

Laboratory Evaluation Procedure

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I. Announced on-site evaluations

- A. Shall be conducted every three years at each lab.
- B. Must be carried out within 90 days after an initial or revised application is deemed complete (unless waived).
- C. Must be carried out within 90 days after the department is notified of lab relocation (unless waived).
- D. Can be conducted when it is deemed necessary to assess corrective action the lab has taken in response to a previous on-site evaluation.
- E. Can be conducted when the department believes the lab is out of compliance with NR 149.

II. Un-announced on-site evaluations

- A. May only be conducted to review compliance after an NOV has been issued.

III. Scheduling

- A. The evaluator will contact the laboratory and set up mutually agreeable dates/times for the evaluation to occur. It is customary to give at least a weeks notice.
- B. A confirmation letter will be sent to the laboratory which may include a request for materials prior to the audit (such as list of methods, LODs, Quality Manual, directions, benchesheets, etc.). The receipt of these materials can help the evaluation be accomplished more efficiently.

IV. Lab Evaluation

- A. Opening conference
 - 1. Introductions, discuss functions of the lab, map out plans for the evaluation, discuss break schedules, request data packages etc.
 - 2. Arrange interviews, lunch, start and stop times to meet the scheduling needs of lab and evaluator
 - 3. Estimate time of closing conference and determine who needs to attend.

- B. Tour of lab
 - 1. Assess lab organization, potential for cross-contamination, and layout.
- C. Evaluate sample receipt process
 - 1. Assess sample receipt, labeling, storage, security, preservation protocols etc.
- D. Review of LIMS or data handling methods.
 - 1. Become familiar with lab labeling and acronym systems.
 - 2. Determine how samples are entered into LIMS and tracked throughout the lab
 - 3. Evaluate record completeness, permanence and security.
 - 4. Assess data reporting and qualification procedures.
- E. Review general analytical equipment, maintenance, calibration and associated records.
- F. Assess reagent storage, preparation, labeling and logs.
- G. Interview analysts for each set of parameters including preparatory steps.
- H. Review data packages covering all the certified/registered parameters.
- I. Review representative historical data encompassing the three years prior to the evaluation.
- J. Summarize notes and findings for closing.
- K. Closing conference
 - 1. Discuss positive practices observed at the lab.
 - 2. Review deficiencies and possible responses.
 - 3. Inform the laboratory if enforcement action is being considered or will take place.
 - a) Enforcement generally proceeds in a stepped fashion
 - (1) Notice of noncompliance (NON)
 - (2) Notice of violation (NOV)
 - (3) Referral
 - 4. Explain the status of any pending applications.
 - a) Certification/registration can be granted immediately day if the parameters being certified/registered for are unaffected by any of the deficiencies found.
 - b) Certification/registration may be delayed if corrective action is needed.
 - 5. Suggest recommended lab practices.
 - 6. Allow time for lab staff questions.
 - 7. Present lab manager with "On-site Evaluation Survey" and explain confidentiality provisions.

V. Evaluation Report

- A. Within one month of the evaluation, the evaluator will prepare a detailed report.

- B. The report will cover positive practices, deficiencies and recommended lab practices.
- C. Evaluator will present an authoritative citation (specific regulatory or method requirement) for each deficiency.
- D. If the report is being issued as an enforcement action, the evaluator must follow code and agency requirements for stepped enforcement.
- E. The laboratory should receive the original signed report that has been peer reviewed and approved by the Section Chief.

VI. Late Evaluation Report

- A. If the evaluation report cannot be sent within 30 days of the conclusion of evaluation then within 10 days (40 days total since the conclusion) the evaluator must send a letter to the lab stating the report is delayed and including an expected delivery date for the report.

VII. Evaluation Closure

- A. The lab is required to respond within 30 days of the report date with a corrective action plan covering how all deficiencies will be addressed.
 - 1. Each deficiency should be addressed with a plan of action and supporting documents.
 - 2. If the corrective action plan is not ready within 30 days then the lab must provide an explanation of the delay and expected delivery date.
- B. Evaluator will review response for acceptability.
 - 1. If the corrective action is complete then the department will notify the lab within 180 days of the conclusion of the on-site evaluation.
 - 2. If further corrective action is needed the department and lab will agree on due date for the next submission.
- C. The second corrective action plan is reviewed (if needed).
 - 1. If the lab has satisfactorily addressed all the deficiencies the evaluator must notify the lab in writing that the evaluation is closed.
 - 2. If more changes are still needed the evaluator may chose to:
 - a) Schedule a second on-site evaluation.
 - (1) If this option is chosen the lab will have a maximum of 90 days after the second evaluation to resolve any deficiencies.
 - b) Terminate the open application (if applicable).
 - c) Initiate enforcement.
- D. After all deficiencies are satisfactorily addressed the evaluator will send a closure letter.
 - 1. The letter will state that the deficiencies appear to be resolved and the lab is in compliance with NR 149.
 - 2. If the report was issued as an enforcement action, steps will be taken to resolve the action.