

ASB Standard 061, Firearms and Toolmarks 3D Measurement Systems
14-Jan-21

#	Section	Type of Comment (E-Editorial)	Comments	Proposed Resolution	Final Resolution
1	Introduction	E	Third bullet point on page 2 "you include an acknowledgement alongside...", "acknowledgement" is misspelled.	Change to "acknowledgment"	Accept
2	4.2.4	T	This section requires that calibration be performed at the facility at installation. Some equipment is calibrated at manufacture, but can be validated at installation without the need for recalibration.	Change the text of this section to read "The laboratory shall have the instrument calibrated or the calibration verified by the manufacturer or instrument provider upon installation."	Reject: Calibration checks are discussed in detail in section 4.2.5.
3	4.2.5.3.2 4.2.5.3.3 4.2.5.4.2 4.2.5.4.3	T	All of these sections reference 'standard units', however, standard units is not a defined term.	Provide a definition for standard units, or revise to use a term like Scientific Units.	Reject: Standard Units is an accepted scientific term used by the discipline.
4	4.3.2	E	The introductory sentence utilizes the work "bracket" as a verb in a context that can be difficult to interpret. ("The check and re-check measurements bracket regular measurements.") Separating this term with a phrase may make it easier to understand.	Insert a phrase to clarify that the term 'bracket' is being used as a verb: "The check and re-check measurements <u>are used to</u> bracket regular measurements." -or- "The check and re-check measurements bracket <u>the</u> regular measurements."	Reject: This sentence is clear as is and it is described in more detail in the remainder of this paragraph.
5			In my opinion the documentation statements in 4.2.1 and 4.3.1 remain too vague and superficial. While the standard as written admirably requires documentation of performance checks and deployment validation its de minimus statement that labs must retain their documentation does not go near far enough. The standard should instead lay out what must be included in documentation. At minimum both sections should be amended to require that labs retain documentation including all data underlying performance checks and deployment validation. In that way the standard will actually allow for full scale review of validation by outside specialists if necessary. That may not be possible if laboratories retain only general summaries of the validation and performance checks performed (as this standard seemingly allows).		Reject: The specific documentation requirements are spelled out in Standard 063 (normative reference to Standard 061). Standard 063 is as detailed as possible given these standards are written to encompass multiple types of 3D technology. Reference Standard 063 4.1.1, 4.1.2.3, 4.1.3.2, 4.1.3.5, 4.2.2.1, and 4.3 .

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6			<p>I appreciate the recognition that validation documentation must be maintained, but agree that more detail is needed to make this requirement meaningful. 4.2.1 and 4.3.1 both say "as per ASB to Standard 063 . . . the laboratory shall . . . document" the deployment validation/performance check.</p> <p>However, Standard 063 doesn't include any specific documentation requirements with respect to the results of (including data generated during) deployment validation/performance checks, so some detail in this standard is necessary. It's an easy enough fix to revise the sentence to require retention of all documentation and data generated during the validation or performance check.</p> <p>I also believe it should expressly state that this data/documentation shall be made available upon request.</p> <p>This would bring the transparency for deployment validation and performance checks in line with requirements for developmental validation in Std 63, sec 4.1.3.5 ("In all cases, the data from a development validation study shall be made available upon request.")</p>		<p>Reject: The specific documentation requirements are spelled out in Standard 063 (normative reference to Standard 061). Standard 063 is as detailed as possible given these standards are written to encompass multiple types of 3D technology. Reference Standard 063 4.1.1, 4.1.2.3, 4.1.3.2, 4.1.3.5, 4.2.2.1, and 4.3 . Further documentation requirements and release of said documents is outside the scope of this document. Accredited laboratories operating under ISO 17025 are already required to provide objective evidence that validations were properly performed.</p>
7			<p>I share the concerns voiced in previous comments by CB member X and CB member Y regarding the failure of Standard 61 to follow the best practices set forth by the IEEE, or to provide sufficient guidance about who should conduct validation studies or how such studies should be designed. Because I recently joined the consensus body, however, I was unable to express my concerns in previous rounds of public comment. Accordingly, I will abstain from voting for Standard 61.</p>		<p>Reject: The IEEE standards are intended for developers while these standards are intended for end users. The software described in these documents can be empirically tested on real-world data. Software performance is important and the document describes three stages of validation testing to ensure that the software meets the needs of the end user.</p> <p>Also, these concerns were discussed at length and resolved in round01 of comment resolutions.</p>