

Summary of SIR Subcommittee Meeting

January 22, 2019

Present: Judy Morgan, Silky Labie, Harold Longbaugh, Carl Kircher, Paul Junio, Lynn Bradley

The third revision of draft Implementation Guidance (IG) document for SIR 290 should be available for the February meeting (thermometer with different correction factors at the ends of the temperature range).

The draft IG document from SIR 282, prepared by Judy, was available for review. This is a question about using a matrix spike in place of a lab control sample in some circumstances, per the language in V1M4 1.7.3.2.3. Silky recalled that Quality Systems Committee had added this language to one of the early NELAC Standards, and it was still there in the 2003 NELAC Standard (Appendix B 1.1.2.1.c). She also explained that the intent was that a MS could be used as long as it meets the criterion for an LCS, but that “intent” was not documented and now many labs don’t use them in that way. Silky recommended that Quality Systems be asked to look at the original request before the guidance is finalized. Further discussion led to a change of course, with a decision to treat this submission as a SIR, sending it to Chemistry with a request that they consult with Quality Systems because of the origination of the language. This was sent on January 24, 2019. A letter to the submitter notifying him of the change was returned by email as undeliverable.

Paul provided the promised draft for IG from SIR 239, which he had shared with Quality Systems committee before delivery to LASEC. The “bottom line” is that there does need to be “historical tracking” but assessors have taken that to extreme by requiring that the analytical sample record itself contain all of the tracking information. Other aspects of the quality system would require that the dates of use for a batch of reagent or some supply used in the analysis, and those records should be sufficient for tracking purposes, although if two batches were in use at the same time, then obviously yes, the sample record would need to specify which one. Judy wanted to have the full LASEC review this draft prior to posting, and it was distributed along with the minutes of the LASEC meeting, on January 23. Paul stated his willingness to continue with any needed follow-up, even though he is rotating off of Quality Systems.

Time expired before the IGs from the NOLA Mentor Session could be addressed. During the full committee meeting, Judy asked for volunteers to take the drafts that Scott and Myron had volunteered to review, since neither did so. Judy herself will review six of those and Silky will review three. (Thank you both!)

The next SIR Subcommittee meeting will be Tuesday, February 26, 2019, at 12:30 pm Eastern.