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National Voluntary Laboratory Accreditation Program

Guidelines for Assessing Calibration Laboratories

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INTRODUCTION

This document was written as a tool to be used when training assessors, both quality system and technical, to the NVLAP process of assessing calibration laboratories. It is fully compliant with the requirements of ISO Guide 10011-1: Guidelines for auditing quality systems - Part 1: Auditing (1990). The document further defines the process for evaluating the technical competence of an applicant laboratory within the limits of the intended scope of accreditation.

Technical assessors are selected for their technical expertise in one or more fields of calibration. This document, therefore, does not teach technical expertise. It does, however, describe which issues need to be addressed, what areas need to be covered, and how the process should work, and offers some guidance on how to conduct the various elements of the assessment.

GUIDELINES FOR ASSESSING CALIBRATION LABORATORIES

THE ASSESSMENT PROCESS

1 Scope

This document describes the Calibration Laboratories Accreditation Program approach to assessing calibration laboratories under the National Voluntary Laboratory Accreditation Program (NVLAP) procedures as defined in Title 15 of the U.S. Code of Federal Regulations, Part 285.

It establishes the basic practices and principles of the assessment process and provides the guidelines for the verification of the applicant laboratory's ability to meet the objectives of the program as defined in NIST Handbook 150, *National Voluntary Laboratory Accreditation Program (NVLAP) Procedures and General Requirements,* hereinafter referred to as the program handbook, as it applies to the intended scope of accreditation.

2 References

The following documents are referenced in this material:

a) NIST Handbook 150, *National Voluntary Laboratory Accreditation Program (NVLAP) Procedures and General Requirements* (current edition);

b) NIST Handbook 150-2, *National Voluntary Laboratory Accreditation Program (NVLAP) Calibration Laboratories Technical Guide* (current edition);

c) ISO 8402: 1994, *Quality management and quality assurance - Vocabulary;*

d) Title 15, U.S. Code of Federal Regulations, Part 285.

3 Definitions

For the purpose of this document, the definitions given in ISO 8402 and the program handbook, together with the following, shall apply.

3.1 applicant laboratory: the calibration laboratory, or calibration laboratory function of an organization, applying to NVLAP for accreditation in the Calibration Laboratories Accreditation Program.

3.2 nonconformance: the failure to meet a specified requirement.

3.3 observation: a statement or finding of fact made during the assessment.

4 Objectives and responsibilities

4.1 Assessment objective

The purpose of the assessment is to provide an unbiased third party evaluation of the applicant laboratory's competency to perform calibrations within the scope of accreditation and to ensure that a quality system, sufficient to maintain that competency, is in place and is followed. The program handbook details the criteria which must be met to satisfy this requirement. NIST Handbook 150-2, *Calibration Laboratories Technical Guide*, provides interpretive guidance but generally does not modify or add to these requirements, except as noted in that Guide.

4.2 Responsibilities

All assessments will be conducted by a lead assessor who may be assisted by as many technical assessors (sometimes called technical experts) as may be required to effectively address the field(s) of calibration to be included in the assessment. The team size is, therefore, dependent on the complexity of the assessment and the expertise of the team members.

All assessors must be free of any conflicts of interest, real or perceived, and must be free from any bias and influences which could affect their objectivity.

4.2.1 NVLAP office

It is the responsibility of NVLAP, based on the laboratory's application, to define the requirements of the assessment, select the lead assessor, and select the team members. At NVLAP's discretion, the lead assessor and/or any team member(s) may be NVLAP or other NIST personnel.

The NVLAP office will make the decision to (1) grant or renew accreditation, (2) suspend accreditation, or (3) propose to deny or revoke accreditation of an applicant laboratory, based on the degree to which the laboratory complies, or fails to comply, with the specific NVLAP requirements.

4.2.2 Technical assessors

Technical assessors are chosen for their expertise in the assessed field(s) of calibration. They are responsible for performing their assigned duties, within their area(s) of expertise, effectively and efficiently, commensurate with the provisions of the program handbook. This includes planning, conducting the assessment, communicating and clarifying program requirements, documenting observations, reporting results, and protecting the confidentiality of documents and proprietary information gathered during the assessment. They are responsible for assessing the competence of the laboratory to perform measurements within their field(s) of expertise.

4.2.3 Lead assessor

The lead assessor normally performs the evaluation of the laboratory's quality system and may also serve as a technical assessor. The lead assessor has overall responsibility for the on-site assessment. This includes authority to make decisions regarding the conduct of the assessment and assessment observations. The lead assessor is also responsible for preparing the assessment plan, interfacing with the applicant laboratory's management, and submitting the assessment report.

4.2.4 Applicant laboratory

The applicant laboratory is responsible for determining the field(s) of calibration, the scope of the assessment, and identifying and initiating corrective action if required.

4.3 Activities

4.3.1 NVLAP office

Upon receipt of application and appropriate fees the NVLAP office:

a) defines the requirements of the assessment;

b) assigns the lead assessor and assessment team;

c) provides lead assessor and technical assessor(s) with all documentation needed to conduct the assessment;

d) with the lead assessor, reviews documentation received for adequacy;

e) schedules a pre-assessment visit (if deemed necessary); and

f) arranges for proficiency test(s) as required.

4.3.2 Lead assessor

The lead assessor will:

a) with the NVLAP office, review the laboratory's documentation for adequacy;

b) comply with applicable assessment requirements pursuant to the program handbook;

c) plan and direct the assessment, prepare working documents, and brief the assessment team;

d) schedule the assessment with the applicant laboratory;

e) report critical nonconformances to the applicant laboratory management immediately;

f) report (to NVLAP and applicant laboratory management) any major obstacles encountered in performing the assessment;

g) report the assessment results clearly, and without delay using NVLAP prescribed checklists and report formats;

h) provide the applicant laboratory's management with a copy of all nonconformances; and

i) reach an agreement (if appropriate) with the applicant laboratory on a schedule of corrective action to be taken to resolve nonconformances.

4.3.3 Technical assessor

Technical assessors will:

a) remain within the scope of the assessment;

b) exercise objectivity;

c) as experts in the field, collect and analyze evidence that is relevant and sufficient to assess the competency of the laboratory regarding the measurements and/or measurement systems assessed;

d) remain alert to any indications of evidence that can influence the assessment results;

e) report findings to the lead assessor; and

f) act in an ethical manner at all times.

4.3.4 Applicant laboratory

The applicant laboratory will:

a) concur with the assessment team selection;

b) provide NVLAP with all pertinent documentation as specified in the program handbook;

c) inform appropriate employees about the objectives and scope of the assessment;

d) appoint qualified staff members to accompany members of the assessment team;

e) provide all resources needed by the assessment team;

f) cooperate with the assessors to permit the assessment objectives to be achieved;

g) comply with all proficiency test requirements;

h) receive the assessment report; and

i) initiate corrective actions, as appropriate, based on the assessment report.

5 Assessment

5.1 Initiating the assessment

5.1.1 Scope

The applicant laboratory makes the final decisions regarding the field(s) of calibration and scope of the assessment and the level of uncertainty of the measurements being assessed. Sufficient objective evidence must be available to the assessment team to demonstrate that the laboratory is competent to carry out specific calibrations, or types of calibrations, in accordance with NVLAP requirements. The resources committed to the assessment must be sufficient to meet its intended scope and depth.

5.1.2 Accreditation period

Accreditation is granted for a specified period, usually one year. Initial accreditation is granted when the laboratory has met all NVLAP requirements. One of four renewal dates is assigned (January 1, April 1, July 1, or October 1) and is usually retained as long as the laboratory remains in the program.

5.1.3 Preassessment

Upon receipt of an application for accreditation, NVLAP will request that certain additional information and documentation be provided, as described in the program handbook. NVLAP and the lead assessor will then conduct an audit of the adequacy of the applicant laboratory's written description of its ability to meet the program requirements. Dependent on the complexity of the assessment, and after successful completion of the adequacy audit, NVLAP may schedule and conduct a preassessment visit. The purpose of the preassessment visit is to further define the conditions of the assessment such as logistics, physical requirements, and depth of technical expertise required.

If at any point during this process the laboratory's system is deemed inadequate to meet program requirements, no further effort will be expended on the assessment until all concerns are resolved to the satisfaction of NVLAP and the applicant laboratory.

5.2 Assessment preparation

5.2.1 Assessment plan

The assessment plan is the responsibility of the lead assessor. However, due to the technical nature of the assessment, much of the planning will require the assistance of the technical assessor(s) assigned for each field of calibration being assessed.

The assessment plan should begin with such basic information as:

a) field(s) of calibration, scope and objectives of assessment;

b) date, time, and place of assessment;

c) schedule of activities;

d) identification of applicant laboratory personnel involved;

e) identification of assessment team members;

f) identification of referenced documentation;

g) schedule of meetings with laboratory management;

h) security and confidentiality requirements; and

i) distribution of assessment report.

The heart of the assessment plan is the assignment of assessor's duties, that is, the matching of specific program requirements, both functional and technical as described in the program handbook, to the assessment team members based on their area(s) of expertise. These assignments are made in part by NVLAP through the selection of assessors based on their field(s) of expertise. However, the lead

assessor may make additional assignments as deemed necessary to satisfy the general requirements of the program.

In addition to the General Operations Checklist provided by NVLAP, there are a few tools available to the lead assessor that may aid in the planning of the assessment. They include:

a) Technical requirements checklists - technically oriented checklists that may be developed as needed.

b) Matrix diagrams - a method for analyzing the relationship between the elements or clauses of the program handbook and the various functions and/or departments within the applicant laboratory. This technique uses a grid pattern of rows and columns, the point of intersection identifying the relationship between the two, thus allowing for the level of relevance (high, low, or no) to be assigned to the relationship. Once completed, the matrix diagram becomes an aid to determining what areas might be most efficiently addressed and establishes horizontal and vertical assessment trails to be followed during the assessment.

c) Flowcharting - a technique that helps to identify key elements of a process or procedure such as logical activities, process input/output, data collection, decision points and subelements. Flowcharting will provide a pictorial analysis of a sequence of operations described by the documentation.

5.2.2 Working documents

Documents required by NVLAP to properly record the assessment of a laboratory's ability to meet program requirements include the following:

a) NVLAP General Operations Checklist;

b) technical requirements checklist prepared by NVLAP and/or the technical assessor(s) to fit the assessment needs;

c) forms for reporting observations;

d) forms for documenting objective evidence in support of observations; and

e) any other document or form developed and used to satisfy a specific assessment requirement.

Any document or form containing confidential or proprietary information must be properly safeguarded.

5.3 Conducting the assessment

5.3.1 Contacting the laboratory

It is expected that there will be much interaction between NVLAP and the applicant laboratory during the initial application process. However, it is the lead assessor's responsibility to make "official" contact with the laboratory, optimally at least one month in advance of the on-site visit. The objectives of this contact are to:

a) mutually agree on a date and time for the on-site assessment;

b) request any additional documentation needed for review;

c) confirm with the laboratory's Authorized Representative the location of the laboratory and the expected time of arrival;

d) establish need for and comply with any security arrangements (clearances, nondisclosure forms, etc.) as may be required;

e) obtain names of laboratory personnel who will participate in the assessment;

f) review list of participating assessors for concurrence;

g) discuss proposed agenda; and

h) arrange for laboratory tour as required.

The lead assessor should document all contacts with the laboratory and notify NVLAP of the confirmed date(s) of the assessment, the acceptance of assessors, and any other pertinent information obtained. It is appropriate at this time to request information about nearby hotels, dining facilities, local transportation, maps, etc. as may be needed.

5.3.2 Opening meeting

Upon arrival at the applicant laboratory's premises, the lead assessor will conduct an opening meeting. In attendance will be the NVLAP assessment team, the laboratory's Authorized Representative, and others participating in the assessment.

The function of the opening meeting is to:

a) introduce assessment team members and laboratory personnel to one another;

b) review the scope and objectives of the assessment;

c) briefly summarize the assessment process, methods and procedures to be used to effect the assessment;

d) review the assessment agenda;

e) establish the official communication link(s) between the assessment team and laboratory personnel;

f) confirm availability of requested resources and facilities needed by the assessment team;

g) review laboratory working hours, breaks and lunch hours (where possible, conform to laboratory's regular operating schedule);

h) arrange for daily informal progress meetings with laboratory management;

i) agree on a time, place, and list of attendees for the closing meeting; and

j) clarify any unclear details and review any potential problems such as union situations, etc.

5.3.3 Observations and evidence

During the course of the assessment, all observations will be documented. Objective evidence to support these observations will be collected and recorded. Sources of evidence may include, but are not limited to:

a) examining documents (quality assurance manuals, procedures, error budgets, calibration reports, training records, equipment maintenance and calibration records, etc.);

b) witnessing calibrations using selected procedures and performed by normal staff, not supervisors or managers;

c) reviewing Measurement Assurance Plan (MAP) results and control charts;

d) tracing one or more items through the calibration process (forward - from receipt to final calibration report, backward - from final calibration report to receipt, and randomly select files or data logs and verify);

e) interviewing engineers and technicians, in private if possible; and

f) examining equipment and facilities (do not operate any equipment - ask regular operator to perform functions).

Any evidence suggesting a nonconformance should be documented and investigated, even if not covered on a checklist. Discuss apparent deficiencies as they are found. Ask questions to discover cause, suggest corrective action (if appropriate), and note if the laboratory is already aware of the deficiency and if corrective action is planned.

The assessment team should meet daily and review its findings. At any time during the assessment, the lead assessor may change the assessment plan and/or team members' assignments if warranted by observations and evidence collected thus far and deemed necessary to fulfill the requirements of the program.

Upon completion of the assessment of all activities and functions defined by the scope, the team will meet and review all observations to determine which will be reported as nonconformances and which will remain observations. The team will ensure that all findings are supported by objective evidence, adequately documented, and identified in terms of the specific program requirements defined in the program handbook. The lead assessor will then review all observations and nonconformances with the responsible laboratory manager.

5.3.4 Closing meeting

At the conclusion of the on-site assessment the lead assessor will conduct a closing meeting. Attendees will include the entire assessment team, the laboratory's Authorized Representative, management representatives, and any other responsible laboratory personnel so authorized. The primary purpose of this meeting is to present the team's findings to the laboratory managers so they clearly understand the results of the assessment. Observations or nonconformances concerning the technical aspects of the assessment should be presented by the appropriate technical assessor. All other observations or nonconformances may be presented by either the lead assessor or the assessor making the observation or nonconformance. For each observation or nonconformance identify the relevant requirement and the objective evidence, in detail, to support the observation or nonconformance. Do not argue your position. Attempt to resolve disagreements, but do not compromise the NVLAP requirement.

The lead assessor will present the team's conclusions regarding its assessment of the laboratory's ability to meet program requirements and its recommendation to NVLAP. The lead assessor will stress that the final decision regarding accreditation will be made by NVLAP; in addition to the on-site assessment, it will depend on such other factors as results of proficiency tests and payment of all fees.

If applicable, a schedule should be agreed to for the initiation and completion of corrective action required to resolve nonconformances. If agreement cannot be reached regarding the existence of nonconformances or a schedule of corrective action, an appeal may be filed with NVLAP by the applicant laboratory. The assessment report should include notice of a proposal to file an appeal and pertinent details.

The lead assessor will notify the laboratory that, as an aid to continual process improvement, NVLAP will send an assessment critique form to laboratory management and will request that it be completed and returned to NVLAP as soon as possible.

5.4 Assessment report

The on-site assessment report will be prepared under the direction of the lead assessor, who will be responsible for its accuracy and completeness. It should contain:

a) the scope and objectives of the assessment;

b) the assessment plan, identification of the team members, and the laboratory's representatives, and assessment dates;

c) completed checklists (NVLAP General Operations Checklist and any prepared specifically for the assessment);

d) the record of observations compiled during the assessment;

e) a summary of significant findings, in narrative form, both positive and negative; and

f) the conclusions and recommendations of the assessment team.

A copy of the report must be left with the applicant laboratory prior to leaving. The lead assessor must forward the report, with all other required documentation, to NVLAP within one week of the conclusion of the on-site assessment.

6 Corrective action

The applicant laboratory is responsible for determining and initiating corrective action needed to resolve any nonconformances observed during the on-site assessment or proficiency test(s). The timetable for completion of the corrective action must be agreed to by NVLAP and the applicant laboratory. Upon completion, the nonconformances will be reassessed by NVLAP using whatever method deemed necessary. Accreditation cannot be granted until all nonconformances are resolved to the satisfaction of NVLAP.

7 Assessment conclusion

The possible outcomes of the assessment process are: a) granting (or renewal) of accreditation; b) denial or revocation of accreditation; and c) suspension of accreditation.

7.1 Granting accreditation

Upon successful completion of the accreditation process, that is, when all necessary program requirements have been met, NVLAP will grant accreditation and will issue (1) a Certificate of Accreditation and (2) a Scope of Accreditation listing the specific field(s) of calibration, parameters, and levels of uncertainty for which the laboratory has been accredited. NVLAP will also provide guidance on referencing the laboratory's accredited status and the use of the NVLAP logo by the laboratory and its clients.

7.2 Denial or revocation

A decision to deny or revoke accreditation is made when the applicant laboratory fails to meet necessary program requirements and it is concluded that the nonconformances are too major and/or too numerous to be corrected in a reasonable timeframe, if at all. The applicant laboratory does have appeal rights as outlined in the program handbook.

7.3 Suspension

Suspension is a temporary removal of the accredited status of a laboratory when it is found to be out of compliance with the terms of its accreditation. The laboratory will be notified of the reasons for and the conditions of the suspension, and the actions required for reinstatement.

The action of suspension is not necessarily tied to the renewal process and may occur at any time for cause. Reasons for suspension include: loss of key personnel, loss of major equipment, damage by fire, changing laboratory location, and proficiency test failure.

APPENDIX A

ASSESSMENT TECHNIQUES

The following is a collection of helpful assessment techniques gleaned from NVLAP's experience in assessing testing laboratories.

a) Set the tone for the assessment:
   - look the part: dress appropriately;
   - act the part: be businesslike, maintain a low profile.

b) Understand your effect:
   - you represent NIST/NVLAP;
   - your negative findings may have adverse effects on laboratory staff members;
   - you may prevent (or limit) the laboratory's ability to do business.

c) Start off on the right foot:
   - give the staff time to adjust to your presence;
   - give management a chance to demonstrate their support.

d) Conform to the laboratory's regular operating schedule as much as possible.

e) Keep the assessment going:
   - avoid wasting time;
   - don't allow socializing to dominate the schedule;
   - don't keep going over the same ground.

f) Ask who, what, when, where, how, and why questions that elicit substantive answers.

g) Ask hypothetical questions.

h) For clarity, verbalize your understanding of specific procedures and how the laboratory operates.

i) Return to an area, if necessary, to gain new information or understanding.

j) Discuss and clarify nonconformances right away.

k) Try to answer all questions but call NVLAP (or follow up) if you cannot respond knowledgeably.

l) Don't emphasize areas in which you have a particular interest at the expense of the assessment.

m) Be determined, decisive and direct.

n) Be honest and fair.

o) Be independent; maintain your objectivity.

p) Don't be confrontational; avoid conflict.

q) Don't argue; if the staff is disdainful, maintain your professionalism and be firm.

r) Keep a sense of proportion; don't pursue trivial matters.

s) Be constructive and helpful if the laboratory is receptive.

t) Don't conduct the assessment as if it were a form of punishment.

u) Be alert to conflicting information from different sources.

v) Don't allow the staff to bog you down with detail.

w) Recognize a "cover-up"; don't allow the staff to emphasize the strong points and gloss over the weak points.

x) Don't get involved in areas that are not within the requested scope of accreditation.

y) Avoid comments about specific manufacturers, suppliers, equipment, or products.

z) Avoid comments about other laboratories or individuals outside or within the laboratory.

aa) Avoid involvement in intralaboratory problems, conflicts, or policies.

bb) Avoid becoming an advocate or lobbyist for anyone in the laboratory.

cc) Don't agree to provide separate "unofficial" findings to the laboratory.

dd) Avoid all situations which might be considered as undue or improper influences on your findings.

ee) Be calm and courteous; thank the staff for its time, assistance and hospitality (even if the visit was strained).

APPENDIX B

INTERVIEW TECHNIQUES

Effective communication is key to a good interview.

> **I know you believe you understand what you think I said, but I am not sure you realize that what you heard is not what I meant.**

Simply put, what is said may be significantly different from what is heard or intended.

The three logical steps to communicating are: what is said; what is heard; and what is understood. Failures occur when there is a breakdown between any two of these steps as follows:

a. "What is said may not be what is heard." This may be caused by such things as lack of interest, boredom, diverted attention, or noise.

b. "What is heard may not be understood." Causes for this may be language problems, unclear messages, use of technical jargon, or speaking above the listener's qualification level.

c. "What is understood may not be accepted." This is bias; the listener may have a negative attitude toward the subject or the speaker.

There are some nonverbal factors to be considered as well. Body posture, facial expressions, and even general appearance have to do with looking and acting the part of a professional assessor. Be aware of the image you are projecting, it may have a direct bearing on the effectiveness of the interview. Other considerations such as vocal tones, volume and delivery can have a direct effect on how the listener receives the communication. Even bad news can be softened if said properly.

This brings us to a discussion of effective questioning techniques. If we assume as the assessor, you have done your homework, and know what questions to ask to gather the data needed, then your job becomes that of a good listener. There is an old rule that says effective interviewing is 20% asking and 80% listening. This implies that the interviews must be well-planned, not only as to subject matter, but also the types of questions asked in order to elicit the desired responses.

There are five basic types of questions available to the assessor. They are:

1. Open: These questions cannot be answered by a simple yes or no and usually require an explanation of some sort. They provide interviewees an opportunity to discuss, in some detail, areas they are familiar with, thus making them more comfortable with the process. Open questions also allow you, as the interviewer, to put to good use your listening skills.

   Example: "Please explain your process for cleaning gage blocks prior to calibration."

2. Closed: This type of question typically requires only a yes or no response. Although closed questions have their place, little information is gained from the response and they tend to restrict communication. Too many closed questions can cause the interview to seem more like an interrogation and less like an interview.

   Example: "Do you clean gage blocks prior to calibration?"

3. Clarifying: Clarifying questions are intended to assure that what was said is what was heard and understood. They are used to obtain details, enhance understanding and eliminate ambiguity.

   Example: "You've explained how you clean gage blocks. Could you tell me more about the chemicals you use?"

4. Leading: These are biasing by nature. They tend to suggest an expected answer, and should be carefully avoided.

   Example: "You do allow 24 hours of stabilization time, don't you?"

5. Antagonistic: Antagonistic questions are another form of interrogation. They arouse negative emotions and tend to put people on the defensive.

   Example: "Why is it that 40% of your gage blocks fail a flatness test because they were improperly cleaned?"

Another useful weapon in the battle to obtain necessary information is silence. Remaining silent after a response to a question implies that more information is wanted and that the answer provided is not sufficient, while not embarrassing interviewees by telling them so. (This assumes, of course, there is more information to be had.) Silence has been described as a vacuum begging to be filled with talk. It may be discomforting to the interviewee but, if well placed, can be effective in extracting information.

Interviews are usually more effective when conducted one-on-one. People are more likely to "open up" if their coworkers (or bosses) are not listening. However, there may be some applications for interviewing more than one person at a time. An example may be interviewing all operators of a measurement system that takes more than one to operate.

Now that we've gotten the interviewee to talk, it is the assessor's turn to listen. Remember the 80%/20% rule and recognize that if you're talking, you're not learning. The whole point of the interview is to gather pertinent data about the system or process being assessed. A good listener will let the speaker know that he or she is listening without interrupting. This may be done by a strategically placed head nod or even simple eye contact. Again, your image is important. If interviewees get the feeling you're not really listening, they will likely stop talking. Take appropriate notes. Record the key points during the interview and fill in the details as soon as practical afterwards. Constant writing of notes during the interview can be alarming to the interviewee. Using your interview planning notes is an effective way to do this. When planning questions we at least expect the answers to fall within a certain range. The expected possible responses can be recorded as a minichecklist and checked off during the interview. It is bad form, however, to anticipate answers and interrupt speakers before they are finished. Pay close attention to what is being said, and ask clarifying questions to be sure you understand the response.

Always be courteous and professional in your actions. If an interviewee is uncooperative, try to work around it by altering your interview technique. However, if you cannot obtain the information you need for a proper assessment, let the lead assessor and/or the appropriate laboratory manager know of the problem. The laboratory is responsible for making objective evidence available to the assessors. Thank interviewees for their time and effort, regardless of their attitude, and keep the door open for follow-up questions as need arises.

APPENDIX C

TECHNICAL ASSESSMENT PROCESS

The following outline is intended to highlight those parts of the assessment process to which the technical assessor(s) should pay particular attention. Some areas do overlap with the evaluation of the quality system (usually done by the lead assessor) and should, therefore, be addressed only to the extent necessary to evaluate technical competence. There must be full understanding between the quality system assessor and the technical assessor(s) as to the division of labor when assignments are made in the assessment plan.

I Review application.

- For each parameter to be assessed, determine:
  - Range(s)
  - Uncertainty(s)

II Review Quality Manual (and other quality documentation) provided with the application.

- Identify the Approved Signatories (for reports, revisions, etc.).
- Identify the authorized signatories for document control.
- Review organizational structure of the laboratory.
  - Identify the Quality Manager (and access to higher management)
  - Identify the Technical Manager
  - Identify the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests
- Identify the processes/procedures defined in the quality manual.
  - Calibration procedures
  - Handling/storage of customer equipment
  - Major equipment and reference standards
  - Calibration/maintenance of equipment
  - Verification practices/MAPs/control schemes, etc.
  - Feedback and corrective action (including customer complaints)
  - Uncertainty determination techniques
- Review sample procedures provided for adequacy and compliance.
- Review any floor plans and work schedules that may be provided.

III Develop on-site plan.

- Lead assessor is in control
- Schedule activities
- Identify players
- Tools
  - NVLAP General Operations Checklist
  - Specific checklists as developed
  - Matrix diagrams
  - Flow charts

IV Conduct on-site visit.

- Conduct opening meeting
  - Meet people
  - Review schedule, facilities, etc.
  - Review laboratory layout

- Review employee training
  - Review employee records (only training records)
  - Review training update procedures
- Visit incoming/outgoing (shipping/handling) areas
- Visit "engineering center" or equivalent
  - Procedure writing/review
  - Complaints handling
  - Special requirements (variance from norm)
  - Equipment/materials specification/purchasing
  - Consumables
- Visit laboratory measurement area
  - Environment
    - Fitness for purpose
    - Monitoring provisions
    - Location suitability
    - Access control
    - Housekeeping
  - Measurement equipment in use
    - General condition
    - Fitness for purpose
    - Calibration status
    - Recall system
    - Tamper-resistant seals
  - Standards in use
    - Usage, handling, and storage
    - Calibration status
    - Accuracy requirements
  - Equipment and Standard Reference Materials
    - Supply (enough to perform calibrations)
    - Maintenance
    - Labeling
  - Measurement process
    - Fitness for purpose
    - Accuracy requirements
    - Operator skill/capability - refer to training
    - Personnel interviews
    - Calibration procedures
      - Availability
      - Current version
      - Properly authorized
      - Adequacy for measurement
    - Responsibility for measurement
    - Error budget/uncertainty analysis
    - Traceability path
    - Measurement control methods
      - Charts
      - MAPs
      - Correlations
    - Measurement data
      - Validation
      - Recording

- Certificates/Reports
  - Necessity of certificate/report
  - Approved Signatory (computer-generated must have verification process)
  - Content
  - Revision procedures
  - Accredited vs. non-accredited calibrations
- Documentation
  - Fitness for purpose
  - Control (authorized signatory)
  - Revision status
  - Documentation must exist for:
    - Organizational structure
    - Protection of client's information and proprietary rights
    - Treatment of clients
    - The quality system
    - The quality manual (see 285.33(c)(2)(i) to (xxii) of NIST Handbook 150 for contents)
    - Audit and review findings
    - Maintenance procedures for equipment and reference material
    - Instructions on use and operation of all relevant (calibration) equipment
    - Measurement assurance and uncertainty analysis
    - Nonstandard calibration methods
    - Statistical techniques used to select samples
    - Computer software
    - Purchase, reception, and storage of consumable materials
    - Identification of items to be calibrated or tested
    - Storage and handling procedures
    - Receipt, retention or safe disposal of calibration or test items
    - Electronic transmission of calibration results
    - Resolution of complaints
    - For Measuring & Test Equipment (M & TE)
      - System to control calibration/verification
      - Plans and procedures for audits and corrective actions
      - Calibration/verification system
      - Exemptions from periodic calibration or verification
      - Evaluation of adequacy of calibration system
- Records
  - Suitability for circumstances
  - Retention period (as defined in quality manual)
  - Security and storage
  - Records shall be maintained for:
    - Technical personnel training/experience
    - Equipment and reference materials (see 285.33(f)(4) of NIST Handbook 150 for content)
    - "As received" condition (of calibration item)
    - Storage under specific environmental conditions
    - Investigations of compliance of subcontractors
    - Subcontractor status
    - Suppliers of support services and supplies
    - Complaints and actions taken
    - Environmental conditions for M & TE
    - M & TE calibrations

- Team meetings
  - Daily
    - Review results
    - Modify schedule (if necessary)
  - Final
    - Discuss observations/nonconformances
    - Resolve differences
    - Write on-site report
- Closing meeting
  - Conducted by lead assessor
  - Present observations/nonconformances
  - Agree on corrective actions to be taken by laboratory (if possible)