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

Ref: IFIA comments on the *“Draft ABC’s of Conformity Assessment”*

Dear Ms. Phelps,

The International Federation of Inspection Agencies (“IFIA”) is pleased to provide comments on the *“Draft ABC’s of Conformity Assessment”*.

IFIA is a trade federation that represents over 60 of the world’s leading independent third-party testing, inspection and certification (TIC) companies. IFIA members offer conformity assessment services, including testing, inspection, certification, systems audits, advisory and training, technical and documentary support. These services help manufacturers gain global market access and help ensure that not only regulatory requirements are fulfilled, but also that reliability, economic value, environmental impact and sustainability are enhanced.

We appreciate the opportunity to offer the following comments and look forward to continuing the discussion and supporting NIST’s efforts.

Sincerely,



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General comments:

IFIA applauds NIST's extensive efforts to consult stakeholders throughout the process of updating the ABC's of Conformity Assessment. This document is a relevant resource for agencies and stakeholders who need to understand the fundamentals of conformity assessment before developing conformity assessment programs. However, IFIA has some concerns with the ABC's document:

- 1) language wrongly implying that conformity assessment guarantees or ensures compliance;
- 2) deviation from international norms as opposed to consistent use of ISO/IEC standards and principles;
- 3) lack of method - neutrality by promoting specific methods of conformity;
- 4) unnecessary emphasis on government-run laboratories; and
- 5) incomplete consideration of international trade aspects.

IFIA recommends that NIST remove any overlap of content between the Considerations and the ABCs documents, since the ABCs is an accompanying document to the Considerations. The ABCs should focus on providing a user-friendly overview of key conformity assessment concepts. The Considerations document should not repeat those concepts but focus on identifying the types of questions/criteria agencies should consider when selecting methods of conformity. Both documents should clearly convey that **there are different avenues for demonstrating compliance**, and **each of these avenues deliver different levels of assurance** which are applied based on what is needed to manage risks and have the level of confidence needed for a given situation.

The document should be rewritten to remove any language that portrays one method as preferential or more "trade-friendly" than another. As a non-regulatory agency, NIST should be "**method-neutral**" in its approach to coordinating conformity assessment in the United States.

Also, the language in the documents seem to conflate methods of conformity with conformity assessment activities and some of the descriptions are not based on international standards. We recommend alignment of the document with the vocabulary and definitions in the ISO/IEC 17000 series.¹ While IFIA understands that US federal agencies are the primary audience for this publication, NIST has acknowledged that other stakeholders – including manufacturers, conformity assessment bodies, service providers, trade

¹ <https://www.iso.org/obp/ui/#iso:std:iso-iec:17000:ed-1:v1:en:sec:3.1>

associations, non-governmental organizations, etc. – may use or rely on the precepts in this document. For this reason, accuracy in defining and describing conformity assessment is paramount.

Specific comments on the ABCs:

1) Language wrongly implying that conformity assessment guarantees or ensures compliance

Line 149: use of the word “ensure” wrongly implies that conformity assessment guarantees or ensure compliance:

“Conformity assessment procedures provide a means of ensuring that the products, services, or systems produced or operated have the required characteristics...”

This is one example of the ABCs’ characterization of conformity assessment as a “guarantee” – there are other similar instances throughout the document that offer an unclear picture of conformity assessment. Conformity assessment is not a guarantee or a control; it is a demonstration that creates an incentive for compliance. The ABCs and Considerations documents should be reviewed to remove any language that implies that conformity assessment guarantees compliance.

2) Deviation from international norms as opposed to consistent use of ISO/IEC principles

Lines 266-268, Fig 1: The inclusion of government as one of the parties that can perform conformity assessment activities along with first, second and third-party is not aligned with ISO CASCO definitions. We recommend sticking to the international definitions based on the ISO/IEC 17000 series and remove government from Fig 1. A note can be added below Fig 1 to elaborate that governments have a unique role in conformity assessment activities related to regulatory requirements and that government is sometimes considered a second party in procurement applications (this should also be corrected in the Considerations document, lines 567-570). This change would keep consistency with ISO/IEC international standards definitions and still note that government has a unique role in conformity assessment.

3) Lack of method - neutrality by promoting specific methods of conformity

As expressed above, the ABCs should focus on providing a user-friendly overview of conformity assessment in a **neutral** manner, without promoting one method over another, and reinforce the principle that **there are different avenues for demonstrating compliance** and **each of these avenues deliver different levels of assurance**.

Conformity assessment is designed to overcome confidence concerns to bring products to market. The appropriate method of conformity (first, second or third-party) is dependent upon regulators' policy goals and/or what markets demand by way of confidence. 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 the use of SDoC would be inappropriate to achieve the goals. We ask that NIST remove all language throughout the document that implies that one method is better than another is; we have highlighted a couple of statements below:

Lines 302-308 states: *“reliance on SDoC is considered a trade-friendly approach to conformity declaration (...) SDoC allows flexibility in the choice of location for conformity assessment activities (...) reducing the cost and time associated with conducting activities”.*

This statement is not true and should be removed or rewritten. This document should not be promoting a specific perspective that one method of conformity is better than another. **In addition, any method of conformity is trade friendly as long as national treatment is provided for conformity assessment bodies.** National treatment can be defined as *“Each Party shall accord to conformity assessment bodies located in the territory of another Party treatment no less favourable than that it accords to conformity assessment bodies located in its own territory or in the territory of any other Party².”* That means that conformity assessment bodies in the exporting country should be authorized to test, inspect and certify certain products in accordance with the legal and technical (standard-based) requirements that apply in the importing country. National treatment helps facilitate trade and time-to-market since manufacturers are free to use the conformity assessment body of their choice and location most appropriate to their business model, instead of having to select from a restricted list of conformity assessment bodies in the destination market only. National treatment also gives regulators greater confidence that requirements are met since regulators would approve the conformity assessment bodies and/or Accreditation Bodies directly instead of via a MRA approach.

In additional, the statement that SDoC is trade-friendly is not consistent with the language on OMB policy Circular A-119, Revised, which states that *“(...) **conformity assessments conducted by private sector conformity assessment bodies can increase productivity and efficiency in government and industry, expand opportunities for international trade, conserve resources, improve health and safety, and protect the environment**”.*

² Trans-Pacific Partnership (TPP) Technical Barriers to Trade Chapter: <https://ustr.gov/sites/default/files/TPP-Final-Text-Technical-Barriers-to-Trade.pdf>

Line 304:

“SDoC (...) reduces the uncertainty associated with mandatory activities by designated conformity assessment bodies as well as associated costs.”

This statement should be removed. A manufacturer may have a higher degree of uncertainty and higher cost regardless of which conformity assessment method is used (SDoC or third-party). In addition, mandatory requirements are not determined by the conformity assessment body but by the program/scheme owner. The conformity assessment body is only determining compliance with the requirements and not imposing additional requirements, as the statement implies.

Costs are driven primarily by the regulatory requirements and not by the method of conformity. Once there is a requirement, there is a need to demonstrate compliance with the requirements. This demonstration can be done either in-house (where the manufacturer has to outfit labs, hire/train engineers, buy/calibrate equipment, etc.) or by a third-party service provider. The costs to demonstrate compliance are about the same whether done in-house or by a third-party; in fact, many times it is less expensive to use a third-party due to economies of scale and technical expertise, which is the reason why companies often rely on third-party conformity assessment service providers to meet their legal obligations even when there is no mandatory requirement to do so. The business cost is compliance and the only way to save costs is to not perform the required conformity assessment that supports demonstration of compliance.

4) Unnecessary emphasis on government-run laboratories

Lines 360-363:

“They may be government regulatory laboratories, government research laboratories, or government supported laboratories”.

It is not clear the reason for emphasizing government laboratories. OMB Circular A-76³ states that the government should not compete with the private sector, and should instead rely on commercial sources to supply the products and services it needs. Government laboratories, which rely on public funds, routinely compete with private sector laboratories in direct violation of A-76. NIST should reinforce the OMB A-76 policy and the need for agencies to refrain from competing with the services provided by the private sector conformity assessment bodies in any conformity assessment activity (testing, inspection, certification, auditing, etc.). Conformity assessment bodies have the ability to scale services, technical expertise, and

³ <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A76/a076.pdf>

innovative technologies to provide such services in a more cost-effective and efficient manner. Taxpayers shouldn't have to finance activities that can be more effectively provided by the private sector.

5) Incomplete consideration of international trade aspects

Lines 556-638: This section needs to be further expanded to include language on national treatment for conformity assessment bodies, which, as discussed in item 3 above, facilitates trade and reduces costs and time-to-market for manufacturers.

National treatment can be defined as *“Each Party shall accord to conformity assessment bodies located in the territory of another Party treatment no less favourable than that it accords to conformity assessment bodies located in its own territory or in the territory of any other Party⁴.”* That means that conformity assessment bodies in the exporting country should be authorized to test, inspect and certify certain products in accordance with the legal and technical (standard-based) requirements that apply in the importing country. National treatment helps facilitate trade and time-to-market since manufacturers are free to use the conformity assessment body of their choice and location most appropriate to their business model, instead of having to select from a restricted list of conformity assessment bodies in the destination market only. National treatment also gives regulators greater confidence that requirements are met since regulators would approve the conformity assessment bodies and/or Accreditation Bodies directly instead of via a MRA approach.

National treatment can be a more effective tool compared to MRAs since MRAs, in the short or medium term, are not always effective methods to facilitate the removal of existing barriers to trade. For MRAs to be effective, they require the same standards, the same methods of conformity assessment and the same accreditation requirements. Past MRAs have had limited success facilitating trade due to the lack of trust in the trading partner's quality infrastructure (standardization, accreditation, conformity assessment, metrology) and, in some instances, have established a non-level playing field for the testing, inspection and certification industry by adding unnecessary and burdensome administrative procedures.

IFIA also recommends that NIST includes language on reciprocity (please see IFIA comments on the Considerations Document Line 1246).

⁴ Trans-Pacific Partnership (TPP) Technical Barriers to Trade Chapter: <https://ustr.gov/sites/default/files/TPP-Final-Text-Technical-Barriers-to-Trade.pdf>

Additional specific comments on the ABCs:

Line 129: We recommend replacing “impact on the marketplace” with “**effect on the assurance that is needed by the purchaser**”:

*“The purpose of this publication is to provide an overview of the topic of conformity assessment to better understand its **effect on the assurance that is needed by the purchaser**”.*

Line 180: Remove “marketplace” and insert “**that can achieve the goals of the user/purchaser**”:

*“(...) use the information resulting from that program to make intelligent choices **that can achieve the goals of the user/purchaser**”.*

Line 182: Replace “assessment body” with “**body that assesses the conformity**”:

*“(...) competence of the **body that assesses the conformity**”.*

Line 262: Insert “**certification report**” after “inspection report”.

Line 274, Fig 2: It is unclear what NIST means by “Arrangements” in this figure. “Arrangements” should either be defined or NIST should refer the reader to a separate section of the document where this topic is further explored.

Line 291: Replace “putting” with “**placing**”.

Line 356: Replace “develop” with “**report**”:

*“Testing laboratories conduct tests and **report** data. The test data reported is used...”*

Line 394: replace “*the object of assessments non-conformity*” with “**non-compliance**” so it reads:

*“Certification activities are conducted only by a third-party and are generally used when the risks associated with **non-compliance** are moderate to high.”*

The new language clarifies that NIST is referring to “risk of non-compliance” and not “risk of the product (or process, person, system), as the original language implies.

Line 410: Replace “other” by “**multiple**”:

*“The attestation may be based on **multiple** conformity assessment activities”.*

Lines 484-485: Replace “and is generally conducted by” with “**these can be conducted by regulators or third-party accreditation bodies**”:

*“There are accreditation programs for testing laboratories, inspection bodies, and certifiers. **These can be conducted by regulators and/or third-party accreditation bodies.**”*

Line 488: Add “**accreditation**” before “bodies” and “**that provide services for**” after “bodies”:

*“specifies requirements for **accreditation bodies that provide services** for accrediting conformity assessment bodies”.*

Lines 488-490: The activities listed (“testing, calibration, inspection etc.) are not activities of accreditation bodies. They are activities of conformity assessment bodies.

Line 490: Replace “Accreditation Bodies” with “**Accreditors**”.

Line 545: Replace “part of” with “**participate as**”.

Line 553-554: At the end of line 553, replace “OSHA performs” with: “**OSHA recognizes private sector conformity assessment bodies as NRTLs and conducts ongoing**” so it reads:

*“**OSHA recognizes private sector conformity assessment bodies as NRTLs and conducts ongoing**” evaluation activities, including audits, to ensure compliance with the policies and continued conformity with requirements.”*

Line 559: Add “**can help**” before “facilitate” so it reads:

*“Effective conformity assessment **can help** facilitate international transactions”.*

Line 622: Replace “countries” with “**members**” and delete “**at the national level**” so it reads:

*“(…) among participating **members** and to simplify the certification of electrical products.”*