

§ 285.14

stayed pending the outcome of the appeal. The proposed denial or revocation will become final through the issuance of a written decision to the laboratory in the event that the laboratory does not appeal the proposed denial or revocation within the thirty-day period.

(2) If accreditation is revoked, the laboratory may be given the option of voluntarily terminating the accreditation.

(3) A laboratory whose accreditation has been revoked must cease use of the NVLAP logo on any of its reports, correspondence, or advertising related to the area(s) affected by the revocation. If the revocation is total, NVLAP will instruct the laboratory to return its Certificate and Scope of Accreditation and to remove the NVLAP logo from all test or calibration reports, correspondence, or advertising. If the revocation affects only some, but not all of the items listed on a laboratory's Scope of Accreditation, NVLAP will issue a revised Scope that excludes the revoked area(s) in order that the laboratory might continue operations in accredited areas.

(d) A laboratory whose accreditation has been voluntarily terminated, denied or revoked, may reapply and be accredited if the laboratory:

- (1) Completes the assessment and evaluation process; and
- (2) Meets the NVLAP conditions and criteria for accreditation.

§ 285.14 Criteria for accreditation.

The requirements for laboratories to be recognized by the National Voluntary Laboratory Accreditation Program as competent to carry out tests and/or calibrations are contained in clauses 4 and 5 of ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, including revisions from time to time.

§ 285.15 Obtaining documents.

(a) Application forms, NVLAP handbooks, and other NVLAP documents and information may be obtained by contacting the NVLAP, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 2140, Gaithersburg, Maryland 20899-2140; phone: 301-975-4016; fax: 301-926-2884; e-mail: nvlap@nist.gov.

15 CFR Subtitle B, Ch. II (1-1-03 Edition)

(b) Copies of all ISO/IEC documents are available from the American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, New York 10036; phone: 212-642-4900; fax: 212-398-0023; web site: www.ansi.org. You may inspect copies of all applicable ISO/IEC documents at the National Voluntary Laboratory Accreditation Program, National Institute of Standards and Technology, 820 West Diamond Avenue, Room 297, Gaithersburg, MD.

PART 286—NATIONAL VOLUNTARY CONFORMITY ASSESSMENT SYSTEM EVALUATION (NVCASE) PROGRAM

Sec.

- 286.1 Purpose.
- 286.2 Scope.
- 286.3 Objective.
- 286.4 Implementation.
- 286.5 Program requirements.
- 286.6 Public consultation.
- 286.7 Evaluation process.
- 286.8 Confidentiality of information.
- 286.9 Maintaining recognized status.
- 286.10 Appeal.
- 286.11 Listings.
- 286.12 Terminations.

AUTHORITY: 15 U.S.C. 272 *et seq.*

SOURCE: 59 FR 19131, Apr. 22, 1994, unless otherwise noted.

§ 286.1 Purpose.

The purpose of this program is to enable U.S. industry to satisfy mandated foreign technical requirements using the results of U.S.-based conformity assessment programs that perform technical evaluations comparable in their rigor to practices in the receiving country. Under this program, the Department of Commerce, acting through the National Institute of Standards and Technology, evaluates U.S.-based conformity assessment bodies in order to be able to give assurances to a foreign government that qualifying bodies meet that government's requirements and can provide results that are acceptable to that government. The program is intended to provide a technically-based U.S. approval process for U.S. industry to gain foreign market access; the acceptability of conformity

assessment results to the relevant foreign government will be a matter for agreement between the two governments.

§ 286.2 Scope.

(a) For purposes of this program, conformity assessment consists of product sample testing, product certification, and quality system registration. Associated activities can be classified by level:

(1) *Conformity level*: This level encompasses comparing a product, process, service, or system with a standard or specification. As appropriate, the evaluating body can be a testing laboratory, product certifier or certification body, or quality system registrar.

(2) *Accreditation level*: This level encompasses the evaluation of a testing laboratory, a certification body, or a quality system registrar by an independent body—an accreditation body—based on requirements for the acceptance of these bodies, and the granting of accreditation to those which meet the established requirements.

(3) *Recognition level*: This level encompasses the evaluation of an accreditation body based on requirements for its acceptance, and the recognition by the evaluating body of the accreditation body which satisfies the established requirements.

(b) NIST operates the NVCASE program as follows:

(1) *Conformity level*: Under this program NIST accepts requests for evaluations of U.S. bodies involved in activities related to conformity assessment. NIST does not perform conformity assessments as part of the program and therefore does not accept requests for such evaluations.

(2) *Accreditation level*: NIST accepts requests for accreditation of conformity assessment bodies only when (i) directed by U.S. law; (ii) requested by another U.S. government agency; or (iii) requested to respond to a specific U.S. industrial or technical need, relative to a mandatory foreign technical requirement, if it has been determined after public consultation that (A) there is no satisfactory accreditation alternative available and the private sector has declined to make acceptable accreditation available, and (B) there is

evidence that significant public disadvantage would result from the absence of any alternative.

(3) *Recognition level*: NIST accepts requests for recognition of bodies that accredit testing laboratories, certification bodies, and quality system registrars when (i) directed by U.S. law; (ii) requested by another U.S. government agency; or (iii) requested to respond to a specific U.S. industrial or technical need relative to a mandatory foreign technical requirement if it has been determined after public consultation that (A) there is no suitable alternative available and (B) there is evidence that significant public disadvantage would result from the absence of any alternative.

§ 286.3 Objective.

The objective of the program is to identify the activities of requesting U.S.-based conformity assessment bodies that have been evaluated as meeting requirements established for their acceptance by foreign governments. The evaluations may be provided by NIST or by bodies recognized by NIST for this purpose under the scope of this program.

§ 286.4 Implementation.

The program is operated on a cost reimbursable basis. It is open for voluntary participation by any U.S.-based body that conducts activities related to conformity assessment falling within the program's scope. A common procedural approach is followed in responding to a request to participate. (See §286.7 Evaluation process.) All evaluation activities rely on the use of generic program requirements based on standards and guides for the operation and acceptance of activities related to conformity assessment. Specific criteria for use in each evaluation are derived from the program requirements, as appropriate, for the mandated foreign technical requirements specified in the request to participate. A request involving a foreign technical requirement not previously addressed by NVCASE will result in an announcement of NIST's intent to develop evaluation criteria specific to the relevant requirements. NIST will contact all

§ 286.5

cognizant and interested federal agencies to coordinate appropriate actions and procedures.

§ 286.5 Program requirements.

NIST provides and maintains documented generic requirements to be applied in evaluations related to accreditation and recognition within the scope of the program. Available documentation is provided on request to prospective program participants and other interested parties. Generic requirements are developed with public input and are based on guides for the acceptance of conformity assessment activities issued by such international organizations as the International Organization for Standardization and the International Electrotechnical Commission. NIST also provides and maintains documented criteria provided in response to requests for evaluations specific to mandated foreign technical requirements. Criteria are developed with public input derived from the application and interpretation of generic program requirements in relation to specified mandated requirements. Both documented generic requirements and specific criteria are developed and maintained with input from the public.

§ 286.6 Public consultation.

NIST relies on substantial advice and technical assistance from all parties interested in program requirements and related specific criteria. Interested U.S. government agencies are routinely to be informed of prospective NVCASE actions, and advice is sought from those agencies on any actions of mutual interest. In preparing program documentation, input is also sought from workshops announced in the FEDERAL REGISTER and open to the general public and other public means to identify appropriate standards and guides and to develop and maintain generic requirements, based on the identified standards and guides. Where relevant Federal advisory committees are available, their advice may also be sought. Similar procedures will be followed with respect to each request for evaluation which necessitates the development of criteria, derived from the generic requirements, specific to mandated foreign technical requirements.

15 CFR Subtitle B, Ch. II (1-1-03 Edition)

§ 286.7 Evaluation process.

(a) Each applicant requesting to be evaluated under NVCASE is expected to initiate the process and assume designated responsibilities as NIST proceeds with its evaluation:

(1) *Application.* The applicant completes and submit a request to be evaluated.

(2) *Fee.* The applicant submits a partial payment with the application and agrees to submit the remaining balance based on evaluation costs as a condition for satisfactory completion of the process.

(3) *Documentation.* The applicant operates a system and procedures that meet the applicable generic requirements and specific criteria. Relevant documentation submitted with the application is reviewed by NIST.

(4) *On-site assessment.* The applicant and NIST cooperate in the scheduling and conduct of all necessary on-site evaluations, including the resolution of any deficiencies cited.

(5) *Final review.* The applicant provides any supplementary materials requested by NIST, then NIST completes the review and decides on appropriate action.

(b) NIST may take one of the following actions with regard to an applicant:

(1) *Certificate.* If an applicant fully demonstrates conformity with all program requirements and specific criteria, NIST issues a certificate documenting this finding. Each certificate is accompanied by a document describing the specific scope of the accreditation or recognition.

(2) *Denial.* If an applicant cannot demonstrate conformity with all program requirements and specific criteria, NIST may deny award of the certificate. An applicant who has failed to complete the evaluation satisfactorily may reapply when prepared to demonstrate full conformance with program requirements.

§ 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.

Natl. Inst. of Stds. & Tech., Commerce

§ 287.1

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.

(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 pre-

pared 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