Non-Conformance Reporting System

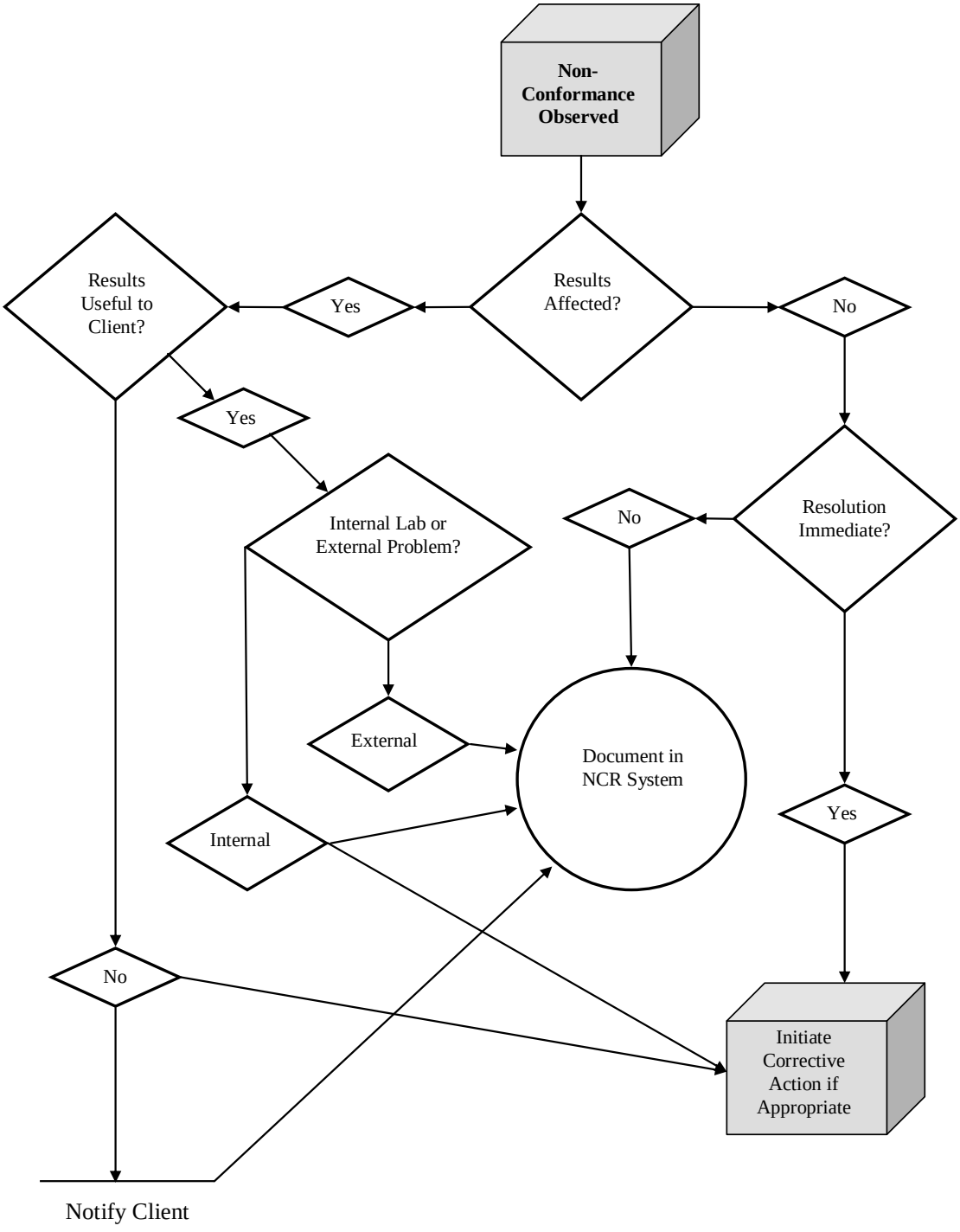
The Non-Conformance Reporting (NCR) System is part of the laboratory's corrective action plan as outlined in the Quality Manual. It is used by the DEP Central Laboratory as a notification system for clients whenever results reported by the lab may be affected by systematic bias or error or whenever documented procedures are not followed. Non-systematic bias (random error) may also be documented in the NCR if there is sufficient reason to notify the laboratory client or to document the event.

Whenever an entry is made to the NCR system for an observation that could potentially affect the quality of reported results, the NCR entry must be associated with a Laboratory Information Management System (LIMS) Event Identifier. The laboratory's client must also be notified (by phone, email or by utilizing the NCR client notification checkbox in the DEP LIMS). The client must be notified by electronic mail or by telephone whenever the requested analyses cannot be performed or when it is determined (using best professional judgment and/or knowledge of the project objectives) that data generated for that event will likely not satisfy the client's needs and objectives. Whenever the client is notified of non-conformances via electronic mail or telephone, the notification must be documented in the NCR system.

Non-conformance observations that do not affect reported results may also be documented in the NCR system for resolution tracking. Such observations may include external and internal audit deficiencies or similar laboratory non-conformances that do not directly affect reported results. Non-conformance observations that have an immediate resolution and that do not affect reported results need not be entered into the NCR (or entered at the discretion of the unit supervisor). The flow chart displayed in Figure 1outlines the decision making process for entering an observation into the NCR.

If an NCR is linked or associated with an event, the NCR is included in the final chemical or biological analysis report that is submitted to the customer. The inclusion of an NCR is prominently displayed in the front page of the final report.

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Appendix of Significant Editorial Changes

02/12/2008 This SOP was re-issued as Bureau SOP LB-002. This SOP replaces SOP CM-010.

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