

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

SUMMARY OF COMMENTS AND RESPONSES

COMMENT PERIOD: December 3, 2018 through January 2, 2019

ALL COMMENTS RECEIVED AFTER THE COMMENT PERIOD

1. **COMMENTS:** OAC 252:307-1-7 Annual Fees

Red River Laboratory: TNI is not a required or must-have laboratory accreditation program. It is the state's choice to be recognized by TNI as accreditation bodies. If a laboratory chose to be accredited by TNI, a reasonable charge to cover ODEQ's cost is fair. However, the laboratory should have the choice to be accredited by any TNI recognized accreditation bodies if ODEQ's charge is not competitive. The laboratory should be given a quote before the start of the evaluation instead of being invoiced at the closing of the assessment.

RESPONSE: Every laboratory may choose whether or not to seek TNI accreditation. However, it is unlikely that any laboratory will have its choice of accreditation bodies should DEQ be noncompetitive. A TNI policy applicable to TNI Accreditation Bodies (ABs) titled "Mutual Recognition Policy for NELAP-Recognized Accreditation Bodies" (POL #3-100 adopted in 2016, at Section IV-5) limits AB activity. ABs may accredit laboratories only in the state where the AB is located or laboratories in states without a State AB.

2. **COMMENTS:**

Red River Laboratory: If ODEQ wants to make TNI program a business, then a business plan should be posted and followed instead of putting these charges into a regulation without any charge details.

RESPONSE: DEQ's goal is to make program fees more closely approximate actual expense. We make every attempt to keep program costs down.

3. **COMMENTS:** OAC 252:307-1-7 Annual Fees

Accurate Laboratories: DEQ's annual fees already appear to cover the costs of operation - data management, auditing, other back ground activities, and corrective action follow ups. What additional items will an audit fee cover that are not currently covered that would justify possibly an additional \$5,000-\$8,000 expenditure?

RESPONSE: Currently, on-site evaluation expense is partly paid by state appropriated funds. The expense of on-site assessment has increased as state appropriation has continued to decrease. Costs associated with the evaluation process have increased as the complexity and competency of assessment has increased. The fee for onsite assessment will be calculated at actual time and labor cost and invoiced after the assessment. Total

assessment cost is directly related to the adequacy and timeliness of pre-assessment documentation and laboratory competency.

4. **COMMENTS:** OAC 252:307-1-7 Annual Fees

Accurate Laboratories: What is the formula used to calculate the audit costs? Is there a standard hourly rate for the auditors involved or is there a sliding scale applied to each auditor? What determines the number of auditors to be used in an audit vs the length of the audit?

RESPONSE: On-site assessment cost will be calculated by the actual assessor's time and labor for on-site assessment activities, per the proposed 252:307-1-7 (b) Calculation of fees. In addition, DEQ has developed a "Guidance for Laboratory Accreditation On-Site Assessment Reimbursement," (Still in draft).