

7 April 2020

To: Gordon Gillerman
Director, Standards Coordination Office
National Institute of Standards and Technology (NIST)
15CFR287@nist.gov
(301) 975-4000

Ref: "Guidance on Federal Conformity Assessment Activities," 15 CFR Part 287,
RIN 0693-AB65, Docket No. 191210-0104

Dear Mr. Gillerman,

The TIC Council Americas is pleased to provide the attached comments on NIST ***Guidance on Federal Conformity Assessment Activities***, 15 CFR Part 287, Docket No. 191210-0104 and would like to extend our thanks to NIST and its staff for moving forward with this revision.

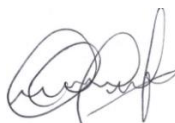
TIC Council is the global trade federation representing the independent third-party Testing, Inspection and Certification (TIC) industry which brings together more than 90-member companies and organizations from around the world to speak with one voice. Its members provide services across a wide range of sectors: consumer products, medical devices, petroleum, mining and metals, food, and agriculture among others. Through provision of these services, TIC Council members assure that not only regulatory requirements are met, but also that reliability, economic value, and sustainability are enhanced. TIC Council's members are present in more than 160 countries and employ more than 300,000 people across the globe.

We appreciate the opportunity to provide feedback on the NIST Guidance on Federal Conformity Assessment Activities, 15 CFR Part 287. Should you have any questions, please don't hesitate to contact Karin Athanas at +1 240 762 8069 / kathanas@tic-council.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Hanane Taidi'.

Hanane Taidi
Director General
TIC Council

A handwritten signature in black ink, appearing to read 'Roberta Telles'.

Roberta Telles
Executive Director
TIC Council Americas
rtelles@TIC-Council.org

General Comments:

TIC Council Americas supports the work of the National Institute of Standards and Technology. NIST’s role to guide agencies’ efforts to implement the guidance on federal agency use of conformity assessment activities is paramount and should be supported.

Conformity assessment is the process used to demonstrate that a product, process, service, or person meets specific requirements and when developing a conformity assessment program, TIC Council Americas supports consideration of the following principles:

1. Reliance on the private sector where capabilities and capacity align with needs
2. Systems that reward manufacturers for utilizing third-parties, event if the conformity mechanism does not require it
3. Compliance with OMB A-76 with respect to government not competing with the private sector
4. Restraint in establishing structures that create de factor monopolies
5. Minimum accreditation requirements to level the playing field
6. Reciprocity provisions that respect trade commitments while ensuring the competitiveness of the US testing, inspection, and certification industry.

There are many different programs in the private sector that are managed by conformity assessment bodies, and also by manufacturers’ trade associations, that can provide the necessary confidence needed by the regulatory agencies to support regulations and Agency objectives. Regulators must regularly evaluate these programs to determine if they provide the necessary level of confidence that they require for compliance to safety, health, and environmental needs.

Regulators must also consider risk, and balance program goals against the level of confidence in the conformity assessment program that is needed. This may result in use of a first, second, or third-party conformity assessment program. Independent third-party conformity assessment bodies, such as TIC Council Americas members, are commonly accredited and regularly assessed by accrediting bodies to perform activities under various international ISO/CASCO standards such as testing (ISO/IEC 17025), inspection (ISO/IEC 17020) and certification (ISO/IEC 17065). We encourage NIST engagement in supporting regulators in evaluating risk factors and program goals to make the best decisions for the success of their programs and where accreditation is considered, we recommend that:

- Regulatory agencies establish baseline requirements for acceptance of accreditation bodies to determine if they have the necessary abilities and technical expertise to assess third-parties to US regulatory requirements and the appropriate standards. These baseline requirements should take into account the source of accreditations as well as the scope of accreditation of the conformity assessment body.
- Where possible, that regulatory agencies rely upon the international system of standards and guides (ISO/IEC/CASCO) for the establishment and maintenance of conformity assessment and accreditation activities.

Specific Comments:

CITATION	CONCERN/CONSIDERATION
§287.2	<p>The definition for conformity assessment is not consistent with the NIST ABCs document. In the NIST ABCs document, NIST directly cites the ISO 17000 definition.</p> <p>Recommend revision to ensure alignment with other publications.</p>
§287.4(a)	<p>It is recommended that NIST replace the link to the <i>Considerations</i> document that connects to the doi.org website and alternatively, link to the document posted to NIST website: https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.2000-02.pdf</p>
§287.4(e)	<p>TIC Council supports the removal of examples from the 15 CFR 287 document</p> <p>Reference to the examples of federal agency conformity assessment programs on the NIST website would provide a larger set of examples of different approaches used.</p>
§287.4(f)	<p>Recommend that the phrase “voluntary consensus conformity assessment related standards” be revised to “voluntary consensus standards.”</p> <p>“Conformity assessment related” is not defined and may cause confusion. Any voluntary consensus standard could be used within a conformity assessment program.</p>
§287.4(i)	<p>This section may cause confusion, the following revisions are recommended for clarity:</p> <p><i>“Assign an Agency Standards Executive the responsibility for coordinating agency-wide implementation of the guidance in this part. The Standards Executive should be who is situated in the agency’s organizational structure such that the Standards Executive is kept regularly apprised of the agency’s regulatory, procurement, and other mission-related activities, and has sufficient authority within the agency to ensure implementation with this part.”</i></p>
§287.5(h)	<p>Recommend that the phrase “conformity assessment related standards” be revised to “voluntary consensus standards.”</p> <p>“Conformity assessment related” is not defined and may cause confusion. Any voluntary consensus standard could be used within a conformity assessment program.</p>