

This report is submitted in compliance with Section 5.5.6 of SOP 2-100_1208_2draft.

While the Accreditation Body Committee has failed to devise a TIA that responds to the LASC identified issue, the committee feels that the existing standards provide its own solution to the identified problem.

The Committee directs attention to V2M2 section 4.3, specifically to 4.3.1 and 4.3.4. The Committee failed to positively affirm the TIA since the new language would add non-ISO17011 language to the standard.

The report is organized as follows:

All public comments
Tally of the ballot
Final version of the Tentative Interim Amendment

All public comments

During the Accreditation Body Committee Meeting of December 16, 2008:

Current language implies that more than 1 person is needed on staff because accreditations and assessments are to be done by independent parties. There was discussion regarding which states might have a problem with this. The consensus was that TIAs (Tentative Interim Amendments) were needed to address sections 4.3.5 and 5.7.3b. The wording of the needed changes and timeline were discussed.

LASC Table

V2:M1 – 4.3.5, 5.7.3b, 6.3.2

Seems to be for ABs that have more than one person on the staff but this is not always the case.

- Potential implementation issue because in some states the assessor and governing AB is the same person. There is no out. With labs there is language that allows for QA Officers to be part of lab management in smaller labs.
- Do smaller states need another person? ½ time person? Can you have one person and define different roles that this person has? Similar to QA Officer for small labs.
- Look at 4.3.1. Make sure that quality system accounts for this. Define safeguards for objectivity. Define how something like 4.3.5 is handled in a one person state accreditation program.

Response: 4.3.5 and 5.7.3b:

The AB committee will add a TIA for 4.3.5 and 5.7.3b. (IT (1-6-08):This TIA has been submitted.)

The ABC proposes to add the following to the end of each sentence

“unless the responsible government authority allows otherwise.”

Comments that have been received on the TIAs to date:

- The TIAs would allow the assessor to be both judge and jury
- The TIAs are counter to ISO 17011 and would affect the ability to cite compliance to the international standard
- Some ABs may need to drop NELAP if the TIAs aren't adopted
- Let the states with a problem figure it out how to address their specific situation
- Cannot change the ISO language directly and need to structure the TIAs differently (this was addressed by placing the proposed additional language into notes)
- Labs are expected to change to implement the new TNI standards, why not ABs as well
- Let standard be adopted as is and let states identify what they can and can't do

The wording of the TIAs limits the scope of the TIAs to the “responsible government authority,” so the onus is on the state government, rather than incorporated entities like A2LA.

The attendees at the Miami Meeting discussed the following oral comments to the TIAs:

- Concern was expressed that the wording allows for everyone to do it with one person and maybe it should be limited to those ABs that cannot do it.
- It was asked whether all the NELAP states were consulted as to whether they can comply. The comments came from LASC, not NELAP. It would help to know if any of the states with a problem can find a way to comply. There is concern about the implied non-compliance with 17011 introduced by the TIAs.
- How can TNI tell a sovereign state government what to do? NELAC has always been a compromise organization for the states that do participate. This issue was not discussed in NELAP and was raised by AB members of LASC.
- The AB committee did discuss this very issue during development of the standard and the requirement was left in.
- It's up to the NELAP Board to determine how to deal with the situation. LASC just raised the question – NELAP board needs to determine how to deal with it.
- NELAP should discuss the issue prior to going to the TIA process. The AB committee initiated the TIA process as they were trying to be sensitive to the timelines needed to implement the TNI standards. NELAP can discuss during their Miami meeting.

- The current NELAC standard does not have this issue.
- The full context of the ISO 17011 language also addresses issues of impartiality and conflict of interest, and that those sections may provide the needed flexibility to AB programs that have insufficient staff to allow signoffs by separate individuals.
- The TIA process was discussed. There is no specific allowance for withdrawing the TIAs. The options appear to be a negative vote by the committee, or amendment of the TIAs after consideration of the public comment. The committee can reject the current version and start over as well.

Kenneth W. Jackson, Ph.D.

Please have the AB Committee consider the following comments.

Section 4.3.5:

This TIA should not move forward.

1. The TNI standard is written to be in compliance with ISO 17011, and modifying this clause would place the standard out of compliance.
2. The proposed TIA was presented prematurely, since no evidence was provided of public discussion to substantiate that any ABs would be unable to be in compliance. Also, NY is misquoted as being out of compliance with the clause; and it was pointed out by Steve Arms that, although FL may be out of compliance now, he had not stated FL would be unable to comply if the standard is adopted.

Section 5.7.3b:

This TIA should not move forward.

1. The TNI standard is written to be in compliance with ISO 17011, and modifying this clause would place the standard out of compliance.
2. There should be no reason why any AB is unable to have an independent internal audit conducted; e.g., by the AB's laboratory QA staff. No evidence was provided that any AB would be unable to meet the requirement.

Tally of the ballot

| | |
|----------------|-----|
| Lynn Bradley | nay |
| Steve Arms | nay |
| Steve Stubbs | nay |
| Sharon Mertens | nay |
| Linda Geddes | nay |
| Dan Dickison | nay |
| Joe Aiello | nay |

Motion fails to achieve a 3/4 affirmative vote.

Final Version TIAs

- a. the section(s) of the standard that should be amended;
V2M1 4.3.5
- b. the rationale for the Tentative Interim Amendment:
Several states (both large and small; KN, NY, NH, FL...) will not be able to comply with the existing standard as written. Specifically; they in fact do not comply with the requirement to have “a person(s) or committee(s) *different* from those who carried out the assessment”. These existing NELAP states will need to lose their existing NELAP recognized status if the language remains as is.
- c. the factor(s) that would determine whether the amendment qualifies as a Tentative Interim Amendment:
It has been determined by the ABC that it is of an emergency nature and that the committee missed the change originally.
- d. the proposed change to the standard, including suggested wording.
The ABC proposes to add to the existing language to the end of the sentence;
“ unless the responsible government authority allows otherwise.”

ABC TIA Two

- a. the section(s) of the standard that should be amended;
V2M1 5.7.3b
- b. the rationale for the Tentative Interim Amendment:
Several states (both large and small; KS, NY, NH, FL...) will not be able to comply with the existing standard as written. Specifically; they in fact do not comply with the requirement to have “personnel *different* from those who perform the activity to be audited”. These existing NELAP states will need to lose their existing NELAP recognized status if the language remains as is.
- c. the factor(s) that would determine whether the amendment qualifies as a Tentative Interim Amendment;
It has been determined by the ABC that it is of an emergency nature and that the committee missed the change originally.
- d. the proposed change to the standard, including suggested wording.
The ABC proposes to add to the existing language to the end of the sentence;
“ unless the responsible government authority allows otherwise.”