LASEC SIR Subcommittee March 28, 2017

Participating: Judy Morgan, Carl Kircher

SIR 26, NELAC Chapter 2

The response does not address the issue. Despite all else, this is a dispute with the AB and should never have been accepted as a SIR. Carl explains that the problem has long since been resolved. Send NOT A SIR letter to submitter.

I have been recently inspected by the State of Florida DOH. The inspection was very well done and along NELAC standards.
The auditor indicated that if we were certified for compound 1,2,4-trichlorobenzene for 8260 we would be required to perform the PT if 1,2,4-trichlorobenzene was offered for any group. It is not currently in the 8260/624 volatile grouping as offered by WIBBY or NIS. It is however listed in the base neutral grouping. We were advised that we would have to perform the volatile analysis using the base neutral sample. We are not currently certified for 8270.

If we put this base neutral PT on the volatile instrument we would ruin the column with the very first PT.

I emailed Steve Arms the program director at the State of Florida and got a similar response.

This is just an example of one parameter there are others that fall into this issue
Thank you for your time.

(revised response from PTPEC, to match SIR 80 – identical text to SIR 80 response – question in 80 was "We are currently accredited for method SW 846 8151, but we want to add Pentachlorophenol by 8151 to our scope. Pentachlorophenol is not listed as requiring PT with the other Herbicides that are analyzed by 8151 that are listed. Therefore, I interpret that as Pentachlorophenol by method 8151 does not require PT.
Our Accrediting Body says otherwise. They contend that because Pentachlorophenol is listed under the Acid Extractables (Method 625 or 8270) that require PT, it also requires PT if we want to add it to our 8151 scope.")

RESPONSE:

The ABs are correct in requesting the analysis of PTs where available by analyte/matrix. While the 2003 NELAC Standard defined an FoPT as having all three elements of matrix, method/technology, and analyte/analyte groups, PT data was not available to establish separate FoPTs according to method/technology. The 2003 Standard also specified that sufficient PT data had to be available, specified as at least 10 valid PT studies with at least 20 participant laboratories in each study, in order to establish concentration ranges and acceptance limits for FoPTs.

When this SIR was initially submitted for consideration, the TNI PT Program worked to establish additional FoPTs for so-called "dual-purpose" and "overlapping" analytes. The NPW FoPT Table that went into effect on 10/3/2011 added an additional listing for 1,2,4-Trichlorobenzene (and Naphthalene)

in the grouping with other Volatile Aromatic analytes for possible use with methods such as EPA 624 and 8260. The same addition was made in the SCM FoPT Table that took effect on 1/3/2012.

The TNI PT Program has no control over the business practices of PT Providers on how they package, market, and distribute their PT samples. Therefore, the only recourse within the auspices of TNI are to petition the PTPEC to add the analyte in question as a separate entry with separate concentration range and acceptance limits. This could be done by submitting an Analyte Request Application to the PTPEC, with a TNI NELAP AB sponsor and supporting PT data justifying the addition of the requested analyte.

AC COMMENTS:

The response needs to be revised to make the instruction clear at the end how laboratories must request analytes for studies.

NH ELAP goes by the subcategory heading listed in the pt tables. I wouldn't require they run an analyte by the "wrong" method. Not sure the response addresses the real issue.

The NELAC FoPT covers both volatile and Base/neutral 1,2,4-trichlorobenzene. The lab needs to partake in both PTs if it wishes to run both 8260 and 8270. The lab should find a PT provider that offers the PT in the volatile fraction.

This should not qualify as a SIR since it is related to a disagreement of an audit finding. However, the first paragraph looks like a reasonable response, the rest is unnecessary,

this isn't an interpretation, it's an explanation

SIR 229

The response does not address the question. Return to Chemistry with a suggestion to amend the response with language similar to “Unless precluded by method …(first sentence). However, (second sentence.)”

2009 TNI

2009 Standard states in 1.7.3.2.3...

Note: The matrix spike may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS.

Is it the intent of the standard that when evaluated by the same criteria, a passing MS replace the LCS in its totality or can an individual target compound failure in the LCS be replaced by an individual acceptable result in a matrix spike sample?

Response:

The standard does allow a laboratory to run an MS instead of an LCS. An MS may not be used to replace a failing LCS.

AC Comments:

This interpretation is unclear, if a method requires an LCS, then the standard cannot supersede this requirement. Also, if using the MS in place of an LCS, then the LCS criteria must be used.

The response doesn't clearly address the submitter's question.

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(plus two comments agreeing with these comments.)

And one comment in support of response -- The response is fine. The standard does allow the use of an MS, it is always understood that method requirements trump the standard. Also they say you can't use an MS to replace a failing LCS, which eliminates the picking and choosing.

SIR 246

Return to Quality Systems with a note to look at §5.8.5 of V1M2 2009.

2009 TNI V1M2 5.8.5(a)

Question: Do labs have to uniquely identify sample containers when received at the lab?

The 2009 standard states: "The laboratory shall have a documented system for uniquely identifying samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time. This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates."

The 2003 standard stated the same but also added: "The laboratory shall assign a unique identification (ID) code to each sample container received in the laboratory. The use of container shape, size or other physical characteristic, such as amber glass, or purple top, is not an acceptable means of identifying the sample."

Since the 2009 standard dropped the wording above in the third paragraph, some are interpreting this to mean the labs do not need to uniquely identify sample containers anymore. However, since the 2009 standard does still include sample containers in the last sentence of the second paragraph, above, some are interpreting that sample containers must be uniquely identified.

I have heard this may be addressed in the upcoming standard, but I don't know that absolutely.

RESPONSE

The language in the Standard does not require individual identification of each sample container beyond the laboratory sample ID.

AC comments (9 negative votes)

The 2009 standard section includes "sample containers" as part of what needs to be uniquely identified. If each container itself does not have a unique ID how do you know which container was used for testing if questions on results occur.

I am against the response based on VIM2 5.8.2 and VIM2 5.8.5 a. The lab must have identifying test items. The system shall be designed and operated to ensure that items cannot be confused physically or when referred to in records or other documents and the laboratory shall have a documented system for uniquely identifying the samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time.

The response is brief, confusing and doesn't address the issue of 3 VOA vials which seems to be of some concern.

The standard clearly states, "This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates." V1M2: 5.8.5.a.

The response doesn't really answer the question. The standard is clear that the lab needs to have a system for identifying samples but it is up to the lab as to how they accomplish it.

SIR 266

Post for AC vote

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M1
Section (eg. C.4.1.7.4)	4.2.1
Describe the problem:	I am having difficult interpreting the requirements outlined in 4.0. The main concern is with our metals department where we run methods 200.7, 6010B, 200.8, 6020. If we are analyzing a PT by all four methods and reporting all methods individually, are 200.7/6010B and 200.8/6020 being treated the same? For example, is a failure for Cobalt by 200.8 equivalent to a failure for Cobalt by 6020, even if our PT demonstrates that we passed Co by 6020? These methods have different digestions and different method requirement at the instrument level. For the 200 series we utilize a hot block digestion and the 6000 series utilizes a microwave digestion. At the instrument level, the control limits for MS/MSDs and blank spikes are different. The requirements for same-source and second-source checks are different. These are different methods. Is each metals failure for ICP a failure for all ICP methods and each ICP-MS failure a failure for all ICP-MS methods? If this is the case, are we able to only run by one method and hold the accreditation for both. The standard references FoPT, with is defined by matrix, technology/METHOD, analyte. Not just based on matrix, technology, analyte. Any clarification would be appreciated. Thank you

Comments:

Response #1:

The use of the term "method" within the definition of Field of Proficiency Testing (FoPT) (2009 V1M1, 3.6) is only included to accommodate EPA's drinking water program where PTs are required per method for the drinking water analytes referenced in the Code of Federal Regulations (CFR), specifically 40 CFR 141.

The use of the term "technology" within the definition of FoPT (2009 V1M1, 3.6) only refers to the determinative analytical technology; preparative techniques/methods are not part of this definition.

In addition, the Note in Section 5.1.1 of V1M1, states the following:
"…If the laboratory is accredited for multiple test methods that use the same technology within a field of accreditation, the laboratory is not required to analyze a PT sample for each test method, except for fields of accreditation for the drinking water accreditation matrix for which a PT sample per test method is required…"

Therefore, using the example provided, for each analyte in the same matrix, the TNI standard only requires PTs for one ICP method (200.7 or 6010B) to maintain accreditation for both ICP methods and one ICP-MS method (200.8 or 6020) to maintain accreditation for both ICP-MS methods

If the laboratory chooses to analyze and report PT results for both methods within a technology (i.e. 200.7 and 6010B for ICP), then an unacceptable score for either of those methods will result in an unacceptable score for both methods due to their shared technology.

See the Note in V1M1, Section 5.1.1, which states the following "….When the laboratory reports an analytical result for an accreditation FoPT within the same field of accreditation and accreditation matrix by more than one test method using the same technology, an unacceptable score for either test method will result in an unacceptable score for all test methods for that accreditation FoPT."

SIR 275

Post for AC vote

Standard Interpretation Request #275 (submitted 9/25/2014)—referred to PT Expert Committee

Standard: 2009 TNI Standard

Volume and Module: V2M2

Section: 4.1.1 f)

Describe the Problem:

V2M2, section 4.1.1 f) states: “notify all Secondary ABs of revocation of accreditation of any laboratory in the program.” Does this standard language require not only for a Primary AB to notify all Secondary ABs of a total revocation of a laboratory’s accreditation, but to also require notification for a partial revocation? We are requesting this SIR since we are debating the interpretation of this requirement within our own program and because we have only been notified by one other AB in regards to total revocation of a laboratory accreditation. We feel there is a need for clarification on how to interpret/implement this requirement and are uncertain if it is being understood and implemented consistently by other ABs.

Comments:

Response #1:

This standard clause does not delineate between the types of laboratory accreditation revocations, total or partial. The standard should be implemented such that Secondary ABs are notified of any revocation, total or partial, of a laboratory’s accreditation.

SIR 277

The examples are no longer valid, since spiking solutions are available for some of the items noted in the standard. Return to Chemistry with request to re-write the response to accommodate that fact. NOTE: this issue was not addressed in the 2016 standard.

2009 TNI 1.7.3.2.2

The Standard states: "The LCS shall be analyzed at a minimum of one (1) per preparation batch. Exceptions would be for those analytes for which no spiking solutions are available, such as TSS, TDS, TVS, TS, pH, color, odor, temperature, dissolved oxygen or turbidity." However, there are now spiking solutions available for some of these analytes such as TSS, TDS, TS, and many labs are using them. The Standard has not been updated to reflect the availability of these solutions, and this exception has been in effect since at least the 2001 NELAC Standard.

Are labs now required by the Standard to analyze an LCS for TSS, TDS, and TS since spiking solutions are now available? Is this section being changed in the 2015 Standard?

RESPONSE:

Laboratories are NOT required by the standard to analyze an LCS for TSS, TDS and TS unless otherwise required by mandated test methods (see for example SM2020 on the use of externally provided standards to assess bias), client requests, and laboratory quality system specifications.

AC Comments:

I disagree. The standard is using these as examples of what spiking solutions are not available. The standard is not stating that LCSs are not required. Spiking solutions are available for solids, so the availability of the spiking solution would negate these as viable examples of where an LCS is not available.

Spiking solutions are available for solids. The Standard states: Exceptions would be for those analytes for which no spiking solutions are available. Therefore, the spiking solution is available and no longer meets the exception criteria.

I agree with Aaren. I put in my rules LCSs are required for solids analyses.

I don't know that spike solutions are available, there are SRM or whole volume QC solutions available which people use as an LCS but I don't know that there are actual spikes. The response does point to the QC section in SM 1020 which discusses QC requirements

SIR 297

Post for AC vote.

Standard	2009 TNI
Volume and Module (eg. V1M2)	V1M4
Section (eg. C.4.1.7.4)	1.6.2 and 1.6.3
Describe the problem:	Are the DOC requirements in V1M4 sections 1.6.2 and 1.6.3 specific to each Matrix-Method-Analyte combination for which a laboratory seeks or maintains accreditation? The language implies that they are, and because laboratories are accredited by Matrix-Method-Analyte, should be, but it is not explicit enough to preclude another interpretation. (Richard Burrows is aware of the issue and is expecting the SIR.)
Comments:	Section 1.6.2 is specific to the matrix-method-analyte combination as illustrated by the references to analytes in 1.6.2.2.a and "all parameters" in 1.6.2.2.d. Therefore, if no other analysis is performed for a matrix-method-analyte combination within a 12 month period, a new IDOC would be required per the last sentence in 1.6.2.
Response:	Section 1.6.2 (IDOC) is specific to each matrix-method-analyte combination. Section 1.6.3 is not specific to each matrix-method-analyte combination. It is the responsibility of the laboratory to document a procedure describing the ongoing DOC and it's adequacy per 1.6.3.1.

SIR #308, sent to Quality Systems

NOTE: this submission is a variation of SIR #108 – interesting how the number fell!

Both SIRs should have matching (if not identical) responses. Thank you.

Post for AC vote.

Standard		2009 TNI Standard
Volume and Module	**(eg. V1M2)**	V1M2
Section	**Section (eg. C.4.1.7.4)**	4.14.1
Question	**Describe the problem:** Per Clause 4.14.1, the internal audit program shall address all elements of the management system, including the testing and/or calibration activities. It is unclear if all test methods need to be audited annually since 4.14 never uses the word "methods" but rather "areas" or "activities". The question is this: Can the test methods be grouped by technology (i.e. GC/MS, ICP/MS, ICP, Spectrophotometry, Gravimetry, Meters, Titrimetry, SFIA, etc.) or does every method have to be audited annually? If grouped by technology, can different test methods within each technology be scheduled annually? The schedule beyond one year would show that tests are rotated for internal audits over time.	
Comments from Committee	Grouping tests by technology allows for the laboratory to address all elements of the management system. This plan of internal audits should be addressed in the laboratory's quality documentation in some place (a policy, procedure, or Quality Manual, for example). The decision to address internal audits by technology is one that may/must be made by the laboratory. A schedule indicating how the laboratory addresses all methods is helpful. Response from A2LA, which was helpful in the QS discussion, and is a way that the committee feels meets the requirements of this Standard: Section 4.14.1 of ISO/IEC 17025 states: "The laboratory shall…..conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this International Standard. The internal audit program shall address all elements of the management system, including the testing and/or calibration activities." It is acceptable for a laboratory to audit a sampling of their management system at each audit interval, as long as their overall audit program specifies how this sampling is to be done such that all elements of the management system and the accredited testing/calibration activities are audited within a given timeframe. It is also important to note that the standard requires auditing all "testing and/or calibration activities", not necessarily all testing and/or calibration methods. For some laboratories, auditing all accredited technologies and/or parameters may constitute a sufficiently thorough and comprehensive audit of their accredited activities, such that auditing all methods (which may be redundant and overlap) may not be necessary - as long as there is no evidence or indication that the depth and expanse of the technical portion of their audit is inadequate. Also, since the standard does not require that a full internal audit be done annually, it is acceptable for a laboratory's audit program to cover the entire management system (including testing/calibration activities) over a span of a number of years, as long as there is no evidence or indication that the timeframe of this cycle is inadequate. Although R102 – Conditions for	

Accreditation requires that each organization retain records at least for the period of time between full A2LA assessments, it also requires that:

"…adequate records…must be available to demonstrate full compliance with the requirements for accreditation."

Therefore, if a laboratory's full audit cycle spans a period of time that is greater than the period of time between full A2LA assessments, they must maintain adequate records for their full audit cycle to demonstrate compliance with the requirements for conducting internal audits. For example, a laboratory may specify a record retention period of two years, but their complete audit cycle may span 5 years. In this case, they must retain full records of each 5-year audit cycle even though it exceeds their normal record-retention period.

Response

No, not every method needs to be assessed annually in the laboratory's internal audits.

Yes, different methods within each technology may be assessed on an annual basis.