

§ 286.8

§ 286.8 Confidentiality of information.

All information collected relative to an applicant during an evaluation is maintained as confidential. Information is released only as required under the terms of the Freedom of Information Act or other legal requirement, subject to the rules of the Department of Commerce for such disclosure as found in 15 CFR part 4.

§ 286.9 Maintaining recognized status.

Each program participant remaining in the program shall continuously meet all program requirements and cooperate with NIST in the conduct of all surveillance and reassessment activities. Participants shall reimburse NIST for expenses incurred for these purposes.

§ 286.10 Appeal.

Any applicant or other affected party may appeal to the NIST Director any action taken under the program. When appropriate, the Director may seek an independent review by the Deputy Chief Counsel.

§ 286.11 Listings.

(a) NIST maintains lists of all bodies holding current NIST program certificates, together with the assessment areas for which they are issued.

(b) NIST also maintains lists of those qualified conformity assessment bodies that are currently accredited by bodies recognized by NIST, along with the activities of the assessment bodies within the scope of the NIST recognition program.

(c) The lists are made available to the public through various media, e.g., printed directories, electronic bulletin boards, or other means to ensure accessibility by all potential users.

(d) With respect to the lists specified in paragraph (a) and (b) of this section, NIST may delist any body if it determines the action to be in the public interest.

§ 286.12 Terminations.

(a) *Voluntary termination.* Any participant may voluntarily terminate participation at any time by written notification to NIST.

15 CFR Subtitle B, Ch. II (1–1–18 Edition)

(b) *Involuntary termination.* If a participant does not continue to meet all program requirements, or if NIST determines it to be necessary in the public interest, NIST may withdraw that participant's certificate. A body that has had its status as a certificate holder terminated may reapply when prepared to demonstrate full conformance with program requirements.

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).

SOURCE: 65 FR 48900, Aug. 10, 2000, unless otherwise noted.

§ 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.

§ 287.2 Definitions.¹

Accreditation means a procedure used to provide formal notice that a body or person is competent to carry out specific tasks. These tasks include: sam-

pling and testing; inspection; certification; and registration.²

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 commission 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 procedure used to provide written assurance that a product, process, service, or person's qualifications conforms to specified requirements.

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

¹Definitions 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), Guide 2 (1996). 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.

²For some agencies, accreditation may mean that a body or person meets requirements defined in a specific section(s) of the CFR. The referenced section(s) may include only limited requirements for demonstration of technical competency.

§ 287.3

(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).

Inspection is defined as the evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging of the conformity of a product, process or service to specified requirements.

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

Recognition means a procedure used to provide formal notice that an accreditation body is competent to carry out specific tasks. These tasks include: the accreditation of testing laboratories and inspection, certification, and registration bodies. A governmental recognition system is a set of one or more procedures used by a Federal agency to provide recognition.

Registration means a procedure used to give written assurance that a system conforms to specified requirements. Such systems include those established for the management of product, process or service quality and environmental performance.

Sampling means the selection of one or more specimens of a product, process, or service for the purpose of evaluating the conformity of the product, process or service to specified requirements.

Supplier's declaration of conformity means a procedure by which a supplier gives written assurance that a product, process, service or organization conforms to specified requirements.

Testing means the action of carrying out one or more technical operations (tests) that determine one or more characteristics or performance of a given product, material, equipment, organism, person's qualifications, physical phenomenon, process, or service according to a specified technical procedure (test method).

§ 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,

15 CFR Subtitle B, Ch. II (1-1-18 Edition)

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 August 10, 2000, the effectiveness of the final 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.

(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.

(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 require-

ments 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.

(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 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.

(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

§ 287.5

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.

(j) Participate in the development of private sector conformity assessment standards to ensure that Federal viewpoints are represented.

(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.

(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.

(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.

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

15 CFR Subtitle B, Ch. II (1-1-18 Edition)

§ 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.

(b) 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.