1 PURPOSE AND SCOPE

This procedure describes NVLAP's process for the review of on-site assessment results, including reported nonconformities and their resolutions. The on-site assessment under review may be a regularly scheduled assessment, a follow-up visit, a special assessment conducted for the purpose of scope expansion or proficiency testing, or a monitoring visit.

2 REFERENCES

2.1 *NVLAP Management System Manual*, 7.5

2.2 NIST Handbook 150, 3.3.3, *Nonconformity notification and resolution*

2.3 APM 23.01, *Granting and Renewing Accreditation*

2.4 OIM 22.03, *Documenting the On-Site Assessment Review*

3 DEFINITIONS

There are no definitions that are specific to this procedure. See MSM, clause 3 for information about general terms and definitions.

4 RESPONSIBILITIES

The following positions and groups have responsibilities that are described in this procedure:

a) Program Managers;

b) Persons who serve as evaluators of on-site assessment results.

5 PROCEDURE

5.1 General

NVLAP conducts an impartial and objective review of the results of each on-site assessment to ensure that a laboratory has successfully met NVLAP requirements for accreditation. This review includes a determination of whether actions taken by a laboratory to resolve nonconformities are sufficient and effective.

5.2 Selection of evaluators

5.2.1 When a laboratory on-site assessment report and all associated nonconformity responses, if any, have been received by NVLAP, the Program Manager (PM) to whom the laboratory is assigned selects an evaluator to review the on-site assessment documentation. The evaluator may be a qualified assessor, technical expert, another PM, or the PM him/herself.

The PM ensures that the evaluator who is selected is free of pressures and conflicts of interest that could compromise the review process and has signed the NVLAP Declaration, thereby agreeing to inform NVLAP of any prior association with any laboratory to be assessed or evaluated.

5.2.2 The implementation of this procedure may vary from program-to-program, depending upon the number of PMs assigned to a program. However, in all cases a person who has been involved in the assessment process, which includes the review and clearance of nonconformities, cannot be the person who makes the accreditation decision and sets the "Accreditation Decision" to PASS in the NVLAP Information System (NIS). (See APM 23.01 for a description of the accreditation decision-making process.)

5.3 Conducting the on-site assessment review

5.3.1 When there are no nonconformities reported, the on-site assessment review is completed within 30 days after the receipt of the report by NVLAP.

5.3.2 If a laboratory has nonconformities, it is required to send a response, which addresses all nonconformities, in writing to NVLAP within 30 days of the date of the on-site assessment report. The PM should acknowledge the laboratory response (by e-mail or by letter) within 24 hours of its receipt by the PM.

5.3.3 The on-site assessment review and clearance of corrective actions is done by a qualified assessor, technical expert, or a PM who will not make the accreditation decision for the laboratory under review. This review is conducted within 30 days from the receipt by NVLAP of the full documentation from the laboratory.

5.3.4 The documentation under review may include all or some of the following, as applicable:

a) NIST Handbook 150 Checklist;

b) Program-Specific Checklist;

c) Test Method Review Summary;

d) On-Site Report forms (Summary, Signature Sheet, and Narrative);

e) corrective action responses to cited nonconformities;

f) other documentation pertinent to the purpose of the on-site, such as results of proficiency testing conducted during the visit.

5.3.5 The evaluator follows the procedures set forth in NIST Handbook 150, 3.3.3, *Nonconformity notification and resolution*, when conducting the review.

5.3.6 The evaluator(s) makes the determination whether the laboratory:

a) meets all on-site assessment requirements;

b) does not meet all on-site assessment requirements; or

c) does not meet all on-site assessment requirements and requires a follow-up visit to determine that nonconformities have been resolved.

5.4 Documenting the on-site assessment review

5.4.1 The evaluator is responsible for documenting the results of the review on the NVLAP On-Site Assessment Review form. Instructions for the completion of this form are found in OIM 22.03, *Documenting the On-Site Assessment Review.*

5.4.2 One On-Site Assessment Review form is used per review. The form may be used by the evaluator, if needed, to record more than one nonconformity requiring action by the laboratory.

5.4.3 The completed and signed form is forwarded to the NVLAP PM, who generates the appropriate notification letter to be sent to the laboratory. OIM 22.03 provides detailed instructions on how to generate the letters from the NIS.

5.4.4 The on-site review phase of the accreditation process is not complete until all nonconformities have been resolved by the laboratory. Several iterations of the steps described above may be required before all corrective actions have been cleared by the evaluator(s). If more than one review is required, the same evaluator(s) should be used, if possible. In such cases, there will a separate On-Site Assessment Review form on record for each review.

5.4.5 The completed On-Site Assessment Review form(s) is not only part of the information that is considered during the decision to grant or to renew an accreditation, but also is the record of fulfillment of this phase of the accreditation process.