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TTLABS ASSESSOR GUIDE

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TTLABS

ASSESSOR GUIDE

June 2007

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ASSESSOR GUIDE

FOREWORD

The TRINIDAD AND TOBAGO LABORATORY ACCREDITATION SERVICE (TTLABS) is a semi-autonomous, governmental unit within the Trinidad and Tobago Bureau of Standards (TTBS) dedicated to operating a nationwide, broad spectrum laboratory accreditation system. Accreditation is a formal recognition of competence that a laboratory can perform specific tests or calibrations.

Accreditation is available to any type of testing or calibration laboratory, be it in the private sector (independent or in-house) or in the government sector. Accreditation is available for virtually all types of tests, calibrations, measurements and observations that are reproducible and properly documented.

This publication is the main body of written guidance provided directly to TTLABS assessors. Assessors are identified as those who, through the conduct of on-site assessments, evaluate the competence of laboratories (ISO/IEC 17025 or ISO 15189) by reviewing the quality management system and examining the testing or calibration processes.

Mission Statement: To continuously provide reliable, high quality accreditation services to laboratories in Trinidad and Tobago and the Caribbean region in accordance with internationally accepted standards and criteria for the operation of an internationally recognized accreditation body, to ensure competence, integrity and confidence in those services and to support the region's mandate for high quality goods and services.

Quality Policy: The management of Trinidad and Tobago Laboratory Accreditation Service, the National Accreditation Body, is fully committed to the provision of services in the area of laboratory accreditation to ensure an acceptable level of satisfaction for all our customers.

The provision of these services will be undertaken with integrity, professionalism, timeliness, reliability and efficiency, consistent with internationally accepted procedures and levels of quality.

It is the policy of TTLABS to operate a comprehensive accreditation system for testing and calibration laboratories and related programs associated with accreditation in accordance with nationally and internationally accepted standards. In pursuing this policy, TTLABS is committed to:

- Achieve customer satisfaction through meeting the needs of accredited bodies and their users;
- Improve the quality of accredited bodies and the data they produce; and
- Increase acceptance of accredited data to facilitate trade.

The TTLABS Secretariat shall work to continuously improve all aspects of its implementation of ISO/IEC 17011 and related international standards and guides. Communications with members, client laboratories, users of accredited laboratories and their customers in response to inquiries will receive top priority of the TTLABS Secretariat in their day-to-day work. TTLABS intends to become internationally recognized through existing multi-lateral arrangements (MLAs) or mutual recognition arrangements (MRAs).

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ASSESSOR GUIDE

1.0 INTRODUCTION

1.1 Purpose

This guide is for TTLABS assessors. It describes the role of each of you in performing assessments for TTLABS. The information presented is intended to spell out your responsibilities as an assessor so as to promote better assessments and to ensure uniformity. Since you will be representing TTLABS directly with applicants, you should understand TTLABS and its mission, goals, programs and processes, the on-site assessment process and the relevant testing and quality management system requirements.

1.2 TTLABS Approach to Accreditation

TTLABS operates a third-party system for accrediting testing and calibration laboratories found competent to perform specific tests or specific types of tests (throughout this document, "tests" includes measurements, analyses and calibrations). Before an accreditation decision is made, a thorough evaluation is performed. The TTLABS evaluation consists of the TTLABS Secretariat review of application information, periodic on-site assessments, results of required proficiency testing, and correspondence between the applicant and TTLABS Secretariat. The primary goal is to verify that a laboratory has attained the level of competence defined by the conditions and criteria for accreditation. For more details about the accreditation process and general criteria for each of these accreditation programs, please refer to documents on the TTLABS web site, www.ttbs.org.tt. For information about the conditions and fees for accreditation, refer to the application packages.

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

1.3 TTLABS Organization

The TTLABS organization is a division of the Trinidad and Tobago Bureau of Standards (TTBS). TTLABS is composed of the Secretariat, which includes the Manager of Laboratory Accreditation, Technical Officer(s), and Administrative Support Officer(s), a Laboratory Accreditation Committee, advisory committees (to be developed), and assessors. The Manager, TTLABS reports to the TTBS Director and TTBS Board of Management (BOM), which are responsible for organizational and financial policy setting. TTBS also provides other administrative and financial support. The TTLABS quality manual describes the functions of each person or group.

Laboratory Accreditation Committee: Members of the Laboratory Accreditation Committee represent industry, suppliers to industry, laboratories, government and various other professions. The Laboratory Accreditation Committee (LAC) sets overall technical policy direction, oversees the development, interpretation and approval of criteria documents, and makes accreditation decisions. Appeals of Committee decisions are made first to the Committee and then to the TTBS Board of Management.

Advisory Committees: TTLABS may set up advisory committees for certain areas as the need arises.

Secretariat: A full-time Secretariat provides the administrative and technical support of TTLABS programs.

Assessors: Technical experts are usually contracted to conduct on-site assessments on an as needed basis operating as independent contractors.

2.0 ROLE OF TTLABS ASSESSORS

2.1 General

The primary role of TTLABS assessors is to conduct on-site assessments of laboratories (applicants).

An on-site assessment is basically a fact-finding mission to obtain objective evidence of conformity with TTLABS program requirements including:

- General criteria (e.g., Part A of the "General Requirements for Accreditation of Laboratories" document);
- Specific criteria for the fields of testing, testing technologies, types of tests, or specific tests for which accreditation is sought (Note that some fields may have program requirements and special assessor checklists to follow in future);
- Policies for proficiency testing, traceability, and use of the TTLABS accredited logo;
- Competence to perform specific tests or specific types of tests;
- Conditions for accreditation (see Part B of the "General Requirements for Accreditation of Laboratories" document); and
- Successful performance in required proficiency testing programs.

Inevitably, you will have to exercise technical judgment based upon objective evidence about conformity with certain accreditation requirements. Since laboratory accreditation is defined as the formal recognition of competence to carry out specific tests or types of tests, you will be judging whether a laboratory is capable of performing those specific tests or types of tests for which it seeks accreditation.

You may also be asked to review information from applicants, such as responses to nonconformities and proficiency test results, for the purpose of determining conformity with accreditation requirements and providing advice to the Laboratory Accreditation Committee, which makes the accreditation decisions. Following the accreditation of the laboratory, you may be called upon at any time through that accreditation cycle to advise the TTLABS Secretariat on the laboratory's request to add tests to their Scope of Accreditation, matters relating to the laboratory's relocation, or to weigh in on a decision to revoke accreditation for a test or analyte through the review of data/information.

Your main contribution is your technical expertise. You and the other assessors assigned to your technical field(s) provide the technical direction and options required to assess each applicant's conformity with the accreditation requirements. The TTLABS Secretariat provides the structure and administrative procedures; you provide the technical support.

One important aim of TTLABS is to evaluate each applicant, in relation to others, as uniformly as possible. Assessments must be fair and even-handed. Interpretations of requirements should be as consistent as possible among all assessors. For example, requirements of ASTM test methods cannot be ignored because it is industry practice or regional preference to do it another way. If you are in doubt about a requirement, please feel free to discuss it with other assessors as well as the TTLABS Secretariat. Keep in mind that if you cannot express nonconformity (nonfulfilment of a requirement) in the words of the requirements, (accreditation standard, specific program requirements, test methods or the laboratory's own policies and procedures) you do not have nonconformity.

2.2 Assessment Assignments

We assign assessors to perform assessments by matching an individual's expertise with a laboratory's requested scope of accreditation, while trying to avoid any conflict of interest. Assessors have the right to refuse acceptance of an assignment. Before accepting an assignment, you need to ask yourself three questions:

1. Is there any conflict of interest that would prevent an impartial assessment?

2. Am I competent in the areas in which the laboratory desires accreditation?
3. Can I perform the assessment in a timely manner? (Remember there must be flexibility in the timing of the assessment to accommodate the laboratory).

In answer to the first question, remember that the assessment must be impartial and thorough. If you are assigned to assess a laboratory for which possible conflict-of-interest questions could be raised, please declare it by advising the Manager, TTLABS. The assessor contract contains TTLABS' conflict-of-interest policy. Two examples of conflicts are: (1) Outright conflict because of ownership in the laboratory or in a competing laboratory; and (2) prior ill-will between the assessor and one or more of the laboratory personnel because of acrimonious disagreements in technical-society activities.

The second question is one that should not be taken lightly -- many of you are consultants and thus think that there is not much that you do not know. Competency ranges, on the one hand, from intimate knowledge of all facets of the activities that are to be assessed -- knowledge developed because you are an international authority in this field and directed a laboratory performing identical work; to knowledge of most of what is to be assessed but only limited understanding of the remainder. Can you become "competent enough" to examine test(s) in which you have limited understanding? The latter case is where the decision becomes critical -- you have to decide the competency issues before you accept the assignment.

Laboratories also have the right to refuse acceptance of an assessor assignment. Although we normally check with the laboratory management beforehand regarding an assessor assignment, if a laboratory does not want you to be the assessor, notify the TTLABS Secretariat immediately.

When you are assigned to perform an assessment, the TTLABS Secretariat sends you copies of the laboratory's application and other pertinent information. Please hold these documents and other privileged information from the applicant secure and in confidence. After completing the assessment and after an accreditation decision is rendered, you should return the documents to the laboratory or TTLABS, destroy them, or otherwise keep them under lock and key, as appropriate.

Normally, you are given 60 (sixty) days to schedule and complete the assessment(s) that you have been assigned. (Occasionally, a faster response may be requested.) If you cannot accommodate that response time please let the TTLABS Secretariat know when you are initially called about an assessment. If the laboratory should end up delaying the assessment beyond 60 days (approximately), please notify TTLABS in writing. You should not schedule an assessment date for a new laboratory unless you have performed a document review and you are quite sure that the laboratory is ready. If you have scheduled an assessment date with a new laboratory that will eventually have to be postponed because of lack of readiness, you may not be able to accept other TTLABS assignments. You will have to use your good judgment and perseverance when deciding to schedule assessments of renewal laboratories because of the pending expiration of their accreditation.

Although it is not always possible, assignments are scheduled so that participating laboratories are assessed by different assessors on successive visits.

Assessors must not discuss assessment assignments, arrangements or scheduling with a laboratory until the TTLABS Secretariat has formally assigned the assessor to that laboratory.

2.3 Team Assessments

Frequently, more than one assessor is required to perform an assessment of a laboratory, particularly when it is enrolled under more than one field of testing or desires a lengthy list of test methods to be assessed. In order to lessen disruption, all assessors on a team, if possible, visit the laboratory during the same time period. In such cases, we designate one "lead assessor" who shall coordinate the arrangements for the assessment, ensure all assessor reports are completed, and serve as the arbiter of any differences in the

assessment team's findings. The lead assessor will also normally be responsible for assessing the quality management system requirements of ISO/IEC 17025 [or ISO 15189](#) and the tests on the draft scopes(s) for which he/she is qualified. The other assessors serving on the assessment team are referred to as "team assessors." Team assessors assist the lead assessor by performing those aspects of the assessment related to their expertise and by assessing general aspects of the criteria as assigned. Team assessors should familiarize themselves with the quality management system to facilitate their portion of the assessment but should not repeat the document review performed by the lead assessor. The lead assessor shall provide all team assessors with the results of the document review. The TTLABS Secretariat will outline the responsibilities of each member of the team in the assessment assignment letters.

Please note that Appendices A and B of this Assessor Guide contain checklists that may be used as guidance by our assessors to fulfill their responsibilities as team leader or team member.

Preparation of the final reports of a team assessment can be handled in several ways. The preferred procedure is to have one collective report, rather than individual reports, left at the laboratory. This ensures that the laboratory as well as the TTLABS Secretariat knows what constitutes all of the assessors' findings. However, this is not always convenient or practical, so separate reports are acceptable. The lead assessor can assume the responsibility of composing the collective assessor report and assessor nonconformity report, or each assessor can prepare separate sheets for inclusion in the final reports. Then the lead assessor can simply collate the pages in a logical order. If one report is left, it is important that proper credit is given in the report to all assessors on the team. This can be accomplished by initialing individual pages or sections of the report. If this is not convenient or practical, then each assessor may complete a separate assessor report and assessor nonconformity report. In every case, each assessor leaves a separate estimated assessment cost form. Please note that all members of a team must submit a final assessment invoice with receipts before any members of the team are paid. Please also note that one set of Laboratory Accreditation Committee assessor report evaluation scores are collectively given to the entire assessor team.

2.4 Surveillance Visits

In addition to regularly scheduled on-site initial and renewal assessments, you may be asked to conduct a surveillance visit. Surveillance visits are scheduled annually between full re-assessment which normally occurs every three (3) years.

The scope of a surveillance visit may range from checking a few designated items from the assessor checklists to a more full review. For all annual surveillance visits, you must be sure to include review of records for organization and management, internal audits, management reviews, corrective/preventive actions, complaints, document control, training, measurement traceability and proficiency testing. Document review of the quality manual is *not* done as a part of a surveillance visit, though you can certainly request a copy of procedures during your review of the corresponding records.

Assessor and nonconformity reports are still written and left with the laboratory as is done during a regular assessment, but not all checklist items need be covered. An abbreviated (mini) report or assessor checklist report can be used.

Even though you may know that you will be responsible for the surveillance visit in the subsequent year, you must wait for formal assignment of the surveillance visit from the TTLABS Secretariat before making plans with the laboratory. When we make assignments for surveillance visits, we will specify what should be examined. However, you are not bound by our instructions if, while you are at the laboratory, you find other items that are possible nonconformities. Surveillance visits generally last no longer than one day on-site.

2.5 Pre-assessment Option

TTLABS assessors may conduct a pre-assessment visit at the option of the laboratory. After a TTLABS assessment has been assigned to you, the laboratory may request a pre-assessment visit especially if you determine that the quality documentation or procedures received do not meet the criteria. You may also be

asked to perform a counseling visit, which is similar to a pre-assessment but occurs before a laboratory actually applies.

In a pre-assessment visit, you may explain the requirements, review the status of the laboratory preparations, point out omissions, and respond to the laboratory's suggestions on correcting nonconformities. **In no event may you do the actual writing or changing of the documentation.**

The application fees paid before the assessment is assigned do not include pre-assessment assessor costs so you should make it clear to the laboratory that the extra visit will cost more.

There will also be occasions when you begin to assess a new or renewal laboratory, and determine that there are major problems that would lead to a large number of significant nonconformities. You can stop the assessment and discuss with the laboratory the need to either turn the assessment into a pre-assessment, or to continue with the assessment with the understanding that a follow-up assessment will most likely be required by TTLABS.

When you have agreement with a laboratory that a pre-assessment is warranted, please do the following:

- Contact the TTLABS Secretariat and identify the laboratory needing a pre-assessment. We will provide you with a special estimated "pre-assessment" cost form. This cost form will also include a special "pre-assessment" number that must be used to charge fees associated with the pre-assessment action.
- Perform the pre-assessment, making a list of the issues and concerns discussed.
- Return the completed estimated pre-assessment cost form, the list of issues and concerns and your final invoice (with receipts attached). We can pay you and bill the laboratory for the pre-assessment at that time. You will be paid at the rate reflected in your current contract.

2.6 Assessing Multi-Laboratory Quality Management Systems

In order to be as uniform and efficient as possible, TTLABS has established guidance for its assessors to perform assessments of laboratories that operate under a corporate level management system. TTLABS endeavours to assign the same assessor(s) to all of the laboratories under one corporate management system, so this guidance is also provided in order to reduce redundancy in reviewing the management system requirements at each of the laboratories that work under the corporate level documents.

Guidance for TTLABS Assessors on Assessing Multi-Laboratory Quality Management Systems

1. Ensure that all policies and procedures required by the standard(s) are in the system during a corporate level system assessment.
2. Determine if there are local procedures that supplement corporate procedures, if this is acceptable and acknowledged under the corporate management system structure, and if the local procedures meet the intent of the accreditation requirements.
3. Verify effective implementation of the corporate level functions during the corporate level assessment (i.e. management system, quality policy, management review, internal audits, corrective/preventive action, document control, training, contract review, complaint system, as applicable).
4. Determine if lessons learned and/or corrective and preventive actions taken at any of the labs in the corporate system are made known to the individual labs to prevent recurrence of nonconformities and to ensure adoption of agreed-to corrective actions/ resolution of complaints.
5. Establish that a single management system is actually in place across all the labs (see 2 above). This

would be accomplished by assessing the implementation at the individual sites. Some of the questions that would also have to be asked:

- How is the document control system implemented at the individual lab and in association with the other labs?
 - Are employees at the individual lab familiar with the applicable policies and procedures (both local and corporate)?
 - How is the corrective action system implemented at the lab level and what are the associated responsibilities?
 - When was the last internal audit of this facility and what were its results?
 - Where and how are the individual lab organizational structure and responsibilities defined?
 - Who is responsible for technical and quality issues at the individual laboratories?
 - Was the management review complete and inclusive of the individual lab and linked to the other lab sites enveloped under accreditation?
 - If the scope of accreditation is not the same at each individual lab, are claims of accreditation limited only to the lab so accredited?
 - Are the responsibility, authority, and interface clear for personnel not located at the individual lab (e.g. purchasing, quality auditors, technical writers) and are these remote personnel aware and trained on unique requirements of the individual lab supported, as applicable?
6. Concentrate more heavily on the technical elements (scope, proficiency testing, test or cal procedures/processes, certificates, shipping/handling, etc.) plus the implementation of the management system elements at the individual sites.

Identify nonconformities as system-level or site-specific level nonconformities. "Redundant" management system elements can be noted in one checklist *that properly notes that this is a multi-laboratory corporate structure and designates those management system nonconformities that apply to all of the applicant laboratories within the corporation*. These system level nonconformities can be addressed one time within one nonconformity report and be considered applicable to all sites as long as evidence exists that they are addressed under the corporate corrective action system and that this system is effectively implemented. The TTLABS Secretariat will contact the assessor if there is any doubt about the effectiveness of the corrective action provided to address system level management system nonconformities.

2.7 Invoices for Services

Assessors are paid in accordance with the terms of their contract. TTLABS offers the option of direct deposit for your assessor payments. Assessors are reimbursed for their time at the contractually agreed rate; travel cost (economy airfare, car rental, gas for car rental, limo/taxi, parking, tolls and mileage); subsistence (hotel, meals); and other visit related costs (telephone, postage, photocopying). Phone expenses for calls to arrange the assessment and one call home for each overnight away from home can be estimated.

Preparation and travel time are chargeable items. Preparation for the assessment including the examination of a laboratory's management system documentation is chargeable; however the time spent to create additional, expanded review notes or checklists beyond the normal utilization of the laboratory-completed assessor checklist and resulting notes/questions to ask is not chargeable. Reviewing standard test methods, and otherwise preparing yourself on the test technologies involved, is considered part of your professional development and, therefore, is not chargeable.

If total round trip travel time exceeds two hours, then each additional hour of travel is chargeable at one-half the assessor labor rate. If an assessor chooses to drive, the chargeable miles shall not exceed an economy airfare and appropriate rental car charges. The time charged for auto travel shall not exceed the time needed to get there by air.

Additional guidance on charging for travel time under special circumstances (acts of God, flight delays

etc.) is addressed in our assessor contracts.

Travel to Foreign Countries: You can charge up to 0.5 days for travel time each way to Caribbean countries, 1.0 day for travel time each way to the Americas, 1.5 days travel time each way to laboratories located in Europe, and 2.0 days travel time each way to laboratories located in Asia and the Asian Pacific Rim.

Complete and submit your own invoice (or bill) rather than using the "Estimated Assessment Cost" form because of the difference between the rate charged laboratories for assessment time and what you are paid directly for your time. Keep the following things in mind when completing an invoice:

- Show your contract hourly rate.
- Check to see that the actual assessment time is the same as the estimated time left at the laboratory. You cannot change the amount of time charged for the assessment after the laboratory representative has signed off on the Estimated Assessment Cost form.
- Exclude any item that would be disallowed. Excluded items include such things as movies at your hotel room.
- Sign and print full name.

The final invoice must be hand delivered or sent in the mail. A facsimile copy is not acceptable. Include receipts for air, car rental, hotel, and any expense that amounts to over \$xx (parking, taxi/limo, etc.). If we have to call to request a receipt, it delays the writing of the assessment payment and billing to the laboratory. An example invoice or form is provided as part of your initial TTLABS assessor-training course.

2.8 Evaluation of Assessors

Because of the crucial nature of the assessment function, the TTLABS Laboratory Accreditation Committee (LAC) has established a policy for determining the acceptability of assessors. As part of the policy, feedback from the laboratories and the TTLABS Secretariat on the performance of assessors is periodically solicited and the Laboratory Accreditation Committee may offer comments on the assessor reports. This information is taken into account in determining the continued acceptability of an assessor. The Laboratory Accreditation Committee initially approves and annually re-approves all assessors.

Each assessor-in-training (AIT) shall normally participate in a team assessment as a team assessor and then as a lead assessor, under the supervision of a person (generally, one of the staff from the TTLABS Secretariat) who has practical knowledge of the conduct of assessments. Newly approved assessors are evaluated again after one year and then put on cycle to be re-evaluated at approximately three-year intervals. You will be informed by the TTLABS Secretariat when you have been assigned to an assessment with oversight. Please do not schedule the assessment until you have confirmed the availability of an evaluator to accompany you. Thirty days' advanced notice to the evaluator is appreciated.

Assessors are paid in accordance with the TTLABS Assessor Compensation Schedule that is included as part of the contract. The assessor's rate of pay increases up to a maximum of \$xxx per day (when serving as a team leader). The number of actual assessments or "credits", attendance at a TTLABS-recognized lead auditor course (+4 credits), successful completion of a TTLABS-recognized lead auditor course (+8 credits), and/or the TTLABS Assessor Training Course (+2credits) or your first TTLABS Assessor Conclave (+2credits) all count towards increased compensation.

After these initial visits with oversight, you may be directed to attend a formal course to improve your knowledge and skills for performing assessments. TTLABS requires completion of a four-day assessor training course, and occasionally offers a five-day ISO/IEC 17025 assessor course, and refresher training through annual meetings of assessors.

Each newly contracted assessor is provided with a hard copy set of TTLABS assessor documents specific to the technical discipline(s) in which competence is recognized. Assessors will be notified of updates to

these documents by email and asked to download the new editions off the TTBS website. There is an assessor-only web page on the TTBS web site where all of the documents necessary to perform a TTLABS assessment can be found and downloaded. To access this page you can enter your full first and last name in the user field and your master id code for your password. Alternately, you can define your own terms to use for the user field and password.

The Laboratory Accreditation Committee shall vote at its regularly scheduled meetings on each potential assessor submitted for approval. At least two-thirds of those in attendance must vote to approve in order for the potential assessor to be accepted as a full-fledged TTLABS assessor. The TTLABS Secretariat provides feedback, both pro and con, when it is considered to be helpful to assessor performance. If possible, sub-par performance is identified hopefully leading to improved performance. The TTLABS Secretariat also sponsors assessor training seminars and conclaves periodically to refresh and update the assessor corps.

Assessor Criteria: TTLABS assessors shall:

- Be peer experts familiar with the type of business to be assessed;
- Be technically competent to assess an applicant's operations in those specific tests, types of test, product areas, or other specifically delineated functions for which accreditation is sought;
- Have the combination of qualifications and experience necessary to enable them to work as members of an assessment team, as lead assessors, or independently, as applicable;
- Be able to communicate effectively, both in writing and orally;
- Have sufficient knowledge of TTLABS policies, process and criteria to communicate accurately with applicants;
- Demonstrate sufficient poise, tact, persistence, integrity, maturity and other personal attributes (see sections below) to carry out assessments; and
- Complete successfully any required training course(s) needed as a prerequisite for assessment in assigned areas.

After completion of each potential assessor's evaluation process, the TTLABS Secretariat determines whether to ask the Laboratory Accreditation Committee to approve the potential assessor, or to continue the training process, or to drop the potential assessor from further consideration. The elements of an assessor's performance that are monitored during on-site assessments are:

- Knowledge of accreditation process; knowledge of assessment process
- Preparation & organization; documentation evaluation
- Oral communication techniques; information collection skills
- Knowledge of criteria/requirements & testing technologies.
- Thoroughness
- Efficiency
- Leadership, tenacity and firmness
- Poise and tact

- Objectivity and judgment
- Quality of written reports

In addition a TTLABS assessor shall:

- Apply assessment principles, procedures and techniques;
- Plan and organize the work effectively;
- Conduct the assessment in a timely manner;
- Prioritize and focus on matters of significance;
- Collect information through effective interviewing, listening, observing and reviewing documents, including records;
- Verify the accuracy of collected information;
- Confirm the sufficiency and appropriateness of assessment evidence to support assessment findings and conclusions;
- Confirm those factors that can affect the reliability of the assessment findings and conclusions;
- Understand the appropriateness and consequences of using sampling techniques;
- Record assessment activities through work documents;
- Prepare assessment reports that are clear and concise;
- Hold information confidential; and
- Communicate effectively, either through personal linguistic skills or through the support of a competent interpreter.

Personal attributes contribute to the successful performance of an assessor. A TTLABS assessor shall be:

- Ethical – fair, truthful, sincere, honest and discreet;
- Open minded – willing to consider alternative ideas or points of view;
- Diplomatic – tactful in dealing with people;
- Observant – constantly and actively aware of physical surroundings and activities;
- Perceptive – instinctively aware of and able to understand and adapt to situations;
- Versatile – able to adapt to different situations;
- Tenacious – persistent, focused on achieving objectives;
- Decisive – reaching timely conclusions based on logical reasoning and analysis;
- Self-reliant – acts and functions independently while interacting effectively with others.

3.0 ON-SITE ASSESSMENT

3.1 General

The on-site assessment is the key part of the accreditation process. It is our face-to-face examination of the laboratory to assess conformity 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 applicant.

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

3.2 Assessment Forms

TTLABS uses on-site assessment forms (checklists, test method review matrix, an assessor report form, and an assessor nonconformity 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 and draft scope(s) were examined; and
- provide information for future assessments, thus facilitating continuity.

TTLABS offers each laboratory three different options for the assessor report of general observations and evidence of conformity with the requirements:

1. The laboratory can choose to have a full narrative report that requires you to write a paragraph addressing each major heading in the ISO/IEC 17025 [\(or ISO 15189\)](#) standard. Very few laboratories choose this option because of the costs associated with your time in writing these reports.
2. The second option requires you to complete a “mini report,” which is a truncated checklist version of ISO/IEC 17025 [\(or ISO 15189\)](#) with specific areas for comments and special information that TTLABS requires, such as information about essential personnel.
3. The laboratory has a third option and can choose to completely forego an assessor report. In these cases, you are required to complete the *Summary of Assessment to ISO/IEC 17025* [\(or ISO 15189\)](#) form (so that TTLABS has a record of essential personnel, proficiency testing, and past corrective action implementation) and the assessor general criteria checklist. When the laboratory chooses this option, it is critical that you make careful and complete records in the assessor general criteria checklist of the objective evidence seen to support conformity with the requirements.

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An asterisk accompanies many of the requirements in the assessor general criteria checklist. These indicate that you are required to note the objective evidence of conformity (or non conformity) that was found for *every* TTLABS assessment; regardless of the report option the laboratory chooses.

Also, regardless of the option chosen, the assessor must complete a full nonconformity report.

3.3 Preparation for an Assessment

The overriding purpose of preparing for an assessment is to organize oneself 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 TTLABS and yourself, waste the laboratory's time, and render the results less valuable. When you receive written authorization from the TTLABS Secretariat to proceed with an assessment, the following steps need to be implemented:

1. Immediately call the laboratory to ask the authorized representative to send you appropriate additional information to review before the visit, particularly the laboratory's quality manual and related documentation, such as important standard operating procedures (SOPs) and test methods. Other documents that may be useful to receive in advance include equipment lists, facility layouts, and proficiency testing results. Assure the laboratory that any laboratory-owned documents sent to you in advance will be held in confidence, can be returned or destroyed once an accreditation decision is reached, and will neither be retained in TTLABS files nor your own personal files. Also, discuss the estimated cost of the assessment with the authorized representative at the time of initial contact.
2. Review the applicant's documentation for completeness and adequacy related to the documentation requirements of the accreditation criteria.
3. Before scheduling the assessment or reassessment, advise the laboratory in writing of gaps, or revisions needed in its documentation to be in conformity with the documentation requirements. If the documentation is found seriously inadequate, do not schedule the assessment if it is a new applicant until the laboratory provides evidence of revision per your instruction. Renewal assessments should still proceed due to the pending expiration of the laboratory's accreditation. Please provide TTLABS with a copy of the document review letter (or email) that is sent to the laboratory prior to the assessment. This will serve as evidence of your preparation for the assessment and will be necessary in order to authorize payment of the preparation time on your assessor invoice.
4. Review all relevant information (e.g., criteria, test methods, quality manual, application information including the laboratory-completed assessor checklist, technician training matrix, previous assessment reports, nonconformity correction letters, proficiency test results). Prepare your own questions based on previous assessment reports and correspondence to address nonconformities previously observed. If available, 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.
5. Estimate the duration of the assessment (and preparation time) to the nearest 1/2 day, and discuss with the laboratory in advance. Be sure the laboratory personnel are clear and in agreement so they are not caught by surprise when presented with the estimated cost form at the exit briefing. Offer the three options for an assessor report and discuss how the different reports would affect your chargeable report writing time. Do not allow the laboratory to set the length of the assessment that may not be sufficient time for a good assessment. The amount of time needed depends upon the size of the laboratory, length and complexity of the laboratory's desired scope of accreditation and problems encountered during the assessment. Typically, assessments last from 2.5 to 4.5 days. Schedule the date of the assessment at least a few weeks in advance, whenever possible, to maximize the possibility of obtaining the best travel arrangements and discounts. Inform the TTLABS Secretariat of the assessment date.
6. Verify with the authorized representative the laboratory location, directions, time of arrival, security arrangements if any, names of laboratory personnel you will meet, number of different shifts the lab may run, suitable lodging arrangements, proposed agenda, requested demonstrations of specific tests, etc. You must take the recommendation for hotel lodgings that the laboratory gives you to ensure that you do not

exceed their budgets, unless you find lodging that is comparable and the laboratory does not object.

7. Develop an agenda. Send a proposed agenda to the laboratory beforehand and state the personnel who you would like to interview based on the organization chart provided in the application. Determine when testing is normally performed so that aspects can be witnessed without requiring a special set-up. Use this agenda in the entry briefing. Send a copy of your agenda to the TTLABS Secretariat prior to the assessment or with your completed assessor deliverables.
8. Complete what you can on the assessment forms before your assessment. For example, you may be able to assess provisions of the criteria regarding documentation (quality manual) requirements if you receive such documentation beforehand. If the laboratory does not want to send its quality manual in advance of your visit, advise the laboratory that the assessment will take at least one extra day of your time

3.4 Entry Briefing

Upon arrival at the laboratory, conduct an entry briefing during which you should:

- Meet with the laboratory's authorized representative and, as appropriate, any others who will be involved in assisting the assessment;
- Explain the purpose of the assessment and the accreditation process;
- Explain that the assessment is a sampling exercise;
- Explain that as "potential nonconformities" are found, the evidence will be shared promptly and that the laboratory personnel are expected to either agree, provide additional evidence, or defend their position to ensure that there are no surprises at the exit briefing;
- Explain that the laboratory can correct and close out nonconformities prior to the exit briefing;
- Discuss the assessor report options, if not already agreed upon;
- Review the times on the previously prepared agenda, conforming as far as possible to the laboratory's working hours, lunch hour, and coffee breaks;
- Discuss the estimated cost of the assessment;
- Confirm the accuracy of application information;
- Confirm the laboratory's desired scope of accreditation and verify that all details of the draft scope(s) are accurate and up-to-date;
- Confirm that all laboratory documents that you previously received and reviewed are still current; advise that the presentation of revised documents will add to the assessment time;
- Ask for one escort who is knowledgeable about the laboratory's management, quality assurance, and procedural systems to ensure cooperation of laboratory personnel;
- Request a meeting room or place where you can be by yourself to review laboratory documentation and records, complete the checklists, and compose your reports;

- Agree on a tentative time for holding the exit briefing;
- Record the names and positions of the attendees and the relevant persons to be interviewed 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, to understand the "flow" of work, and to meet the relevant personnel (if appropriate).

3.5 Typical Steps of an Assessment

After the entry briefing, an assessment may be performed in any order. You should plan a sequence of activities with which you are most comfortable. However, keep in mind that a major component of laboratory accreditation is evaluation of a laboratory's competence to perform testing. So while the goal of an assessment is to verify that the laboratory fulfills all applicable TTLABS general accreditation requirements, sufficient time and attention must be given to assessment of the scope(s) of testing. A typical sequence of an assessment is as follows:

1. Conduct an entry briefing.
2. Examine and discuss test plans, procedures, reports, proficiency testing results, data logs, and related records.
3. Perform vertical audits, tracing various tests from receipt of sample to final test report.
4. Witness demonstrations of selected procedures by laboratory personnel to evaluate dexterity skills and to detect subtle deviations from procedures that cannot be established by simple questioning.
5. Verify that testing follows the standard test methods and/or SOPs by requesting a copy of the test method from the technician before witnessing the testing.
6. Interview technicians and supervisors to ensure that laboratory policies and procedures are understood and implemented.
7. Observe equipment demonstrations and examine accommodations.
8. Check on the resolution of nonconformities from the previous assessment and note the status in your report.
9. Examine and discuss with management and staff the quality manual and related documentation, internal audit and management review records, personnel competency records, equipment maintenance and calibration records, sample handling, and record keeping procedures.

Note: Accreditation of one-man labs is possible. TTLABS acknowledges that two requirements of ISO/IEC 17025 ([or ISO 15189](#)) could affect a one-man lab. Section 4.13 requires the internal auditor to be independent of the activities being audited, *wherever resources permit*; this is the allowance that a one-man lab needs. Section 4.1.5j requires appointing deputies for key managerial personnel. Since this cannot be done, the one-man lab will have to explain what will be done; essentially either subcontract the work or shut the business down until the manager returns.

10. Examine and discuss the laboratory's conformity with the TTLABS advertising policy and

the use of their TTLABS-accredited logo.

11. Determine that the designated quality manager and deputy quality manager are both knowledgeable about the Conditions for Accreditation (Part B of LAS-Q001 General Requirements for Accreditation of Laboratories), and the criteria/requirements for accreditation.
12. Record your findings on the assessor checklists, test method review matrix and note paper (this is your "raw data"). Check the factual accuracy of your notes periodically during the assessment. Please be sure to refer back to the words of the ISO/IEC 17025 (or ISO 15189) standard when recording your findings of conformity and nonconformity.
13. Using the appropriate form (full, mini or checklist), compose an assessor report, summarizing the assessment findings on conformity with accreditation requirements.
14. Include proficiency testing (PT) programs in which the laboratory is enrolled, the results reviewed, and evidence that the laboratory follows its documented corrective action procedures. Please remind the laboratories that they must respond promptly to TTLABS with their corrective actions for outlying PT results. They should not wait for the TTLABS Secretariat to prompt them with a letter.
15. Using the appropriate form, compose an assessor nonconformity report recording all observed nonconformities against the applicable standard(s), program requirements, test method requirements, proficiency testing, conditions for accreditation, and policies on traceability and use of the logo. (These should have been discussed with laboratory personnel at the time that they were observed.)
16. Using the appropriate form, prepare an estimated assessment cost.
17. Conduct an exit briefing -- discuss findings; make sure nonconformities are fully explained and understood (see 15 above); review the draft scope of accreditation with the laboratory and make any changes directly to the scope provided by the TTLABS Secretariat; initial any revisions and obtain initials of the laboratory representative on the draft scope; have the laboratory read and sign the cover pages of the assessor report and the assessor nonconformity report as well as the estimated assessment cost form.
18. Leave a copy of the assessor report, assessor nonconformity report, and estimated assessment cost; make a copy for yourself; mail the originals including the marked-up scope of accreditation, completed checklists and, if applicable for the field of testing, the last two proficiency test reports to TTLABS Secretariat.

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3.6 Assessment Reports

The TTLABS Secretariat provides a master code number and assessment ID number for each laboratory that should be included on each page of the assessment reports, forms and any attachments. The cover sheets of the reports and the assessor general criteria checklists (i.e., the forms provided by TTLABS) identify the laboratory by name and location and also identify the essential personnel and other technical personnel. These sheets and assessor checklists are sent to the Laboratory Accreditation Committee.

Assessor Report. Keep in mind that this report is read by people not at the assessment and by the next assessors for future assessments. The report must be a stand-alone document. After you have completed the assessment, ask the laboratory for a desk and some time alone to prepare a final assessment report. You may have already begun the report during the assessment so that you are only adding final touches. If providing a full narrative report. Use the 24 major headings of ISO/IEC 17025 (or ISO 15189) as the major headings of the report. You may use the blank sheet provided (or plain lined white paper) following the assessor report cover sheet to compose your findings. Make sure you refer to and include the laboratory's

desired scope of accreditation. The scope must clearly identify the specific tests or types of tests for which you assessed the laboratory. Include any changes that were made as a result of your assessment, such as the laboratory adding tests that were not originally identified in the completed application or withdrawing its request for accreditation for certain tests because of nonconformities which it chooses not to resolve. Make sure you distinguish between a laboratory-requested deletion and your citation of a nonconformity that the laboratory intends to correct.

Provided the writing is legible, handwritten reports are acceptable, but typewritten text is preferred. You are also allowed to make use of the laboratory personnel's word processing capability if they give you permission. We do not type handwritten reports but copy and send them directly to the TTLABS Laboratory Accreditation Committee members. You should make sure the laboratory understands that the TTLABS Secretariat does not follow up with another more formally typed report. If you think there is a problem reading your reports, you may want to get the reports typed before you send them to us, but make sure that this does not delay submittal of the reports by more than a few days. This time is not chargeable to the laboratory.

Write anything that is significant and factual about what you have observed and objective evidence that you have collected. Identify which test methods were specifically observed and the degree to which they were assessed using the test method matrix form. This report does not have to be long; it should be concise. Detail whether or not the laboratory has enrolled in any required proficiency testing programs, what tests, what results so far, how close the proficiency test reflects normal practice, and an evaluation of its corrective action in response to unacceptable results.

Assessor Nonconformity Report: The nonconformity report specifically and explicitly identifies those item(s) that you believe the laboratory must correct in order to meet the criteria or perform the test methods properly. The identified nonconformities need not be repeated in the assessor report. A simple reference (i.e., "see nonconformity report") under the applicable section of the assessor report is preferred. At a minimum, a nonconformity statement must describe the evidence of nonconformity including a reference to the specific clause of the requirements of ISO/IEC 17025 or test method requirement that is not satisfied. Number the nonconformities for ease of correlating with the laboratory's corrective action response. If the applicant is deficient against only one part of a requirement, the nonconformity must be written to identify where exactly the applicant is deficient.

In cases where an assessment team is compiling a nonconformity report, it is helpful to identify which team member is citing the specific nonconformities so that the TTLABS Secretariat can follow up with the appropriate assessor if necessary.

You may recommend suitable corrective action, but be careful not to disclose any proprietary information that you may have learned from another laboratory. Be careful not to dictate what is recommended because there may be several alternative corrective actions that the laboratory could consider. It is the laboratory's decision to choose among suitable corrective actions.

You can encourage the lab to correct nonconformities found during the course of the assessment before the exit briefing. These nonconformities must still be included in the nonconformity report. If objective evidence is provided that closes the nonconformity, note that the nonconformity was satisfactorily resolved, and cite (or attach) the objective evidence you observed. You must ensure that the laboratory personnel have properly exercised their corrective action procedure to close the nonconformity, and note this in your statement that closes the nonconformity.

Recommendations: There are some experts who believe that recommendations in assessment reports are not advisable. When an assessor provides solutions to someone else's problems, a decrease in quality may be the actual result. Several reasons for this are suggested:

1. Many problems by their very nature are often difficult to solve. They may require a very extensive root cause analysis or in-depth investigation. In the limited time for an assessment, the assessor cannot always devote the resources necessary to find the

underlying cause(s) of a problem, so the solution is inadequate.

2. The laboratory often does not understand the reason for the recommendation and may be miffed at you for suggesting it in the first place. So the laboratory takes an inappropriate action on purpose just to show you how far off base you are.
3. An assessor usually recommends a solution based upon prior experience in a similar situation, but because the solution was "not-invented-here" it becomes suspect; however, the assessor is more than "50 miles from home" and therefore an "expert."
4. The assessor is assuming partial ownership of the recommended corrective action with neither the authority nor resources to correct it, and when you take away ownership, you tend to remove responsibility and accountability.

Because of your "authoritative" position, there is a great deal of pressure on the laboratory to do exactly as you recommend. The job of an assessor is to provide factual information on what is deficient to laboratory management. Laboratory management must decide how to correct nonconformities. This does not mean you should just identify nonconformities and depart, but you should not impose your methods and approaches on the laboratory. If asked, then you should certainly offer the benefit of your experience in a manner that can benefit the laboratory. Finally, one other reason suggested for avoiding recommendations is the increased exposure to liability should recommendations go awry. TTLABS advises its assessors to avoid offering recommendations, but if you do, offer them orally in the form of a question (e.g. have you considered doing ...?)

Estimated Assessment Cost Form. At the conclusion of your assessment, you need to complete an estimated assessment cost form that the TTLABS Secretariat provides. It is important that you use the estimated assessment cost form provided by TTLABS because it contains pertinent information from our database specific to each laboratory assigned to you. Leave a signed copy with the laboratory during the exit briefing. After returning from the trip, send in a final invoice for actual expenses incurred (on a separately prepared form) as soon as possible so that we can pay you quickly. Include copies of any receipts over twenty-five dollars. Make sure the amount of assessor days charged is identical to that stated on the estimated assessment cost form.

3.7 Exit Briefing

The exit briefing is your oral discussion of the content of your reports with the laboratory. You may need to revise some portions of the reports as a result of this discussion, so do not fret about "line outs." Just initial all changes. Use pagination. It is also a good practice to initial all pages of the reports particularly if you are part of a group assessment. At a minimum, the laboratory's quality manager or equivalent and superior should attend the exit briefing. For our future reference, identify all laboratory personnel who attended the exit briefing on the first page of the assessor report form or in an attachment. An exit briefing should be limited to one hour, unless senior management of the laboratory wants to constructively cover the laboratory assessment in great detail.

The exit briefing should include the following:

1. Thanks to the lab for its hospitality
2. Compliments made and criticisms constructively delivered
3. Reports delivered -- summarized and/or read orally
4. Nonconformities reported
5. Need for corrective action supported by objective evidence of implementation stated

6. Advise lab to respond within 30 days
7. Leave the *Instructions: Responding to the Assessor Nonconformity Report form*
8. Discuss revisions to the draft scopes, with sign off by assessor(s) and laboratory representative
9. Get the lab representative's signature on each report cover page
10. Explain the next steps in the accreditation or renewal of accreditation process
11. Thank the laboratory once again

For each nonconformity, describe the finding and the justification or reason for stating the finding (cite the applicable provision of the criteria or test method). Ensure that the laboratory understands each of the nonconformities. Instruct the laboratory that its corrective action response should include the necessary objective evidence that the corrective actions have been implemented or completed. Responses stated in the future tense are not acceptable as evidence of nonconformity resolution. Leave the laboratory with the *Instructions: Responding to the Assessor Nonconformity Report* provided with the assignment paperwork.

Some of the nonconformities you identify may be challenged. Remember that the laboratory's technical personnel may also be experts and differences of opinion may arise. Try to work out any differences and be satisfied that the TTLABS criteria have been met. However, do not argue. As appropriate, record your finding as a nonconformity and ask the laboratory to refute it in writing to the TTLABS Secretariat. The TTLABS accreditation process provides a second level evaluation that includes a review by the TTLABS Secretariat and the TTLABS Laboratory Accreditation Committee of your assessment reports and correspondence from the laboratory responding to the cited nonconformities.

Advise the laboratory representatives to write the TTLABS Secretariat within 30 days with the corrective actions and objective evidence. The letter must be signed by an authorized official of the laboratory who can certify that the statements made in the letter are correct. Indicate that your reports and the letter responding to nonconformities will not be forwarded to the Laboratory Accreditation Committee until the nonconformities are corrected or refuted. Ask the laboratory representatives to copy you with the corrective action at the same time they write TTLABS.

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

During the exit briefing, watch for warning signs of difficulties in obtaining conformity. For certain difficult assessments, a private conference with top management may be necessary.

3.8 Copies of Assessment Reports

Make sure all three forms (i.e., the "Assessor Report," the "Assessor Nonconformity Report," and the "Estimated Assessment Cost") are signed by an appropriate laboratory official. Be sure that the draft scope(s) are reviewed and initialed by you and the appropriate laboratory representative. Obtain two photocopies of the three reports. Leave one with the laboratory. Take the other with you for your records, and send the original to the TTLABS Secretariat. You should not leave a copy of the test method matrix or checklists (because of the possibility that your "rough notes" will contradict your official report to the laboratory). We don't prevent you from leaving these documents if the laboratory makes a strong plea for them and you have ensured that there is nothing contradictory, offensive or inflammatory in these documents.

After you have left the laboratory, mail the original copy of the checklists, draft scope(s) and test method

review matrix (make a photocopy for your records) along with the signed original of the report forms to the TTLABS Secretariat. Do not give the laboratory the responsibility for mailing your assessor reports to TTLABS. Please do it yourself so we will have a timely receipt. Please be sure that every requirements box in the general criteria checklist has been completed, minimally with a tick mark and your personal notation that you concur because this checklist is sent to the Laboratory Accreditation Committee to give them additional information to allow them to make a decision on granting accreditation.

Although assessors do not make formal recommendations to accredit or withhold accreditation, if the assessor notes any issues or concerns beyond what is included in the reports that could affect this decision, a separate note to notify the TTLABS Secretariat of these situations should be included with the assessor reports.

3.9 Assessment Follow-up

Occasionally, technical questions that can only effectively be answered by you are raised as a result of the corrective action response of the laboratory. In these cases, the TTLABS Secretariat calls or sends the response to you (before an accreditation decision ballot is issued to the Laboratory Accreditation Committee) for a judgment on whether or not the corrective action response is complete and adequate for closure. If the response is adequate for closure, a ballot is issued to the Committee. If it is not, the TTLABS Secretariat writes the letter asking for further response.

If the laboratory personnel have not copied you on the corrective action when they responded to TTLABS, the corrective action response is sent to you at the same time as the Laboratory Accreditation Committee ballot is issued. If you believe there is something the TTLABS Secretariat overlooked, please contact the Manager, TTLABS immediately. Unless the review of a corrective action response is especially lengthy or difficult, you are not compensated for your time. However, if you feel that you will expend significant additional time (more than two hours) reviewing corrective actions (e.g. measurement uncertainty budget review) please discuss this with the laboratory before you leave the lab and add this time to the estimated cost form that you leave with the laboratory. There may be times when you will not know at the time of the exit meeting that a corrective action review will take an unusual amount of time, or at some point after the assessment, you will be asked to approve a large number of scope changes. Should you run into this situation, please contact the TTLABS Secretariat to discuss the additional amount of time it will take you. We will alert the laboratory, invoice them accordingly and pay you for this time.

3.10 Disposition of Assessment Records

All information on the laboratory as well as documents related to the assessment must be treated as confidential information and must be kept in secure/locked files when in your custody. The assessment documentation you are asked to keep upon conclusion of your assessment is only to be used for your reference in case there are any follow-up inquiries that may occur before the Laboratory Accreditation Committee has completed its accreditation decisions.

Once an accreditation decision has been made, you may return the assessment documentation to the TTLABS Secretariat or dispose of it properly. However, the TTLABS Secretariat may come back to you at any time during the laboratory's three-year term of accreditation to ask for your technical input or advice, so it is prudent to retain your records through the three-year accreditation resulting from your assessment.

4.0 ASSESSMENT CONDUCT AND TECHNIQUES

4.1 General

More than your technical expertise is required to conduct an assessment successfully. Understanding and interpreting all the criteria are of prime importance. There are also certain procedural items, ethical issues, assessment concepts, and questioning techniques to bear in mind. These are covered in this section.

4.2 Conducting an Assessment

To conduct an assessment properly, the following guidelines need to be heeded:

1. Abide by the Association's conflict-of-interest policy. If you are in doubt about a potential conflict of interest, call the Manager, TTLABS to discuss the issue.
2. Do not promote your consulting services before or during the course of the assessment and resolution of all nonconformities found. And remember, TTLABS will rely on you to weigh in on accreditation actions for the laboratory you assessed for two years after the assessment was completed. After that, consulting can not be prevented, but please note, you would not be able to return to that laboratory for at least **4 years** after the consultancy was completed. If the laboratory wanted to add to their Scope of Accreditation after your assessment and before the next full assessment, we would have to assign a different assessor to perform that interim assessment.
3. TTLABS does not endorse any products or services. Please refrain from making any comments about your likes/dislikes for specific products or services, especially those used by the lab.
4. Treat proprietary and confidential information as such. Safeguard the confidences of all parties in the assessment and accreditation process, of all present and former enrolled laboratories, including such information disclosed in the context of communications relating to an anticipated professional relationship with potential applicants.
5. Be honest, objective, and avoid bias. Personal dislikes/prejudices must not interfere with the assessment.
6. Be factual; verify findings. Do not rely solely on what people tell you happen -- try to confirm by examining records of calibrations, audits, initials of any QC checks, proficiency test data, documentation of corrective actions, etc.
7. Be thorough and fair. It is essential that the assessor leave the laboratory personnel with the feeling that they have received a thorough and fair assessment. This entails talking to and visiting with as many people as possible. Any one of us can walk into a laboratory and form unfavorable views and develop a "gut feel." We may well be right, but this does not prevent us from doing a thorough, formal investigation and preparing a factual report of nonconformities. Once all the relevant facts are clear, write up nonconformities in a neutral, non-inflammatory way.
8. Be independent. You decide what will be examined.
9. Be determined, decisive and direct. Once there is enough evidence to form the basis for a sound conclusion, there is no point in going over the same ground.
10. Keep the assessment moving; be aware of the overall progress of the assessment so as to avoid wasting time on trivia. Avoid lengthy, digressive conversations. Once you have sufficient information to judge the competence of the laboratory in a given area, move on. Time consuming scrutiny of every detail is not necessary if you can reach a fair judgment with just a few key observations. Further probing is overkill and a waste of time.

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11. Do not conduct other business during the assessment. Turn off your cell phone. Plan to pick up your calls during breaks or lunch, if necessary.
12. Make every effort to disrupt as little as possible the normal operating schedule of the laboratory while conducting an assessment.
13. 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.
14. 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 objective evidence relating to it. If the discussion reaches an impasse, 'agree to disagree.' Do not get involved in an argument. Go on to the next item.
15. Be prepared to return to an area, if necessary, to obtain new information and to reassess the operation in the light of new information.
16. Keep a sense of proportion. The magnitude and significance of nonconformity is a vital issue. Make allowances. Put errors in perspective. Never lose sight of the use to which test results are put. Do not pursue unimportant errors. This wastes time and effort and risks alienating the laboratory.
17. Be helpful. 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" or proprietary information in an attempt to be helpful. Open literature sources are preferred.
18. 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 TTLABS Secretariat.
19. At the end of each day, give the laboratory representatives a brief summary of what has been happening and any nonconformity found. 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 nonconformity encountered. In some situations the nonconformity 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.
20. Avoid all situations that could be construed as undue or improper influences on your assessment findings.
21. Plan to pay for all meals. Although the laboratory ultimately pays the cost of assessment, you are reimbursed by TTLABS for out-of-pocket expenses directly. Be prepared to eat lunch by yourself at all times, but if laboratory personnel wish 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. A short business lunch is preferable and you can certainly request, in the interest of time, that the laboratory bring a quick lunch into the laboratory for you.
22. Avoid social meetings of laboratory personnel.
23. Do not request favors from laboratories which could be construed as improper or an imposition.
24. Do not accept gifts from a laboratory before, during or after an assessment.

25. Avoid stating personal philosophies.
26. Avoid making derogatory remarks about specific manufacturers or suppliers of equipment or about their products.
27. Avoid making derogatory remarks about individuals either within or outside of the laboratory.
28. Avoid becoming involved in intra-laboratory personnel problems.
29. Do not make unreasonable demands for information when it is not clear that the information will further enlighten you or even be able to be reviewed during the visit.
30. 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.

4.3 Information Collection

Assessment is an information collection process that entails verifying application information, interviewing and questioning the laboratory personnel, examining facilities, equipment, and records, and reviewing applicable proficiency testing results. A successful information collection requires planning and preparation. Have a clear idea of what information you are looking for that would provide the necessary objective evidence to demonstrate conformity with the accreditation requirements.

Plan interview/questioning sessions with those personnel who can best provide the information you are seeking. Usually, this is an appropriate cross section of the staff. Identify, ideally as part of the entry briefing, what personnel you would like to interview and have the laboratory arrange for them to be ready when you are. For each person interviewed, establish who the person is, what the person's duties are, and what do you want to accomplish from the interview. It is desirable to have a list of questions or notes prepared beforehand. Know not only what questions you will ask, but why you are asking them.

Although being flexible is difficult given the time constraints, do not schedule time so tightly that there is no time to explore issues that come up which may not be exactly in line with what you expected, but appear to be fertile ground. Some of the best information gained may come by chance.

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). Such differences may be indicative of a problem or nonconformity that needs to be resolved.

Collect information as you go by observing and listening to what is going on around you. Laboratory personnel should be doing the majority of the talking. In addition to writing down comments in response to the checklist items, it may be helpful for later recall to take legible and retrievable notes on the following:

- 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 the 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 nonconformities.) and

- Latest revision dates of manuals, 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? This is perhaps the most important, yet difficult to assess, factor in determining the competence of a laboratory and the overall quality of test results that it produces. A lack of specialized training may be a suitable finding.
- 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 working level technician should be the one to answer the questions, explaining that the purpose of the assessment is to see what is actually being done and to verify that the proper procedures are being implemented.
- Are the staff knowledgeable of the laboratory's quality policies and associated procedures and location of such documentation?
- What is the condition of facilities and equipment? Are measuring instruments properly maintained and calibrated?
- Are the policy and procedural documents used and followed correctly?

One of the key objectives of the assessment is to ascertain whether the laboratory can retrieve the necessary facts to substantiate its test reports. A good approach for assessing a laboratory's retrieval system is to trace a test report through the testing process back to receipt of sample. We recommend this approach be used for the baseline investigation. Start with the final results or that which the client sees (i.e., the formal test report). If the results are supported by documentation generally at the work bench level (logs showing data transfers and other supporting logs are available, specimen identification is traceable, the proper tests/analyses were performed, QA/QC procedures and checks carried out) then by inference, the system from receipt of sample to the issuance of test report is in place and adequate. If this approach uncovers a problem, a more detailed scrutiny is warranted to evaluate the seriousness of the problem. Then it is a matter of determining whether the problem is a nonconformity requiring correction or perhaps simply a weakness that needs improvement and warrants a mention as a concern. Keeping careful notes of the objective evidence is essential to help you prepare complete and accurate reports.

If the laboratory is a multi-shift operation, some effort should be made to visit with the alternative shifts or at least observe the change in shifts. If a portion of the scope is performed at a "satellite" laboratory, effort should be made to visit there as well. TTLABS will add testing at a satellite laboratory to the applicant laboratory's scope of accreditation if that satellite laboratory is within close proximity to the applicant laboratory (within approximately 50 miles), operates under the same management system, and has access to a supervisor who is knowledgeable about the testing and is readily available to handle problems and issues that arise at the satellite laboratory. You must indicate the satellite laboratory's location and the testing performed there on the draft scope(s) of accreditation.

If the laboratory performs field or site testing, assessment of these operations is required, including if possible, the actual demonstration of testing in the field.

4.4 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. The following questions can be helpful when analyzing any system or process:

- What is happening?
- Why is it happening?
- Where is it happening? Why is it happening there?
- When was it done? Why was it done then?
- Who did it? Why was it done by that person?
- How was it done? Why was it done that way?

Be careful not to overuse the "why" questions since they can be intimidating. Ask "how" type questions which help identify the process used. For example, "Show me exactly how you carry out this task." The follow-up question should be aimed at getting specific examples of the process at work. Then, the results should be addressed followed by questions addressing deployment in all areas of the laboratory. To determine depth of understanding/deployment, use questions such as "Can you describe some examples of how you have . . .?" or "Describe what you would do if . . .?"

Remember that the technician may answer, "Because the SOP says to . . ." whereas a more definite response should be expected from a supervisor. Consider how to clarify the answers. 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?", and "How do you do that?" are recommended. If there is a variation from written procedures, then ask, "Why do you do it that way?" Questions which require data as a response help verify and clarify the laboratory's conformity with the criteria, such as "How often?", "How many?", "May I see three examples of ...?", or "May I see a copy of . . .?"

Hypothetical questions are good when little objective evidence is available. The "What if ..." or "Let us suppose ..." or "I don't understand ..." type of statement or question is usually effective in such situations.

Silence after a short answer to a question can be extremely powerful. Some people find silence uncomfortable and to break it they may volunteer something more. 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. Be careful about being too 'tricky' or conveying an "I'm gonna getcha" demeanor. It is important to assume the laboratory is "innocent" until proven "guilty."

Observe what is not said by the laboratory staff. If answers are superficial or evasive, be prepared to continue the line of questioning. Repeat the question in a slightly different way if the answer is grossly inadequate.

If it appears that your question has been misinterpreted or the answer is vague, continue with a more detailed question or with an example of what you are seeking, e.g., a copy of a document that references the information. Use a piece of evidence to focus the person -- talk about that specific thing rather than

generalities. Have patience, especially if people do not understand or misinterpret the questions. Simple, straightforward questions are best. Put the question in plain, generic text. Avoid asking questions that suggest the answers you expect.

Attempt to put the staff members at ease at the beginning of a questioning session since they probably will be nervous. Introduce yourself and ask the staff members some easy questions about their background to get them comfortable. Small talk and some humor at the beginning also put them at ease. Take a non-threatening approach; smile and use appropriate eye contact. Show interest in their work by asking them to "show and tell" you about it. Establish a good rapport so they do not 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. Describe what you would like to better understand and what you are trying to accomplish. Keep the following points in mind:

- Be calm, polite and reasonably friendly. Treat others the way you want to be treated.
- Direct questions to the person who performs the task being assessed, and not that person's supervisor; unless, of course the person performing the task is not doing it correctly. In such a case, maybe training or supervision needs to be improved and the logical one to address such problems is the person's superior.
- Be interested in the person's work and responses.
- Allow time for the person to formulate replies to your questions.
- Allow time for the person to add something that you did not ask about.
- Use no more than 20% of "air time."
- Exercise careful listening and catch clues of special issues to pursue.
- Stick to the subject and avoid going off on tangents.
- Respect interpersonal distance; do not get in "someone's face."
- Never talk down to anyone, but talk the "lab's language."
- Do not be or appear to be distrustful of people or to regard their responses with criticism.
- Give credit where credit is due. A compliment, sincerely given, goes a long way towards eliciting cooperation.
- Thank people for their time.

4.5 Sampling

An assessment is ultimately an exercise in sampling due to time and cost considerations. Even in the smallest facility, you will not be able to examine every document, procedure, record, or person in the time available. A 100 percent examination of all data related to each test method for example would be a huge waste of time. Unable to examine everything, all you can do is to examine "samples" of the auditable items and base your findings on the outcome.

Sampling is therefore an accepted approach to accumulating assessment evidence. Sampling involves estimating the rate of occurrence of a particular characteristic or estimating population totals by examining less than all the items of a population. You are primarily concerned with determining technical competence and obtaining sufficient evidence to provide a sound basis for determining conformity or nonconformity

with requirements. Sufficient evidence is objective, factual, relevant, useful, adequate and convincing, so that a prudent informed person would reach the same conclusions.

For most assessment situations, assessors use judgmental sampling rather than statistical sampling. In some circumstances, statistical sampling may be more appropriate than judgmental sampling. Before deciding to use statistical sampling, the assessor must keep in mind the objectives of the overall assessment objective (i.e., is the laboratory competent to perform specific tests and is its management system implemented in accordance with the standard(s)?). The assessor must also identify the population characteristics of interest, and estimate the degree of risk that is acceptable. After making those determinations, it may be advisable to use statistical sampling if the assessor has a well-defined population and can easily access the necessary documentation. However, this is rarely the case during assessments.

Judgmental sample selection is based on your sound and seasoned judgment. Three basic issues determine which items are selected:

- Importance of the item to the process examined. The more critical a group of items to the integrity of the system, the greater your need for a high level of confidence in your findings and the greater the size of the sample you will have to take. In extreme cases, you may indeed have to make provision for a 100% inspection of certain groups of critical items.
- Relative risk. Items prone to error due to their nature, complexity or age should be given special attention.
- Representative ness. Besides importance and risk considerations, you should be satisfied that the sample approach provides breadth of coverage over all types of processes (tests) in the scope.

Random selection may be a useful approach for many assessment situations. In this method, you select the sample items without intentional bias to include or exclude certain items in the population. Hopefully, it is your best estimate of a representative sample, but defined probability concepts are not employed and statistical inferences cannot be made. Both the time constraints and practicalities of the assessment situation mean that the samples you take are very small in statistical terms.

If this non-statistical sampling approach sounds unsettling, you nevertheless can adopt some positive strategies to increase the effectiveness of the assessment. Recognize the limitations of sampling, and determine the size of your task, and plan your assessment strategy and sampling programs in advance. At some stage in every assessment, you will need to examine the audit trail -- tracing forwards or backwards through the system to ensure that at each step there is unbroken traceability. When following this path you will branch laterally into procedures associated with each step. At other times you will choose to do a "horizontal" audit -- taking a particular element (e.g., training) of the standard and examining its correct implementation across all sections of the organization. With proper planning, you can often aggregate the results you obtain from small, individual samples you have taken in each section into a much larger composite sample more truly representative of the organization as a whole. As a general rule, you should always sample randomly unless the evidence coming to you suggests otherwise; for example the unexpected discovery of a breakdown in an otherwise good system or conflicting information coming from other aspects of the assessment might demand a more directed examination of that particular element of the system. As the assessment proceeds, evaluate the findings in the context of the evidence and continuously ask yourself questions about the significance of what you are finding (or not finding) in the samples you are taking.

In an initial assessment, you can expect to find quite a number of nonconformities -- elements of the requirements that have been overlooked or misinterpreted, or are not being consistently implemented. Theoretically, this should not happen in an accredited laboratory subject to periodic internal audits as required by the standard(s). The discovery of any major nonconformity or even an appreciable number of minor nonconformities in an accredited laboratory must raise serious doubts about the effectiveness of the internal audit system. Therefore, review of the results of internal audits is always an important activity in

any assessment, but especially so when an unexpected level of nonconformities is encountered.

Sampling of the Scope of Tests: You need to cover all fields of activity included in the scope of accreditation based upon the basic reference elements of ISO/IEC 17025. Include each test method or test technology from the draft scope(s) on the test method review matrix. At a minimum, for each test method or technology, confirm that the laboratory has competent people, calibrated and maintained equipment and appropriately documented procedures to conduct each test.

From there, for a given type of test, you should assess the key methods for the types of materials or product in the scope and select tests (including specifying test items and test methods where appropriate) that can be witnessed during the assessment and which should produce confidence in the competence of the laboratory to perform all tests proposed for the scope of accreditation. Possible criteria for sampling of these tests may be:

- Evidence of capability (proficiency, validation), experience, implementation of the quality management system;
- Consequence of errors;
- Frequency of use;
- Technical complexity;
- Balance between standard methods and non-standard ones; and
- Balance between complete observations of test performance and checks of test reports or inspection of test facilities.

No quantitative predetermined rules can be given for the number of tests to be considered. The number of selected tests must be large enough to allow reliable conclusions to be drawn from the assessment for each type of test, but they must not create unreasonable costs to the testing laboratory.

4.6 Laboratory Tactics

In an ideal world, all laboratories would view your assessment as an opportunity for improvement. However, assessments are often viewed as a nuisance. Some laboratories see them as just a necessary cost of doing business. Their goal is to "survive" the assessment or just "get by." Often, laboratories with such an "attitude" will use tactics that do not promote an effective assessment. Such tactics need to be recognized and addressed in a professional manner should they be employed.

Assessment Managers: Occasionally, the laboratory will try to assert control of the assessment by setting the agenda for you and determining who you will interview and who is off-limits. This should not happen if you have set the "ground rules" in advance of the assessment with the laboratory's authorized representative.

Everything is Beautiful Type: The laboratory will attempt to impress you by showing you only the best points of its system and gloss over the weak points. Be careful not to get caught up with such enthusiasm -- maintain your objectivity.

Pre-selected Records: Similarly, the laboratory determines what documents and records you will examine for conformity to requirements. Random selection determined by you is the only approach to ensure that the laboratory's selection has not been culled for nonconformities.

Challengers: Some laboratories may pose various challenges to you. They may challenge your authority, your competence, and your technical knowledge. They may try to intimidate you in the hope of talking you out of cited nonconformities. They may complain about the process. They may attack your integrity. You

need to recognize the psychology that may be involved. People generally take great pride in their system. They may think they have the best laboratory in the business. Receiving negative assessment results is very much like a death in the family. Their first reaction is shock, disbelief, and denial. They do not believe you did a good job. They find fault with your conduct of the assessment. They find all kinds of minutia to rebut your findings even though much of it may be irrelevant. Hopefully, the laboratory can get beyond this stage and begin to recognize that you may be right.

Time wasters: Since the laboratory pays actual costs of assessment time, deliberate tactics to slow down the assessment are rarely employed. Nevertheless, there are situations created by the laboratory which unintentionally waste time:

- "Snow Job": At the beginning of assessments, some laboratories provide an elaborate presentation about who they are, and what they do to try to impress you. Often, the topics covered are outside the scope of the assessment. Although these presentations may be helpful, assert control if they get out of hand.
- "Schmoozers": Employees of the firm outside the laboratory or perhaps the founder "emeritus" of the laboratory, who does not actually manage the day-to-day affairs anymore, comes by to say hello and the next thing you know you have talked about the good old days for half the morning. Tactfully cut short such idle conversation.
- Long Lunch: The laboratory insists on taking you out to a nice place to eat that turns into a three-hour excursion. Politely decline the invitation unless you believe you can obtain useful information about the management of the laboratory and you have the time.
- Interruptions: The laboratory staff you are interviewing may be constantly interrupted to take phone calls, sign reports, etc. If you have set an agenda properly, you should expect the laboratory staff to be able to give you full attention for the hour or two you are interviewing each one. Politely ask that all calls be held until the interview is finished.
- Absent Staff: If you have given plenty of advance notice of the assessment, the laboratory should ensure that its essential personnel are available during the assessment. If one or more essential personnel (i.e., indispensable to the laboratory's competency to perform a particular test) are not available, then either the scope of accreditation needs to be reduced or you have to come back another time when the essential personnel are available.
- Advice Seekers: Often, since you have great technical knowledge and experience, laboratory staff are seeking to "pick your brain." (They may also be trying to flatter you or stroke your ego in the hope that you lighten up on negative findings.) While this is fine for short periods, do not let the assessment turn into a consulting task.
- Detail Persons: Information that the laboratory staff volunteers is so overwhelming and in so much detail that you cannot perform a satisfactory systems assessment. In other words, there are so many "trees" that you cannot see the "forest." To be successful, concentrate on what is important, and do not get bogged down in unnecessary detail.
- "Politicians": Some laboratory staff are good talkers -- they speak at length and say nothing of substance. They never answer your questions directly or may deflect the discussion to an unrelated topic. Again, assert control and be politely persistent in pursuing the topics of direct interest to the assessment.

4.7 Assessment Report Writing

The objective of assessment reporting is to communicate directly, succinctly and accurately. Each report must use a tone and strategy appropriate to the significance of the information presented. Report language

should be creative; word choice and organization should reflect varying degrees of significance among items presented.

If the laboratory requests that you write a full narrative report, we suggest beginning with introductory information, purpose and scope of assessment, status of prior nonconformities and corrective action implementation (renewal reports and surveillance reports only), proficiency testing participation and then continue by formatting the report in accordance with the major sections of ISO/IEC 17025.

Some of the laboratories will request that you complete a mini-report. Complete all sections of the mini report, and attach any additional comments that you may have to address, for example, the elements of specific program requirements. We encourage embellishment of the mini report in the comments section, where appropriate. Just remember that you will have an opportunity to state your nonconformities in the nonconformity report, so leave the comments section of the mini-report for your positive thoughts, unusual observations, and compliments. A simple note in the comments section to "See nonconformity # ___" will suffice, should you find any nonconformities relating to that section of the standard.

We also ask you to indicate whether you are citing general criteria nonconformities, specific criteria nonconformities or both. General criteria nonconformities hold up the entire accreditation of the laboratory until the nonconformity is resolved. For example, "*There are no internal audit records available*" or "*The laboratory does not have a complaint handling procedure*".

Specific criteria nonconformities result in a reduction in the scope of accreditation, but they do not hold up the accreditation for methods not associated with the nonconformity. For example, "*The hardness machine had not been calibrated in accordance with the laboratory's calibration program.*" Though the assessor would cite section 5.6.1 of ISO/IEC 17025, this nonconformity would still be considered specific criterion nonconformity because the lab could be accredited for everything else assessed except Hardness until the nonconformity was resolved. As another example, "*The analytical balance had not been calibrated.*" This would require the accreditation of any test methods dependent on use of this analytical balance to be delayed until the nonconformity was resolved, but the rest of the scope could be accredited.

If you are completing the general criteria assessor checklist for use as the assessor report, we encourage your comments in the comments sections, and as noted earlier, each asterisked requirement requires you to note the objective evidence of conformity or non-conformity that you reviewed.

Also, in some fashion (initials, arrows, stamp, etc.) indicate, for each clause in the checklist, where the laboratory is conforming to the requirements of the standard.

Please also check to be sure that your indications of nonconformity in the assessor checklist(s) agree with, and are accounted for, in your nonconformity report.

Remember that for surveillance visit reports and renewal assessment reports, you must report on the status of prior nonconformities and implementation of the corrective actions from the previous assessment.

4.8 Writing Assessment Findings

Several principles in wording assessment findings (both the findings of conformity as well as nonconformity) are important to keep in mind.

Do not cite nonconformities against any of the information contained in the laboratory's application for accreditation. The application is our tool for collecting information. It cannot be considered part of the laboratory's management system documents. For example, it is the assessor's job to review the training records to determine who is properly trained. The Technical Staff Matrix in our application could be incorrect or could have been submitted before additional training took place.

Do Not Draw Conclusions without Substantiation (i.e., Objective Evidence). For example, you find

that the laboratory's calibration program is informal but there is evidence of calibration being done, two ways of reporting the finding are:

1. The lab has no calibration program. [bad]
2. The calibration program is not documented. [better]

This holds true for positive findings as well. For example, you witness several tests and sample others for parts of their procedures and find everything to be in conformity. You could report:

1. The lab is in conformity with all tests in its scope. [bad]
2. The tests witnessed (i.e., [cite standard designations]) and procedures observed (e.g., sample preparation, glassware washing) were correctly performed. [better]

State the Exact Nature of the Nonconformity. Requirements may be stated without specifying when and at what intervals. For example, chemical test, the requirement may be "Method detection limits shall be determined and documented." If the required activity is not being performed consistently, clearly state the fact. If the MDLs have been determined, but some have not been documented, the finding should state both facts.

1. The method detection limits have not been determined and documented for some methods. [bad]
2. Documentation of the method detection limits for several methods (i.e., GC for, AA for, ICP for) was not available. [better]

Avoid generalities. Vague reporting and generalities can confuse and mislead the reader. Specific quantities should be used rather than non-definitive modifiers as "several," "some" or "not all." For example, the first version is too vague -- it leaves the reader wondering what is inadequate.

1. Conformity with some of the laboratory's chain-of-custody procedures is inadequate. [bad]
2. Three out of three chain-of-custody records reviewed were not signed in the box indicated as required by the laboratory's own procedure (SOP-123). [better]

Communicate the Extent of the Problem Fully. Although a finding is worded factually, it may not contain enough information to fully communicate the nature and extent of the nonconformity. For example, the first version is incomplete:

1. The high precision analytical balance is next to a drafty doorway. [bad]
2. The location of the high precision analytical balance next to the doorway without any protective shielding offers the potential for significant air movements affecting readings during weighing operations as required by clause 5.3.2 of ISO/IEC 17025. [better]

Avoid Extreme, Inflammatory or Negative Language. Refrain from using disparaging or disrespectful words such as careless, awful, dangerous, incompetent, weak, inept, or uneducated. Content and rhetoric should be selected to show positive benefits and gain commitment from the laboratory. Be constructive by presenting positive findings along with the negative findings and give credit for management action.

Use familiar terminology. All readers of your report may not be well versed in the type of laboratory or test technologies assessed. To facilitate clear understanding, spell out all obscure acronyms, abbreviations or regulatory jargon upon their initial use and define them if necessary.

Do Not Focus Criticism on Individuals or their Mistakes. Tie nonconformities to the system, not the

people. In most cases, nonconformities are due to system failures. If necessary, identify people by their position only.

Identify the Requirements Reference. The basis for nonconformity may not always be clear to the laboratory or other readers of the report. Always identify the requirements (e.g., ISO/IEC 17025 clause), test standard requirement, proficiency test requirement or relevant policy as part of the nonconformity. Where you identify the requirement citation in the text of the nonconformity is a matter of personal style and effectiveness of communication. Nevertheless, keep in mind that you do not have nonconformity if you cannot express it in the words of a relevant requirement within the standard.

1. An internal audit has not been conducted since 1998. [bad]
2. Internal audits as required by clause 4.13 of ISO/IEC 17025 have not been scheduled since 1998. [better]

Avoid Writing a Solution as a Nonconformity Statement. Ensure in your nonconformity reports that documentation of discrepancies state the observations of nonconformities (i.e., evidence against relevant clause(s) of requirements) and not recommendations for correcting the nonconformities. The laboratory may have another way to correct the nonconformity that you had not thought of, but may be perfectly acceptable.

1. The laboratory needs records for equipment maintenance. [bad]
2. There were no observed records of maintenance for the tensile and hardness testers and balances as required by clause 5.5.5 of ISO/IEC 17025 [better]

4.9 Submission of the Completed Assessment Report

To assist the TTLABS Secretariat in readily determining if the contents of the assessment package are complete, please submit your reports with the documents in the following order:

1. Optional cover memo with any special notes or instructions the TTLABS Secretariat may need to know concerning this assessment;
2. The agenda, if not already provided;
3. Evidence of the document review (correspondence with the laboratory);
4. The assessor report (narrative, mini report, or assessor checklist);
5. The nonconformity report (attach any objective evidence that closes nonconformities);
6. The draft scope(s) of accreditation, revised and initialed by lab and assessor(s);
7. The test method matrices;
8. The assessor checklist(s);
9. The estimated assessment cost form(s);
10. Your final invoice with receipts, if available at the time; and
11. Any other relevant attachments.

5.0 NONCONFORMITIES

5.1 Identifying Nonconformities

Nonconformity is a non-fulfillment of a requirement or a departure from a condition or criterion for accreditation. Keep in perspective the magnitude of any nonconformity found and avoid making an issue out of trivial discrepancies, human errors, or isolated mistakes. Isolated errors may be due to someone having an off-day (a random error rather than a systematic problem). 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 nonconformities after tracing the testing process for 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 nonconformities 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 laboratory staff. If several serious nonconformities 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 needs to take place.

Be sure of the facts and discuss observed nonconformities with the laboratory person involved in the problem area. Give the person the fullest opportunity to explain the problem before reaching a conclusion. Sometimes further information can be provided that changes your first impressions. When nonconformity is found, you may ask questions that lead the laboratory to discover its cause. However, identifying underlying causes for certain difficult problems may require a very extensive analysis or in-depth investigation, which you are not required to perform, nor should you if the time is not available. If you can determine the underlying cause, encourage the laboratory to make a proposal for corrective action. 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 nonconformity and has analyzed the cause of the nonconformity and has taken action to implement corrective action.

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

The causes of nonconformities can be categorized as follows:

- Lack of top management support (often the most significant underlying cause and a contribution to the other causes).
- Lack of system -- measures has not been taken to ensure than an activity is performed or performed properly.
- Lack of training of the personnel -- system has been developed and documented, but the staff is unaware or does not know how to use it.

- Lack of time -- too much pressure of work, overwork, or inadequate manpower.
- Lack of resources -- incorrect equipment.
- Lack of motivation 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 do not comply.

5.2 Typical Nonconformities

One of the most common nonconformities is that one or more aspects (e.g., internal audits, management reviews, handling complaints, record keeping, calibrations, etc.) of the quality management system are not being carried out as required by the laboratory's own documentation. The system, as described in the quality manual and other documents, procedures or instructions, is simply ignored or has not been understood by the staff.

Other typical nonconformities are usually found in a laboratory's documentation (including its written policies, procedures and records), equipment, accommodation, or personnel.

Typical documentation nonconformities include:

- Required items in the criteria are not addressed in the quality manual and related documentation.
- Outdated copies of documents are still in use.
- Responsibility for keeping documents updated is not assigned.
- No maintenance records of equipment are kept.
- Required content in test reports is missing.
- Measurement uncertainty budgets have not been established.

Typical equipment nonconformities include:

- Calibration and supporting documentation is lacking (traceability to national standards is not established adequately).
- Equipment is substandard, out-of-tolerance, unprotected and/or has not been calibrated or verified at suitable intervals.
- Substitute equipment is used without acceptable evidence that it performs as specified for the standard involved.

Typical accommodation nonconformities include:

- Temperature and humidity requirements of test methods are not being satisfied.
- Incompatible activities are not adequately separated.

Typical personnel related nonconformities include:

- Objective evidence is not available in laboratory files that attest to the training/certification of competence of the personnel.
- Based on demonstration and interviews, personnel are not adequately trained initially to perform

their tasks or on-the-job practice becomes careless and has (usually unintentionally) departed from prescribed procedures over time.

5.3 Resolution of Nonconformities

Nonconformity is identified by the assessor based on objective evidence found during the assessment. A nonconformity citation indicates the objective evidence found of non-conformity against a clause (or clauses) of the standard, test method or applicant's own management system documentation. From the laboratory's viewpoint, a cited nonconformity must either be corrected or challenged as not nonconformity at all. One way or the other the nonconformity must be resolved before accreditation can be granted.

The TTLABS Secretariat role is to oversee the assessment process by reviewing the assessor deliverables and cited nonconformities. The TTLABS Secretariat attempts to ensure that the assessor has interpreted the criteria correctly and verify the assessor's judgments regarding nonconformities (by definition, a nonconformity requires a written response from the laboratory) versus assessor recommendations or advice for improvement that do not require a written response from the laboratory. If the TTLABS Secretariat questions the assessor's interpretation of the criteria, usually the Manager, TTLABS will contact the assessor for further input. If the TTLABS Secretariat finds that the nonconformity should not have been cited, the nonconformity will be stricken from the report, and the laboratory will be alerted that they do not need to provide a corrective action response to that nonconformity. The assessor is also told that the nonconformity is inappropriate. The TTLABS Secretariat receives the laboratory's response to cited nonconformities and provides the initial review of the adequacy of its response. The TTLABS Secretariat assembles the necessary documentation for a vote by the Laboratory Accreditation Committee. The TTLABS Secretariat provides the laboratory with a list of the Laboratory Accreditation Committee panel members prior to sending the package to the Committee panel so that the laboratory can assist them in avoiding a possible conflict of interest by indicating which Committee members should not receive the laboratory's assessment package. See Part C of the "General Requirements for Accreditation of Laboratories" for complete details of the accreditation process.

The Laboratory Accreditation Committee ensures that the laboratory conforms to the criteria and that the nonconformities are adequately resolved. The Laboratory Accreditation Committee weighs the laboratory's response to correct its nonconformities in light of their seriousness. If any member of the Laboratory Accreditation Committee needs further evidence that adequate corrective action has indeed been taken, then the laboratory is asked to provide it. The Laboratory Accreditation Committee may not only request further documentation but, in some cases, may also request a follow up assessment. This is carried out by the TTLABS Secretariat.

All accreditation decisions by the Laboratory Accreditation Committee that are adverse to the laboratory may be appealed first to the Committee itself, and then to the TTBS Board of Management.

6.0 FINAL WORDS OF ADVICE

Keep in mind that you are a fact finder; you do not make decisions or even recommendations regarding accredited status. You render findings based on objective evidence regarding conformity or nonconformity with requirements. If you have any problem during an assessment or questions regarding TTLABS appropriate procedures or policies, do not hesitate to consult with the TTLABS Secretariat.

It is well understood that the high regard we strive to obtain from others for the TTLABS accreditation programs will result largely from the technical rigor of our assessments and the fair and cooperative way in which we serve our customers. We appreciate your crucial role and your efforts to make TTLABS programs of world-class status.

APPENDIX A

TTLABS TEAM LEADER RESPONSIBILITIES

Preparation

- ___ makes initial call to the laboratory
- ___ inquires about hotel and directions (maps); may make hotel reservations for team members
- ___ works out travel logistics between team members (sharing rental cars, etc.)
- ___ works out the assessment date between the lab and the team
- ___ ensures that the team members have received all of the information they need from the lab to perform their technical functions
- ___ ensures that the team members understand the roles and responsibilities each of them have and are comfortable with the assignments made by the TTLABS Secretariat; makes assignments to ensure coverage of the requirements (e.g. who's covering PT?)
- ___ drafts the agenda
- ___ decides on any team meetings prior to the assessment
- ___ ensures that necessary lab personnel will be available

Document Review

- ___ performs a full, thorough document review of the quality manual, etc. to check conformity with ISO/IEC 17025 (relevant elements of sections 4 and 5) [or ISO 15189](#).
- ___ writes the document review report letter to the lab

On site

- ___ leads the opening and closing meetings
- ___ ensures that each team member receives the lab's cooperation for the technical assessment
- ___ assesses implementation of the quality management system policies and procedures and completes those relevant sections of the assessor checklist(s)
- ___ determines the presence of nonconformities and writes them up
- ___ confers with the team members as needed to determine conformity with the requirements of ISO 17025, section 5 (The team leader can gather that information and add it to his/her checklist, or can ask the team members to complete the relevant sections of their own checklists for eventual submission to the TTLABS Secretariat.)
- ___ arranges sufficient team caucuses during the assessment to ensure that the assessment is on pace, is adequately covering the scope(s) and the team is not encountering any problems

___ serves as a sounding board for the laboratory personnel and /or team if any conflicts occur

Report Writing

___ gathers all necessary information from the team members in order to deliver a complete, comprehensive assessment report

___ ensures that the nonconformity report is completed by the closing meeting

___ completes his/her own estimated cost form (ECF) and ensures that the ECF for the team members are reasonable

___ submits final invoice to the TTLABS Secretariat

Follow Up Issues

___ is prepared and available to answer any questions posed by the laboratory staff about the laboratory in general, the management system and the portion of the scope(s) assessed, if any.

Team Harmony

___ manages the team and controlling conflicts between team members, or between team members and the laboratory personnel

___ resolves any disagreements between assessors *outside* the presence of the laboratory

___ arbitrates between a team member and laboratory personnel in such a way as to ensure that team unity and harmony is maintained and projected to the laboratory

___ calls the TTLABS Secretariat as needed for help to resolve any conflicts between assessors, or between the laboratory personnel and assessor(s), but *never* calls in the presence of the laboratory

APPENDIX B

TTLABS TEAM MEMBER RESPONSIBILITIES

Preparation

- ___ stays in communication with the team leader as logistics are arranged; alerts the team leader to any difficulties
- ___ makes sure of proper preparation to perform the assigned portion of the assessment (team members can contact the laboratory with specific questions concerning the assigned portion of the assessment; just let the team leader know)

Document Review

- ___ Reviews any procedures or methods related to their assigned portions of the draft scope(s) of accreditation
- ___ Reviews those portions of the laboratory's quality manual, etc. to ensure full understanding of the system (e.g. the lab's handling of calibration for certain equipment)

On site

- ___ Assesses the assigned portions of the scope(s)
- ___ Completes the relevant sections of the ISO/IEC 17025 [\(or ISO 15189\)](#) checklist and any relevant technical checklists, as requested by the team leader
- ___ completes the test method matrix for the assigned tests or calibrations
- ___ determines the presence of nonconformities and writes them up

Report Writing

- ___ keeps accurate records of their assigned portions of the assessment
- ___ provides the team leader with the documents necessary to complete the assessment report (e.g. checklists, test method matrices, scope revisions, evidence to close nonconformities)
- ___ makes oral or written contributions to the assessment report, as requested by the team leader
- ___ Completes ECF and leaves a copy for the lab
- ___ Submits final invoice to the TTLABS Secretariat

Follow up Issues

- ___ Is prepared and available to speak with the TTLABS Secretariat about laboratory requests for changes to the scope(s) of accreditation relative to his/her assessed portions of the scope(s)

7.0 REFERENCES

A2LA “Assessor Guide”, July 2003