Frequently Asked Questions (FAQs) for the TCEQ Laboratory Accreditation Program:

FAQs:

- What must a laboratory do to be able to report analytical environmental data to the TCEQ?

- What must a laboratory do to achieve PRIMARY accreditation?

- What is the process after a laboratory submits an application for PRIMARY accreditation?

- How does a laboratory renew/maintain their PRIMARY accreditation?

- Is there a grace period for renewal of a PRIMARY accreditation?

- How does a laboratory add parameters to a current PRIMARY scope of accreditation?

- What is the process after a laboratory submits an application to add parameters for PRIMARY accreditation?

- Will a laboratory lose PRIMARY accreditation if it is not in compliance with the PT requirements?

- What must a laboratory do to achieve SECONDARY accreditation?

- What is the process after a laboratory submits an application for SECONDARY accreditation?

- How does a laboratory renew/maintain their SECONDARY accreditation?

- Is there a grace period for renewal of a SECONDARY accreditation?

- How does a laboratory add parameters to a current SECONDARY scope of accreditation?

- What is the process after a laboratory submits an application to add parameters for SECONDARY accreditation?

- Where can I find additional information?

Frequently Asked Questions (FAQs) for the TCEQ Laboratory Accreditation Program:

What must a laboratory do to be able to report analytical environmental data to the TCEQ?

> In order to report certain analytical environmental data to the TCEQ, a laboratory must be accredited under NELAP. The requirements can be found in the Texas Administrative Code, Subchapter A:
>
> http://texreg.sos.state.tx.us/public/readtac%24ext.ViewTAC?tac_view=4&ti=30&pt=1&ch=25

What must a laboratory do to achieve PRIMARY accreditation?

> In order to achieve primary accreditation, a laboratory must complete all of the following requirements:

- Implement a quality assurance system that meets the requirements of the 2016 TNI Standard.

- Submit a completed application:

  https://www.tceq.texas.gov/downloads/compliance/labs/tceq20132.pdf

- Include the appropriate fees from page five of the application.

- Fill out the Fields of Accreditation (FoA) sheets showing the analytes, methods, and matrices for which the laboratory is requesting accreditation:

  https://www.tceq.texas.gov/downloads/compliance/labs/tceq20132a.pdf/

  If requesting accreditation for a few methods/analytes in one or two matrices, then complete only the applicable sheets (not all 144 pages).

- Include current copies of the laboratory's Quality Manual or equivalent document, analytical SOPs, method detection limit studies (MDLs), if applicable, demonstrations of capability (DOCs), and any other documents referenced in the two checklists on pages 09-12 of the application. Electronic copies of these documents sent via e-mail or included in a CD-ROM are acceptable.

- Submit a Technical Manager Qualification Form for each laboratory technical manager showing the technical managers meet the requirements in the appropriate discipline(s). See Sections 5.2.6.1 and 5.2.6.2 of Volume 1, Module 2, of the 2016 TNI Standard (TNI V1M2-5.2.6.1 and 5.2.6.2). Copies of college transcripts are required (unofficial copies are acceptable) in order to verify the educational requirements in Section 5.2.6.1 and copies of operator permits or facility permit to verify the requirements in Section 5.2.6.2.

Frequently Asked Questions (FAQs) for the TCEQ Laboratory Accreditation Program:

https://www.tceq.texas.gov/downloads/compliance/labs/tceq20132b.pdf

- Achieve a history of two (2) successful (acceptable scores) PT studies out of the most recent three (3) attempts as required by TNI V1M1-5.1.1 for each Field of Proficiency Testing (FoPT) for which the laboratory is requesting accreditation. The two (2) PT studies must be performed no more than eighteen (18) months prior to submitting the application and the opening date of the second study must be at least seven (7) calendar days after the closing date of the first study. The closing date of the most recent successful PT study for an FoPT must be no more than six (6) months prior to the application for initial accreditation, and the laboratory shall continue to participate in PT studies at least semi-annually (no more than seven (7) months apart between consecutive attempts) from that point on. The results must come from a recognized provider. The accreditation program does not accept PT results provided by the laboratory.

  NOTE: Analytes that are not on the TNI FoPT table for the applicable matrix do not require PTs for initial or continuing accreditation. All other requirements in the standard still apply.

  The list of FoPTs, broken down by matrix, can be found here:

  http://www.nelac-institute.org/fopt.php

  The list of recognized PT providers can be found here:

  http://www.nelac-institute.org/ptproviders.php

- Successfully pass an on-site assessment, unless the laboratory is granted interim accreditation. An on-site assessment must be successfully passed for final accreditation.

What is the process after a laboratory submits an application for PRIMARY accreditation?

Once received, an administrative review of the application is conducted. In order for an application to be deemed administratively complete, all documentation must be completely filled out by the laboratory, the quality manual and other supporting documents must be present, and PT requirements must be met, if applicable. If there are any discrepancies, the laboratory is notified and given an opportunity to address any issues.

Once the application is *complete*, it is put in line for a technical review. A technical review is normally conducted within 45 days of an application being considered administratively complete. An assessor will review the laboratory's quality manual, analytical SOPs, MDLs, DOCs, and the four pages of checklists from the application (along with the supporting documentation included in the

application) to ensure everything meets the requirements of the standard. If there are any discrepancies, the laboratory is notified and given an opportunity to address any issues.

Once all issues identified during the technical review have been successfully addressed, the application is put in line for an on-site assessment. If the TCEQ is not able to conduct the assessment within six months, interim accreditation may be granted for up to one year prior to completing the on-site assessment process and issuing final accreditation. Interim accreditation is **NOT** automatically granted or guaranteed to a laboratory. Interim accreditation is evaluated by management on a case-by-case basis. Considerations include the current assessment schedule and the completeness of the laboratory's application.

After the on-site assessment has been completed, a report is issued to the laboratory. The laboratory is given up to two opportunities to address any deficiencies identified in the report. Once an acceptable corrective action plan is put forth by the laboratory, final accreditation is issued for a period of one year.

How does a laboratory renew/maintain their PRIMARY accreditation?

In order to maintain accreditation, laboratories must renew their accreditation every year (i.e., pay fees and show proof of maintaining a successful history of passing PTs, if applicable) and undergo an on-site assessment every two years (+/- six months).

If there have been no changes to the laboratory's key accreditation criteria (personnel and facilities) and the laboratory does not plan on making any changes to its current scope of accreditation, then a paid billing receipt serves as a renewal application.

If the laboratory has made changes to key accreditation criteria, then an abbreviated application is required. The abbreviated application must include, at a minimum, at least pages one and seven of the application as well as any other pages indicating changes from the last information on record.

If the laboratory intends to request changes to its current scope of accreditation, then the procedures for an amendment application apply. (See the link on the main accreditation web page or the FAQs related to amendments.) In this case, the $250 administrative fee is not required because it's included in the annual renewal fee. Any applicable category fees are still required.

NOTE: The renewal process is NOT linked to the biennial assessment schedule. Renewal dates will not be moved to accommodate assessments. Assessment dates will not be moved to accommodate renewals. However, if the lead assessor finds sufficient cause, renewal of an accreditation may be denied by the program manager as a result of the on-site assessment.

Frequently Asked Questions (FAQs) for the TCEQ Laboratory Accreditation Program:

<u>Is there a grace period for renewal of a PRIMARY accreditation?</u>

There is no mechanism in place for a grace period. If laboratory fees are not received by the due date, the laboratory's accreditation is not renewed. The laboratory's accreditation ends on the expiration date on the certificate. If the laboratory decides it does need the accreditation after the expiration date has passed, the laboratory will have to start the accreditation process from the beginning. The accreditation process may take several months.

Renewal checks that arrive after the renewal date are returned to the laboratory.

<u>How does a laboratory add parameters to a current PRIMARY scope of accreditation?</u>

In order to add parameters to a current primary NELAP scope of accreditation, a laboratory must submit:

- An amended application. At a minimum, the application must include at least pages one and seven of the application as well as any other pages indicating changes from the last information on record.

  The current application may be obtained at the following link:

  https://www.tceq.texas.gov/downloads/compliance/labs/tceq20132.pdf

- The marked FoA sheets showing what analytes/methods the laboratory is requesting to add.

  Our FoAs can also be found on our web page or directly here:

  https://www.tceq.texas.gov/downloads/compliance/labs/tceq20132a.pdf/

  If you are only requesting the addition of a few methods/analytes in one or two matrices, only complete the applicable sheets (not all 144 pages).

- A $250 administrative fee. This fee is not required if the change of scope is done as part of the laboratory's annual renewal.

- Appropriate fees for any methods in **NEW** categories for which the laboratory isn't **ALREADY** paying category fees. For example:

  ➢ If a laboratory is currently accredited for a microbiology method in drinking water and wants to add accreditation for a microbiology method in non-potable water, then additional fees would be required. However, if the laboratory is currently accredited for a microbiology method in drinking water and wants to add a second microbiology method in drinking water, then no additional fees would be required.

Frequently Asked Questions (FAQs) for the TCEQ Laboratory Accreditation Program:

> ➢ If a laboratory that is only accredited for a microbiology method in drinking water and wants to add a metals method in drinking water, then additional fees would be required. However, if this same laboratory wants to add another microbiology method in drinking water, then no additional fees would be required.

- SOPs for **ANY** requested methods.

- DOC/MDL data for the new parameters. This includes DOC certification statements that include all of the requirements listed in Section 1.6, Volume 1 of the appropriate modules in the 2016 TNI standard.

- Achieve a history of two (2) successful (acceptable scores) PT studies out of the most recent three (3) attempts as required by TNI V1M1-5.1.1 for each Field of Proficiency Testing (FoPT) for which the laboratory is requesting accreditation. The two (2) PT studies must be performed no more than eighteen (18) months prior to submitting the application and the opening date of the second study must be at least seven (7) calendar days after the closing date of the first study. The closing date of the most recent successful PT study for an FoPT must be no more than six (6) months prior to the application for initial accreditation, and the laboratory shall continue to participate in PT studies at least semi-annually (no more than seven (7) months apart between consecutive attempts) from that point on. The results must come from a recognized provider. The accreditation program does not accept PT results provided by the laboratory.

  NOTE: Analytes that are not on the TNI FoPT table for the applicable matrix do not require PTs for initial or continuing accreditation. All other requirements in the standard still apply.

What is the process after a laboratory submits an application to add parameters for PRIMARY accreditation?

An administrative review of the applications is normally conducted within fifteen days of arrival. The administrative review ensures everything is completely filled out, all required documentation has been submitted, and all PT requirements have been met, if applicable. If there are any discrepancies, the laboratory is notified and given an opportunity to address any issues.

Once a **complete** application is received, it is put in line for a technical review. An assessor will review the laboratory's documentation to ensure everything meets the requirements of the standard. A technical review is normally conducted within 45 days of an application being considered administratively complete. If there are any discrepancies, the laboratory is notified and given an opportunity to address any issues.

Frequently Asked Questions (FAQs) for the TCEQ Laboratory Accreditation Program:

Once all issues identified during the technical review have been successfully addressed, an updated certificate and scope of accreditation is issued to the laboratory and will remain valid until the laboratory's annual renewal date.

NOTE: There are not "expedited" procedures for amendment requests. Amendment requests submitted as part of the annual renewal process are given priority over "out of cycle" amendment requests.

Will a laboratory lose PRIMARY accreditation if it is not in compliance with the PT requirements?

Laboratories will lose accreditation for any affected parameters if they are not in compliance with the PT requirements of the TNI Standard at the time of annual renewal; the affected parameters will NOT be included in the new scope of accreditation.

The laboratory has the option of dropping parameters from their scope at any time or performing supplemental PT studies in order to get back into compliance. The laboratory can also reapply for reaccreditation of any of these parameters at any time (the usual requirements for an amended application will apply).

However, if renewal of a parameter is denied due to PT issues, this is considered a partial denial of accreditation. Under the requirements of the Texas Administrative Code, the laboratory cannot reapply for this parameter until at least six months have passed. At this point, the PT requirements of the standard for initial accreditation (TNI V1M1-5.1.1) will apply.

What must a laboratory do to achieve SECONDARY accreditation?

In order to achieve secondary accreditation, a laboratory must:

- Submit a completed application:

  https://www.tceq.texas.gov/downloads/compliance/labs/tceq20132.pdf

- Include the appropriate fees from page five of the application

- Fill out the Fields of Accreditation (FoA) sheets showing the analytes, methods, and matrices for which the laboratory is requesting accreditation:

  https://www.tceq.texas.gov/downloads/compliance/labs/tceq20132a.pdf/

  If requesting accreditation for a few methods/analytes in one or two matrices, only complete the applicable sheets (not all 144 pages).

Frequently Asked Questions (FAQs) for the TCEQ Laboratory Accreditation Program:

> NOTE: If a parameter is not listed in the FoAs, then the program does NOT offer accreditation for it. As a result, the laboratory cannot be accredited by the TCEQ for that particular parameter. The fact that the laboratory may have accreditation for it from its primary accreditation body has NO bearing.

What is the process after a laboratory submits an application for SECONDARY accreditation?

Once received, a review of the application is normally conducted within fifteen days of arrival to compare the requested FoAs against the laboratory's scope of accreditation from their primary accreditation body or bodies. Anything that matches gets added to the scope. If there are any discrepancies, the laboratory is contacted for additional information as follows:

- If a parameter from the primary scope is missed, please notify the program with the correct page.

- If there is an issue with the primary scope, please contact the primary accreditation body so they can make the necessary changes. The parameters will be included in your Texas secondary scope once they have been added to the primary scope.

- If the requested parameter(s) are not on the primary scope, they will be removed from the requested scope upon confirmation.

Once the scopes have been reconciled, the laboratory will be issued a certificate and scope for secondary accreditation.

NOTE: The program relies on the laboratory's primary accreditation body to verify the laboratory's compliance with the requirements of the TNI Standard for initial and continued accreditation. Key laboratory personnel are not vetted, and PTs are not reviewed for secondary accreditations.

How does a laboratory renew/maintain their SECONDARY accreditation?

Laboratories must renew their accreditation every year (i.e., pay fees and show proof of maintaining their primary accreditation).

If there have been no changes to the laboratory's key accreditation criteria (personnel and facilities) and the laboratory does not plan on making any changes to its current scope of accreditation, then a paid billing receipt serves as a renewal application.

If the laboratory has made changes to key accreditation criteria, then an abbreviated application is required. The abbreviated application must include, at a minimum, at least pages one and seven of the application as well as any other pages indicating changes from the last information on record.

Frequently Asked Questions (FAQs) for the TCEQ Laboratory Accreditation Program:

If the laboratory will be requesting changes to its current scope of accreditation, then the procedures for an amendment application apply. (See the link on the main accreditation web page or the FAQs related to amendments for secondary accreditation.) In this case, the $250 administrative fees are not required; it's included in the annual renewal fee. Any applicable category fees are still required.

The laboratory's secondary scope of accreditation will be verified against the scope from its primary accreditation body. Anything that matches will remain on the scope. If there are any discrepancies, the laboratory is contacted:

- If a parameter from the primary scope is missed, please notify the program and indicate the correct page.

- If there is an issue with the primary scope, please contact the primary accreditation body so they can make the necessary changes. We will then include the parameters in your Texas secondary scope once they have been added to the primary scope.

- If the requested parameter(s) are not on the primary scope, they will be removed from the renewal scope upon confirmation.

Once the scopes have been reconciled, the laboratory will be issued a renewal certificate and scope for secondary accreditation.

Is there a grace period for renewal of a SECONDARY accreditation?

There is no mechanism in place for a grace period. If fees have not been received by the due date, accreditation will NOT be renewed; the laboratory will not be accredited beyond the expiration date on the certificate. If the laboratory decides it does need the accreditation after the expiration date, the laboratory must start the accreditation process from the beginning.

Renewal checks that arrive after the renewal date will be returned to the laboratory.

How does a laboratory add parameters to a current SECONDARY scope of accreditation?

In order to add parameters to a current secondary NELAP scope of accreditation, a laboratory must submit:

- An amended application. It must include, at a minimum, at least pages one and seven of the application as well as any other pages indicating changes from the last information on record.

Frequently Asked Questions (FAQs) for the TCEQ Laboratory Accreditation Program:

The current copy of the application can be downloaded here:

https://www.tceq.texas.gov/downloads/compliance/labs/tceq20132.pdf

- A $250 administrative fee. This fee is not required if the change in scope is done as part of the laboratory's annual renewal.

- Appropriate fees for any methods in **NEW** categories for which the laboratory isn't **ALREADY** paying category fees. For example:

  ➢ If a laboratory is currently accredited for a microbiology method in drinking water and wants to add accreditation for a microbiology method in non-potable water, then additional fees would be required. However, if the laboratory is currently accredited for a microbiology method in drinking water and wants to add a second microbiology method in drinking water, then no additional fees would be required.

  ➢ If a laboratory that is only accredited for a microbiology method in drinking water and wants to add a metals method in drinking water, then additional fees would be required. However, if this same laboratory wants to add another microbiology method in drinking water, then no additional fees would be required.

- Fill out the Fields of Accreditation (FoA) sheet(s) showing the analytes, methods, and matrices for which the laboratory is requesting accreditation:

  https://www.tceq.texas.gov/downloads/compliance/labs/tceq20132a.pdf/

  If requesting accreditation for a few methods/analytes in one or two matrices, only complete the applicable sheets (not all 144 pages).

NOTE: If a parameter is not on Texas' FoAs, then accreditation for that parameter is not offered. The fact that the laboratory may have accreditation for it from its primary accreditation body has NO bearing.

<u>What is the process after a laboratory submits an application to add parameters for SECONDARY accreditation?</u>

A review of the applications is normally conducted within fifteen days of arrival. The requested FoAs are compared against the laboratory's scope of accreditation from their primary accreditation body or bodies. Anything that matches gets added to the scope. If there are any discrepancies, the laboratory is contacted for additional information as follows:

Frequently Asked Questions (FAQs) for the TCEQ Laboratory Accreditation Program:

- If a parameter from the primary scope is missed, please notify the program with the correct page.

- If there is an issue with the primary scope, please contact the primary accreditation body so they can make the necessary changes. The parameters will be included in the laboratory's Texas secondary scope once they have been added to the primary scope.

- If the requested parameter(s) are not on the primary scope, they will remove from the requested scope upon confirmation.

Once the scopes have been reconciled, the laboratory will be issued an updated certificate and scope that remains valid until the laboratory's annual renewal date.

NOTE: There are not "expedited" procedures for amendment requests. Amendment requests submitted as part of the annual renewal process are given priority over "out of cycle" amendment requests.

Where can I find additional information?

The NELAC Institute (TNI) has a wealth of resources available to laboratories:

http://www.nelac-institute.org/index.php