Summary of SIR Subcommittee Meeting

June 26, 2018

Present: Judy Morgan, Silky Labie, Carl Kircher, Lynn Bradley (Bill Hall submitted email comments)

Six SIR submissions that had been determined not to be valid SIRs were flagged during the screening process as potential candidates for Implementation Guidance. These had been languishing for several years, but were identified by reviewing all prior SIR submissions.

SIR 268

Standard	2009 TNI Standard V1M2 14.14.1 and 14.15.1
Describe the problem:	What is meant by a "predetermined schedule" for internal audits and management reviews? Does this mean a specific date and/or time? For eg: June of every year, the last week of October of every year, May 10th-21st of every year etc. Or does this mean an interval of performance? For eg. on an annual basis.

Consensus of the subcommittee's discussion was that the schedule and scope of a lab's internal audits should be included in the quality system documentation, and any deviations from that procedure should be documented. Kristin will be asked to draft the guidance for this issue, since she noted that Utah gets many inquiries about this topic.

SIR 282

Standard	2009 TNI Standard V1M4 1.7.3.2.3 and Note
Describe the problem:	The language in the note under Section 1.7.3.2.3 is as follows, "The matrix spike may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS" seems to indirectly indicate that an analyte in the MS which meets the LCS acceptance criteria may be used in place of the same analyte in the LCS that does not pass the LCS criteria. In short, if an analyte in the LCS fails the LCS acceptance criteria can you use the same analyte from the MS instead if it meets the LCS acceptance criteria. My interpretation is that this is not the intent of the note in this section of the standard to allow this however I have received questions from several sources regarding the applicability of the above requiring further explanation.

This issue is addressed in the 2016 standard, so that the guidance must match those requirements. Judy agreed to draft the guidance.

SIR 290 – this SIR was reviewed by Quality Systems, that determined it was an implementation question

Standard	2009 TNI Standard V1M2 5.5.13.1.b
Describe the problem:	Our laboratory is required to calibrate all thermometers annually against a NIST traceable thermometer, bracketing the range of use. If the 2 temperatures that the thermometer is calibrated produce different correction factors, which correction factor is used?
Committee Comments	Technical considerations aren't all provided in this SIR The Correction Factor should be the one for the temperature at which the thermometer is being used Which temperatures were used for bracketing the calibration? At what temperature is the thermometer being used / what is the range of use for the thermometer? What were the correction factors that were found? ****NOTES PRIOR TO PROVIDING A RESPONSE**** The laboratory shall maintain records of established correction factors to correct all measurements. The laboratory shall have a procedure to describe how it handles such a situation. NIST SP819 says that any variability found among correction factors on a thermometer must be within the uncertainty of the thermometer.
Response:	This problem appears to be a technical issue and not a request for interpretation of the Standard. TNI EL-V1M2 Section 5.5.13.1 b states "All support equipment shall be calibrated or verified at least annually, using a recognized National Metrology Institute, such as NIST, traceable references when available, bracketing the range of use. The results of such calibration or verification shall be within the specifications required of the application for which this equipment is used or: i) the equipment shall be removed from service until repaired; or ii) the laboratory shall maintain records of established correction factors to correct all measurements." The TNI Standard does not prescribe control limits which must be met in order for a piece of equipment, whether analytical or support, to be determined to be acceptable. TNI EL-V1M2 Section 5.5.7 states "Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 4.9)." Correction Factors that are within the error of measurement of the thermometer in question are not expected to impact the results of that thermometer. Unless prescribed by method or regulation, it is up to the laboratory to determine which correction factor shall be used. The TNI Quality Systems Committee cannot be the arbiter of method, instrument, or equipment questions, as that is outside the Charter of this Committee.

Discussion included a comment that the guidance might recommend that the level of certainty needed for the range of use should be a determining factor. Carl agreed to draft language for the guidance.

SIR 291

Standard	2009 TNI Standard EL-V1M4-2009 1.7.3.3 Sample Specific Controls
Describe the problem:	What approach is acceptable to demonstrate matrix effects on field samples when the laboratory is not provided with sufficient sample volume to perform an MS/MSD with the sample batch, particularly in the scope of organic 1L extractions? If sufficient volume is not submitted for the MS and/or MSD, then there is also not sufficient volume for a sample and duplicate pair either. Most laboratories are not responsible for sampling and should not be held as such, but some TNI accrediting authorities are citing laboratories for this very issue and have taken a hard "line in the sand" approach on this matter. The laboratory should be responsible for providing sufficient instruction and materials to samplers, but shouldn't be held responsible for something completely beyond their control. If the samplers don't obtain sufficient volume for whatever reason, why is the laboratory responsible? The TNI standard doesn't seem to provide much guidance on what actions that the laboratory should take in this event and mere qualification of data doesn't appear to be an acceptable alternative to the aforementioned TNI accrediting authorities. If you need further information, please feel free to contact me at your convenience. Please advise and thank you!

Conversation focused on whether a lab can avoid responsibility for sampling conducted by the client. The 2003 NELAC standard allowed sample rejection; does the lab need to consider the client's desires and needs? Carl agreed to draft the guidance.

SIR 292 – this was submitted by an AB and is about the practice of "remote data assessment". It is not appropriate for implementation guidance.

SIR 324

Standard	2009 TNI Standard V1M4 1.7.3.1 & 1.7.3.2

Describe the problem:
We receive filtered, preserved samples from clients for dissolved trace metals analysis. We also receive samples that clients request we filter in-house for dissolved metals analysis. These are filtered by a receiving group, who also preserves after filtration. Both types of samples are sent to the analysts already filtered and preserved.
Analysts perform no filtration of samples for dissolved analysis.
1. Do analysts need to filter a MB and LCS to analyze with the filtered samples they receive? This would mean they are treating the MB & LCS differently than they treat samples.
2. Does the in-house receiving group need to filter a MB to create a MB in a similar matrix as the

samples?
3. Does the in-house receiving group need to filter an LCS? They have never spiked samples or made up standards before.
Thank you!!

After discussion about whether the receiving group, if it filters a sample upon receipt, also needs to filter a method blank and perhaps an LCS, and whether it is appropriate to hold the lab responsible for what should have been done when the sample was collected. This submission will be reconsidered for sending to the Chemistry committee as a valid SIR.