

SUMMARY

TNI CHEMISTRY EXPERT COMMITTEE MEETING

August 5, 2024

The Chemistry Expert Committee (CEC) met at 1:00 PM PT on Monday August 5, 2024 during the Environmental Measurement Symposium held in Garden Grove California. The meeting utilized a face-to-face format with participation open to any attendees of the symposium. Chair Michelle Wade, the CEC Chair, conducted the meeting.

Welcome and Introduction of Current CEC Membership

Michelle welcomed all the meeting participants and attendees and introduced those members present and recognized those members unable to attend. She also expressed her thanks to all the Associate members of the CEC who have played an invaluable role in CEC activities. The Chair also announced that the CEC has one vacancy that can be filled by a member of any of the interested categories (i.e., lab, AB or Other). Interested parties can submit an application, available on the TNI website (www.nelac-institute.org), for consideration.

Presentation of Meeting Format

Bob described the face-to-face format of the meeting as an opportunity to advise interested parties of the CEC's recent activities and to provide a forum to address questions and to receive comments and/or suggestions relative to the proposed language and other potential changes in EL V1M4 as well as the current Draft Standard under consideration by the CEC.

Roll Call

Joseph Manzella, OCSD (Lab)	Present
Nicole Cairns, NYS DOH (Lab)	Absent
Melissa Jackson, OR ELAB (AB)	Absent
Calista Daigle, Pace (Lab)	Present
Tony Francis, Saw Environmental (Other)- Vice Chair	Absent
Durant Maske, Southern Companies (Lab)	Present
Stephanie Rippeon, A2LA (AB)	Present
Donaciano Cantu, Red River Scientific (other)	Present
Anand Mudambi, US EPA	Present
Denice Johnson, NEORSD (Lab)	Present
Ali Boren, State of Vermont (AB)	Present
Joann Slavin, NYSDOH (AB)	Present
Chad Stoike, ALS Global (Lab)	Absent
Michelle Wade, Pace Analytical Services (Lab)- Chair	Present
Robert Wyeth, Program Administrator	Present

A quorum was present for the meeting.

A number of Associate members of the CEC, recognized by the Chair. were also present as attendees of the face-to-face meeting, along with approximately 70 other participants representing various stakeholders and interest groups.

Approval of the Agenda

The agenda was previously provided to all committee members and is presented as Attachment 1 below. The agenda was approved by unanimous consent of the committee members present.

Review and Approval of July Minutes

A copy of the July 2024 minutes was previously provided to all committee members. The review and approval of the July minutes will be accomplished by e-mail ballot in order to preserve time for the conduct of the face-to-face meeting and receipt of public comment.

Review of Recent Activities

Michelle advised the attendees of the committees' recent activities. In addition to the completion of an Internal Audit of committee performance, which indicated compliance with TNI SOPs and Policies/Procedures, the CEC had three major on-going activities. The first was the committee's efforts to respond to new Standard Interpretation Requests (SIR) and to resolve existing SIR not yet brought to completion. The second action focused on development of a series of questions for use in TNI's credentialing efforts. The third and by far the most time-consuming activity was the committee's efforts to fully review and develop, consistent with the posted Notice of Intent to Modify EL V1M4, changes in Module 4 to improve the chemistry standard and address all previous stated concerns based primarily on public comments and SIRs.

Credentialing Questions – At the request of the Credentialing work group, the CEC prepared and submitted approximately 50 questions that could potentially be used for their efforts. After review by the credentialing group, a final approved list of questions was re-submitted for their use.

SIR Status

As previously reported, the committee has no SIR to which they have not submitted the required response. No new responses have been received from the LASEC/AC regarding any unresolved SIRs. One specific SIR, SIR 426 concerning use of surrogates, has been completed resolved and the resolution posted on the TNI website. The committee has also received a number non-valid SIRs. These non-valid SIRs do not require a response to the LASEC/AC but the committee does review them and may offer clarifying language in the Draft Standard.

Five such non-valid SIRs (NV SIR) were reviewed by the CEC. NV SIR 486 and 487 both dealt with verification failures and "rules" for acceptability on one or multiple instruments. NV SIR 488, which was addressed to the CEC, Microbiology Expert Committee and the Quality Management System committee, dealt with quality system matrix identification. NV SIR 492 requested information on re-validation of moved instruments. The final NV SIR 493 also dealt with the handling of failed criteria. These non-valid SIRs were either not addressed by EL V1M4 or were considered to be "how to" type questions which are not the purview of the standard.

EV 1M4 DS Development

As previously stated, this particular activity was a dominant and major effort for the CEC during the past number of months. The process utilized by the committee, the current

status of their efforts as well as comments/suggestions following presentation of the proposed changes are presented below.

Process – As previously reported, the key sections of the module requiring potential modification based upon comments received and SIRs, were assigned to work groups who focused their attentions on these critical sections of the module. Each work group completed their reviews and recommendations and returned said recommendations for full committee consideration. The committee then began a detailed review of each section of the module with specific focus on the work group recommendations. The process will continue, with continuing public input, until a Draft Standard is posted for comment on the TNI website.

Status – Currently the committee has reviewed the module and accompanying recommendations through section 5.4.1, MDL determination. The MDL sections of the module was the first of the critical sections of the module that necessitated review and modification. The other critical sections yet to be fully addressed are Demonstration of Capabilities and Calibration.

Review and Public Comment – As the topic of MDL and its associated issues (i.e., initial and on-going verification, LOQ, etc.) are of critical concern, Michelle return discussion to the beginning of the section for purposes of receiving public input.

In presenting the committee's recommendations, Michelle pointed out that changes reflect the application of the EPA MDL procedure unless methods require an alternative. Public comments suggested alternate MDL procedures, in special cases that meet AB approval should be included. The present proposal specifically states the EPA procedure dated September 27, 2017. A suggestion was to use or add (most current version) to the language of this section. Another question was asked regarding the reasoning for the 30-day requirement in section 5.4.1.2.a to repeat the MDL verification. A follow-up inquiry addressed what to do with the data surrounding the failed MDL verification. The committee proposed addition of language to state that if the MDL verification fails, no data can be reported to the MDL.

Michelle then moved on to the section on LOQ. She stated that changes were proposed to accommodate the EPA MDL procedure but that other proposed changes were minor. A question was asked relative to the use of the term "corrective action" versus simply "action" as the term corrective action is believed to imply a specific and more stringent process which made no be applicable. The consensus of participants appeared to suggest to the committee to retain the use of corrective action here and throughout the module.

With regard to LOQ verification, a request was made for the committee to include some additional language on the actions and/or consequences of LOQ verification failures.

The presentation of proposed changes to section 5.4.4 reference Documentation followed. Michele noted only a few proposed changes. Discussion included one suggestion that the committee add language which would mirror the handling of method blank data from the MDL procedure.

Sections 5.5 Evaluation of Precision and Bias and 5.6 Evaluation of Selectivity had not non-editorial changes. Both sections received no comments and/or suggestions from meeting participants.

The remainder of the CEC session was devoted to discussion of Demonstration of Capabilities (DOC). Specifically, sections 6.0, 6.1 (Initial DOC) and 6.2 (On-Going DOC) were reviewed and offered for comments. Early in this discussion, one suggestion was to eliminate all of the requirements for DOC. The commenter stated that the laboratory management is ultimately responsible for the overall quality of the data they provide and it is their responsibility to ensure that all of its employees are capable and competent to perform assigned tasks. They further suggested that the laboratories Quality System Manual would contain all the necessary elements of demonstrating competence of staff. While there appeared to be some agreement with this suggestion, it was believed that ABs would want some structure for DOC evaluation and that its overall removal from M4 would be unacceptable.

Attendees were of the opinion that the DOC language should not be abandoned but modification and/or a different approach could be beneficial.

Much discussion centered on the question of DOC for support staff (i.e., personnel who perform extractions, digestions, etc. but do not perform analysis). While the CEC sees this topic as a serious issue, none of the comments/suggestions appeared to result in a resolution acceptable to a consensus of the attendees. This issue will require further development by the CEC.

AS Michelle continued to review the proposed changes in the module, the potential use of single blind samples, CRM, or other form of quality control samples should be an alternative to LCS currently required in the standard.

After continuing discussion of both initial and on-going DOC, another suggestion was to delete the requirements for on-going DOC while adding additional flexibility in the determination of the initial DOC.

One final approach to DOC in EL V1M4 that was presented was to basically redevelop the section by simplifying it, consistent with the approach used in ISO 17025, present minimum requires and provide a Guidance Document recommending a “how to perform” the DOC. This approach seemed to find support with meeting attendees particularly as EL V1M4 is not intended to be a “how to” which sections 6.1 and 6.2 appear to be.

Throughout the meeting numerous comments as to minor concerns were voiced. In response to these comments, Michelle made multiple editorial, grammatical and semantic changes to the existing and newly proposed language of the module. In the following attachment, these changes as well as comments requiring the CEC attention are presented.



V1M4 Combined
Revisions Draft August

The meeting concluded at Section 7.0 Technical Requirements. The CEC will continue development of the DS of EL V1M4 at its future meetings.

The meeting was adjourned at approximately 5:00 PM PT. The next scheduled meeting of the CEC is September 4, 2024.

Attachment 1

Chemistry Expert Committee
Summer Meeting Agenda
Environmental Measurement Symposium
Garden Grove, California
August 5, 2024

Michelle Wade, Chair
Tony Francis, Vice-Chair

- Welcome and Introduction of Current CEC membership
 - Presentation of Meeting Format
- Roll Call
- Agenda Approval
- Status of July Minutes

- Review Of Recent Activities
 - Credentialing questions
 - SIR Status
 - EL V1M4 DS Development
 - Process
 - Status
 - Review and Public comment
-

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