NBSIR 85-3137

NVLAP Assessment and Evaluation Manual

Peter S. Unger

U.S. DEPARTMENT OF COMMERCE
National Bureau of Standards
Office of Product Standards Policy
Gaithersburg, Maryland  20899

April 1985
NVLAP ASSESSMENT AND EVALUATION
MANUAL

Peter S. Unger

U.S. DEPARTMENT OF COMMERCE
National Bureau of Standards
Office of Product Standards Policy
Gaithersburg, Maryland 20899

April 1985

U.S. DEPARTMENT OF COMMERCE, Malcolm Baldrige, Secretary
NATIONAL BUREAU OF STANDARDS, Ernest Ambler, Director
NVLAP ASSESSMENT AND EVALUATION MANUAL

FOREWORD

The National Voluntary Laboratory Accreditation Program (NVLAP), established in 1976, is administered by the NBS Office of Product Standards Policy. NVLAP is a voluntary system for assessing and evaluating testing laboratories and accrediting those found competent to perform specific test methods or types of test methods. Individual laboratory accreditation programs (LAPs) for specified product or service areas are established in response to requests and demonstrated need.

This publication is the main body of written guidance provided to NVLAP technical experts (TEs), who serve as assessors and evaluators. The general policies and practices of NVLAP assessment and evaluation are described. The specific, technical details for assessing and evaluating laboratories under each LAP are provided in appendices tailored for each LAP. The appendices are not part of this publication.

ACKNOWLEDGEMENTS

The author wishes to recognize the significant contributions of several sources. NVLAP staff members, Harvey Berger, Robert Gladhill, Wiley Hall, Jeffrey Horlick, and John Locke, each made helpful suggestions on the structure and content of the document. NVLAP assessors, Charles Gilbo and Sidney Levinson, also provided useful insights. Several concepts developed in this publication were based on writings of and discussions with staff of Australia's National Association of Testing Authorities. Finally, Lisa Drake, NVLAP staff secretary, provided the tedious, but necessary, typing and production support.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Title Page</th>
<th>i</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreword</td>
<td>ii</td>
</tr>
<tr>
<td>Acknowledgements</td>
<td>ii</td>
</tr>
<tr>
<td>Table of Contents</td>
<td>iii</td>
</tr>
</tbody>
</table>

## I. INTRODUCTION

- Purpose 1
- NVLAP Approach to Accreditation 1
- Role of NVLAP Technical Experts 1
- Assessment Assignments 2
- Monitoring Visits 3

## II. ON-SITE ASSESSMENT

- Assessment Forms 3
- Preparation for an Assessment 4
- Entry Briefing 5
- Typical Steps of an Assessment 5
- Preparing an Assessment Report 6
- Exit Briefing 6
- Completing an Assessment Report 7

## III. ASSESSMENT CONDUCT AND TECHNIQUES

- Conducting an Assessment 8
- Information Collection 10
- Questioning Techniques 11

## IV. DEFICIENCIES

- Identifying Deficiencies 12
- Typical Deficiencies 14

## V. TECHNICAL EVALUATION

15
I. INTRODUCTION

Purpose

This manual is for use by NVLAP technical experts (TEs). It describes the role of a NVLAP TE in performing the assessment and evaluation functions of NVLAP.

The information presented here is intended to spell out your responsibilities as a TE. Since you will be representing NVLAP directly with applicants, you should understand the entire NVLAP accreditation process, including NVLAP policies and procedures, sequence of events, as well as the on-site assessment. The NVLAP accreditation process is described in handbooks specially prepared for each laboratory accreditation program (LAP). LAP handbooks are part of the application package provided to potential applicants. In addition to describing the accreditation process, each LAP handbook identifies the specific criteria and other technical requirements for accreditation.

NVLAP Approach to Accreditation

NVLAP is a system for accrediting testing laboratories found competent to perform specific testing services. Before an accreditation decision is made, a thorough evaluation is performed. The NVLAP evaluation consists of a review of application information, periodic on-site assessments, results of required proficiency testing, and correspondence between the applicant and NVLAP. The goal of an evaluation is to verify that a laboratory has attained a minimum level of competence as defined by the conditions and criteria for accreditation. However, we also encourage laboratories to improve testing performance above the minimum level through the use of proficiency testing and by using technical experts as assessors and evaluators.

The NVLAP approach to accreditation is basically non-adversarial. We view our role as one of assisting applicants to attain and maintain their accredited status. However, we are firm in requiring compliance with accreditation requirements and a laboratory's accreditation may be denied, suspended or revoked if compliance is not achieved.

Role of NVLAP Technical Experts

NVLAP TEs have a dual role in the accreditation process. One role is to conduct on-site assessments of applicants. The other role is to evaluate
information on applicants, including assessment reports, responses to deficiencies, and proficiency test results, for the purpose of recommending appropriate accreditation actions.

Your main contribution is your technical expertise. You and the other TEs assigned to your LAP(s) provide the technical direction and opinions required to evaluate each applicant's compliance with the accreditation requirements. NBS/NVLAP staff provide the structure and administrative procedures; you provide the technical support. NBS technical staff and others may also be available for consultation.

One important aspect of NVLAP is that each applicant be evaluated, in relation to others, as uniformly as possible. Assessments and evaluations must be fair and even-handed. Interpretations of requirements should be consistent among all TEs within a LAP. If you are in doubt about a requirement, please feel free to discuss it with other TEs as well as the relevant NVLAP staff.

Assessment Assignments

We assign TEs to perform assessments by matching individual expertise with a laboratory's requested scope of accreditation, as well as by trying to avoid any conflict of interest. If you are assigned to assess or evaluate a laboratory for which possible conflict-of-interest questions could be raised, please advise us. Although it is not always possible, assignments are scheduled so that every participant gets a different assessor on successive visits.

Laboratories have the right to refuse acceptance of an assessor assignment. Although this rarely happens, if a laboratory does not want you to be the assessor, notify NVLAP staff immediately. When we have before-the-fact information about whether a laboratory will accept a certain TE, we contact the laboratory before making the assignment.

When you are assigned to perform an assessment, we will send you copies of the laboratory's application form, proficiency test data, and any other pertinent information. Please keep these documents in confidence. After completing the assessment, you should return the documents to NVLAP.

Normally, you will have at least 60 days to schedule and complete the assessment(s) that you have been assigned. Occasionally, a faster response may be requested.

On your first one or two assessments you will normally be accompanied by a NVLAP staff person. After this initial visit(s) you will generally be on your own. Occasionally, you may be accompanied by a NVLAP staff person or possibly a new TE in training.
Monitoring Visits

In addition to regularly scheduled on-site visits, you may be asked to conduct monitoring visits which may be scheduled for cause or on a random selection basis during the accreditation period. These visits serve to verify reported changes in the laboratory facilities and operations or to explore possible reasons for poor performance in proficiency testing. The scope of the monitoring visit may range from checking a few designated items from the checklists to a complete review. An assessment report is still written and left with the laboratory as is done during a regular assessment, but not all checklist items need be covered or completed.

When we make assignments for monitoring visits, we will specify what should be examined, but you are not bound by our instructions if, while you are at the laboratory, you find other items that need to be reviewed. Monitoring visits generally last no longer than one day.

II. ON-SITE ASSESSMENT

The on-site assessment, a key part of the accreditation process, is our face-to-face examination of the laboratory. Before initial accreditation, and periodically thereafter, on-site assessments of each NVLAP participant are conducted to assess compliance with accreditation requirements. Assessments may last from one to several days and may involve more than one assessor depending on the scope of accreditation desired by the laboratory.

Specific aspects of a NVLAP on-site assessment are described under separate headings below.

Assessment Forms

NVLAP uses on-site assessment forms (checklists and an assessment report form) to:

- ensure uniformity of assessments among assessors;
- guide each assessment;
- provide a place for recording notes during an assessment;
- help assessors prepare exit briefings and assessment reports;
- provide evidence that an assessment was performed and that all applicable aspects of the laboratory were examined; and
- provide information for future assessments, thus facilitating continuity.
The structure and content of assessment forms can vary depending on the LAP. Each assessment form contains checklists and a report form. Specific instructions are provided with the on-site assessment form used in your LAP(s).

Some general tips in completing the checklists:

- Make sure that each item on the checklists either is answered or that there is a definite indication that no answer was feasible or applicable.
- Keep as many notes as possible on the checklists; where there is insufficient space, use additional sheets of paper.
- Although many of the items on the checklists are arranged in a suggested sequence, you may alter the sequence as you see fit.

Preparation for an Assessment

The overriding purpose of preparing for an assessment is to organize yourself to use the time available during the assessment to the best possible advantage. Failure to adequately prepare will slow down the assessment, create an unfavorable impression of NVLAP and yourself, waste the laboratory's time, and render the results less valuable. The following steps are recommended when preparing for an assessment:

1. Notify the laboratories at least one month in advance whenever possible.
2. Discuss with each laboratory, by telephone, the laboratory location, directions, dates, time of arrival, security arrangements, names of laboratory staff you will meet, suitable lodging arrangements, proposed agenda, requested demonstrations of specific tests, etc. Ask the laboratory to send you appropriate information to review before the visit (e.g., QA manual and procedures). Assure the laboratory that any documents they are willing to send you in advance will be held in confidence, will be returned upon completion of the assessment, and will not be retained in NVLAP files nor your own personal files.
3. Review all relevant information (e.g., criteria, test methods, QA manual, application information, previous assessment reports, deficiency correction letters, proficiency test results). Prepare your own questions based on previous assessment reports and correspondence to address weaknesses previously observed. Review the laboratory's proficiency test results and look for trends that might indicate an apparatus or procedural weakness. This information may indicate what tests need to be demonstrated.
4. Develop an agenda. If time allows, send a proposed agenda to the laboratory beforehand and state who at the laboratory you would like to have available, particularly to attend the exit briefing.
5. Complete what you can on the assessment forms before your assessment.

Entry Briefing

Upon arrival at a laboratory you are going to assess, conduct an entry briefing during which you should:

- meet with the laboratory's authorized representative and all others who will be involved in assisting the assessment;
- explain the purpose of the assessment and set the agenda;
- ask for one escort who is knowledgeable about the laboratory's management, quality assurance, and procedural systems to ensure cooperation of laboratory personnel;
- confirm that any laboratory documents that you may have previously reviewed are still current;
- request a meeting room or place where you can be by yourself to review laboratory documentation and records, to complete the checklists, and to compose your findings;
- discuss the schedule for the day, conforming as far as possible to the laboratory's working hours, lunch hour, and coffee breaks;
- agree on a tentative time for holding the exit briefing;
- write down all names and positions of relevant persons for future reference;
- note who speaks for the laboratory and who is knowledgeable so that you may refer back to the appropriate "information resource" later in the assessment; and
- walk through the portion of the site to be assessed to see the layout and to meet the relevant laboratory personnel.

Typical Steps of an Assessment

After the entry briefing, an assessment may be performed in any order. To some extent, the checklist questions follow a logical sequence and dictate the order to pursue for some aspects of the assessment, but you need not follow that order. Some assessors plan a sequence of activities with which they are more comfortable. However, keep in mind that the goal of an assessment is to verify that the laboratory complies with all applicable NVLAP accreditation requirements. A summary of a typical sequence of an assessment is as follows:
1. Conduct an entry briefing.

2. Examine QA manuals, personnel competency records, equipment maintenance and calibration records, sample handling, and recordkeeping procedures.

3. Examine test plans, reports, data logs, and related records.

4. Trace one or more samples from receipt to final test report.

5. Witness demonstrations of selected procedures by laboratory staff.

6. Interview technicians.

7. Physically examine equipment and facilities.

8. Formulate impressions about the overall management and organization.

9. Conduct an exit briefing--discuss findings, particularly deficiencies.

10. Complete written assessment report, have laboratory sign it, and leave a copy.

Preparing an Assessment Report

After you have completed the checklists, find a place where you can review your notes on the checklists and collect your thoughts. Summarize your findings on the assessment report form. Write anything that is significant about what you have observed, whether complimentary or negative. However, before an exit briefing, be sure to:

- respond to all applicable checklist items;
- decide which findings must be presented as deficiencies requiring corrective action by the laboratory; and
- describe each deficiency on the appropriate assessment report sheet.

Exit Briefing

At a minimum, the laboratory's QA manager or equivalent and his superior should attend the exit briefing. It is useful for future reference to identify the attendees at the exit briefing on the first page of an assessment report. An exit briefing will usually not last more than one hour.

For each deficiency, describe the finding, the justification or reason for stating the finding and, if appropriate, the proposed corrective action. Make sure that the laboratory understands each deficiency and what is required to achieve compliance.
Some of the deficiencies you identify may be challenged. Remember that the laboratory's technical staff may also be experts and differences of opinion may arise. Try to work out any differences and be satisfied that the NVLAP criteria have been met. However, don't argue. As appropriate, record your finding as a deficiency and ask the laboratory to refute it in their response to NBS. The NVLAP accreditation process provides a second level evaluation which includes a review by other technical experts and NVLAP staff of your assessment report, the checklists, results of proficiency testing, and correspondence from the laboratory responding to the cited deficiencies.

Do not be overly concerned about differences that may arise; they can be worked out later. Our experience to date indicates that participants look to NVLAP assessors for guidance and do not consider them as adversaries.

Advise the laboratory to write NBS within 30 days describing action taken or planned to be taken for each specific deficiency identified in the assessment report. The letter must be signed by an authorized official of the laboratory who can certify that the statements made in the letter are correct.

If any deficiencies are noted at laboratories which are currently accredited, such deficiencies must be corrected within 30 days or they may face suspension or revocation of accreditation. When out-of-calibration apparatus is cited, explain that the apparatus should not be used until corrective action has been completed.

During the exit briefing, watch for warning signs of difficulties in obtaining compliance. For certain difficult assessments, a private conference with top management may be necessary or a separate follow-up note to NBS should be considered if there were major problems at the laboratory that you could not be openly or comfortably discussed with the laboratory management.

**Completing an Assessment Report**

Make any necessary revisions or additions to the assessment report in light of the exit briefing. At least one laboratory representative, preferably the authorized representative, must sign the assessment report indicating that it has been discussed during the exit briefing. Leave a copy of the report with the person who signs it or allow the laboratory to photocopy the report. **Do not** leave a copy of the checklists (because of the possibility that your "rough notes" will contradict your official assessment report to the laboratory).

After you have left the laboratory, mail the original copy of the checklists along with the signed original of the report to NBS and retain a copy of all sheets in case the originals are lost in the mail or we need you to refer back to them during the technical evaluation. After an accreditation decision is made by NBS, you should return all documents pertaining to the assessment to NBS. Mail all documents to:
III. ASSESSMENT CONDUCT AND TECHNIQUES

More than your technical expertise will be required to conduct an assessment successfully. There are certain procedural items, ethical issues, assessment concepts, and questioning techniques to bear in mind. These are covered in this section.

Conducting an Assessment

To conduct an assessment properly, the following guidelines should be followed:

- Make every effort to disrupt as little as possible the normal operating schedule of the laboratory while conducting an assessment.
- Be determined, decisive and direct. (Once there is enough evidence to form the basis for a sound judgement, there is no point in going over the same ground.)
- Keep the assessment moving; be aware of the overall progress of the assessment so as to avoid wasting time on trivia.
- Be honest and fair. (Personal dislikes/prejudices must not interfere with the assessment.)
- Be independent. (You decide what will be examined)
- Recognize the difference between a "clean-up" job and a "cover-up" job. There is normally no need to worry about clean-ups that a laboratory carries out before you arrive. Clean-ups rarely solve major problems, but show that the laboratory is concerned about the outcome of the assessment. Dispense with cover-ups and get to the heart of each problem.
- Discuss any problems right away. (This deters arguments later on when people's memories have grown hazy, and allows you to clarify the problem and collect new information relating to it. If the discussion reaches an impasse, do not get involved in an argument; go on to the next item.)
- Be prepared to return to an area, if necessary, to obtain new information and to reassess the operation in the light of new information.
Keep a sense of proportion. (The magnitude and significance of a deficiency is a vital issue.) Make allowances. (Put errors in perspective.) Don't pursue unimportant errors, which wastes time and effort and risks alienating the laboratory.

Be constructive at all times; when a deficiency is found, suggest possible corrective action if you are certain that such action would satisfy the requirement. If wrong in your assumptions or conclusions, it is best to admit it and apologize. Such an attitude elicits cooperation and respect from the laboratory.

Be helpful; Suggest any procedures which would be beneficial if the opportunity presents itself. Your helpful suggestions need not be NVLAP-oriented. Do what is reasonable to establish an attitude that leads the laboratory to eagerly welcome the next assessor. Be careful, however, that you do not give away some other laboratory's "trade secret" in an attempt to be helpful. Open literature sources are preferred.

At the end of each day, give the laboratory representatives a brief summary of what has been happening. The summary is a courtesy measure. It limits the need to make embarrassing revelations at the exit briefing and in the assessment report by forewarning the people of the nature of any deficiencies encountered. In some situations the deficiency you observe early in your assessment can be corrected before the exit briefing. Most laboratories are thankful to be given the chance to put their house in order discreetly.

Try to answer all questions posed; if you lack information, offer to provide an answer at a later date and be sure to follow up, or refer questions to the NVLAP staff.

Thank the laboratory for its assistance and hospitality. Even if there were some contentious issues and you had to differ, you should still indicate that you appreciated the laboratory's cooperation.

Treat privileged information as such.

Avoid all situations which could be construed as undue or improper influences on your assessment findings.

Do not request favors from laboratories which could be construed as improper or an imposition.

Plan to pay for all meals. You will be reimbursed by NBS. Be prepared to eat lunch by yourself at all times, but if the laboratory staff wishes to join you, that is acceptable. In some cases the only reasonable facility is a laboratory-supplied eating facility. Lunch supplied by the laboratory in these cases is acceptable. However, always offer to pay.

Avoid making derogatory remarks about specific manufacturers or suppliers of equipment or about their products.
Avoid making derogatory remarks about individuals either within or outside of the laboratory.

Avoid becoming involved in intra-laboratory personnel problems.

Information Collection

Assessment is an information collection process that entails verifying application information, questioning staff, examining facilities, equipment, and records, and reviewing applicable proficiency testing results. Collect information as you go by observing and listening (laboratory staff should be doing the majority of the talking) to what is going on around you. To assist in completing the checklists, it may be helpful to note the following:

- Key persons interviewed;
- Applicable document designations, revision dates, where found, and descriptions;
- Equipment numbers and identification to cross reference with calibration and maintenance records;
- Sample/specimen identification system.
- Identification of document/information/equipment recipients in laboratory;
- Flow charts showing how the laboratory functions in terms of input (sample receipt), prerequisites (people, equipment, etc.), processing (testing procedures), and output (test report). (This systems approach to viewing a laboratory's operation may be useful in identifying weaknesses and underlying causes of deficiencies); and
- Latest revision dates in the QA manual, procedures, and instructions.

It may also be useful as you go along to take mental notes concerning the following questions:

- Do the laboratory staff members know their jobs?
- Do the lab managers/supervisors want to answer all questions? Some want to cover all questions either in the fear that their subordinates will commit an error that will reflect adversely on them, or because they feel it is their right and responsibility to speak up since they know what is going on. In this situation, you must make it clear that the "worker" should be the one to answer the questions, explaining that this is the purpose of the assessment to see what is actually being done and to verify that the proper procedures are being implemented.
Does the staff try to bluff its way out of a tight corner?

Does the staff know the QA manual and associated procedures and where these documents are?

What is the condition of facilities and equipment? Are the requisite calibration tags or stickers on the equipment?

Does it appear that the QA and procedural documents are used?

Every assessment involves collecting information on a laboratory's quality assurance system. The objective of this "information collection" is to ascertain whether the laboratory can recall the necessary facts to substantiate its test reports. Three approaches for assessing a laboratory's quality assurance system are to:

1. trace a test through the testing process forward from receipt of sample to final test report;
2. trace a test back from final test report to receipt of sample; or
3. randomly select certain files, data sheets, reports, etc.

The first two approaches are generally more efficient and effective. Some questions on the checklists are sequenced to use these two approaches. Random selection may be too haphazard and not give you a complete understanding of the system. We recommend that either of the first two approaches form the baseline investigation. The third approach is used when many additional test methods must be covered. Keeping careful notes is essential to help you prepare a complete assessment report.

**Questioning Techniques**

Effective questioning is vital to an assessment's success. It is of great value in assessing to keep the systems concept in mind, to separate the laboratory's work into input, prerequisites, process, and output, and to ask questions on each of these individually and in turn. You should voice your understanding of how the system works so that the laboratory can correct any misconceptions.

Ask questions that require a substantive response (e.g., "Who, What, How, When, Where, and Why" questions force a substantive response) rather than a "Yes/No" answer. Questions that require a "Yes/No" answer are useful when you need to clarify particular points. Statements or questions such as: Show me what you do./ Where do you put that?/ How do you do that?/ are recommended. If there is a variation from written procedures, then ask "Why do you do it that way?"

Hypothetical questions are good when little objective evidence is available. The "What if . . ." or "Let us suppose . . ." or "I don't understand . . ." type of question is usually effective in such situations. Avoid asking questions that suggest the answers you expect.
Silence can be extremely powerful. Some people find silence uncomfortable and to break it they may volunteer something they "shouldn't." When you look at people and say nothing, they may feel a response is expected, or because they are not quite sure what the response should be, they may say more than they otherwise would. This often produces information of use.

Observe what is not said by the laboratory staff. If answers are superficial or evasive, be prepared to continue the line of questioning.

Be alert to differences in information presented to you from different sources (i.e., conflicting answers from staff members or differences between documented procedures and what is actually observed or said).

Attempt to put the staff at ease at the beginning of a questioning session since they will probably be nervous and, if so, react by becoming withdrawn or defensive, or worse--by responding aggressively. You should not be aggressive in return, but you must be thorough (and occasionally persistent) enough to establish the factual situation. Keep the following points in mind:

- Direct questions to the person who performs the task being assessed, and not to that person's superior.
- Never talk down to anyone.
- Talk the "lab's language".
- Give credit where credit is due. A compliment, sincerely given, goes a long way towards eliciting cooperation.
- Be interested in the laboratory's work and responses.
- Don't appear to be distrustful of people or to regard their responses with criticism.
- Be calm and courteous and thank people for their time.

IV. DEFICIENCIES

Identifying Deficiencies

A deficiency is a departure from or an instance of noncompliance with a condition or criterion for accreditation. Keep in perspective the magnitude of any deficiency found and avoid making an issue out of trivial deficiencies, human errors, or isolated mistakes. Isolated errors may be due to someone having an off-day. Examine records for clarity, completeness, and consistency, and be alert to anomalies which may be a symptom of much deeper problems. If you find no deficiencies after tracing the testing process by a random selection of tests, then you can probably
conclude that there is a system present, working and known to the personnel concerned. If only one or a few minor deficiencies are found, then the system, rather than not being implemented, may be in a period of development or may need to be better instilled into the staff. If several deficiencies are found, then:

- the system may need to be revised or changed;
- the system may need to be more fully developed and documented;
- the staff members may need to be more adequately trained to perform their functions as part of the system; or
- a combination of some or all of these corrective actions need to take place.

Make sure that observed deficiencies are discussed. Sometimes further information can be provided and change your first impressions. When a deficiency is found, ask questions to discover its cause. After determining the underlying cause, you should try to suggest corrective action that would satisfy the requirements. Always remember that cheap, quick, simple, but effective corrective action is more likely to be acted upon promptly by the laboratory, particularly if it sounds easy to implement.

It is helpful to note whether a laboratory is already aware of a deficiency. If so, determine what action has been taken to analyze the cause of the deficiency and to implement corrective action. If the laboratory was unaware of the deficiency, encourage the laboratory to make a proposal for corrective action.

Obviously, some deficiencies are more critical than others. It is virtually impossible, however, to provide decision rules for objectively ranking deficiencies. This is where your expert technical judgment rules.

The causes of deficiencies can be categorized as follows:

- Lack of system--measures have not been taken to ensure that an activity is performed or performed properly.
- Lack of indoctrination/training of the personnel--system has been developed and documented, but staff is unaware or doesn't know how to use it.
- Lack of discipline on the part of the personnel involved in implementation of the system as documented--the personnel have been trained in how to operate the system but don't comply.
- Lack of time--too much pressure of work, overwork, or inadequate manpower.
- Lack of resources--incorrect equipment.
- Lack of top management support.
Typical Deficiencies

Deficiencies are usually found in a laboratory's documentation, equipment, or personnel. Typical documentation deficiencies include:

  o Required items in the criteria are not addressed.
  o Contents of instructions are not adequate.
  o Procedures/test plans do not have sufficient detail.
  o Outdated copies of documents are still in use.
  o The system, as described in the QA manual or instructions, has been ignored.
  o Samples/specimens bear no identification to permit traceability.
  o Responsibility for keeping documents updated has not been assigned.
  o No planned maintenance records of equipment are available.

Typical equipment deficiencies include:

  o Equipment is out-of-tolerance and/or has not been calibrated or verified at requisite intervals.
  o Cleanliness is inadequate.
  o No provision is made for protected storage in the laboratory.
  o Substitute equipment is used without acceptable evidence that it performs as specified in the standard involved.

Typical personnel deficiencies include:

  o Supervision is inadequate.
  o On-the-job practice is careless.
  o Personnel are not adequately trained to perform their tasks.
  o Objective evidence is not available in laboratory files that attests to the training/certification of competence of the personnel.
V. TECHNICAL EVALUATION

Technical evaluations (second level reviews) of all applicants are normally conducted at NBS. The usual procedure for new applicants is to have one or more TEs and NVLAP staff, who were not involved in the assessment, review the NVLAP evaluation folder for each laboratory. The evaluators provide technical judgments on whether an applicant complies with the conditions and criteria for accreditation and make recommendations on appropriate accreditation actions to take accordingly. In some cases a special form is used to record TE evaluation recommendations. A TE recommendation is based on:

- information provided on the application;
- assessment reports;
- actions taken by the laboratory to correct deficiencies observed during the on-site visit;
- results of proficiency testing from current and previous assessment periods; and
- information from any monitoring visits that may have been done.

When a laboratory is not considered to be in compliance with all requirements, we notify it and request additional information to allow the laboratory to demonstrate compliance. Occasionally, an additional assessment may be necessary.

The NVLAP staff prepares the paperwork including the transmittal of additional correspondence to any laboratory which the evaluators deem needs to respond more fully to unresolved deficiencies before accreditation can be recommended.

When notification describing specific deficiencies is made, the laboratory must respond within 30 days of notification and provide documentation or certification by an authorized member of management that the specified deficiencies have been corrected. Clarification of some issues may be requested by telephone. All deficiencies must be corrected before accreditation is granted.

When a laboratory satisfies all requirements, the Director of the NBS Office of Product Standards Policy signs and transmits a certificate and scope of accreditation to the laboratory.
**Title and Subtitle:** NVLAP Assessment and Evaluation Manual

**Author:** Peter S. Unger

**Performing Organization:**
National Bureau of Standards
Department of Commerce
Washington, DC 20234

**Publication Date:** April 1985

**Abstract:**
This manual explains the role of an assessor and evaluator under the National Voluntary Laboratory Accreditation Program (NVLAP). Policies, procedures, and techniques for conducting a NVLAP on-site assessment of a testing laboratory are described. Deficiencies (or departures from the accreditation criteria) and the technical evaluation leading to accreditation recommendations are also discussed.

**Keywords:**
- accreditation
- assessment
- evaluation
- laboratory
- testing

**Availability:**
- Unlimited
- For Official Distribution, Do Not Release to NTIS
- Order From National Technical Information Service (NTIS), Springfield, VA. 22161

**Price:** $7.00