

LASEC SIR Subcommittee May 23, 2017

Present: Judy Morgan, Carl Kircher, Bill Hall, Kristin Brown

SIR #304 transmitted to Quality Systems Expert Committee for response

This was returned from QA in January 2017 but never received the email. Request seems to equate gas microliter syringes with gas-tight milliliter syringes but response is acceptable. Post for vote.

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	5.5.13.1.e

Describe the problem:

Volume 1, Module 2, Section 5.5.13.1.e states, "Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) shall be checked for accuracy on a quarterly basis."

Our laboratory analyzes VOCs in air, and uses gas tight syringes up to 100 mL to prepare gas standards. We are unsure of whether or not we must complete quarterly checks on these syringes.

We're hesitant about using DI water to perform the quarterly checks on these syringes because they're used for preparing gas standards and we're unsure if moisture in the syringe would affect standard preparation. We're also unaware of how we could complete the quarterly checks using air. Our syringe vendor only offers a verification certificate for newly purchased syringes. For these reasons, it may be impractical to complete quarterly checks.

As I understand it, glass microliter syringes do not require quarterly checks because they deliver such a small volume that a quarterly check would be impractical. Knowing this, if our 100 mL gastight syringes are similar in form (and from the same vendor) as our glass microliter syringes, would they require quarterly checks or not? At a minimum is there any documentation we'd have to have on file for the syringes?

Comments:

Response: If the syringe in question is neither Class A nor a glass microliter syringe, then it must be checked for accuracy on a quarterly basis. The laboratory must have documentation on file of this quarterly check.

Then, four SIRs that seem to have been mislaid with LASEC. Content is pasted below (from excel file,) while dispositions are noted here.

SIR 71 – item #3 is the only question. This should not have been a SIR under the 2003 standard, and was addressed in the 2009 standard. Return to requestor with “not a SIR” memo and advise resolving the issue with lab’s AB.

SIR 105 – NOT a SIR, does not provide a section of the standard for interpretation. The question should be directed to the lab’s AB.

SIR 171 – this is a dispute with the AB, so should not have been accepted as a SIR. Send NOT A SIR letter. Also, advise new Asbestos committee of the issue – source of 2 std deviations was a NIST/NAVLAT asbestos checklist from ‘way back.

SIR 203 – an interpretation is not possible, this is a “how-to-comply” question that falls to the mutual recognition and accreditation scheme policies. Send “NOT A SIR” letter to submitter.

#	Date Submitted	Section of Standard	Actual Request

With the rise in use of third parties assessors, there are increasing number of examples where there are possibilities for conflicts of interest that would not normally occur with State AB employed assessors.

For example,

1) Is there a conflict of interest (or potential for conflict) where an third party assessor is hired to assess an organization, where that assessor or the organization to which they belong may also be hired to provide quality assurance or other laboratory improvement consulting to the laboratory being audited.

2) Is there a conflict of interest (or potential for conflict) where an third party assessor is hired to assess an organization, where a direct competitor of that assessor or the organization to which they belong may be hired to provide quality assurance or other laboratory improvement consulting to the laboratory being audited.

If the answer to either is yes, please describe how much assistance qualifies as a conflict of interest, and where is this accounted for in the standard.

71 6/19/2009 2003: 3.6.4 Standards of Professional Conduct for Assessors

3) Is it the responsibility of the third party assessor or the accrediting body to determine if the potential for conflict of interest exists.

105	1/14/10		<p>General question: does the accreditation process include all steps in the process, including sample prep? Specifically, if a lab is not accredited but performs the digestion of a water sample for method 6020 analysis then sends the digested aliquot to an accredited lab for the actual analysis can the results be considered valid from an accredited lab?</p>
171	5/10/11	2003: D.6.5.1.1.g	<p>We are accredited by NELAP for Asbestos in water by TEM. At our last audit we were deficient for our TEM grids that they didn't meet the $2s < 5\%$ requirement. We obtained grids that were certified as meeting that requirement except the data would seem to cast doubt in that statement. The company took 400 measurements and obtained the following:</p> <p>mean= 9098.74um s=507.31um 95% confidence interval= 49.87um</p> <p>2 standard deviations is about 11% which is 95%, but their 95% CI is calculated correctly and is so small because they used a lot of points, but more than 5% of the time measured results will exceed that range.</p> <p>My question here is: I cannot find a reference to the 2 standard deviation performance criteria anywhere except NELAC. What I am finding is that you need to determine the average grid area. The method does not even discuss establishing performance criteria. With that being said and the apparent difficulty in finding appropriate grids shouldn't laboratory established criteria be allowed as long as that information is communicated to the client and incorporated into the uncertainty of measurement calculation? If that is unacceptable would it be acceptable to measure each grid opening as it is counted and dispense with the average area?</p>

203	3/29/12	2009: V2M1: 4.1 through 4.2.2.1	<p>There is a need to clarify and provide a standards interpretation of the 2009 TNI Standard as to whether the language (including consideration of the any notes associated with clauses) found in V2M1, 4.0 Accreditation Body, sections 4.1 through and including 4.2.2.1 would prohibit and/or in some form limit the ability of TNI's NELAP Accreditation Council from accepting an application from and/or recognizing a non-governmental legal entity as a NELAP-recognized Accrediting Body. If the language does prohibit and/or limit this ability, please explain why and to what extent. If the language does not prohibit and/or limit in any way limits this ability, please explain why.</p>
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