

TNI Corrective Action Committee Report to the TNI Board of Directors

Approved by the TNI Board of Directors on September 12, 2012

Introduction

On August 8, the Board decided to undertake a formal corrective action process to determine what occurred in the development of the 2009 Standard, with the intent to suggest actions to improve this process for the current Standards being revised. The draft Quality Management plan states:

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.

Subsequently, an ad hoc task force was formed, led by Sharon Mertens (then Vice Chair of the TNI Board, with representatives from the NELAP AC, PT Committee, CSD-EC, LASEC, TNI Board and TNI staff.

This report presents the methodology, findings or discussion items and recommendations of this committee. The appendix to this report includes suggested modifications to one of the Standards development SOPs, a flow chart that illustrates the proposed process changes we are recommending, and more details about the key findings that were discussed.

We believe that the next step, following Board approval, would be to hand this over to the Consensus Standards Development Executive Committee for implementation and to ask the LASEC and NELAP AC to review their respective processes and modify their procedures accordingly.

Methodology

The job of the task force was not to do a detailed review of each of the comments and/or concerns that came out of the 2009 Standard approval process, but rather to take a critical look at the process as a whole. Our goal was simple – to document the issues and recommend process improvements.

The committee was formed with members representing key stakeholders who were part of the development of the 2009 TNI Standard. The goal was to have a recommendation for the Board by early summer. With this in mind, it was felt that a smaller group could cover the necessary topics more quickly. The group met once or twice a month from early March to the present.

Table 1 – 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

The group approached the task by identifying a list of key findings from the 2009 Standard development process. The detailed list is included as Attachment 1 to this report. Observations regarding the root cause of those findings and problem resolution, where there was any, came primarily from within the group itself although several in the group consulted outside resources and shared their findings with everyone.

Each of these findings was discussed in the task force meetings. Summaries of those discussions are also included in Attachment 1.

Overall, we agreed that the documented process was generally followed. Since TNI was a brand new organization, adopting a new Standard with a new process, we have to give a lot of credit to our systems, staff and volunteers for everything that did go right. Our focus could be on corrective action to improve the process itself, rather than its implementation. We quickly focused on four main areas where there are gaps or weaknesses in the system. These are described in the recommendations below.

The group reviewed all of the pertinent TNI SOPs. We also discussed the processes used by ISO and ASTM and drew upon ideas from those organizations that we thought could be helpful.

Recommendations

During the course of discussion, it became clear that there were just a few main areas where there were gaps or problems. The task force thought that the following need to be addressed.

- 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 a Standards Review Council 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.
- Develop better mechanisms to track issues that are deferred to future rounds of standards development to be sure that all worthy recommendations are addressed.
 - Sometimes recommendations have merits but cannot be addressed in the current VDS. These are tabled by the committee, presumably to be addressed later. We should have a more formal way of tracking these.
- 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.
- Consider establishing a standardized review cycle for updates to the standard as ISO does. The suggestion would be every 5 years. Rewriting regulations more frequently is excessively burdensome on state ABs. We realize that it may take some time to establish such a cycle but this would be a good goal for the future.

A flow chart is included as Attachment 2 which illustrates the change in the process that we would recommend. We also reviewed section 5 of SOP 2-100 and are recommending changes in this document. These recommended changes are attached as Attachment 3. It is our understanding that the LASEC are reviewing their process SOP and will take these recommendations into consideration as a part of that.

The bottom line is that all of the committees, their members and others who were involved in the process, tried to do a good job in following the procedures that were established and putting out the 2009 Standard. However, the Standard was finalized and approved using a process that was new to the organization. There may have been mistakes or inconsistencies and certainly things that should be done better in the future.

While adding additional review as recommended would add time to the overall process, the goal to recognize inconsistencies and problems that could stall implementation before the Standard is finalized could actually make the overall process (i.e. time to implementation) easier and shorter.

Attachment 1 Key Findings for 2009 TNI Standard

1. 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.

The task force agreed with this finding.

2. Some commenters felt their comments were not heard; the standards development process used by the expert committees could be improved.

The current process has the TNI membership vote on a Voting Draft Standard. The expert committee then reviews the comment, and if ruled persuasive, changes the Standard. However, the commenter does not get a chance to vote again, or send in a rebuttal comment. Commenters are not notified of the outcome of their comment other than by reviewing the Response to Comments document. This practice is what most other consensus standards organization use.

The task force made the following observations –

- *Some comments were tabled until the next version of the Standard (the expert committee can do this)*
- *Some comments were given in public forum but not submitted on the form. Others didn't use the form.*
- *This was our first time through the process as developed. People may have been frustrated because they didn't understand how it was supposed to work.*
- *Perhaps there needs to be a "sanity check" by the CSDB or an editorial board such as that used by ASTM and other standards development group.*
- ***There is no obvious feedback mechanism to let members who submitted comments know why their comments were rejected (or, for that matter, accepted). It might be helpful to add another step in the process to allow the member ship to review changes that were made to the Standard after the committees consider comments.***

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

The standards development process, started before the formation of TNI, assumed that once an expert committee had approved a standard, the work was done. With the formation of TNI in 2006, two additional steps were added to the process, a review for suitability to be performed by the Laboratory Accreditation System Executive Committee, and a vote to adopt into the NELAP program, performed by the NELAP Accreditation Council. Separate SOPs were developed for these other two steps. The current process does not allow for serious concerns about implementing the Standard to be considered until very late in the process.

The task force agreed that there are inconsistencies between these SOPs and at least 2 of them lack necessary detail with regards to work flow and timing. These SOPs should also be modified to reflect the recommendations of this group (if adopted). Therefore, the SOP revision should probably be the last step in this process.

4. Significant concerns from NELAP representatives were not given appropriate attention.

Several commenters submitted negative votes on particular issues that were ruled non-persuasive. The commenters generally did not indicate the serious nature of their concern, and given the

Attachment 1 cont.
Key Findings for 2009 TNI Standard

feedback issues discussed in number 2 above, these issues were not escalated to the appropriate level until too late in the process.

Task force comments: At the time, there didn't seem to be any comments that were "show stoppers" from any ABs. Perhaps the LASEC review should be moved up in the process. The task force also spent time talking about the timing on the AC review. As the "customer", they may need to have a different kind of review, input, in addition to the regular membership review in standards development process. Perhaps some of these significant concerns were overlooked because of the sheer size of the job of reviewing the initial Standard. It should be easier in the future, when there are only a few changes to any particular Standard. Nevertheless, critical reviewers, such as ABs, should be reminded of the importance of their timely and thorough review. We should recognize that people, being people, can make mistakes. We need a system that is consistent, but we should build in contingencies, where we can, to allow us to address oversights or mistakes.

5. The NELAP Accreditation Council supports the consensus process, even if they disagreed with the language in the Standard.

Many concerns with the 2009 Standard were voiced by the Council, but every member voted to implement the Standard despite their concerns. This has resulted in the Standard not being implemented by some ABs.

The task force discussed the fact that this was the first time through the standards adoption process and most of the ABs were feeling the pressure to adopt a Standard, even with imperfections. This has been a learning process for all. The ABs are less likely to ignore potential problems and try to take the time needed to work through them.

6. The 2009 Standard was a significant change from the 2003 NELAC Standard. This resulted in over a thousand comments.

The committees were overloaded with comments and under pressure to complete their step of the process in a short time frame, and thus some comments may not have received the attention they deserved.

The task force agreed that the sheer volume of work on this first effort could have been overwhelming. As we were looking at the entire Standard, this could be expected. This situation shouldn't happen again.

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

In 2005, when INELA decided on a new approach to the Standard, the committees were given responsibility for specific modules and volumes, and were directed to use ISO 17011 and 17025, but detailed guidance about both the organization and content of the Standard were not provided.

The task force agreed that the level of understanding of what was needed varied depending upon committee members and input from outside contributors. This can easily happen with volunteer committees. An editorial board or committee could provide overall guidance or be available to answer questions.

Attachment 1 cont.
Key Findings for 2009 TNI Standard

8. Many TNI Members were preoccupied with the combination of INELA and NELAC while the new Standard was being developed.

Most of the current leadership of TNI along with many other individuals were highly focused on the efforts that led to the formation of TNI in November 2006, and subsequently, on getting TNI up and running. This focus meant that the review of the Voting Draft Standard did not get the attention it deserved.

The task force had mixed feelings on this finding. In spite of all of the organizational changes that were going on at the time, there were a lot of comments and a lot of debate. Many things that could also have been "show stoppers" were fixed before they became problems. A few issues did slip through but there could have been a lot more.

9. 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.

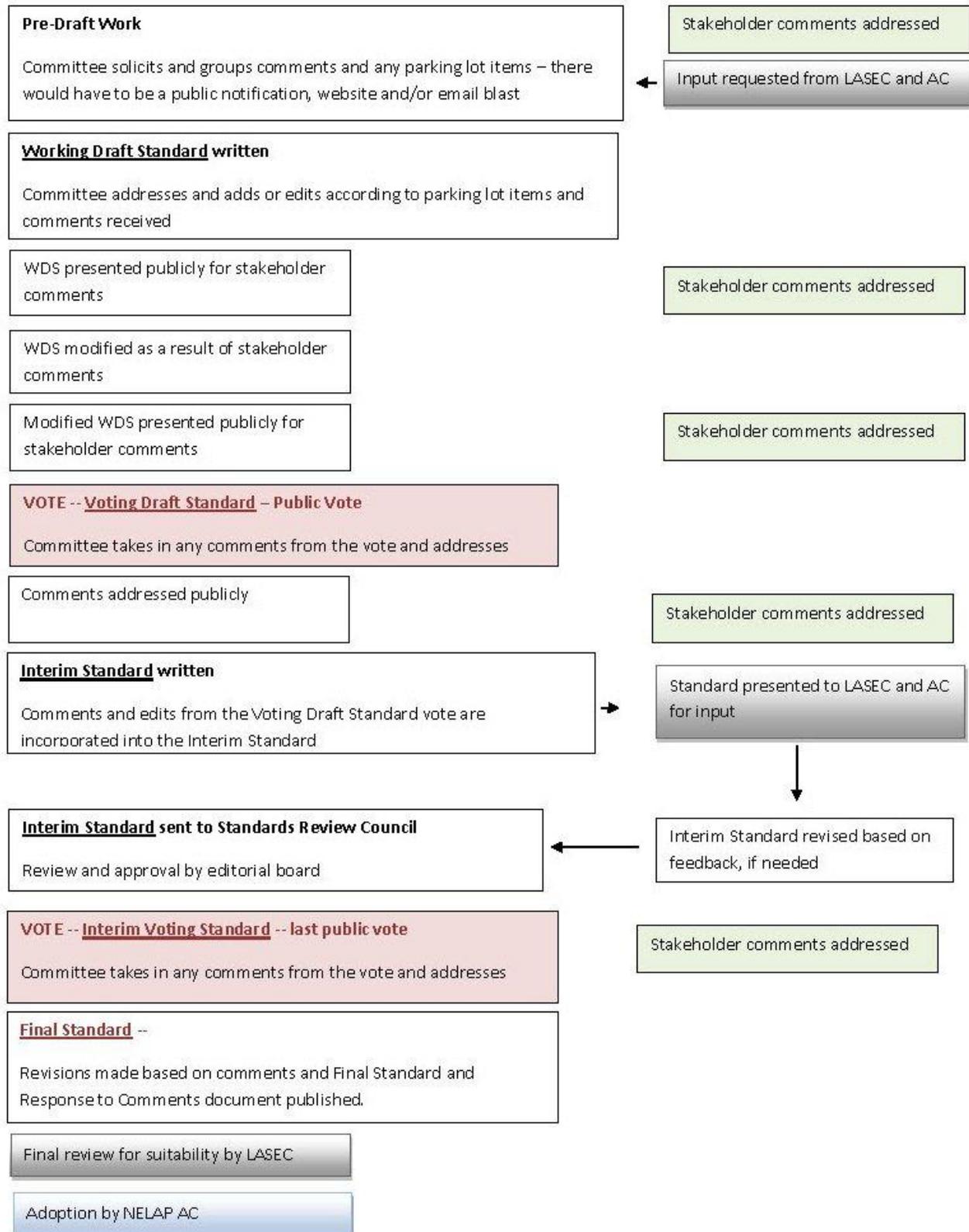
The task force discussed the value of an editorial review to catch issues such as this. We discussed the ASTM and ISO process where there is a high level editorial committee that takes a "big picture" look at the Standards before they are put out for vote. This is different than the Uniformity of Standards review that we do and more like the review our policy committee does for SOPs and internal policies.

10. 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.

Attachment 2 Development and Implementation of TNI Standards for NELAP

Development and Implementation of TNI Standards for NELAP



Attachment 3

TNI Corrective Action Committee Proposed Modifications to SOP-2-100 (Procedures Governing Standards Development)

June 2012

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.
- 5.2.2 During the approximately six-month period preceding a TNI semi-annual meeting, the Expert Committees develop modules of a working draft standard. The Committee Chair may delegate the standard-writing process to the Committee Members or to any task group formed from the Committee Members, Affiliates and Associate Committee Members. All Committee Members, Affiliates and Associate Committee Members are afforded the opportunity to contribute to the standard-development process. All stakeholder input is gathered and considered in the standards-writing process. If the WDS will be an update of an existing TNI standard, any stakeholder input provided since the adoption of the original standard will also be considered.
- 5.2.3 An official vote of the Committee Members, with at least two-thirds of the members in concurrence, is required for release of the working draft standard by an Expert Committee for publication. The working draft standard is published at least thirty (30) days prior to the TNI semi-annual meeting at which it will be discussed.
- 5.2.4 The working draft standard is discussed publicly at the TNI semi-annual meeting. At this time, any TNI member or any member of the public may propose changes from the floor for consideration by an Expert Committee, and may also submit to the committee written comments within fifteen (15) days following the meeting.
- 5.2.5 Within ninety (90) days following the close of the above comment period after the TNI semi-annual meeting, an Expert Committee may modify the working draft standard based on comments received during the public debate and those received within the fifteen (15) day timeframe following the TNI semi-annual meeting. The Committee Members vote to accept the Modified Working Draft Standard (MWDS). A two-thirds favorable majority vote of the Committee Members is required for passage.
- 5.2.6 The MWDS is published at least thirty (30) days prior to the next TNI semi-annual meeting at which it will be discussed.
- 5.2.7 The MWDS is discussed publicly at the TNI semi-annual meeting. At this time, any TNI member or any member of the public may propose changes from the floor for consideration by an Expert Committee, and may also submit to the committee written comments within fifteen (15) days following the meeting.

5.3 Voting Draft Standard

- 5.3.1 Within ninety (90) days following the close of the above comment period after the TNI semi-annual meeting, an Expert Committee may again modify the working draft standard/MWDS from consideration of the comments received during the public debate and those received within the fifteen (15) day timeframe following the TNI semi-annual meeting. The Committee Members vote to accept the new modified working draft standard/MWDS. A two-thirds favorable majority vote of

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Attachment 3 cont.
TNI Corrective Action Committee Proposed Modifications to
SOP-2-100 (Procedures Governing Standards Development)

- the Committee Members is required for passage. The ~~working draft standard~~ MWDS then becomes the TNI Voting Draft Standard (VDS).
- 5.3.2 All Committee Members, Affiliates and Associate Committee Members may vote on their committee's modules of the Voting Draft Standard. Each Committee Member, Affiliate and Associate Committee Member has one vote. All voting is conducted by electronic ballot.
- 5.3.3 At least fifteen (15) days prior to voting, the Voting Draft Standard is published, together with an electronic ballot form. TNI shall indicate conspicuously on the ballot that negative votes should be accompanied by written comments related to the proposal and that negative votes unaccompanied by such written comments will be recorded as "negative without comments" without further notice to the voter. Such ballots, however, will not be counted as either negative or positive. TNI is not required to solicit any comments from the negative voter.
- 5.3.4 At least fifteen (15) days after publication of the Voting Draft Standard, the voting period for ballots shall begin. The voting period shall last for thirty (30) days. Early voting will be permitted; i.e., all votes cast from the date of publication of the electronic ballot form up to forty-five (45) days after the date of its publication will be accepted. Each Committee Member, Affiliate and Associate Committee Member will vote on one of the following positions:
- Affirmative
 - Affirmative with comment
 - Negative with comment
 - Abstain
- 5.3.5 A negative vote may be withdrawn at any time by written electronic submission to TNI. The voter shall instruct TNI if the withdrawn negative is to be changed to an affirmative vote or to an abstention.
- 5.3.6 In order for the Voting Draft Standard to pass, an affirmative vote of at least two-thirds of the Committee Members is required, and all written comments accompanying votes cast by Committee Members, Affiliates and Associate Committee Members must be considered and brought to resolution as described below (Sections 5.3.7, 5.3.8 and 5.3.9). Ballot items returned as negative without comment shall be recorded as negative without comment. Ballot items returned unmarked shall be considered as unreturned ballots.
- 5.3.7 All written comments accompanying negative or affirmative votes cast by Committee Members, Affiliates and Associate Committee Members shall be recorded and considered publicly during the next TNI semi-annual meeting. Each Expert Committee will meet in separate session to consider those comments received on its modules of the standard. These meetings will be open to the public. Following its discussion, each written comment shall be ruled persuasive or non-persuasive by a simple two-thirds vote of the Committee Members present. No written comment shall be dismissed because it does not provide alternative language or a specific remedy to the negative vote. The committee may, subject to the restrictions in 5.3.8, prioritize the comments and may place any comments on hold until the next revision cycle of the standard, if the comments are too numerous to be dealt with in the time-frame available until the TNI Standard is published. Any comment placed on hold must be addressed during the next revision cycle of the standard and must be recorded and considered as a comment at that time.
- 5.3.8 An Expert Committee may prioritize the comments received and may place a comment on hold until the next revision cycle of the standard if all of the following conditions are met:
- The comment would introduce a concept that had not been subject to public review by being included in a related proposal as published in the Voting Draft Standard.

Attachment 3 cont.
TNI Corrective Action Committee Proposed Modifications to
SOP-2-100 (Procedures Governing Standards Development)

- The comment would change the text proposed by the Expert Committee to the point that the Expert Committee would have to restudy the text of the Voting Draft Standard
- The comment would propose something that could not be handled properly within the time frame for processing the changes.

In making the determination whether to place a comment on hold, the Expert Committee may consider relevant factors, including but not limited to: the extent to which the comment proposes a change that is new and/or substantial; the complexity of the issues raised; and whether sufficient debate and public review have taken place. The negative commenter must be informed, in writing, of the reasons the comment has been placed on hold.

- 5.3.9 A persuasive negative vote or an objection received from a member of the public will require the Expert Committee to consider whether modification of the Voting Draft Standard is appropriate. The committee may modify the standard, if such modification will lead to removal of the cause for the negative vote. The modified standard must then be made available through publication on the TNI website, together with a Response to Comments document summarizing all persuasive and non-persuasive votes and their resolution, and any objections received from the public and their resolution, for all Committee Members, Affiliates, Associate Committee Members and the public to review. Within fifteen (15) days of this publication, any Committee Member may change his or her vote, providing written electronic notice to TNI. The vote is then re-tallied and, in order to pass, requires an affirmative vote of at least two-thirds of the combined affirmative and negative votes cast by Committee Members. Within fifteen (15) days the tally from the vote on the Voting Draft Standard is published as: number of affirmative votes; number of persuasive negative votes; number of non-persuasive negative votes; number of negative votes without comment; and number of abstentions.

5.4 Interim Standard

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.

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5.4.3 The Interim Standard shall be submitted to the ~~Standards Editorial Board~~ Standards Review Council 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.

5.45 TNI Standard

Attachment 3 cont.
TNI Corrective Action Committee Proposed Modifications to
SOP-2-100 (Procedures Governing Standards Development)

- | 5.4.1 If the ~~Voting Draft~~ Interim Standard passes, it becomes the TNI 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 will be so notified and will 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 TNI Standard is made available to all interested parties, including standards-adoption organizations.

- | 5.4.3 If any appeal is upheld by the appeals panel, the affected module or section of the TNI Standard is withdrawn by the Expert Committee that developed that module or section for processing during the next revision cycle.