Event Level Authorization Process and Checklist

The Program Administrator (or designee) must affix their signature and the date of review to all final reports. The signature (either an electronic image or in indelible ink) of the Administrator or designee indicates that the appropriate review checks listed below were performed on the date indicated. Designees authorized to certify final reports are listed in the Quality Manual.

1.0 ELECTRONIC SIGNATURE POLICY

The laboratory utilizes electronic signatures in the process of certifying analytical reports. Pictures of the signatures of laboratory managers are stored in Oracle as binary large objects (BLOBs) and are associated with the user's personnel record. This BLOB is inserted into the final laboratory report PDF when the LIMS event is certified. Because the user has logged in to their password-secured account and the process is automated, only the signature of the manager certifying the report can be used for indicating the data have been reviewed and authorized for release.

2.0 REVIEW PROCESS

A review of the final reports includes the following checks and associated corrective actions.

2.1 The report (electronic or paper) is examined to ensure that all pages are printed without flaws that obscure any information. If there are critical errors in producing the report, the problem is investigated and once resolved, the report is regenerated.

2.2 All data are examined to ensure that results are consistent with project expectations. If there appears to be any anomalous or suspect data reported, the report is routed to the appropriate group supervisor for confirmation of the results. In some cases, a memorandum may be attached to the report to explain any apparently anomalous results to the client.

2.3 All comments are examined for clarity. If ambiguous comments are detected, the report is routed to the appropriate group supervisor for clarification of the comments.

2.4. If holding times are exceeded for an analysis or preparation, all results are checked to ensure they are flagged with a "Q" qualifier. If not, the report is routed to the appropriate group supervisor for corrective action. Test level comments are used to indicate the reason for the expiration.

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2.5. Field duplicates are spot checked to ensure that results are consistent with expectations for the project. If suspect field duplicate results are detected, the appropriate group supervisor is consulted. A memorandum may be attached to the report or a test level comment may be used to notify the client that precision for field duplicates has exceeded expectations.

2.6. Field, equipment, and trip blanks are examined for obvious evidence of contamination. Contaminated field QC blanks are confirmed whenever possible. The appropriate group supervisor may be consulted to ensure that contamination was not detected in laboratory blanks. A check of the laboratory's negative controls can be performed by examining the accompanying electronic data deliverable described below if available. A memorandum may be attached to the report or a test level comment may be used to notify the client that blank contamination was detected.

2.7. The quality control data are examined for completeness. Results that are associated with quality control failures are flagged with a "J" qualifier. A test level comment is used to alert the client to any quality control failures. If deviations from this policy are detected, the report is routed to the appropriate group supervisor for corrective action.

2.8. The usability of the generated data is assessed relative to known or stated project objectives as communicated to the laboratory. If the known or stated data quality objectives or data usability goals were not met, the supervisor and/or project manager is contacted to determine how to proceed to best meet those goals.

2.9. Any other appendices or non-conformance reports associated with the final report are examined for completeness.

2.10. Documentation from any overflow laboratories performing any of the analyses in the event is reviewed. Upon job authorization a copy of the overflow report is placed in the event folder as well as posted to an electronic site for FTP transfer.

2.11. After the report has been successfully reviewed and deemed complete, the report is certified in the Report Certification module of LIMS. The date and time of certification and the signature of the certifier are automatically appended to the final report. The final report, ADaPT files (if required), field paperwork and any other associated paperwork is then posted to an FTP server and the client sent an e-mail with instructions on how to retrieve it. The laboratory retains a hard copy of the cover page of all final reports. The laboratory retains the electronic PDF file of the signed final reports as well as associated electronic data files.

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3.0 ELECTRONIC DATA REVIEW

Many of the elements of data review can be performed electronically. The FDEP Laboratory uses a software product, **A**utomated **Da**ta **P**rocessing **T**ool (ADaPT), to review some data electronically for completeness, content, integrity and quality. During the report generation process, where requested by the customer, the LIMS generates an electronic data deliverable (EDD) suitable for processing through ADaPT. All appropriate EDDs are processed through ADaPT to ensure 1) completeness and content of data elements and compliance with quality assurance requirements; 2) consistency with data reporting requirements; 3) integrity with regard to specified data assessment criteria and 4) usability vis-à-vis client or program quality objectives. Details regarding the use and functionality of ADaPT can be found at:
http://www.dep.state.fl.us/waste/ADaPT/

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