



DEPARTMENT OF COMMERCE

National Institutes of Standards and Technology

15 CFR Part 287

**[Docket No.:** 191210-0104]

**RIN:** 0693-AB65

Guidance on Federal Conformity Assessment Activities

**AGENCY:** National Institute of Standards and Technology (NIST), United States Department of Commerce.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The National Institute of Standards and Technology (NIST) requests comments on proposed revisions to regulations updating policy guidance on Federal agency use of conformity assessment that reflects advancement in conformity assessment concepts, and the evolution in Federal agency strategies and coordination in using and relying on conformity assessment.

The provisions are solely intended to be used as guidance for agencies in their use and reliance on conformity assessment to meet agency requirements and do not preempt the agency authority and responsibility to make decisions authorized by statute or required in establishing regulatory, procurement, or programmatic activities.

**DATES:** *For Comments:* Send comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number: 191210-0104, through the *Federal e-Rulemaking Portal*: <http://www.regulations.gov> (search using the docket number). Follow the online instructions for submitting comments. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

See SUPPLEMENTARY INFORMATION for file formats and other information about electronic

filing. All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. NIST reserves the right to publish relevant comments publicly, unedited and in their entirety. Personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Do not submit confidential business information, or otherwise proprietary, sensitive or protected information. Comments that contain profanity, vulgarity, threats, or other inappropriate language or content will not be posted or considered.

**FOR FURTHER INFORMATION CONTACT:** Mr. Gordon Gillerman via email at 15CFR287@nist.gov, or by phone at (301) 975-4000.

**SUPPLEMENTARY INFORMATION:**

**I. Purpose of This Guidance**

The guidance outlines Federal agencies' responsibilities for using conformity assessment to meet respective agency requirements in an efficient and cost-effective manner for the agency and its stakeholders. To reduce unnecessary burden and make productive use of federal resources, this guidance emphasizes that agencies should consider coordinating conformity assessment activities with those of other appropriate government agencies (Federal, State, and local) and with those in the private sector. This guidance does not preempt agency authority and responsibility to make decisions authorized by statute or required in establishing regulatory, procurement, or program activities. This guidance also does not preempt agency authority and responsibility in determining or implementing procurement, regulatory, or programmatic requirements.

**II. Background**

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 directs NIST to “coordinate technical standards activities and conformity assessment activities of Federal, State, and local governments with private sector technical standards activities and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the

development and promulgation of conformity assessment requirements and measures” (15 USC 272(b)(13)). NIST originally issued the guidance found in 15 CFR 287 (this Guidance) on August 10, 2000, in response to Office of Management and Budget (OMB) Circular A-119 (February 10, 1998) directing the Secretary of Commerce to issue guidance to Federal agencies to ensure effective coordination of Federal conformity assessment activities (65 FR 48894). The January 2016 revision to OMB Circular A-119 re-emphasizes NIST’s role in issuing guidance to agencies as well as Federal agencies responsibilities with respect to conformity assessment. NIST is revising this guidance to reflect progression in conformity assessment concepts and evolution in Federal agency strategies and coordination in using and relying on conformity assessment.

The proposed revision to this guidance is one of several activities undertaken by the NIST Standards Coordination Office to update its guidance, training, and other artifacts that help agencies develop and use conformity assessment. As a first activity, NIST provided significant input to the conformity assessment related policies of OMB Circular A-119. NIST released two NIST Special Publications (SPs) in September 2018. NIST SP 2000-01, *ABCs of Conformity Assessment*, serves as a primer for the topic of conformity assessment, and NIST SP 2000-02, *Conformity Assessment Considerations for Federal Agencies* provides agencies with a path to follow in considering the development, use or improvement of conformity assessment to meet their requirements. This proposed revision to 15 CFR 287 represents NIST’s most recent effort to provide Federal agencies with up-to-date tools for effective use of conformity assessment.

In developing this revision to 15 CFR 287 the NIST Standards Coordination Office (SCO) leveraged the expertise and experience of the members of the Interagency Committee on Standards Policy (ICSP) and the ICSP Conformity Assessment Work Group (CAWG). NIST met with the ICSP and CAWG for input on the revision and received comments from eight agencies on an early draft version. NIST seeks public comment on this proposed revision; see Section IV. Request for Comment.

## Summary of significant proposed changes

NIST is seeking public comments on the proposed changes. Brief explanations of significant proposed changes are included below. The full text of 15 CFR part 287 is available at

<https://www.govinfo.gov/content/pkg/CFR-2015-title15-voll/pdf/CFR-2015-title15-voll-part287.pdf>.

The proposed changes in full text appear at the end of this notice. A table showing each clause of 15 CFR 287 and the related changes can be found at

[https://www.nist.gov/document/15CFR287\\_NPRM\\_ChangesTable.pdf](https://www.nist.gov/document/15CFR287_NPRM_ChangesTable.pdf). Significant proposed changes are to:

1. Revise sections throughout part 287 to clarify that agencies use conformity assessment in meeting agency programmatic needs in addition to the currently stated regulatory and procurement needs. Using conformity assessment for agency programmatic needs emphasizes the voluntary nature of many conformity assessment programs. This emphasis aligns with OMB Circular A-119.
2. Revise throughout part 287 to reflect direction to agencies in the NTTAA and related guidance in OMB Circular A-119 regarding the use of and participation in the development of voluntary consensus standards related to conformity assessment topics. See OMB Circular A-119 for a discussion of voluntary consensus standards.
3. Revise the definition of *conformity assessment* (§ 287.2) by adding the term persons to the list of possible focus of conformity assessment. Some concepts discussed in the definition are removed; the reader is directed to NIST Special Publication 2000-01, *ABCs of Conformity Assessment*, found at <https://doi.org/10.6028/NIST.SP.2000-01> for these concepts.
4. Remove the following terms because they are no longer used in part 287: accreditation, certification, inspection, recognition, registration, supplier's declaration of conformity, and testing (§ 287.2).
5. Add new responsibilities for NIST (§ 287.3) to (1) issue guidance, training material and other material that assist Federal agencies in understanding and applying conformity assessment; and (2)

participate in the development of conformity assessment related standards. Both of these roles reflect NIST leadership and conformity assessment expertise.

6. Remove the responsibility for NIST to collect and disseminate information on Federal, State and private sector conformity assessment activities in § 287.3 (a-penultimate clause) and state conformity assessment practices (§ 287.3(c)). Information about Federal, State and private sector conformity assessment activities is electronically discoverable and available from many sources. NIST uses exemplar Federal conformity assessment programs and private sector activities as resource material on <https://standards.gov>.
7. Extend the timeframe for NIST to review the effectiveness of part 287 from three to five years (§ 287.3).
8. Add the responsibility for Federal agencies to develop and implement conformity assessment in a manner that meets objectives, reduces unnecessary burden on stakeholders, makes productive use of resources, and meets international trade obligations (§ 287.4).
9. Remove the responsibility for Federal agencies to harmonize requirements for quality and environmental management systems for procurement and regulation purposes (§ 287.4(k)). This responsibility is no longer necessary due to the widespread adoption among agencies of the same voluntary consensus standards related to management systems resulting in reliance on the same requirements.
10. Remove the examples of how an agency may implement a specific part of the guidance (§ 287.4).  
The examples in the current guidance served, in part, as tutorial in nature. The experience of Federal agencies in applying conformity assessment concepts makes examples unnecessary.
11. Expand the Federal agency responsibility to consider using the activities and results of other conformity assessment programs to enhance the effectiveness of existing or proposed new programs. The current responsibility was scoped to enhancing the safety and efficacy of proposed requirements and measures (§ 287.4(c)).

12. Remove the standards and conformity assessment related organizational names as examples (§ 287.4). The inclusion or exclusion of names may be perceived as endorsement or criticism.
13. Reflect that U.S. access to international markets is achievable through many mechanisms. The current language is specific to recognition agreements and infrastructure (§ 287.4(i),(l),(m)). The revised language recognizes that other mechanisms (not just recognition) can facilitate acceptance of standards and conformity assessment results to increase market access for U.S. products and services.
14. Add additional guidance to Federal agencies for their selection, role, and responsibilities of the Agency Standards Executive (§ 287.5(n)). The expansion of guidance is consistent with the roles and responsibilities assigned to the Agency Standards Executive in the revision of OMB Circular A-119.
15. Add new responsibilities for the Agency Standards Executive that 1) encourages the Agency Standards Executive's participation in the Interagency Committee on Standards Participation (ICSP) and 2) encourages the Executive to promote agency participation in ICSP working groups. These responsibilities reflect the value of ICSP participation and interaction with other ICSP members.
16. Modify the responsibilities of the Agency Standards Executive by removing the three goals listed and adding specific responsibilities based on the goals (§ 287.5(a)). The three goals were transferred to the revision of OMB Circular A-119. The new resultant responsibilities in this part are to encourage effective use of conformity assessment and resources; assist the agency in developing policy positions and help resolve issues related to conformity assessment; and promote Federal agency participation in conformity assessment related standards development and coordination activities.
17. Remove the responsibilities for the Agency Standards Executive to consult with NIST, as necessary, in the development and issuance of policies for meeting the guidance in this part (§ 287.5(d)) and coordinate with NIST in carrying out the responsibilities in this part (§ 287.5(c)). The removal reflects the evolution of the role of an Agency Standards Executive and lack of need, for the most

part, for consultation. The ICSP is used as the mechanism for coordination among the Agency Standards Executives and NIST.

### **III. Applicability of This Guidance**

This guidance applies to all agencies, which set policy for, manage, operate, or use conformity assessment activities and results. ‘Agency’ means any Executive Department, independent commission, board, bureau, office, government-owned or controlled corporation, or other establishment of the Federal government. It also includes any regulatory commission or board, except for independent regulatory commissions insofar as they are subject to separate statutory requirements regarding policy setting, management, operation, and use of conformity assessment activities. It does not include the legislative or judicial branches of the Federal government although those branches may use this guidance to inform their own use of conformity assessment.

### **IV. Request for Comments**

NIST is requesting comments about 15 CFR part 287. When submitting comments, remember to:

1. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
2. The following file formats are encouraged: PDF, MS Word, txt.
3. Please organize your comments by referencing the relevant section number in the proposed regulatory text.
4. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
5. Provide specific examples to illustrate your concerns and suggest alternatives.
6. Explain your views as clearly as possible.

7. All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. NIST reserves the right to publish relevant comments publicly, unedited and in their entirety. Personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Do not submit confidential business information, or otherwise proprietary, sensitive or protected information. Comments that contain profanity, vulgarity, threats, or other inappropriate language will not be posted or considered.
8. Make sure to submit your comments by the comment period deadline identified.

## **V. Classification**

### *Executive Order 12866*

This rulemaking is not a significant regulatory action under Executive Order 12866.

### *Executive Order 13771*

This rule is not subject to the requirements of Executive Order 13771, because its likely impact is *de minimis*.

### *Executive Order 13132*

This proposed rule does not contain policies with Federalism implications as defined in Executive Order 13132.

### *Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) requires the preparation and availability for public comment of “an initial regulatory flexibility analysis” which will “describe the impact of the proposed rule on small entities.” (5 U.S.C. 603(a)). Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the proposed rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this rulemaking, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination is as follows: A description of this proposed rule, why it is being considered, and the objectives of this proposed rule are contained in the preamble. The statutory basis for this proposed rule is provided by 15 U.S.C. 272, which requires NIST to coordinate Federal, State, and local standards activities and conformity assessment activities with private sector standards activities and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures. To ensure effective coordination, the Secretary of Commerce must issue guidance to the agencies. The proposed rule would provide policy guidance on Federal agency use of conformity assessment activities. These provisions are solely intended to be used as guidance for agencies in their conformity assessment activities. It is not anticipated that external entities, including any small businesses, small organizations, or small governments, will experience significant or adverse economic impacts from this rule.

The information provided above supports a determination that this proposed rule would not have a significant economic impact on a substantial number of small entities. Because this rulemaking, if implemented, is not expected to have a significant economic impact on any small entities, an initial regulatory flexibility analysis is not required.

#### *Paperwork Reduction Act*

This proposed rule contains no new collection of information subject to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

#### *National Environmental Policy Act*

This proposed rule will not significantly affect the quality of the human environment. Therefore, an environmental assessment or Environmental Impact Statement is not required to be prepared under the National Environmental Policy Act of 1969.

## **List of Subjects in 15 CFR Part 287**

Conformity assessment, Procurement, Trade agreements, Voluntary standards.

For the reasons stated in the preamble, the National Institute of Standards and Technology proposes to revise 15 CFR part 287 to read as follows:

### **PART 287 – GUIDANCE ON FEDERAL CONFORMITY ASSESSMENT**

#### **Sec.**

287.1 Purpose and scope of this guidance.

287.2 Definitions.

287.3 Responsibilities of the National Institute of Standards and Technology.

287.4 Responsibilities of Federal agencies.

287.5 Responsibilities of Agency Standards Executives.

Authority: 15 U.S.C. 272.

#### **§ 287.1 Purpose and scope of this guidance.**

(a) The guidance outlines Federal agencies' responsibilities for using conformity assessment to meet respective agency requirements in an efficient and cost-effective manner for the agency and its stakeholders. To reduce unnecessary burden and make productive use of Federal resources, this guidance emphasizes that agencies should consider coordinating conformity assessment activities with those of other appropriate government agencies (Federal, State and local) and with those in the private sector.

(b) Using conformity assessment in a manner consistent with this guidance supports U.S. Government efforts to pursue conformity assessment activities in a manner that reduces unnecessary burden on international trade and increases market access for U.S. products and services.

(c) This guidance applies to all agencies, which set policy for, manage, operate, or use conformity assessment. This guidance does not preempt the agencies' authority and responsibility to make decisions

authorized by statute or required to meet programmatic objectives and requirements. These decision-making activities include: determining the level of acceptable regulatory or procurement risk; setting the level of protection; balancing risk, cost and availability of technology (where statutes permit) in establishing regulatory, procurement, and program requirements.

(d) Each agency retains broad discretion in its selection and use of conformity assessment activities and may elect not to use or recognize alternative conformity assessment approaches if the agency deems the alternatives to be inappropriate, inadequate, or inconsistent with statutory criteria or programmatic objectives and requirements. Nothing contained herein shall give any party any claim or cause of action against the Federal government or any agency thereof. Each agency remains responsible for representation of the agency's views on conformity assessment in matters under its jurisdiction. Each agency also remains the primary point of contact for information on the agency's regulatory, procurement or programmatic conformity assessment actions.

#### **§ 287.2 Definitions.**

For the purposes of this part:

*Agency* means any Executive Department, independent commission, board, bureau, office, government-owned or controlled corporation, or other establishment of the Federal government. It also includes any regulatory commission or board, except for independent regulatory commissions insofar as they are subject to separate statutory requirements regarding policy setting, management, operation, and use of conformity assessment. It does not include the legislative or judicial branches of the Federal government.

*Agency Standards Executive* means an official designated by an agency as its representative on the Interagency Committee for Standards Policy (ICSP) and delegated the responsibility for agency implementation of OMB Circular A-119 and the guidance in this part.

*Conformity assessment* means any activity concerned with determining directly or indirectly that requirements are fulfilled. Requirements for products, services, systems, persons, and organizations are

those defined by law or regulation, by an agency in regulatory or procurement actions, or an agency programmatic policy. Conformity assessment does not include mandatory administrative procedures (such as registration notification) for granting permission for a good or service to be produced, marketed, or used for a stated purpose or under stated conditions. Conformity assessment terminology is contained in NIST Special Publication 2000-01, *ABCs of Conformity Assessment* (2018) found free of charge at: <https://doi.org/10.6028/NIST.SP.2000-01>. The definitions included in NIST Special Publication 2000-01 are based on voluntary consensus standards. See OMB Circular A-119 for a description of voluntary consensus standards and recommendations for their development and use by Federal agencies.

*NIST* means the National Institute of Standards and Technology, an agency within the United States Department of Commerce.

### **§ 287.3 Responsibilities of the National Institute of Standards and Technology.**

(a) Issue guidance, training material, and other material to assist Federal agencies in understanding and applying conformity assessment to meet their requirements. Material is available at <https://www.standards.gov>.

(b) Chair the Interagency Committee on Standards Policy (ICSP); encourage the ICSP to address issues related to agency conformity assessment program development, use, and implementation; and provide resource support to the ICSP and its working groups related to conformity assessment issues, as needed.

(c) Work with agencies through the ICSP to coordinate Federal, State and local conformity assessment activities with private sector conformity assessment activities.

(d) Participate in the development of voluntary consensus standards, recommendations and guidelines related to conformity assessment to ensure that Federal viewpoints are represented.

(e) Increase awareness in the importance of conformity assessment through development and publication of conformity assessment resources. Material is available at <https://www.standards.gov>.

(f) To the extent that resources are available and upon request by a state government agency, work with that state agency to reduce duplication and complexity in state conformity assessment activities.

(g) Review, within five years from the issuance date of this part, the effectiveness of this guidance and recommend modifications to the Secretary as needed.

#### **§ 287.4 Responsibilities of Federal agencies.**

Each agency should:

(a) Implement the policies contained in the guidance in this part. Agencies may rely on NIST Special Publication 2000-02 *Conformity Assessment Considerations for Federal Agencies* found free of charge at <https://doi.org/10.6028/NIST.SP.2000-02>.

(b) Develop and implement conformity assessment in a manner that meets regulatory, procurement, and programmatic objectives; reduces unnecessary burden on stakeholders; makes productive use of Federal resources; and meets international trade agreements and obligations.

(c) Provide a rationale for its use of specified conformity assessment in rulemaking, procurement actions and agency programs to the extent feasible. Further, when notice and comment rulemaking is otherwise required, each agency should provide the opportunity for public comment on the rationale for the agency's conformity assessment decision.

(d) Work with other Federal agencies to avoid unnecessary duplication and complexity in Federal conformity assessment activities.

(e) Consider leveraging the activities and results of other governmental agency and private sector programs in lieu of creating government-unique programs or to enhance the effectiveness of proposed new and existing conformity assessment.

(f) Give a preference for using voluntary consensus conformity assessment related standards, guides and recommendations in their operations. Each agency retains responsibility for determining which, if any, of these documents are relevant to its needs. See OMB Circular A-119 for a description of voluntary consensus standards and recommendations for their development and use by Federal agencies.

(g) Participate, as needed, representing agency and Federal viewpoints in efforts designed to improve coordination among governmental and private sector conformity assessment activities such as those to develop voluntary consensus conformity assessment related standards, guidelines and recommendations.

(h) Work with NIST, other Federal agencies, ICSP members, and the private sector to coordinate U.S. conformity assessment needs, practices and requirements in support of the efforts of the U.S. Government and U.S. industry to increase international market access for U.S. products and services.

(i) Assign an Agency Standards Executive the responsibility for coordinating agency-wide implementation of the guidance in this part who is situated in the agency's organizational structure such that the Agency 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.

#### **§ 287.5 Responsibilities of Agency Standards Executives.**

Each Agency Standards Executive should:

(a) Carry out the duties in OMB Circular A-119 related to conformity assessment activities.

(b) Encourage effective use of agency conformity assessment related resources.

(c) Provide ongoing assistance and policy guidance to the agency on significant issues in conformity assessment.

(d) Contribute to the development and dissemination of 1) internal agency policies related to conformity assessment issues and 2) agency positions on conformity assessment related issues that are in the public interest.

(e) Work with other parts of the agency to develop and implement improvements in agency conformity assessment activities.

(f) Participate in the Interagency Committee on Standards Policy (ICSP) as the agency representative and member.

(g) Promote agency participation in ICSP working groups related to conformity assessment issues, as needed.

(h) Encourage agency participation in efforts related to the development of conformity assessment related standards, recommendations and guidelines consistent with agency missions, authorities, priorities, and resources.

(i) Establish an ongoing process for reviewing the agency's conformity assessment programs and use and identify areas where efficiencies can be achieved through coordination within the agency and among other agencies and private sector conformity assessment activities.

Kevin A. Kimball  
Chief of Staff

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