

§ 285.8

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 deficiencies 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 deficiencies during the on-site assessment, and deficiencies 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 deficiencies have either been corrected and/or a plan of corrective actions as described in the NVLAP handbooks.

(3) If substantial deficiencies have been cited, NVLAP may require an additional on-site assessment, at additional cost to the laboratory, prior to granting accreditation. All deficiencies 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.

§ 285.8 Proficiency testing.

(a) NVLAP proficiency testing is consistent with the provisions contained in ISO/IEC Guide 43 (Parts 1 and 2), Proficiency testing by interlaboratory comparisons, where applicable, including revisions from time to time. Proficiency testing may be organized by NVLAP itself or a NVLAP-approved provider of services. Laboratories must

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

participate in proficiency testing as specified for each LAP in the NVLAP program handbooks.

(b) *Analysis and reporting.* Proficiency testing data are analyzed by NVLAP and reports of the results are made known to the participants. Summary results are available upon request to other interested parties; e.g., professional societies and standards writing bodies. The identity and performance of individual laboratories are kept confidential.

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

(2) Proficiency testing deficiencies 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; and

(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 deficiencies and actions to be taken to resolve the deficiencies. Denial or suspension of accreditation will result from failure to resolve deficiencies.

§ 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 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 designated 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