

Guidance for Laboratory Accreditation On-Site Assessment Reimbursement:

The Oklahoma Department of Environmental Quality (DEQ) Laboratory Accreditation Program performs on-site assessments or evaluations of laboratories located in Oklahoma to ensure compliance to the Laboratory Accreditation Rules. A comprehensive on-site assessment of each laboratory is performed prior to granting initial accreditation and at least every two years thereafter to ensure continued laboratory compliance.

Section I. Application and Pre-assessment

Off-site pre-assessment activities include the following:

1. Application review for completeness
2. Proficiency Testing (PT) summary review for two acceptable tests out of the last three participations per analyte.
3. Laboratory Quality Assurance Plan or Quality Manual is reviewed for completeness and applicability.
4. Laboratory Standard Operating Procedures (SOP), Administrative Procedures and analytical demonstrations of capability (DOC) are reviewed for completeness and acceptability.
5. The scheduling of the assessment on a mutually agreed date.
6. An on-site assessment cost estimate may be developed and provided to the laboratory with the completion of review and acceptance of activities 1-4 above.

Section II. On-Site Assessment and Corrective Action

Assessment

On-site assessment includes the following: sample management and accession, laboratory information system review, instrumentation, quality control (QC), recordkeeping, training, sample preparation, sample analysis by approved methodology, and analytical final reporting.

On-site assessments are routinely conducted for a laboratory new to the program requesting initial application and the required once every two-year assessment for continued re-accreditation.

On-site assessment may be conducted when a laboratory is adding a new field of accreditation.

During an assessment, the DEQ may require the laboratory to perform an analysis of an unknown test sample directly observed by a DEQ assessor.

By state rule, on-site evaluation may be unannounced. An unannounced assessment conducted in response to a complaint or in connection with a potential enforcement action is not charged an

on-site reimbursement fee, though the Department may seek to recapture these costs through subsequent penalty action.

Corrective Action or Corrective Action Plan “CAP”

Corrective Action Plans are the responses a laboratory must provide to the DEQ for “Findings” or “Nonconformities” revealed during the assessment. The CAP must include a plan of action to correct deficiencies or findings and to eliminate the cause of the non-conformity to prevent recurrence and must also include a schedule for implementation.

CAPs must be submitted in writing to the DEQ within 30 days following receipt of the DEQ evaluation report. The DEQ has an additional 45 days to review and require revisions, or accept the adequacy of the CAP. Routinely, the proposed corrections are accepted and the process is concluded within 60 days or sooner.

Section III. Reimbursement

The on-site assessment fee is a reimbursement to the DEQ, capped at \$10,000 per individual laboratory, for assessor time and labor covering all phases of the assessment from pre-assessment activities through on-site assessment and corrective action review. Reimbursable activities may include:

- a. A review of the application and documents supplied with the application for completeness;
- b. Preparation of the checklists used for the assessment;
- c. Meetings and communications with the applicant related to the assessment;
- d. Travel to and from the laboratory;
- e. Assessment of the laboratory;
- f. Preparation of the assessment report(s); and
- g. Review of any corrective action plan(s).

Reimbursement includes any travel expense, per-diem and hotel expense. This would include meals and lodging for assessments that require an overnight stay due to the logistics of travel, and costs of transportation, which for public transportation shall include all fares and which for non-public transportation. Reimbursable transportation expenses include mileage, any tolls, and parking fees.

More than one assessor may be assigned to the assessment based on the complexity of the laboratory, as well as the scope and complexity of a laboratory’s request for accreditation. Assessor time is calculated by the hour as time worked for the pay period and includes employee benefits and related indirect charges. The assessor will code time to a laboratory specific sub-category or project code

The laboratory will be invoiced for reimbursable expenses, to be paid within 45 days of receipt of the assessment invoice. By state rule, accreditation will be denied, revoked, or suspended if the laboratory fails to pay the costs associated with the on-site assessment.

Section IV. Assessment Fee Examples

Oklahoma Administrative Code 252:302 Field Laboratory Accreditation

The initial on-site evaluation fee is \$1000. The renewal on-site evaluation fee is \$500 annually rather than \$1,000 every two years.

Field Laboratory Initial Application Fee

Initial Accreditation	\$381.14
Evaluation Fee (Initial)	<u>\$1,000.00</u>
Total	\$1,381.14

Field Laboratory Renewal Accreditation Fee

Renewal Accreditation	\$381.14
On-site Evaluation (renewal)	<u>\$500.00 (annually)</u>
Total	\$881.14

A Renewal Late Fee will be assessed if the application is not received before the filing deadline of June 15th of each year.

Renewal Accreditation	\$381.14
Renewal Late fee	\$108.90
On-site Evaluation (renewal)	<u>\$500.00</u>
Total	\$990.04

Oklahoma Administrative Code 252:301 Laboratory Accreditation and 307 TNI Laboratory Accreditation

These accreditations are for the small wastewater discharge permittee lab up to large commercial laboratories. The assessment fee examples are based on assessor hours and activities utilized to review a representative number of methods. The number of participating assessors is dependent upon laboratory scope and complexity.

Estimates: On-Site Assessment Variable Costs by Lab Complexity

Assessment Description	Basic Laboratory	1-Assessor	1-Assessor	Complex Laboratory	Team of 2 Assessors
Days for Assessment	Hours	1 day Assessment	3 day Assessment	Hours	2 day Assessment
Preparation: Read Quality Assurance Manual & SOPs, PTs, retrieve reported data	20	\$937.72	\$937.72	48	\$4,501.44
Travel to site	4	\$187.54	\$187.54	4	\$375.09
Assessment Time	8-24	\$375.09	\$1,125.26	16	\$1500.48
Report & data review	8	\$375.09	\$375.09	16	\$1500.48
CAP Review	16	\$750.17	\$750.17	12	\$1,125.36
Transportation (Vehicle cost-* 1 vehicle; ** 2-vehicles)	\$113.33/vehicle	\$113.33*	\$339.99*		\$453.32**
Per Diem (if required)	\$66.00/day		\$198.00		\$132.00
Hotel (if required)	\$81.00/night		\$243.00		\$162.00
Total Time	56-72	\$2,625.61	\$3,375.79	96	\$9,002.85
Total Cost		\$2,738.94	\$4,156.78		\$9,750.17

Example: Basic Laboratory On-Site Assessment Fee

The example below represents the assessment fee for a smaller laboratory performing a small number of test methods, such as an industrial accredited laboratory performing compliance discharge testing.

This assessment fee is based on one (1) assessor’s time for one (1) day.

Preparation Time:	20 hours	\$ 937.72
Assessment Time (including travel time):	8 hours	\$ 375.09
Reporting and Corrective Action time:	20 hours	\$ 937.72
Total Assessors time	48 hours	\$ 2,250.53
Transportation		\$ 113.33
Total On-Site Reimbursable		\$2,363.86

Example: Commercial Laboratory Assessment Fee

This example represents the assessment fee for a commercial laboratory. An assessment fee is based on the laboratory’s fields or categories of accreditation (inorganic, organic, radiochemistry, microbiology, whole effluent toxicity), as well as the amount of time to evaluate the laboratory. This example is based on time for two (2) assessors with two (2) days on-site and includes preparation for the assessment, travel, on-site time, report compilation and finalization, and corrective action plan review(s).

Preparation time:	48 hours	\$4,501.44
Assessment time (including travel time)	20 hours	\$1,875.57
Reporting and Corrective Action review	28 hours	\$2,625.84
Total Assessors time	96 hours	\$9,002.85

Transportation	\$ 453.32
Travel expenses (per diem and hotel)	\$ 294.00
Total Cost On-Site Reimbursable	\$9,850.17

Frequently Asked Questions

Why do you have to pay this new fee?

The DEQ LAP is one of very few accreditation programs in the country that has no on-site assessment fees. The number of laboratories requesting accreditation continues to increase. The costs associated with the accreditation process have increased as appropriated funding has remained low. And as EPA requires the implementation of new procedures for NPDES and SDWA compliance testing, the complexity and time it takes to assess a laboratory also increases.

How will this affect my current accreditation status?

The laboratory should see no affect in their accreditation status.

How long will my assessment be?

For new (initial) laboratories, the cost estimate examples above provide an approximation of assessment time based on actual laboratory assessments performed by DEQ. It's important that all requested pre-assessment documents are received within the requested time.

How to estimate the cost of the assessment?

The DEQ will provide a cost estimate at the time of assessment scheduling. This estimate is based on the fields of testing or categories, the number of methods, technological diversity, and the completeness of the preassessment documentation. The numbers within the table above are estimates based on previous DEQ assessments. This has been compiled to provide an on-site assessment fee range from basic to complex assessments.

When will the invoice be mailed?

There will be a delay in issuing the invoice so that the DEQ may compile total assessment time per assessor, using DEQ specific time and labor coding. Invoices cannot be processed until the DEQ pay period has ended and assessor time has been validated. The invoice will be compiled with DEQ's confirmation of acceptance of all corrective actions, which routinely is no more than 45 days after the acceptance of all corrective action plans.

How will the DEQ minimize disruption to your laboratory?

The DEQ makes every effort to review a complete set of documents prior to arriving on-site to reduce the time that is required in the laboratory. By providing a complete data packet with all documentation of testing, chain of custody (COC), raw data runs, standard/reagent solution logs with certificate of analysis (COA), calibrations, and quality control evaluation steps, and final reporting, the on-site assessment time is reduced therefore reducing assessment expense.