

Submitted via: sp2000-01@nist.gov

February 26, 2018

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

Ref: Intertek comments on the “Draft ABC’s for Conformity Assessment” document

Dear Ms. Phelps,

Intertek is pleased to provide comments on the “Draft ABC’s for Conformity Assessment” document.

Intertek is a leading Total Quality Assurance provider to industries worldwide, and is a leading United States provider of quality and safety services for a wide range of industries around the world. Our network of more than 1,000 laboratories and offices and over 42,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers’ operations and supply chains.

Intertek supports NIST’s development of the “Draft ABC’s for Conformity Assessment” document and looks forward to continuing to work with NIST to insure that the resulting document provides the necessary guidance and information that will be useful to both Federal Agencies and other stakeholders in understanding the concepts of conformity assessment.

Thank you for the opportunity to offer the following comments. If you have any questions regarding our submission please feel free to contact me at 202-255-0350 or at joan.sterling@intertek.com.

Sincerely,

J. E. Sterling

Joan E Sterling
Intertek
Vice President, Public & Government Affairs





General comments:

Intertek fully supports NIST's efforts to consult stakeholders throughout the process of updating the *"Draft ABC's for Conformity Assessment"* document. This document is an educational foundation for agencies and stakeholders who need to understand the fundamentals of conformity assessment. It is essential that Federal Agencies are familiar with this basic information prior to the development of conformity assessment programs.

We have divided our comments into two sections. The first are issues that we believe are overarching comments on the nature and content of the document. The second section provides specific comments and language changes to the current draft that support these principle issues.

Section 1: Overarching Comments

- Language incorrectly indicating that conformity assessment guarantees or ensures compliance;
- Deviation and inconsistency with the globally accepted terminology in the ISO/IEC 17000 group of standards and principles related to conformity assessment; confusion between "methods of conformity" and "conformity assessment activities"
- Lack of neutrality regarding the different methods of conformity. This is reflected in the promotion of first-party conformity assessment over other methods;
- Emphasis regarding the use of government laboratories, which is in direct conflict with **OMB A 76** that prohibits government competition with private sector resources, unless there is a legitimate documented reason, such as national security.
- Incomplete consideration of international trade aspects.

Intertek recommends that NIST remove any overlap of content between the *"Draft Conformity Assessment Considerations for Federal Agencies"* document and the *"Draft ABC's for Conformity Assessment"* document. The *"Draft ABC's for Conformity Assessment"* document is an **accompanying** document to the *"Draft Conformity Assessment Considerations for Federal Agencies"* document. Therefore the *"Draft ABC's for Conformity Assessment"* document should focus on providing a user-friendly overview of conformity assessment concepts in an educational and neutral manner.

The *"Draft Conformity Assessment Considerations for Federal Agencies"* document should not repeat those concepts, but instead focus on identifying the types of questions/criteria agencies should consider when selecting methods of conformity to achieve their goals. Both documents should clearly convey that **there are different avenues for demonstrating compliance**, and **each of these avenues provide different levels of assurance** which are applied based on what is needed to manage risks and have the level of confidence needed for a specific situation.

Intertek recommends that the documents be rewritten to reflect "method-neutral" language and remove any language that portrays one method as preferential, or more "trade-friendly", than another. As a non-



regulatory agency, NIST should strive to be “method-neutral” in its approach to providing guidance and coordinating conformity assessment in the United States.

Conformity Assessment and the demonstration of compliance itself does not have any impact on trade. The issue that is being implied is one of National Treatment, in other words are the requirements the same for domestic and non-domestic manufacturers or conformity assessment service providers. National Treatment is 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 Party¹.”

This means that conformity assessment bodies in the exporting country should be authorized to test, inspect, and certify products, processes, or services 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 appropriately accredited/recognized conformity assessment body of their choice, in the location most appropriate to their business model, instead of being limited to a restricted selection of conformity assessment bodies in the destination market only. National Treatment also gives regulators greater confidence that requirements are met because regulators would approve conformity assessment bodies and/or accreditation bodies directly, instead of via a Mutual Recognition Agreement that provides a decreased level of confidence.

Additionally, the language in the documents seem to confuse “methods of conformity” with “conformity assessment activities” and some of the descriptions are not based on the ISO/IEC 17000 definitions that apply to conformity assessment. Intertek recommends aligning the document with the vocabulary and definitions in the ISO/IEC 17000 series.²

While Intertek understands that U.S. Federal Agencies are the primary audience for this publication, NIST has acknowledged that other stakeholders, which include: manufacturers, conformity assessment bodies, service providers, trade associations, non-governmental organizations, etc. will also rely on the principles in the “*Draft ABC’s of Conformity Assessment*” document. For this reason, accuracy in defining and describing conformity assessment is essential.

Sections 2: Specific comments

Line 129 -130 edit:

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

¹ Trans-Pacific Partnership (TPP) Technical Barriers to Trade Chapter: <https://ustr.gov/sites/default/files/TPP-Final-Text-Technical-Barriers-to-Trade.pdf>

² <https://www.iso.org/obp/ui/#iso:std:iso-iec:17000:ed-1:v1:en:sec:3.1>



Intertek recommends the above change as it more accurately reflects that this is an educational document addressing the basics of conformity assessment methods and activities.

Line 149 edit:

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

The use of the word “ensure” incorrectly states that conformity assessment guarantees or ensures compliance. This is only one such example of the “Draft ABC’s for Conformity Assessment” document characterization of conformity assessment as a “guarantee” – there are other similar instances throughout the document that offer a confusing picture of conformity assessment. Conformity assessment is not a guarantee; it is a demonstration that creates an incentive for compliance. The “Draft ABC’s for Conformity Assessment” document should be reviewed to remove any language that implies that conformity assessment guarantees compliance.

Lines 177-187 edits:

*It is vital for purchasers, sellers, and other interested parties to understand the conformity assessment process to competently judge the value of a particular conformity assessment program and to use the information resulting from that program to make intelligent **marketplace choices that can achieve the goals of the user/purchaser.***

*The quality of the conformity assessment information conveyed depends on: the impartiality and competence of the ~~assessment~~-body **that assesses the conformity**; the types of assessment activities included in the program; and the adequacy and appropriateness of the standards against which the product is evaluated. Improperly conducted conformity assessment activities may result in widespread purchaser deception and **potential negative consequences to health, safety, and environmental impacts**. If properly conducted, however, conformity assessment can furnish valuable information to: **regulators, consumers, purchasers and** the marketplace, and can serve as the basis for increased opportunities for national and international trade.*

Intertek recommends the above changes to clarify both the intent and outcomes of conformity assessment procedures.

Line 226 edit:

*regulation can provide an efficient method of conveying information needed by a purchaser/**user***

Intertek recommends adding the above language for clarity.

Line 256 edit:



3. Conformity Assessment Concepts

Intertek recommends reorganizing and rewriting this whole section to separate conformity assessment methods from conformity assessment activities. Section 3 confuses these two separate concepts in multiple ways. Section 3.1 discusses the attestation of a first-party (which is the result of a conformity assessment activity). Section 3.2 discusses the inspection activity. Section 3.3 discusses the testing activity. Sections 3.4, 3.4.1, and 3.4.2 all discuss the attestation of a third-party (which is the result of conformity assessment activities). Section 3.5 is also a third-party attestation.

It is unclear why the “Draft ABC’s of Conformity Assessment” document does not discuss all methods of conformity assessment (first party, second party, and third party) in one place. Nor why it does not discuss all the conformity assessment activities (sampling, inspection, testing, auditing, and surveillance) in one place? The outcomes of these activities produce attestations (declarations) and should also be discussed together.

We have provided our edits to the language as written in hopes that NIST will reorganize the document in a more educationally useful and logical way using the correct terminology.

Line 262 edit:

*A determination is made based on evidence of conformity (such as a test report, inspection report, **certification report**, or audit).*

Intertek recommends adding the above language for clarity.

Lines 266-268, Fig 1 edit:

NIST includes government as one of the parties that can perform conformity assessment activities along with first, second and third-party. Intertek recommends using 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 change would maintain consistency with ISO/IEC international standards definitions and still note that government has a unique role in conformity assessment.

Lines 280-283 edit:

3.1. ~~Suppliers Declaration of Conformity~~ **First-party conformity assessment**

~~First party conformity assessment Suppliers Declaration of Conformity is o~~One way to show that a product, process, or service conforms to specific requirements. **This can result in a is** ~~through~~ supplier’s declaration of conformity (SDOC), which is a “declaration” as defined in ISO/IEC 17000:2004 (ISO 170000, 2004), i.e. first party attestation, **where the conformity assessment activity is performed by the person or organization that provides the “object” and the** supplier provides written confidence of conformity.



Intertek recommends that the definitions as specified in ISO/IEC 17000 be used consistently through this document to maintain consistency and avoid confusion. Further, this is not a conformity assessment activity, but an attestation (declaration) and should be moved to a more appropriate place in the document.

Line 291 edit:

*This form of declaration is generally used when the risk associated with noncompliance is low, there are suitable penalties in place for ~~putting~~**placing** non-conformant products on the market,*

Intertek recommends the above editorial comment for clarity.

Lines 302-308 edits:

~~*Reliance on SDoC is considered a trade-friendly approach to conformity declaration. From a manufacturer's perspective, the SDOC allows flexibility in the choice of location for conformity assessment activities, and reduces the uncertainty associated with mandatory activities by designated conformity assessment bodies as well as associated costs. This approach allows manufacturers to use conformity assessment bodies in whom they have confidence and which are most conveniently located in relation to where the product is produced, reducing the cost and time associated with conducting activities.*~~

Intertek recommends that these statements be removed. This document should be “method neutral” in relation to conformity assessment and not be promoting a specific perspective that one method of determining conformity is better than another. **All methods of conformity assessment are trade friendly as long as national treatment is provided for conformity assessment bodies**, and that is what provides for flexibility and reduces uncertainty while allowing for services to be provided in the most convenient location.

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 Party³.”

For example CABs in the exporting country should be authorized to test, inspect and certify products, processes, or services 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 because manufacturers are free to use the appropriately accredited/recognized conformity assessment body of their choice, in the location most appropriate to their business model, instead of being required to select from a restricted list of CABs in the destination market only.

³ Trans-Pacific Partnership (TPP) Technical Barriers to Trade Chapter: <https://ustr.gov/sites/default/files/TPP-Final-Text-Technical-Barriers-to-Trade.pdf>



National Treatment also gives regulators greater confidence that requirements are met because regulators would approve conformity assessment bodies and/or accreditation bodies directly, instead of via a Mutual Recognition Agreement that provides a decreased level of confidence.

In addition, 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**”.

As expressed above, the “Draft ABC’s for Conformity Assessment” document 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. If the “Draft ABC’s for Conformity Assessment” document will cover international trade considerations, the document should do so in a comprehensive and neutral manner.

Conformity assessment is designed to address confidence needs in bring products to market. The appropriate method of conformity (first, second or third-party) is dependent upon regulatory policy goals and/or the confidence needs of the market and the users. When SDoC is enough to satisfy confidence needs, there is not a market for third-party 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.

Line 304-305 edits:

~~*From a manufacturer’s perspective, the SDOC allows flexibility in the choice of location for conformity assessment activities, and reduces the uncertainty associated with mandatory activities by designated conformity assessment bodies as well as associated costs*~~

Intertek offers the following comments to support removal of this false statement. This paragraph implies that costs are derived from a particular method of conformity. A manufacturer may have a higher degree of uncertainty and higher cost regardless of which conformity assessment method is used (first-party or third-party). Costs are driven 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 in multiple ways. It can be performed by the first party (where the manufacturer/supplier must build 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 performed by a first-party 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. This is the reason why organizations 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.** We ask that these types of statements which are not based on data or empirical evidence be removed. This document should be method-neutral and not promote the perspective that one method of conformity is “better” than another.



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.

Lines 341-344

3.3. *Testing*

~~Testing laboratories support diverse industries and affect the entire operation of U.S. industry and the U.S. regulatory system. Corporate and regulatory decisions are made based on test results produced by testing laboratories.~~

It is unclear what is being conveyed in this paragraph and Intertek recommends deletion. As stated above, the definitions as specified in ISO/IEC 17000 should be used consistently through this document to maintain consistency and avoid confusion.

Lines 352-355 edits:

~~Appropriate accreditation to The use of this standard ISO/IEC 17025 may also assist in cooperation between testing laboratories and other conformity assessment bodies through acceptance of results between countries. Test reports may be accepted from one country to another without the need for further testing, thus assisting with international trade.~~

Intertek offers the above edits for clarity. Additionally the discussion of acceptance of test reports will require significant further information to prove accurate and useful. There are many ways that accreditation (which is what we think NIST is talking about in this sentence), can assist with the confidence needs of different economies to accept accredited test reports. The acceptance can be part of a program/scheme or other mechanisms.

Line 356 edits:

~~Testing laboratories conduct tests and report develop data.~~

Intertek offers the above editorial comment for clarity.

Line 360-362 edits:

~~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.~~



It is not clear why there should be an emphasis on government laboratories or subsidized laboratories in the document. OMB Circular A-76⁴ clearly 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. Intertek recommends that NIST reinforce in the “Draft ABC’s for Conformity Assessment” the OMB A-76 policy and the need for Agencies to refrain from choosing State Owned Enterprises over 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 innovative technologies to provide such services in a more cost-effective and efficient manner. Taxpayers should not have to finance duplicative activities that are more effectively provided by the private sector.

Line 410 edits:

*The attestation may be based on ~~multiple~~ **other** conformity assessment activities.*

Intertek recommends the above editorial clarification.

Lines 484-485 edits:

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

Intertek recommends the above editorial clarification.

Line 488-490 edits:

*specifies requirements for **accreditation** bodies **that provide services** for accrediting conformity assessment bodies. ~~Accreditation activities include tasks such as testing, calibration, inspection, certification, management systems, persons, products, processes and services, and validation and verification.~~ Accreditation Bodies ~~ers~~ use the ISO/IEC standards and guides with the technical and specific program requirements to assess compliance of a conformity assessment system*

Intertek recommends the above editorial clarifications. The activities listed (testing, calibration, inspection etc.) are not activities of accreditation bodies. They are activities of conformity assessment bodies. If NIST’s intent is to list the potential scopes that conformity assessment bodies could be accredited to then this will need to be rewritten correctly.

Lines 394 – 402 edits:

⁴ <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A76/a076.pdf>



Certification activities are conducted 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 the third-party's decision-making process being free from any influence ~~between of~~ the first ~~and/or~~ second parties. Certification activities include the following:

- Evaluation of evidence of conformity;
- Determination ~~of compliance whether product complies~~;
- Attestation of conformity granted (i.e. certificate issued); and
- Surveillance and/or ongoing renewal process

Intertek recommends language to clarify that NIST is referring to the "risk of non-compliance" and not the "risk of the product (or process, person, system), as the original language implies. The next clarification is that first and second parties are separate interests.

Line 545 edits:

*In addition, program owners **should** consider whether the **conformity assessment** organizations **that will be required to** performing specific conformity assessment activities (i.e. testing, inspection, certification) need to be accredited, or participate ~~in as part of a member~~ peer assessment group.*

Intertek recommends these above clarifying editorial comments.

Line 553 edits:

*OSHA **accredits private sector conformity assessment bodies as Nationally Recognized Testing Laboratories (NRTLs) and conducts ongoing** ~~performs~~ evaluation activities, including audits, to ensure compliance with the policies and continued conformity with requirements.*

Intertek recommends these above clarifying editorial comments.

Line 559 edits:

*Effective conformity assessment **can help** facilitates international transactions.*

Intertek recommends these above clarifying editorial comments, as this is just one factor that impacts international transactions.

Lines 556-638 edits:



Section 5. International/Regional Cooperation is incomplete, and if included in the “Draft ABC’s of Conformity Assessment” will not provide an adequate explanation of the current structure. Below are some areas where serious deficiencies exist:

Lines 606-617 edits:

~~Accreditation bodies are established worldwide providing authoritative oversight to conformity assessment bodies.~~ Accreditation bodies **from around the world** have formed regional “cooperations” and established “arrangements” **with the intent to** recognize the equivalence of members accreditations. The evaluation process of the regional accreditation cooperation is conducted by member accreditation bodies based on peer evaluation **of each other**. The use of mutual recognition agreements **may** provides a global network of ~~accreditation conformity assessment~~ **accredited** bodies ~~to that may assist in improving acceptance of providing~~ reliable conformity assessment results. ~~through acceptance of data generated by the accredited bodies thus reducing technical barriers to trade.~~ Parties, **which in this case are the Accreditation Bodies**, to the agreement agree to accept each other's results rather than each other's ~~accreditation certification marks~~. **This may result in the acceptance of:**

- a. the conformity assessment bodies that have been accredited by one member of the agreement to also be accepted as competent by another signatory to the agreement**
- b. test results or certification reports prepared by a conformity assessment body, that has been accredited by an accreditation body participating in the mutual recognition agreement**
- c. the accreditation body that has been recognized by the regulatory authority in a jurisdiction, in one participating country cant who may also be accepted in other participating jurisdictions countries for the purpose of meeting regulatory conformity assessment results requirements of the importing country.**

Intertek has found that in practice these types of agreements or arrangements are of limited value in the effectiveness for either improving redundant accreditations for conformity assessment bodies, or for improving market access of goods and services. The confidence needs of regulatory authorities are more likely to be met through a more direct assurance process. This generally happens through direct accreditation by regulators, or by a full review and acceptance process of third party accreditation bodies that have proven they have both the technical competence and knowledge of specific regulatory requirements.

Line 618-623 edits:

~~MRAs Other types of agreements can also be established between two or more organizations located in different countries to accept each other's conformity assessment results, 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 IEC **CB** scheme), which ~~is designed to promote the reciprocal recognition of test results among the participating~~



~~members countries and to simplify the certification of electrical products at the national level. an international system for mutual acceptance of test reports and certificates dealing with the safety of electrical and electronic components, equipment and products. It is a multilateral agreement among participating countries and certification organizations, which aims to facilitate trade by promoting harmonization of national standards with International Standards and cooperation among accepted National Certification Bodies (NCBs) worldwide.~~⁵

Intertek recommends the above edits for clarity of the IECEE CB Scheme. The key components that make this work is the requirement that members follow **all** rules of the schemes, and the peer assessment requirements.

Lines 635-638 edits:

Mutual recognition programs ~~are vital to international trade.~~ They may help remove technical barriers to trade, quicken the circulation of goods and services entering the markets, eliminate the need for retesting and/or recertification and thus reduce the costs incurred, and ensure that regulatory conformity assessment requirements are met.

Intertek recommends the above edits to this paragraph. There is are only a few mutual recognition programs that actually deliver what is promised. It is imperative that the potential participants in such program are required to follow **all** the rules specified within the program to make it successful. We have found that when this is not the case the program has little chance of providing the confidence needed.

Additional comments:

Section 5 needs to be further expanded to include language on national treatment for conformity assessment bodies, which, as discussed 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 Party⁶.” 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.

⁵ <https://www.iecee.org/about/cb-scheme/>

⁶ Trans-Pacific Partnership (TPP) Technical Barriers to Trade Chapter: <https://ustr.gov/sites/default/files/TPP-Final-Text-Technical-Barriers-to-Trade.pdf>



National treatment can be a more effective tool than MRAs because, in the short or medium term, MRAs have proven to rarely be 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.