

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

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. Recommended Language: <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.
Bob Shannon	3.9*	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. 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". Recommended Language: <i>See above</i>	Persuasive	Committee agreed to look at the definition and revise. Preference would be to use ISO/IEC definition if available.
Mike Miller	3.9*	Reason: Thing is a very non scientific term. Thing = inanimate object. Air, water, soil, microbes, molecules, atoms are not usually considered things. Recommended Language: <i>Replace "Thing" "Substance" Substance= a species of matter</i>	Persuasive	Committee agreed to look at the definition and revise. Preference would be to use ISO/IEC definition if available.
Craig Sprinkle	3.11*	the definition of proficiency testing is too limiting (refers only to laboratory tests and under controlled conditions) and is not the same as the definition provided in proposed Vol II. Proficiency Testing: A means to evaluate an organization's performance relative to a given set of criteria, through testing and/or measurement of unknown samples provided by a Proficiency Testing Provider. Recommended Language: <i>See above</i>	Non-Persuasive (1st part) / Persuasive	Definition changed to match current definition in Volume II
Marty Hackman	3.11*	The definition of PTs is very sparse. The definition references "analysis of unknown samples". This is not really correct. The sample is unknown to the laboratory only but the actual values are well documented by the PT provider (as required by TNI Standards). The definition of PTs should incorporate this. Additionally, the definition only mentions a third party as the source of the "unknown samples" when it should reference the PT provider and provide further definition of the PT provider. Recommended Language: <i>N/A</i>	Persuasive	Changed definition to match VII
Susan Butts	3.11*	Section 3.11 includes a definition of Proficiency Test. The definition is not consistent with Volume 2 General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations. Recommended Language: <i>Recommend the definitions used in 3.29, 3.30, and 3.31 from Volume 2 be used in Volume 1.</i>	Persuasive	Changed definition to match VII
Mike Miller	3.11*	Match definition in Vol. 2 Recommended Language: <i>Recommend the definitions used in 3.29, 3.30, and 3.31 from Volume 2 be used in Volume 1.</i>	Persuasive	Changed definition to match VII
Carl Kircher	3.12	The proposed definition for "Chain of Custody" includes sample receipt at the laboratory, but the box in Clause 1 says that the Standard user should substitute FSMO for the term "laboratory." Chain of Custody Form: Record that documents the possession of the samples from the time of collection by a FSMO to receipt in a testing laboratory. The record generally includes ... Recommended Language: <i>See above</i>	Persuasive	Changed as suggested
Mark Murphy	4.2.8	Change to be 4.2.1 Recommended Language: <i>See above</i>	Non-persuasive	Non-ISO version published does not list reference to ISO clauses 4.2.1-4.2.7, however they do exist. Updated Non-ISO version to reflect this
Mark Murphy	4.2.8 (g)	Add to sentence: "... the data integrity procedures shall be annually reviewed and updated by management, as needed." Recommended Language: <i>"... the data integrity procedures shall be annually reviewed and updated by management, as needed."</i>	Persuasive	Changed with slight modification to punctuation as suggested
David Caldwell	4.3.2.1 and 4.5 (of Volume 2)	Section 4.3.2.1 and 4.5 talk about governmental bodies and non governmental bodies. However 4.3.2.1 might be in conflict with 4.5 on non-governmental bodies. Recommended Language: <i>N/A</i>	Non-Persuasive	Committee could not find where the two sections conflict with each other, agreed to leave as written
Mike Miller	4.5	The ISO Language only requires the sub contractor to follow ISO STD Recommended Language: <i>Add 4.5.5 - A competent subcontractor is one that, for example, complies with this TNI Standard for the work in question</i>	Persuasive	Changed as suggested
Mark Murphy	4.14.1.1	Needs a reference to types of 'scope of accreditations' available. Recommended Language: <i>N/A</i>	Non-persuasive	Committee felt that it will ultimately be the ABs who will define "scope" and should not be listed here in Standard. Section 7.1.3.2.2 of V2 addresses this as well.
Mark Murphy	5.1.3	"Field samples and measurements shall be representative of the environment, setting or process sampled or measured. The FSMO shall select and document each sampling or measurement location and time that represents the identified subject." ('Identified subject' is not clear in this context. Needs a definition or different phrase.) Recommended Language: <i>N/A</i>	Persuasive	Changed - See comment below
Bob Shannon	5.1.3	This requirement is imprecisely worded. In the worst case, it could be taken as a blessing of problematic sampling or field measurements. Specifically, location, time, and other environmental conditions all affect measurements and sampling activities. They need to be monitored and documented to ensure that conditions are consistent with known, documented limitations of the sampling or measurement process in question (as defined in the governing SOP). Perhaps it would be more accurately expressed as: Recommended Language: <i>"The FSMO shall select and document sampling or measurement location, time and conditions that will guarantee that measurements or samples obtained are representative of the identified subject."</i>	Persuasive	Changed similar to recommended (but removed word "guarantee"
Bob Shannon	5.1.3	Grammar Issue Recommended Language: <i>Change "represents" to "represent"</i>	Persuasive	Changed as suggested

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Susan Butts	5.3.1	5.3.1 includes a note which states "field personnel should document sampling and measurement conditions that may affect the quality of results..." This appears to be in conflict with 5.10.10 which states "all relevant information, including special conditions, must be retained in the sampling records." If the "special conditions" documented in 5.10.10 are the same as "sampling and measurement conditions" in 5.3.1.1, I recommend that "Note" be removed and to make this part of the standard to be consistent with 5.10.10. Recommended Language: See above	Non-persuasive	Committee felt that these two sections address separate items. 5.3.1 is documentation in the field of special conditions, etc... 5.10 is reporting of info, they may overlap but are not the same. ISO language also covers requirement of what should be documented that note supports, agreed to leave as written
Mark Murphy	5.4.3	Laboratory-Developed Methods (Should it be 'FMSO-Developed Methods?') Recommended Language: 'FMSO-Developed Methods'	Non-persuasive	Section header is from ISO, we do not want to change the terminology here. Refer to table at beginning regarding substituting "FSMO"
Mike Miller	5.4.3.1	There is no language that focuses on environmental field sampling and measurement needs. The FSMO developed methods shall contain procedures for the following activities: selection and documentation of field sampling and measurement points, collection, preservation, and transportation of samples; and operation of measurement instruments under variable conditions in the field environment. Records shall be maintained for these activities. Field measurement method calibration, calibration verification and quality control steps shall be performed and recorded. Program specific regulations, project specific procedures and client-specified data quality objectives shall be respected. Recommended Language:	Non-persuasive	Committee felt ISO language is sufficient and several of the suggested wording is already covered in other sections of the Standard.
Mike Miller	5.4.4 NOTE	There is no language that focuses on environmental field sampling and measurement needs. l) the field measurement instrument calibration, calibration verification, and quality control procedures acceptance limits, m) the sample result shall meet the customers data quality objectives. Recommended Language:	Non-persuasive	Committee felt that recommended letter (l) is already covered in another section of Standard and recommended (m) is implied already in Standard and does not need to be specified here
Susan Butts	5.5.3	5.5.3 includes a note. The language in the note sounds like language that should be part of the scope. Recommended Language: See above	Non-persuasive	Note refers to applicability of Standard and not a requirement. Committee felt better left as a note.
Carl Kircher	5.9	The proposed language for clause 5.9.1(f) is a phrase, which matches the listings for 5.9.1(a) through (e) in the ISO Standard. Clauses 5.9.1(a) through (e) are a list of items that the required monitoring of validity of tests and calibrations MAY include but not be limited to. However, clause 5.9.1(g) is a complete sentence that appears to specify a requirement (rather than a list of possible monitoring method inclusions). Also, please make the editorial change to remove the apostrophe in the second-to-last word. Recommended Language: Recommended wording: Re-number the proposed Section 5.9.1(g) to be a separate clause 5.9.2, as follows: 5.9.2 The FSMO shall establish a proficiency testing program that is applicable to its scope.	Persuasive	Added as 5.9.2 and moved existing 5.9.2 to new 5.9.3
Mark Murphy	5.9.1	Numbering system should be corrected. Add to sentence: "Verification of a measurement calibration using a second source, where applicable." Indicate the minimum frequency for the verifications and PT testing. The various scopes of testing programs should be defined. Recommended Language: See above	Non-persuasive	Numbering is correct, the non-ISO version does not have the first few ISO letters. The ISO language states this list "includes, but is not limited to" so therefore the committee felt the language did not need to be changed. The committee, as in other sections, did not feel scope should be further specified in this section.
Mike Miller	5.9.2	ISO section is missing from Standard 5.9.2 Quality control data shall be analysed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported. Recommended Language:	Non-persuasive	Section is in VII as written in ISO, reference to section not contained in Non-ISO version. I added reference to ISO/IEC 5.9.2 in non-ISO version
Bob Shannon	5.9.1(g)	Grammar Issue Recommended Language: change "It's" to "its"	Persuasive	Changed as suggested
Mark Murphy	5.10.2	Correct numbering system. It appears that words are missing at the beginning of each of the three subsections of 5.10.2. Recommended Language: See above	Non-persuasive	Numbering is correct, the non-ISO version is missing several letters that are ISO language. The words missing at beginning are also ISO language
Bob Shannon	5.10.2	This requirement seems to assume that the test will use blanks, spikes and duplicate samples. While this covers many tests, it does not apply to all. Recommended Language: ...results for any quality controls, such as field blanks,....	Persuasive	Reworded section slightly
Carl Kircher	5.10.2(i)	The additional phrase is confusing. Recommended Language: including phone number of the person authorizing the report.	Persuasive	Changed as suggested
Bob Shannon	5.10.10	In the QS committee, we talked about the need to identify each container separately since a sample may be split between containers, preserved differently for different tests. Does this need address here? Recommended Language: N/A	Persuasive	Change made to refer identifier to each sample container