

Summary of SIR Subcommittee Meeting

June 25, 2019

Present: Judy Morgan, Gail Warren, Silky Labie, Lynn Bradley (Bill Hall sent email review of SIR)

Participants discussed the three revised draft Implementation Guidance documents from the June subcommittee meeting. The same new revision was agreed upon for documents about “Initial Volume Entered Incorrectly” and “Expired Standard”, to better present the who-should-be-notified sentences by using the language from the “Time Stamp Error” document. With that change, all three were approved for posting to the website.

A revised response to SIR 301 was received from the Microbiology committee. Participants found the revised response to contradict the initial response but that it still leaves open the definition of “sample” and how to distinguish that from “plates”, plus it adds a new undefined term, “mid-blank”. Discussion noted that the purpose of performing blanks is to demonstrate cleanliness and sterility, and wondered how (or whether) this language might apply to a setup using a manifold with multiple funnels.

The subcommittee’s recommendation was to return this response to Microbiology with a request to clarify the apparent contradiction and to clarify the definition of sample (particularly to distinguish sample from plate), to ensure that the response will also address the 2016 Standard, and to suggest that an Implementation Guidance document might be useful (in addition to the interpretation itself) to explain handling single versus multiple filtration units. The draft response was returned to Microbiology on July 13.

Judy also asked that everyone review the remaining 4 revised draft IG documents in preparation for the July 23 meeting.

The next SIR Subcommittee meeting will be Tuesday, July 23, 2019, at 12:30 pm Eastern.