

# Lab Evaluation Standard Operating Procedure (SOP)

This SOP is meant as a guide. All lab evaluations differ to some extent due to many factors such as size of the lab, scope of the work, and personnel involved. It is up to evaluator discretion how the actual evaluation is structured and carried out.

## **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. Evaluation Preparation**

- A. Contact laboratory and set up mutually agreeable dates/times for the evaluation to occur.
- B. Send confirmation letter to laboratory and request materials to be sent.
  - 1. Requested materials may include: current list of methods, LODs, Quality Manual, current control limits, directions to lab, benchsheets, etc.
- C. Record the date the evaluation is scheduled as "entry date" in the LabCert database on "scheduling" and "evaluation" pages.
- D. Set up travel arrangements (reserve car, hotel etc. as needed).
- E. Assess materials received, review methods, evaluate department data, check into permit requirements, review previous evaluation reports/responses, check on PT sample results etc.

## **IV. Laboratory 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 staff.
  - 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 become familiar with the 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.
- L. Database management- Audit Records.

Upon return to the office evaluator will record the "exit date" in the LabCert database. The exit date is the last date the evaluator was at the lab (will be the same as the entry date for one day evaluations).
- M. Database management- Facility information.

Update any changes necessary in the LabCert database, including key personnel, contact information, new methods, etc.
- N. Out-of-State Lab Invoices.

No more than two weeks after completing an evaluation of an out-of-state lab, evaluators will use a standard spreadsheet to provide central office administrative personnel with an itemized list of travel expenses related to the evaluation.

O. Personal Travel expense reimbursement.

Any audit related expenses should be entered through the TRIPS system on the DNR intranet.

## V. Evaluation Report

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

B. The report should cover positive practices, deficiencies and recommended lab practices.

C. Evaluator must tie all deficiencies to an authoritative citation (specific regulatory or method requirement). The deficiency must be phrased to include the citation or list the citation directly after the deficiency language.

D. If the report is being issued as an enforcement action, the evaluator must follow code and agency requirements for stepped enforcement.

1. This may include involvement of DNR enforcement and legal personnel.

2. Record details of enforcement under the enforcement page in the LabCert database.

E. Report must be submitted for peer review within lab certification program.

F. Make necessary changes to report after resolving peer review comments.

G. Convert report to PDF file and name using "FID\_YYYYMM" – using the year/month the report was completed.

H. Submit report to Science Services Section Chief for approval.

I. Record "report date" in the LabCert database. Report date is the date the report is finalized and sent to the lab.

J. Save a copy of the report on the SS drive under Lab Cert/Audit/Report/PDF in PDF format.

K. Send the laboratory the original with the evaluator's signature and text stating it has been peer reviewed and approved by Section Chief.

1. Include supplemental handouts or other information to help lab resolve deficiencies.

L. Send photocopies or electronic copies to the associated wastewater engineer, and other interested parties.

M. File a hard copy in the facility file.

## 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.

B. The late report letter can be sent by email, fax or standard postal mail.

C. A hard copy of letter is placed in the file and a record that the letter was sent and the new due date is recorded in LabCert database.

## 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. 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) Request further corrective action.
- 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. The resolution must be recorded on the enforcement tab of the LabCert database.
- E. A copy of the closure letter is saved to the SS drive Lab Cert/Audit/Closure in PDF format and in the facility files (hard copy and electronic). The "completion date" is recorded in the LabCert Database. Completion date is the date the closure letter was sent out to the lab.