

Summary of SIR Subcommittee Meeting

April 23, 2019

Present: Judy Morgan, Silky Labie, Bill Hall, Carl Kircher, Lynn Bradley

Participants discussed four interpretations returned from the Chemistry Expert Committee. Outcomes were as follows:

SIR 282 – This was initially determined to not be a valid SIR, but when the subcommittee tried to write implementation guidance, they realized that it should have been an SIR, so was sent to the Chemistry committee with a request to consult QS as well, since Chemistry did not exist when the 2009 standard was written. The interpretation provided by Chemistry is acceptable, but the subcommittee will drop the final sentence before posting for AC vote. That sentence states that the wording will be clarified in the next revision of that standard and is not needed in the interpretation.

SIR 297 -- this is supposed to be an updated response, addressing DOC requirements, but participants found it confusing and possibly incorrect in its description of the relationship of LCS and PT samples. §1.6.2 does not specify that each analyte have a separate DOC and §1.6.1 adds the concept of “class of analytes” in the Note, but nowhere is “class of analyte” or “measured parameter” defined. Further, a PT sample cannot serve as an IDOC. This response will be returned to Chemistry with a request to rewrite the response referencing the 2009 standard and rephrasing the “cannot be said” language to clearly declare its meaning. Additionally, an interpretation ought not to reference current activities of ABs.

SIR 339 – this interpretation answers the question and will be posted for vote. An additional phrase will be added at the end of the second sentence of the interpretation to allow for the possibility of specific program requirements, and the edited interpretation will be returned to Chemistry as an FYI.

SIR 340 – this interpretation answers the question. For clarity, the phrase “In order to comply” was added to the beginning of the third sentence, and “should” changed to “would”. The reference to the guidance document is inappropriate for an interpretation, and was deleted.

Participants were asked to review the clean drafts of implementation guidances (five documents) and be prepared to either revise or approve them at the May meeting.

The next SIR Subcommittee meeting will be Tuesday, May 28, 2019, at 12:30 pm Eastern.