



# LABORATORY ASSESSMENT INSTRUCTIONS FOR ASSESSORS

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## 1 Preparation for the On-Site Assessment

**1.1** After receiving the on-site package, the lead assessor contacts the Authorized Representative (AR) of the laboratory to discuss the upcoming assessment. NVLAP's goal is to have the on-site performed within the first 6 months of the renewal cycle. The lead assessor establishes the date of the assessment by coordinating with all assigned assessors and the AR and notifies the NVLAP Program Manager (PM) of the scheduled date. The lead assessor should also provide the lab with his/her contact information in case any changes or questions should arise. The scheduled date should be at least 45 days beyond the date the bid(s) was approved. Any assessor requiring further information not provided in the on-site package may request the laboratory to send them the additional information.

NOTE 1 Do not purchase tickets or commit any money prior to receiving a copy of the purchase order authorization. The time from when NVLAP approves the bid until the purchase order is authorized is normally less than 30 days.

NOTE 2 If you have been informed by the NVLAP PM that the assessment work will be processed via convenience check, do not purchase tickets or commit any money prior to receiving an approval e-mail with processing instructions from the NVLAP PM.

**1.2** The lead assessor conducts a review of the laboratory's management system documentation and notifies the AR of any findings at least two weeks prior to the on-site assessment. The lead assessor provides a draft agenda at this time. The lead assessor shall record the completion date of this review on the On-Site Assessment Summary (see section 4).

NOTE If the nonconformities found during the document review are serious enough to recommend not proceeding with the on-site assessment, the lead assessor notifies the NVLAP PM immediately. The PM will decide whether or not to proceed with the on-site assessment and will notify the laboratory in writing of the decision.

**1.3** The lead assessor contacts the AR and the other assessor(s) two to five days prior to the on-site assessment to confirm the assessment date(s) and final logistics (e.g., pre-meeting breakfast, opening meeting time, etc.).

## 2 On-Site Assessment Report

### 2.1 Overview of On-Site Assessment Report

The On-Site Assessment Report is comprised of the several parts:

- Signature Sheet with On-Site Assessment Narrative Summary,
- NIST Handbook 150 Checklist,
- Program-Specific Checklist (if required), and
- Test Method Review Summary (TMR) (if required).

These are the tools you will use in assessing and reporting a laboratory's conformance with the NVLAP accreditation criteria. When completed, they become part of the laboratory's accreditation record. The

records are retained by NVLAP, and are used by other assessors during subsequent assessments. PDF versions (as well as Word and Excel versions, as applicable) of these forms and checklists are available on the NVLAP website from the Assessor Resources page.

Please note that some programs may have pre-populated TMRs that you would receive with the on-site package. If you do not use the forms electronically, please ensure that you write legibly.

You must identify all of the laboratory's nonconformities (failures to comply with the NVLAP criteria) that you found during the on-site visit. In addition, you must review the last on-site assessment report to verify and document that actions taken by the laboratory to resolve all previously reported nonconformities have been effective. The On-Site Assessment Report includes your comments on the nonconformities and any comments that you wish to make in writing to the laboratory. If any questions or ambiguities arise during the course of the assessment and you cannot reach a conclusion about a finding, contact your NVLAP Program Manager for clarification.

## **2.2 On-Site Assessment Report Signature Sheet and Narrative Summary**

The Signature Sheet must be signed by you and the Authorized Representative of the laboratory, who thereby makes a commitment to respond, as appropriate, to any nonconformity documented in the report. The On-Site Assessment Narrative Summary is comprised of sections that are numbered to correspond to the major subclauses of NIST Handbook 150, *NVLAP Procedures and General Requirements*. It is used to report your general overview, evaluation and impressions of the laboratory's quality and competence and to provide the laboratory and NVLAP with a clear understanding of the laboratory's strengths and weaknesses. There is no need to reiterate specific nonconformities previously noted in the checklists.

Space is provided on page 3 of the narrative summary to record changes, additions, and deletions to the laboratory's scope of accreditation. This page may be replaced by a properly annotated copy of the laboratory's scope of accreditation or reference to an electronic file with the changes clearly indicated.

It is important to ensure that the table in section 5.10 lists all of the Approved Signatories that are identified in the laboratory's application. General guidance on this section is that each signatory either has a yes in the "Was performance observed?" column or in the "Were training record reviewed?" column. Please note that performance observed also refers to interviews to assess knowledge and does not specifically mean performance of a test. Use your best judgment as to how to meet this guidance in the time allotted and prevailing conditions at the time of assessment. A strategy for laboratories with greater than ten signatories should be addressed with the PM prior to the assessment.

**NOTE** An Approved Signatory is defined as "An individual who is designated by a laboratory and deemed competent by NVLAP to sign accredited laboratory test or calibration reports." Personnel should not be designated as a signatory solely based on their position. Any variation between signatories listed in the application and noted in this chart shall be clearly identified to allow for correction and possible findings pertaining to notification to NVLAP of signatory changes.

## **2.3 NIST Handbook 150 Checklist**

All NVLAP programs use the NIST Handbook 150 Checklist, which contains the requirements published in NIST Handbook 150. The checklist items are numbered to correspond to Clauses 4 and 5 and Annexes A and B of NIST Handbook 150.

## **2.4 NIST Handbook 150-x series checklist**

The NIST Handbook 150-x series checklists (Program-Specific Checklists) are based on program-specific requirements defined in the NVLAP program handbooks. They address the same areas as the NIST Handbook 150 Checklist, but with specific emphasis on the requirements of the particular laboratory accreditation program.

## **2.5 Test Method Review Summary**

The Test Method Review Summary is a matrix used to list various test methods in rows and the various attributes of what was assessed in columns. Codes are provided to demonstrate the level of detail of how an attribute was assessed. As there is variability between programs in this area, assessors should contact the responsible PM for further guidance on how to complete these forms.

## **2.6 Guidelines for completion of report**

The following guidelines should be followed when preparing the On-Site Assessment Report:

- When you and the AR sign the Signature Sheet, be certain that the AR understands that the laboratory must respond in writing to NVLAP within 30 days regarding resolution of all nonconformities identified in the checklists and in the On-Site Assessment Narrative Summary.
- When using the checklists, clearly identify and describe each nonconformity. Since NVLAP requires the laboratories to reference the nonconformity in their responses, the following is requested:
  - If multiple assessors are used, the initials of the assessor should be in the body of the text for a comment or nonconformity.
  - If there is more than one comment or nonconformity under the same requirement, ensure they are separated and identified somehow. X1, X2, C1 is one suggested way.
- When using the Narrative Summary, comment on the strengths and weaknesses of the laboratory. It can also be used to describe or list personnel interviewed, tests or calibrations observed, methods used, etc. (if not described elsewhere).
- Clearly distinguish between nonconformities and comments as stated above. The laboratory is only required to respond to nonconformities.
- You are encouraged to send the NVLAP Program Manager additional comments on the assessment of the laboratory that you may not wish to include in the On-Site Assessment Report. Specific guidance on the need for monitoring visits will assist NVLAP to ensure that only competent laboratories are accredited.

## **3 Presentation of report**

Closing meetings and the presentation of the report will vary widely depending on factors such as how the assessor(s) recorded the report, number of participants, whether visual equipment is available, etc. Use your best judgment and work with the lab to create a mutually acceptable closing presentation.

The report can be left with the AR in electronic or paper form. The only thing that needs to be printed is the signature page, which is signed by all assessors and the AR.

#### **4 On-Site Assessment Summary**

The On-Site Assessment Summary is a one-page status report of the assessment that the lead assessor signs. It is **not** part of the On-Site Assessment Report and is not to be left with the laboratory.

#### **5 Transmittal of On-Site Assessment Report and Summary**

Send NVLAP the On-Site Assessment Report and the On-Site Assessment Summary in either electronic format (highly preferred) or in paper format. If the documents are in electronic format, several transmission mechanisms exist. If sending by e-mail, send to [nvlap@nist.gov](mailto:nvlap@nist.gov) and send a courtesy copy (cc) the PM. If you have scanning ability, the required paper items that you have (signed Summary, signed Signature Sheet, lab audit schedule, and attendance sheets) can also be e-mailed.

If you do not have scanning ability, you can fax the required items to 301-926-2884. Another option is to save the electronic documents on a CD and mail it with the required paper items in the 9 x 12 business reply envelope provided to you in the on-site package.

NVLAP still accepts mailing of the hard copy reports in the previously mentioned envelope.

#### **6 Laboratory Assessment and Related Services Invoice**

Use the Laboratory Assessment and Related Services Invoice to report the costs you incurred in performing the on-site assessment(s), being sure to show the number of hours worked and to break down the total amount by labor and miscellaneous and travel expenses. This form may be downloaded from the NVLAP website from the Assessor Resources page under "Other Forms and Information for Assessors."

Refer to and follow the mailing, fax, or e-mail instructions on the invoice form. Do not send the invoice to NVLAP.

**NOTE** If you were informed by the NVLAP PM, via e-mail, that your assessment work will be processed via convenience check, follow the invoicing instructions received in the e-mail message.

#### **7 Disposition of on-site assessment documents**

The On-Site Assessment Report shall be treated with the utmost confidentiality. The contents of the report shall not be shared with anyone other than NVLAP staff, the laboratory Authorized Representative, and yourself. As the need for NVLAP to contact you regarding these reports diminishes over time and NVLAP has copies, please consider that you do not need to retain these items and dispose of them in a manner that will not jeopardize confidentiality.

**NOTE** In addition to the confidentiality provisions of NIST Handbook 150 paragraph 1.7, NVLAP, administered by NIST, and the laboratory seeking accreditation acknowledge and agree that the accreditation assessments and proficiency testing work done by NIST/NVLAP is done in accordance with the authority granted to NIST by Title 15 United States Code Section 3710a. The Parties further agree that to the extent permitted by law, NIST will protect

information obtained during application, on-site assessment, proficiency testing, evaluation, and accreditation from disclosure pursuant to Title 15 USC 3710a(c)(7)(A) and (7)(B) for a period of five (5) years after it is obtained.

For the first five years that laboratory information is held by NVLAP, both confidentiality provisions will be in force — NIST Handbook 150 and 15USC3710a. Information in NVLAP's possession for more than five years will continue to be held in confidence under the provision of NIST Handbook 150.