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TNI Corrective Action Committee Report

June, 2012

Presented at NEMC, August 2012

TNI Corrective Action

- *Corrective actions include a determination of the nature and extent of the problem, the root cause of the problem, and alleviation of the problem as soon as practical, including implementing appropriate corrective actions and actions to prevent recurrence, documenting all corrective actions, and tracking such actions to closure. Review of the effectiveness of implementation of the corrective action is performed by the QA Director or QA Manager, as appropriate, and reported to the BOD.*

Ad Hoc Task Force

- Chartered by the BOD
- Review development of the 2009 Standard with the intent to improve this process for the current standards being revised.
- Critical look at the process as a whole
- Document the issues
- Recommend process improvements

Task Force Members

Name	TNI Organization
Sharon Mertens	BOD, LAB Expert Committee
Jerry Parr	Executive Director
Susan Wyatt	NELAP AC, TNI BOD
Kirstin Daigle	LASEC, PT Committee
Ken Jackson	CSD EC, TNI Staff
Jack Farrell	TNI BOD
Patsy Root	TNI BOD
Bob Wyeth	CSD EC

Approach

- Review key findings
- Discussion – root cause analysis
  - Conferred with outside sources if necessary
- Reviewed pertinent SOPs
- Reviewed general nature of concerns and complaints about the process

Key Findings

The consensus process was used well.

The Expert Committees followed SOP 2-100 diligently. More than 1000 comments were provided in 2006 and 2007 and all comments were considered carefully and a response to comments document was prepared that summarized all decisions.

Some members felt their comments were not heard; the …process used by the expert committees could be improved.

Current process:

- TNI membership votes on a Voting Draft Standard.
- Expert committee reviews comments, and if ruled persuasive, changes the standard.
- The commenter does not get a chance to vote again, or send in a rebuttal comment.
- Members who comment are not notified of the outcome of their comment other than by reviewing the Response to Comments document.

Three SOPs govern standards development, review and approval process and these SOPs were not prepared to work in concert.

- Standards Development, LASEC suitability review, NELAP adoption & implementation.

- The committee will recommend changes to these.

Significant concerns from NELAP representatives weren't given appropriate attention

- "Show stoppers" weren't identified prior to finalization of the standards.
- Issues weren't escalated to the appropriate level until too late in the process.

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- **The NELAP AC supports the consensus process, even if they disagreed with the language in the standard.**

- **2009 Standard was a significant change. Over 1,000 comments were submitted**

- **Many active members were preoccupied with the combination of INELA & NELAC while the new standard were being developed**

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Committees were not given clear expectations of what should or should not be in the standard.

When INELA decided on a new approach to the standard, the committees were directed to use ISO 17011 and 17025, but detailed guidance about both the organization and content of the standard were not provided.

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ISO language was omitted by the Quality Systems committee in parts of the standard because they felt it was not appropriate. Since the language was never put up for vote, and no one compared the TNI standard to 17025, this was not caught until 2010.

Each expert committee operated independently which resulted in a lack of coordination and uniformity between the standards.

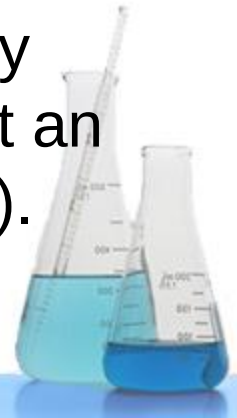
This was not a major factor but we recommend that the CSDB EC take a look at this to determine whether there is anything they can do to improve communication and coordination between the expert committees.

Recommendations

- Modify the process from the time the expert committee receives comments on the VDS to when the standard becomes final
- Examine the process used by the NELAP EC and LASC to review the standard.
- Develop better mechanisms to track issues.
- Review and modify SOPs

The process from the time the expert committee receives comments on the VDS to when the standard becomes final should be modified.

- Consider adding an additional step to allow those who made comments to review how the committee used those comments to make changes;
- Consider an additional vote on the VDS by the membership after changes (based on comments) are made.
- Consider forming an editorial board to review any standards for policy, content, consistency, etc. at an organizational level (similar to Policy Committee).



Examine the process used by the NELAP EC and LASC to review the standard.

- Consider adding an earlier review to identify “show stopper” issues. This could occur before the WDS goes to VDS.

- Explore better mechanisms to solicit input from the ABs (as customers) before and during standards development to ensure that their needs are understood by the expert committees. Be sure to include input from non-NELAP ABs, especially those that will become NELAP ABs in the near future.

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Develop better mechanisms to track issues that are deferred to future rounds of standards development to be sure that all worthy recommendations are addressed.

Review SOPs 2-101, 3-103 and 3-106 for completeness and consistency. Update them to reflect any process changes that result from our recommendations.

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Development and Implementation of TNI Standards for NELAP

Pre-Draft Work

Committee solicits and groups comments and any parking lot items – there would have to be a public notification, website and/or email blast

← Input requested from LASEC and AC

Stakeholder comments addressed

Working Draft Standard written

Committee addresses and adds or edits according to parking lot items and comments received

WDS presented at **semi-annual meeting** for stakeholder comments

Stakeholder comments addressed

WDS modified as a result of stakeholder comments

Modified WDS presented at **semi-annual meeting** for stakeholder comments

Stakeholder comments addressed

VOTE -- Voting Draft Standard – Public Vote

Committee takes in any comments from the vote and addresses

Comments addressed publicly at TNI **semi-annual meeting**

Stakeholder comments addressed

Interim Standard written

Comments and edits from the Voting Draft Standard vote are incorporated into the Interim Standard

→ Standard presented to LASEC and AC for input

↓

Interim Standard revised based on feedback, if needed

← **Interim Standard sent to Editorial Board**

Review and approval by editorial board

VOTE -- Interim Voting Standard -- last public vote

Committee takes in any comments from the vote and addresses

Stakeholder comments addressed

Final Standard --

Revisions made based on comments and Final Standard and Response to Comments document published.

Final review for suitability by LASEC

Adoption by NELAP AC

Maybe it's easier to see in the SOP (SOP 2-100)

5.2 Working Draft Standard

5.2.1 Before starting preparation of the Working Draft Standard (WDS), Expert Committees publish a notice of Intent to Prepare or Revise a Standard, which invites stakeholders to provide input. Those stakeholder groups who may subsequently adopt the standard (e.g., the NELAP Accreditation Council; and the Laboratory Accreditation System Executive Committee) will also be asked for their input.

5.4.1 If the Voting Draft Standard passes, it becomes the Interim Standard. If any module fails, it is returned to the Expert Committee for processing during the next revision cycle. All individuals who provided votes or who submitted public review comments that were ruled non-persuasive shall be so notified and shall be informed of their right to appeal. Any appeals registered with TNI must be considered in accordance with Section 6 of this Policy.

5.4.2 The Interim standard shall be presented for further input to those stakeholder groups who may subsequently adopt the standard (e.g., the NELAP Accreditation Council; and the Laboratory Accreditation System Executive Committee). As a result of this input the Expert Committees may further modify the Interim Standard.

5.4.3 The Interim Standard shall be submitted to the Standards Editorial Board for review and approval. The Editorial Board may recommend further changes, which will be incorporated prior to the Board's approval.

5.4.4 If the Interim standard has been modified, the Committee Members vote to accept the modifications . A two-thirds favorable majority vote of the Committee Members is required for passage.

5.4.5 The Interim Standard undergoes the voting process described in Section 5.3.1 through 5.3.6 above.

Next steps

- Present today;
- Present the report to BOD, CSDB, NELAP AC, LASEC
- Review, respond, react
- Improve the process!

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Questions?