

Summary of SIR Subcommittee Meeting

November 27, 2018

Present: Judy Morgan, Kristin Brown, Carl Kircher, Harold Longbaugh, Lynn Bradley

The SIR Subcommittee met and reviewed draft Implementation Guidance documents for SIRs 290 and 291, prepared by Harold. The draft for SIR 291 will be edited for grammar (Lynn will do this, it will be IG 4-003 Adequate Sample Volume for MS-MSD) and Kristen reviewed it for consistency with V1M2, so that one is essentially complete and approved. The draft for SIR 290 will need to be rewritten, as the subcommittee concluded that the Quality System committee's initial response isn't the best answer or the best practice to put forward in guidance. Two additional SIRs were assigned to other subcommittee members and are expected to be available soon.

Participants received the reviewed drafts of IG from the New Orleans Mentor session (thank you to Dorothy and Nick), but there was not time to review them. Participants were asked to read them over before the December subcommittee meeting, and Scott and Myron have been nagged to complete their reviews of the remaining drafts. Participants also discussed how to handle the detailed references that were tracked down at Judy's request, and determined that all of the non-ISO text should be retained in the Reference section while the ISO text would need to be cited by section number only.

The next SIR Subcommittee meeting will be Thursday, December 20, 2018, at 12:30 pm Eastern. This is rescheduled due to the normal day being a holiday and also a conflict with the LAB Expert Committee meeting.