pertinent portions of the document assigning rights in the alphanumeric designation. Such application must be filed within six months of the date of assignment.

(f) An alphanumeric designation that is reactivated after it has been transferred or assigned shall remain in active status until the expiration of the five year period that began upon the issuance of the alphanumeric designation to its original owner.

[61 FR 50558, Sept. 26, 1996. Redesignated and amended at 65 FR 39803, 39804, June 28, 2000; 72 FR 30704, June 4, 2007]

§ 280.324 Change in status of trademark registration or amendment of the trademark.

(a) The Director, USPTO, shall designate the certificate of recordal as inactive, upon:

(1) Issuance of a final decision on appeal which refuses registration of the application which formed the basis for the certificate of recordal;

(2) Abandonment of the application which formed the basis for the certificate of recordal;

(3) Cancellation or expiration of the trademark registration which formed the basis of the certificate of recordal; or

(4) An amendment of the mark in a trademark application or registration that forms the basis for a certificate of recordal. The certificate of recordal shall become inactive as of the date the amendment is filed. A new application for recordal of the amended trademark application or registration may be submitted to the Commissioner at any time.

(b) Certificates of recordal designated inactive due to cancellation, expiration, or amendment of the trademark registration, or abandonment or amendment of the trademark application, cannot be reactivated.

[61 FR 50558, Sept. 26, 1996. Redesignated and amended at 65 FR 39803, 39804, June 28, 2000]

§ 280.325 Cumulative listing of recordal information.

The Director, USPTO, shall maintain a record of the names, current addresses, and legal entities of all recorded manufacturers and their recorded insignia.

[65 FR 39804, June 28, 2000]

§ 280.326 Records and files of the United States Patent and Trademark Office.

The records relating to fastener insignia shall be open to public inspection. Copies of any such records may be obtained upon request and payment of the fee set by the Director, USPTO.

[61 FR 50558, Sept. 26, 1996. Redesignated and amended at 65 FR 39803, 39804, June 28, 2000]

PART 285—NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM

Sec.

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

SOURCE: 66 FR 29221, May 30, 2001, unless otherwise noted.

§ 285.1 Purpose.

The purpose of this part is to set out procedures and general requirements under which the National Voluntary Laboratory Accreditation Program (NVLAP) operates as an unbiased third party to accredit both testing and calibration laboratories. Supplementary technical and administrative requirements are provided in supporting handbooks and documents as needed, depending on the criteria established for specific Laboratory Accreditation Programs (LAPs).

[85 FR 60060, Sept. 24, 2020]

§ 285.2 Confidentiality.

To the extent permitted by applicable laws, NVLAP will protect the confidentiality of all information obtained relating to the application, on-site assessment, proficiency testing, evaluation, and accreditation of laboratories.

§ 285.3 Referencing NVLAP accreditation.

The term *NVLAP* (represented by the NVLAP logo) is a federally registered certification mark of the National Institute of Standards and Technology and the federal government, who retain exclusive rights to control the use thereof. Permission to use the term and/or logo is granted to NVLAP-accredited laboratories for the limited purposes of announcing their accredited status, and for use on reports that describe only testing and calibration within the scope of accreditation. NIST reserves the right to control the quality of the use of the term *NVLAP* and of the logo itself.

§ 285.4 Establishment of laboratory accreditation programs (LAPs) within NVLAP.

NVLAP establishes LAPs in response to legislative actions or to requests from private sector entities and government agencies. For legislatively mandated LAPs, NVLAP shall establish the LAP. For requests from private sector entities and government agencies, the Chief of NVLAP shall analyze each request, and, after consultation with interested parties through public workshops or other means to ensure open participation, shall establish the requested LAP, if the Chief of NVLAP determines there is need for the requested LAP.

[66 FR 29221, May 30, 2001, as amended at 76 FR 78815, Dec. 20, 2011]

§ 285.5 Termination of a LAP.

(a) The Chief of NVLAP may terminate a LAP when he/she determines that a need no longer exists to accredit laboratories for the services covered under the scope of the LAP. In the event that the Chief of NVLAP proposes to terminate a LAP, a notice will be published in the FEDERAL REGISTER setting forth the basis for that determination.

(b) When a LAP is terminated, NVLAP will no longer grant or renew accreditations following the effective date of termination. Accreditations previously granted shall remain effective until their expiration date unless terminated voluntarily by the laboratory or revoked by NVLAP. Technical expertise will be maintained by NVLAP while any accreditation remains effective.

§ 285.6 Application for accreditation.

A laboratory may apply for accreditation in any of the established LAPs. The applicant laboratory shall provide a completed application to NVLAP, pay all required fees and agree to certain conditions as set forth in the NVLAP Application for Accreditation, and provide management system documentation to NVLAP (or a designated NVLAP assessor) prior to the assessment process.

[85 FR 60060, Sept. 24, 2020]

§ 285.7 Assessment.

(a) *Frequency and scheduling.* Before initial accreditation, during the first renewal year, and every two years thereafter, an on-site assessment of each laboratory is conducted to determine compliance with the NVLAP criteria.

(b) *Assessors.* NVLAP shall select qualified assessors to evaluate all information collected from an applicant laboratory pursuant to § 285.6 of this part and to conduct the assessment on its behalf at the laboratory and any other sites where activities to be covered by the accreditation are performed.

(c) *Conduct of assessment.* (1) Assessors use checklists provided by NVLAP so that each laboratory receives an assessment comparable to that received by others.

(2) During the assessment, the assessor meets with management and laboratory personnel, examines the quality system, reviews staff information, examines equipment and facilities, observes demonstrations of testing or calibrations, and examines tests or calibration reports.

(3) The assessor reviews laboratory records including resumes, job descriptions of key personnel, training, and competency evaluations for all staff members who routinely perform, or affect the quality of the testing or calibration for which accreditation is sought. The assessor need not be given information which violates individual privacy, such as salary, medical information, or performance reviews outside the scope of the accreditation program. The staff information may be kept in the laboratory's official personnel folders or separate folders that contain only the information that the NVLAP assessor needs to review.

(4) At the conclusion of the assessment, the assessor conducts an exit briefing to discuss observations and any nonconformities with the authorized representative who signed the NVLAP application and other responsible laboratory staff.

(d) *Assessment report.* At the exit briefing, the assessor submits a written report on the compliance of the laboratory with the accreditation requirements, together with the completed checklists, where appropriate.

(e) *Deficiency notification and resolution.* (1) Laboratories are informed of nonconformities during the on-site assessment, and nonconformities are documented in the assessment report (see paragraph (d) of this section).

(2) A laboratory shall, within thirty days of the date of the assessment report, provide documentation that the specified nonconformities have either been corrected and/or a plan of corrective actions as described in the NVLAP handbooks.

(3) If substantial nonconformities have been cited, NVLAP may require an additional on-site assessment, at additional cost to the laboratory, prior to granting accreditation. All nonconformities and resolutions will be subject to thorough review and evaluation prior to an accreditation decision.

(4) After the assessor submits their final report, NVLAP reviews the report and the laboratory's response to determine if the laboratory has met all of the on-site assessment requirements.

[66 FR 29221, May 30, 2001, as amended at 85 FR 60060, Sept. 24, 2020]

§ 285.8 Proficiency testing.

(a) *Proficiency testing requirements.* Proficiency testing undertaken to meet the criteria for NVLAP accreditation shall be consistent with the provisions contained in NIST Handbook 150, *NVLAP Procedures and General Requirements* (incorporated by reference, see § 285.16), where applicable, including revisions from time to time. Laboratories must participate in proficiency testing as specified for each LAP in the NVLAP program handbooks.

(b) *Analysis and reporting.* Proficiency testing results are analyzed by NVLAP and results of the analysis are made known to the participants. Any result not meeting the criteria specified in the NVLAP LAP program handbook is identified as a nonconformity.

(c) *Proficiency testing nonconformities.* (1) Unsatisfactory participation in any proficiency testing program is a technical nonconformity which must be resolved in order to obtain initial accreditation or maintain accreditation.

(2) Proficiency testing nonconformities are defined as, but not limited to, one or more of the following:

(i) Failure to meet specified proficiency testing performance requirements prescribed by NVLAP;

(ii) Failure to participate in a regularly scheduled ''round'' of proficiency testing for which the laboratory has received instructions and/or materials;

(iii) Failure to submit laboratory control data as required; or

(iv) Failure to produce acceptable test or calibration results when using NIST Standard Reference Materials or special artifacts whose properties are well-characterized and known to NIST/NVLAP.

(3) NVLAP will notify the laboratory of proficiency testing nonconformities and actions to be taken to resolve the nonconformities. Denial or suspension of accreditation will result from failure to resolve nonconformities.

[85 FR 60060, Sept. 24, 2020]

§ 285.9 Granting accreditation.

(a) The Chief of NVLAP is responsible for all NVLAP accreditation actions, including granting, denying, renewing, suspending, and revoking any NVLAP accreditation.

(b) Initial accreditation is granted when a laboratory has met all NVLAP requirements. One of four accreditation renewal dates (January 1, April 1, July 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 nonconformities 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.

[66 FR 29221, May 30, 2001, as amended at 85 FR 60060, Sept. 24, 2020]

§ 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 designated items to a complete review. The assessors may review nonconformity resolutions, verify reported changes in the laboratory's personnel, facilities or operations, or evaluate proficiency testing activities, when appropriate.

[85 FR 60060, Sept. 24, 2020]

§ 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 NIST Handbook 150, *NVLAP Procedures and General Requirements* (incorporated by reference, see § 285.16).

[85 FR 60061, Sept. 24, 2020]

§ 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 B119, Gaithersburg, MD. For access to the NIST campus, please contact NVLAP by phone at 301–975–4016 or by email at *NVLAP@nist.gov* to obtain instructions for visitor registration.

[66 FR 29221, May 30, 2001, as amended at 72 FR 36347, July 3, 2007; 85 FR 60061, Sept. 24, 2020]

§ 285.16 Incorporation by reference.

Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at National Institute of Standards and Technology, National Voluntary Laboratory Accreditation Program (NVLAP), National Institute of Standards and Technology, 100 Bureau Drive, Room B119, Gaithersburg, MD and is available from the source(s) listed in the following paragraph(s). It is also available for inspection at the National Archives and Records Administration (NARA). For

access to the NIST campus, please contact NVLAP by phone at 301–975–4016 or by email at *NVLAP@nist.gov* to obtain instructions for visitor registration. For information on the availability of this material at NARA, email *fedreg.legal@nara.gov* or go to *www.archives.gov/federal-register/cfr/ibr-locations.html*.

(a) National Institute of Standards and Technology (NIST), U.S. Department of Commerce, 100 Bureau Drive, Room B119, Gaithersburg, MD, 301–975–4016 *NVLAP@nist.gov*, *www.nist.gov/publications/*.

(1) NIST Handbook 150, *National Voluntary Laboratory Accreditation Program Procedures (NVLAP) and General Requirements,* authored by Dana S. Leaman and Bethany Hackett, 2020 Edition, August 2020, 2020 (*NVLAP Procedures and General Requirements*) *https://nvlpubs.nist.gov/nistpubs/hb/2020/NIST.HB.150-2020.pdf;* into §§ 285.8(a) and § 285.14.

(2) [Reserved]

(b) [Reserved]

[85 FR 60061, Sept. 24, 2020]

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

Sec.

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.