LASEC SIR Subcommittee July 26, 2016

Present: Judy Morgan, Kristin Brown, Carl Kircher

SIR 108

Return to Quality Systems – response does not answer the question

Section (e.g. C.4.1.7.4)	5.4.13.1
Describe the problem:	In the description of internal audits, it states "The internal audit program shall address all elements of the quality system, including the environmental testing activities." Does this mean that every method has to be audited yearly? For Labs that are running 300 or more methods this doesn't seem reasonable.
Comments	Section 5.4.2.1 states 'The laboratory shall establish implement and maintain a quality system based on the required elements in this chapter and appropriate to the type, range and volume of environmental testing activities it undertakes.' It isn't too high a standard to expect that each method would be audited once per year. It is possible that there wouldn't be a complete, exhaustive audit if there are no problems in the past. There could be more than a review of SOPs to qualify as a method review, and it is likely that a more in depth review would be required if issues were uncovered. The laboratory must determine how it will conduct is assessment of its environmental activities, and the lab must establish its procedure for doing this.
Response	The Internal Audit that is required in 5.4.13 is of the laboratory's quality system. It is possible to assess a laboratory's quality system without auditing to every SOP.
Comment – not a response	Are elements equivalent to just methods? Are elements PT samples, analytical SOPs, non-method SOPs, training records, management statements…. Can this be reflected in technologies (i.e., ICP/MS, GC/MS), so that you catch all analytes over two years? All methods may not have the same in-depth annual internal audit (this ma be an analyst interview, observation of the method, or some other assessment), but all methods are fully assessed over a set timeframe. The laboratory is

	obligated to expand its assessment schedule if issues are identified during its internal audit.

SIR #285

Keep first two sentences of response, move the rest into committee comment section. Post for AC vote

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M5
Section (eg. C.4.1.7.4)	1.7.3.2
Describe the problem:	Can you please clarify what is meant by "methods tha specify colony counts such as membrane filter or plated media." Does this mean all methods that are enumeration? Or just the membrane filter and plated media methods? Thank you! The intention was for all enumerated methods to have duplicate counts so that all enumerative methods can be evaluated for consistency between analysts. Follow up with SM indicates that the intention was only to include membrane filtration methods. This would then exclude heterotrophic plate counts with regard to SM but the language in the std suggests that it should be included. The TNI 2015 std will be edited to include clarification across all enumerated methods.
Committee Comments:	"I agree that in the case of this SIR and the current std it is only colonies, but should it always be? The overriding issue is "can all of the analysts interpret positive results in the same way?" Do all of the analysts see the same number of positive tubes or fluorescence? As I told Patsy, for Enterolert there are different shades of fluorescence (blue, green and white). Had I not done this in my lab, I would not have known that I needed to retrain an analyst. I am of the opinion that enumerated means enumerated. Can a different/multiple analyst(s) give you consistent results over all the enumerated methods? The only way to know for sure is to have the all of them interpret the same tubes or colonies or positive wells and compare the results"
Response:	Comparability of responses found in environmental microbiological testing is an important laboratory tool for ensuring comparability between multiple analysts or parallel counts determined in a laboratory with only a single analyst. The current language in the 2009 TNI Standard relates to the colony counts determined with membrane filter testing and plated media. The revised version of Volume 1,

Module 5 will clarify the language to include all testing that produces enumerated results. Until such time as the revised version of the module is approved and implemented, parallel counts at the laboratory must be performed for all membrane filter method testing and methods that include the use of plated media that results in colony growth by performing the count comparison on one (or more) positive sample(s) in each month when the testing is done with the acceptance criteria in the existing Standard met.

SIR #290, referred to Quality Systems Expert Committee July 24, 2015

Response is "wordy" but the question isn't quite an interpretation request, but decided to treat it as an SIR even tho the outcome is up to either the lab or the client. Omit first and last sentences and keep all remaining text. Post for AC vote.

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	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.

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.”

Response:

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.

SIR #296

Recommend removing middle sentence of response. Return to QS with explanation, ask if that’s okay. Returned to QS on 2/17/17

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	5.2.6.1
Describe the problem:	The 2009 standard, below (b), no longer contains the wording "environmental" analysis in the area of experience. Since it now states "such analysis" does this pertain to any type of laboratory experience in chemical, physical or environmental sciences (not just environmental)? b) Any technical manager of an accredited environmental laboratory limited to inorganic chemical analysis, other than metals analysis, shall be a person with at least an earned associate's degree in the chemical, physical or environmental sciences, or two (2) years of equivalent and successful college education, with a minimum of sixteen (16) college semester credit hours in chemistry. In addition, such a person shall have at least two (2) years of experience performing such analysis. And on the same topic, the 2009 standard for (c) below for limited microbiological analytes also no longer contains the wording "environmental" and just states "microbiological analyses", so may this also be interpreted as

	any microbiological laboratory analyses and not just environmental? c) Any technical manager of an accredited environmental laboratory engaged in microbiological or biological analysis shall be a person with a bachelor's degree in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering with a minimum of sixteen (16) college semester credit hours in general microbiology and biology and at least two (2) years of experience in the environmental analysis of representative analytes for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience. A person with an associate's degree in an appropriate field of the sciences or applied sciences, with a minimum of four (4) college semester credit hours in general microbiology may be the technical manager(s) of a laboratory engaged in microbiological analysis limited to fecal coliform, total coliform, E. coli, and standard plate count. Two (2) years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree. In addition, each person shall have one (1) year of experience in microbiological analyses.
Committee Comments:	Section 4.1.7.2 b) also states that the Technical manager 'be experienced in the fields of accreditation for which the laboratory is seeking accreditation."
Response(s):	The terms "such analysis" indicates that the technical manager shall have experience in the fields of accreditation for which the laboratory is seeking accreditation. The experience required is of environmental analysis in the first question, and environmental microbiological analysis in the second. In both cases, the Standard requires that the analyses performed which would qualify as experience are those that would be performed by the laboratory at which a person would be the technical manager.

SIR 297

Return to Chemistry (done 2/17/17) with question, why is §1.6.3 not specific? Seems non-sensical

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 necessarily specific to each matrix-method-analyte combination.

SIR #301, sent to Microbiology Expert Committee April 8, 2016

This now defines sample to mean plates. Seems an excessive leap, but posted for vote.

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M5
Section (eg. C.4.1.7.4)	1.7.3.1 ii
Describe the problem:	The micro standard discusses a method blanks to be performed every (10) samples. My question is what denotes a sample? My example is SM9222D that for each client's sample we will probably perform 3 dilutions - but the sample is the same. So would it be required to do a blank every 10 plates or every 10 job #s/samples?
Committee Comments:	If a lab were using only one filtration set up and running all of the aliquots through it, the "mid" blank is considered a system cleanliness check. As the purpose of the "mid" blank is to check the analyst's technique for carryover or other possible contamination, in this case, "sample" refers to every 10 plates. Any less frequency would constitute increased risk as there would be difficulty determining the last valid point and therefore require invalidation or qualification of multiple client samples.
Response:	The requirement of the standard is to perform a blank at least every 10 plates.

SIR #302, referred to Quality Systems Expert Committee

Originally scheduled for June 2016 meeting, but did not happen – email discussion established that it should be posted for vote

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	TNI V1M2
Section (eg. C.4.1.7.4)	5.2.6.1.c
Describe the problem:	Please clarify 16 hours of microbiology and biology Is it 16 hours combined total of microbiology and biology? Is it 16 hour of microbiology and 16 hours of biology 32 hours total?
Comments:	Any technical manager of an accredited environmental laboratory engaged in microbiological or biological analysis shall be a person with a bachelor's degree in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering with a minimum of sixteen (16) college

	semester credit hours in general microbiology and biology and at least two (2) years of experience in the environmental analysis of representative analytes for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience. A person with an associate's degree in an appropriate field of the sciences or applied sciences, with a minimum of four (4) college semester credit hours in general microbiology may be the technical manager(s) of a laboratory engaged in microbiological analysis limited to fecal coliform, total coliform, E. coli, and standard plate count. Two (2) years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree. In addition, each person shall have one (1) year of experience in microbiological analyses.
Response:	The requirement is for a combined minimum 16 hours of microbiology and biology, not for 16 hours of each.