

## **Revising Volume 2 of the TNI Environmental Lab Sector Standard: The Process Used**

When TNI was incorporated in the fall of 2006, one of its first activities was to update the 2003 NELAC Standard, since that document included multiple references to entities that no longer existed. TNI determined that the revised standard would be based on ISO/IEC standards and be modular so that any AB could adopt all or portions of the new standard for use.

Since TNI retained the committee structure from NELAC and INELA that included both what is now the Laboratory Accreditation Body Expert Committee (LAB) and the On-Site Assessment Committee (OSA, merged into LAB in 2012). Each of those committees prepared its own version of a module for Volume 2, the AB module. The LAB module became Volume 2 Module 1 (V2M1) and the OSA Module became Volume 2 Module 3 (V2M3), with Module 2 being the Proficiency Testing module (V2M2). The TNI language inserted into the ISO text differed, since the focus of the two committees differed. There was considerable overlap but not full agreement between the two modules.

The NELAP ABs lived with a “combined” checklist for the triennial peer review evaluations and made it work, and since there were no changes desired to the actual content of the standard itself, these two modules were not revised when the 2016 revisions to the standard were initiated. However, after combining the two committees, it no longer made sense to retain both modules of Volume 2, and in 2017, LAB began the process of combining the two modules into one, intending to use the then-active 2004 version of ISO/IEC 17011.

The first stage of revision consolidated all of the TNI-added language into one copy of ISO/IEC 17011, retaining the same placement within the ISO text. The TNI wording from V2M3 was moved into V2M1, with the V2M3 language identified by a single underline. Each unit of TNI language was reviewed to eliminate duplication and the appropriate placement of that TNI language was considered, as well. For the drafts, text locations from the 2009 standard have been retained in parenthesis. A few new modifications were added, and these words are identified with a double underline. As in other TNI standards, ISO language is italicized and TNI language is plain text.

Once that stage was completed, it became apparent that the revision and restructure of ISO/IEC 17011 would be completed before TNI’s V2M1 could be finished, so in consultation with TNI’s Board of Directors and the NELAP Accreditation Council (AC), LAB determined to shift to using the 2017 revision of ISO/IEC 17011 as the basis for its revised module.

The second stage became placing all of the once-reviewed TNI language into the “new” ISO/IEC 17011:2017, with the LAB Chair making an initial determination of appropriate placement into the ISO document. All identifying underlining and original location information have been retained. The committee again worked through the entire module, considering each insertion of TNI language for appropriate location in the new ISO structure and also considering whether the altered ISO language required modification of the TNI language. Modifications to TNI language made at this stage are noted with double underline.

The third stage of this revision was to consider the impact of both the removed ISO definitions and requirements plus the additional ISO definitions and requirements in the 2017 revision of ISOIEC 17025, to ensure that any dropped requirements were either replaced in the new structure with something similar, or else that they could be reasonably omitted, and also to ensure that the new requirements of the 2017 revision did not conflict with any known practices or policies of the NELAP AC. This process was lengthy but smooth, and required no further substantive revisions, but needed to be done for completeness’ sake.

The fourth and final stage consisted of three parts – review of language omitted from the NELAC 2003 standard during the creation of the TNI 2009 standard, review of all Standard Interpretation Requests pertinent to V2M1 and V2M3, and consideration of a few “parking lot” items leftover from the creation of the 2009 TNI standard. Once these were addressed, LAB went back through the document one final time to address items flagged during prior stages for revisit to make a final decision once the standard met all other reviews.

During the two-plus years of this revision process, each LAB session at conference has addressed the issues being worked on at that time, but because of the ISO copyright restrictions, it has not been possible to distribute working drafts. All verbal comments offered by participants in those sessions have been recorded (without identification) and will be reviewed along with comments that arrive from this publication and request for comment. In accordance with the Consensus Standards Development Program’s Standards Development SOP 2-100, each individual submitting comments in response to this notice will eventually receive a response stating how the comments were addressed.