

**Response to Comments  
on  
Voting Draft Standard  
published November 15th, 2012  
Volume II**

Member Name	Standard Section	Comment	Ruling	Comments
Marty Hackman	General	As an assessor, the fact that ISO 17025 clauses are only referenced but not in the Standard makes my job almost impossible to perform since I now must have two sets of documents before me and be able to correlate the two sets of documents to properly evaluate the laboratory. Each ISO 17025 reference must be spelled out.  <b>Recommended Language:</b> <i>N/A</i>	Non-persuasive	The Standard is available with ISO language on the TNI website for purchase. We cannot post Standard with ISO language for review on website.
Craig Sprinkle	3.29	This definition is too restricting for FSMO in that it refers to "performance under controlled conditions". I suggest the following revised definition (similar to definition in Section 3.11 of Vol I:  <b>Recommended Language:</b> <i>Proficiency Testing: A means to evaluate an organization's performance relative to a set of criteria, through testing or measurement of unknown samples provided by a Proficiency Testing Provider.</i>	Non-persuasive	Definition left to match other definitions of PT within TNI
Carl Kircher	3.30	The definition for "Proficiency Testing Provider" contains poor English language wording, and it introduces a new acronym (FOPT) that has not been defined within the FSMO or NEFAP program. Also, since the acronym PTP appears later in Clause 7.15.2, PTP should be added to the definition here.  <b>Recommended Language:</b> <i>3.31: Proficiency Testing Provider (PTP): Any private party or government entity accredited by a TNI recognized PTPA that meets the stringent criteria to produce and distribute PT samples, evaluate study results against published performance criteria, and report the results to FSMOs, ABs, and its PTPA.</i>	Persuasive	Changes made as recommended
Bob Shannon	3.33*	In the definition of Measurement, suggest changing "by comparison to a standard unit" to "by comparison to a standard, where available a National Standard", Consider adding a note similar to that in 8.2.2 of volume 2. NOTE: Traceability of measurement results should be referenced to National or International Standards where applicable.  <b>Recommended Language:</b> <i>Further, this definition seems to be imprecise. The definition reads: "... the dimensions, quantity, capacity, or other characteristic of a thing or event." Suggest replacing "thing or event" with the term "measurand".</i>	Persuasive	Committee agreed to look at the definition and revise. Preference would be to use ISO/IEC definition if available.
Mike Miller	3.33*	Air, water, soil, microbes, molecules, atoms are not usually considered things. <b>Recommended Language:</b> <i>Thing = inanimate object Substance= a species of matter</i>	Persuasive	
Mike Miller	4.1.1	period in middle of sentence, Seek misspelled  <b>Recommended Language:</b> <i>The accreditation body shall seek.....The NELAC Institute, who</i>	Persuasive	Seek is spelled correctly and period is actually a comma which is appropriate in ISO version, those changes were not in published non-ISO version
Carl Kircher	4.3.2.1	The proposed changes to this clause are confusing. <b>Recommended Language:</b> <i>The accreditation body, within the scope and applicability of its policies and procedures and, for government ABs, its applicable rules and regulations, shall also establish one or more committees for assistance ...</i>	Persuasive	Agreed and change made
Susan Butts	4.5.1	includes two notes. These notes use the word "shall". If these are to be enforceable requirements, they should not be notes, but be written as part of the standard.  <b>Recommended Language:</b> <i>N/A</i>	Persuasive	Committee felt that neither note belonged in Standard. Change made to remove both Note 1 and Note 2 from Standard
Randy Querry	5.2 NOTE	Language in the note: Reference to ISO/IEC 9001 needs to be amended to just ISO 9001. <b>Recommended Language:</b> <i>ISO 9001</i>	Persuasive	Agreed and change made
Mike Miller	5.3.2(b)	Add following language:  <b>Recommended Language:</b> <i>of completion of the review and send documentation to the AB accreditor.</i>	Persuasive	Committee believes suggested language would be redundant as sending to accreditor is implied already. However change was made to add "send documentation to NEFAP"
Craig Sprinkle	6.2.6.1(iv)	There is a missing verb in the qualifying sentence?  <b>Recommended Language:</b> <i>Be judged proficient by the accreditation body.</i>	Persuasive	Change had already been made to Standard with ISO language. Change did not get copied to non-ISO document posted
Carl Kircher	6.2.6.2 (b)	The proposed new language refers to a "TNI approved Basic Assessor Training Course." To me knowledge, there are currently no such TNI approved courses. Have the standards for TNI approval of training courses been formulated? Do these standards need to go through the Consensus Standard Development process?  <b>Recommended Language:</b> <i>"... This training program requires assessors to participate in an Assessor Basic Training Course, including attainment of a passing score on the written examination for the course."</i>	Persuasive	Change made as recommended
Craig Sprinkle	7.1.3.2.1 NOTE*	Spelling errors  <b>Recommended Language:</b> <i>N/A</i>	Persuasive	Change had already been made to Standard with ISO language. Change did not get copied to non-ISO document posted
Bob Shannon	7.1.3.2.1 NOTE*	Spelling errors  <b>Recommended Language:</b> <i>"anlayte"</i>	Persuasive	Change had already been made to Standard with ISO language. Change did not get copied to non-ISO document posted
Mike Miller	7.1.3.2.1 NOTE	Program list was deleted from 7.1.3.1.  <b>Recommended Language:</b> <i>as required by regulatory programs.</i>	Persuasive	Removed reference to specific programs and inserted term "regulatory" before programs

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Carl Kircher	7.2.1.1.1(i)	An editorial change is needed to add an apostrophe, since FSMO is used in the possessive case in the proposed new language. <b>Recommended Language:</b> <i>a description of the FSMO's proficiency testing program, and copies of the results of the proficiency testing performed, if applicable;</i>	Persuasive	Agreed and change made
Carl Kircher	7.7.2.1(b)(v)	The proposed change refers to "this Standard." I interpret this Standard to be the Volume 2 document that is being reviewed. However, the FSMO is being assessed against the Volume 1 standard rather than this volume that pertains to the AB. <b>Recommended Language:</b> <i>"... concerning the FSMO's accreditation status and conformance to the FSMO Volume 1 Standard."</i>	Persuasive	Committee originally voted non-persuasive at open meeting but reconsidered on subsequent conference call and changed as recommended
Carl Kircher	7.7.3.1(a)	The proposed change refers to "this Standard." I interpret this Standard to be the Volume 2 document that is being reviewed. However, the FSMO is being assessed against the Volume 1 standard rather than this volume that pertains to the AB. <b>Recommended Language:</b> <i>"... for determining compliance with the FSMO Volume 1 Standard, either at ..."</i>	Persuasive	Committee originally voted non-persuasive at open meeting but reconsidered on subsequent conference call and changed as recommended
Carl Kircher	7.7.6.1(g)	The proposed change refers to "this Standard." I interpret this Standard to be the Volume 2 document that is being reviewed. However, the FSMO is being assessed against the Volume 1 standard rather than this volume that pertains to the AB. <b>Recommended Language:</b> <i>(g) "of reasonable duration sufficient to demonstrate compliance with the FSMO Volume 1 Standard, dependent upon a balance of ..."</i>	Persuasive	Committee originally voted non-persuasive at open meeting but reconsidered on subsequent conference call and changed as recommended
Carl Kircher	7.7.6.2 c)	The proposed change refers to "this Standard." I interpret this Standard to be the Volume 2 document that is being reviewed. However, the FSMO is being assessed against the Volume 1 standard rather than this volume that pertains to the AB. <b>Recommended Language:</b> <i>"responding to knowledge that the FSMO is no longer in compliance with the FSMO Volume 1 Standard."</i>	Persuasive	Committee originally voted non-persuasive at open meeting but reconsidered on subsequent conference call and changed as recommended
Susan Butts	7.8.1.1(a)	7.8.1.1 a) includes a note. This note uses the word "must". If this is to be an enforceable requirement, it should not be a note, but be written as part of the standard. <b>Recommended Language:</b> <i>N/A</i>	Persuasive	Changed "must" to "should" and left as a note
Carl Kircher	7.9.2.1.2	The opening 3 paragraphs and NOTE 1 have some incorrect applications of English, which lead to confusion. Also, a new acronym "NEFAP" appears, which has not been defined. Does it need to appear in the standard at all? <b>Recommended Language:</b> <i>Preliminary accreditation is used by newly formed Accreditation Bodies in order to initiate an accreditation program. It is recognized that new ABs &lt;delete comma&gt; may need additional time to establish a full program, and these new accreditation bodies may issue preliminary accreditation status to its applicants. Accreditation Bodies seeking recognition in the applicable TNI Program shall be able to grant a preliminary accreditation status to FSMO's who meet requirements outlined below if an on-site assessment cannot be conducted in a reasonable timeframe as listed below in section c. After two years of operation, the accreditation body must not issue preliminary accreditation since the Accreditation Body's program must be fully established within that timeframe. NOTE 1: The AB is given time with this clause to obtain applicants, perform a document review of the applicant's information and prepare for the on-site assessment.</i>	Persuasive	Removed reference to TNI NEFAP Program
Carl Kircher	7.9.2.1.2 (b)	There is a mis-spelling of "competency" in the proposed new language. In addition, there is a reference to ISO 17025 clauses 5.9.1(a) through (e) but no mention to clauses (f) and (g) that are proposed for addition in the FSMO Volume 1 standard. <b>Recommended Language:</b> <i>(b) Preliminary accreditation may be granted in the event the FSMO completes all the accreditation requirements, except for the successful demonstration of competency. During the preliminary period, in the absence of available proficiency testing or other means of demonstrating competency, the AB shall verify that the FSMO has conducted the quality control monitoring as detailed in ISO/IEC 17025:2005 5.9.1(a) through (e), and in the FSMO Volume 1 Standard clauses 5.9.1(f) and (g). -and 5.9.2 (as I commented on the Volume 1 ballot)</i>	Persuasive	Reworded section to include letters (f) and (g), removed reference to ISO/IEC 17025 and instead referenced Volume I
Susan Butts	7.9.2.1.2 NOTE 2	This note uses the word "must". If this is to be an enforceable requirement, it should not be a note, but be written as part of the standard. <b>Recommended Language:</b> <i>N/A</i>	Persuasive	Agreed and language a requirement and thus added to section
Carl Kircher	7.9.2.1.3 (f)	This clause refers to Clause 5 of this Standard, meaning the Volume 2 standard. It is the AB and not the FSMOs who have to implement the management system and quality manual requirements in this volume. Should this language be changed to the management system and quality manual requirements in the FSMO Volume 1 standard? <b>Recommended Language:</b> <i>(f) failure to implement a management system and quality manual as defined in Clause 4 in the FSMO Volume 1 Standard.</i>	Non-persuasive	Committee believes the reference to sections here both apply to V2 alone and does not require adding the reference to the V1 Standard
Carl Kircher	7.9.2.1.4(a)	The proposed change refers to "this Standard." I interpret this Standard to be the Volume 2 document that is being reviewed. However, the FSMO is being assessed against the Volume 1 standard rather than this volume that pertains to the AB. <b>Recommended Language:</b> <i>(a) "... retained by the FSMO for those areas where it continues to meet the requirements of the FSMO Volume 1 Standard."</i>	Persuasive	Committee originally voted non-persuasive at open meeting but reconsidered on subsequent conference call and changed as recommended

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Carl Kircher	7.9.2.1.4 NOTE 1	The proposed change refers to "this Standard." I interpret this Standard to be the Volume 2 document that is being reviewed. However, the FSMO is being assessed against the Volume 1 standard rather than this volume that pertains to the AB. <b>Recommended Language:</b> NOTE 1: "... allow a FSMO time to correct deficiencies or an area of non-compliance with the FSMO Volume 1 Standard."	Persuasive	Committee originally voted non-persuasive at open meeting but reconsidered on subsequent conference call and changed as recommended
Carl Kircher	7.9.2.1.5(a)	The proposed change refers to "this Standard." I interpret this Standard to be the Volume 2 document that is being reviewed. However, the FSMO is being assessed against the Volume 1 standard rather than this volume that pertains to the AB. <b>Recommended Language:</b> (a) "... or measurement / analytical methods where it continues to meet the requirements of the FSMO Volume 1 Standard."	Persuasive	Committee originally voted non-persuasive at open meeting but reconsidered on subsequent conference call. "this Standard" appears twice in this section, the first use is indeed referring to V2 and was left alone, the second use was referring to V1 and has been changed as suggested
Craig Sprinkle	7.9.2.1.2(b)	Spelling errors <b>Recommended Language:</b> N/A	Persuasive	Spelling of two words was already corrected in ISO version, change had not been made in Non-ISO version
Bob Shannon	7.15.2*	orthography - remove extraneous hyphen from accredit-ting <b>Recommended Language:</b> See above	Persuasive	Change had already been made to Standard with ISO language. Change did not get copied to non-ISO document posted
Randy Querry	7.15.2*	spelling correction suggestion- "accredit-ting" <b>Recommended Language:</b> The accreditation body providing accreditation...	Persuasive	Change had already been made to Standard with ISO language. Change did not get copied to non-ISO document posted
Carl Kircher	7.15.2	The proposed change refers to "this Standard." I interpret this Standard to be the Volume 2 document that is being reviewed. However, the FSMO is being assessed against the Volume 1 standard rather than this volume that pertains to the AB. Also, a spelling correction is recommended. <b>Recommended Language:</b> The accreditation body accrediting to the TNI FSMO Volume 1 Standard shall use a TNI PTPA approved PTP for applicable and available PT samples.	Persuasive	Committee originally voted non-persuasive at open meeting but reconsidered on subsequent conference call and changed as recommended
Ron Mills	Section 8	Definition of CAB is not clearly stated <b>Recommended Language:</b> N/A	Non-persuasive	Definition of CAB is clearly stated in Volume II Section 3.10