ANSI-ASQ National Accreditation Board

ANAB

Submitted February 26, 2018

Subject: ANAB Response to the Request for Comments on NIST Draft Conformity Assessment Publication SP2000-01: ABC's of Conformity Assessment

Because the ABC document is intended to act as an explanatory document for those with little or no knowledge of conformity assessment systems and the different approaches available, it should be written to inform the reader about what conformity assessment is and is not, and so no conclusion is drawn.

TAs currently written, the document appears to promote some methods of conformity assessment over others. The document is heavily focused on product certification; most of the examples and language used are product-specific. The section on product certification list benefits that are applicable to the internationally recognized conformity assessment model as a whole, not product certification exclusively. The document does not adequately describe other methods of conformity assessment available. It implies that product certification is the type of conformity assessment to be used when risk associated with nonconformity is high, but the internationally recognized third-party accreditation framework in all aspects is built to reduce the risk.

In addition, the document appears to favor SDoC without providing adequate information on consequences of its use. The information on SDoC should be revised to clarify that when deciding to use SDoC there has to be a legislative framework available to deal with any issue that arise. The document states that SDoC is a "trade-friendly" approach but this could be misleading because many countries do not accept SDoC. Also, there is a higher likelihood of having to repeat a conformity assessment activity such as testing under SDoC. Under the internationally recognized third-party model that likelihood decreases significantly.

Section-specific comments follow:

Section:	**Reason:**	**Suggested Change:**
General	Replace references to specific version of standards, as these change quite frequently.	
Section 1 - Introduction: Second Paragraph	Document is dominated by product certification in examples and language used. The reference to "object of conformity assessment" should be used through the document anywhere where general concepts are being described to ensure neutral tone of the document.	Introduce the definition of "object of conformity assessment" as a term applicable to products, services, persons, and systems. Revise the paragraph using examples and language general to conformity assessment and not product-specific.
Lines 170-174	Provide the reader with more general examples of conformity assessment activity.	Conformity assessment can verify that a particular product, service, or system meets a given level of quality or safety, and provide the purchaser or user or user with explicit or implicit information about its characteristics, the consistency of those characteristics, and/or performance. Conformity assessment can also increase a purchaser's user's confidence, furnish useful information to a purchaser or user, and help to substantiate a company's advertising and labeling claims …
Line 183	Provide the reader with a more general example of conformity assessment activity.	…..program; and the adequacy and appropriateness of the standards against which the object of conformity assessment is evaluated.
Section 2:	The section does not provide the reader with full understanding of all types of conformity assessment activities.	Revise the section to include examples of system and personnel certification or revise to be more generic with references to object of conformity assessment.
Line 260	Missing references to system.	Conformity assessment examines an object of assessment (such as a product, process, service, system, or person)

		and evaluates whether the object meets specified requirements.
161/162	Clarify that audit also produces a report. Revise wording in brackets (such as test, inspection, or audit report)	A determination is made based on evidence of conformity (such as a test, inspection, or audit report).
Line 164	replace surveillance with ongoing oversight.	
Figure 2 – line 275/276	The term "registrars" is no longer used in favor of "certification bodies" or, more specifically, "management systems certification bodies."	Last column replace term "Registrars" with management systems certification bodies. Revise reference to ISO/IEC 17021 to ISO/IEC 17021-1. Add section on ISO/IEC 17024 Personnel Certification Bodies. ISO/IEC 17065 is for Product Certification Bodies. First row of the column to ready "Product Certification". In the last row revise "Product Certification Bodies".
Figure 2.	Because the reader may not have any understanding of the type of mutual recognition arrangements that are applicable to the international conformity assessment standard, the figure should be revised to include references to IAF and ILAC to enhance understanding of the international system.	In the second row, include appropriate references to IAF and ILAC mutual recognition arrangements.
Line 277/278	Clarification and linking to the introductory paragraph comments.	The following sections cover many conformity assessment activities used to determine whether an object of conformity meets specified requirements.
Line 294/296	SDoC is applicable to all types of conformity assessment.	ISO/IEC 17050-1:2004 "Conformity assessment – Supplier's declaration of conformity – Part 1: General Requirements" (ISO 17050-1, 2004) specifies general requirements for a supplier's declaration of conformity of

		an object to the specified requirements be attested, irrespective of the sector involved. The object of a declaration of conformity can be a product, process, management system, person or body.
Section 3.2	The section does not describe inspection as a type of conformity assessment activity.	Add after line 219 - "ISO/IEC 17020 defines requirements for the operation of various types of bodies performing inspection. The broad definition of inspection in the standard allows great flexibility in application from systems to services and raw material to finished products."
lines 320/327	Unless it is conducted under the IAF-ILAC model, there is no guarantee that the activity is not conducted by a first, second, or third party. In 3.1, 3.3, and 3.4 the focus is on third party.	Delete the following paragraph. "Inspection can be performed by first, second, or third parties."
Section 3.4.	Product certification is a type of certification, equivalent to management systems and personnel.	Identify as a subsection of section 3.4. 3.4 Certification: 3.4.1 Product Certification 3.4.2 Management Systems Certification 3.4.3 Personnel Certification
Lines 394 and 402	Third-party conformity assessment activities such as testing and inspection services are also used when risk associated with the object of assessment nonconformity elevated. The concepts introduced in this section are applicable to all types of third-party conformity assessment programs including management systems certification, inspection, testing, etc.	Replace "certification activities" with "third-party conformity assessment activities" in line 394. Line 400 replace "product" with "object of conformity assessment". Move section to before section 3.2 as an introduction to third-party conformity assessment activities.
Lines 421 to 441	This information is applicable to all types of certification.	Move to the beginning of the section 3.4.

Section 3.4.1	"Certification bodies" is more widely used globally than "Registrars" and even in the United States certification bodies is preferred. Information on management systems certification is lacking.	Suggested revisions: The certification of management systems is sometimes referred to as registration. Management system certification is conducted by third-party . A management system is the way in which an organization manages the inter-related parts of its business in order to achieve its objectives. These objectives can relate to product or service quality, operational efficiency, environmental performance, health and safety in the workplace, and many more. ISO/IEC 17021-1 contains principles and requirements for the competence, consistency, and impartiality of bodies providing audit and certification of all types of management systems. The management systems certification process involves assessing the compliance of documented policies and procedures with management system requirements according to a specific scope. At a minimum, an annual audit of the implementation of the system requirements to the scope is conducted on a continuing basis. Certification bodies issue certificates and publish lists of certified organizations and their scopes of certification. Management system standards have been published by ISO relating to quality, security,

		environmental, food safety, energy performance, anti-bribery, and other industry-specific operations. Such as some of the most commonly used management system standards are: ISO 9001, *Quality management systems – Requirements with Guidance for use* ISO 14001 *Environmental management systems -- Requirements with guidance for use* ISO 22000, *Food safety management systems - Requirements for any organization in the food chain* ISO 27001, *Information technology - Security techniques - Information security management systems - Requirements* In addition, many industries and government agencies have used an ISO-developed management system standard and added industry-specific requirements (e.g., the International Aerospace Quality group with the AS 9100, Quest Forum with TL 9000 program for the telecommunications industry, and DoE through the Superior Energy Performance program).
Section 3.5:	The paragraph incorporates ISO/IEC 17011 and a description of the IAF-ILAC peer evaluation model that is only based on third-party oversight.	Revise as follows: There are accreditation programs conducted by third parties for testing laboratories, inspection bodies, and certifiers.
Figure 3:	Missing references.	Include other conformity assessment standards such as ISO/IEC 17021-1 and ISO/IEC 17024. Update the bottom of the pyramid to include facilities and systems.

Line 502	The first sentence is incorrect as there is not place within accreditation for peer evaluation; the intent of accreditation is independent oversight.	Separate accreditation from the rest of the paragraph.
Line 502 to 512	The paragraph appears to include peer evaluation systems among CABs as well as ABs. There are two systems in place for peer evaluation: the IAF-ILAC systems for accreditation bodies and some schemes where CABs peer evaluate one another such as the IECex scheme. The IAF-ILAC model is widely accepted and recognized by many governments and industries.	If the intent is to describes both, the difference between the two should be clarified and explained in detailed as the two are very different from each other.
Line 510	The reader with background in conformity assessment may read the reference to "organization" and not think it includes entities such as industry, associations, etc.	Replace reference to "organization" with "specifier" and link to the bullets that follow the paragraph for examples of a specifier.
Line 529	ISO/IEC 17067 is specific to product certification. Schemes are applicable to all types of conformity assessment bodies and conformity assessment programs.	Remove reference to ISO 17067.
Line 539/542	Missing references.	Factors to be considered include the type of conformity assessment activities and specific requirements to be met, such as testing laboratories meeting the requirements of ISO/IEC 17025; inspection bodies and ISO/IEC 17020; certification bodies and ISO/IEC 17021-1, ISO/IEC 17024 or ISO/IEC 17065; and use of supplier declaration of conformity per ISO/IEC 17050 …
Line 548 to 555.	It would be best to use an example of a government program where third-party accredited conformity assessment services and international conformity assessment standards are used. OSHA program does not address either one of these points. This approach would be in line with the NTTAA and OMB A119.	Include examples of a program to align with the intent of NTAA and OMB A119.

Section 5:	This section needs to include information on IAF, ILAC, and regional cooperations such as IAAC. These cooperations play a crucial role in the overall third-party conformity assessment system. The section should include a discussion on the oversight of ABs, ILAC and IAF. The document should illustrate the difference between how ABs operate as ILAC and IAF members versus ABs that do not participate, as there is a significant difference.	**Suggested text below:** The IAF and ILAC mutual recognition agreements are internationally recognized forms of approval; signatories have demonstrated their conformance with specified standards and requirements. Accreditation by a signatory of the ILAC MRA and/or IAF MLA provides assurance that decisions are based on reliable results, thus minimizing risk. The International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) provide this international oversight. ABs that are signatories of the ILAC and/or IAF mutual recognition agreements (MLAs or MRAs) must conform with the requirements of ISO/IEC 17011 as applicable program-specific requirements, and are admitted to the agreements for a specific capability, for example, as an accreditor for testing labs or for management systems certification bodies. Technical competence of the AB and conformance to the requirements is verified through rigorous on-site evaluation by other members of the IAF or ILAC community. This evaluation provides evidence or confirmation that an AB operates in accordance with international requirements when providing oversight of accredited CABs. It also provides assurance that the AB understands the CAB's process and can attest to the CAB's competence.

Thank you for the opportunity to provide input. ANAB will gladly provide advice and reasoned input based on our relevant experience as a global accreditation body.

Respectfully,

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