



KYLE PITSOR

Vice President, Government Relations

February 26, 2018

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

Transmitted electronically to sp2000-02@nist.gov

Re: NIST Special Publication 2000–02: Conformity Assessment Considerations for Federal Agencies

Dear Ms. Carnahan,

As the leading trade association representing the manufacturers of electrical and medical imaging equipment, the National Electrical Manufacturers Association (NEMA) provides the attached comments in response to the December 27, 2017, solicitation of public comments on the Draft NIST Special Publication 2000–02: Conformity Assessment Considerations for Federal Agencies.

NEMA represents nearly 350 electrical equipment and medical imaging manufacturers that make safe, reliable, and efficient electrical and medical imaging products and systems. Our combined industries account for 360,000 American jobs in more than 7,000 facilities covering every state. Our industry produces \$106 billion shipments of electrical equipment and medical imaging technologies per year with \$36 billion exports.

Attached please find a matrix of comments. We are open to discussing these comments further and providing additional details at your request. Our Member companies count on your careful consideration and we look forward to outcomes that meet their expectations.

If you have any questions on these comments, please contact Craig Updyke at 703-841-3294 or craig.updyke@nema.org or Joel Solis at 703-841-3267 or joel.solis@nema.org.

Sincerely,

A handwritten signature in black ink that reads 'Kyle Pitsor'. The signature is written in a cursive, flowing style.

Kyle Pitsor
Vice President, Government Relations

Attachment

Matrix of NEMA Comments on “Conformity Assessment Considerations for Federal Agencies DRAFT, December 2017”

Line	Section	Item	Category	Subject And Comment	Proposal
10, 11	Executive Summary	Paragraph	General	Both producer and economic operators (i.e., any professional in the supply chain whose activity does not affect the safety properties of a product) should have been included in the list since both have strong incentives, like the threat of private liability claims related to nonconformity products, to verify compliance with relevant standards.	The primary goal of conformity assessment is to give purchasers, producers and economic operators , and users confidence that the products and services meet appropriate requirements.
101-103	Introduction, Audience	Sentence	General	Although the language here is intended to be both general and inclusive, it fails to throw sufficient light on the federal interest in compliance and enforcement.	Federal participants in the process include conformity assessment program owners, subject matter experts, regulators, agency counsel and levels of management within a Federal agency, including parties responsible for surveillance and enforcement .
113-115	Introduction, Audience	Paragraph	General	To be consistent with Section “Addressing international obligations, equivalency or recognition”, line 1252-1253, knowledge of U.S. trading partners conformity assessment programs that may be relevant should be identified early in the process.	For each specific conformity assessment program, it is also important to have a contextual knowledge of the agency mission and regulation governing the conformity assessment program, specific markets and sectors in the U.S., U.S. trading partners’ conformity assessment procedures and international economies, and the current state of conformity assessment programs within the scope of interest.
159-161	Introduction, Federal Policy Context of this Document	Paragraph	General	To be consistent with Section 2. Lines 344-345, need to expand on reference to the “private sector”.	To reduce unnecessary burden and make more productive use of Federal resources, the NIST guidance suggests that each agency coordinate its conformity assessment activities with those of other appropriate government agencies and with those of the private and private sector (including Federal, state, local and tribal) .
361	Elements of a Conformity Assessment Program	Sentence	General	Typographical error.	levering leveraging
379-381	Section 2, Objectives and Goals	Paragraph	General	To be consistent with lines 226-227, suggest rephrasing the term “conformity assessment standards”.	There is variation of the conformity assessment terms used in legislation, and at times not consistent with the nomenclature used in conformity assessment standards related to conformity assessment topics .
410-411	Section 2, Elements of a Conformity Assessment	Sentence	General	To be consistent with Footnote 4 and line 727, NIST should encourage program owners to seek out private sector technical standards developers as a source for providing conformity assessment	Federal program owners should also consider using conformity assessment organizations, and experts in the private sector and private sector technical standards developers to gain insight into these concepts.

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	Program, E			concepts.	
428-433	Section 2, Elements of a Conformity Assessment Program, E	Paragraph	General	Sentence is difficult to follow. To improve readability, suggest providing the numerous examples in bullet form.	Examples of objects of conformity include: <ul style="list-style-type: none"> motorcycle helmets (products) that meet the U.S. Department of Transportation Federal Motor Vehicle Safety Standard 21811; financial, insurance, genealogy, investigators and others (organizations) meeting the U. S. National Technical Information Service requirements for the safe and secure use, access, storage and management of the Limited Access Death Master File; and contracting professionals (persons) meeting the Federal Acquisition in Contracting Program requirements for Federal Government contracting and procurement activities.
442	Section 2, Elements of a Conformity Assessment Program, E	Sentence	General	Recommend striking last line as it repeats what is said in line 439-440, “Testing is usually performed on a sample of the product and produces definitive results in a test report.”	Testing is considered to produce definitive results in a test report.
480-481	Section 2, Elements of a Conformity Assessment Program, E	Sentence	General	Introduce a new term “certification system” that is only used once. Suggest replacing with “certification program” to keep consistency with rest of document, as in line 526, 529, 978, 999, ect.	certification programs For example, inspection is often used in the surveillance activities of certification systems program.
737-738	Section 2, Requirements and Specifications, B	Sentence	General	Wording errors.	A test method that prevents innovated innovative technology from demonstrating conformity may impede the innovation from being in entering the market.
743-745	Section 2, Requirements and Specifications, C	Sentence	General	Wording error?	Most often the evidence is provided through testing, inspection, or audit for conformity to the requirements or standards selected to instantiate substantiate the requirements.
760-761	Section 2, Requirements and Specifications, D	Sentence	General	The sentence “Flawed test data...or the environment” is misplaced and should be move to the last sentence of the paragraph, following line 764 which discusses “good test data”.	Flawed test data can result in the entry into the market of defective products capable of causing serious injury or harm to the user or the environment.
766-767	Section 2, Requirements and Specifications, D	Sentence	General	The use of the word “and” should be replaced with “in”. This is a good opportunity to introduce the audience to the term “professional judgement”, see Glossary term “inspection”, since the sentence is dealing with ambiguity in reaching a determination on conformity.	Ambiguous requirements and in standards or ambiguity in the test, inspection or audit method will require the use of professional judgement and eventually require attention.

812-813	Section 2, Requirements and Specifications, D	Sentence	General	Subject of the sentence is inconsistent with lines 779-781 which states that the subject of this paragraph was to be “3) and <u>understanding</u> of the concept of risk.” “Understanding” conveys a less extensive treatment than “determining.” Suggest replacing “determining risk” with “understanding the risk”.	In general, determining understanding the risk involves analyzing the severity of the consequences of non-conformity, and the likelihood of products or services being non-conformant.
876	Section 2, Conformity Assessment Roles, Activities and Policies, A	Sentence	General	Wording error.	Too little resource and Without sufficient resources, the agency could become a bottle-neck in the ability of the program to meet demand.
1035	Section 2, Conformity Assessment Roles, Activities and Policies, A	Sentence	General	Wording, suggest replacing “product” with “produce”.	Organizations performing testing, inspection, and audit activities should apply the test methods, etc. consistently and product produce the same results for the same object of conformity.
1146-1147	Section 2, Conformity Assessment Roles, Activities and Policies, B	Sentence		Policies to protect confidential or proprietary information should extend to personnel, manufacturing locations and suppliers. Suggest revising lines 1146-1147	Policies should support the confidentiality of a product under development, and the confidentiality of a product not yet publicly announced, and the confidentiality of personnel, manufacturing locations and suppliers.
1195	Section 2, Conformity Assessment Roles, Activities and Policies, B	Sentence	General	Wording, suggest replacing “make” with “maker.”	consider requiring the decision maker of the appeal to be higher in the organizational hierarchy
1193-1196	Section 2, Conformity Assessment Roles, Activities and Policies, B	Sentence		According to ISO/IEC 17065, “[t]he certification body shall only grant authority to make a certification decision, or any decision in the handling of complaints and appeals, to an individual or group that is impartial with respect to the product(s).” So when it comes to appeals, the concern is with objectivity which can be more appropriately addressed by ensuring the impartiality of the individual or group, rather than on one’s position in the organizational hierarchy, a	An appeals process to manage when the supplier or conformity assessment organization does not agree with the decision of the conformity assessment program. The program owner should consider requiring the decision maker of the appeal to be higher in the organizational hierarchy than an individual or group that is impartial with respect to the decision maker of the approval; and

				term that has been defined in the Glossary.	
1239-1244	Section 2, Conformity Assessment Roles, Activities and Policies, B	Paragraph		Expand this section to reference additional means for displaying a mark or label on a product to be consistent with FCC's Electronic Labeling Guidance.	Policies should exist when a mark or label is required. Not all Federal agency conformity assessment programs require a mark or label on the product, or displayed on the product's integrated (non-removable) display screen, or alternatively on the package. Approval marks and labels are a resource need to both the program owner who must manage and enforce the use of the mark or label, and the supplier who must manage and display the mark or label. The symbols used in connection with the certification mark or label should be capable of being interpreted without further definition.
1353-1356	Section 2, Operations and Improvement, A	Paragraph		Suggest that when a Federal agency decides to actively engage in voluntary consensus standards activities, that the procedures provide guidance on how to comply with antitrust law when attending these types of meetings.	Federal agency programs should consider developing procedures for program engagement in specification development activities or voluntary consensus standards activities (if appropriate). These procedures may address the nature of engagement relationships such as monitoring standard development activities, active participation, possible leadership roles in these activities, etc. If the nature of the engagement relationship is active participation in standard development activity, the procedures should include guidance on how to comply with antitrust law when attending these types of meetings.