

February 26, 2018

Ms. Lisa Carnahan and Ms. Amy Phelps  
Standards Coordination Office  
National Institute of Standards and Technology  
100 Bureau Drive  
Gaithersburg, MD 20899

Re: NIST's "Draft Conformity Assessment Considerations for Federal Agencies" (Special Publication 2000-02)  
and "Draft ABC's of Conformity Assessment" (Special Publication 2000-01)

Dear Lisa and Amy,

The American Council of Independent Laboratories (ACIL), founded in 1937, is the trade association representing independent, commercial scientific and testing laboratories. Its members are professional services firms engaged in testing, product certification (including medical devices), consulting, and research and development, including several internationally accredited organizations and their laboratory partners. Affiliated membership is available to manufacturer's laboratories, consultants, and suppliers to the industry.

ACIL commends and thanks NIST for the transparency and outreach to stakeholders that have been employed in this effort. From the NIST Workshop for Developing Conformity Assessment Guidance in early 2017, the publishing and opportunity to comment on these drafts, and all of the formal and informal encouragement and communication in soliciting stakeholder engagement along the way, ACIL views NIST's approach as a best practice of government engaging stakeholders to develop meaningful guidance.

ACIL believes addressing and incorporating the feedback below will enhance what is already a thoughtful pair of guidance documents for Federal Agencies. We commend NIST for taking on this difficult task of establishing a tool that can be leveraged for facilitating public-private engagement and strengthen confidence in the United States' conformity assessment programs, which in turn strengthens our position for international trade.

Respectfully,



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See Attachment – ACIL Concerns

## **ACIL Concerns Regarding NIST Draft Conformity Assessment Publications**

Given the interrelationship between the two documents, ACIL is submitting this combined response for both NIST's "Draft Conformity Assessment Considerations for Federal Agencies" (Special Publication 2000-02) and "Draft ABC's of Conformity Assessment" (Special Publication 2000-01).

### **Clarify the intended usage and interrelationship of the two documents, better define the expectations for and definition of conformity assessment, eliminate redundancy, and guide agencies to decisions:**

ACIL suggests that the "ABCs" document act as a primer for those agency personnel not familiar with conformity assessment. The aim is to help them understand the concepts before attempting to use to "Considerations" document as guide for developing a conformity assessment program.

With that aim in mind, the ABCs document should provide an accurate description of what conformity assessment is and is not. Conformity assessment is not a guarantee or a control – it is a demonstration that creates an incentive for compliance. The document(s) should not wrongly imply that conformity assessment guarantees or ensures compliance.

The core content of the Considerations document begins on line 826 with Defining the Conformity Assessment Model. We recommend reorganizing the document to begin with the definition of the model. Prior to line 826, much of the text is a regurgitation of the ABC's of conformity assessment. We suggest referencing to the ABCs document to eliminate redundancy, reduce the size of the Considerations document, and create a better interrelationship between the two.

The Considerations document also ends prematurely. It doesn't offer conclusions to help agencies make their choices. This is a missed opportunity because the conclusion could be developed into a checklist or set of guiding questions for agencies to use when determining the appropriate conformity assessment system to develop. Without this, an agency considering a conformity assessment program would have a lot of information, but not the steps to guide them to decisions.

## **Remove and avoid unnecessary bias regarding supplier's declaration of conformity (SDoC), government laboratories and public versus private sector solutions:**

The ABCs document should not be used to promote one method of conformity assessment over another (e.g. debating the merits of SDoC/first-party versus second-party or third-party). The purpose of discussing the types of conformity assessment is to reinforce the principle that there are different avenues/types, the reason for which is because they deliver different levels of assurance and are applied based on what is needed to manage risks and instill the necessary level of confidence.

The Considerations document would be a more appropriate place to identify the types of questions agencies should consider when selecting methods of conformity (see above comment about developing a conclusion to the Considerations document). However, again, this should not be about debating the merits of one method over another, but about guiding agencies to apply some criteria/considerations that are helpful to evaluate when making those decisions.

There are several other examples of public sector bias and bias toward particular methods of conformity assessment. ACIL strongly requests the following bias be amended:

The testing sections of the documents present a bias to government/university labs for testing, when private sector laboratories provide more abundant and often more cost-effective capabilities; in most cases, private sector labs assessed as to their competency by an accrediting body. This should be changed to provide a neutral description of laboratories instead of predominantly highlighting government laboratories. By doing so, NIST would reinforce the directive and spirit of Office of Management and Budget (OMB) Circular A-119, which points agencies to rely on private sector standards and conformity assessment activities in lieu of government-unique standards/programs unless it is impractical or otherwise inconsistent with the law.

Within section 3.3 of the ABCs document is an example of the bias in the document ACIL is identifying with the first choice in the list of labs are all government or government supported labs (highlighted in bold italics). The "also" list is clearly delegated to second class citizenship.

"Testing can be performed by first, second, or third parties as well as by laboratories differing widely in size, legal status, purpose, range of testing services offered and technical competence. ***They may be government regulatory laboratories, government research laboratories, or government supported laboratories. They can also be college/university laboratories,*** private sector laboratories,

laboratories affiliated with or owned by industrial firms or industry associations, or manufacturers' in-house laboratories."

The blanket statement "reliance upon SDoC is considered a 'trade-friendly' approach to conformity assessment." is inaccurate. SDoC should not be highlighted as a preferred solution, but equally balanced with descriptions of 2nd and 3rd party conformity assessment. Here is our desired change:

- SDoC, 2nd party or 3rd party is dependent upon what regulators have determined is needed and/or what markets demand by way of confidence. Fundamentally, conformity assessment is designed to overcome confidence concerns to bring objects of conformity assessment to market.
- When SDoC is enough to satisfy confidence needs, there is not a market for third-party to provide services; conversely, where greater confidence is needed, SDoC does not solve that issue.

Lines 607 through 610 of the ABCs document should be revised to take into account recognition by others means than peer evaluation. While organizations such as International Laboratory Accreditation Cooperation (ILAC) use this process, others, such as the North American Laboratory Accreditation Cooperation (NACLA) use paid assessors to conduct evaluations but also meets the requirements of ISO/IEC 17011. Again, the language should be balanced to represent that there are different solutions that provide different levels of benefit and costs that should be chosen based on the risks they are intended to mitigate.

We encourage NIST to balance the appropriate use of the example of the OSHA NRTL program (e.g. ABCs document Page 18). While it is an example of saving costs by leveraging third party certification, it does not leverage private sector capabilities for third party accreditation, instead it is performing its own first party evaluations of its certifiers.

Throughout both documents, the language used is predominantly product focused. This excludes that conformity assessment methods and approaches can be used to provide confidence for services, processes and systems as well. These can collectively be generalized and defined (in the ABCs document) as the "object of conformity assessment". Since product is intuitive, the definition could benefit from the inclusion of an example for system and personnel certification.

## **Correct deviations from international norms, out of date references, and incomplete descriptions of aspects of conformity assessment:**

Language within both documents deviates from international norms. Consideration should be given to consistently using ISO principles. For example: the “Government” callout in ABCs visual (page 10) as something equally defined as 1st party, 2nd party, 3rd party, etc. is not aligned with ISO principles. We agree government has a unique role as a regulator, which could be called out in a different fashion (e.g. a general sentence as opposed to its own unique “box”).

In figure 2 on Page 10 of the ABCs document, there are out of date terms and standards used: The term “registrars” is no longer used, and has been replaced with “Management Systems Certification Bodies”. Their corresponding standard is now ISO/IEC 17021-1. This table is missing Personnel Certification Bodies / ISO/IEC 17024. The box with ISO/IEC 17065 should be labeled “Product Certification Bodies”.

In the ABCs document, Section 3.2, Inspection, should reference ISO/IEC 17020, which 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.

In Section 3.4 of the ABC’s document, Product Certification should be established as its own subsection on Page 13. The way it is currently written, Management Systems and Personnel appear to be a subset of product, which is incorrect. Similarly, Lines 321 through 341 on Page 15 are applicable to management systems and personnel certification as well. We suggest moving these to the beginning of 3.4 to follow definition of certification as per ISO 17000 and include examples from other program besides product certification in the last bullets (lines 436-441).

In the ABCs document, Line 444, the term “registration” is no longer used. This should be removed or made to be in past tense.

Throughout both documents, to prevent out of date references, when referencing ISO and IEC standards, it’s suggested to remove the dates from the standards as they are revised on a periodic basis (typically every five years).

In the ABCs document, Page 18, Figure 3 should be updated to include other standards such as 17021-1 and 17024. The bottom of the pyramid should also list facilities and systems.

In the ABC’s document, Section 5 should include examples and information on IAF/ILAC and regional co-operations such as IAAC and NACLA.