

Summary of Policy Committee Meeting  
May 20, 2010

1. Roll Call

Alfredo Sotomayor, Committee Chair, called the meeting to order at 1:00 PM CDT on May 20, 2010. Attendance is recorded in Attachment 1.

Alfredo reported that Bob Wyeth and John Applewhite have resigned from the Policy Committee. Alfredo will ask Betsy Kent for a replacement for John since he represented Technical Assistance. Silky Labie can represent CSDB in Bob's place temporarily.

There were no comments on the previous minutes and Alfredo will forward for posting on the TNI website.

2. Program Updates

Jerry Parr reported that the TNI Board did not meet this past week, so there was no action on pending SOPs or the bylaws revisions.

Silky Labie reported that a TIA for Quality systems was underway.

John Moorman reported that NEFAP is currently voting on the AB evaluation SOP 10-105. NEFAP meets Monday and he will send the SOP if approved.

Gary Dechant reported that the PT board is reviewing the PTPA evaluation SOP in light of upcoming evaluations. He also reported that the PT expert committee has requested LASC to develop guidance on how to implement the new TIAs. The committee commented that an SIR could be requested to document the action needed.

Steve Stubbs reported for the NELAP Board that the onsite and lab observation has been completed for the MN application. AB fee assessments will begin in June. The NELAP board has been asked to approve new DW FoPTs, but has some concerns and has asked for clarification from the PT Board. They are also working on an action plan in response to the TNI Board memo.

Jerry Parr reported that the TNI board has submitted a grant application to EPA and will hold a strategic planning meeting at the end of June.

3. NEFAP SOP 10-104

Questions about this SOP that were submitted to Marlene Moore have not been answered yet, so no vote can be taken. The TNI Board meets again on June 9, so it may be possible to get it on their agenda by then.

Jerry also shared with the committee some guidance that he had received from TNI's legal counsel on appeals. The attorney emphasized that simplification was the key for parties to embrace any alternate dispute resolution process. He also remarked on the differences between arbitration and mediation, although both terms tended to be used interchangeably in the TNI SOPs.

The Policy Committee determined that the comments did not have any impact on the NEFAP SOP as currently drafted.

#### 4. SOP 1-105: Process for Creating Guidance

At the last meeting, Alfredo asked Gary, Silky, and JoAnn to develop a list of scenarios and options for guidance development and approval that can be considered and discussed at the next meeting. Gary and Silky exchanged some ideas via email which are pasted below. The biggest concern if level of review of the proposed guidance, if that can be resolved, it was agreed that the committee can move forward.

Gary's thoughts:

I generally have no issue with SOP 1-105 except with section 10 on review and approval. I do believe section 9.2.2 is redundant with what is being done in section 10.0 but that's just an observation.

I believe section 10 should state:

- 1) The guidance will be reviewed by the Policy Committee or by a workgroup appointed by the Policy Committee.
- 2) The review will be commensurate with the purpose and complexity of the guidance.
- 3) The review will determine if the guidance meets the original purpose as specified in the proposal and if it meets the definition of guidance as specified in this SOP.
- 4) The Board may request interpretations or comments from other appropriate TNI organizations on guidance that specifically applies to sections in the Standard or to other TNI functions.
- 5) The guidance will be approved by the Policy Committee based on the results of the review.

Note that I dropped the allowance of the publication of "Drafts". I personally don't like issuing drafts until at least a preliminary review is done.

I'm not sure if this was my task so if I need to do something else please let me know.

Silky's response:

I agree with Gary, but have a couple of comments:

1. I am not clear what "Board" Gary refers to in point 4.
2. It seems evident that any guidance issued under the TNI name needs review. As such, if it is a technical document (i.e. one that helps to implement or comply), it should be reviewed by a panel of experts in the subject to ensure that it is technically sound (not that all will agree with the concept). If it is a guidance and helps to implement or comply with the standard, then it should be reviewed by a panel from the accrediting authorities and the related expert committee to ensure consistency with the standard, and that it reflects the intent of the specified standard. While all accrediting authorities may not agree with approach (although it would be desirable, the standing committee members must agree that it meets the intent of the standard.
3. Finally, the Policy Committee or workgroup appointed by the committee should review for only compliance with the guidance policy. The policy committee should not review for technical content unless something obvious appears to have been overlooked by the technical reviewers.
4. This process would ensure that the document was peer reviewed before being issued under the TNI name.
5. Also, there may need to be a process to recall a document in cases where it may no longer be relevant or if found to be technically incorrect.

Alfredo had also sent a link to another guidance website:

<http://isotc.iso.org/livelink/livelink/fetch/2000/2122/-8835176/8835194/3541460/customview.html?func=ll&objId=3541460&objAction=browse&sort=name>

Additional discussion on this issue:

- There is a difference between posting something that is developed by TNI and something that is developed by someone else. If produced by TNI, we need to be assured that it is sound. We also need to be sure that it does not get used or enforced as a requirement.
- Documents not developed by us could be segregated on the website with a disclaimer. "These may be useful documents but TNI has not reviewed content".

- Alfredo proposed a *technical* review and a *conformance* review. See Attachment 1.
- There was a suggestion that the Policy Committee should only be involved in conformance reviews. Other committees should do technical reviews.
- How would we address document revisions? Would they have to go through the entire review process again? Might depend on the extent of revisions.
- Does approval of guidance expire?
- All guidance should be reviewed when the standards are revised.
- Sunset review of guidance should be an IT responsibility.

Alfredo's proposed review criteria were presented for discussion. There was general concurrence with the types of review: technical and conformance. Levels of review were discussed and Alfredo asked everyone to consider and give him feedback. He will insert language related to levels of review into draft guidance SOP and send out for discussion. This SOP may be approved by email.

#### 6. Next steps

Alfredo will make revisions to the guidance SOP and send out for review.  
 John Moorman will follow up with Marlene More on Policy Committee questions about the NEFAP SOP 10-104 and present for possible vote.  
 Review and possible vote on NEFAP 10-105.

#### 7. Next meeting

The next meeting will be June 1, 2010, at 1:00 pm CDT.

Regular meetings will be the first Tuesday and third Thursday of each month.

**Table 1  
Attendance**

| <b>Name</b>              | <b>Representing</b>         | <b>Present</b> |
|--------------------------|-----------------------------|----------------|
| <b>Alfredo Sotomayor</b> | <b>TNI Board</b>            | <b>X</b>       |
| <b>Bob Wyeth</b>         | <b>At Large, CSD Board</b>  | <b>Absent</b>  |
| <b>Gary Dechant</b>      | <b>PT</b>                   | <b>X</b>       |
| <b>John Applewhite</b>   | <b>Technical Assistance</b> | <b>Absent</b>  |
| <b>Jo Ann Boyd</b>       | <b>LASC</b>                 | <b>Absent</b>  |
| <b>Silky Labie</b>       | <b>CSD</b>                  | <b>X</b>       |
| <b>Jerry Parr</b>        | <b>Ex Officio</b>           | <b>X</b>       |
| <b>Steve Stubbs</b>      | <b>NELAP Board</b>          | <b>X</b>       |

|                          |                  |               |
|--------------------------|------------------|---------------|
| <b>Susan Wyatt</b>       | <b>Advocacy</b>  | <b>Absent</b> |
| <b>Mei Beth Shepherd</b> | <b>Associate</b> | <b>X</b>      |
| <b>John Moorman</b>      | <b>NEFAP</b>     | <b>X</b>      |
| <b>Carol Batterton</b>   | <b>TNI Staff</b> | <b>X</b>      |
|                          |                  |               |

## **Attachment 1**

### **Review Point**

Proposal for creating guidance  
Final version of guidance  
When guidance is revised

### **Types of Review**

#### **Technical (T)**

Content accuracy and soundness  
Procedural details  
Utility

#### **Conformance with Guidance Restrictions (C)**

Does not create, modify, replace, or repeal a requirement  
Does not establish policy  
Does not create an SOP  
Does not create expectations of universal applicability

### **Level of Review**

|                        | <b>Minimal (I)</b> | <b>Moderate (II)</b> | <b>Maximum (III)</b> |
|------------------------|--------------------|----------------------|----------------------|
| <b>Technical (T)</b>   |                    |                      |                      |
| <b>Conformance (C)</b> |                    |                      |                      |

Examples to Match:

Implementation of multiple provisions of Standard  
Implementation of limited sections of Standard  
Best practices for assessors  
Use of checklists  
Free documents

Documents for sale

Interpretation of an entire analytical method

Interpretation of limited sections of analytical method

How to obtain accreditation for a laboratory in a state that is not a TNI AB

What PTs can tell about laboratory performance

The ABCs of document control

Concordance of ISO 17025 and TNI Standards

The SDWA Certification Manual and TNI Standards

How to prevent fraud in your laboratory

Tips for promoting consistency of assessments

QM template