

SUMMARY
TNI CHEMISTRY EXPERT COMMITTEE MEETING
May 6, 2020

The Chemistry Expert Committee (CEC) met by teleconference on Wednesday May 6, 2020 at 2:00 PM ET. The teleconference was recorded solely for the purpose of preparation of the minutes. The recording was deleted immediately upon generation of the draft summary of the committee meeting. Chair Valerie Slaven led the meeting.

Roll Call

Valerie Slaven, PDC (Lab) – Chair	Present
Jay Armstrong, VA DGS (AB)	Present
Paula Blaze, NJ DEP (AB)	Present
Eric Davis, Horizon (Other)	Present
Deb Gaynor, Independent Consultant (Other)	Absent
Shawn Kassner, Pace (Lab)	Present
Max Patterson, UT DOH (AB)	Present
Charles Neslund, Eurofins (Lab)	Present
Colin Wright, Florida DEP (Lab)	Present
Calista Daigle, Quality Consulting (Other)	Present
Tony Francis, Saw Environmental (Other)	Present
Ali Boren, State of Vermont (AB)	Present
Lee Wolf, Consultant (Other)	Present
Chad Stoike, ALS Global (Lab) – Vice Chair	Present
Michelle Wade, A2LA (AB)	Present
Robert Wyeth, Program Administrator	Present

The attached agenda (Attachment 1) was presented. Bob requested that “Old Business” be added to the agenda and suggested three items. First the topic of technical manager, second the Status of the summer TNI/NEMC meeting and third the issue of internal audit response.

A quorum was present and the meeting proceeded. Associate members Paul Junio, Arthur Denny, Karna Holquist, Chris Fuller, Terrell Maske, Nicole Cairns, David Smith, Kelvin Yuen, Carl Kircher, and Farid Ramezanzadeh also participated in the call.

April Meeting Minutes

The April 1, 2020 minutes (Attachment 2) were presented, a motion to accept the April minutes was made by Max and seconded by Shawn. The committee unanimously

approved the April minutes which will be forwarded to William for posting on the TNI website.

Review of SIRs

Consistent with the requirements of SOP 2-100, all SIRs previously received must be addressed in preparation of modifications to the Standard/Module or section. Valerie presented the SIR summary and shared it with all attendees remotely. Attachment 3 presents this SIR Summary Document.

Review of the SIR summary indicated that the primary unresolved (but not the only issues) items relate to Section 1.6 (DOC) of Module 4. There is one SIR each related to Section 1.5 (LOQ) and 1.7 (Technical Requirements) which the committee must ultimately address. The following agenda item presents the discussion of the committee related to section 1.6.

SIR 199 response was suggested by Valerie to remain unchanged; all Matrix/Method/Analytes (M/M/A) must meet criteria without use of marginal Exceedance. Committee believed some clarification maybe necessary in the Module.

SIR 237 needs to be addressed by the committee.

SIR334/336 also requires some clarification as to specificity of requirements in Section 1.6.2 and 1.6.3.

SIR 339 concerning labs adding accreditation after 1 yr of performance and use of CDOC as an IDOC needs to be addressed.

DOC Standard Language

The primary topic of discussion centered upon the use of Marginal Exceedance (ME) in DOC determinations. After much discussion, it was general consensus of the committee that the use of ME in IDOC was not needed since an IDOC is already determined by the average of the four results. It was discussed that removing the use of the average and adding in ME would actually tighten the requirements. However since LCSs are an acceptable form of CDOC the use of ME was acceptable with documentation by the laboratory of how lab derived limits were determined and that such determinations and use were contained within the lab's Quality Management Plan (by whatever name). Generally felt that standard should include some type of language on how said limits could be determined. The concept of ME may require clarification in the standard.

It was also the consensus of the committee that in use of PT data ME were not to be utilized.

For a new lab generally the assessor members of the committee felt all M/M/A should meet established criteria and that only that an acceptable average recovery should not include more than 1 ME (as opposed to the current standard which allows more than one ME if not consecutive). For a new lab initially seeking accreditation no ME should be allowed in the results was one stated opinion.

The committee further agreed that focus needs to be given to what are commonly referred to as "poor performers". It was further recognized that some M/M/A should virtually never be a ME but specific identification of these analytes was likely outside the scope of the Standard. Generally felt that these compounds should be documented by the lab and criteria set for acceptance of results within the Quality Manual which would obviously be within the purview of the ABs.

Once again some confusion existed during discussion based upon requirements of the lab versus the analyst. Committee felt that lab IDOC was primarily a Validation issue and should be approached in the standard from that perspective. It was also suggested that individual IDOC should be emphasized as a part of analyst training.

Conclusions (while not necessarily final at this point) but for reference in drafting proposed changes to existing language was no ME in IDOC (lab or analyst) and M/M/A specific. Also believed there must be an annual lab DOC which is M/M/A specific. Allowance also should be made for a minimal number or specific requirements of ME in analyst CDOC particularly if LCS at lower concentration levels is used for the process; but would not be M/M/A specific.

Standard regardless of repeating language should address 4 separate sections (whether in the validation section for lab requirements or not) one each for Lab IDOC, Lab CDOC, Analyst IDOC and Analyst CDOC.

Section 1.6.1.c allows a lab/individual who has been running a method for at least one year to utilize a CDOC (or on-going DOC) as an IDOC for accreditation assuming records are on file that an IDOC is not required. Assumption is that no changes have been made in any aspect of the operation of the method. Comment was this was relevant to labs joining in TNI accreditation and may not be relevant any longer...some believed it was still useful. An example was municipal labs asking for accreditation of analytes frequently. Generally, if appropriately following the 2016 Standard and running a method for more than a year, IDOC or not, a lab could support data requirements for accreditation.

Suggested that “grandfathering” language be removed but a number of examples illustrate some utility of the language. Could be removed from some sections and left in others.

Next month’s call will focus on developing language for Laboratory method validation and potential clarify or remove the term “lab IDOC”. Val will initiate the activity by preparing some draft language for consideration.

Old Business

Technical Manager

Bob requested that agenda item be maintained and be addressed at a future time. Committee member are directed to the Minutes of the April 1, 2020 meeting for previous discussions and status of discussions.

Status of Summer TNI/NEMC meeting

Bob reported that the TNI/NEMC Face-to-Face meeting originally scheduled for Minneapolis, MN in August has been converted to a Virtual meeting due to impacts from the COVID-19 pandemic. TNI committee meeting will be held in August by normal conference call means. The symposium of NEMC presentations will be presented virtually. The Steering Committee is finalizing the technical program and more information will be provided shortly including the associated fees. Costs associated with the virtual conference will depend on sessions attended by each individual while numerous other sessions (plenary session, showcase, etc) will be offered at no charge.

Response to Internal Audit

Bob reminded the committee the responsibility to provide corrective actions to the recently completed internal audit still need to be prepared. The primary responsibility rests with Val and Bob but the committee will be asked to review and approve responses prior to submission.

The meeting of the committee concluded at 3: 30 PM ET on a motion by Michelle and a second by Eric. The next scheduled conference call for the committee is Wednesday June 3, 2020 at 2:00 PM ET.M

Attachment 1

Meeting Agenda

Chemistry Expert Committee

Wednesday May 6, 2020, 1:00 -2:30 pm CST

1. Roll Call
2. Approval of April 2020 Minutes
3. Review of SIRs
4. DOC standard language
5. Old Business
 - Technical Manager
 - Status of Summer TNI/NEMC meeting
 - Internal Audit Response

Attachment 2



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Attachment 3



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