Accreditation to the 2016 TNI Standard

Frequently Asked Questions

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1. Do I have to transition my laboratory to the 2016 TNI Standard?

If your laboratory is located in a TNI state, it will be accredited to the standard set forth by your state's accreditation body (AB). Not all states have implemented the 2016 Standard at this time. If your laboratory is accredited by a non-governmental AB you can choose which standard to be accredited to depending on the needs of your clients.

2. Does the 2016 TNI Standard affect proficiency testing?

The proficiency testing module of the 2009 TNI Standard was limited in detail and contained requirements preventing its implementation by some TNI Accreditation Bodies ABs. The 2016 Standard contains revisions to allow all TNI ABs to implement.

Examples of changes include: 1) Evaluating and reporting PT sample results down to the laboratory's limit of quantitation (LOQ) has reverted back to evaluating and reporting PT sample results down to the prescribed Proficiency Testing Reporting Limit (PTRL). 2) PT frequency requirements were changed from 5-7 months apart to a maximum of 7 months apart with a minimum of 7 days between PT studies. 3) Clarification of an "acceptable" PT score versus a "successful" PT evaluation has been achieved to ensure laboratories understand that there is more to obtaining a successful evaluation than just reporting an acceptable result.

3. Why do changes to definitions matter?

Words have meaning and meanings matter. What is a "parameter?" What does "in-depth data monitoring" actually describe? What is a standard or reagent "lot?" These clarifications assist laboratories and ABs to be on the same page in terms of operations and accreditation.

For example, "data integrity" has been amended to include specific components to ensure it is treated as a system and not as something that can just be checked off.

4. Do we treat thermometer calibrations the same as in the 2009 Standard?

This change has been enthusiastically received. No, rather than having to bracket the range of use, the laboratory can now utilize a single-point calibration (with a few caveats).

Other support equipment requirements have also been revised (e.g., calibration of support equipment, volumetric dispensing devices, and daily incubator checks).

5. Have all modules of the 2009 Standard been changed?

Module 7, Quality Systems for Whole Effluent Toxicity Testing, is the only module to remain unrevised in the 2016 Standard. Modules 1-6 have undergone revision to varying degrees. For example, Module 6, Quality Systems for Asbestos Testing, had minor revisions whereas Modules 5 and 6 (microbiology and radiochemical testing, respectively) have been substantially reworked. Be sure to review each module affecting your laboratory since some changes are considerable.

6. Have demonstrations of capability (DOCs) been standardized for all tests?

No. The procedures for performing DOCs for a given test depends on which technical module it falls under.

For example, DOCs for asbestos and chemistry testing has been revised for clarity allowing for more options and reinforces they are specific to each individual who performs the test. Radiochemical testing includes the analysis of blanks to address method performance at background activity.

7. Have procedures for detection limits changed?

Yes. In order to be more consistent with the EPA method detection limit (MDL) procedure in 40 CFR Part 136, significant revisions to Module 4 have been made. For example, MDL studies must include both spike and blank data from multiple days. Also, ongoing quarterly verification analysis is required.

Note: The definition of MDL in Module 2 is different from the EPA definition of an MDL. The procedure outlined in Module 4 is also different. To avoid confusion on which procedure to use if "MDL" is used without distinction, Module 4 uses the term to Detection Limit (DL) to clarify that when a lab uses the term MDL, they are using the Part 136 procedure.

8. What happened to "Notes?"

Notes have never been enforceable, they are given as guidance. Some notes in the 2009 Standard have been eliminated to avoid confusion and others have been converted to language that is now part of the 2016 Standard. It has been clarified that notes, as always, are for guidance purposes only.

9. What do I need to do to transition my laboratory to the 2016 TNI Standard?

First, get in touch with your AB. Find out *their* timeline of implementation so you can plan *your* timeline.

Second, review the 2016 Standard and become familiar with the changes. Luckily, not everything has changed, therefore the more you are able to understand it the better equipped you will be during your laboratory's transition.

Third, develop a transition plan. It is recommended that labs conduct a gap analysis between your current system and the requirements of the 2016 Standard to assist in focusing efforts to the areas requiring the most attention.

Fourth, update your laboratory's quality management system and technical documents to meet the new requirements.

Last, provide training to all staff, regardless of position, that have an impact on data and quality systems. Usually, a one-time meeting is not sufficient to ensure compliance with all involved. Continual improvement is always the goal.

10. How long does it typically take to gain accreditation from IAS?

During the initial meeting with applicants, IAS will ask if the laboratory has a specific schedule for achieving accreditation. The amount of time it takes for a laboratory to get accredited by IAS depends on the readiness of the laboratory. IAS usually schedules the onsite assessment after the laboratory submits the application for accreditation, pre-assessment questionnaire and all relevant laboratory documentation to demonstrate their readiness and compliance with the standard. Following the IAS assessment and closure of all corrective actions by the laboratory, IAS issues a certificate of accreditation and the associated scope of accreditation. The scope of accreditation is uploaded onto the IAS website and remains in the public domain as long as the laboratory meets all the required criteria for accreditation. The entire process may generally take two months for laboratories that are prepared for the assessment and meet the requirements of the standards.

11. Can my lab get accredited to both the TNI and ISO/IEC 17025 standards?

Yes, IAS can include both standards in the same assessment for laboratory accreditation.

This FAQ sheet is not meant to be a comprehensive list of requirements for accreditation.

About IAS The International Accreditation Service is a non-profit, globally recognized accreditation body. IAS is a NELAP recognized Non-Governmental Accreditation body. Established in 1975, the IAS headquarters is in Brea, California. IAS is a signatory to the International Laboratory Accreditation Cooperation (ILAC) for testing laboratories, calibration laboratories and inspection agencies. Some of the federal agencies that accept IAS accreditation programs include the U.S. Food and Drug Administration and the U.S. Environmental Protection Agency.

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