

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

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## **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](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 2009 TNI Standard.
- Submit a completed application:

[http://www.tceq.texas.gov/assets/public/compliance/compliance\\_support/qa/tceq20132.pdf](http://www.tceq.texas.gov/assets/public/compliance/compliance_support/qa/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:

[http://www.tceq.texas.gov/assets/public/compliance/compliance\\_support/qa/tceq20132a.pdf](http://www.tceq.texas.gov/assets/public/compliance/compliance_support/qa/tceq20132a.pdf)

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

- Include a copy of the laboratory's current 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 10-13 of the application. Electronic copies of these documents sent via e-mail or included in a CD-ROM are acceptable.
- Provide sufficient documentation showing the technical managers for the laboratory 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 2009 TNI Standard (TNI V1M2-5.2.6.1 and 5.2.6.2). We DO require copies of college transcripts (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. If the technical managers have already been recognized by the TCEQ or another TNI accreditation body, then the above information is not required. If the technical manager has been previously recognized by TCEQ, we would need to be informed of that fact so we can look up the information in our database. If the technical manager has been previously recognized by another accreditation body, the laboratory needs to provide the name of the state so we can verify the information.

- Successfully pass two Proficiency Test (PT) samples as required by TNI V1M1-4.1.1 for each Field of Proficiency Testing (FoPT) for which the laboratory is requesting accreditation. PT samples must be analyzed within the last 18 months prior to the application date of accreditation, with the analysis date of the most recent PT sample being no more than six months from the application date. The analysis dates of the two studies have to be at least fifteen days apart. The results must come from a recognized provider. We will not accept copies of the result from 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 found during the technical review have been successfully addressed, the application is put in line for an on-site assessment. If TCEQ is not able to conduct the assessment within six months, we may (but are not required to do so) grant the laboratory interim accreditation for up to one year prior to completing the on-site assessment process and issuing final accreditation. Interim accreditation is **NOT** promised to any laboratory that applies. The decision to offer interim accreditation is made by management on a case-by-case basis, depending on how heavy the assessment schedule is and the quality 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 listed 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 (pay the 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 least page one (so we know the name of the laboratory) and page seven (so the laboratory recertifies compliance with the standard) as well as any other pages indicating changes from our current information.

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.) In this case, the \$250 admin fees are not required; 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 and 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.

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

There is no mechanism in place for a grace period. If a laboratory does not get the fees to us by the due date, we will NOT renew its accreditation. 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 has passed, the laboratory will have to start the accreditation process from the beginning. For a primary accreditation, this will most likely be a multi-month process.

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

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

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

- An amended application. It must include at least page one (so we know the name of the laboratory) and page seven (so the laboratory recertifies compliance with the standard) as well as any other pages indicating changes from our current information.

You can download the current copy of the application from our web page here:

[http://www.tceq.texas.gov/field/qa/env\\_lab\\_accreditation.html](http://www.tceq.texas.gov/field/qa/env_lab_accreditation.html)

Or directly here:

[http://www.tceq.texas.gov/assets/public/compliance/compliance\\_support/qa/tceq20132.pdf](http://www.tceq.texas.gov/assets/public/compliance/compliance_support/qa/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:

[http://www.tceq.texas.gov/assets/public/compliance/compliance\\_support/qa/tceq20132a.pdf](http://www.tceq.texas.gov/assets/public/compliance/compliance_support/qa/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, fees are required if a laboratory, which is only accredited for Standard Method 9223 in drinking water, wants to add EPA Method 200.7 in drinking water to its scope of accreditation. Fees are not required if that same laboratory wants to add Standard Method 9215B in drinking water, another microbiological test method.
- 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 2009 TNI standard.
- The results of two successful PT samples for each requested Fields of Proficiency Testing (FoPTs) as required by TNI V1M1-4.1.1. PT samples must be analyzed within the last 18 months prior to the application date of accreditation, with the analysis date of the most recent PT sample being no more than six months from the application date. The analysis dates of the two studies have to be at least fifteen days apart. The results must come from a recognized provider. We will not accept copies of the results from 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 we have a **complete** application, 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.

Once all issues found during the technical review have been successfully addressed, an updated certificate and scope of accreditation is issued to the laboratory for a period good until the laboratory's annual renewal date.

NOTE: We do not have "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 by the time we issue its 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 we deny renewal of a parameter 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 V1M1-4.1.1) will apply.

### What must a laboratory do to achieve SECONDARY accreditation?

In order to achieve secondary accreditation, a laboratory must:

- Submit a completed application:

[http://www.tceq.texas.gov/assets/public/compliance/compliance\\_support/qa/tceq20132.pdf](http://www.tceq.texas.gov/assets/public/compliance/compliance_support/qa/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:

[http://www.tceq.texas.gov/assets/public/compliance/compliance\\_support/qa/tceq20132a.pdf](http://www.tceq.texas.gov/assets/public/compliance/compliance_support/qa/tceq20132a.pdf)

If you are only 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 our FoAs, then we do NOT offer accreditation for it. As a result, the laboratory cannot be accredited by 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 we missed a parameter from the primary scope, please let us know and point us to 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, then we need confirmation of that fact and we will remove them from the requested scope.

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

NOTE: We rely 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. We do NOT vet key laboratory personnel and we do NOT review PTs for secondary accreditations.

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

Laboratories must renew their accreditation every year (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 had changes to key accreditation criteria, then an abbreviated application is required. The abbreviated application must include at least page one (so we know the name of the laboratory) and page seven (so the laboratory recertifies compliance with the standard) as well as any other pages indicating changes from our current information.

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 admin fees are not required; it's included in the annual renewal fee. Any applicable category fees are still required.

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

- If we missed a parameter from the primary scope, please let us know and point us to 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, then we need confirmation of that fact and we will remove them from the renewal scope.

Once the scopes have been reconciled, we will issue the laboratory 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 a laboratory does not get the fees to us by the due date, we will NOT renew its accreditation; 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 will have to start the accreditation process from the very 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 least pages one (so we know the name of the laboratory) and seven (so the laboratory recertifies compliance with the standard) as well as any other pages indicating changes from our current information.

You can download the current copy of the application from our web page here:

[http://www.tceq.texas.gov/field/qa/env\\_lab\\_accreditation.html](http://www.tceq.texas.gov/field/qa/env_lab_accreditation.html)

Or directly here:

[http://www.tceq.texas.gov/assets/public/compliance/compliance\\_support/qa/tceq20132.pdf](http://www.tceq.texas.gov/assets/public/compliance/compliance_support/qa/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, fees are required if a laboratory, which is only accredited for Standard Method 9223 in drinking water, wants to add EPA Method 200.7 in drinking water to its scope of accreditation. Fees are not required if that same laboratory wants to add Standard Method 9215B in drinking water, another microbiological test method.
- A filled out Fields of Accreditation (FoA) sheet(s) showing the analytes, methods, and matrices for which it is requesting accreditation:

[http://www.tceq.texas.gov/assets/public/compliance/compliance\\_support/qa/tceq20132a.pdf](http://www.tceq.texas.gov/assets/public/compliance/compliance_support/qa/tceq20132a.pdf)

If you are only 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 our FoAs, then we do NOT offer accreditation for it and there is no way for the laboratory to get accreditation for it. The fact 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 to add parameters for SECONDARY accreditation?

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:

- If we missed a parameter from the primary scope, please let us know and point us to the correct page.
- If there is an issue with the primary scope, 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, then we need confirmation of that fact and we will remove them from the requested scope.

Once the scopes have been reconciled, we will issue the laboratory an updated certificate and scope for a period good until the laboratory's annual renewal date.

NOTE: We do not have "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>