

[30 September 2010 Draft proposal for revision of **Guidance on Federal Conformity Assessment Activities**

Proposed additions in yellow

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

15 CFR Part 287

[Docket No. **xxxxx**] RIN **xxxxxxx**

Guidance on Federal Conformity Assessment Activities

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: ~~Final~~ **Revised** policy guidance.

SUMMARY: This document contains **revised** policy guidance on Federal agency use of conformity assessment activities. The provisions are solely intended to be used as guidance for agencies in their conformity assessment activities and do not preempt the agencies' authority and responsibility to make regulatory procurement decisions authorized by statute or required to meet programmatic objectives and requirements.

DATES: This guidance becomes effective ~~August 10, 2000~~ **[insert effective date]**.

FOR FURTHER INFORMATION CONTACT: **Gordon Gillerman**, Director, Office of Standards Services, National Institute of Standards and Technology, MS 2100, Gaithersburg, MD 20899-2100. Phone: (301) 975-4000.

SUPPLEMENTARY INFORMATION:

Background

This guidance outlines Federal agencies' responsibility for evaluating the efficacy and efficiency of their conformity assessment activities. Each agency is responsible for coordinating its conformity assessment activities with those of other appropriate government agencies and with those of the private sector to make more productive use of the increasingly limited Federal resources available for the conduct of conformity assessment activities and to reduce unnecessary duplication.

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. "Agency" means any Executive Branch Department, independent commission, board, bureau, office, agency, 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 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.

History of the Guidance

In February 1996, The National Technology Transfer and Advancement Act (NTAA) of 1995 was enacted by Congress. Section 12 of the Act directed NIST to coordinate conformity assessment activities of Federal, state and local entities with private sector technical standards activities and conformity assessment activities with the goal of eliminating any unnecessary duplication of conformity assessment activities. The Office of Management and Budget (OMB) Circular A-119, revised February 19, 1998 directed the Secretary of Commerce to issue guidance to the agencies to ensure effective coordination of Federal conformity assessment activities.

Initial guidance was published by NIST on August 10, 2000. Since that time, several changes have occurred in standards and conformity assessment activities. The use of accreditation by several government agencies has grown greatly in the last ten years.

Rulemaking Requirements

Under 5 U.S.C. 553(b)9A), this guideline is not subject to the notice and comments requirements of the Administrative Procedure Act. Furthermore, pursuant to 5 U.S.C. 553(d)(2), the guideline is not subject to the delayed effective date requirements of the Act. The Director has chosen to publish this document for comment only to obtain input from persons who may be affected by the guidance.

PRA Clearance

The policy statement does not contain a collection of information for purposes of the Paperwork Reduction Act.

Executive Order 12866

It has been determined that the action is significant for purposes of Executive Order 12866.

Regulatory Flexibility Act

This action is exempt from the analytical requirements of the Regulatory Flexibility Act because notice and comment are not required for this action by section 553 of the Administrative Procedure Act or any other law.

List of Subjects in 15 CFR Part 287

Accreditation, conformity assessment, procurement, reporting and recordkeeping requirements.

For the reasons set forth in the preamble, Part 287 is added to subchapter J of chapter II in Title 15 of the Code of Federal Regulations (CFR) 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 an Agency Standards Executive.](#)

Authority: Sec. 12, Pub. L. 104-113, 110 Stat. 782 (15 U.S.C. 272).

Sec. 287.1 Purpose and scope of this guidance.

- 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.
- 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.
- 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.

Sec. 287.2 Definitions.\1

\1\ Definitions of accreditation, certification, conformity assessment, inspection, supplier's declaration of conformity, registration and testing are based on the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC), 17000:2004. In certain industrial sectors, it is recognized that organizations other than ISO or IEC may issue definitions relevant to conformity assessment, such as the Codex Alimentarius Commission with respect to the food industry sector.

Accreditation means a third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

Agency means any Executive Branch Department, independent commission, board, bureau, office, agency, 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 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.

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.

Certification means a third-party attestation related to products, processes, systems or persons. Note 1. Certification of a management system is sometimes called registration. Note 2. Certification is applicable to all objects of conformity assessment except for conformity assessment bodies themselves, to which accreditation is applicable.

Conformity assessment means a demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. Note 1. The subject field of conformity assessment includes activities such as sampling, testing, calibration, inspection, certification, as well as accreditation of conformity assessment bodies. Note 2. The expression "object of conformity assessment" or "object" is used to encompass any particular material, product, installation, process, system person or body to which conformity assessment is applied. A service is covered by the definition of product.

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 or user interest (second party) either directly or by another party on the supplier's or buyer's behalf, or by a body that is independent of the person or organization that provides the object, of user interests in that object (third party).

Inspection means examination of a product design, product, process, or installation and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements.

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

Recognition means an acknowledgement of the validity of a conformity assessment result provided by another person or body.

Sampling means provision of a sample of the object of conformity assessment according to a procedure.

Supplier's declaration of conformity means a first-party attestation that the object of conformity assessment meets specified requirements.

Testing means determination of one or more characteristics of an object of conformity assessment, according to a procedure. Note 1. Testing may determine performance of a given product, material, equipment, organism, person's qualifications, physical phenomenon, process, or service according to a specified technical procedure (test method).

Sec. 287.3 Responsibilities of the National Institute of Standards and Technology.

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.

- b. Encourage participation in the ICSP by all affected agencies and ensure that all agency views on conformity assessment are considered.
- 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.
- d. Review within three years from [insert date of this publication], the effectiveness of the final guidance and recommend modifications to the Secretary as needed.

Sec. 287.4 Responsibilities of Federal agencies.

Each agency should:

- a. Implement the policies contained in the guidance in this part.
- 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.
- 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. In order to gain confidence that conformity assessment results are obtained from a competent conformity assessment body, Federal agencies should rely on the multi-lateral mutual recognition arrangements of the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF). For example, the Consumer Product Safety Commission (CPSC) is relying on the accreditation body signatories to the ILAC Mutual Recognition Arrangement (Arrangement) to accredit laboratories which provide test results for CPSC regulatory compliance. The US Environmental Protection Agency (USEPA) is requiring certification bodies to be accredited by signatories to the Multilateral Agreement (MLA) of the International Accreditation Forum in support of the Energy Star Program. Other agencies, such as the Department of Defense, the Nuclear Regulatory Commission, the Coast Guard and the Food and Drug Administration, have similar programs or plans to make use of these international arrangements to underpin their conformity assessment activities and requirements.
- 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.
- 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 laboratory.

- 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.
- 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 International Laboratory Accreditation Cooperation (ILAC), the International Accreditation Forum (IAF), the International Organizations for Standardization's (ISO) Committee on Conformity Assessment (CASCO), conformity assessment related activities of private sector bodies such as the American National Standards Institute (ANSI), and ICSP working groups dealing with conformity assessment issues.
- 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.
- 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 agreements with foreign national and international private sector organizations and any resulting activities/requirements resulting from those negotiations/ agreements such as the ILAC MRA and IAF MLA.
- j. Participate in the development of private sector conformity assessment standards to ensure that Federal viewpoints are represented. 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.
- k. 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.
- l. 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.

- m. Assign an Agency Standard Executive responsibility for coordinating the agency-wide implementation of the guidance in this part.

Sec. 287.5 Responsibilities of an Agency Standards Executive.

In addition to carrying out the duties described in OMB Circular A- 119 related to standards activities, an Agency Standards Executive should:

- 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.

Ensure that agency participation in conformity assessment related activities is consistent with agency missions, authorities, priorities, and budget.

- c. Cooperate with NIST in carrying out agency responsibilities under the guidance in this part.
- d. Consult with NIST, as necessary, in the development and issuance of internal agency procedures and guidance implementing the policies in this part.
- 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.
- f. Work with other parts of his/her agency to develop and implement improvements in agency conformity assessment related 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.

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