

Summary of SIR Subcommittee Meeting April 22, 2014

Present: Judy Morgan, Bill Hall, Lynn Bradley.
(Kristin Brown and Carl Kircher both participating in evaluations)

FAQs after Review by Policy Committee

Judy noted that Alfredo (Policy Chair) called her to discuss Policy Committee's review and they believe that Policy Committee can approve the "process" for preparing these items (which do qualify as guidance) without having to review each individual FAQ. And, they will need to be called something other than FAQ. What follows is an excerpt from the draft Policy Committee minutes:

Committee consensus was that the FAQ examples provided are "process descriptions" and thus do qualify as guidance, rather than FAQs (as described in the SOP 1-105 as not being subject to that SOP.) Differing opinions were offered about whether the Policy Committee should review future FAQs originating as SIRs or if review by the relevant Expert Committee would be more appropriate, since they are more likely to address technical matters. There was also general agreement that a clear simple answer would be preferred over the use of "examples" and that, if examples are to be included, there is no question that the FAQs must be considered guidance.

All agreed that the disclaimer from the SOP 1-105 would need to be included and that the FAQs needed some form of document control (version control, perhaps), and finally agreed that review by the appropriate Expert Committee should also occur.

SIR 180

Judy had discussed this SIR with the NELAP Accreditation Council (AC,) as agreed with the Subcommittee earlier. The Council was comfortable with the definitions and expressed appreciation for the background work that Judy did to establish the ISO usage and meaning of the terms "standard" and "test method" and seemed relieved that this issue can finally be settled with one more round of revision.

ACTION ITEM: Lynn to inquire whether TNI has a copy of ISO Guide 2 (2004) which contains all of the definitions and other necessary information about the ISO standards, and if we do not own one, to request that it be purchased.

SIR 200

Judy discussed this SIR with the NELAP AC also, as previously agreed. The discussion clarified that V1 contains a requirement that labs must notify the AB if the technical manager is absent for more than 35 days. This requirement is different than the V2 requirement to notify the AB of replacement of "key personnel" in V2. The response to this SIR will necessarily have two parts – one to be about what is in V1, and the other that if the AB does not have regulation or policy requiring notification, that it can't be required until V1 is revised to include the replacement of personnel notification. What follows is excerpted from the draft AC minutes, for that discussion:

The requirement to notify the AB of a change in "key personnel" (including the QM) resides in V2, which the labs are not supposed to need or be required to purchase. Also, "key personnel" is nowhere defined. Most ABs have addressed the notification requirement in policy or regulation,

but some others have not and do not enforce the requirement because it is not part of V1 and thus they cannot require that it be done.

Additional clarification emerged during the discussion. V1M2 4.1.7.2(e) states that if the Technical Supervisor (or Technical Director, TD) is absent for more than 35 days, the lab must notify its AB, but does not actually address a replacement of the individual. V1M2 4.1.7.1 does state that a QM may also be the TD – a provision not in the ISO language but added as a “note” for the small lab’s benefit. Thus, if the QM is so stated to be equivalent to the TD, then the same notification requirement should apply, but it was only during this conversation that we all realized this notification was only about absence, not replacement.

This is the part that can be clarified through an interpretation. Cathy offered to send Judy the language from Virginia’s regulations, about the notification requirement, since that might be helpful in crafting some part of the SIR response.

The V2M3 7.0 (a-f) requirements to notify the AB need to be added to V1 and Quality Systems Expert Committee has already been asked to include that in its active revision of the standard.

Participants also noted that EPA publication 815-R-05-004 (Manual for the Certification of Laboratories Analyzing Drinking Water), Chapter III section 13.4 requires that the lab to notify “the appropriate Certifying Authority” within 30 days of “major changes in personnel, equipment, or laboratory location.” “Major change in personnel” is therein defined as loss or replacement of the lab supervisor or the unavailability of a specific analyst to perform analyses for a particular parameter which only that analyst conducts.

This SIR response will be revised and re-posted for vote.

SIR 108

Lynn agreed to follow up with Paul Junio on the status of this SIR.