

2015 MNELAP REFRESHER

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MNELAP Coordinator

Welcome to the 2015 Minnesota Environmental Laboratory Accreditation Program (MNELAP) Refresher course that is being provided to meet the 2003 NELAC Standards and the MNELAP's quality documentation requirements for annual ongoing assessor training.

Agenda

- MNELAP Update
- TNI National Standard
- Current developments
- Changes to methods and checklists
- Assessment Skills and Techniques
- MDH and MNELAP policies and procedures review
- Onsite review

The agenda items are based on the 2003 NELAC Standard and MNELAP's standard operating procedure established for Assessor Training (ELAP-P-03-2). The current 2009 TNI Standard no longer requires annual refresher training, MNELAP plans to move away from the required annual training and provide updates and trainings on an as needed basis. For example, information and training sessions may be provided when there are changes to MNELAP's policies or procedures, the TNI Standard, Method Update Rules or other State or Federal changes.

MNELAP Update

- MNELAP moved from the Public Health Laboratory Division to Environmental Health Division
- ELDO update
- Remote analyst/data reviewer
- ATP Fecal Coliform by Colilert®-18 Quanti-Tray

MNELAP officially transferred Divisions into a newly formed section, "Environmental Health Operations Center" (EHOC) within the Environmental Health Division, which has little if any impact on contract assessors. Lynn Boysen remains the will primary contact for assessment and Program questions. Justine Greene, EHOC manager, will be able to also provide assistance and she can be reached at justine.greene@state.mn.us. The EHOC is in the process of hiring additional personnel, and will notify you when additional personnel come on board.

The primary accreditation tool used for the regulated laboratory community, the assessors and MNELAP remains the Environmental Laboratory Data Online (ELDO) system. There have been several updates that are planned or have been taken in the last year:

- ✓ added many new fields of testing
 - ✓ updating ELDO so that labs can pay application fees electronically
 - ✓ Updating ELDO to allow labs and assessors to request fields of testing through ELDO
- Hopefully, moving forward we will be able to update the assessment module, remove dated methods and documents and ensure the fields of testing that updated versions for current regulations.

- MNELAP recently was informed about the use of a remote analyst located outside of the physical commercial laboratory building. At this time MNELAP has no rules or policies that govern this practice of using remote analysts. As MNELAP learns more about remote analyst use, training and assessment; MENLAP will provide guidance on how to best assess the remote analyst. MNELAP is looking for any guidance and assistance on

the use of remote analysts and the future policies and rules that may need to be implemented.

- EPA Region 5 has granted Minnesota labs a Limited Use Alternative Test Procedure (ATP) to analyze fecal coliform under the Clean Water Program by Colilert®-18 (Fecal Coliforms) – Quanti-tray. As an assessor doing work on behalf of MNELAP, please be aware of this ATP for fecal coliform and please ask to see the authorization letter from the EPA Region 5.

TNI National Standard – Latest Standards Development Activity

Volume (V) Module (M)	Volume Title	Module Title	Last Activity	End Date
V1M1	Management and Technical Requirements for Laboratories Performing Environmental Analysis	Proficiency Testing	IS	7-8-2015
V1M2		Quality Systems General Requirements	MWDS	5-20-2015
V1M3		Quality Systems for Asbestos Testing		
V1M4		Quality Systems for Chemical Testing	VDS IS	7-5-2015 1-17-2015
V1M5		Quality Systems for Microbiological Testing	VDS	7-4-2015
V1M6		Quality Systems for Radiochemical Testing	VDS	5-15-2015
V1M7		Quality Systems for Toxicity Testing		
V2M1	General Requirements for Accreditation Bodies Accrediting Environmental Laboratories	General Requirements		
V2M2		Proficiency Testing	IS	7-9-2015
V2M3		On-Site Assessment		
V3	General Requirements for Environmental Proficiency Test Providers	N/A	VDS	7-4-2015
V4		N/A	VDS	7-4-2015

Please note that The NELAC Institute (TNI) is updating several of the consensus standards governing laboratories, proficiency testing providers and accreditation bodies. The standards development process takes place in many stages and drafts, please see the table for the last activity for each of the volume/modules and the associated key, which describes the last activity step and standard type:

Activity Key:

- IS = Interim Standard
- MVDS = Modified Voting Draft Standard
- MWDS = Modified Working Draft Standard
- VDS = Voting Draft Standard
- WDS = Working Draft Standard

TNI is moving along with the implementation of the updated TNI Standard. The next TNI Standard will be released in the next couple of years and implemented by States as their Rules and Laws allow.

TNI National Standard – PT Update

- New Non-Potable Water (NPW) and Solid and Chemical Material (SCM) Proficiency Testing (PT) Tables
- Asbestos PTs in Drinking Water

The newest Non-Potable Water and Solid and Chemical Material Proficiency Testing (PT) tables go into effect April 1, 2016. The changes that were made to both of FoPT tables were very similar changes, please see below for a summary:

- ✓ In the Base/Neutrals analyte list, corrected the TNI analyte code and name for the analyte formerly referred to as bis(2-Chloroisopropyl) ether. The corrected analyte name is 2,2'-Oxybis(1-Chloropropane). The analyte code has also been corrected from 5780 to 4659. (This change originated with a request from ELAB to resolve an inconsistent naming issue.)
- ✓ Added a footnote as a reference for the change in analyte name to bis(2-Chloroisopropyl) ether. In the NPW FoPT Table, the new footnote is Footnote 18. In the SCM FoPT Table, the new footnote is Footnote 13.
- ✓ In the Petroleum Hydrocarbons analyte list, corrected the TNI analyte code for n-Hexane Extractable Material (O&G) to 1803. The previous code was 1860, which is the code used for Oil & Grease (Freon Extractable Material) and now Code 1803 is the correct code to use for n-Hexane Extractable Material (O&G).

At this time the State of New York (NY) is the only available PT provider that supplies drinking water PTs for asbestos; however, New York will only supply PTs to labs who hold accreditation by the New York Environmental Lab Accreditation Program (NY ELAP). The TNI Accreditation Council has been in discussions with the EPA's Technical Support Center for guidance on what to do with labs that are not accredited by New York ELAP. Currently, Minnesota requires safe drinking water labs to become accredited by NY ELAP, which

enables the laboratory to receive PT samples and have an onsite assessment by a NY ELAP assessor. At this time, MNELAP does not have any qualified drinking water asbestos assessors. If there are qualified and interested assessors for asbestos assessments, please notify lynn.Boysen@state.mn.us.

TNI National Standard – Latest On Demand Trainings

Testing Requirements in EPA Regulations

Webcast by Jerry Parr

Hyphenated Techniques in Ion Chromatography in Environmental Analysis

Webcast by Jay Gandhi, PhD

Sample Preparation for Ion Chromatography in Environmental Analysis

Webcast by Jay Gandhi, PhD

Basics of Ion Chromatography in Environmental Analysis

Webcast by Jay Gandhi, PhD

Working with the New MDL

Webcast by Richard Burrows

The 2015 EPA Method Update Rule

Webcast by Jerry Parr

The NELAC Institute Offers on Demand Trainings, at little or no cost, that teach regulations, technical areas and method changes. If you are interested please register for the trainings at <http://www.nelac-institute.org/index.php>

At this time MNELAP does not offer assessors course tuition or reimbursement for courses or continuing education.

TNI National Standard – Upcoming Conferences

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| • Tulsa, Oklahoma | January 25 – 29, 2015 |
| • Orange County California | August 8 – 12, 2016 |
| • Washington DC | August 7 – 11, 2017 |

The NELAC Institute (TNI) offers conference twice a year that cover analytical, regulatory and Standard developments. The conferences highlights include:

- ✓ Meetings of TNI Committees to further TNI efforts on environmental laboratory accreditation, proficiency testing, and accreditation of field sampling and measurement organizations;
- ✓ An exhibit program showcasing the latest innovations in environmental monitoring;
- ✓ Discussion of the new consensus standards in development for detection and quantitation, instrument calibration, proficiency testing and field activities;
- ✓ An Assessment Forum;
- ✓ A general session with updates about TNI programs;
- ✓ An open meeting of US Environmental Protection Agency's Environmental Laboratory Advisory Board; and
- ✓ A training course on the new radiochemistry standard.

For more information on the conference meeting topics, attendees, meeting notes and future dates, please see the following website: <http://www.nelac-institute.org/index.php>

Current Developments

- **SW-846 Update V**
 - Published in the Federal Register on August 13, 2015
- **Method Update Rule – 2015**
 - Proposed rule in the Federal Register on February 19, 2015

The Final Update V of SW-846 was published in the Federal Register on August 13, 2015. The update provides updated methods (i.e. 8 new and 15 revised) for the identification and analysis of Resource Conservation Recovery Act (RCRA)-related wastes, and also introduce and explain new or modified concepts in use, such as Lower Limit of Quantitation (LOQ) and calculations of relative standard error. MNELAP plans to add the updated methods to the Environmental Laboratory Data Online fields of testing in 2016.

- EPA is proposing the following revisions and changes noted in Method Update Rule (MUR):
 - ✓ revised Agency analytical methods;
 - ✓ revised methods published by voluntary consensus standard bodies, such as ASTM International and the *Standard Methods* Committee;
 - ✓ methods positively reviewed under the [Alternate Test Procedures](#) (ATP) program;
 - ✓ changes to clarify the procedures for EPA approval of nationwide and limited use ATPs; and
 - ✓ amendments to the procedure for determination of the method detection limit (MDL).

Assessment Skills and Technique - Assessment Scheduling

- Minn. Stat. §645.44, Subd. 5 defines the State's Legal Holidays, and also proclaims "No public business shall be transacted on any holiday, except in cases of necessity"

Please avoid scheduling onsite assessments on any state holiday, per Minnesota Statutes 645.44, which defines holidays as the following:

Subd. 5. Holiday.

"Holiday" includes New Year's Day, January 1; Martin Luther King's Birthday, the third Monday in January; Washington's and Lincoln's Birthday, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Christopher Columbus Day, the second Monday in October; Veterans Day, November 11; Thanksgiving Day, the fourth Thursday in November; and Christmas Day, December 25; provided, when New Year's Day, January 1; or Independence Day, July 4; or Veterans Day, November 11; or Christmas Day, December 25; falls on Sunday, the following day shall be a holiday and, provided, when New Year's Day, January 1; or Independence Day, July 4; or Veterans Day, November 11; or Christmas Day, December 25; falls on Saturday, the preceding day shall be a holiday. **No public business shall be transacted on any holiday, except in cases of necessity and except in cases of public business transacted by the legislature, nor shall any civil process be served thereon.** However, for the executive branch of the state of Minnesota, "holiday" also includes the Friday after Thanksgiving but does not include Christopher Columbus Day. Other branches of state government and political subdivisions shall have the option of determining whether Christopher Columbus Day and the Friday after Thanksgiving shall be holidays. Where it is determined that Columbus Day or the Friday after Thanksgiving is not a holiday, public business may be conducted thereon.

Assessment Skills and Technique – MNELAP Required Steps

- 1) Create assessment in ELDO
- 2) Send lab required assessment documents and request receipt confirmation prior to onsite
- 3) PDF completed lab documentation and send to MNELAP after onsite
- 4) Disputed Observations/Findings
- 5) Enter Assessment information and observations into ELDO Assessment Module

As assessors working on behalf of MNELAP, please do the following required steps for onsite assessment scheduling and documentation:

1) After an assessor confirms the date(s) with the laboratory, immediately create the assessment in the ELDO system. Please fill in the assessment dates and team (if needed) and save the assessment as DRAFT. These actions will allow MNELAP to remove the lab from future reminder notifications and it serves as the notification to MNELAP that the assessment team is established and fits the size and scope of the laboratory and is in compliance with Minnesota Statutes 144.98.

2) The MNELAP templates must be used. The required assessment documents per MNELAP's established procedure for assessing laboratory compliance (ELAP-P-04), the following forms/notifications must be saved in portable document format (PDF) and sent electronically to the lab prior to the assessment:

- ✓ Onsite Assessment Notification (ELAP-F-08)
- ✓ Agenda (ELAP-F-09)
- ✓ Appraisal Form (ELAP-F-12)

Please copy Lynn Boysen, MNELAP Coordinator, on the email to ensure the documents are saved to the laboratory's file on the MNEALP network server. Also, please place a lab note in the labs file that the documents were sent. **The laboratory must acknowledge receipt of the documents!** The laboratory receipt confirmation must be noted in the lab notes, and again please ensure Lynn Boysen is copied on the lab confirmation and to ensure the confirmation is saved the lab's file on the network server.

3) The MNELAP templates must be used. The required assessment documents used at the onsite per MNELAP SOP-ELAP-P-04 are the following documents:

- ✓ Assessment Conference Checklist and Attendance Roster (ELAP-F-10) to record the opening and closing meetings and participants
- ✓ Quality Systems checklist (ELAP-Q-07)

4) Any disputed findings must be reported by the lead assessor to the MNELAP Coordinator. MNELAP will determine the validity of the contested observation and communicate any needed next steps to the assessor or laboratory.

5) Please ensure the correct date and times of the assessment are entered in the assessment module, as the ELDO system defaults to a time and date. Please be sure to include all the laboratory personnel at the opening and closing meetings and interviewed during the onsite, as well as any contractors or technical experts in attendance.

Assessment Skills and Technique – MNELAP References

- ELDO Assessor User Training
- MNELAP Documents (i.e. SOPs, QM, checklists, templates, forms)
- Call or email MNELAP

MNELAP offers on-demand training for the use of the Environmental Laboratory Accreditation Online (ELDO) system and specifically assessor user training is located at: <http://www.health.state.mn.us/divs/phl/accreditation/assessoruserch2/assessoruserch2.htm>

The MNELAP established quality system procedures and policies are available for review and use inside ELDO by navigating the menus inside the ELDO system in the following manner:

ELDO>Documents>MNELAP Documents

If you have specific questions or concerns about the use of ELDO, Minnesota Laws or Rules, or the MNELAP policies or procedures, please contact MNELAP.

Thank you!

- Thanks for your continued work with MNELAP and we look forward to 2016
- Reminder- **Assessors, please send any outstanding assessment documents submitted to MNELAP as soon as possible!**

The MNELAP contact information:

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