

in any calibration certificate, test report or test certificate of amendment to a report or certificate.

(7) The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of these procedures are met and that confidentiality is preserved.

(1) *Subcontracting of calibration or testing.* (1) Where a laboratory subcontracts any part of the calibration or testing, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its subcontractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect of the work being subcontracted. The laboratory shall advise the client in writing of its intention to subcontract any portion of the calibration or testing to another party.

(2) The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a register of all subcontracting.

(m) *Outside support services and supplies.* (1) Where the laboratory procures outside services and supplies, other than those referred to in these procedures, in support of calibrations or tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests.

(2) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

(3) The laboratory shall maintain records of all suppliers from whom it

obtains support services or supplies required for calibrations or tests.

(n) *Complaints.* (1) The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

(2) Where a complaint, or any other circumstances, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this section or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with this section.

[59 FR 22750, May 3, 1994]

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 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.

§ 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, 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 certifi-

cates, 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 prepared to demonstrate full conformance with program requirements.