

**TITLE 252. DEPARTMENT OF ENVIRONMENTAL QUALITY
CHAPTER 307. TNI LABORATORY ACCREDITATION**

RULE IMPACT STATEMENT

Before the Water Quality Advisory Council, January 8, 2019

Before the Environmental Quality Board, February 15, 2019

- 1. DESCRIPTION:** The gist of these rules and the underlying reason for this rulemaking is to make the Laboratory Accreditation Rules internally consistent, to update accreditation requirements to reflect current EPA standards for analysis, and to make program fees more closely approximate program costs for accreditation. The Department is proposing to amend 252:307-1-3, Definitions, to correct typographical errors, and by inclusion of new definitions. The definition for Basic Environmental Laboratory adds the analyte Escherichia coli. New definitions are added for “critical nonconformity” and “nonconformity.” The Department is proposing to amend 252:307-1-4, Incorporation by reference, to incorporate the latest changes to EPA Primary Drinking Water Regulations, National Standards for Solid Waste Test Methods, and EPA Test Procedures for the Analysis of Pollutants. A significant result of the update to EPA Test Procedures for the Analysis of Pollutants is the amendment of the procedure for the determination of the Method Detection Limit (MDL), which will apply to all permittees and accredited laboratories. The Department is proposing to amend 252:307-1-5, Accreditation classes and fields of accreditation with the deletion of fields of accreditation in the heading. The Department is proposing to amend 252:307-1-7, Annual fees, adding a new fee to recover the actual cost for assessors’ time and effort in performing onsite assessments. The gist of this rule is to more accurately reflect the Department’s full cost for performing laboratory accreditation, and reduce reliance on State appropriated funds. The Department is proposing to amend 252:307-9-8, Failure to perform, clarity to the suspension policy for proficiency testing failure. This language is added to meet TNI requirements.
- 2. CLASSES OF PERSONS AFFECTED:** The classes of persons affected are the owners and operators of laboratories that are DEQ accredited or applying for DEQ accreditation.
- 3. CLASSES OF PERSONS WHO WILL BEAR COSTS:** The classes of persons who will bear costs are the owners of laboratories that are accredited by the DEQ Laboratory Accreditation Program to perform environmental analyses, and potentially their customers.
- 4. INFORMATION ON COST IMPACTS FROM PUBLIC/PRIVATE ENTITIES:** The DEQ has not received any information from other public or private entities concerning the cost impacts of the proposed regulation.
- 5. CLASSES OF PERSONS BENEFITTED:** Oklahoma laboratories analyzing compliance samples will benefit through the clarification of accreditation requirements

and the utilization of new compliance test methods. All citizens may benefit from these rule changes through the redirection of costs from taxpayers to the laboratories.

6. PROBABLE ECONOMIC IMPACT ON AFFECTED CLASSES OF PERSONS:

Accredited laboratories will pay the costs for an on-site evaluation, every two years. This cost varies by the size and complexity of the laboratory and are estimated at \$2,250 to \$10,000. Oklahoma businesses previously accredited by an out-of-state TNI authority will realize no accreditation fee increase and may realize a decrease in accreditation fees, a result of no longer paying both an Oklahoma accreditation fee and TNI accreditation fee.

7. PROBABLE ECONOMIC IMPACT ON POLITICAL SUBDIVISIONS: The Department does not foresee any economic impact on political subdivisions due to this rulemaking.

8. POTENTIAL ADVERSE EFFECT ON SMALL BUSINESS: The Department anticipates no adverse effects on small businesses.

9. LISTING OF ALL FEE CHANGES, INCLUDING A SEPARATE JUSTIFICATION FOR EACH FEE CHANGE:

The fee changes associated with this rulemaking are intended to make program fees more closely approximate program costs for accreditation. Currently, on-site evaluation expense is partly paid by state appropriated funds. Costs associated with the evaluation process have increased, while appropriated funding has not increased.

252:307-1-7. Annual fees

(a) **Applicable fees.** The following fees apply:

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| (11) <u>Onsite Assessment Fee</u> | <u>Reimbursable Expenses</u> |
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(b) **Calculation of fees.** In addition to the application fee required for initial, renewal and interim accreditation, a laboratory must submit the applicable category fee. Fees for accreditation amendment, as described in OAC 252:307-5-2, consists of the accreditation amendment fee. The onsite assessment fee shall be calculated at actual cost and includes but is not limited to the following: assessor(s) time and labor (preliminary document review, total travel, time-on-site, report preparation, and corrective action review), transportation, per diem (if required), as described in 252:307-7-1. The onsite assessment will be invoiced at the closing of the assessment.

10. PROBABLE COSTS AND BENEFITS TO DEQ TO IMPLEMENT AND ENFORCE: The proposed fees will ensure the program has adequate funding to cover costs of on-site evaluations. The proposed rulemaking ensures that environmental analyses comply with current federal Clean Water Act Regulations.

11. PROBABLE COSTS AND BENEFITS TO OTHER AGENCIES TO IMPLEMENT AND ENFORCE: There will be no costs to other agencies, but they may benefit with the ability to utilize compliance data produced utilizing the most recent approved analytical test methods.

12. **SOURCE OF REVENUE TO BE USED TO IMPLEMENT AND ENFORCE RULE:** The cost of the Laboratory Accreditation Program will now be funded almost exclusively by user fees charged to participants. Implementation and enforcement of this rule will be funded by fees.
13. **PROJECTED NET LOSS OR GAIN IN REVENUES FOR DEQ AND/OR OTHER AGENCIES, IF IT CAN BE PROJECTED:** The Department anticipates a slight increase in revenue from the user fees, but this increase will be offset by the increased complexity of accreditation standards utilized in the accreditation of laboratories.
14. **COOPERATION OF POLITICAL SUBDIVISIONS REQUIRED TO IMPLEMENT OR ENFORCE RULE:** Implementation and enforcement of this rule would be handled solely by the Department, and no cooperation by other political subdivisions would be required.
15. **EXPLANATION OF THE MEASURES THE DEQ TOOK TO MINIMIZE COMPLIANCE COSTS:** Oklahoma is the only state in the region that does not charge users for on-site evaluations. The Department evaluated Regional state programs to ensure Oklahoma's program costs are adequate and appropriate.
16. **DETERMINATION OF WHETHER THERE ARE LESS COSTLY OR NONREGULATORY OR LESS INTRUSIVE METHODS OF ACHIEVING THE PURPOSE OF THE PROPOSED RULE:** The Department has determined this method to be the least intrusive and least costly for each category of affected facility to achieve the purpose of the proposed rule.
17. **DETERMINATION OF THE EFFECT ON PUBLIC HEALTH, SAFETY, AND ENVIRONMENT:** The Department has determined this rulemaking would have little to no effect on public health, safety, and environment.
18. **IF THE PROPOSED RULE IS DESIGNED TO REDUCE SIGNIFICANT RISKS TO THE PUBLIC HEALTH, SAFETY, AND ENVIRONMENT, EXPLANATION OF THE NATURE OF THE RISK AND TO WHAT EXTENT THE PROPOSED RULE WILL REDUCE THE RISK:** This proposed rulemaking is not intended to reduce significant risks to public health, safety, and environment.
19. **DETERMINATION OF ANY DETRIMENTAL EFFECT ON THE PUBLIC HEALTH, SAFETY, AND ENVIRONMENT IF THE PROPOSED RULE IS NOT IMPLEMENTED:** The proposed rulemaking would not have any detrimental effect on public health, safety, or environment if not implemented.
20. **PROBABLE QUANTITATIVE AND QUALITATIVE IMPACT ON BUSINESS ENTITIES (INCLUDE QUANTIFIABLE DATA WHERE POSSIBLE):** Public, private, and industrial laboratory accreditation expenses would increase slightly.

THIS RULE IMPACT STATEMENT WAS PREPARED ON: November 29, 2018