Summary of SIR Subcommittee Meeting

October 23, 2018

Present: Judy Morgan, Bill Hall, Carl Kircher, Harold Longbaugh, Lynn Bradley plus Paul Junio, guest

The Quality System Expert Committee's response to SIR 329 was recently completed, after several discussions. The QS Chair, Paul Junio, offered to be available when the subcommittee considered the response. The response submitted to the subcommittee is included in Attachment 1.

At conference in New Orleans, QS thought they had reached a suitable response, but then afterwards, one committee member reflected that the first response would have meant that all Class A glassware would need to be tracked, and further discussion within QS led to the response below, by a majority vote but not all committee members supporting it.

After much discussion within the subcommittee about whether and how to define the "purpose of use" for equipment versus an exhaustive listing of equipment needing to be identified in the analytical record, Judy offered two options: that we submit the QS response to the NELAP AC, expecting it to be kicked back as unacceptable and unenforceable, or that we decide that SIR 329 is not a valid SIR but will be treated as Implementation Guidance. Judy did ask that, if it becomes Implementation Guidance (IG), the QS committee should prepare it.

Finally, the subcommittee settled on using Implementation Guidance, with the justification that no one answer can be appropriate for every situation and that it will be impossible to write a concise response to such a complex question. One subcommittee member suggested that we were making the response too complicated but in the end, that individual did not object to changing to IG.

Paul agreed to draft the IG, and mentioned that perhaps it could help settle outstanding questions of some of the older SIRs, as QS begins its next revision of the standard.

There was no time remaining to review the draft IG documents as assigned in June. Harold had submitted drafts of the two IGs assigned to him, and Judy asked that other subcommittee members review those documents and be prepared to discuss them at the November meeting.

Attachment 1

SIR 329

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	4.13.2.1 & 4.13.3.a
Describe the problem: Please see the attached file.	
Upload a File	2016-TNI-Support-Equipment-SIR_18-Jul-2018.docx
Comments:	[editor] the attached file is reproduced below without any identifying marks. The question asked has been **bolded**
Response:	Glass microliter syringes and Class A glassware are exempted from any traceability requirements as it relates to individual results because they need only be verified as required in 5.5.2 prior to being placed into service. With that noted exception, all support equipment requiring calibration must be traceable to individual results. Any support equipment requiring only verification then would not need to be traceable to individual results. Additional information - Support equipment verification requirements vary in their timeframes. Where something must be verified prior to each day of use, that verification would apply to any data from that day. Where the verification is prior to first use, then it would apply to any data associated with that use. The laboratory must retain all records necessary to establish an audit trail and allow the history of the samples to be followed through its documentation and records. To accomplish this, the laboratory must establish links to various activities such as equipment calibrations or verifications, standards source and preparation, sterilization checks etc. These links may or may not be in a single record – it is up to the laboratory to ensure that the record system design meets the audit trail and history requirements of 4.13.2.1 and 4.13.3.a. We have already exempted glass microliter syringes and Class A glassware from any ongoing verification. They must be verified prior to use. It stands to reason that they shouldn't need ongoing tracking in their usage, as we have said they don't need tracking.

18 July 2018
TNI Program Administrator
The NELAC Institute

We seek a Standard Interpretation Request (SIR) for the 2016 TNI Standard, EL-V1M2-Rev.2.1, Sections 4.13.2.1 and 4.13.3.a.

Both 4.13.2.1 and 4.13.3.a are general standards that do not prescribe specific items be traced to analytical measurements. The TNI standard makes a clear distinction between laboratory instrumentation used to generate analytical data and support equipment such as balances, ovens, volumetric dispensing devices (pipettes) and temperature monitoring devices. Section 5.5.13.1 of the standard requires that support equipment be properly maintained and calibrated, but does not require the tracking of individual pieces of equipment. Previous discussions with our accreditation body had indicated that, while traceability to measuring equipment is required, support equipment should be documented as being calibrated and maintained but not necessarily linked to individual test results.

We have been a NELAC accredited lab since 2001 and have witnessed a steady and increasing application of traceability requirements being applied by some assessors over the years. We believe that traceability requirements for support equipment are being extended beyond the intent of the standard and can potentially be extended to the point of absurdity while contributing little to data quality. Traceability requirements for support equipment are often a burden for labs while offering little value and no improvement in data quality. Even more concerning is that these additional requirements to maintain traceability for support equipment ultimately divert attention from matters that have greater data quality implications.

One argument that has been advanced by some assessors is that the tracking of individual pieces of support equipment should enable one to calculate the amount of uncertainty contributed by that device (balance, pipette) to the final uncertainty in the concentration of analyte in the sample. While this argument is theoretically valid, such a calculation (the consideration of a specific pipette in the calculation of a specific result) is virtually never conducted in practice. In fact, in the many years of operation of our laboratory, traceability of support equipment to individual measurements has never been an issue, and we are unaware of any other environmental laboratories where it has been an issue either (other than in audits). The measures of accuracy and precision reported by labs are generally made at the level of the analytical instrument. The sample precision reported by labs to customers encapsulates all the uncertainties of intermediate measurements (metadata) carried out by support equipment prior to analysis. It also includes the variability in sampling conducted in the field.

> We believe that as long as all support equipment is properly calibrated, and the calibration documented using established protocols, there should be no need for labs to track the identity of individual pieces of support equipment to individual results. The cumulative extra work that some TNI auditors have, or are seeking to impose, upon laboratories, when compared to any potential gain, is onerous. We feel our lab is spending time and resources to collect large amounts of data, the only purpose of which is to satisfy an audit, and is therefore a potential for an audit deficiency. There is an argument that environmental factors may have more impact on precision and accuracy than the differences between individual calibrated pipettes, for example. Should we be tracking lab temperature and humidity to individual data points? Should we be tracking the make, model, and serial number of our air-conditioning unit? A number of similar factors that may be considered to affect uncertainty in a theoretical sense could be cited, but likewise are of little practical value for establishing uncertainty.

In conclusion, the generality of sections 4.13.2.1 and 4.13.3.a allows for unrestricted interpretation of what should be documented and traceable. We would therefore appreciate your assistance in clarifying

traceability requirements for support equipment. **Does TNI contend that all support equipment is required to be traced to individual results, or is there a distinction between analytical equipment, that is required to be traced to individual results, and support equipment, that is required to be calibrated and correctly maintained, but not necessarily traceable to individual results? If the former, then where exactly is the limitation on what is required to be traceable?** It is our hope that TNI will consider a cost to benefit comparison in their deliberation on this SIR.

Thank you for your consideration of this issue.