SUBMITTED ELECTRONICALLY VIA EMAIL TO SP2000-02@NIST.GOV

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

Dear Ms. Carnahan,

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 2000-02: Conformity Assessment Considerations for Federal Agencies.*

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 partner with businesses, manufacturers, retailers, trade associations, and international regulatory authorities to provide solutions and address the risks of increasingly complex global supply chain.

UL supports NIST's efforts to fulfill its responsibility under the National Technology Transfer and Advancement Act (NTTAA) and Office of Management and Budget (OMB) Circular A-119 to provide guidance to US federal agencies on conformity assessment issues. In that respect, while updating the *ABCs of Conformity Assessment* (Special Publication 2000-01) and issuing this *Considerations* document are helpful, NIST should also proceed with revising the 2000 *Guidance on Federal Conformity Assessment* as codified in 15 CFR 287 to ensure it remains aligned with the 2016 revision to OMB A-119 and these newer NIST publications.

UL also applauds NIST for focusing on the importance of federal agencies engaging stakeholders when considering the conformity assessment activities on which it will rely. NIST has modeled this best practice in its own outreach to stakeholders in the development of this document by holding a public workshop in February 2017 and participating in numerous discussions with conformity assessment bodies, trade associations, industry associations, and others over the course of many months. UL is pleased that NIST also published notice of the availability of this document – and the companion *ABCs* – in the *Federal Register*.

Nevertheless, UL has identified some significant concerns with the *Considerations* document as currently drafted. These are outlined below:

1. **Throughout the document, NIST misses opportunities to reinforce the spirit and principles of OMB A-119 (2016) with respect to conformity assessment.** In executing its OMB A-119 responsibility to "coordinate Federal, State, and local standards activities and conformity assessment activities with private sector standards development and conformity standards activities," NIST often has limited its coordinating role to regulators, with inconsistent engagement with the private sector. To NIST's credit, the efforts to reach out to private sector stakeholders in the development of the *Considerations* document are a step in the right direction; in continuing such outreach, however, NIST should seek to be inclusive and transparent and avoid "cherry-picking" amongst the private sector voices it consults. Additionally, NIST should avail itself of the many opportunities throughout the *Considerations* to reinforce OMB A-119 and NTTAA principles

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around agencies leveraging private sector conformity assessment expertise and activities where appropriate to meet the agency objectives/needs and otherwise consistent with law.

2. **While OMB A-119 is method-neutral when it comes to conformity assessment, the NIST *Considerations* document fails to take a neutral approach in describing methods of conformity.** There are a number of examples peppered throughout the document that use prejudicial language to paint first party conformity assessment (i.e., supplier's declaration of conformity, SDoC) favorably while challenging the potential costs and efficiency of more "robust" and "independent" methods such as third-party. This bias also runs counter to the conformity assessment neutral position of the Office of the US Trade Representative in the negotiation of trade agreements, and specifically that of the horizontal Technical Barriers to Trade chapter. NIST does federal agencies a disservice by its failure to describe various methods of conformity assessment neutrally. Instead of using language like "trade-friendly" to describe SDoC (thereby implying that third-party should always be the last resort), NIST should instead offer federal agencies a set of questions they can leverage that would lead them into their own determination as to what the appropriate level of conformity assessment is needed to meet the objective at hand, manage risks, and deliver confidence needed. UL recommends NIST consider and incorporate the set of questions presented to them by the International Federation of Inspection Agencies (IFIA), outlined below:

    - Is a high level of confidence required?
    - Is the perceived risk high?
    - Is there a documented history of (industry) compliance?
    - Is there a documented history of (industry) non-compliance?
    - Do regulatory authorizing/statutory provisions provide severe penalties and an effective deterrent?
    - How strong is the need for impartiality?
    - Are there voluntary, market-driven schemes that address confidence needs?
    - Are there relied upon international schemes that can be leveraged?
    - Specific to *products*:
        - Are products regulated primarily manufactured in countries with a history of risk factors and other issues?
        - Are products manufactured in complex and fragmented supply chains?
        - Is there evidence that product liability is an effective deterrent?
        - What are the societal risks of non-compliant products?
        - Who bears the cost of market surveillance?
        - How likely is the need for recall or correction action?
        - How effective is the model in supporting anti-counterfeiting enforcement?

3. **The *Considerations* document confuses rather than clarifies the distinctions between conformity schemes/programs and bodies and the role of each in conformity assessment.** For example, lines 980 through 986 present a combination of factors related to conformity assessment bodies and conformity assessment schemes. The factors related to bodies are competence of personnel and adequacy of facilities and equipment. The factors related to schemes are adequacy of the product standard, the number and type of testing and inspection methods used, size of the sample and types of sampling methods, use of quality management system requirements for producers of the object undergoing conformity assessment, and the nature/extent of surveillance activities. Also, in lines 1024-1027 surveillance is implied to be a choice of the conformity assessment body when surveillance is one of the key elements of the scheme.

4. **The role of surveillance in conformity assessment is consistently mischaracterized in the draft *Considerations.*** One such example is found on lines 545-546, where NIST describes the role of surveillance as "provid[ing] confidence in ongoing conformity once initial conformity has been determined" when, in reality, it would be more accurate to state that the goal of surveillance is to "maintain the validity of the attestation." When coupled with the misconception perpetuated in the *ABCs* document that conformity assessment *ensures* that specific products, processes, services, systems, persons, or bodies *always* fulfill requirements, federal agencies could be led to wrongly believe that conformity assessment *guarantees* compliance when, in actuality, it provides assurance by creating an incentive to fulfill requirements – and to do so on an ongoing basis.

5. **The document confuses rather than clarifies the distinction between management systems/management system requirements and requirements in ISO/IEC Standards for conformity assessment bodies (ISO/CASCO Standards).** In lines 1277 through 1286 the *Considerations* document erroneously describes ISO CASCO standards as setting management system requirements. ISO CASCO standards set requirements for the competence, consistency, and impartiality of conformity assessment bodies. These standards include *one* section of requirements labeled "Management System Requirements." The CASCO standards set these requirements to ensure the conformity assessment body establishes a management system to self-assess and assure the ongoing fulfillment of requirements in the rest of the standard. To imply that ISO CASCO standards *are* management system standards or are wholly management system requirements is a serious misstatement.

UL affirms NIST's desire to provide a better understanding of conformity assessment to US federal agencies looking to it for guidance. While well-intentioned, the current *Considerations* falls short of achieving the clarity necessary to provide optimal value to federal agencies. Absent NIST reconsidering some elements of the approach it has taken, UL offers specific recommendations in the attached Appendix to help resolve inaccuracies, address some of the aforementioned areas, and bring greater clarity and alignment with internationally accepted conformity assessment concepts. 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 *Considerations* and the companion *ABCs.* UL looks forward to continuing to collaborate with NIST to help support federal agencies considering conformity assessment programs. Please do not hesitate to contact me if you have any questions regarding these comments.

Sincerely,

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Appendix - Specific Recommendations

1. Introduction

Federal Policy Context of this Document:

Recommendation #1: With respect to lines 146-148, NIST should consider framing this policy by using the language taken directly from OMB A-119 (2016) as follows:

> Agencies should also design conformity assessment programs with the objectives of further outcomes that are closely aligned with market dynamics and otherwise maximize net benefits to society. In this context, agencies should recognize the possible contribution of private sector conformity assessment activities. When properly conducted, 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.

- Rationale: In describing the policies for Federal agencies outlined in OMB Circular A-119 in lines 138-155, NIST cites most of the OMB A-119 language verbatim, with the exception of the third bullet where it extracts the first sentence on "market dynamics" and "net benefits to society" without offering the subsequent context provided in OMB A-119. Such context is important because it underscores the importance of leveraging the private sector, which is the very spirit of the NTTAA and OMB A-119.

2. Elements of a Conformity Assessment Program

Objectives and Goals:

Recommendation #2: Amend lines 413-418 to read as follows (*Text recommended to be deleted is indicated by strikethrough; text recommended to be added is indicated by underline)*:

> The basic principle of conformity assssessment[10], see Figure 1, is that an *object of conformity* (i.e., product, service organization, process, or person, etc.) is evaluated to ~~determine if~~ demonstrate it meets *requirements*~~. The *determination* is based on~~, which creates *evidence of conformity* (e.g., a test report, inspection report, audit report). An organization may *attest* (a statement to convey assurance) ~~to this conformity~~ that fulfillment has been demonstrated based on the ~~determination~~ evidence of conformity and the activities used to create it. *Surveillance activities* support continued validity of the attestation for on-going ~~conformity of the product, service, organization process, or person~~ assurance of fulfillment of requirements.

- Rationale: These proposed edits more accurately define the principle of conformity by using internationally accepted conformity assessment language. In addition, these modifications would help dispel any misconception that conformity assessment ensures or guarantees compliance instead of a demonstration that requirements have been fulfilled.

Recommendation #3: Amend the language in Figure 1 (The Conformity Assessment Process) as follows:

> 1. In the "Attestation" box, modify the language to read "Who says performance has been demonstrated?
> 2. In the "Surveillance" box, modify the language to read "What about assurances next week?"

- Rationale: UL recommends these edits to provide greater alignment between the NIST *Considerations* document and conformity assessment language accepted internationally (via ISO definitions/terminology).

Recommendation #4: On line 441, strike the phrase “in the conformity” and replace with “as a basis for”.

- Rationale: Test results are used as a basis for attestation; this edit simply underscores this.

Recommendation #5: On line 474, after “conformity assessment” insert the word “activity”.

- Rationale: This edit would clarify that inspection is a specific activity of conformity assessment, rather than encompassing the entirety of conformity assessment.

Recommendation #6: On lines 478 and 479, modify the sentence to read “Many inspection programs are the basis for product markings such as the US Department of Agriculture meat grades or certificates which attest to the conformity of inspected products.

- Rationale: Inspection, by definition in ISO/IEC 17000 Annex A, does not include issuance of an attestation. Issuance of an attestation is a required element of conformity assessment, but is differentiated as a separate activity from inspection.

Audit:

Recommendation #7: On line 486, before “management systems” insert the phrase “for example”.

- Rationale: Audit activity does not apply solely to management systems, so it is more appropriate to use management systems as an example than imply audit activity is limited to such systems.

Recommendation #8: Consider deleting lines 488 to 501.

- Rationale: A description of auditing as a conformity assessment activity is confusing when it includes such detailed information about management systems. Management systems are only one type of object that can be effectively evaluated by auditing. For example, financial auditing can be the basis for an attestation that an accounting system meets specified requirements. If detailed information about management systems is needed in the *Considerations* document, then it should be placed in some other location and not combined with auditing.

Attestation:

Recommendation #9: On lines 504-505, after the word “consider” insert “fulfillment of” and replace the word “met” with “demonstrated”.

- Rationale: Use of the terminology around “fulfillment” and “demonstration” is consistent with ISO principles and internationally accepted and used terminology.

Recommendation #10: On line 507, strike the word “typically”.

- Rationale: The word “typically” is not needed as an attestation is based on a review of conformity assessment activities.

Recommendation #11: On line 508, after the phrase “verification of” insert the following: “the suitability, adequacy, and effectiveness of”.

- Rationale: The term “review” is specifically defined in ISO/IEC 17000 and that definition should be utilized.

Certification:

Recommendation #12: On line 524 strike the word “organization” and replace it with the word “system”.

- Rationale: This edit is intended to bring additional consistency to how conformity assessment is characterized throughout the document and to greater align the NIST *Considerations* with international (ISO) principles and terminology.

Recommendation #13: On line 537, strike the word “conducted” and replace it with the word “issued”. Also delete “and includes some form of surveillance activity”.

- Rationale: Per ISO/IEC 17000, certification is a type of attestation – not a conformity assessment process. As a result, a certification is issued, not conducted. A certification scheme (a conformity assessment scheme in which the attestation is certification) can include surveillance activities. Failure to maintain the accuracy of these concepts will only lead to confusion when federal agencies (or others) seek to establish conformity assessment in practice.

Surveillance:

Recommendation #14: On line 544, strike the word “conformity” and replace it with “assurance”.

- Rationale: Making this suggested change would help dispel any misconceptions users may have that conformity assessment provides a *guarantee* of compliance rather than an *assurance* that specified requirements have been fulfilled.

Recommendation #15: On lines 545-546, strike the phrase “provide confidence in ongoing conformity once initial conformity has been determined” and replace it with the phrase “maintain the validity of the attestation”.

- Rationale: This change is recommended to more accurately describe the function and value of surveillance and to ensure such activities are properly characterized in the document, per the point (#4) UL raises in its “General Observations.”

Recommendation #16: On lines 563-568, the description of first, second, and third parties mistakenly tracks with the parties to a transaction for the object of conformity. These lines should be rewritten to reflect first, second and third parties have a broader meaning to conformity assessment:

- First party: individual or group supplying the object of conformity or having the same interests in the object of conformity (e.g., investors, business partners of the supplier such as contract manufacturers, advertisers, etc.);

- Second party: individual or group with a need for confidence or assurance that specified requirements are fulfilled (This is not just the purchaser – it can include underwriters of insurance for the purchaser, distributors, and retailers who deliver the object to the end purchaser, and regulators who seek to protect the interests of the purchaser or end user of the object); and
- Third party: individual or group whose interests are independent of first and second parties (using this definition of third parties, the concept of independence does not need to be addressed again – rather, the more critical requirements for impartiality can be the focus).

- Rationale: Effective concepts of first, second, and third parties that can capture all individuals and groups related to a conformity assessment are much more powerful in helping federal agencies consider conformity assessment.

Listing:

Recommendation #17: On line 583, strike the words “is not in itself” and replace with the words “may or may not be” before the word “attestation”.

- Rationale: It is possible for a listing to be an actual attestation. It is also possible that a listing is a pointer to the actual attestation, and in this case a series of listings is more commonly thought of as a Directory.

Requirements and Specifications

D. Determine Confidence Point

Recommendation #18: The term “Confidence point” is a poor choice in lines 773 through 823. What is being described is optimal conformity assessment – it delivers needed confidence considering the consequences of noncompliance and the cost of conformity assessment. Discussion of risk should be *part of* a discussion of the consequences of noncompliance, not separate from it. In lines 813-815 additional factors to consider are erroneously labeled as part of risk considerations. Rather, these are factors that contribute to the confidence/assurance the conformity assessment delivers.

- Rationale: Confusing and mixed-up concepts will make consideration of conformity assessment more difficult for federal agencies.

Conformity Assessment Roles, Activities and Policies

A. Define the Conformity Assessment Model

Recommendation #19: Strike lines 879-891 in their entirety.

- Rationale: NIST should remove references to “independence” in their discussion of “steps and factors in arriving at a conformity assessment model”. Models are not independent – only bodies are. The preferred descriptions UL has offered of first, second, and third parties under Recommendation #16 give the concepts needed to discuss the relative merits of conformity assessment schemes performed by first, second, and third parties. The concept of “independence” is effectively captured in these descriptions and should not be referenced again here or elsewhere (e.g., line 901). UL believes that the key question (i.e. “step” or “factor”) in arriving at a conformity assessment model is to determine whether a first party, second party, or third party performs the conformity assessment activities.

Recommendation #20: On line 903, after the sentence ending “objectives” add the following sentence: “Similarly, the use of a less robust model does not always lead to a program that is optimally effective and/or efficient for achieving conformity assessment program goals and meeting broader objectives.”

- Rationale: As UL noted in its “General Observations,” one of the significant flaws with the *Considerations* document as drafted is its failure to achieve neutrality with respect to the methods of conformity assessment described. The sentence in lines 901-903 unfairly calls out use of “the most independent” (problematic in itself per the rationale provided in Recommendation #19) and “most robust model” (often third-party) as not always leading to a program that is effective or efficient. UL argues that same argument could be applied to less robust models. In reality, different methods exist and are applied based on what is needed to manage risks and reach the level of confidence required to meet the need or objective at hand. The method – irrespective of level of robustness – is only effective and efficient when it delivers the assurance required in an appropriate and timely manner.

Recommendation #21: On lines 932-934, delete “and provide the market with acceptable confidence”.

- Rationale: There is no role for the federal government to weigh in on market needs for confidence. Federal government regulators need only look after their own confidence needs. Hopefully, existing market-related conformity assessment can also meet regulator confidence needs, which makes existing conformity assessment more valuable and makes the overall market more efficient. However, the regulator should not get involved in the market’s confidence needs – for example, the need of a distributor to be confident of the fulfillment of requirements for the product he/she is distributing. Overburdening regulators with roles and concerns that do not belong to them is a hindrance to their consideration of conformity assessment.

Recommendation #22: On line 960, strike the sentence “Reliance on an SDoC is considered to be a trade-friendly approach to conformity”.

- Rationale: The use of this sentence by NIST, a federal government agency, prejudices potential readers and users of the *Considerations* to default to SDoC when, in many instances, it may be more appropriate to consider or apply a different method of conformity assessment. The use of SDoC, second party, or third party is dependent upon what regulators determine is needed and/or what markets demand by way of assurance. When SDoC is enough to satisfy those needs, there is not a market for third-party to provide services; conversely, where greater assurance is necessary, there is little pertinence for SDoC. The language in the current draft gives the perception that NIST is passing judgment the various methods of conformity assessment rather than arming federal agencies with a set of tools or questions to arrive at that determination on their own, with the consultation of the US Trade Representative. Additionally, the subsequent sentence (“From a manufacturer’s perspective…”) is adequate to communicate why industry may prefer this method over others.

Recommendation #23: On lines 1083-1096, suggest NIST replaces these lines with an actual example of surveillance.

- Rationale: What is being described is a regulatory inspection activity, not surveillance to assure the ongoing validity of an attestation. While certainly a very valuable activity that

utilizes an activity that is also utilized in conformity assessment (inspection), it likely falls outside the field of conformity assessment since there is no attestation involved.

Recommendation #24: On lines 1277-1291 the document indicates the program owner should develop competence requirements. However, ISO CASCO standards generally require the conformity assessment body to develop specific competence requirements for their staff. The text should be amended to more appropriately reflect that.

- Rationale: Giving this message to federal regulators will confuse them when they then read ISO CASCO standards for conformity assessment bodies. Consideration should be given proper characterization of the ISO CASCO standards, per point #5 made in UL's "General Observations" section.

Recommendation #25: Lines 1320-1323 should be rewritten to more closely align with ISO CASCO requirements.

Rationale: As currently written, the text indicates that accreditation bodies use specific competence requirements in addition to ISO CASCO standards. This is generally untrue. ISO CASCO requirements actually put the obligation on the conformity assessment body to set specific competence requirements. In the most recent revision of ISO/IEC 17011 for accreditation bodies, ISO CASCO clearly indicated that accreditation bodies attest to fulfillment of requirements *including* competence requirements – competence is not attested outside of fulfillment of requirements. Further, the text indicates accreditation bodies attest if appropriate. This is incorrect since accreditation is a type of attestation – it is not possible to accredit without attesting. Inconsistencies between this document and the ISO CASCO standards will hinder federal agencies' consideration of conformity assessment.

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.