

On-Site Assessment Committee Meeting Minutes
September 2, 2009
1:00 PM – 1:55 PM EST

Attendance

Committee Members

Nilda Cox, Lab – absent (sent replacement)
Don Cassano, other – present
Myron Getman AB - absent
John Gumper, other - absent
Mark Mensik, other – absent
Faust Parker, Lab - present
Denise Rice, EPA - present

Associate Members

Robert Dean
Melanie Myers

Guidance Documents Status

Basic Assessor Training Guidance - The Chair of the Committee received no comments on the guidance since the announcement was placed in the TNI news letter.

Technical Assessor Course Curriculum Guidance – This guidance is ready to be issued. It just needs a disclaimer to comply with upcoming requirements from the Policy Committee.

Laboratory On-site Assessment Guidance – This document is ready to be issued. To comply with upcoming policy, a disclaimer will be placed on the cover page.

Discussion: We were working towards the guidance becoming a standard, so they disclaimer will be a good thing.

NEMC/TNI San Antonio Meeting August 11, 2009:

The CSDB held a meeting at the conference. The Chair updated the Committee on guidance documents and the Policy Committee, ISO copyright questions and the On-site Assessment Checklist. Below are excerpts from the Board meeting minutes covering the topics of guidance and ISO copyright. During the Board meeting it was stated that Quality Systems would develop the checklist for the Quality Systems Module but that the OSA Committee should write a checklist on the On-Site module for use by Assessors in their assessments. The assessor would not need to verify that the lab had purchased a copy of ISO, only that the lab had a copy of ISO.

The Chair opened the topic for discussion: The committee was just as surprised as the Chair. The general consensus was to give this task away. Mr. Cassano wanted to know what the implementation was for the new standard. That would have a bearing on how soon this needed to be done. One suggestion was give it to the technical assistance committee. We could also check to see if Charlie Dyer wants to do the checklists again. The issue is to get it right and you won't know that until assessors start using it. We should use the other checklist as a model; just update the old checklist for the new standard. We could use the crossover document as a basis for the wording changes. The Chair will try to assemble the documents needed to start to compile the checklist. Mr. Parker will obtain the current Quality System checklist so we can determine what it is we need to do. We also need to obtain the new checklist from Quality Systems to avoid duplication of effort. We will begin to put the checklist together in November.

Excerpts from the TNI Board Meeting Minutes:

The second session on Tuesday afternoon included a presentation from the copyright attorney addressing issues that accreditation bodies have with using the new standards in a regulatory context. Ken reported that the attorney had indicated that:

- Labs may be provided with a checklist using the ISO copyrighted language as long as the lab has purchased the TNI standards. Just having a copy of the ISO 17025 or 17011 is not sufficient.
- Copyrighted language may be embedded in state regulations. State ABs that incorporate the TNI standards by reference may have to provide a copy for the public in the agency library or other public place.
- There is some concern that there may be ISO language in a “non-ISO” version of the standards on the web. Jerry will check on this.

The other discussion topic for the CSDB was proposed policy on guidance documents. The CSDB is concerned about the use of the term “guidance document”. They are concerned that guidance documents can become de facto standards. Another name may be needed.

Alfredo Sotomayor, Chair of the Policy committee, stated that if a committee chair feels that guidance is needed, there will be a process to approve the development of guidance.

Discussion of Editorial Changes to Technical Assessor Course Curriculum Guidance:

The Chair entertained editorial changes to the guidance. In addition, the wording for the disclaimer was discussed. The disclaimer needs to state that this is guidance designed to help meet the requirements of the standard. It is not a standard, SOP nor policy and does not supersede any existing standard, SOP or policy which is implemented. Mr. Parker suggested that the disclaimer be the same for all guidance. Ms. Rice will check with Mr. Sotomayor about standard language.

Next Scheduled Meeting: October 14, 2009, 1PM EST.