



SUBMITTED ELECTRONICALLY VIA EMAIL TO SP2000-01@NIST.GOV

February 26, 2018

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

Dear Ms. Phelps,

On behalf of UL LLC, I am pleased to submit comments with respect to the National Institute of Standards and Technology's (NIST) request for comments on *NIST Special Publication 2000-01: ABC's of Conformity Assessment*.

UL is a global, independent, safety-science company that has championed progress and safety for more than 120 years. Guided by our mission, UL's 14,000 professionals promote safe working and living environments for all people. UL uses research, standards, and conformity assessment to continually advance and meet ever-evolving safety challenges, and partners with businesses, manufacturers, retailers, trade associations, and international regulatory authorities to provide solutions and to address the risks of increasingly complex global supply chain.

UL supports NIST's efforts to modernize the *ABCs of Conformity Assessment* (hereafter *ABCs*) to ensure that this publication, originally published in 1997, accurately reflects the current landscape for conformity assessment. While UL understands that US federal agencies are the primary audience for this publication, as well as the accompanying *Conformity Assessment Considerations for Federal Agencies* (SP 2000-02), NIST also rightly acknowledges that other stakeholders – including manufacturers, conformity assessment bodies, service providers, trade associations, non-governmental organizations, etc. – may use or rely on precepts in this document. For this reason, accuracy is paramount.

From UL's perspective, the *ABCs* could be improved and made more effective by providing an accurate description of what conformity assessment is/is not and why it is so prevalent. If the purpose of the document is to provide a basic introduction to conformity assessment, the *ABCs* should be made more basic and the level of detail contained in the current draft is unnecessary. If, however, NIST is trying to provide a more detailed and thorough introduction of conformity assessment concepts to agency personnel requiring a relatively complete comprehension of the basics, then corrections are needed.

UL has identified five primary concerns with the *ABCs* as drafted:

1. The document perpetuates the misconception that conformity assessment *ensures* that specific products, processes, services, systems, persons or bodies *always* fulfill requirements. It wrongly implies that conformity assessment *guarantees* compliance when, in actuality, it provides assurance by creating an incentive to fulfill requirements.
2. The document incorrectly indicates that the "parties" related to conformity assessment are the same as the "parties" in the buy-sell transaction for the object of conformity assessment. Further, the document separates out government as if government entities fall outside first, second, or third parties. While UL agrees with NIST that government plays a "unique role in regulation" (Fig. 1), it usually acts as a second party or, in some instances, a third party (rarely a first party).

3. The document confuses rather than clarifies the differences between attestations and other conformity assessment activities on which attestation is based. While this is explained in ISO/IEC 17000 Annex A, the proposed *ABCs* are not aligned.
4. The document incorrectly states that accreditation is applicable to programs/schemes. Accreditation by definition only applies to conformity assessment bodies; the fulfillment of specified requirements by schemes/programs is not part of accreditation.
5. As drafted, the *ABCs* (and similarly, the *Considerations*) fails to take a neutral approach in describing methods of conformity. Nowhere is this more blatant than in the use of language in Section 3.1 to describe Suppliers Declaration of Conformity (SDoC) as “a “trade-friendly approach” without providing broader context of the intersection of conformity assessment and international trade. The *ABCs* is not the right place for debating the merits of SDoC versus second party or third party; the purpose of discussing the types of conformity assessment is not to promote one over another, but to reinforce the principle that different methods exist and are applied based on what is needed to manage risks and reach the level of confidence needed for the situation. In this respect, the *Considerations* document would be the more appropriate venue to identify the types of questions agencies should consider when selecting methods of conformity.

UL appreciates the opportunity to provide recommendations to NIST for improving the *ABCs of Conformity Assessment*. UL supports NIST’s efforts to modernize this outdated document and provide a better understanding of conformity assessment concepts to federal agency personnel responsible for considering, developing, operating, and using conformity assessment programs. While well-intentioned, the current *ABCs* falls short of its goal and NIST should reconsider the approach it has taken. In proceeding to final publication of this document, UL strongly recommends that NIST give careful consideration to providing an accurate description of what conformity assessment is/is not and offering context for why it is so prevalent. Absent that, UL offers specific recommendations in the attached Appendix to help resolve inaccuracies in the aforementioned areas. In addition, UL recommends that NIST review resources developed by the private sector (such as UL’s series of courses on “Conformity Assessment Essentials”) for consideration as potential training tools for federal agencies. UL would be happy to discuss access to our materials with you.

Again, thank you for giving the conformity assessment stakeholder community and the general public the opportunity to review and comment on the *ABCs* and the companion *Considerations*. UL looks forward to continuing to collaborate with NIST to help support federal agencies in their development, operation, and use of conformity assessment programs. Please do not hesitate to contact me if you have any questions regarding these comments.

Sincerely,



Ann M. Weeks
Vice President, Global Government Affairs
UL LLC
1850 M Street NW, Suite 1000
Washington, DC 20036
Email: Ann.Weeks@ul.com
Phone: +1 202.296.1435

Appendix – Specific Recommendations:

1. Introduction:

Recommendation #1: On line 148 after “fulfilled”, add a footnote that would read as follows: “In this document, while ‘product’ is frequently used the statements apply equally to processes, services, systems, persons or bodies.”

- Rationale: This will reinforce the user’s understanding that conformity assessment is not limited merely to product conformity, but could be used as a demonstration that requirements around processes, services, systems, persons, or bodies are fulfilled.

Recommendation #2: On line 149, change “ensuring” to “assuring”.

- Rationale: As stated in point 1 under the General Observations outlined previously, the document perpetuates the misconception that conformity assessment *ensures* that specific products, etc. *always* fulfill requirements. Modifying this language to “assuring” properly denotes the purpose of conformity assessment, which is to provide *assurance* by creating an incentive to fulfill requirements.

Recommendation #3: On line 153, after “competence” insert “of the bodies/organizations performing” before “those activities...”.

- Rationale: UL proposes this language to help correct the concern we outlined in point 4 in our “General Observations.”

Recommendation #4: Instead of the footnote on page 17 of the document, on line 154, after “third party” add a footnote to read as follows: “The collection of all activities that are repeatedly applied to a specified group of products, processes, services, systems, persons or bodies is referred to as a ‘conformity assessment program’ or ‘program’ in this document. Internationally, ‘programs’ are usually referred to as ‘schemes.’”

- Rationale: This proposed footnote would help more clearly define what conformity assessment is and bridge the gap between how NIST is describing conformity assessment concepts and how such concepts are defined and considered globally.

Recommendation #5: On line 155, modify the phrase “operate distinctly” to “are operated distinctly.”

- Rationale: This proposed edit would reinforce that conformity assessment is a body operating a scheme.

Recommendation #6: On line 156, strike “quality” and replace with “competence, consistency and impartiality.”

- Rationale: Modifying the language as suggested will incorporate internationally-accepted terminology used to describe conformity assessment activities.

Recommendation #7: On line 162, after “products” add “processes, services, systems, persons or bodies”.

- **Rationale:** This will reinforce the user's understanding that conformity assessment is not limited merely to product conformity, but could be used as a demonstration that requirements around processes, services, systems, persons, or bodies are fulfilled.

Recommendation #8: On line 170, strike "verify" and replace with "assure".

- **Rationale:** UL proposes this language to correct the concern we outlined in point 1 under our "General Observations." Again, conformity assessment exists to provide *assurance* by creating an incentive to fulfill requirements. The use of the word "assure," in lieu of "verify," would better align with ISO/IEC terminology used to describe conformity assessment.

Recommendation #9: On line 181, after "impartiality" add "consistency".

- **Rationale:** Modifying the language as suggested will incorporate internationally-accepted terminology used to describe conformity assessment activities.

2. Role of Standards in Conformity Assessment:

Recommendation #10: Edit lines 223-227 to read as follows (*Text recommended to be deleted is indicated by strikethrough; text recommended to be added is indicated by underline*):

Standards are vital tools of industry and commerce promoting an market understanding, for example, between purchasers and sellers ~~and, thus~~ enabling mutually beneficial commercial transactions. Information on a product's conformance (or nonconformance) to a particular standard or technical regulation can provide an efficient method of conveying information needed by a purchaser and other interested parties on the product's safety and suitability."

- **Rationale:** The use and benefits of standards goes beyond buyers and sellers, just as the concepts of first, second, and third parties in conformity assessment go far beyond buyers and sellers.

3. Conformity Assessment Concepts:

Recommendation #11: Edit lines 257-265 to read as follows (*Text recommended to be deleted is indicated by strikethrough; text recommended to be added is indicated by underline*):

In addition to information on the standards used, those who rely on conformity assessment results also need to know and understand which types of conformity assessment activities were included in the ~~process~~ conformity assessment program. Conformity assessment examines an object of assessment (such as a product, process, service, or person) and ~~evaluates~~ demonstrates whether the object meets specified requirements. A ~~determination~~ decision whether fulfillment of requirements has been demonstrated is made based on evidence of conformity (such as a test report, inspection report, or audit). ~~An organization may attest to this conformity based on a determination. An attestation that fulfillment has been demonstrated is issued based on the decision.~~ Support for on-going ~~conformity of the object~~ validity of the attestation is accomplished through surveillance. Accreditation provides confidence that conformity assessment ~~programs and organizations~~ bodies meet requirements.

- **Rationale:** These proposed changes are an attempt to address what is at the heart of UL's concerns about the ABCs document as drafted. To provide a true introduction to conformity assessment concepts, accuracy is critical and NIST should rely on internationally accepted

and used terminology. This will help eliminate confusion about what conformity assessment is (a demonstration) and is not (a guarantee).

Recommendation #12: Figure 1 should be amended as follows:

1. In the “First Party” box, after “or” add “any individual” before the word “organization.” After the word “organization,” add the phrase “with the same interests in the object of conformity assessment”.
 2. In the “Second Party” box, after “user” add the phrase “or any individual or organization with a need for assurance that specified requirements are fulfilled”.
 3. In the “Third Party” box, strike the phrase “An independent entity that has no interest in” and replace with “Individual or organization whose interests are independent of”.
 4. Delete the box for “Government” altogether and add a sentence separate from the figure that denotes government’s unique role in regulation and potential roles (i.e., rarely a first party, usually a second party, sometimes a third party).
- Rationale: Modifications to the boxes for “First Party,” “Second Party,” and “Third Party” in Figure 1 will provide greater alignment with internationally accepted and used conformity assessment terminology. In addition, these changes will help correct the concerns outlined in point 2 in UL’s “General Observations” as previously noted.

Recommendation #13: Remove Figure 2 (“Conformity Assessment Standards”) altogether.

- Rationale: Only the third row of the table provides useful information based on the text immediately preceding it.

Recommendation #14: On lines 277-278, strike the phrase “determine whether” and replace with “demonstrate”.

- Rationale: UL proposes this language to correct the concern we outlined in point 1 under the “General Observations” outlined previously. Again, conformity assessment exists to provide *assurance* by creating an incentive to fulfill requirements. The use of the phrase “determine whether” implies a guarantee, rather than a demonstration, of conformity.

3.1. Suppliers Declaration of Conformity

Recommendation #15: Edit lines 281-288 to read as follows (*Text recommended to be deleted is indicated by strikethrough; text recommended to be added is indicated by underline*):

One way to ~~show~~ attest that a product, process, ~~or service, system, person or body~~ conforms to specific requirements is through supplier’s declaration of conformity (SDoC), which is a “declaration” as defined in ISO/IEC 17000:2004 (ISO 17000, 2004), ~~i.e., a first party attestation, where the supplier provides written confidence of conformity.~~ The supplier makes a declaration that requirements have been met based on:

- ~~the manufacturer’s confidence in the quality control system, and/or~~
 - the results of testing, inspection, or audits undertaken by the manufacturer or other parties on its behalf.
- Rationale: UL proposes these edits to improve accuracy of the description of SDoC as a method of conformity. As the text states, SDoC is, by definition, an attestation. ISO/IEC 17000 indicates an attestation is always based on determination function activities and would never be based on an assumption, regardless of the efficacy of the quality management system.

Recommendation #16: On line 290, strike “This form of” to begin the sentence with “Declaration is generally used...”. Replace the word “risk” with “consequences (accounting for risk)”.

- Rationale: SDoC is not a “form” of a “declaration” – SDoC and “declaration” are one in the same. Also, the consequences of noncompliance take into account the relative risk of noncompliance.

Recommendation #17: On line 301, before the word “testing” insert “reports of”.

- Rationale: Testing is an activity. Attestation is based on the *results* of activities. In addition, these changes will help correct the concerns outlined in point 3 in UL’s “General Observations” as previously noted.

Recommendation #18: On line 302, strike the sentence “Reliance upon an SDOC is considered a trade-friendly approach.”

- Rationale: The ABCs document should be used to introduce conformity assessment concepts in a neutral, unbiased way, and is not the appropriate place to debate the merits of SDoC versus second party or third party conformity assessment. In using this language in the description of SDoC, NIST implies judgment that this method of conformity assessment is preferential to others and could prejudice the reader/user of the document. In reality, the method of conformity is dependent upon what regulations have determined is needed and/or what markets demand in the way of confidence. Fundamentally, conformity assessment is designed to overcome confidence concerns and demonstrate fulfillment of requirements for products, processes, services, systems, persons, or bodies.

Recommendation #19: On line 306, after the phrase “allows manufacturers to” add “perform activities themselves or” before “use conformity assessment bodies”.

- Rationale: Addition of this phrase clarifies common options manufacturers have when using an SDoC approach to demonstrate conformity.

Recommendation #20: On line 308, end the sentence after “produced”. Begin the next sentence with “Both reduce”.

- Rationale: This proposed edit will emphasize that both factors contribute to reducing time and costs.

3.2. Inspection:

Recommendation #21: At line 320, insert information about ISO/IEC 17020 comparable to the information about ISO/IEC 17025 at line 347.

- Rationale: Discussion of the related ISO/IEC 17xxx series standard should be included in all of these types of sections to provide optimal alignment.

Recommendation #22: On line 322, after “drawn” insert the following sentence: “Per ISO/IEC 17000, inspection is an activity to develop information about the object’s fulfillment of requirements. It does not include an attestation. Rather, inspection is used as a basis for an attestation.”

- **Rationale:** This proposed modification helps address point 3 as outlined in UL's "General Observations" and adds clarity to the definition of "inspection" in the ABCs.

Recommendation #23: On line 330, strike the phrase "acceptability against" and replace with "fulfillment of".

- **Rationale:** Use of the proposed phraseology will provide greater alignment with internationally accepted and used conformity assessment terminology.

Recommendation #24: Edit lines 337-340 to read as follows (*Text recommended to be deleted is indicated by strikethrough; text recommended to be added is indicated by underline*):

~~Inspection may also utilize product marking to attest to the conformity of inspected products. For example, the U.S. Department of Agriculture ensures that inspects meat and poultry products are correctly labeled and packaged~~ for fulfillment of labeling and packaging requirements.

- **Rationale:** The purpose of the recommended edits is to remove confusion around the relationship between "inspection" and "attestation" (per point 3 in UL's "General Observations") and to more accurately align the text with internationally accepted and used language on conformity assessment as a demonstration of fulfillment of requirements.

3.3. Testing:

Recommendation #25: On line 342, strike the word "laboratories" and change "support" to "supports".

- **Rationale:** Testing in and of itself supports diverse industries; laboratories are merely the means of conducting such tests.

Recommendation #26: On line 374, after "activity" insert the following sentence: "Per ISO/IEC 17000, testing is an activity to develop information about the object's fulfillment of requirements. It does not include an attestation. Rather, testing is used as a basis for an attestation."

- **Rationale:** This proposed modification helps address point 3 as outlined in UL's "General Observations" and adds clarity to the definition of "inspection" in the ABCs

3.4. Certification:

Recommendation #27: On lines 389-390, strike "that operate conformity assessment programs".

- **Rationale:** This qualifying phrase is unnecessary. ISO/IEC 17065:2005 at its core defines general requirements for certification bodies to ensure competence, consistency, and impartiality. By their very nature, certification bodies perform conformity assessment activities.

Recommendation #28: Edit lines 394-402 to read as follows (*Text recommended to be deleted is indicated by strikethrough; text recommended to be added is indicated by underline*):

~~Certification activities are conducted~~ (the actual attestation) is issued only by a third-party and ~~are~~ generally used when the risks associated with the object of assessments non-conformity are moderate to high. This provides a higher level of confidence in compliance ~~to purchasers and users~~ due to third-party's decision-making process being free from any influence

~~between~~ from the first and second parties. ~~Certification a~~Activities on which certification is based include the following:

- Evaluation of evidence of conformity;
 - Determination whether product complies;
 - Attestation of conformity granted (i.e., certificate issued); and
 - Surveillance and/or ongoing renewal process, although this may be optional, depending on the certification program.
- Rationale: These proposed edits are designed to ensure greater accuracy and alignment with internationally accepted terminology and norms for conformity assessment.

Recommendation #29: On line 404, after “Certification” insert the phrase “programs are usually designed to” and change “provides” to “provide”.

- Rationale: The entire program operated by a competent body is what provides confidence/assurance. This change will reinforce the contribution of both.

Recommendation #30: Edit lines 409-411 to read as follows (*Text recommended to be deleted is indicated by strikethrough; text recommended to be added is indicated by underline*):

The attestation or statement by a certification body is based on decisions made following review of evidence that fulfillment of requirements ~~have~~ has been demonstrated ~~met~~. The attestation ~~may be~~ is based on other conformity assessment activities.

- Rationale: These edits are intended to bring the ABCs into greater alignment with internationally accepted and used conformity assessment terminology.

3.4.1. Management System Certification:

Recommendation #31: On line 447, strike the phrase “in compliance with” and replace with “as a demonstration of fulfillment of”.

- Rationale: These edits are intended to bring the ABCs into greater alignment with internationally accepted and used conformity assessment terminology.

Recommendation #32: Edit lines 458-459 to read as follows (*Text recommended to be deleted is indicated by strikethrough; text recommended to be added is indicated by underline*):

An audit is conducted of the implementation of the ~~system requirements to that~~ policies and procedures for the scope on a continuing basis.

- Rationale: The purpose of this edit is to properly show the relationship of the policies/procedures and their implementation.

3.4.2. Personnel Certification:

Recommendation #33: On line 468, strike the phrase “in a consistent and comparable way” and replace with “with competence, consistency, and impartiality”.

- Rationale: This recommended edit is designed to bring consistency in use of conformity assessment terminology throughout the ABCs document.

Recommendation #34: Strike lines 469-472 in their entirety.

- Rationale: This statement is not true – personnel certification can use evaluation techniques other than examinations. Incorrect statements should not be included in this document.

3.5. Accreditation

Recommendation #35: On line 482, strike the words “programs and”.

- Rationale: This edit is intended to help address the concern we raised in point 4 in our “General Observations.” The document incorrectly states that accreditation is applicable to programs/schemes. Accreditation by definition only applies to conformity assessment bodies; the fulfillment of specified requirements by schemes/programs is not part of accreditation.

Recommendation #36: Change line 488 from “activities include tasks” to “applies to bodies performing activities”.

- Rationale: Accreditation does not “include” the tasks cited; it applies to the bodies performing those activities. Incorrect statements should not be included in this document.

Recommendation #37: On line 492, strike the word “system” and replace with “body”. Similarly, on line 494 strike the word “systems” and replace with “bodies”.

- Rationale: This edit is intended to further help address the concern we raised in point 4 in our “General Observations.” Accreditation by definition only applies to conformity assessment bodies, not systems.

Recommendation #38: Strike lines 495-499 in their entirety and replace with the following sentence: “The requirements used in accreditation of conformity assessment bodies create a type of hierarchy (refer to Figure 3).”

- Rationale: This edit is designed to simplify the description, as Figure 3 speaks for itself.

Recommendation #39: On line 502, strike the phrase “within accreditation”. After “confidence,” strike the word “among” and insert the phrase “about the fulfillment of requirements by”.

- Rationale: This recommended edit is intended to bring greater consistency and accuracy in the use of internationally accepted conformity assessment language.

Recommendation #40: Edit lines 503-505 to read as follows (*Text recommended to be deleted is indicated by strikethrough; text recommended to be added is indicated by underline*):

Peer assessment is an organized system used at regional and international levels to provide increased confidence that accreditation bodies or conformity assessment bodies ~~are~~ meet competent competence and operating under the defined requirements.

- Rationale: Peer assessment is a conformity assessment activity and thus relates to fulfillment of requirements, not judgment about competence separate from requirements.

Recommendation #41: Edit lines 511-512 to read as follows: “the need for additional testing, inspection, ~~or~~ certification, or accreditation in different countries to which the object of assessment is sold”.

- Rationale: This change would reinforce that peer assessment applies to reducing demand for accreditation.

4. Scheme Ownership:

Recommendation #42: On line 532, replace “products, processes and services” with “certification of products”.

- Rationale: ISO/IEC 17067 does not address schemes for certification of processes and services.

If you have any questions regarding these recommendations, please contact Sarah Owen, Global Government Affairs Manager, at sarah.owen@ul.com or +1 202.530.6163.