

15 CFR Part 287 - Guidance on Federal Conformity Assessment
Table of Proposed Changes

Current Text	Change (New, Revised or Removed Text)	Proposed Text
Changes to 287.1 - Purpose and Scope		
<p>(a) This part provides guidance for each Federal agency to use in evaluating the efficacy and efficiency of its conformity assessment activities. Each agency should coordinate its conformity assessment activities with those of other appropriate government agencies and with those of the private sector to reduce unnecessary duplication. This guidance is intended to help Federal agencies improve the management and coordination of their own conformity assessment activities with respect to other government entities and the private sector. This will help ensure more productive use of the increasingly limited Federal resources available to conduct conformity assessment activities. This will also support the role of the U.S. Government in pursuing international trade and other related negotiations and agreements with foreign countries and U.S. industry in pursuing agreements with foreign national and international private sector organizations.</p>	<p align="center">Revised</p>	<p>(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.</p>
<p>(b) This guidance applies to all agencies, which set policy for, manage, operate, or use conformity assessment activities and results, both domestic and international, except for activities carried out pursuant to treaties.</p>	<p align="center">Revised</p>	<p>(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.</p>

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<p>(c) This guidance does not preempt the agencies’ authority and responsibility to make regulatory or procurement 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 and procurement objectives; and determining or implementing procurement or regulatory requirements necessary to meet programmatic or regulatory objectives. Each agency retains broad discretion in its selection and use of regulatory and procurement conformity assessment practices and may elect not to use or recognize alternative conformity assessment practices if the agency deems them 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 and procurement conformity assessment actions.</p>	<p align="center">Revised</p>	<p>(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.</p> <p>(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.</p>
<p><i>Changes to 287.2 - Definitions</i></p>		
<p>Accreditation</p>	<p align="center">Removed</p>	
<p>Certification</p>	<p align="center">Removed</p>	

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<p>Conformity assessment means any activity concerned with determining directly or indirectly that requirements are fulfilled. Requirements for products, services, systems, and organizations are those defined by law or regulation or by an agency in a procurement action. Conformity assessment includes: sampling and testing; inspection; supplier’s declaration of conformity; certification; and quality and environmental management system assessment and registration. It also includes accreditation and recognition. 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 activities may be conducted by the supplier (first party) or by the buyer (second party) either directly or by another party on the supplier’s or buyer’s behalf, or by a body not under the control or influence of either the buyer or the seller (third party).</p>	<p align="center">Revised</p>	<p>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.</p>
<p>Inspection</p>	<p align="center">Removed</p>	
<p>Recognition</p>	<p align="center">Removed</p>	
<p>Registration</p>	<p align="center">Removed</p>	
<p>Sampling</p>	<p align="center">Removed</p>	
<p>Suppliers Declaration of Conformity</p>	<p align="center">Removed</p>	
<p>Testing</p>	<p align="center">Removed</p>	
<p>Changes to 287.3 - NIST Responsibilities</p>		
<p>(a) Work with agencies through the Interagency Committee on Standards Policy (ICSP) to coordinate Federal, state and local conformity assessment activities with private sector conformity assessment activities. NIST chairs the ICSP; assists the ICSP in developing and publishing policies and guidance on conformity assessment related issues; collects and disseminates information on Federal, state and private sector conformity assessment activities; and increases public awareness of the importance of conformity assessment and nature and extent of national and international conformity assessment activities.</p>	<p align="center">New</p>	<p>(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.</p>
<p>(b) Encourage participation in the ICSP by all affected agencies and ensure that all agency views on conformity assessment are considered.</p>	<p align="center">Revised</p>	<p>(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.</p>

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(c) To the extent that resources are available, develop information on state conformity assessment practices; and, upon request by a state government agency, work with that state agency to reduce duplication and complexity in state conformity assessment activities.	Revised	(c) Work with agencies through the ICSP to coordinate Federal, State and local conformity assessment activities with private sector conformity assessment activities.
	New	(d) Participate in the development of voluntary consensus standards, recommendations and guidelines related to conformity assessment to ensure that Federal viewpoints are represented.
	New	(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 .
	New	(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.
(d) Review within three years from August 10, 2000, the effectiveness of the final guidance and recommend modifications to the Secretary as needed.	Revised	(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.
Changes to 287.4 - Responsibilities of Federal Agencies		
(a) Implement the policies contained in the guidance in this part.	Revised	(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) Provide a rationale for its use of specified conformity assessment procedures and processes in rulemaking and procurement actions 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.	Revised	(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.
(c) Use the results of other governmental agency and private sector organization conformity assessment activities to enhance the safety and efficacy of proposed new conformity assessment requirements and measures. An example of this would be to collect and review information on similar activities conducted by other Federal, state and international organizations and agencies and private sector organizations to determine if the results of these activities can be used to improve the effectiveness of a proposed Federal agency conformity assessment activity.	Revised	(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.

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<p>(d) Use relevant guides or standards for conformity assessment practices published by domestic and international standardizing bodies as appropriate in meeting regulatory and procurement objectives. Guides and standards for sampling, testing, inspection, certification, quality and environmental management systems, management system registration and accreditation are issued by organizations which include, but are not limited to, the American National Standards Institute, the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), the International Telecommunications Union (ITU) and the Organization for Economic Cooperation and Development (OECD), the World Health Organization (WHO), and the Codex Alimentarius Commission. Each agency retains responsibility for determining which, if any, of these documents are relevant to its needs.</p>	<p align="center">Revised</p>	<p>(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.</p>
<p>(e) Identify appropriate private sector conformity assessment practices and programs and consider the results of such practices and/or programs as appropriate in existing regulatory and procurement actions. Responsibility for the determination of appropriateness rests with each agency. Examples: an agency could use the results of private sector or other governmental conformity assessment activities to schedule procurement type audits more effectively. This could allow agencies to reduce the number and extent of audits conducted at companies which are performing in accordance with contract specifications and which are under review by a third party or another agency and to concentrate agency audit efforts on companies which have shown problems in conforming to contract specifications. Another example is the Federal Communications Commission's (FCC) Telecommunication Certification Body (TCB) program, which allows designated private entities to issue telecommunications equipment approvals for specified regulatory requirements. In addition, under Part 15, FCC premarketing approval requirements for certain types of equipment have been replaced with suppliers declaration of conformity to the regulations, provided test results supporting the declaration are obtained from an accredited testing lab.</p>	<p align="center">Revised</p>	<p>(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.</p>
<p>(f) Consider using the results of other agencies' conformity assessment procedures. Example: An agency could use the results of another agency's inspection/audit of a supplier to eliminate or reduce the scope of its own inspection/ audit of that supplier.</p>	<p align="center">Revised</p>	<p>(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.</p>

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<p>(g) Participate in efforts designed to improve coordination among governmental and private sector conformity assessment activities. These efforts include, but are not limited to, the National Cooperation for Laboratory Accreditation (NACLA) organization, the National Environmental Laboratory Accreditation (NELAC), the International Organizations for Standardization’s (ISO) Committee on Conformity Assessment (CASCO), conformity assessment related activities of the American National Standards Institute (ANSI), and ICSP working groups dealing with conformity assessment issues.</p>	<p align="center">Revised</p>	<p>(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.</p> <p>(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.</p>
<p>(h) Work with other agencies to avoid unnecessary duplication and complexity in Federal conformity assessment activities. Examples: An agency can participate in another agency’s conformity assessment activities by conducting joint procurement audits/ inspections of suppliers that sell to both agencies. An agency can share conformity assessment information with other agencies. An agency can use conformity assessment information provided by other agencies to the extent appropriate to improve the effectiveness and efficiency in its own conformity assessment activities. Conformity assessment information may include: Conformity assessment procedures and results, technical data on the operation of conformity assessment programs, processing methods and requirements for applications, fees, facility site data, complaint review procedures, and confidentiality procedures.</p>	<p align="center">Revised</p>	<p>(d) Work with other Federal agencies to avoid unnecessary duplication and complexity in Federal conformity assessment activities.</p>
<p>(i) Encourage domestic and international recognition of U.S. conformity assessment results by supporting the work of the U.S. Government in international trade and related negotiations with foreign countries and U.S. industry in pursuing agreement with foreign national and international private sector organizations and any resulting activities/requirements resulting from those negotiations/agreements.</p>	<p align="center">Revised</p>	<p>international obligations moved to (b)</p>
<p>(j) Participate in the development of private sector conformity assessment standards to ensure that Federal viewpoints are represented.</p>	<p align="center">Revised</p>	<p>(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.</p>

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(k) Work with other agencies to harmonize Federal requirements for quality and environmental management systems for use in procurement and regulation, including provisions which will allow the use of one quality or environmental management system per supplier facility in the Federal procurement process and the sharing and usage of audit results and related information as appropriate.	Removed	
(l) Work with other ICSP members, NIST, and the private sector to develop national infrastructures for coordinating and harmonizing 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.	Revised	(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.
(m) Work with other ICSP members, NIST, and the private sector as necessary and appropriate to establish criteria for the development and implementation of governmental recognition systems to meet government recognition requirements imposed by other nations and regional groups to support the efforts of the U.S. Government to facilitate international market access for U.S. products.	Revised	(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.
(n) Assign an Agency Standard Executive responsibility for coordinating the agency-wide implementation of the guidance in this part.	Revised	(i) Assign an Agency Standard 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 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.
Changes to 287.5 - Responsibilities of Standards Executives		
	New	(a) Carry out the duties in OMB Circular A-119 related to conformity assessment activities.
a) Promote the following goals: (1) Effective use of agency conformity assessment related resources and participation in conformity assessment related activities of agency interest. (2) Development and dissemination of agency technical and policy positions. (3) Development of agency positions on conformity assessment related issues that are in the public interest.	Revised	(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.
(b) Ensure that agency participation in conformity assessment related activities is consistent with agency missions, authorities, priorities, and budget.	Revised	(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.

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(c) Cooperate with NIST in carrying out agency responsibilities under the guidance in this part.	Revised	(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.
(d) Consult with NIST, as necessary, in the development and issuance of internal agency procedures and guidance implementing the policies in this part.	Revised	(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.
(e) Establish an ongoing process for reviewing his/her agency's existing conformity assessment activities and identifying areas where efficiencies can be achieved through coordination with other agency and private sector conformity assessment activities.	Revised	(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.
(f) Work with other parts of his/her agency to develop and implement improvements in agency conformity assessment related activities.	Revised	(e) Work with other parts of the agency to develop and implement improvements in agency conformity assessment activities.
(g) Report to NIST, on a voluntary basis, on agency conformity assessment activities for inclusion in the annual report to the Office of Management and Budget (OMB) on the agency's implementation of OMB Circular A-119.	Removed	