

MITA Comments RE: NIST Special Publication 2000-01: ABC's of Conformity Assessment

195		1	ed	<p>“not” is missing</p> <p>TBT agreement reads:</p> <p>5.1.2 conformity assessment procedures are <u>not</u> prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade.</p>	<p>“not prepared ...”</p>	
204		2	te	<p>It is not the standard itself, it is the quality and national or international recognition of the standard, See also lines 232 to 236</p>	<p>“quality and national or international recognition of the standard”</p>	
224		2	te	<p>The understanding is also with authorities like market surveillance authorities or notification authorities, e.g. FDA 510(k) clearance</p>	<p>“purchasers, sellers and market surveillance or notification authorities”</p>	
275		3	te	<p>The notion “N/A” for SDoC in the rows Arrangements and Accreditation is not justified. ISO 17050 requires that an SDoC must be based on evidence. This evidence may originate from a test and test report of a third party lab or from a manufacturers lab that may even be accredited to ISO 17025 and may be supported by a quality management system that may be certified by an accredited registrar to ISO 9001. See also lines 286 to 288 and 294 to 301</p>	<p>Replace “N/A” by “Not determined” and explain in a footnote or link to chapter 3.1</p>	
315-340		3.2	ge	<p>The requirement for impartiality according to ISO 17020 of the inspection body is missing</p>	<p>Add e.g. in line 320 after the first sentence: “The body performing inspection needs to be impartial from the subject of inspection. The requirements for impartiality are laid down in ISO 17020.”</p>	
356		3.3	te	<p>Laboratories perform measurements</p>	<p>Complement the first sentence to read:</p> <p>“Testing laboratories conduct tests and develop data by performing measurements. Measurements are defined by ISO/IEC GUIDE 99 (2.1) as: process of experimentally obtaining one or more values that can reasonably be attributed to a quantity.</p>	
370-375		3.3	ge	<p>Plenty of independent additional information is available from EUROLAB</p>	<p>Consider adding References to:</p> <ul style="list-style-type: none"> • EUROLAB Policy Paper The role of laboratories in testing, inspection and certification http://www.eurolab.org/NewsArticle.aspx?NewsId=236&CatId=4 • EUROLAB Position Paper First-, second- and third-party testing – how and when 	

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					http://www.eurolab.org/publications.aspx?FileTypeId=14
393		3.4	te	Subjects of certification are not only products but also services, processes of providers and persons	After object produced add “, services offered, processes applied or competence of persons”
488-490		3.5	te	Accreditation activities do not include tasks such as testing, calibration, inspection, certification, management systems, persons, products, processes and services, and validation and verification. See also lines 553 to 555 where OSHA is the accreditor of the NRTLs See also lines 606-607	Accreditation activities include - on a random base - tasks such as supervising tests, audits or inspections, checking calibration of laboratory test equipment, checking test, audit or inspection reports for correctness and consistency, checking the quality management system for adequacy and completeness of accredited third parties offering services tasks such as testing, calibration, inspection, certification, management systems, persons, products, processes and services, and validation and verification.
492		3.5	te	Accreditors do not assess compliance of a conformity assessment system but of conformity assessment bodies.	Accreditors use the ISO/IEC standards and guides with the technical and specific program requirements to assess compliance of a conformity assessment body.
				Accreditors neither make use of assessment bodies nor do they assess CA systems	One important attribute of accreditation is the use of competent auditors to perform assessments of conformity assessment bodies.
500		3.5	ge	Missing is a mentioning that accreditation is performed on a non for profit base and a non-competitive base. The accreditation body or bodies shall be governmentally recognized like ANSI-ASQ National Accreditation Board (ANAB).	Put governmental agencies on top of the pyramid. Explicitly give reference to ANSI-ASQ National Accreditation Board (ANAB) in chapter 3.5 and that accreditation is performed on a non for profit base and a non-competitive base.
519-521		4	ed	Sentence incomplete, there seem words missing in line 521 between “assessment program” and “the conformity assessment program owner”	Complete sentence or reword
527		4	te	Add International Standards Organisations to the list. See lines 620-623	
618-623			te	According to the definitions given in lines 587 and 601 MRA are between governments, the IECEE scheme is between peer assessed test labs	Replace MRA by mutual recognition arrangement . In case this is meant define and use a different abbreviation than MRA that is linked to mutual recognition agreements in line 600
644-671		References	ed	ISO/IEC ≠ International Organization for Standardization.	Replace “International Organization for Standardization. ISO/IEC” by “International Organization for Standardization/ International Electrotechnical Commission. ISO/IEC”
650		References	ed	Missing words	

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				(ISO 17020, 2012). International Organization for Standardization. ISO/IEC 17020:2012 "Conformity Assessment – Requirements for the operation of various types of bodies." 2012.	"Conformity assessment — Requirements for the operation of various types of bodies <u>performing inspection</u> " 2012	
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