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February 26, 2018

Lisa Carnahan
Amy Phelps
National Institute of Standards and Technology
100 Bureau Drive, Stop 2100
Gaithersburg, MD 20899

RE: NIST Special Publication 2000–01: ABC's of Conformity Assessment

Dear Lisa and Amy:

The Advanced Medical Technology Association (AdvaMed) is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical technology. AdvaMed's member companies range from the largest to the smallest medical product innovators and manufacturers, with nearly 70 percent of our members generating less than $100 million in annual sales. AdvaMed's member companies produce innovations that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments.

We support the use by federal agencies of international voluntary consensus standards to meet regulatory requirements, which will further efforts to harmonize global medical technology regulations. Using international voluntary consensus standards to meet regulatory requirements has many benefits, including introducing efficiencies for both the regulators and the medical device industry. Use of international voluntary consensus standards for regulatory purposes helps minimize unnecessary costs and delays in patient access to innovative new devices.

We applaud the National Institute of Standards and Technology (NIST) for issuance of this Special Publication, which we believe will be a helpful resource for users of conformity assessment, including medical device manufacturers. We also appreciate the extensive outreach that NIST engaged in to gather feedback prior to issuing the document in the *Federal Register*. In the interest of making this already helpful document as useful as possible, we offer technical edits in the form of specific line edits below.

Thank you for the opportunity to submit these comments. Please do not hesitate to contact me at jwolszon@advamed.org or 202-434-7230 if you have any questions.

Sincerely,

/s/

Jamie Wolszon
Associate Vice President
Technology and Regulatory Affairs

Line Number	Paragraph / Figure /Table	Proposed Change (additions indicated in underline; deletions indicated in strikethrough)	Comment / Rationale
194-96	1	The agreement requires that conformity assessment procedures not be "prepared, adopted and applied with a view to, or with the effect of, creating unnecessary obstacles to international trade."	The document appears to have inadvertently omitted the word “not” in citing the Agreement on Technical Barriers to Trade.
204	2	The quality and national or international recognition of standards used in a conformity assessment program have significant impact on the validity of the program, the value of the information conveyed and the program's cost.	We believe that the quality and national or international recognition of the standard plays an important role in conferring these benefits.
224	2	Standards are vital tools of industry and commerce promoting an understanding between purchasers~~,~~ ~~and~~ sellers, and regulatory authorities. Standards enable ~~and enabling~~ mutually beneficial commercial transactions.	Standards also promote understanding for regulatory authorities. We note, for instance, FDA’s use of FDA-recognized standards in the 510(k) review process.
232	3	Standards used in conformity assessment should be clearly and concisely written, readily understood, precise, and technically credible~~, and contain, only unambiguous requirements for objective verification.~~	We would recommend that this document consider the possibility of conformity assessment for risk-based standards. Risk-based standards, by their very nature, are not necessarily unambiguous requirements for objective verification. However, many such risk-based standards are very important to the medical device industry.

Line Number	Paragraph / Figure /Table	Proposed Change (additions indicated in underline; deletions indicated in strikethrough)	Comment / Rationale
275	Figure 2	Replace “N/A” with “Not Determined” Provide a footnote to chapter 3.1 regarding supplier’s declaration of conformity (SDOC) explaining that: <u>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 laboratory. Alternatively, this evidence may originate from a manufacturer’s laboratory that may be accredited to ISO 17025, and supported by a quality management system certified by an accredited registrar to ISO 9001.</u>	We note that 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 laboratory. Alternatively, this evidence may originate from a manufacturer’s laboratory that may be accredited to ISO 17025, and supported by a quality management system certified by an accredited registrar to ISO 9001. We propose adding text accordingly.
315-340	3.2	Inspection is defined in ISO/IEC 17000:2004 (ISO 170000, 2004) as the "examination of a product, process, service, or installation or their design and determination of its conformity with specific requirements, or on the basis of professional judgement, with general requirements. <u>The body performing inspection needs to be impartial from the subject of inspection. The requirements for impartiality are outlined in ISO 17020.</u>	We believe the requirement for impartiality of the inspection body according to ISO 17020 should be added.

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356	3.3	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."	We believe it would be helpful to add the concept that laboratories perform measurements, and to provide a definition of measurements.
370-375	3.3	We would recommend that NIST consider adding references to: • 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 http://www.eurolab.org/publications.aspx?FileTypeId=14	We believe that these references provide useful, independent, additional information on the topic of laboratory testing.
392-393	3.4	The goal of certification is to provide confidence to interested parties that objects produced, services offered, processes applied or competence of persons providing services, meet specified requirements.	We would propose revising to reflect that subjects of certification are not limited to products, but also may include services and processes of providers and persons.

Line Number	Paragraph / Figure /Table	Proposed Change (additions indicated in underline; deletions indicated in strikethrough)	Comment / Rationale
488-490	3.5	Accreditation activities include, on a random basis, tasks such as supervising tests, audits or inspections, checking calibration of laboratory test equipment, checking test, audit or inspection reports for correctness and consistency, and checking the quality management system for adequacy. Accreditation activities also include checking the completeness of accredited third parties offering service tasks such as testing, calibration, inspection, certification, management systems, persons, products, processes and services, and validation and verification.	The activities described in the original text are activities of the conformity assessment bodies. We have proposed text that we believe reflects the activities of the accrediting bodies.
492	3.5	Accreditors use the ISO/IEC standards and guides with the technical and specific program requirements to assess compliance of a conformity assessment ~~system~~ body.	We propose a technical edit to reflect that accreditors assess compliance of conformity assessment bodies, not conformity assessment systems.
492 - 494	3.5	One important attribute of accreditation is the use of competent ~~assessment bodies~~ auditors to perform assessments of conformity assessment ~~systems~~ bodies.	We propose a technical edit to reflect that accreditors use competent auditors to perform assessments of conformity assessment bodies.

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500	3.5	Put governmental agencies on top of the pyramid. Explicitly reference ANSI-ASQ National Accreditation Board (ANAB) in chapter 3.5 and that accreditation is performed on a not-for-profit basis and a non-competitive basis.	We believe it would be helpful to add at the top of the pyramid the concept that an accreditation body or bodies shall be governmentally recognized like ANAB. We also would recommend explaining that accreditation is performed on a not-for-profit basis and a non-competitive basis.
519-521	4	Please note, this document refers to the federal agency or department that develops and maintains the rules, policies, procedures, etc. for its conformity assessment program <u>as</u> the conformity assessment program owner.	We believe the word “as” was inadvertently omitted from this sentence.
527	4	Many different organizations can act as a conformity assessment program owner such as: • Certification bodies; • Government or regulators; • Purchasing agencies; • Trade associations; ~~and~~ • Consumer organizations.; <u>and</u> • International standards development organizations.	We believe it would be helpful, and consistent with other parts of this document, to add international standards development organizations to this list of organizations that can act as a conformity assessment program owner.

Line Number	Paragraph / Figure /Table	Proposed Change (additions indicated in underline; deletions indicated in strikethrough)	Comment / Rationale
618-623	5	~~MRAs~~ Mutual recognition arrangements can also be established between two or more organizations located in different countries to accept each other's conformity assessment data and/or conformity assessment marks or certificates of conformity. An example is the IEC's System for Conformity Testing to Standards for Safety of Electrical Products (the IECEE scheme), which is designed to promote the reciprocal recognition of test results among the participating countries and to simplify the certification of electrical products at the national level.	This section of the document distinguishes between mutual recognition agreements and mutual recognition arrangements. We believe that in this instance, given the example of the IECEE scheme, which is between peer-assessed test laboratories, that the latter is intended. We would propose clarification that mutual recognition arrangement is intended here.
644-671	References	(ISO/IEC 17000, 2004). International Organization for Standardization/International Electrotechnical Commission. ISO/IEC 17000:2004 644 “Conformity assessment — Vocabulary and general principles” 2004.	The documents referenced in these lines are ISO/IEC documents. The reference section appears to have inadvertently omitted the mention of IEC. We would add IEC to these references. We have provided a specific example of how we believe the text should read in lines 644-645, which we would recommend repeating up through line 671.
649-651	References	(ISO 17020, 2012). International Organization for Standardization. ISO/IEC 17020:2012 649 “Conformity Assessment – Requirements for the operation of various types of bodies performing inspection” 2012.	We propose revising to include the full title of the referenced standard.