



THE INSTITUTE REVIEW

Third Quarter 2014



Table of Contents

<u>Article</u>	<u>Page</u>
Registration is Open for the 2015 Forum on Laboratory Accreditation	3
Summary of Joint Committee Meeting about Revision and Update of the 2009 TNI Environmental Laboratory Sector Standard	4
NELAP States Current Standard Being Implemented and Ability to Transition to the New 2015 Standard	7
Strategic Planning Meeting Report.....	9
Exploring the Future of National Accreditation	10
Update to the 40 CFR Part 136 MDL Procedure.....	11
LAMS Update	15
Update on Recognition of Non-Governmental Accreditation Bodies	16
Report on Assessment Forum and Methods Panel.....	17
Continuous Improvement: Clean Water Act Methods	18
NEFAP Mobile Laboratory Subcommittee Update	19

THE INSTITUTE REVIEW

Third Quarter 2014



Registration is Open for the 2015 Forum on Laboratory Accreditation

By Jerry Parr, Executive Director

Registration is open for the 2015 Forum on Laboratory Accreditation, to be held at the Hyatt Regency in Crystal City, VA from February 2 – 5, 2015. The Forum will feature open public meetings of all TNI committees to allow quality professionals, chemists, analysts, microbiologists, engineers, and managers from federal and state agencies; commercial, municipal, state, and federal laboratories; and many others who are actively involved and interested in accreditation issues to review what has been done and participate in the efforts to establish a national environmental accreditation program.

The 2015 Forum will include:

- Meetings of all TNI committees;
- A special session celebrating 20 years of a national accreditation effort;
- An Assessment Forum with topics on root cause analysis and corrective actions, QA/QC for microbiology, and standards interpretation;
- A meeting of EPA's Environmental Laboratory Advisory Board (ELAB);
- A general session with updates about TNI programs; and
- A special training session on effectively using social media.

For more information, go to the 2015 conference website at <http://www.nelac-institute.org/meetings.php>.

2015 SUPER BOWL XLIX

Super Bowl Party!

Come in early on Sunday and join your friends and colleagues for a Super Bowl Party.

The festivities will begin at 6:00 pm.



Summary of Joint Committee Meeting about Revision and Update of the 2009 TNI Environmental Laboratory Sector Standard

By Lynn Bradley, NELAP Program Administrator

At the Environmental Measurements Symposium in Washington, DC, during August, 2014, the Consensus Standards Development Executive Committee (CSDEC), the NELAP Accreditation Council (AC), and the Laboratory Accreditation Systems Executive Committee (LASEC) met to discuss current status, expected progress and eventual adoption of the individual volumes and the final package for the revised TNI Environmental Laboratory Sector Standard (ELSS).

The Program Administrator for the CSD, Ken Jackson, described the standards development process being used for the 2015 Standard as laid out in the revised Standards Development SOP 2-100-Provisional. These changes reflect the recommendations of the Corrective Action Task Force in 2012, and include encouraging more involvement and feedback from potential users of the Standard, with particular attention to users' ability to implement the Standard.

Ilona Taunton, TNI Program Administrator who staffs TNI's Educational Delivery System, noted the greatly increased emphasis on outreach by the CSD program, with each expert committee holding webinars at the various stages of development beginning in late spring 2014 – Working Draft (WDS), Voting Draft (VDS) and Interim (IS) Standards. The webinars have been well attended and seem to be effective in involving the community. This use of webinars began with the Calibration Interim Standard, but has become an essential part of the total process. Each Expert Committee Chair described which volume and module it is revising, as well as the expected completion dates for that module (see the accompanying table, Status of Standards Revision, for details).

Judy Morgan, Chair of the LAS, explained that LAS reviews standards prior to recommending that the AC either a) adopt them, b) adopt them once appropriate policies and procedures are in place, or c) return them to the Expert Committee(s) if there is some aspect that cannot be implemented in a state regulatory environment. LAS fulfills many functions for NELAP, including this one. With admiration and praise, Judy noted that June Flowers, previous Chair of LAS, orchestrated review of the current 2009 TNI Standard, which was done all on the massive final document rather than during development, as is being done now.

As envisioned prior to this meeting, LAS' review was set to occur at the IS stage for each module. After the Calibration IS, it became clear that LAS needs to review the individual standards earlier in the process, probably beginning immediately after expert committee approval of the VDS. Both the CSDEC Standards Development SOP 2-100 and the LASEC Standards Review for Suitability SOP 3-106 will be reviewed and revised as necessary to accommodate lessons learned during this first use.

Aaren Alger, Chair of the AC, described that each state Accreditation Body (AB) member of the AC must also review the Standard prior to adoption, asking the question "Can I implement it?". This must occur during development as well as immediately prior to the final adoption, and is necessary, in addition to having various Accreditation Body (AB) representatives participate with the Expert Committees, LAS, and the AC, as the Standard is being developed and undergoing prior reviews and revisions. Aaren noted that the fully revised Standard will be adopted as a complete package, not individual revised modules, as they are finished. A goal date for implementation can then be set.

For a new Standard to be adopted, it must be an improvement over the existing version, not just a change or word-smithing, since the regulation development process consumes not only staff time, but also political capital for state agencies. Also, since each state's process is different, there will necessarily be a "rolling implementation" with the 2015 Standard, as has occurred with previous "new" Standards. As implementation progresses, each AB will recognize other ABs' accreditations regardless of the Standard in use by individual ABs.



Summary of Joint Committee Meeting about Revision and Update of the 2009 TNI Environmental Laboratory Sector Standard cont.

One consistent request was voiced by all of the meeting participants: To please allow time for the stakeholders to “stabilize” to the standard in place. Revising the Standard every few years is disruptive to the entire accreditation process. The other notable concept that emerged during this session was that, while the language of the ELSS Standard is developed through the consensus process, it ultimately gets implemented in a regulatory environment, and thus must be “auditable” and “enforceable.” The state-by-state status for implementation of standards is in the accompanying State AB Status table.

Jerry Parr wrapped up the session by noting the issues that need to be addressed for implementing a new standard, in addition to the actual development of that standard, and promised that a further update will take place at the winter Forum on Laboratory Accreditation in Crystal City, Virginia.

- Training for labs and assessors, particularly in the technical requirements
- Update the Quality Manual Template and Small Lab Handbook
- Prepare checklists
- Prepare a crosswalk of old-to-new standards
- Identify improvements/changes in the new Standard for presentations – by expert committee and for incorporation into a white paper on the new Standard
- Ensure that existing SIRs are incorporated into the new Standard (being done now)
- Prepare needed policies and update SOPs as required

Status of TNI Standards Revision Table on next page



Summary of Joint Committee Meeting about Revision and Update of the 2009 TNI Environmental Laboratory Sector Standard cont.

Status of TNI ELSS Standard Revisions

Expert Committee	Volume/Module	Status	Expected Date for Final Standard
Proficiency Testing (PT modules and volumes are considered critical for the 2015 Standard)	V1/M1 (Lab PT)	Will become IS after addressing comments from VDS.	All expected to be completed by August 2015.
	V2/M2 (AB PT)		
	V3 (PT Providers)	WDS comments (few) incorporated, likely to proceed directly to VDS.	
	V4 (PTPAs)	WDS comments (few) reviewed, ready to become VDS.	
Quality Systems	V1/M2 (Quality Systems General Requirements)	Comments on 2012 version addressed; chem, rad & micro handed off to separate committees.	Probably only a TIA to V1/M2 needed.
	V1M3 (Asbestos)	No plans to revise	
	V1M7 (Toxicity Testing)	No plans to revise	
Chemistry	V1/M4 Sections 1.7.1-1.7.2 (Calibration)	IS comments discussed August 4; will need to be voted on again.	Likely complete in winter 2015.
	Quantitation	Under development, but not yet WDS.	Unknown. May not be part of 2015 Standard.
Microbiology	V1/M5	Comments on WDS closed September 5. Modified WDS should be posted by publication of newsletter.	Probably complete in August 2015.
Radiochemistry	V1/M6 – Changes made to address differences from “traditional” chemistry with rewording and reorganizing for clarity, but not altering core content.	WDS comments complete. Modified WDS should be posted by publication of newsletter.	VDS by early spring 2015. Expected completion by August 2015.
Laboratory Accreditation Body	V2/M1 (AB General Requirements) V2/M3 (AB On-Site Assessment)	No revisions anticipated to either module.	



NELAP States Current Standard Being Implemented and Ability to Transition to the New 2015 Standard

By Lynn Bradley, TNI Staff

State AB Status for Current and Future Standard

State AB	In use now	Process for Implementing New Standard	Constraints Known Now	Anticipated Timeline
FL	2003	Rule development required using new process. Cannot utilize "adopt by reference", but must cite a specific document w/unique identification number.	If adopts 2009, would not adopt the PT modules. Uncertain whether to adopt 2009 or await 2015 version.	Unknown – new process untried.
IL	2009 as of September 2014	Rule change accomplished in September 2014, adopting TNI Standard by reference	Adopting future revisions of the TNI Standard expected to be readily accomplished.	Expected timely adoption.
KS	2003, assessing to 2009	Rule development underway (6-9 mo. process, does not require legislative approval), but may omit PT modules of 2009.	Cannot adopt by reference, but the KS regulation needs to be modified regardless of the Standard.	Possible timely adoption of 2015, if repeat rulemaking allowed.
LA DEQ	2009 since June 2013	Counsel found a way to implement 2009 Standard w/o rulemaking, which they hope to repeat for 2015.	(Rulemaking process is similar to LA DHH below, if it must be done.)	Expected timely adoption.
LA DHH	2009 since December 2012	Process: Sends rule draft to labs, addresses comments until agency and stakeholders are satisfied, then must seek legislative approval.	If time limit for finishing rule is exceeded, must restart the process.	Uncertain
MN	2003/2009 assess to either per lab choice	Regulation cites "most current Standard" of NELAP/TNI.		Expected timely adoption.
NH	2003	Current regulation sunsets in 2016, so will likely adopt 2009 without PT modules.	2015 Standard will arrive too late to be adopted in needed rulemaking.	Uncertain – a new rulemaking will be required.
NJ	2009 — nonconformances cited to 2003 & 2009	Rulemaking underway with regulation to adopt-by-reference the most recent version of the TNI Standards.	None currently known.	Proposal targeted for publication in the 10/20/14 NJ Register. Adoption targeted for publication in Mar/Apr 2015 NJ Register.
NY	2003	The quality systems sections may be adopted by 'incorporating through reference'. Other modules (PT, personnel qualifications) need to be consistent with existing regulation.	Will not adopt 2009 Standard because unable to implement current PT module. Will consider 2015 Standard when available.	Uncertain
OR	2009	Regulations require 1.5-2 years, with draft, hearings, legislative, and then Governor's approval. Will begin new rule when Standard is adopted by AC.	Hopes to incorporate "adoption by reference" into new rule.	Expected timely adoption.
PA	2009	Rule language adopts by reference. Presently treading lightly with PT module implementation.	Requires development of new checklists, etc., for new Standard prior to implementation.	Expected timely adoption.
TX	2009	Existing rule cites "current TNI Standard".		Expected timely adoption.



NELAP States Current Standard Being Implemented and Ability to Transition to the New 2015 Standard cont.

State AB Status for Current and Future Standard cont.

State AB	In use now	Process for Implementing New Standard	Constraints Known Now	Anticipated Timeline
UT	2009	Rule change to cite different Standard expected to require only weeks to accomplish.		Expected timely adoption.
VA	2003	Final regulation incorporating the 2009 TNI Standard "by reference" currently awaits Governor's signature. A new Standard will require a new rulemaking process.	Will require rule revision to move to 2015 Standard.	Expected timely adoption
OK (expect early 2015 appl'n for recognition as NELAP AB)	State only for now	Rule development underway to adopt 2009 Standard. Process: At rule announcement, Governor receives and approves text, then there's a "council" plus the DEQ, then rule requires approval by state legislature.	Had to withdraw earlier set of rules and start over.	Would need new rule to adopt 2015 Standard, so several years at best (?).

THE INSTITUTE REVIEW

Third Quarter 2014



Strategic Planning Meeting Report

By Sharon Mertens, Milwaukee MSD and Chair, TNI Board of Directors; and Carol Batterton, TNI Staff

The TNI Board of Directors, program chairs and staff met in Milwaukee on October 7 and 8 for strategic planning. This is something that the Board does every 3-4 years to review the organization's mission, programs, progress towards goals, and future plans. Setting aside this time enables us to focus on the long term issues that will affect our growth and direction, which we can't always do during the course of normal meetings.

A key role of the Board in this meeting was to provide guidance and input to the strategic plan. The TNI staff took those ideas and is currently working on a final plan, which should be ready to present to the Board and available to the membership in the coming months.

Another activity during strategic planning was a review of the TNI Quality Management Plan. This document has been in draft for some time now, but the Board recognizes the value of this for our organization and has committed to finalizing this document by the January 2015 Board meeting. Some of the important elements of this document will include:

- Background information on our organization, including mission, structure, and programs;
- Corrective action, continuous improvement and internal audits: This will include internal audits of committee operations and programs; databases and tables (e.g. FoPT), management, financial, and website.
- Basic definitions of terms commonly used in our organization;
- Our code of ethics and governance guidelines.

This document should be a valuable reference for everyone who participates in TNI.

The Board also reviewed and discussed all of the available committee charters and future plans. These will be given final approval and posted on the website soon.

THE INSTITUTE REVIEW

Third Quarter 2014



Exploring the Future of National Accreditation

By Steve Arms, FL DOH and Carol Batterton, TNI Staff

Following the summer meeting, over sixty (60) people participated in a workshop to “*Explore the Future of National Accreditation*”. The purpose of the workshop was to focus on brainstorming solutions to issues and barriers to national accreditation identified by non-NELAP states and other stakeholders.

Based on feedback received prior to the workshop from non-NELAP states and other stakeholders, the input fell roughly into three (3) categories of issues/barriers:

1. Concerns related to communication and outreach
2. Concerns related to technical standards or approach to accreditation
3. Concerns related to state programs and EPA involvement

This feedback was summarized and questions formulated to solicit solutions to the issues and/or barriers. Participants rotated through three (3) breakout sessions organized around these issues to offer their suggestions and ideas to address the issues and promote advancement of national accreditation.

Following the breakout sessions, the ideas and solutions generated from the breakout session were summarized and presented to the TNI Board at their strategic planning meeting to be considered for inclusion in the upcoming revision of TNI’s strategic plan. TNI plans to host a webinar later this year to summarize the results of this effort. Stay tuned for details.

The Advocacy Committee would like to extend its sincere thanks to all who have participated in helping TNI develop its vision for the future. Without the dedication and insights of so many, it would not be possible.



Update to the 40 CFR Part 136 MDL Procedure

By Richard Burrows, TestAmerica

Starting in 2012, the Chemistry Expert Committee (CEC) started to consider how the TNI specifications for Limit of Detection (LOD) should be updated for the next version of the Standard. In light of the fact that most environmental testing laboratories currently use the EPA's MDL procedure in 40 CFR Part 136, Appendix B, several options were evaluated.

Option 1 – Incorporate a more rigorous procedure, such as the procedure developed by the Detection/Quantitation Federal Advisory Committee (DQFAC) or the ASTM Interlab and Within Lab Detection Estimate (IDE/WDE).

EPA invested a tremendous amount of resources into the DQFAC and a procedure for estimating detection limits was developed. However, this procedure was never implemented, and in retrospect, the reason appears to be that the procedure was too complex as well as too much of a change from the current MDL. The ASTM procedures are also very complex, and very different from the current MDL. Since EPA had been unsuccessful with this approach despite investing millions of dollars, the committee decided not to attempt the same effort.

Option 2 – Abandon the detection limit altogether (we don't need no stinking MDLs)

At first glance, this option sounds very attractive — after all, no one believes that the current procedures are effective, and they do take a lot of work. Unfortunately, on closer examination there are serious problems with this option. First, we have to consider the effect that abandoning the detection limit would have on the meaningfulness of the Quantitation limit (LOQ). The LOQ is defined as the lowest concentration at which an analyte can be reported with a given degree of confidence. If no detection limit is used, then any result below the LOQ is defined as a “non-detect”. Since most environmental tests have a somewhat negative bias due to less than 100% recovery, this means that most results for a true concentration at the LOQ would be reported as non-detect. If we are saying that the LOQ is the level at which we have confidence in the data, at the very least those concentrations should not result in mostly false negatives.

A second and potentially even more serious objection is that the pressure on laboratories to report lower and lower level results (often for the purposes of risk assessment) would result in the LOQ becoming the new detection limit, and getting forced down to unreasonable levels.

The committee considered these objections to be serious enough that the initially attractive option of abandoning the detection limit could not be taken.

Option 3 – Fix the problem in the TNI Standard for LOD

Since the MDL procedure is generally considered unreliable, the committee considered developing a new and different procedure for incorporation into the TNI Standards. However, the MDL procedure is pervasive, included in many methods, quality assurance plans, and in other documents. It seemed likely that if the committee took this route, laboratories would be put into the position of needing to establish two different detection limits, a TNI detection limit and a MDL. Obviously, this would create great confusion, so the committee abandoned this option.

Option 4 – Update the MDL

Since it appeared that the 40 CFR Part 136 MDL procedure was not going away, one option was to create an update that would be incorporated into Part 136 and replace the current procedure. With this approach, the potential conflict between a TNI detection limit and the MDL could be avoided. EPA appeared open to this path, so the committee commenced development of a MDL update, which was submitted to EPA early this year. After EPA review, the procedure, with minimal changes, will be published in the Federal Register shortly as part of a Methods Update Rule.



Update to the 40 CFR Part 136 MDL Procedure cont.

Developing an Updated MDL

The committee had two main principles guiding the development of an updated procedure. The first was that the most serious limitations and problems of the current MDL had to be addressed. The second was that the MDL procedure should be changed as little as possible, so that the updated procedure would still be recognizable as a MDL. These two principles often appeared to conflict with each other, but ultimately helped the committee develop and update with a good chance of implementation.

To describe the update, it is first necessary to define a few terms, since terms related to detection limits have historically been used by different individuals and organizations to mean different things, resulting in considerable confusion.

Limit of Detection (LOD): The TNI LOD, and the LOD in this paper, is the lowest result that can be reliably distinguished from a result from a method blank. It is equivalent to Currie's Critical Level (LC). The MDL is a LOD.

Detection Limit (LD): Currie's Detection Limit, or LD, is not used in the TNI Standard or in the MDL procedure for reasons that will be described later. It is the lowest true concentration that will reliably give a result above the MDL.

Quantitation Limit: The TNI Limit of Quantitation (LOQ) and other quantitation limits, such as the EPA MRL and Currie's LQ, are generally considered to be the lowest concentration at which a given level of precision and accuracy are demonstrated.

The single most serious problem with the current MDL is that it does not reliably establish the level at which a result indicating presence of an analyte in the sample matrix can be reliably distinguished from a blank. This problem is especially acute for methods where detections do not require qualitative identification criteria, such as ICP-OES and ICP-MS. The qualitative identification criteria in most GC-MS methods (qualifier ions, ion ratios) help make this problem less severe for GC-MS, but the problem still exists for analytes that may be found in blanks (lab contaminants) and becomes more severe as detection limits become lower. In general, as detection limits become lower, the problems caused by the failure of the current MDL to consider blanks become worse, and so this is a problem that is becoming worse every day as instrument sensitivity increases and desired detection limits become lower. The revised procedure fully addresses the blank issue by incorporating a detection limit calculated from blanks (MDLB) as well as a detection limit calculated from spikes (MDLS), as in the current procedure. The higher of the MDLB and MDLS becomes the MDL. Since laboratories generate method blanks with each batch of samples, no additional sample analysis is required – the routine method blanks are used for the MDLB determination.

Another serious problem with the current procedure is that the MDL is usually calculated from a set of seven (7) samples analyzed all on the same day. This resulting short term variance may not, and probably does not, properly reflect the variance exhibited by the method over the course of a year, and so the MDL calculated is too low. The new procedure corrects this problem by requiring that MDL replicates be spread over time. This was an area where compromise was necessary – more data is desirable, but the procedure must not be too onerous. Accordingly, the minimum number of replicates remains at seven (7). Once the MDL is generated, verification samples are analyzed quarterly, and the results from these quarterly verifications are evaluated annually.

The current MDL is silent on the issue of multiple instruments that are assigned the same MDL. The revision clarifies requirements — at least two (2) replicates are required on each instrument to initiate the MDL — and then at least one (1) replicate must be done per quarter for the ongoing verification.

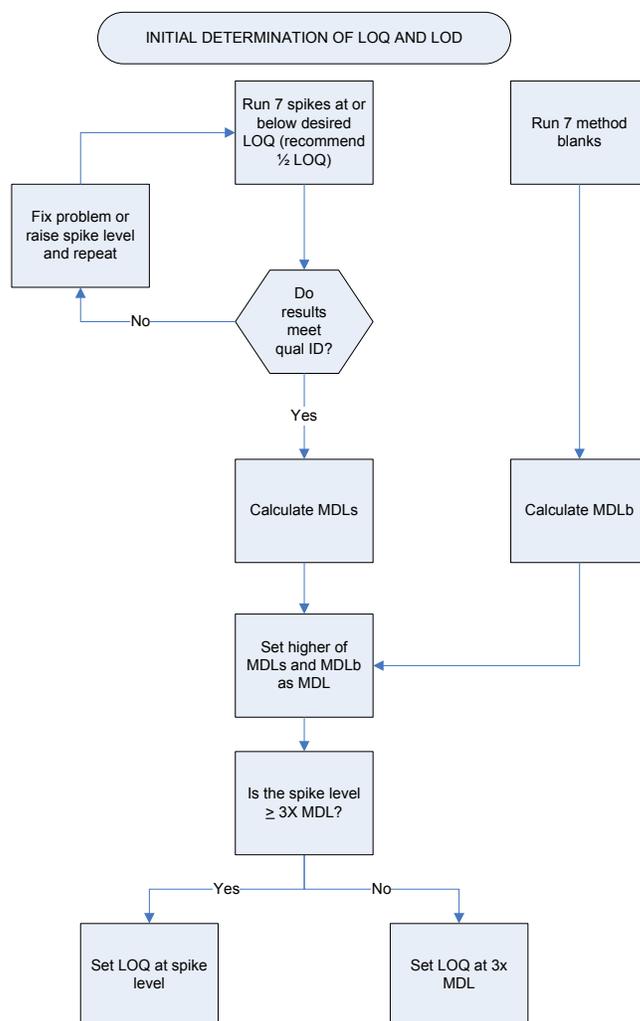
It has been argued that a limitation of the current MDL is that it does not incorporate Currie's LD, and therefore does not define the lowest true concentration that will reliably give a result above the MDL (i.e., the lowest true



Update to the 40 CFR Part 136 MDL Procedure cont.

concentration that will be reliably detected and reported). The committee considered these arguments but ultimately decided not to incorporate LD, for two reasons. First, we considered that adding LD would change the MDL too much, violating the principle that the revised MDL should still be recognizable as a MDL. Second, we noted that values such as the MDL, LD and the LOQ are only estimates, not absolute numbers. The current MDL procedure notes that the confidence interval for the MDL is from 2.2 times the MDL to 0.64 times the MDL, and that is under the very best of circumstances, without even considering that most analytical instruments experience significant variability in ultimate sensitivity from day to day or even sample to sample when analyzing dirty matrices. Instead, the committee decided that it would be best to revise the TNI requirements for the LOQ, in order to ensure that the LOQ has at least the properties of LD; in other words, to ensure that a true concentration at the LOQ will reliably return a result above the MDL, and therefore be detectable and reportable. These revisions to the LOQ are about to be published as a Working Draft Standard.

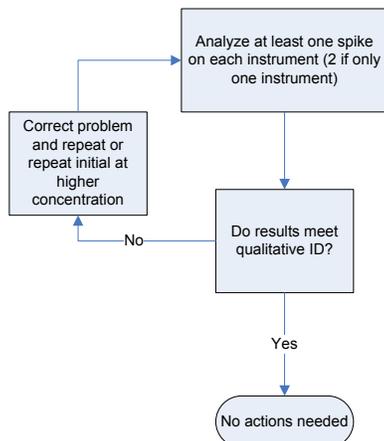
The following flow charts indicate how a laboratory would use the same spikes and method blanks to determine and verify both the MDL and the LOQ, following EPA's revised MDL procedure and the revised TNI LOQ requirements.



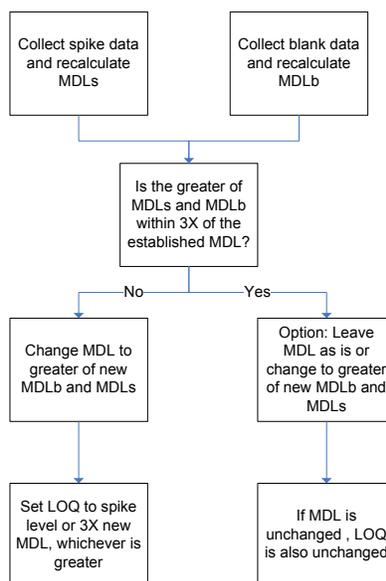


Update to the 40 CFR Part 136 MDL Procedure cont.

QUARTERLY VERIFICATION



ANNUAL RECALCULATION



THE INSTITUTE REVIEW

Third Quarter 2014



LAMS Update

By Dan Hickman, TNI Staff

The Laboratory Accreditation Maintenance System (LAMS) is available by clicking on the large orange button on the TNI website Home page. Not only can you search for an accredited laboratory by TNI Lab Code, partial laboratory name, location state, and/or Accreditation Body (AB), you can also apply filters, including multiple method/analyte combinations.

The left sidebar gives you access to a wealth of other data. This is the only place you will find all the current method and analyte codes, as well as the matrix and technology tables. While the analyte table is a great place to locate CAS numbers, you can also filter the method table by current EPA approval (Drinking Water or Waste Water) and find technology, official title, and method source information. And you can refer to the table to find the Standard Methods Committee approval date of their methods (listed as Revision Date).

Both of these tables can be downloaded as a CSV file by selecting the option at the top of the page. Then you can easily order, search, and filter in a spreadsheet. Some ABs and laboratories have downloaded these tables to use in their own databases. Keep in mind that these tables are updated regularly.

Below are the links that allow you to request a method or analyte code not already found in the tables. Normal response for new codes is 1 or 2 days.

THE INSTITUTE REVIEW

Third Quarter 2014



Update on Recognition of Non-Governmental Accreditation Bodies

*By Carol Batterton, TNI Staff and Alfredo Sotomayor, WI
Department of Natural Resources*

In July, the Non-Governmental Accreditation Body (NGAB) Working Group completed its work on the SOP to evaluate accreditation bodies wishing to grant laboratory accreditations to the TNI Standard. The SOP was forwarded to the Policy Committee for review. Following Policy Committee review, the SOP will be presented to the TNI Board for endorsement.

Also in July, the TNI Board appointed members to the TNI Non-Governmental Accreditation Body Recognition Committee (TNRC). This committee will make decisions about recognition of NGABs. The TNRC members are: Judy Morgan, Kim Watson, Marlene Moore, Daniel Lashbrook, and Joe Aiello. Judy Morgan will serve as Chair.

The NGAB working group and the TNRC are holding joint conference calls for a period of time to have a smooth transition and complete the remaining tasks to prepare for accreditation of NGABS. Pending items include the development of supporting documents and forms for the evaluation process, training for evaluators, and a budget and fees for the program.

The target date for implementation of the program is February 2015.

THE INSTITUTE REVIEW

Third Quarter 2014



Report on Assessment Forum and Methods Panel

By Barbara A. Escobar, Pima County, AZ

During the August 2014 Environmental Measurement Symposium in Washington, D.C., the day long Assessment Forum started with a packed house eager to hear about EPA Program and Standard Methods Updates. The following presenters gave a brief overview of their recent program updates:

- Daniel Hautman, from the USEPA Office of Water, covered Drinking Water Methods
- Adrian Hanley & Lem Walker, both from the USEPA Office of Water, covered Wastewater Methods
- Kim Kirkland, from USEPA RCRA, covered SW-846 Methods
- Andy Eaton, from Eurofins Eaton Analytical, covered Standard Methods updates

Once the presenters gave their updates, questions were opened up to the audience where much dialogue was centered around the QA requirements for methods that do not specify them, and how to link QC sections in Standard Methods to their corresponding revised methods. Some of the discussion also veered to the review and approval of in-line analyses, and what QC or calibrations, and audit reviews should be required. This interchange was an obvious opportunity for stakeholders to meet (put a face to the name), and to be aware about pressing issues on all fronts.

After a delicious, informative and fun lunch break, audience members returned to the Assessment Forum to get feedback from various panelists on the “Changing Face of Accreditation”, which was to:

- Provide an open forum to discuss the evolving changes within accreditation.
 - ◆ How are ABs handling the changes they encounter?
 - ◆ How are third-party accreditors handling the changes they encounter?
- Gather stakeholder input on effective strategies for handling variations in accreditation.
- Present a third-party perspective on accretor variations affecting implementation and reporting audits.

Predetermined questions were posed to the panelist for discussion. The following are a few example questions:

- Are there any mechanisms for ensuring that different assessors will be assessing all laboratories in a fair, consistent, and comparable way?
 - ◆ What oversight should there be?
- What mechanisms are in place to consult on different interpretations and who makes the call on the finding?
- As a third-party assessor, at what point does providing feedback on laboratory corrections during an audit become consultancy vs. a routine assessment?

The selection of panelists made the diverse discussion relevant to several of the audience members.

- Stephen Arms, Florida DOH
- Lynn Boysen, Minnesota DOH
- Jack Farrell, AEX, Inc.
- Douglas Leonard, Laboratory Accreditation Bureau
- Mitzi Miller, Dade Moller Associates, Inc.
- Mathew Sica, ANSI/ASQ national Accreditation Board

The Forum was then ended with a presentation from Mitzi Miller from Dade Moller Associates, Inc., who discussed “Accretor Differences in Implementing and Reporting Audits.”

Every Assessment Forum is planned to provide engaging topics to assessors, accreditors and laboratories. Many of the past, revealing presentations are accessible on the TNI webpage at <http://www.nelac-institute.org/meeting-presentations.php>.



Continuous Improvement: Clean Water Act Methods

By Zonetta E. English, Louisville and Jefferson County MSD

The United States Environmental Protection Agency (USEPA) Office of Water is expected to release for comment the latest update of the Clean Water Act (CWA) in 40 CFR Part 136 in December 2014. Often this is referred to as the CWA Method Update Rule (MUR). An overview of updates and collaborations of improving environmental monitoring were presented in August at the National Environmental Monitoring Conference (NEMC) held in Washington, DC.

Adrian Hanley, USEPA Senior Chemist leading the MUR effort, summarized the proposed changes in the following areas:

- Revisions/new methods by EPA and other Voluntary Consensus Standard Bodies (VCSB) such as ASTM International and the Standards Methods Committee
- New Methods that were positively reviewed under the Alternate Test Procedures (ATP) program
- General corrections to Part 136
- Revision to the Method Detection Limit (MDL) Procedure Appendix B

A few of the highlighted methods from EPA and the Standards Methods Committee discussed were BOD, TDS, TSS, Total Cyanide, Total Nitrogen, and EPA Methods: 624, 625 and 608. These method updates reflect the collaborative work from EPA Program Offices and Regions along with technology vendors, states, and laboratory organizations. The EPA methods will reflect technology updates that have occurred over the past twenty (20) years. The significance of these updates is the harmonization of methods across EPA program offices. These changes will significantly reduce the workload for environmental labs that perform analyses for multiple programs.

Several ATP(s) were discussed: Nitrate-Nitrogen, Ammonia as N, Fecal Coliform, and Total Kjeldahl Nitrogen (TKN). Also discussed was a Total Phosphorus procedure that will be utilized for biologically treated effluent in the pulp and paper industry.

Mr. Handley noted that the general changes to Part 136 will include corrections for typographical errors and removal of the use of mercury thermometers in six (6) methods.

The revised MDL Procedure will address blank contamination and account for the inter-instrument variability and changes in instrument sensitivity over time that occurs in normal laboratory operations. The TNI Chemistry Expert Committee (CEC), led by Dr. Richard Burrows, has been diligently working on a revised procedure for several years. Some of the committee members participated on the original Federal Advisory Committee on Detection and Quantitation (FACDQ). The laboratory will be required to analyze seven (7) aliquots spiked at 2-10 times higher than the expected MDL and seven (7) blank aliquots. These aliquots will be analyzed performing all steps of the method including sample preservations, if applicable.

In summary, the proposed MUR is expected to be released this December for public comment. The plan is that the MUR will be promulgated in late 2015 if all adverse comments are addressed and responded to by this timeframe.



NEFAP Mobile Laboratory Subcommittee Update

By Paul Bergeron, LADEQ, Subcommittee Chair

The NEFAP Mobile Laboratory Subcommittee convened in February to reorganize and report to the NEFAP Executive Committee. Three (3) new officers were selected and the subcommittee has been conducting teleconferences approximately every fourth Friday of the month. In recent teleconferences, the subcommittee worked on its mission statement and identified organizations with which to discuss the topic of mobile laboratories.

In addition to preparing a new survey of mobile laboratory stakeholders, the subcommittee conducted a review of the 2009 NELAP Standard with emphasis on comparing and contrasting the mobile laboratory requirements in the Field Sampling and Measurement Organizations (FSMO) sector and the Environmental Laboratory (EL) sector. The subcommittee also reviewed the mobile laboratory accreditation requirements of NELAP member states, with the review to expand to non-NELAP member states and non-governmental accreditation bodies. The subcommittee noted that it has not completed the standard review and stakeholder survey process and is offering no specific recommendations at this time.

At the Field Activities Committee (FAC) meeting in Washington DC, the subcommittee reported its current findings as follows:

1. Accreditation of Sampling — The FSMO sector applicability sections for both Conformity Assessment Bodies (CABs) and Accreditation Bodies (ABs) mentions “sampling” as an accredited activity, but the equivalent EL sector sections do not.
2. Management System — Both the FSMO sector and the EL sector module for CABs require the management system to cover work performed in mobile laboratories.
3. Sampling Activity —
 - a. The FSMO sector requirements incorporate by reference the ISO:IEC 17025 standard sections and notes, which define and require sampling plans and procedures, as well as the documentation of deviations, additions, and exclusions to the procedures, identification of the sampler, and environmental conditions.
 - b. The FSMO sector establishes the requirement for the CABs to document the sampling subject, location, time, method, and equipment used.
 - c. The EL sector module and notes define and require sampling plans and procedures, as well as the documentation of sampling time, date, data, procedure, sampler, environmental conditions, and exclusions, additions or deviations to the procedure.
4. Mobile Laboratory Definition —
 - a. The FSMO sector references the ISO definition of CABs, but does not identify mobile laboratories separately.
 - b. The equivalent EL sector modules and notes define mobile laboratories or includes a reference in the description of CABs.
5. Assessment by Accreditation Bodies —
 - a. The FSMO sector does not specify mobile settings.
 - b. The EL sector module references mobile settings for initial, surveillance and reassessments, and also refers to the FSMO sector for assessment of sampling and measurement activities.



**NEFAP Mobile Laboratory Subcommittee Update
cont.**

6. Content of Applications for Accreditation —

- a. The FSMO sector lists “mobile” as an example of an accreditation type and requires the applicant to provide a summary of the mobile units to be considered for the accreditation.
- b. The equivalent EL sector module section does not.

7. Accreditation Scope —

- a. The FSMO sector and notes allow for “umbrella” accreditation or “individual” accreditation for mobile laboratories operating in the same location or the same management system.
- b. The equivalent EL sector module does not contain such provisions.

The subcommittee also noted that the FSMO sector requirements apply to sampling and measurement activity conducted discretely, continuously, or at intervals by unattended equipment whereas the equivalent EL sector module requirements do not; and the EL sector modules address proficiency testing frequency requirements whereas the FSMO sector requirements do not.

With regard to the mobile laboratory accreditation requirements of NELAP member states, the subcommittee reported that there are states which require separate primary accreditation for each mobile laboratory, and there is at least one (1) state which grants secondary accreditation to mobile laboratories. The subcommittee also found that there are states which require primary accreditation for samples taken from within their geographic boundaries. The subcommittee observed that if the majority of states require primary accreditation for each laboratory “unit”, then there is no national accreditation program for mobile laboratories.

The subcommittee presented two (2) additional definitions of a mobile laboratory — one from a multi-state agency organization’s accreditation program and one from a NELAP AB’s requirements. Unlike the latter two definitions, the definition in the Standard listed examples of mobile laboratory configurations. The subcommittee drafted a seven (7) part definition for the audience to consider:

1. A person/body conducting sample collection without a physical structure;
2. A person/body conducting sample collection in a van or enclosure (e.g. non-permanent building or shed);
3. A person/body conducting sample analysis without a physical structure;
4. A robot/person/body conducting sample analysis in a trailer or other movable enclosure;
5. A robot/person/body conducting sample collection and sample testing without a physical structure;
6. A robot/person/body conducting sample collection, sample preparation, and sample testing in a van or enclosure (e.g. non-permanent building or shed); and
7. A robot/person/body conducting sample collection, sample preparation, and sample testing in a trailer or other movable structure.

The subcommittee added that using a vehicle identification number or tag to track mobile laboratories may not be useful if the laboratory’s work is conducted outside of an enclosure.

The subcommittee concluded its presentation with a comparison of the assessment and accreditation requirements for fixed-base laboratories and mobile laboratories. In most states, the mobile laboratory must obtain primary accreditation from the state in which it is operating, whereas the fixed-base laboratory may obtain secondary accreditation to work on samples originating from the secondary AB. A fixed-base laboratory may obtain one accreditation for multiple rooms and facilities under the same roof whereas the home base of the

THE INSTITUTE REVIEW

Third Quarter 2014

NEFAP Mobile Laboratory Subcommittee Update cont.



mobile laboratories must obtain primary accreditation for each laboratory. In contrast to the requirement that a fixed-base laboratory pass two (2) proficiency tests per year for one instrument performing the analysis, a mobile laboratory must pass two (2) proficiency tests per year for each instrument performing the analysis. Finally, fixed-base laboratories granted secondary accreditation are not subject to an assessment by the secondary AB, but mobile laboratories not granted secondary accreditation must undergo an assessment by the primary AB.

The subcommittee is looking for additional information and people to contribute in the efforts of this subcommittee. Additional information may be obtained by contacting the chair or any subcommittee member.