

§ 285.10

1, or October 1) is assigned to the laboratory and is usually retained as long as the laboratory remains in the program. Initial accreditation is granted for a period of one year; accreditation expires and is renewable on the assigned date.

(c) Renewal dates may be reassigned to provide benefits to the laboratory and/or NVLAP. If a renewal date is changed, the laboratory will be notified in writing of the change and any related adjustment in fees.

(d) When accreditation is granted, NVLAP shall provide to the laboratory a Certificate of Accreditation and a Scope of Accreditation.

§ 285.10 Renewal of accreditation.

(a) An accredited laboratory must submit both its application for renewal and fees to NVLAP prior to expiration of the laboratory's current accreditation to avoid a lapse in accreditation.

(b) On-site assessments of currently accredited laboratories are performed in accordance with the procedures in § 285.7. If deficiencies are found during the assessment of an accredited laboratory, the laboratory must follow the procedures set forth in § 285.7(e)(2) or face possible suspension or revocation of accreditation.

§ 285.11 Changes to scope of accreditation.

A laboratory may request in writing changes to its Scope of Accreditation. If the laboratory requests additions to its Scope, it must meet all NVLAP criteria for the additional tests or calibrations, types of tests or calibrations, or standards. The need for an additional on-site assessment and/or proficiency testing will be determined on a case-by-case basis.

§ 285.12 Monitoring visits.

(a) In addition to regularly scheduled assessments, monitoring visits may be conducted by NVLAP at any time during the accreditation period. They may occur for cause or on a random selection basis. While most monitoring visits will be scheduled in advance with the laboratory, NVLAP may conduct unannounced monitoring visits.

(b) The scope of a monitoring visit may range from checking a few des-

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ignated items to a complete review. The assessors may review deficiency resolutions, verify reported changes in the laboratory's personnel, facilities, or operations, or administer proficiency testing, when appropriate.

§ 285.13 Denial, suspension, revocation, or termination of accreditation.

(a) A laboratory may at any time voluntarily terminate its participation and responsibilities as an accredited laboratory by advising NVLAP in writing of its desire to do so.

(b) If NVLAP finds that an accredited laboratory does not meet all NVLAP requirements, has violated the terms of its accreditation, or does not continue to comply with the provisions of these procedures, NVLAP may suspend the laboratory's accreditation, or advise of NVLAP's intent to revoke accreditation.

(1) If a laboratory's accreditation is suspended, NVLAP shall notify the laboratory of that action stating the reasons for and conditions of the suspension and specifying the action(s) the laboratory must take to have its accreditation reinstated. Conditions of suspension will include prohibiting the laboratory from using the NVLAP logo on its test or calibration reports, correspondence, or advertising during the suspension period in the area(s) affected by the suspension.

(2) NVLAP will not require a suspended laboratory to return its Certificate and Scope of Accreditation, but the laboratory must refrain from using the NVLAP logo in the area(s) affected until such time as the problem(s) leading to the suspension has been resolved. When accreditation is reinstated, NVLAP will authorize the laboratory to resume testing or calibration activities in the previously suspended area(s) as an accredited laboratory.

(c) If NVLAP proposes to deny or revoke accreditation of a laboratory, NVLAP shall inform the laboratory of the reasons for the proposed denial or revocation and the procedure for appealing such a decision.

(1) The laboratory will have thirty days from the date of receipt of the proposed denial or revocation letter to

appeal the decision to the Director of NIST. If the laboratory appeals the decision to the Director of NIST, the proposed denial or revocation will be 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.

(b) Copies of all ISO/IEC documents are available for purchase from the American National Standards Institute's eStandards Store at <http://webstore.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, 100 Bureau Drive, Room B115, Gaithersburg, MD. For access to the NIST campus, please contact NVLAP by phone at 301-975-4016 or by e-mail at NVLAP@nist.gov to obtain instructions for visitor registration.

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

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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