particular compound. By comparing the metabolism of the chemical exhibiting the toxic effect in the animal with the metabolism found in humans, it may be possible to assess the potential for toxicity in humans or to estimate the equitoxic dose in humans.

Similarly, in vitro studies can provide insights into the chemical's potential for biological activity; and under certain circumstances, consideration of structure-activity relationships between a chemical and other

structurally related compounds can provide clues to the test chemical's possible toxicity. More reliable in vitro tests are presently being developed to minimize the need for live-animal testing. There is also increased emphasis on generating mechanism-of-action and pharmacokinetics information as a means of increasing understanding of toxic processes in humans and nonhumans.

Route of exposure - The U.S. EPA often approaches the investigation of a chemical with a particular route of exposure in mind (e.g., an oral exposure for a drinking water contaminant or an inhalation exposure for an air contaminant). In most cases, the toxicologic data base does not include detailed testing on all possible routes of administration, with their possibly significant differences in factors such as mechanism-of-action and bioavailability. In general, the U.S. EPA's position is that the potential for toxicity manifested via one route of exposure is relevant to considerations of any other route of exposure, unless convincing evidence exists to the contrary. Consideration is given to potential differences in absorption or metabolism resulting from different routes of exposure, and whenever appropriate data (e.g., comparative metabolism studies) are available, the quantitative impacts of these differences on the risk assessment are delineated.

Length of exposure - The U.S. EPA is concerned about the potential toxic effects in humans associated with all possible exposures to chemicals. The magnitude, frequency, and duration of exposure may vary considerably in different situations. Animal studies are conducted using a variety of exposure durations (e.g., acute, subchronic, and chronic) and schedules (e.g., single, intermittent, or continuous dosing). Information from all these studies is useful in the hazard identification phase of risk assessment. For example, overt neurological problems identified in high-dose acute studies tend to reinforce the observation of subtle neurological changes seen in low-dose chronic studies. Special attention is given to studies involving low-dose, chronic exposures, since such exposures can elicit effects absent in higher dose, shorter exposures, through mechanisms such as accumulation of toxicants in the organisms.

Quality of the study - Evaluation of individual studies in humans and animals requires the consideration of several factors associated with a study's hypothesis, design, execution, and interpretation. An ideal study addresses a clearly delineated hypothesis, follows a carefully prescribed protocol, and includes sufficient subsequent analysis to support its conclusions convincingly.

In evaluating the results from such studies, consideration is given to many other factors, including chemical characterization of the compound(s) under study, the type of test species, similarities and differences between the test species and humans (e.g., chemical absorption and metabolism), the number of individuals in the study groups, the number of study groups, the spacing and choice of dose levels tested, the types of observations and methods of analysis, the nature of pathologic changes, the alteration in metabolic responses, the sex and age of test animals, and the route and duration of exposure.

Weight-of-Evidence Determination

As the culmination of the hazard identification step, a discussion of the weight-of-evidence summarizes the highlights of the information gleaned from the principal and supportive studies. Emphasis is given to examining the results from different studies to determine the extent to which a consistent, plausible picture of toxicity emerges. For example, the following factors add to the weight of the evidence that the chemical poses a hazard to humans: similar results in replicated animal studies by different investigators; similar effects across sex, strain, species, and route of exposure; clear evidence of a dose-response relationship; a plausible relation between data on metabolism, postulated mechanism-of-action, and the effect of concern; similar toxicity exhibited by structurally related compounds; and some link between the chemical and evidence of the effect of concern in humans.

Dose-Response Assessment

Concepts and Problems

Empirical observations have generally revealed that as the dosage of a toxicant is increased, the toxic response (in terms of severity and/or incidence of effect) also increases. This dose-response relationship is well- founded in the theory and practice of toxicology and pharmacology. Such behavior is observed in the following instances: in quantal responses, in which the proportion of responding individuals in a population increases with dose; in graded responses, in which the severity of the toxic response within an individual increases

with dose; and in continuous responses, in which changes in a biological parameter (e.g., body or organ weight) vary with dose.

In evaluating a dose-response relationship, certain difficulties arise. For example, one must decide on the critical endpoint to measure as the "response." One must also decide on the correct measure of "dose." In addition to the interspecies extrapolation aspects of the question of the appropriate units for dose, the more fundamental question of administered dose versus absorbed dose versus target organ dose should be considered. These questions are the subject of much current research.

Selection of the Critical Data

Critical study - Data from experimental studies in laboratory animals are often selected as the governing information when performing quantitative risk assessments, since available human data are usually insufficient for this purpose. These animal studies typically reflect situations in which exposure to the toxicant has been carefully controlled and the problems of heterogeneity of the exposed population and concurrent exposures to other toxicants have been minimized. In evaluating animal data, a series of professional judgments are made which involve, among others, consideration of the scientific quality of the studies. Presented with data from several animal studies, the risk assessor first seeks to identify the animal model that is most relevant to humans, based on the most defensible biological rationale (e.g., for instance using comparative pharmacokinetics data). In the absence of a clearly most relevant species, the most sensitive species (i.e., the species showing a toxic effect at the lowest administered dose) is used by risk assessors at U.S. EPA, since there is no assurance that humans are not at least as innately sensitive as the most sensitive species tested. This selection process is more difficult when the routes of exposure in the animal tests are different from those involved in the human situation under investigation. In order to use data from controlled studies of genetically homogeneous animals, the risk assessor must also extrapolate from animals to humans and from high experimental doses to comparatively low environmental exposures, and must account for human heterogeneity and possible concurrent human exposures to other chemicals.

Although for most chemicals there is a lack of well-controlled cohort studies investigating noncancer endpoints, in some cases an epidemiologic study may be selected as the critical data (e.g., in cases of cholinesterase inhibition). Risk assessments based on human data have the advantage of avoiding the problems inherent in interspecies extrapolation. In many instances, use of such studies, as is the case with animal investigations, involves extrapolation from relatively high doses (such as those found in occupational settings) to the low doses found in the environmental situations to which the general population is more likely to be exposed. In some cases, a well-designed and well-conducted epidemiologic study that shows no association between known exposures and toxicity can be used to directly project an RfD (as has been done in the case of fluoride).

Critical data - In the simplest terms, an experimental exposure level is selected from the critical study that represents the highest level tested in which "no adverse effect" was demonstrated. This "no-observed-adverse-effect-level" (NOAEL) is the key datum gleaned from the study of the dose-response relationship and, traditionally, is the primary basis for the scientific evaluation of the risk posed to humans by systemic toxicants. This approach is based on the assumption that if the critical toxic effect is prevented, then all toxic effects are prevented.

More formally, the NOAEL is defined in this discussion as the highest experimental dose of a chemical at which there is no statistically or biologically significant increase in frequency or severity of an adverse effect in individuals in an exposed group when compared with individuals in an appropriate control group. As noted above, there may be sound professional differences of opinion in judging whether or not a particular response is adverse. In addition, the NOAEL is a function of the size of the population under study. Studies with a small number of subjects are less likely to detect low-dose effects than studies using larger numbers of subjects. Also, if the interval between doses in an experiment is large, it is possible that the experimentally determined NOAEL is lower than that which would be observed in a study using intervening doses.

Critical endpoint - As noted under "Traditional Approach to Assessing Systemic Toxicity", a chemical may elicit more than one toxic effect (endpoint), even in one test animal, or in tests of the same or different duration (acute, subchronic, and chronic exposure studies). In general, NOAELs for these effects will differ. The critical endpoint used in the dose- response assessment is the effect exhibiting the lowest NOAEL.

Reference Dose (RfD)

The reference dose (RfD) and uncertainty factor (UF) concepts have been developed by the RfD Work Group in response to many of the problems associated with ADIs and SFs, as outlined under "Traditional Approach to Assessing Systemic Toxicity" above. The RfD is a benchmark dose operationally derived from the NOAEL by consistent application of generally order-of-magnitude uncertainty factors (UFs) that reflect various types of data sets used to estimate RfDs. For example, a valid chronic animal NOAEL is normally divided by an UF of 100. In addition, a modifying factor (MF), is sometimes used which is based on a professional judgment of the entire data base of the chemical. These factors and their rationales are presented in Table 1.

The RfD is determined by use of the following equation:

$$RfD = NOAEL / (UF \times MF)$$

which is the functional equivalent of Equation 1. In general, the RfD is an estimate (with uncertainty spanning perhaps an order-of-magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD is generally expressed in units of milligrams per kilogram of body weight per day (mg/kg/day).

The RfD is useful as a reference point from which to gauge the potential effects of the chemical at other doses. Usually, doses less than the RfD are not likely to be associated with adverse health risks, and are therefore less likely to be of regulatory concern. As the frequency and/or magnitude of the exposures exceeding the RfD increase, the probability of adverse effects in a human population increases. However, it should not be categorically concluded that all doses below the RfD are "acceptable" (or will be risk-free) and that all doses in excess of the RfD are "unacceptable" (or will result in adverse effects).

The U.S. EPA is attempting to standardize its approach to determining RfDs. The RfD Work Group has developed a systematic approach to summarizing its evaluations, conclusions, and reservations regarding RfDs in a "cover sheet" of a few pages in length. The cover sheet includes a statement on the confidence (high, medium, or low) the evaluators have in the stability of the RfD. High confidence indicates the judgment that the RfD is unlikely to change in the future because there is consistency among the toxic responses observed in different sexes, species, study designs, or in dose-response relationships, or that the reasons for existing differences are well understood. High confidence is often given to RfDs that are based on human data for the exposure route of concern, since in such cases the problems of interspecies extrapolation have been avoided. Low confidence indicates the judgment that the data supporting the RfD may be of limited quality and/or quantity and that additional information could result in a change in the RfD.

Exposure Assessment

The third step in the risk assessment process focuses on exposure issues. For a full discussion of exposure assessment, consult U.S. EPA's guidelines on the subject (U.S. EPA, 1987). In brief, the exposure assessment includes consideration of the size and nature of the populations exposed and the magnitude, frequency, duration and routes of exposure, as well as evaluation of the nature of the exposed populations.

Risk Characterization

Risk characterization is the final step in the risk assessment process and the first input to the risk management (regulatory action) process. The purpose of risk characterization is to present the risk manager with a synopsis and synthesis of all the data that should contribute to a conclusion with regard to the nature and extent of the risk, including:

a. The qualitative ("weight-of-evidence") conclusions as to the likelihood that the chemical may pose a hazard to human health.

b. A discussion of the dose-response information considered in deriving the RfD, including the UFs and MFs used.

c. Data on the shapes and slopes of the dose-response curves for the various toxic endpoints, toxicodynamics (absorption and metabolism), structure-activity correlations, and the nature and severity of the observed effects.

d. Estimates of the nature and extent of the exposure and the number and types of people exposed.

e. Discussion of the overall uncertainty in the analysis, including the major assumptions made, scientific judgments employed, and an estimate of the degree of conservatism involved.

In the risk characterization process, a comparison is made between the RfD and the estimated (calculated or measured) exposure dose (EED). The EED should include all sources and routes of exposure involved. If the EED is less than the RfD, the need for regulatory concern is likely to be small.

An alternative measure that may be useful to some risk managers is the margin of exposure (MOE), which is the magnitude by which the NOAEL of the critical toxic effect exceeds the estimated exposure dose (EED), where both are expressed in the same units:

MOE = NOAEL (experimental dose) / EED (human dose).

When the MOE is equal to or greater than UF x MF, the need for regulatory concern is likely to be small.

"Hypothetical, Simplified Example of Determining and Using RfD" contains an example of the use of the concepts of NOAEL, UF, MF, RfD, EED, and MOE.

Application in Risk Management

Once the risk characterization is completed, the focus turns to risk management. In reaching decisions, the risk manager utilizes the results of risk assessment, other technological factors, and legal, economic and social considerations in reaching a regulatory decision. These additional factors include efficiency, timeliness, equity, administrative simplicity, consistency, public acceptability, technological feasibility, and nature of the legislative mandate.

Because of the way these risk management factors may impact different cases, consistent -- but not necessarily identical -- risk management decisions must be made on a case-by-case basis. For example, the Clean Water Act calls for decisions with "an ample margin of safety"; the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) calls for "an ample margin of safety," taking benefits into account; and the Safe Drinking Water Act (SDWA) calls for standards which protect the public "to the extent feasible." Consequently, it is entirely possible and appropriate that a chemical with a specific RfD may be regulated under different statutes and situations through the use of different "regulatory doses (RgDs)."

That is, after carefully considering the various risk and nonrisk factors, regulatory options, and statutory mandates in a given case (i), the risk manager selects the appropriate statutory alternative for arriving at an "ample" or "adequate" margin of exposure [MOE(i)]. As shown in Equation 2 below, this procedure establishes the regulatory dose, RgD(i) (e.g., a tolerance under FIFRA or a maximum contaminant level under SDWA), applicable to the case in question:

$$RgD(i) = NOAEL / MOE(i) \qquad \text{(Equation 2)}$$

Note that different RgDs are possible for a given chemical with a single RfD. Note also that comparing the RfD to a particular RgD(i) is equivalent to comparing the MOE(i) with the UF x MF:

$$RfD/RgD(i) = MOE(i) / (UF \times MF).$$

In assessing the significance of a case in which the RgD is greater (or less) than the RfD, the risk manager should carefully consider the case- specific data compiled by the risk assessors, as discussed under "Risk Characterization". In some cases, additional explanation and interpretation may be required from the risk assessors in order to arrive at a responsible and clearly articulated final decision on the RgD.

It is generally useful to the risk manager to have information regarding the contribution to the RfD from various environmental media (e.g., air, water and food). Such information can provide insights that are helpful in

choosing among available control options. However, in cases in which site-specific criteria are being considered, local exposures through various media can often be determined more accurately than exposure estimates based upon generic approaches. In such cases, the exposure assessor's role is particularly important. For instance, at a given site, consumption of fish may clearly dominate the local exposure routes, while, on a national basis, fish consumption may play a minor role compared to ingestion of treated crops.

Work is underway in the U.S. EPA to apportion the RfD among the various environmental media. For example, consider the case of a food-use pesticide which is a contaminant in drinking water. In selecting among risk management actions under the Safe Drinking Water Act, it might be prudent to assume an RfD for drinking water purposes which is some fraction of the total RfD. Such an apportionment would explicitly acknowledge the possible additional exposure from ingestion of treated crops. The apportionment of the RfD would, in general, provide additional guidance for risk managers of the various media- specific programs.

Other Directions

In addition to the development of reference doses, the U.S. EPA is pursuing other lines of investigation for systemic toxicity. For example, the Office of Air Quality Planning and Standards is using probabilistic risk assessment procedures for criteria pollutants. In this procedure, the population at risk is characterized, and the likelihood of the occurrence of various effects is predicted through the use of available scientific literature and of scientific experts' rendering their judgments concerning dose-response relationships. This dose-response information is then combined with the results of the exposure analysis to generate population risk estimates for alternative standards. Through the use of these procedures, decisionmakers are presented with ranges of risk estimates in which uncertainties associated with both the toxicity and exposure information are explicitly considered. The Office of Policy, Planning and Evaluation is investigating similar procedures in order to balance health risk and cost. In addition, scientists in the Office of Research and Development have initiated a series of studies designed to increase the reliability of risk assessments. They are investigating the use of extrapolation models as a means of estimating RfDs, taking into account the statistical variability of the NOAEL and underlying UFs. ORD is also exploring procedures for conducting health risk assessments that involve less- than-lifetime exposures. Finally, they are working on approaches to ranking the severity of different toxic effects.

Hypothetical, Simplified Example of Determining and Using RfD

Experimental Results

Suppose the U.S. EPA had a sound 90-day subchronic gavage study in rats with the data in Table 2.

Analysis

Determination of the Reference Dose (RfD)

Using the NOAEL - Because the study is on animals and of subchronic duration,

UF = 10H x 10A x 10S = 1000 (Table 1)

In addition, there is a subjective adjustment (MF) based on the high number of animals (250) per dose group: MF = 0.8. These factors then give UF x MF = 800, so that

RfD = NOAEL/(UF x MF) = 5/800 = 0.006 (mg/kg/day).

Table 2. Hypothetical Data to Illustrate the Reference Dose Concept

Dose mg/kg/day	Observation	Effect Level
0	Control—no adverse effects observed	–
1	No statistically or biologically significant differences between treated and control animals	NOEL
5	% decrease* in body weight gain (not considered to be of biological significance); increased ratio of liver weight to body weight; histopathology indistinguishable from controls; evaluated liver enzyme levels	NOAEL
25	20% decrease* in body weight gain; increased* ratio of liver weight to body weight; enlarged, fatty liver with vacuole formation; increased* liver enzyme levels	LOAEL

*Statistically significant compared to controls.

Using the LOAEL - If the NOAEL is not available, and if 25 mg/kg/day had been the lowest dose tested that showed adverse effects,

UF = 10H x 10A x 10S x 10L = 10,000 (Table 1).

Using again the subjective adjustment of MF = 0.8, one obtains

RfD = LOAEL/(UF x MF) = 25/8000 = 0.003 (mg/kg/day).

Risk Characterization Considerations

Suppose the estimated exposure dose (EED) for humans exposed to the chemical under the proposed use pattern were 0.01 mg/kg/day (i.e., the EED is greater than the RfD). Viewed alternatively, the MOE is:

MOE = NOAEL/EED = 5 (mg/kg/day) / 0.01 (mg/kg/day) = 500.

Because the EED exceeds the RfD (and the MOE is less than the UF x MF), the risk manager will need to look carefully at the data set, the assumptions for both the RfD and the exposure estimates, and the comments of the risk assessors. In addition, the risk manager will need to weigh the benefits associated with the case, and other non-risk factors, in reaching a decision on the regulatory dose (RgD).

APPENDIX H

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Appendix I

Chemicals Available in IRIS

USE ONLY FOR SCREENING Values from IRIS 9/1/90
Consult IRIS for Update and Whenever Possible, Site Specific
Lipid, Consumption and Bioaccumulation Factors Should be
Used in Application of RAC in Regulatory Action.

CAS number	Chemical Name	RfD mg/kg/day	q1* /mg/kg/day	Estimated BCF 3% Lipid	RAC (mg/l) RL: 10E-6 0.0065 kg/day Consumption	RAC (mg/l) RL: 10E-6 0.020 kg/day Consumption
50000	Formaldehyde	0.2	**			
50293	p,p'-DDT	0.0005		40000	0.0001	0.00004
50328	Benzo[a]pyrene	**	**	10960		
51285	2,4-Dinitrophenol	0.002		5.2	4	1
55185	N-Nitrosodiethylamine	**	150	0.40	0.0002	0.00006
56235	Carbon tetrachloride	0.0007	0.13	29.72	0.003	0.0009
56359	Tributyltin oxide	0.00003				
56382	Parathion	**	**	87.6		
57125	Cyanide, free	0.02				
57249	Strychnine	0.0003		0.4	8	3
57749	Chlordane	0.00006	1.3	3804	0.000002	0.0000007
58899	gamma-Hexachlorocyclohexane	0.0003		146.8	0.00002	0.000007
58902	2,3,4,6-Tetrachlorophenol	0.03		416	0.8	0.3
60297	Ethyl ether	0.2		0.77	3000	900
60515	Dimethoate	0.0002		0.4	6	2
60571	Dieldrin	0.00005	16	32.04	0.00002	0.000007
62384	Phenylmercuric acetate	0.00008		0.58	2	0.5
62533	Aniline	**	0.0057	0.84	2	0.7
62737	Dichlorvos	0.0008	0.29	0.4	0.1	0.3
62759	N-Nitrosodimethylamine	**	51	0.4	0.0005	0.0002
63252	Carbaryl	0.1		12.2	90	30
64186	Formic acid	2				
65850	Benzoic acid	4		4.92	9000	3000
67561	Methanol	0.5		0.4	14000	4000
67641	Acetone	0.1	**	0.4		
67663	Chloroform	0.01		5.56	20	6
67721	Hexachloroethane	0.001	0.014	700	0.001	0.0004
70304	Hexachlorophene	0.0003		40000	0.00008	0.00002
71363	n-Butanol	0.1		0.71	2000	500

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71432	Benzene	**	0.029	7.84	0.05	0.01
71556	1,1,1-Trichloroethane	0.09		14.52	70	20
72208	Endrin	0.0003	**	32.04	0.1	0.03
72435	Methoxychlor	0.005	**	2564	0.02	0.007
72548	p,p'-DDD	**	0.24	12840	0.000004	0.000001
72559	p,p'-DDE	**	0.34	40000	0.0000008	0.0000002
74839	Bromomethane	0.0014		1.13	10	4
74908	Hydrogen cyanide	0.02				
75058	Acetonitrile	0.006		0.4	200	50
75070	Acetaldehyde	**	**	0.4		
75092	Dichloromethane	0.06	0.0075	1.54	0.9	0.3
75150	Carbon disulfide	0.1				
75252	Bromoform	0.02	0.0079	11.92	0.1	0.04
75274	Bromodichloromethane	0.02		7.16	30	10
75354	1,1-Dichloroethylene	0.009	0.6	7.44	0.002	0.0008
75694	Trichloromonofluoromethane	0.3		13.36	200	80
75718	Dichlorodifluoromethane	0.2		6	400	100
75876	Chloral	0.002		3.23	7	2
75990	Dalapon, sodium salt	0.03		2.31	100	50
76131	CFC-113	30		63.2	5000	2000
76448	Heptachlor	0.0005	4.5	692	0.000004	0.000001
77474	Hexachlorocyclopentadiene	0.007	**	744	0.1	0.03
77781	Dimethyl sulfate	**	**	0.4		
78002	Tetraethyl lead	0.0000001				
78488	Merphos oxide	0.00003				
78591	Isophorone	0.2	0.0041	9	0.3	0.09
78831	Isobutyl alcohol	0.3		0.56	6000	2000
78864	2-Chlorobutane	**	**	15.5		
78933	Methyl ethyl ketone	0.05	**	0.4	1000	400

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79005	1,1,2-Trichloroethane	0.004	0.057	6.64	0.03	0.009
79016	Trichloroethylene	**	0.011	9.84	0.1	0.03
79061	Acrylamide	0.0002	4.5	0.4	0.006	0.002
79107	Acrylic acid	0.08		0.4	2000	700
79221	Methyl chlorocarbonate	**				
79345	1,1,2,2-Tetrachloroethane	**	0.20	19.52	0.003	0.0009
80057	Bishpenol A.	0.05		166.8	3	1
81812	Warfarin	0.0003		4.76	0.7	0.2
82688	Pentachloronitrobenzene	0.003		1160	0.03	0.009
83794	Rotenone	0.004		91.2	0.5	0.2
84662	Diethyl phthalate	0.8	**	17.2	500	200
84720	Ethylphthalyl ethylglycolate	3		7.92	4000	1000
84742	Dibutyl phthalate	0.1	**	808	1	0.4
85007	Diquat	0.0022				
85449	Phthalic anhydride	2				
85687	Butyl benzyl phthalate	0.2	**	1120	2	0.6
85701	Butylphthalyl butylglycolate	1		372.4	30	9
86306	N-Nitrosodiphenylamine	**	0.0049	50	0.04	0.01
87683	Hexachlorobutadiene	0.002	0.078	397.2	0.0004	0.0001
87821	Hexabromobenzene	0.002		4560	0.005	0.002
87865	Pentachlorophenol	0.03		1568	0.2	0.07
88062	2,4,6-Trichlorophenol	**	**	106		
88857	Dinoseb	0.001		239.2	0.05	0.01
91941	3,3'-dichlorobenzidine	**	0.45	117	0.0002	0.00007
92524	1,1-Biphenyl	0.05		243.2	2	0.7
92875	Benzidine	0.002	230	2.8	0.00002	0.000005
93652	MCPP	0.003		48	0.7	0.2
93721	2,4,5-TP	0.008	**	143.2	0.6	0.2
93765	2,4,5-Trichlorophenoxyacetic acid	0.01		81.6	1	0.4

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94746	MCPA	0.0005		27.32	0.2	0.06
94757	2,4-Dichlorophenoxyacetic acid	0.01		20.96	5	2
94815	MCPB	0.01		50.4	2	0.7
94826	4-(2,4-Dichlorophenoxybutyric acid	0.008		38.56	2	0.7
95487	o-Cresol	0.05	**	7.6	70	20
95498	o-Chlorotoluene	0.02		88	2	0.8
95501	1,2-Dichlorobenzene	0.09	**	103	9	3
95578	2-Chlorophenol	0.005		8.8	6	2
95658	3,4-Dimethylphenol	0.001		24.72	0.4	0.1
95943	1,2,4,5-Tetrachlorobenzene	0.0003		1404	0.002	0.0007
95954	2,4,5-Trichlorophenol	0.1		176.4	6	2
96184	1,2,3-Trichloropropane	0.006		5.84	10	4
98011	Furfural	0.003		0.54	60	20
98077	Benzotrichloride	**	**	283		
98828	Cumene	0.04		138	3	1
98862	Acetophenone	0.1		2.82	400	100
98953	Nitrobenzene	0.0005		4.92	1	0.4
99354	1,3,5-Trinitrobenzene	0.00005		1.93	0.3	0.09
99650	m-Dinitrobenzene	0.0001		3.08	0.4	0.1
100414	Ethylbenzene	0.1	**	66.8	20	5
100425	Styrene	0.2		29.24	80	20
100447	Benzyl chloride	**	0.17	21.5	0.003	0.001
100527	Benzaldehyde	0.1		2.42	500	100
101213	Chlorpropham (CIPC)	0.2		96.4	20	7
101553	p-Bromodiphenyl ether	**	**	2179		
101611	44'Methylenebis(NN'dimethyl)aniline	**	0.046	888	0.0003	0.00009
103231	Di-(2-ethylhexyl)adipate	0.7		40000	0.2	0.06
103333	Azobenzene	**	0.11	175.2	0.0006	0.0002
105602	Caprolactam	0.5		0.4	10000	4000

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106376	1,4-Dibromobenzene	0.01		181.2	0.6	0.2
106445	p-Cresol	0.05	**	7.6	70	20
106478	p-Chloroaniline	0.004		5.32	8	2
106898	Epichlorohydrin	0.002	0.0099	0.4	3	0.9
106934	1,2-Dibromoethane	**	85	3.76	0.00003	0.00001
106990	1,3-Butadiene	**		5.08		
107028	Acrolein	**	**	0.4		
107051	Allyl chloride	**	**	2.20		
107062	1,2-Dichloroethane	**	910	2.26	0.000005	0.000002
107131	Acrylonitrile	**	0.54	0.4	0.05	0.02
107186	Allyl alcohol	0.005		0.4	100	40
107211	Ethylene glycol	2		0.4	60000	20000
107302	Chloromethyl methyl ether	**	**	0.4		
108101	Methyl isobutyl ketone	0.05		1.38	400	100
108316	Maleic anhydride	0.1				
108394	m-Cresol	0.05	**	7.6	70	20
108452	m-Phenylenediamine	0.006		0.4	200	50
108883	Toluene	0.2	**	25.52	80	30
108907	Chlorobenzene	0.02	**	28	8	3
108918	Cyclohexylamine	0.2		1.92	1000	400
108941	Cyclohexanone	5		0.69	80000	30000
108952	Phenol	0.6		2.33	3000	900
109693	1-Chlorobutane	**	**	15.5		
110009	Furan	0.001		1.75	6	2
110543	n-Hexane	**	**	179		
110861	Pyridine	0.001		0.53	20	7
111444	Bis(chloroethyl)ether	**	1.1	0.98	0.01	0.003
114261	Baygon	0.004		2.81	20	5
115297	Endosulfan	0.00005				

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115322	Dicofol	**	0.44	9680	0.000003	0.0000008
116063	Aldicarb	**	**	1.21		
117817	Bis(2-ethylhexyl)phthalate	0.02	0.014	40000	0.00002	0.000006
118741	Hexachlorobenzene	0.0008		18800	0.0005	0.0001
118967	2,4,6-Trinitrotoluene	0.0005		2.27	2	0.8
120127	Anthracene	0.3	**	550	6	2
120616	Dimethyl terephthalate	0.1		11.56	100	30
120821	1,2,4-Trichlorobenzene	**	**	383.6		
120832	2,4-Dichlorophenol	0.003		42	0.8	0.3
121142	2,4/2,6-Dinitrotoluene mixture	**	0.68	5.96	0.002	0.0009
121697	N-N-Dimethylaniline	0.002		11.16	2	0.6
121755	Malathion	0.02		3.83	60	20
121824	RDX	0.003	0.11			
122349	Simazine	0.002	**	15.36	1	0.5
122394	Diphenylamine	0.025		115.2	2	0.8
122429	Propham	0.02		18	10	4
122667	1,2-Diphenylhydrazine	**	0.80	35.36	0.0004	0.0001
123331	Maleic hydrazide	0.5		0.4	10000	4000
123911	1,4-Dioxane	**	0.011	0.4	3	0.8
124403	Dimethylamine	**	**	0.4		
124481	Dibromochloromethane	0.02		9.24	20	8
126987	Methacrylonitrile	0.0001		0.42	3	0.8
127184	Tetrachloroethylene	0.01		38.72	3	0.9
129000	Pyrene	0.03	**	1280	0.3	0.08
131113	Dimethyl phthalate	**	**	2.51		
131895	4,6-Dinitro-o-cyclohexyl phenol	0.002		800	0.03	0.009
133062	Captan	0.013				
133073	Folpet	0.1	0.0035			
133904	Chloramben	0.015		8.24	20	6

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137268	Thiram	0.005				
139402	Propazine	0.02		47.2	5	1
141662	Bidrin	0.0001		0.4	3	0.9
141786	Ethyl acetate	0.9		0.54	20000	6000
143339	Sodium cyanide	0.04				
145733	Endothall	0.02		0.4	600	200
148185	Sodium diethyldithiocarbamate	0.03				
150505	Merphos	0.00003				
151508	Potassium cyanide	0.05				
156605	trans-1,2-Dichloroethylene	0.02		2.5	90	30
206440	Fluoranthene	0.04	**	1280	0.3	0.1
298000	Methyl parathion	0.00025		25.48	0.1	0.03
298044	Disulfoton	0.00004		60	0.007	0.002
300765	Naled	0.002		65.9	0.3	0.1
302012	Hydrazine/Hydrazine sulfate	**	3.0			
309002	Aldrin	0.00003	17	1638	0.0000004	0.0000001
319846	alpha-Hexachlorocyclohexane	**	6.3	146.8	0.00001	0.000004
319857	beta-Hexachlorocyclohexane	**	1.8	146.8	0.00004	0.00001
319868	delta-Hexachlorocyclohexane	**	**	146.8		
330541	Diuron	0.002		23.56	0.9	0.3
330552	Linuron	0.002	**	51.6	0.4	0.1
460195	Cyanogen	0.04				
504245	4-Aminopyridine	**	**	0.4		
506616	Potassium silver cyanide	0.2				
506649	Silver cyanide	0.1				
506683	Cyanogen bromide	0.09				
506774	Chlorine cyanide	0.05				
507200	t-Butylchloride	**	**	12.2		
510156	Chlorobenzilate	0.02		434	0.5	0.2

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541731	1,3-Dichlorobenzene	**	**	103		
542621	Barium cyanide	0.07				
542756	1,3-Dichloropropene	0.0003	**	2.94	1	0.4
542881	Bis(chloromethyl)ether	**	220	1.05	0.00005	0.00002
544923	Copper cyanide	0.005				
556887	Nitroguanidine	0.1				
556887	Nitroguanidine	0.1	**			
557211	Zinc cyanide	0.05				
563122	Ethion	0.0005		191	0.03	0.009
563688	Thallium acetate	0.00009	**			
576261	2,6-Dimethylphenol	0.0006		24.72	0.3	0.08
592018	Calcium Cyanide	0.04				
598776	1,1,2-Trichloropropane	0.005		17.4	3	1
608731	tech-Hexachlorocyclohexane	0.003	1.8	146.8	0.00004	0.00001
608935	Pentachlorobenzene	0.0008		5120	0.002	0.0005
615543	1,2,4-Tribromobenzene	0.005		524	0.1	0.03
621647	N-Nitrosodi-N-propylamine	**	7.0	1.85	0.0009	0.0003
630104	Selenourea	0.005				
630206	1,1,1,2-Tetrachloroethane	0.03		39.72	8	3
709988	Propanil	0.005		105.2	0.5	0.2
732116	Phosmet	0.02		15.2	10	4
759944	S-Ethyl dipropylthiocarbamate	0.025		68.4	4	1
765344	Glycidyaldehyde	0.0004				
834128	Ametryn	0.009		40.4	2	0.8
886500	Terbutryn	0.001		83.6	0.1	0.04
924163	N-Nitroso-di-n-butylamine	**	5.4	12.68	0.0002	0.00005
930552	N-Nitrosopyrrolidine	**	2.1	0.4	0.01	0.004
944229	Fonofos	0.002		193.6	0.1	0.04
950378	Methidathion	0.001				

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957517	Diphenamid	0.03		10.72	30	10
961115	Tetrachlorovinphos	0.03		64.8	5	2
1024573	Heptachlor epoxide	0.000013	9.1	13.72	0.00009	0.00003
1071836	Glyphosate	0.1	**			
1116547	N-Nitrosodiethanolamine	**	2.8	0.4	0.01	0.003
1163195	Decabromodiphenyl ether	0.01	**	40000	0.003	0.0009
1314325	Thallic oxide	**	**			
1314621	Vanadium pentoxide	0.009				
1314847	Zinc phosphide	0.0003				
1330207	Xylenes	2	**			
1332214	Asbestos	**	**			
1336363	Polychlorinated biphenyls	**	7.7			
1445756	Diisopropyl methyl phosphonate	0.08		0.4	2000	700
1563662	Carbofuran	0.005		14.32	4	1
1582098	Trifluralin	0.0075	0.0077	1784	0.0008	0.0003
1596845	Alar	0.15		0.4	4000	1000
1610180	Prometon	0.015		40.8	4	1
1646884	Aldicarb sulfone	0.0003		0.4	8	3
1689845	Bromoxynil	0.02		36.36	6	2
1689992	Bromoxynil octanoate	0.02		5800	0.04	0.01
1861321	Dacthal	0.5		327.6	20	5
1861401	Benefin	0.3		1784	2	0.6
1897456	Chlorothalonil	0.015		178.4	0.9	0.3
1910425	Paraquat	0.0045				
1912249	Atrazine	0.005	**	26.96	2	0.6
1918009	Dicamba	0.03		14.08	20	7
1918021	Picloram	0.07		11.56	70	20
1918167	Propachlor	0.013		16.72	9	3
1929777	Vernam	0.001		179.2	0.06	0.02

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1929824	Nitrapyrin	0.0015		79.2	0.2	0.07
2008415	Butylate	0.1		292	4	1
2050477	p,p'-Dibromodiphenyl ether	**	**	11882		
2104645	EPN	0.00001		648	0.0002	0.00005
2164172	Fluometuron	0.013		10.08	10	5
2212671	Molinate	0.002		35.28	0.6	0.2
2303175	Triallate	0.013		388	0.4	0.1
2310170	Phosalone	0.0025				
2312358	Propargite	0.02				
2385855	Mirex	0.000002		752	0.00003	0.000009
2425061	Captafol	0.002				
2439103	Dodine	0.004				
2691410	Octahydro-1,3,5,7-tetranitro-1,3,5,	0.05				
2921882	Chlorpyrifos	0.003		800	0.04	0.01
3337711	Asulam	0.05		0.4	1000	500
3689245	Tetraethyldithiopyrophosphate	0.0005				
5234684	Carboxin	0.1		3.37	300	100
5902512	Terbacil	0.013		5.4	30	8
6108107	epsilon-Hexachlorocyclohexane	**	**	146.8		
6533739	Thallium carbonate	0.00008	**			
7287196	Prometryn	0.004		71.2	0.6	0.2
7439921	Lead and compounds	**	**			
7439965	Manganese	0.1	**			
7439976	Mercury, (inorganic)	**				
7440020	Nickel, soluble salts	0.02	**			
7440144	Radium 226 and 228	**	**			
7440144	Radium 228 (and 226)	**	2.6E-5/pCi/L			
7440224	Silver	0.003				
7440360	Antimony	0.0004				

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CAS number	Chemical Name	RfD mg/kg/day	q1* /mg/kg/day	Estimated BCF 3% Lipid	RAC (mg/l) RL: 10E-6 0.0065 kg/day Consumption	RAC (mg/l) RL: 10E-6 0.020 kg/day Consumption
7440382	Arsenic, inorganic	**	**			
7440393	Barium	0.07				
7440417	Beryllium	0.005	4.3			
7440428	Boron (Boron and Borates only)	0.09				
7440439	Cadmium	**	**			
7440473	Chromium(VI)	0.005	**			
7440508	Copper	**	**			
7440611	Uranium, natural	**	**			
7446186	Thallium(I) sulfate	0.00008	**			
7723140	White phosphorus	0.00002	**			
7773060	Ammonium sulfamate	0.25				
7782414	Fluorine (soluble fluoride)	0.06				
7783008	Selenious acid	0.003				
7783064	Hydrogen sulfide	0.003				
7791120	Thallium chloride	0.00008	**			
7803512	Phosphine	0.0003				
8001352	Toxaphene	**	1.1	414	0.00002	0.000008
8001589	Creosote	**	**			
8007452	Coke oven emissions	**				
8065483	Demeton	0.00004				
10102439	Nitric oxide	0.1				
10102440	Nitrogen dioxide	1				
10102451	Thallium nitrate	0.00009	**			
10265926	Methamidophos	0.00005		0.4	1	0.4
10453868	Resmethrin	0.03		11900	0.03	0.009
10595956	N-Nitroso-N-methylethylamine	**	22	0.4	0.001	0.0004
12035722	Nickel subsulfide	**	**			
12039520	Thallium selenite	0.00009	**			
12122677	Zineb	0.05				

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12427382	Maneb	0.005				
13463393	Nickel carbonyl	**	**			
13593038	Quinalphos	0.0005		42.8	0.1	0.04
13684634	Phenmedipham	0.25		124	20	7
14797558	Nitrate	**				
14797650	Nitrite	0.1				
14859677	Radon 222	**	1.8E-6/pCi/L			
15299997	Napropamide	0.1		156	7	2
15972608	Alachlor	0.01		226	0.5	0.2
16065831	Chromium(III)	1				
16672870	Ethephon	0.005				
16752775	Methomyl	0.025				
17804352	Benomyl	0.05				
19044883	Oryzalin	**		31.1		
19408743	Hexachlorodibenzo-p-dioxin mixture	**	6200			
19666309	Oxadiazon	0.005				
20859738	Aluminum Phosphide	0.0004				
21087649	Metribuzin	0.025				
21725462	Cyanazine	0.002		3.64	6	2
22224926	Fenamiphos	0.00025		21.5	0.1	0.04
22967926	Methyl mercury	0.0003				
23135220	Oxamyl	0.025				
23564058	Thiophanate-methyl	0.08		2.92	300	100
23950585	Pronamide	0.075		33.92	20	8
24307264	Mepiquat chloride	0.03				
25057890	Bentazon	0.0025				
25329355	Pentachlorocyclopentadiene	**	**			
26628228	Sodium azide	0.004				
27314132	Norflurazon	0.04				

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28249776	Thiobencarb	0.01		71.6	2	0.5
29232937	Pirimiphos-methyl	0.01		66.7	2	0.5
30560191	Acephate	**	0.0087	0.4	3	1
32534819	Pentabromodiphenyl ether	0.002	**			
32536520	Octabromodiphenyl ether	0.003	**			
33089611	Amitraz	0.0025				
33820530	Isopropalin	0.015		5520	0.03	0.01
34014181	Tebuthiuron	0.07		0.4	2000	600
35367385	Diflubenzuron	0.02		44.8	5	2
35554440	Imazalil	0.013		19.84	7	2
36483600	Hexabromodiphenyl ether	**	**			
36734197	Iprodione (Rovral)	0.04				
39148248	Fosetyl-al	3	**			
39515418	Danitol	0.0005		5170	0.001	0.0003
39638329	Bis(2-chloroisopropyl) ether	0.04		21.9	20	6
40088479	Tetrabromodiphenyl ether	**	**			
40487421	Pendimethalin (Prowl)	0.04		3416	0.1	0.04
41851507	Chlorocyclopentadiene	**	**			
42874033	Oxyfluorfen	0.003		11040	0.003	0.001
43121433	Bayleton	0.03		39.28	8	3
43222486	Difenzoquat	0.08				
49690940	Tribromodiphenyl ether	**	**			
50471448	Vinclozolin	0.025				
51218452	Metolachlor	0.1	**	252.4	4	1
51235042	Hexazinone	0.033		348.4	1	0.3
51630581	Pydrin	0.025		35200	0.008	0.002
52315078	Cypermethrin	0.01		10320	0.01	0.003
52645531	Permethrin	0.05		40000	0.01	0.004
55285148	Carbosulfan	0.01				

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55290647	Dimethipin	0.02	**			
57837191	Metalaxyl	0.06		24.1	30	9
58138082	Tridiphane	0.003				
59756604	Fluridone	0.08		1856	0.5	0.2
60207901	Propiconazole	0.013				
60568050	Furmecyclox	**	0.030			
62476599	Sodium acifluorfen	0.013				
63936561	Nonabromodiphenyl ether	**	**			
64902723	Chlorsulfuron	0.05		19.0	30	9
65195553	Avermectin B1	0.004				
66215278	Cyromazine	0.0075		0.54	200	50
66332965	Flutolanil	0.06				
66841256	Tralomethrin	0.0075		40000	0.002	0.0007
67485294	Amdro	0.0003				
67747095	Prochloraz	0.009	0.15			
68085858	Cyhalothrin/Karate	0.005		10700	0.005	0.002
68359375	Baythroid	0.025		40000	0.007	0.002
69409945	Fluvalinate	0.01		40000	0.003	0.0009
69806402	Haloxyfop-methyl	0.00005				
72128020	Fomesafen	**	0.19			
72128020	Fomesafen	**	0.19			
74051802	Sethoxydim	0.09				
74115245	Apollo	0.013				
74223646	Ally	0.25				
76578148	Assure	0.009				
76738620	Paclobutrazol	0.013				
77182822	Glufosinate-ammonium	0.0004				
77323843	Trichlorocyclopentadiene	**	**			
77323854	Tetrachlorocyclopentadiene	**	**			

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77501634	Lactofen	0.002				
78587050	Savey	0.025				
79277273	Harmony	0.013				
81335377	Imazaquin	0.25				
81335775	Pursuit	0.25	**			
82558507	Isoxaben	0.05				
82657043	Biphenthrin	0.015		40000	0.004	0.001
83055996	Londax	0.2				
85509199	NuStar	0.0007				
88671890	Systhane	0.025				
90982324	Chlorimuron-ethyl	0.02				
101200480	Express	0.008				

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EPA

Technical Support Document For Water Quality-based Toxics Control

RESPONSIVENESS SUMMARY

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General

1. **The TSD needs to be peer reviewed.**

   EPA Response: We feel EPA has provided ample opportunity for review of the TSD. The Williamsburg workgroup met in December, 1988, and was composed of a diverse group of people from EPA Regions, States, environmental groups, trade associations, academia, private industry, and municipalities. This group was formed to determine what changes were needed in the document. Based on the workgroup's inputs, EPA produced a first draft TSD in November, 1990. This draft was sent out to workgroup members, and anyone else upon request, for review and comment. EPA considered each comment and made changes to the document. A second revised draft TSD was noticed in the Federal Register on May 11, 1990. Over 2500 copies of the new draft were sent out. Between the two drafts, we received 120 comments from a diverse group of people. EPA considered each individual comment and made changes to the document where necessary.

2. **The TSD doesn't apply to CSO discharges.**

   EPA Response: We acknowledge that the TSD was written with continuous discharges in mind. However, there is no reason why the general concepts and some of the recommendations of the TSD cannot be extended to CSO or other rainfall related discharges. The dynamic model applications in the TSD have been used over the last 10 years to address water quality problems related to CSOs. EPA believes that this model can also be applied to address toxic problems with CSOs.

Chapter 1: Approaches to Water Quality-based Toxics Control

Overview: Added more information and clarification to support EPA's position with regard to the major issues addressed in the comments.

1. **The cause and effect relationship between effluent toxicity and instream impacts is not adequately documented, and other factors that may cause instream impacts have not been addressed. EPA's use of the CETTP studies was criticized.**
   EPA Response: The revised draft TSD has been changed to include more documentation to support our position on the cause and effect relationship between effluent toxicity and instream impacts. Supporting information on a study conducted on the Trinity River in Texas was added as well as more

detailed explanation of the CETTP studies. EPA evaluated the results of the CETTP studies, the North Carolina studies, and the Trinity River study and found that if toxicity is present after considering dilution, instream impact will also be present. EPA's finding is now clearly stated in the TSD and referenced. The TSD now includes a discussion of Parkhurst's major criticisms of the CETTP studies and why EPA feels those criticisms are unfounded. The TSD also acknowledges that biological, physical, and chemical factors of the community can influence the actual effects that effluent toxicity may cause in the receiving water.

2. **Toxicity test method precision is too variable to be used in NPDES permits.**

EPA Response: The revised draft includes all available precision data for both acute and chronic toxicity tests; this includes intralaboratory and all available interlaboratory test results. Raw precision data is presented in table form in Appendix A and discussed within the chapter. EPA evaluations, as well as published literature reviews which include estimates of whole effluent precision data are presented. EPA is comfortable with the conclusion that whole effluent toxicity tests are no more variable than chemical analytical methods and therefore stands behind the recommendation that toxicity test methods be used in NPDES permits.

The same data contained in the TSD has been used by EPA in proposing adoption of the toxicity methods into EPA's regulations at 40 CFR 136. The toxicity methods were proposed for adoption on December 4, 1989. Comments were received and will be answered upon notice of EPA's decision regarding these methods. The decision is expected in April 1991.

3. **The biological criteria/bioassessment approach is not yet part of EPA's water quality regulations and should not yet be used in the regulatory process. For the best assessment of sources and causes, EPA should use a "weight-of-evidence approach."**

EPA Response: As previously stated in the TSD (per section 131.11(b)(2) of the Water Quality Standards Regulation), biological criteria can supplement existing chemical-specific criteria and provide an alternative to chemical-specific criteria where such criteria cannot be established. To acknowledge the current evolving status of the use of biocriteria, EPA's statement in the TSD has been revised to read: "To better protect the biological integrity of aquatic communities, EPA recommends that States <u>begin to</u> develop and implement biological criteria in their water quality standards."

EPA does not agree with use of the "weight-of-evidence" approach in this context because biosurveys are too complex to override the other two methods (i.e., chemical-specific and whole effluent toxicity). The TSD now explains EPA's position that the concept of "independent application" be applied to water quality-based situations. Since each method has unique as well as overlapping attributes, sensitivities, and program applications, no single approach for detecting impact should be considered uniformly superior to any other approach. For example, the inability to detect receiving water impacts using a biosurvey alone is insufficient evidence to waive or relax a permit limit established using either of the other methods. The most protective results from each assessment conducted should be used in the effluent characterization process (Chapter 3). The results of one assessment technique should not be used to contradict or overrule the results of the other(s).

However, EPA recognizes that there are instances when the whole effluent, chemical specific, and biological criteria approaches will give disparate results. The TSD was revised to recommend that permitting authorities use a more complex way to assess excursions beyond standards and establishing permit limits to provide assurance that simplifying assumptions are not the cause of the apparent discrepancy. The TSD also now includes examples of where the whole effluent toxicity test protocols may conflict with critical environmental parameters to lead to an apparent disparity between the whole effluent toxicity and chemical specific approaches.

4. **The problem of false positives (i.e., instream impact predicted by toxicity test where none exists) is not addressed.**

EPA Response: The revised draft TSD now addresses the problem of toxicity test interferences caused by environmental parameters and explains that there may be a few unusual situations where the pH, temperature, hardness, salinity, and solids requirements of the testing procedures differ greatly from the worst environmental conditions for these parameters. In these situations, the effluent toxicity tests may either over or under predict the toxicity in the ambient receiving water. An example of this is where ammonia is present and the highest expected ambient water temperature is 20°C whereas the chronic toxicity test must be conducted at 25°C. Since a higher temperature causes more ammonia toxicity, the temperature requirements of the test may induce toxicity not found in the ambient water. In such an instance, the regulatory authority must carefully look at the test protocols and all the data collected to determine if the facility is actually contributing to toxicity in the ambient water. A toxicity identification evaluation (TIE) may be necessary to

make this determination. If this analysis shows a toxicity test result to be artificial due to environmental parameters, then that test should be overridden by subsequent toxicity tests conducted.

5. **Current standard algal toxicity test methods lack the ability to provide useful data on the ecological impact of a discharge and should not be recommended as a test species. EPA should recommend three species representing two different phyla be used for toxicity testing. EPA's recommendation to use surrogate (rather than resident) species in toxicity testing as being more protective seems contrary to the site specific nature of the permitting process.**

   EPA Response: To address concerns with the algal test and to allow more flexibility in testing, the recommendation in the TSD has been changed to "fish, invertebrate, and plant." EPA will not modify its recommendation to include only 2 phyla. EPA's objective in requiring 3 species from 3 different phyla is to be predictively protective.

   The TSD's discussion of the use of surrogate species was expanded to explain that to use a resident organism, a facility would have to develop a protocol to culture the organism and to assess intra- and inter-laboratory variability. Such testing is more costly, more difficult, and potentially subject to more variability (disease, age, etc.) than standardized testing. In any case, organisms collected directly from the receiving water itself should never be used because their health cannot be assured.

6. **More documentation is needed for the statement that the "IC25 is approximately the analogue of an NOEC." Before EPA makes such a broad ranging recommendation, there must be sufficient data to establish an overall relationship.**

   EPA Response: The language in the revised draft has been clarified to better explain what an IC25 is and how it is calculated. EPA believes that there is sufficient data to support the statement that the "IC25 is approximately the analogue of an NOEC." The data in Appendix A is presented so that both hypothesis testing and IC25 calculations of an NOEC can be compared. A statistical analysis using minimum significant differences is graphically presented in Figure 1-1. Figure 1-1 shows that an NOEC calculated using the IC25 is comparable to an NOEC calculated using hypothesis testing, and that the relationship is statistically sound.

7. **The data in the TSD shows that whole effluent toxicity is not additive.**

   EPA Response: The cited article in the TSD and the TIE data were reviewed. These data support EPA's position that acute toxicity is additive. However, the data do not support additivity of chronic toxicity. Therefore, the TSD was changed to reflect this.

8. **There are insufficient chemical-specific field data to support that exceedances of the criteria cause instream impacts.**
   EPA Response: The field studies referenced in Chapter 1 for chemical specific criteria investigations were conducted over twenty years ago. The field investigators dosed a stream with toxicants to measure the response. This approach is not possible today because it would violate the States water quality standards. Since that time, EPA has developed a method of using laboratory toxicity data on specific chemicals to derive data.

Chapter 2: Water Quality Criteria and Standards

Overview: Revised introduction to summarize key regulatory requirements; reorganized into clearly defined aquatic life and human health discussions; added more information on what should be considered when allowing mixing zones; added more in-depth discussion of criteria for human health protection.

1. **Water quality criteria are not reliable due to data gaps or errors in derivation. Site-specific criteria should not be limited to being more stringent than the national criteria.**

   EPA Response: Changing the general procedure for deriving WQ criteria is not within the scope of the TSD. In the near future EPA expects to re-examine the general procedures for deriving aquatic life criteria, and will request public comment thereon. While EPA requests public comment on all WQ criteria documents before publishing them in final form, EPA accepts comment on criteria at any time and can correct errors through criteria summary documents that it distributes from time to time. Finally, there is no Agency policy, set forth in the TSD or elsewhere, that prevents state-wide or site-specific criteria from being less stringent than the national criteria.

2. **Provide more clarity on how to prohibit lethality within the mixing zones?**

   EPA Response: The TSD has been amended to clarify the goals of EPA's recommendations on mixing zones. It now states that mixing zone conditions should not be lethal to organisms

passing through it. Survival of organisms that might wish to reside permanently in a mixing zone is not assured by past or current policy.

Because the chronic criteria may be exceeded at the end of the pipe there is a potential for lethality to sensitive organisms that attempt to reside permanently in the mixing zone. Part of the intent of the recommendations of the 1985 TSD and 1991 TSD is to protect the survival of organisms passing through the mixing zone. In all cases, exposures to concentrations above the CCC and CMC cannot be correctly interpreted without accounting for the duration of exposure.

3. **The TSD is flawed because it assumes that mixing zones exist. The Great Lakes Water Quality Agreement precludes use of flow augmentation as a substitute for adequate treatment.**
EPA Response: The TSD recommendations in no way authorize mixing zones where otherwise prohibited. In addition, the recommendations on mixing zones do not advocate management of reservoirs for flow augmentation.

4. **TSD should at a minimum be against mixing zones for persistent and bioacccumulative toxicants, and the burden of justifying mixing zones for non-persistent and non-bioacccumulative toxicants should be on the discharger. The Great Lakes Water Quality Agreement calls for zero discharge of pollutants and elimination of persistent and bioaccumulative toxicants. The Clean Water Act also has a goal of zero discharge of pollutants.**

EPA Response: The TSD continues to note that EPA regulations allow mixing zones at the discretion of the State. The TSD also discusses options that should be considered when determining whether to allow mixing zones for aquatic life and human health protection. For protection of aquatic life, a mixing zone may be permitted as long as its size is sufficiently limited that it does not significantly impair the integrity of the water body as a whole, and it does not cause lethality to organisms passing through the mixing zone. For protection of human health, mixing zones should be restricted such that they do not encroach on areas often used by the public for fishing, and particularly where stationary species such as shellfish are harvested; mixing zones may also be restricted to compensate for uncertainties in the protectiveness of the water quality criteria or uncertainties in the assimilative capacity (TMDL) of the water body.

Bioaccumulative pollutant problems are not fundamentally caused by mixing zones. Bioaccumulation is generally a system-wide problem that occurs when the appropriate TMDL for a water body as a whole is exceeded. Consequently, EPA does not consider mixing zone restrictions to be the best mechanism

for addressing such problems. However, eliminating mixing zones can be used as a device to further reduce the loading below the TMDL, although the results are not as predictable as a direct reduction of the TMDL would be. Chapter 2 has been now been modified to state the factors that should be considered in judging whether a mixing zone causes significant health or ecological risks.

It should be noted that the TSD deals with WQ based effluent limits (i.e., those needed to protect aquatic life and human health), implemented primarily under the specific requirements of Sections 301, 303, and 304 of the CWA. Under this framework, zero discharge of pollutants is generally required where the water quality standard or the Total Maximum Daily Load is set at zero.

5. **The TSD should allow mixing zones for all toxicants including bioaccumulative pollutants. Furthermore, fate processes (such as sedimentation or decay) that occur within mixing zones should be taken into consideration.**

   EPA Response: The TSD now sets forth specific conditions under which denial of mixing zones would be appropriate. EPA regulations also allow (while neither encouraging nor discouraging) States to use mixing zones. The recommendations of the TSD implicitly discourage consideration of fate processes such as sedimentation or decay. Mixing zones are an allowance for variations in concentration due to incomplete mixing, over small spatial scales, usually too small for fate processes to significantly reduce concentrations.

6. **Limiting all dischargers to 0.3 TUa is akin to a technology based approach such as a 30 mg/L BOD or suspended solids limit. The TSD should consider the resulting instream water quality.**

   EPA Response: The mixing zone discussion has been modified to provide different alternatives for assuring that instream goals and standards are met. Not exceeding 0.3 TUa at the end of the pipe is one of the recommended ways to assure survival of organisms passing through the mixing zone. Nevertheless, the discussion has been modified to de-emphasize the technological requirements and emphasize the attainment of instream goals.

7. **EPA should provided more information on the tests it used to arrive at an LC50/LC1 ratio of 0.3. According to the data presented in the TSD, the 0.3 ratio is overly conservative in most cases.**

   EPA Response: The magnitude of the acute WET criterion is based on data collected from a number of facilities in EPA

Region 4. These data show that 90% of the facilities exhibited an LC1 which was no less than 0.3 times the LC50. This is different from the 0.5 factor used to derive a chemical specific acute criterion.

8. **The acute toxicity criterion of 0.3 TUa is below detection. How would it be implemented?**

EPA Response: The implementation of this criterion would be identical to that used for specific chemicals. This implementation is expressed in Chapter 5.

9. **The 1-hour averaging period for the acute criteria (CMC) is overly restrictive, does not correspond to the 48-96 hour toxicity tests, and cannot be modeled with existing EPA WQ models. Elsewhere in the document, EPA indicates that 24 hours is an appropriate averaging period for modeling purposes. Both concentration and exposure time are important, since for many toxicants the 96-hour LC50 is dramatically higher than the 1-hour LC50. The 1-hour averaging period is technically unsupported by the limited information presented. EPA appears to have edited the data presented in Appendix D to include only those data that support the 1-hour averaging period. EPA should present all available data on the effect of exposure duration on toxicity.**

EPA Response: EPA agrees that both concentration and exposure time are important. The TSD has now been modified to note that the 1-hour averaging period is based on ammonia, a fast-acting toxicant. As the 1-hour averaging period was intended to be protective even for the fastest acting toxicants, it may be overly conservative for many pollutants. Consequently, the TSD recommends allowance for site-specific (or chemical-specific) modification of the averaging periods. Alternative averaging periods can be developed from data on the time course of mortality in acute toxicity tests.

EPA expects that for many pollutants, such site-specific or state-wide alternative averaging periods, if developed using adequate data, may be greater than the period recommended for national criteria. Furthermore, EPA recognizes that a 24-hour acute averaging period may be appropriate in some modeling contexts, where concentrations do not change rapidly over short time periods.

While Appendix D of the TSD presents some examples of pollutants for which a short averaging period, on the order of hours, might be appropriate, the TSD was not intended as the mechanism by which EPA would develop a rationale for the acute averaging period. The averaging periods were set forth in 1985 in the "Guidelines for Deriving...National Criteria". In the near future EPA intends to review and perhaps modify

the Guidelines, and may at that time consider the feasibility of different acute averaging periods for different chemicals.

10. **The rationale for the 4-day averaging period is weak. Chronic toxicity tests for most species require much longer than four days. The field studies presented in Chapter 1 indicate that longer term excursions are needed to produce ecological effects. EPA inappropriately picked examples of pollutants with low acute-chronic ratios to justify the 4-day averaging period. A 30-day averaging period (per the freshwater ammonia criteria document) should be acceptable, particularly in cases where concentrations do not change rapidly.**

    EPA Response: The TSD has been modified to note that EPA selected the 4-day chronic averaging period based on the shortest period that chronic effects may be observed for certain chemicals.

    As the 4-day period was selected for provide adequate protection in all cases, EPA recognizes that longer averaging periods may be appropriate for many pollutants, and recommends using site-specific or state-wide pollutant-specific alternative averaging periods, where scientifically supported. EPA believes that selection of an appropriate chronic averaging period is technically difficult, with less applicable data than is available for selecting the acute averaging period. EPA agrees that the acute-chronic ratio is a confounding influence in interpreting the duration needed to produce a chronic effect endpoint. Where an appropriate acute criterion is in force, the chronic averaging period need not be shortened simply because the acute-chronic ratio is low.

    The TSD does not supersede the freshwater ammonia criteria document, and thus EPA still recommends an averaging period of as long as 30 days for ammonia, where concentrations do not vary excessively.

11. **EPA's recommended once in three year return frequency for criteria excursions is overly conservative. Appendix D presents time periods needed for ecological recovery from severe or catastrophic stresses, not slight stresses caused by marginal criteria excursions. The frequency of significant criteria excursions, comparable to those that caused the measurable ecological impacts set forth in Chapter 1, would be much less than for marginal criteria excursions. EPA should present data on the ecological differences between sites with different excursion frequencies. EPA should develop guidance on how to establish site-specific allowable frequencies.**

EPA Response: EPA has used Appendix D to set forth information on time periods needed for ecological recovery from severe or catastrophic stresses. EPA's recommended 3-year return interval was set forth in the 1985 "Guidelines for Deriving Numeric National Criteria...", and a review or revision of this recommended frequency was not within the scope of the TSD. Nevertheless, EPA intends to address the excursion frequency during the upcoming revision of the Guidelines.

EPA expects that criteria exceedances can cause adverse effects and that the magnitude of the effect will depend on many things including the magnitude and duration of the exceedance. EPA believes that all adverse effects are not necessarily unacceptable, but that pollution should not be allowed to subject aquatic communities to long-term or regular short-term adverse effects. All dramatic adverse effects are certainly unacceptable.

EPA believes that the 3-year return interval can be justified by the Appendix D data if one makes the assumption that the type of ecological impact shown in Appendix D could be caused by fairly small criteria excursions. The concentrations causing the Appendix D impacts were in fact not known. EPA recognizes that the chemical and ecological field data summarized in Chapter 1 suggest that successive excursions well above the criteria would be needed to cause severe impacts. EPA also recognizes that the probability of large excursions can be calculated to be extremely small compared to the probability of marginal excursions.

EPA does not have information to allow direct comparisons of ecological quality versus criteria excursion frequency, except possibly as could be inferred from the field data shown in Chapter 1. EPA does not intend at this time to set forth guidance on developing site-specific allowable frequencies.

Nevertheless, in general, EPA recommends that ecosystems not spend a substantial portion of time in a state of recovery from pollution stresses, and that pollution stresses not significantly increase the total stress experienced by organisms in the ecosystem. If the criteria are set appropriately, a marginal excursion might be expected to have little or no measurable impact, and little or no time period needed for recovery. The probability of a marginal criteria excursion nevertheless has a calculable relationship with the probabilities of severe criteria excursions. Consequently, a scientifically justified site-specific or state-wide frequency could be developed by considering (a) the probability (estimated by simulation or by statistical calculation) of a range of excursions of differing severity, coupled with (b) the estimated ecological recovery period for

the corresponding different degrees of impact. Based on the total period of recovery from a full range of possible events, compared with the sum of return intervals for such events, the allowable frequency for the marginal criteria excursion could be established.

12. **The once in three year excursion frequency does not take into consideration the likelihood of apparent excursions caused by the inherent variability of the analytical tests.**

    EPA Response: The allowable frequency for criteria excursions should refer to true excursions of the criteria, not to spurious excursions caused by analytical variability or error. In evaluating data on chemical concentrations or toxicity units, it is desirable to subtract the analytical error log variance from the observed log variance in order to arrive at the true log variance contributing to criteria excursions.

13. **The IRIS (Integrated Risk Information System) data base should be peer reviewed before it is used to update and generate RACs. The TSD should not imply that a State can update its standards simply by inserting the latest IRIS information into the equation used to calculate the criteria.**

    EPA Response: EPA's IRIS data base reflects the latest information about the Agency's health assessments for specific chemicals. While the material in the data base is internally reviewed, the Agency does not plan to have it undergo external peer review. Use of IRIS information for developing state water quality standards or discharge permits in no way relieves the State of applicable requirements for public notice and comment.

14. **The fish consumption rates used to derive residue-based criteria and RACs are unrealistically high for many waters.**

    EPA Response: EPA recommends using site-specific fish consumption rates whenever such information can be obtained.

15. **The harmonic mean is not an appropriate design flow. The arithmetic mean flow should be used.**

    EPA Response: For carcinogens it is appropriate to determine the long-term arithmetic mean exposure concentration. Because flow is not normally distributed, using the arithmetic mean flow for design purposes will underestimate the mean concentration.

    Using the downstream harmonic mean flow will result in closely estimating the mean concentration, providing that the streamflow is not dominated by the effluent flow, and provided that the effluent input is not correlated to the streamflow.

16. **Discussion of sediment criteria and biological criteria is premature. The TSD should not advocate that states and regions implement regulatory controls based on such criteria.**

EPA Response: The biological criteria and sediment criteria sections have been modified. EPA has undertaken development of biological criteria and sediment criteria with the intent that they would, after development, have regulatory applications.

EPA does not intend to imply that these approaches can or should necessarily be used at this time to implement controls. Nevertheless, EPA believes that the states, the regulated community, and the interested general public need to know how EPA is proceeding with these criteria, and what the future regulatory implications may be. EPA is not advocating that sediment criteria, by themselves, be used to establish remediation target levels. EPA also recognizes that sediment criteria cannot be used for setting discharge limits without first developing a scientifically sound basis for predicting the effect of effluent quality on sediment quality. EPA is not suggesting that sediment quality concerns would necessarily be more limiting on dischargers than water quality concerns.

17. **Aquatic life protection as measured by whole effluent toxicity and chemical specific criteria are not applicable to waters without aquatic life designated uses.**

EPA Response: The TSD explains that numeric water quality criteria are developed by States to protect the designated uses within the water quality standards. However, the TSD also reiterated EPA's position, as expressed in the June 2, 1989, Federal Register preamble on the 304(l) promulgation was added, that the narrative criteria apply to all waters to prohibit acute toxicity.

18. **The food chain multiplier factors in the RAC calculation should be deleted because it is contrary to measured levels and BCF estimations.**

EPA Response: The differences between bioconcentration and bioaccumulation have been recognized in the scientific literature for a number of years. Data published by Thomann in Environmental Science and Technology (June 1989) show that bioaccumulation can be over 100 times higher than bioconcentration. Published critiques on EPA's dioxin criterion have also expressed that bioaccumulation is more important than bioconcentration for pollutants with log water octanol partition coefficients greater than 6. EPA believes

that consideration of bioaccumulation through use of the food chain multiplier is consistent with the existing knowledge of bioconcentration factors.

Chapter 3: Effluent Characterization

Overview: Simplified the chapter organization; cited regulatory requirements (40 CFR 122.44(d)); revised the discussion on effluent bioconcentration evaluation to conform with the new draft document.

1. **Determining the need for an effluent limit in the absence of effluent monitoring data does not address the required factors of 40 CFR § 122.44(d)(1)(ii).**

   EPA Response: EPA maintains the position that regulatory authorities may make a finding of reasonable potential even where effluent monitoring data is not available. EPA disagrees with the commenter on the issue of whether the required factors can be addressed in the absence of effluent monitoring data. Box 3-1 of the TSD was revised to illustrate how the recommended procedure for making reasonable potential determinations in the absence of effluent monitoring data will address each of the 4 required factors.

2. **Including bioconcentration and bioaccumulation recommendations in the TSD is premature. Approaches to this problem require much more peer review, input and development.**
   EPA Response: EPA agrees with this comment. The draft bioconcentration guidance that was referenced in the draft chapter 3 has not yet been released for public comment and does require additional peer review. The majority of the chapter 3 discussion on the specifics of this guidance was removed; the remaining sections specifically state that the procedures in the draft guidance should not be used by regulatory authorities until the guidance is finalized by EPA.

3. **In determining reasonable potential, the cumulative effluent discharge to a receiving water should be considered instead of single discharges.**

   EPA Response: EPA agrees with this comment. The draft of chapter 3 did not draw a clear enough distinction between the terms "cause" and "contributes to" in the context of the reasonable potential determination. Chapter 3 now states that where multiple discharges collectively are causing or show the reasonable potential to cause or contribute to an excursion of water quality standards, limits must be developed for each discharger to protect against such collective excursions. This is underscored by adding the exact regulatory language of 122.44(d). Finally, the document now has recommendations on the use of toxicity testing in multiple discharge situations.

4. **Guidance is needed on how to demonstrate that chemical-specific limits alone are sufficient to achieve applicable water quality standards, thus obviating the need for a WET limit.**

   EPA Response: EPA agrees with this comment. Regulations at 122.44(d)(1)(v) provide that WET limits are not necessary where the permitting authority demonstrates that chemical-specific limits are sufficient to protect water quality standards. The draft of chapter 3 did not clearly recognize this point and provided no guidance on how to make this demonstration. Chapter 3 now reiterates this regulatory provision with a new section entitled "Using a Chemical-specific Limit to Control Toxicity." This new section recommends that the discharger conduct a TIE to identify causative toxicants. Where the causative toxicants are controlled by chemical-specific limits, the permitting authority may make the determination that WET limits are not necessary.

5. **The multiple conservative assumptions in the effluent characterization methodology (the effluent is most toxic to the most sensitive life stage at the time of lowest stream flow and peak design flow) are overkill.**

   EPA Response: EPA does not agree that multiple conservative assumptions amount to overkill. This comment implies that EPA recommends establishing effluent limits to protect against toxic impacts that are never projected to occur. In truth, EPA only recommends establishing effluent limits where toxic impacts are projected to occur. Estimates of toxic impact should be made assuming that the effluent is most toxic to the most sensitive species or lifestage at the time of lowest available dilution because these are conditions that can be expected to occur. For the most part chapter 3 remains unchanged as a result of this comment. However, EPA has added a short discussion that suggests that the regulatory authority may choose to assess reasonable potential using a stochastic dilution model which incorporates both ambient dilution and effluent variability to project toxic impact.

6. **EPA should not recommend a 3 species minimum. The algae test and the marine tests are not sufficiently studied.**
   EPA Response: Chapter 3 continues to recommend as a minimum that 3 species be tested quarterly for a minimum of 1 year where toxicity tests are used to make decisions regarding the need for WET limits. Experience indicates that algal tests can be a highly sensitive test species for some pollutants. Furthermore, using a plant adds another trophic level to the test regimen. EPA rejects the assertion that the algal tests are not sufficiently studied. For both freshwater and marine

waters, the use of 3 species is more protective than 2 species since a wider range of species sensitivity can be measured.

7. **EPA should not recommend that ambient toxicity tests be conducted at worst case low flow conditions.**

   EPA Response: EPA disagrees with this comment. Chapter 3 continues to recommend that ambient toxicity testing be conducted during appropriate low flow or worst case design periods. In order for the results of ambient toxicity tests to form the basis for decisions about whether toxicity controls are needed, the test must reflect the conditions that such controls would be designed to protect. If a regulatory authority's policy is to protect at the 7Q10 flow, than the ambient tests must be conducted at flows that are very near the 7Q10. Otherwise, the regulatory authority will learn very little from the ambient test about whether toxicity limits are necessary for a particular discharge.

8. **Reasonable potential determinations should not be based on whole effluent toxicity data alone. Toxicity data and instream survey data should be used together in a weight of evidence approach.**

   EPA Response: We disagree. As discussed in the response to comment no. 2 in Chapter 1, EPA considers that water quality standards apply independently of each other. Whole effluent toxicity measures a different biological endpoint than do instream survey data.

9. **One piece of effluent data projecting an excursion above a water quality standard is insufficient to justify setting an effluent limit.**

   EPA Response: EPA disagrees. EPA's position is that where even one data point shows that an excursion of a state water quality standard is projected, the Director may determine that permit limits for whole effluent toxicity or for specific chemicals are necessary. In making such a determination, NPDES regulations requires that the Director also account for existing controls on point and nonpoint sources, the variability of the pollutant parameter in the effluent, the sensitivity of the species to toxicity testing (for whole effluent), and where appropriate the dilution of the effluent in the receiving water. In addition, the Director should consider all other available information pertaining to the discharger to assist in making an informed judgement.

Chapter 4: Exposure Assessment and Wasteload Allocation

Overview: Clarified terminology for mixing zone and design flow conditions.

1. **Clarify or reevaluate Agency's position with respect to key mixing zone issues: including how to establish geographical boundaries of mixing zones and point of application of criterion for persistent bioaccumulative pollutants, and how to prevent lethality in the mixing zone.**

   EPA Response: The revised TSD states as it did in previous drafts that the mixing zone size should be minimized and the dimensions should be based on the site-specific conditions. As previously stated, site-specific evaluations should also be conducted by the permitting agency to determine whether to allow a mixing zone for discharge of bioaccumulative pollutants. The TSD was revised to expand the three approaches for preventing lethality in the mixing zone to four approaches. The new approach includes submission of actual data to show that a drifting organism would not be exposed to 1-hour average concentrations exceeding the CMC. In addition, clarification was provided on the approach not requiring the use of a high velocity discharge to show that the CMC is met. Approaches for preventing lethality in the mixing zone conform with the position taken in Chapter 2.

2. **Clarify or reevaluate Agency's position on appropriate critical flows for toxicants which have potential human health impacts and/or aquatic life impacts.**

   EPA Response: It was determined that the harmonic mean flow was appropriate for evaluation of human health impacts that are of concern due to long-term exposures (e.g., cancer). The TSD was revised to clarify the use of harmonic mean flow and its appropriateness for use in water quality modeling to evaluate human health impacts (e.g., a step-by-step calculation procedure was added). Additional clarification was provided for the use of hydrologically-based 7Q10 and 1Q10 flows for the evaluation of "worst case" scenarios for determining potential aquatic life impacts.

3. **EPA should present <u>all</u> valid modeling approaches and determine the best water quality model for each water quality condition.**

   EPA Response: The models described in the text were those EPA considers to be comprehensive to evaluate most water quality conditions. Because of all the potential site-specific scenarios, it is beyond the scope of the document to present <u>all</u> of the valid approaches that could be used for

water quality modeling. The permitting authority needs to evaluate the data available for the site and select the water quality model that is best for calculating the receiving water concentrations and the TMDLs.

4. **Specific caveats should be added to the model descriptions.**

   EPA Response: It is beyond the scope of the document to provide all of the caveats that are applicable for each of the models. Although the commenters presented specific caveats for a model, they were not incorporated since it was beyond the scope of revising the document to determine all the cases that the caveat could apply.

5. **Commenters want additional explanation or justification for the assumptions and applications for the equations presented in the TSD.**

   EPA Response: The TSD already contained a sufficient explanation or referenced the documents which contained the rationale.

6. **The water quality model "DYNTOX" and the software program HHD FLOW are not available.**

   EPA Response: DYNTOX is not currently available but should be accessible by early 1991. HHD FLOW is not available, but DFLOW is available, and the TSD has been changed to reference this software package.

7. **Guidance on regulating nonpoint sources should be included in the TSD.**

   EPA Response: It is beyond the scope of the document to include information on regulating non-point sources.

8. **Guidance should be given in the discussion on design flow for persistent pollutants.**

   EPA Response: Persistent pollutants should be assessed in the same way as bioaccumulative pollutants.

9. **The human health section does not provide direction regarding the percentage of fish that are taken from a given area.**

   EPA Response: The percentage of fish should be determined based on site-conditions. The WLA criteria are conservative estimates based on heavy consumption of fish or a potentially large contaminated area.

10. **The TSDs discussion on mixing zones' contribution to human health is overemphasized.**

    EPA Response: The TSDs discussion on mixing zones has been revised and does not overemphasize the contributions to human health.

11. **EPA should revise its discussion of modeling WLAs for human health toxicants because it is misleading since it suggests that the method should be used whether the applicable criterion is a drinking water standard intended to prevent acute effects on humans or criterion established for Deriving Numerical National Water Quality Criteria.**

    EPA Response: The TSD does not discuss acute human health effects; therefore, it was determined that the discussion is not misleading.

Chapter 5: Permit Requirements

Overview: Added clarifications and examples to support the existing text; gave equal weight to developing limits based on a dynamic and steady state wasteload allocations; added discussion on metals, average and maximum permit limits, single dilution tests, variability, and mass-based limits.

1. **The two value, steady-state model approach to permit limit derivation is overly conservative with too many built-in safety factors. As a result the limits derived are too stringent.**

    EPA Response: EPA has revised Chapter 5 of the TSD to emphasize the development of permit limits that are as exact as possible to attain and maitain water quality standards. Chapter 5 now recommends the use of the statistical limit derivation procedure which provides for two options. The first option uses a steady state model approach for development of the wasteload allocation (WLA) and long term average (LTA). Since this approach relies on critical condition assumptions regarding effluent characteristics and receiving water characteristics, this approach may derive limits that are more restrictive than the second option. The effluent characteristics of importance are pollutant concentrations, pollutant concentration variation, and effluent flow. The receiving water characteristics of importance are pollutant concentrations and receiving water flow.

    Where a discharger or permitting authority believes that the steady state model approach results in overly restrictive permit limits, under the revised TSD the discharger or permitting authority has the alternative of using a dynamic

model approach. Under the dynamic model approach worst case assumptions are minimized and more accurate receiving water concentrations of a pollutant can be calculated. In general, dynamic models account for the daily variations of and relationships between flow, effluent and environmental conditions and therefore directly determine the probability that a water quality standards exceedance will occur. Because of this, dynamic models can be used to develop wasteload allocations which more exactly maintain the water quality standards at the return frequency requirements of the standards. The WLA is first developed by iteratively running the dynamic model with successively lower LTAs until the model shows compliance with the water quality standards. With this approach now a recommended option in the TSD, this major issue is resolved. A disadvantage of using dynamic model outputs to develop permit limits is the lack of necessary data for effluent variability and receiving water flows.

2. **The discussion of below detection levels is confusing. EPA should not be setting water quality-based limits below detection levels, especially since variability of a test method is greater the closer the results are to the detection level.**

   EPA Response: The discussion of below detection level limits in the draft TSD was unclear. Since the time of the draft TSD, EPA issued its guidance on setting permit limits below the detection level for dioxin. This guidance uses a minimum level (ML) to ascertain compliance with limits set below detection levels. The TSD was revised to follow the dioxin guidance (May 21, 1990 Memorandum from LaJuana Wilcher, "Strategy for the Regulation of Discharges of PHDDs and PHDFs from Pulp and Paper Mills to Waters of the United States"). Specific values for the minimum level are found in the description of methods 1624 and 1625 for some organic compounds. (See the appendix to 40 CFR 136.)

3. **EPA's criteria recommend that limits be derived for toxicant in the soluble form or biologically available form, yet many permit limits are being written and compliance being based upon the total recoverable form of metals. The TSD should address this issue and give guidance on developing limits only for bioavailable forms of pollutants.**

   EPA Response: The TSD has been revised to cite the regulatory requirements at 40 CFR 122.45(c) and to provide three options for use where a state has not developed a method for determining total recoverable permit limits based on a dissolved or acid soluble water quality criterion. The three options are 1) assume complete availability of the total recoverable metal, 2) use the method in the EPA wasteload allocation guidance manual for toxics in rivers to relate the

two, and 3) use site specific data to develop a relationship.

4. **EPA's regulations do not allow permit limits based on one day maximum concentrations for POTWs.**

   EPA Response: The NPDES regulation at 40 CFR 122.45(d) require the use of a 7-day average unless impractical. The discussion on the expression of permit limits now states that EPA considers the 7-day average limit for POTWs to be impractical for the purposes of controlling the discharge of toxics. The reason for this statement is that control of the 7-day average in lieu of control of the 1-day maximum will allow for unmeasured short-term excursions of an acute water quality standard.

5. **TREs should not be required as a permit condition to respond to a violation of a whole effluent toxicity limit. The proper response by the permitting authority is through use of enforcement mechanisms.**

   EPA Response: The discussion on TREs was changed to <u>not</u> recommend that the TRE or accelerated monitoring be included in the permit to respond to permit limit violations but rather be part of the enforcement response. This was done to help distinguish between monitoring only provisions and enforcement of permit limits. This should reduce confusion about the difference between enforcement on a single event violation of a limit and the need for multiple violations before a TRE is warranted.

6. **Permit limits should be increased to consider analytical variability. EPA should consider using the approach it proposed in the Amelia River study.**

   EPA Response: EPA disagrees with the proposal. A discussion was added to explain how EPA considers analytical variability in developing permit limits. The discussion states that since this variability is an intrinsic part of all data collection (effluent monitoring, wasteload allocation development, and water quality standards development), and that the variability can go both ways (higher or lower), that EPA does not separate it out from all other variability factors. EPA's Amelia River study is not final; the approach cited may not be included in the final report.

   Although difficult, it may be possible to determine what proportion of the observed variability can be attributed to sampling error, and what proportion can be attributed to the method of measurement. Regardless, the TSD makes use of a coefficient of variation that includes both sources of variability. This is not unreasonable since sampling for monitoring purposes also results in the inclusion of these

two sources of variability. Any consideration of upstream concentrations in the WLA will also include analytical variability. There is no "true" calculation in the process of developing permit limits because there is analytical uncertainty throughout the process. Instead, LTAs should be calculated from the WLAs using the same CV that is also used to calculate permit limits from the most limiting LTA. It is unimportant exactly what CV is used because the most restrictive LTA itself is used only for determining the desired treatment performance level. However, this procedure assures (99 or 95% confident) that the permit limits will be less than or equal to the more limiting LTA.

7. **Since permit limits were derived based on 95th and 99th percentile probabilities, that occasional exceedances of permit limits should be allowed on the same basis.**
EPA Response: In statistics, the selection of an acceptable probability level reflects the level of confidence that is desired of the results. As such, an acceptable level must be defined prior to performing any statistical procedure. As stated in the TSD, the probability basis of 0.99 for the daily maximum limit, and 0.95 for the average monthly limit have been used historically in connection with development of the effluent guideline limitations and have been well accepted upheld in legal challenges to the guidelines. These values are tied to monitoring frequencies that are required for each limit. There is no mixing of two probability bases since they are distinct and separate limits. The goal in establishing these levels is to allow the regulatory agency to distinguish between adequately operated wastewater treatment plants with normal variability from poorly operated treatment plants.

8. **Permit limits should vary with flow conditions in the receiving waters since exposure is based on dilution with receiving water flow.**

EPA Response: EPA partially agrees but only to the extent that the limits are seasonally based. The seasonal approach has been used by permitting authorities for setting permit limits to protect against excursions of dissolved oxygen and ammonia standards. However, seasonal limits are different than limits which vary daily based on river flow. EPA is not convinced that a daily variable approach would be universally practical given wastewater treatment response and performance; for this reason EPA has not included procedures for this approach. In addition, the discharger has the option of using dynamic modeling to develop permit limits. Since dynamic modeling considers all receiving water flows, this option would provide the discharger a less restrictive permit limit than would be obtained by using steady state modeling.

9. **If limits were derived that were overly stringent due to the worst case assumption of the steady state model, and if in the future the permittee conducted dynamic modeling which resulted in less stringent limits, permittees would be bound to the previous limits due to the anti-backsliding requirements.**

EPA Response: There is no absolute prohibition. EPA's September 1989 guidance document on antibacksliding contains EPA's interpretation of the Clean Water Act provisions in §402(o) and §303(d)(4). This guidance also does not contain an absolute prohibition. It is EPA's position that the CWA's anti-backsliding provision and EPA's existing regulations do not uniformly prohibit the incorporation into a permit of less stringent limits, standards, or conditions. In certain situations (i.e., under Sections 402(o) and 303(d)(4) of the CWA), less stringent limits or conditions may be permissible.

Section 402(o)(1) provides that backsliding from water quality-based limits is prohibited except in compliance with Section 303(d)(4). Section 303(d)(4)(A) only allows establishment of less stringent limits in a permit for discharge into a non-attainment water only if two conditions are met: 1) the existing permit limit must have been based on a TMDL or other WLA established under Section 303, and 2) attainment of water quality standards must be assured. Section 303(d)(4)(B) allows establishment of less stringent limits in a permit for discharge into an attained water only where relaxation is consistent with a State's antidegradation policy.

Section 402(o)(2) also outlines exceptions to the general prohibition against backsliding from water quality-based permit limitations. Under Section 402(o)(3), backsliding may be allowed: 1) where there have been material and substantial alterations or additions to the facility; 2) where good cause exists due to events beyond the permittee's control and for which there is no reasonably available remedy; 3) where the permittee has installed and properly operated and maintained required treatment facilities; and 4) where new information justifies backsliding from water quality-based permit limitations and other Section 301(b)(1)(C) limitations.

10. **EPA does not have guidance on how to conduct a chronic TRE and therefore limits should not be derived based upon chronic endpoints.**

EPA Response: EPA is aware of the need for guidance on conducting TREs for chronic toxicity. EPA's Duluth laboratory is near completion of a draft guidance document. The guidance document will be widely available when finished. Regardless, the lack of a finished guidance document is not

a valid reason to allow for excursions above a narrative standard as measured by chronic whole effluent toxicity. Some dischargers have been able to comply with chronic toxicity limits and identify and control sources of chronic toxicity. EPA experience has shown that portions of the published TRE procedures for solving incidences of acute toxicity (EPA/600/2-88/070, EPA/600/2-88/062, EPA/600/3-88/034) can be used for resolving incidences of chronic toxicity.

11. **EPA should allow adequate time for facilities to come into compliance with water quality-based permit limits.**
EPA Response: EPA is aware that facilities may need time to comply with newly established effluent limits. This has been accomplished in the past in NPDES permits by allowing compliance schedules within the permit. Regulatory agencies use of compliance schedules for water quality-based effluent limits are governed by recent decisions regarding the Star-Kist Caribe ruling by EPA's Chief Judicial Officer (CJO). On March 8, 1989, in review of the evidentiary hearing request by Star-Kist Caribe, the CJO ruled that compliance schedules for water quality-based effluent limits may not be included in NPDES permits unless explicitly authorized by the State in its water quality standards or implementation regulations. The ruling was based on an interpretation of section 301(b)(1)(C) of the Clean Water Act. Later, on Septermber 4, 1990, the CJO granted a stay of the ruling to allow EPA and States to use compliance schedules for water quality-based limits where such schedules are consistent with State policy. In any case, the allowance for compliance schedules is a State decision which may ultimately need to be expressed in water quality standards.

12. **Effluent limits should be set within the ability of treatment technology.**

EPA Response: EPA is aware that there may be a number of water quality-based permit limits for toxics which may be presently unachievable with existing wastewater treatment technology. However, the NPDES regulations at 40 CFR 122.44(d) require that effluent limits more stringent than those established based on a treatment technology basis must be set to achieve water quality standards.

13. **The limit derivation procedures for human health should use the same statistical procedures as used for deriving limits for aquatic life. Permit limits should be derived from the harmonic mean effluent concentration.**

EPA Response: Since compliance with permit limitations is by regulation determined on a daily and monthly basis, it is necessary to set permit limitations expressed in these

contexts that meet a given WLA every month. The statistical procedures for permit limit derivation in the TSD are designed to accomplish this for aquatic life protection where the use of shorter term averaging periods is consistent with two number aquatic life criteria.

However, if the TSD procedures were directly used for setting permit limits on bioconcentratable pollutants, both maximum daily and average monthly permit limits could exceed the wasteload allocation necessary to meet the criterion. These two permit limits would assure that the long term average effluent discharge would comply with the human health derived WLA only if the assessment of the effluent variability was precise. With bioconcentratable pollutants where exposure duration ranges up to 70 years, EPA believes that effluent variability cannot be reliably estimated from existing data for exposure periods a year. If the effluent variability was over-estimated when establishing the permit limits, then a facility could be discharging in compliance with the permit limits but would be exceeding the wasteload allocation for human health protection. This approach is clearly unacceptable.

This problem does not arise when using the TSD statistical procedure for setting permit limits for protecting against aquatic toxicity. In this case, the monthly average and daily maximum permit limits are more closely related to the four day average and one hour maximum used as exposure periods for the criteria. Any imprecision in assessing effluent variability would therefore not have as great an effect on the permit limits.

14. **Effluents may not always demonstrate a log-normal distribution. The TSD should present procedures for using other distributions.**

EPA Response: EPA believes, after reviewing the database used to establish effluent guidelines, that the log-normal distribution best characterizes effluents. EPA's analysis of these data are provided in Appendix E. The general characteristics of the lognormal distribution (it is only positive and is skewed towards extreme high values) make it an appropriate distribution for dealing with effluent concentrations. According to Gilbert (1987), the lognormal distribution is the only available 2-parametric distribution that can routinely be applied to environmental data. Since the Agency is not providing derivation procedures for alternate data distributions, it is not necessary to test for lognormality of effluent data. Permitting authorities can develop their own methods using other probabilistic distributions.

Chapter 6: Enforcement

Overview: No major changes made in recommendations; added clarifications and explanations.

1. **One effluent test failure should not equal a violation; provisions should be made to delay punitive enforcement action where legitimate efforts are being made; permittees should not be held in violation of their toxicity limit while conducting a TRE.**

   EPA Response: The current draft still emphasizes the principle that any single exceedance is a violation and is subject to a full range of enforcement responses. However, the draft has been caveated with discussion on EPA's guidance which outlines a systematic review of all violations to determine the appropriate level of enforcement. EPA's enforcement guidance is included in an appendix.

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