General

Requirements

for

Accreditation

of Laboratories

[Part A includes all ISO/IEC Guide 25 requirements]

This document is reproducible and this is encouraged for accreditation purposes.

January 1997

GENERAL REQUIREMENTS FOR ACCREDITATION OF LABORATORIES

January 1997

Foreword

The AMERICAN ASSOCIATION FOR LABORATORY ACCREDITATION (A2LA) is a non-profit, nongovernmental, public service, membership organization dedicated to operating a nationwide, broad spectrum laboratory accreditation system. Accreditation is defined as a formal recognition of competence that a laboratory can perform specific tests or types of tests. Accreditation is available to any type of testing laboratory, be it in the private sector (independent or in-house) or in the government sector.

A2LA was formed in 1978, as a practical and efficient organization to develop and manage a system to verify and recognize competent testing laboratories. Accreditation is available for virtually all types of tests, calibrations, measurements and observations which are reproducible and properly documented.

The accreditation of laboratories is offered in the following fields of testing:

Biological	**Mechanical**	**Acoustical & Vibration**	**Nondestructive**
Chemical	**Environmental**	**Construction Materials**	**Geotechnical**
Electrical	**Thermal**	**Calibration**	

Special programs are developed in response to user needs and may cut across more than one field of testing. If only a few tests from a second field are to be included and all testing is managed in one facility under one quality system, these tests may be added to the scope of accreditation in the primary field at no charge for a second field. If there are two managers of equivalent status responsible for the testing in each field, accreditation will be necessary in both fields.

Users of accredited laboratories are advised to seek the Scope(s) of Accreditation from any accredited laboratory or from A2LA. The Scope(s) of Accreditation identifies the specific tests or types of tests or calibration capability for which the laboratory is accredited.

The general requirements (general criteria) for accreditation used by A2LA are from the international standard, ISO/IEC Guide 25 - 1990, "General requirements for the competence of calibration and testing laboratories" which follow in part A. Additional program requirements (specific criteria) for specific fields of testing (e.g. environmental) or specific programs (e.g. fasteners) which are necessary to meet particular user needs (e.g. USEPA, PL 101-592: Fastener Quality Act) complement these general requirements in particular areas.

In effect, A2LA accreditation attests that a laboratory has demonstrated that:

a) it is competent to perform specific tests or specific types of tests;
b) its quality system addresses and conforms to all elements of ISO/IEC Guide 25, is documented per Guide 25, and is fully operational;
c) it conforms to any additional requirements of A2LA or specific fields of testing or programs necessary to meet particular user needs.

It is A2LA policy not to accredit or renew accreditation of a laboratory that fails to meet the above criteria [see part B, Conditions for Accreditation and part C,

Accreditation Process, sections on deficiencies, accreditation decisions and suspension or withdrawal of accreditation.]

F:\WP\MAN\REQ\GENERAL.REQ012297 **_____,**
President

GENERAL REQUIREMENTS FOR ACCREDITATION

Table of Contents

PART A

GENERAL REQUIREMENTS FOR THE COMPETENCE OF CALIBRATION AND TESTING LABORATORIES (ISO/IEC Guide 25-1990) *WITH EXPLANATORY NOTES*

Introduction by A2LA

All laboratories accredited by the American Association for Laboratory Accreditation (A2LA) are required to comply with ISO/IEC Guide 25 -- 1990, "General requirements for the competence of calibration and testing laboratories", unless there is some unusual circumstance in the laboratory which might make compliance with a specific provision not appropriate.

In this Guide attention is paid to the activities of both calibration and testing laboratories and account is taken of other requirements for laboratory competence such as those laid down in the OECD Code of Good Laboratory Practice (GLP) and the ISO 9000 series of quality assurance standards.

According to the Guide's own Introduction (paragraph 7), laboratories meeting the requirements of this Guide comply, for calibration and testing activities, with the relevant requirements of the ISO 9000 series of standards, including those of the model described in ISO 9002 when they are acting as suppliers producing calibration and test results.

For laboratories engaged in specific fields of testing such as the chemical (toxicology) field (see for example the OECD Code of Good Laboratory Practice) or the environmental field, these requirements may need amplification with specific criteria which include additional requirements.

The text that follows, including the NOTES, come directly from Guide 25 (in gothic print). *A2LA Explanatory Notes (sections in italics) are interpretative guidance on particular requirements in the text. These explanatory notes are not to be interpreted as additional requirements.*

Guide 25 covers both calibration and testing laboratories, so the pairing of "calibration and test" is frequently repeated. In this context, test laboratories should ignore the word "calibration" (with the exception of section 9) and calibration laboratories should ignore the word "test."

1. Scope

1.1 This Guide sets out the general requirements in accordance with which a laboratory has to demonstrate that it operates, if it is to be recognized as competent to carry out specific calibrations or tests.

1.2 Additional requirements and information which have to be disclosed for assessing competence or for determining compliance with other criteria may be specified by the organization or authority granting the recognition (or approval), depending upon the specific character of the task of the laboratory.

1.3 This Guide is for use by calibration and testing laboratories in the development and implementation of their quality systems. It may also be used by accreditation bodies, certification bodies and others concerned with the competence of laboratories.

2. References

ISO/IEC Guide 2: 1986, General terms and their definitions concerning standardization and related activities

International vocabulary of basic and general terms in metrology (VIM): 1984, issued by BIPM, IEC, ISO, and OIML

ISO 8402:1986, Quality - Vocabulary

ISO 9000:1987, Quality management and quality assurance standards - Guidelines for selection and use

ISO 9001:1987, Quality systems - Model for quality assurance in design/development, production, installation and servicing

ISO 9002:1987, Quality systems - Model for quality assurance in production and installation

3. Definitions

The relevant definitions from ISO/IEC Guide 2, ISO 8402 and the International vocabulary of basic and general terms in metrology (VIM) are applicable, the most relevant being quoted below together with further definitions applicable for the purposes of this Guide.

3.1 laboratory: Body that calibrates and/or tests.

NOTES:

1. In cases where a laboratory forms part of an organization that carries out other activities besides calibration and testing, the term "laboratory" refers only to those parts of that organization that are involved in the calibration and testing process.

2. As used herein, the term "laboratory" refers to a body that carries out calibration or testing

- **at or from a permanent location,**
- **at or from a temporary facility, or**
- **in or from a mobile facility.**

3.2 testing laboratory: Laboratory that performs tests. [ISO/IEC Guide 2 - 12.4]

3.3 calibration laboratory: Laboratory that performs calibrations.

3.4 calibration: The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measurand.

NOTES:

1. The results of a calibration permits the estimation of errors of indication of the measuring instrument, measuring system or material measure, or the assignment of values to marks on arbitrary scales.

2. A calibration may also determine other metrological properties.

3. The result of a calibration may be recorded in a document, sometimes called a calibration certificate or a calibration report.
4. The result of a calibration is sometimes expressed as a calibration factor, or as a series of calibration factors in the form of a calibration curve. [VIM - 6.13]

3.5 test: A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

> **NOTE - The result of a test is normally recorded in a document sometimes called a test report or a test certificate. [ISO/IEC Guide 2 - 12.1, amended]**

3.6 calibration method: Defined technical procedure for performing a calibration.

3.7 test method: Defined technical procedure for performing a test.

3.8 verification: Confirmation by examination and provision of evidence that specified requirements have been met.

> **NOTE - In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.**
>
> **The result of verification leads to a decision either to restore in service, to perform adjustments, or to repair, or to downgrade, or to declare obsolete. In all cases it is required that a written trace of the verification performed shall be kept on the measuring instrument's individual record.**

3.9 quality system: The organizational structure, responsibilities, procedures, processes and resources for implementing quality management. [ISO 8402 - 3.8, without the notes]

3.10 quality manual: A document stating the quality policy, quality system and quality practices of an organization.

> **NOTE - The quality manual may call up other documentation relating to the laboratory's quality arrangements.**

3.11 reference standard: A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. [VIM - 6.08]

3.12 reference material: A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. [ISO Guide 30 - 2.1]

3.13 certified reference material (CRM): A reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body. [ISO Guide 30 - 2.2]

3.14 traceability: The property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons. [VIM - 6.12]

3.15 proficiency testing: Determination of the laboratory calibration or testing performance by means of interlaboratory comparisons. [ISO/IEC Guide 2 - 12.6, amended]

3.16 requirement: A translation of the needs into a set of individual quantified or descriptive specifications for the characteristics of an entity in order to enable its realization and examination.

4. Organization and management

4.1 The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the requirements of this Guide.

A2LA Explanatory Note: *The laboratory can be a public or private entity, an established business or corporation, or an identifiable division or in-house activity of a business or corporation, which meets the applicable legal requirements of the governmental jurisdiction in which it conducts business. Legal identifiability aids in addressing issues of liability/accountability, uniqueness, composition/scope and independence of operation.*

4.2 The laboratory shall:

a) have managerial staff with the authority and resources needed to discharge their duties;

A2LA Explanatory Note: *Laboratory management needs the authority to assure quality and protect integrity of results. Laboratory management needs the support of senior management reflected in adequate budget, equipment, facilities and people. Increased backlog, missed delivery dates, excessive errors, etc., are often signs of inadequate resources and/or authority.*

b) have arrangements to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;

A2LA Explanatory Note: *Both in-house as well as commercial laboratory personnel should be insulated from work-related undue pressures which would compromise the quality of work. The source of undue pressure may be internal (e.g., management pressure, deadlines) or external (e.g., customer complaints, priority requests). Management should decide which types of undue pressure the staff might encounter and implement clear policies and instructions for countering them. Precautions should be taken to ensure that there are no conflicts of interest between staff and clients. If relevant, the laboratory should have a written policy against acceptance of gifts and gratuities by employees from clients in order to avoid perception of conflict of interest. Also, a policy for handling internal complaints or concerns from employees should be included. Communications (priority requests, complaints, status inquiries, etc.) could be directed through supervision or administrative personnel. Ethics programs, skip-level management interviews, arbitrator programs, etc., may also provide avenues of coordination that preclude adverse effects resulting from commercial pressures. All these efforts may be included in the quality manual or issued as policy statements to employees.*

c) be organized in such a way that confidence in its independence of judgement and integrity is maintained at all times;

A2LA Explanatory Note: *When there is a possibility of staff being placed under pressure by clients or other sections of the organization, reporting relationships should be established to isolate staff from this pressure. The boundaries, expectations and responsibilities of the employee in dealing with the client may need to be specified in order to maintain independence of judgement and integrity. For captive laboratories, there may be in-house requirements concerning gift/favors and a*

policy of limiting the influence of those in the organization who profit from "in-spec" test results. See clause 4.2 b) for a related requirement.

d) specify and document the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

A2LA Explanatory Note: The laboratory should have an organization chart and job descriptions for these personnel. See clauses 5.2 b), c), and e) for documentation required in the quality manual.

e) provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;

A2LA Explanatory Note: A2LA assessors pay particular attention to the mode of supervision of staff. In small laboratories, the technical manager must decide who can work under general direction and who requires closer supervision. Technical personnel must be fully briefed and instructed on their particular duties. Adequate supervision must be provided at each level of the staff structure to ensure close adherence to laboratory procedures and accepted techniques at all times. Individuals assigned direct supervisory responsibilities should be knowledgeable of the methods, practices and procedures for the calibration or tests being performed, of evaluating results, and of making decision that affect the quality of the results. Job descriptions and training records should reflect this. The assigned span of control for supervisors should not be so extensive that it limits their effectiveness. If an assessor observes deficiencies in the conduct of calibrations or tests, the cause may be judged to be inadequate supervision and this clause would be cited in the deficiency statement.

f) have a technical manager (however named) who has overall responsibility for the technical operations;

A2LA Explanatory Note: Technical operations include standards selection, work assignment, and calibration or test method selection. The technical manager, or section leaders in large laboratories, must have sound knowledge of the principles of the relevant technical discipline(s) for their span of control, provide adequate supervision and have the ability to make critical evaluations of test results for applications of interest to the laboratory's customers.

g) have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;

A2LA Explanatory Note: Responsibility for the quality system should be assigned to an individual whose position in the organization allows the individual to operate free of pressures which may represent a conflict to the quality of calibration or testing. The quality manager's job may be a full-time or a part-time job, depending on the size of the staff. If the size of the laboratory permits, it is desirable to have different persons holding quality-manager and technical-manager posts. In cases

where such an arrangement is not possible, as in small laboratories, there should be sufficient safeguards against any bias on the part of the quality manager arising from that person's involvement in the day-to-day operation as technical manager. For example, it should be clear to the staff when the person is acting in the quality-manager capacity as opposed to the technical manager function. Identification of the titled position responsible for the quality system should be included in the quality manual. The quality manager may be remotely located as long as the system is maintained.

h) nominate deputies in case of absence of the technical or quality manager;

A2LA Explanatory Note: Arrangements for designating the person(s) acting in the absence of the technical manager and quality manager should be documented to ensure continuity of operation in case of absence(s). Designated persons should have the required knowledge and expertise to assume these duties. If the integrity of the laboratory is jeopardized by lack of other key staff, deputies for those positions should also be provided. Designated deputies should have the required knowledge and expertise to assume the position or the activities should be appropriately curtailed where knowledge and expertise do not exist with the deputy.

i) where relevant, have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights;

A2LA Explanatory Note: A laboratory should identify any customer information or material that is considered confidential or proprietary, or identify non-confidential items by exception or use other appropriate means and have appropriate policies and procedures in place to protect the customer's interest. This may include confidentiality requirements internal to the laboratory's organization as well as policies on patents and inventions. See clause 5.2 r) for documentation required in the quality manual.

j) where appropriate, participate in interlaboratory comparisons and proficiency testing programs.

A2LA Explanatory Note: Listing of the proficiency testing programs, the frequency of participation, and the reporting requirements to accreditation bodies and/or regulatory bodies should be included in the quality manual. When proficiency testing is mandatory for accreditation, it should be identified in the quality system documentation. See clauses 5.2 n) and 5.6 b) for similar requirements related to proficiency testing.

5. Quality system, audit and review

5.1 The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of calibration and testing activities it undertakes. The elements of this system shall be documented. The quality documentation shall be available for use by the laboratory personnel. The laboratory shall define and document its policies and objectives for, and its commitment to good laboratory practice and quality of calibration or testing services. The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned. The quality manual shall be maintained current under the responsibility of the quality manager.

A2LA Explanatory Note: *Laboratory activities may already be incorporated in a quality manual covering a parent organization's total range of operations. If so, it may be necessary to extract that information and expand on it to establish quality policy and objectives, and perhaps create a separate manual, specifically relating to the laboratory's functions. A policy may be a definite course of action, strategy, principle or rule that guides present and future decisions. A procedure is a particular way of doing something or a series of steps followed for a particular activity.*

The laboratory's quality manual needs to reflect the actual policies and practices of the laboratory. For this reason, it will be a document which is unique to the laboratory. The content, structure and format of the manual should reflect this uniqueness.

The policy statements should reflect top-management commitment. The statements should indicate the title of the person responsible for the technical operation in accordance with the policy statements and the title of the person having overall responsibility for maintaining the quality manual and should include their names and signatures. The senior-most person at the facility should indicate concurrence with the policy statement.

The laboratory may communicate these policies through the use of (1) a controlled distribution list of individuals having numbered copies of the quality documentation, e.g. quality manual and standard operating procedures, and (2) a documented laboratory training program.

Revision to the quality system documentation is the responsibility of the quality manager. Revisions may be prompted by events such as the annual review of the quality system by the laboratory management, suggestions from staff, or investigations of complaints.

5.2 The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of this Guide.

A2LA Explanatory Note: *The first step in developing a quality manual and related quality-system documentation is to decide on the physical format (allowing for ease of amendment) and the table of contents. You may use this document as a guide and ISO 10013, Guide for the Contents of Quality Manuals. It is preferable that the people who do the actual tasks draft their parts of the manual. The person responsible for the quality system fills in the gaps in the information and becomes the editor and coordinator of the document's production. The writers should start by describing what is now done in the laboratory. The writers should be conscious of writing for the laboratory staff, not for an accreditation body or customers.*

The quality manual should be written so that a person who is technically proficient can, after reading the quality manual and related quality documentation, competently manage the laboratory.

At a minimum, the quality manual should serve as a basic reference document to all quality-system documentation of the laboratory. Where a procedure is required by the 5.2 clauses to be included in the quality manual, a summary could suffice, provided it contains references to more detailed documents which are actively part of the quality system.

The list of subjects for the manual provided in clause 5.2 is the minimum. There are requirements for documented procedures in other sections of Guide 25 (e.g., clauses 8.2, 10.1, 10.4, 10.5, 10.7, 10.8, 11.4, 13.7, 15.2, and 16.1) It is desirable that the manual and related quality documentation address all sections of Guide 25. For example, there should be documentation addressing section 7 of Guide 25, Accommodation and Environment.

The quality manual and related quality documentation shall also contain:

a) a quality policy statement, including objectives and commitments, by top management;

A2LA Explanatory Note: A formal statement, signed by the top laboratory management (e.g., those who have chief operational and fiscal responsibility for the laboratory) expressing the objectives and commitment to and intent of management and staff to provide reliable calibration or testing services to its customers (or something similar) should be included at the beginning of the quality manual.

b) the organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

A2LA Explanatory Note: An organization chart or charts with the reporting relationship to any parent organization or ownership should normally be a sufficient presentation of the organization and management structure of the laboratory.

c) the relations between management, technical operations, support services and the quality system;

A2LA Explanatory Note: The responsibilities that each of the named groups have within the quality system and how they interrelate should be specified. Flow charts, interface maps, or written descriptions of work processes defining responsibilities and demonstrating interactions among the various organizational units may be provided. Clauses 5.2 b) and c) are often addressed in the same section of the quality manual.

d) procedures for control and maintenance of documentation;

A2LA Explanatory Note: The procedures, responsibilities, and authorities for drafting, changing, approving, issuing documents and data (which can be in the form of any type of media) needed for conducting the laboratory's business (e.g., procedures, drawings, schedules, work plans, job orders, test methods), including the quality manual and related quality documentation, should be documented. The documents and data should be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document-control procedure identifying the current revision status of documents should be established and be readily available to preclude the use of invalid and/or obsolete documents. The control of documents should ensure that (a) the pertinent issues of appropriate documents are available at all locations where operations essential to the functioning of the quality system are performed; (b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use; (c) any obsolete documents retained for legal or knowledge-preservation purposes are suitably identified.

Changes to documents and data should be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations should have access to pertinent background information upon which to base their review and approval.

Where practicable, the nature of the change should be identified in the document or the appropriate attachments. This explanatory note is based upon the text of section 4.5 of ISO 9001-1994.

e) job descriptions of key staff and reference to the job descriptions of other staff;

A2LA Explanatory Note: The job descriptions for key personnel (e.g., directors, managers, supervisors, designated laboratory signatories, laboratory technical experts, or individuals whose loss would significantly lessen laboratory competence) should be included or referenced in the quality manual. Those for other personnel should be included or referenced in the quality manual and maintained elsewhere. See related clauses 5.2 b) and c).

f) identification of the laboratory's approved signatories (where this concept is appropriate);

A2LA Explanatory Note: ISO/IEC Guide 2 defines an "approved signatory" as a person who is recognized by an accreditation body as competent to sign accredited-laboratory test reports. This concept will only be implemented for a specific field of testing or special program, such as the program intended for approval under the Fastener Quality Act.

Signatory approval may be granted only to staff designated by the laboratory. Any staff person competent to evaluate calibration or test results critically and occupying a position involving responsibility for the adequacy of results is eligible for approval as a signatory of endorsed reports. Consequently, approved signatories should demonstrate understanding of the requirements for accreditation.

The foregoing criteria provide for signatory approval of officers located in the staff structure between senior management and technicians. The criteria will require persons in management to have retained sufficient contact with calibration or test procedures to maintain an ability for critical evaluation of results. The criteria will also provide for technician-level signatories when responsibility is extended to this level.

The major attributes taken into account when assessing the suitability of a staff member for approval as a signatory are:

- *qualifications and experience;*
- *position in the staff structure;*
- *familiarity with calibration or test procedures and awareness of any limitations of these procedures;*
- *knowledge of the procedures for recording, reporting and checking results;*
- *awareness of the needs for periodic recalibration of equipment; and*
- *awareness of the requirements and conditions for A2LA accreditation, particularly those related to calibration or test reports.*

Signatory approval may be limited to one, several or all calibrations or tests covered by the accreditation. Signatory approval will be granted in the context of the particular features of the laboratory; it is not a personal qualification and it is not transferable from one laboratory to another. Signatory approval is available to consultants to the laboratory provided that both parties sign an agreement demonstrating that the consultant has the appropriate authority over calibration or testing. Part-time staff are also eligible for signatory approval provided that, when called upon to sign endorsed reports, they have access to and knowledge of relevant matters related to that particular calibration or test.

Any specific requirements for approved signatories in a field or special program will be specified in the appropriate A2LA program requirements document (i.e., yellow booklet).

g) the laboratory's procedures for achieving traceability of measurements;

A2LA Explanatory Note: Reference to the methods and procedures used to establish the traceability path to: a national standard of measurement; an intrinsic standard of measurement; or other acceptable source, should be included. Clauses 9.2 and 9.3 define the requirements for achieving traceability. See also the related clauses 5.2 j), l) and m).

h) the laboratory's scope of calibrations and/or tests;

A2LA Explanatory Note: A formal listing or description of the types of tests or calibrations provided by the laboratory and covered by the quality system should be included in the quality manual, not just the formal list of calibrations or tests or types of calibrations or tests reviewed in their A2LA assessment. General descriptions of the types of calibration or testing found in advertising brochures should satisfy this requirement as long as it covered everything. So, the scope of testing in the quality manual may be more general than in the official "A2LA Scope of Accreditation." It may also include other types of testing which are not part of the formal A2LA accreditation. The formal "A2LA Scope of Accreditation" agreed to by A2LA for the laboratory may be included in the manual but does not have to be so included.

i) arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

A2LA Explanatory Note: The arrangements for this review may be in the form of a written policy stated in the quality manual, in a standard operating procedure, or a responsibility documented in the job descriptions of one or more of the senior laboratory management usually involving at least the technical manager. This requirement is to ensure that the laboratory has the capacity to perform additional work of the kind it is currently performing and also that it is capable of performing new work of a kind not now being done. The manual should describe policies or procedures to screen an incoming test request to determine whether it is within the laboratory's capacity. Consideration should be given to: (a) customer's requirements for accuracy and turn-around time; (b) the range of tests normally performed; (c) available resources including equipment, staff, and space; and (d) workload. Evidence of this review should be recorded. The form this takes would vary (e.g. a request for a small number of tests may require only an authorizing signature whereas for a large number of tests, a formal management review of the laboratory's

capability may be necessary, with such review being documented.) This clause is comparable to clause 4.3 of ISO 9001-1994.

j) reference to the calibration, verification and/or test procedures used;

A2LA Explanatory Note: A listing of the test specifications, standard test methods, technologies, calibrations and other routine laboratory operations should be referenced in the quality manual. Where some laboratories perform tests to hundreds of standards and customer-unique specifications, representative lists of the types of standards and specifications for test may be acceptable. A system of identification of these procedures and how they are selected should also be included. Section 10 describes the requirements for documenting these procedures.

k) procedures for handling calibrations and test items;

A2LA Explanatory Note: See section 11 for more details on handling calibration and test items (e.g., samples).

l) reference to the major equipment and reference measurement standards used;

A2LA Explanatory Note: These could be listed as part of an equipment inventory, calibration schedule, or test procedures addressed in clause 5.2 j) and/or included in standard operating procedures.

m) reference to procedures for calibration, verification and maintenance of equipment;

A2LA Explanatory Note: The policies and procedures addressing these topics should be referenced or identified in the quality manual.

n) reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes;

A2LA Explanatory Note: See clause 5.6 for related requirements.

o) procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur;

A2LA Explanatory Note: The procedures should describe the implementation of immediate corrective action as well as action taken to prevent re-occurrence and ensure that relevant information on actions taken are recorded and submitted for management review described in clause 5.4. Also refer to clause 13.6 on prompt determination and notification to clients. The clause is comparable to clause 4.14 of ISO 9001-1994.

p) the laboratory management arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications;

A2LA Explanatory Note: Laboratory management is responsible for ensuring that laboratory policies and procedures are adhered to. The arrangements for known and controlled departures should be in a written policy that is stated in the quality manual or in a standard operating procedure. **The specific departure may be**

documented in a manner similar to that used in a corrective/preventive action procedure.

q) procedures for dealing with complaints;

A2LA Explanatory Note: *Staff should be trained to be open to customer dissatisfaction with the laboratory service offered and should explore, in such cases, ways to identify the essence of any complaint associated with that unhappiness. See section 16 for the requirements for the policy and procedures for handling complaints.*

r) procedures for protecting confidentiality and proprietary rights;

A2LA Explanatory Note: *Procedures should identify what customer-supplied items, equipment, or information (e.g., trade secrets, design and performance criteria), as well as calibration or test results, need to be held secure and how to do so. Details of these procedures may be incorporated in procedures for reviewing new work (clause 5.2 i)) and/or handling of calibration or test items (clause 5.2 k and section 11) and reporting under section 13.*

s) procedures for audit and review.

A2LA Explanatory Note: *Based on definitions provided in ISO 8402: a quality audit is an examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives; whereas a management review is a formal evaluation by top management of the status and adequacy of the quality system in relation to quality policy and objectives. These are separate functions and should be treated separately (i.e., document one set of procedures for internal audits and another for management reviews). Requirements for audits are defined in clause 5.3. Requirements for management reviews are defined in clause 5.4. Records requirements for both are defined in clause 5.5.*

5.3 The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibrations or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

A2LA Explanatory Note: *This clause requires that the laboratory have its own internal audit system. Internal audits are those of the laboratory itself which can be by an outside audit professional (see section 15). It is not sufficient to rely only on external (second- or third-party) audits. To be effective and complete, the audit program should include the full scope of Guide 25, the laboratory's own quality system requirements, and the full range of calibrations and tests performed. A2LA assessment may complement, but not substitute for, the laboratory's own audits. Internal audits should include audits of data quality. Audits should determine:*

- *whether procedures described in the quality system are being followed; and*
- *whether objectives (as defined by the quality system) are being achieved;*

- *whether designated duties are being carried out satisfactorily; and*

- *whether there are opportunities for improvements.*

The internal audit system should include not only technical activities but also the activities which support the technical operations (e.g., quality assurance functions, purchasing, document control, etc.). Internal audits should be scheduled on the basis of the status and importance of the activity to be audited and should be carried out by personnel independent of those having direct responsibility for the activity being audited. Each aspect of the quality system should be audited at least once per year. The results of the audits should be recorded (see clause 5.5) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area should take timely corrective action on deficiencies found during the audit. Follow-up audit activities should verify and record the implementation and effectiveness of the corrective action taken in response to previous audits. The results of internal audits form an integral part of the input to management-review activities. Since this clause requires the auditor to be "independent, wherever possible," of the activities to be audited, it is expected that any lack of independence and its basis be documented.

5.4 The quality system adopted to satisfy the requirements of this Guide shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

A2LA Explanatory Note: The laboratory's management with executive responsibility should review the quality system at defined intervals sufficient to ensure continuing suitability and effectiveness in satisfying these requirements and the laboratory's stated quality policy and objectives. The above is based upon text of clause 4.1.3 of ISO 9001. All of the elements of the laboratory's quality system should be reviewed in relation to:

- *matters arising from the previous review;*

- *reports from third-party (e.g., A2LA) assessments;*

- *reports from audits by clients;*

- *results of internal audits, including corrective actions implemented;*

- *results of participation in proficiency testing;*

- *results of in-house quality checks;*

- *details of any complaints from clients;*

- *staff training (for both new and existing staff members);*

- *adequacy of staff, equipment and facility resources; and*

- *future plans and projections for new work, new staff, new equipment, etc.*

5.5 All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.

A2LA Explanatory Note: *Records of (1) internal audits and (2) management reviews should include agendas, completed checklists, reports, proposed and completed corrective actions and follow up to ensure changes are implemented. Corrective action is required whenever objective evidence arises that the quality system is not functioning properly (see clause 5.2 o of Guide 25). Corrective action may be required at two levels;*

- *When there is a need to correct an immediate failure. This might involve retesting and withdrawing an invalid test report and issuing a new report.*
- *When there is a need to investigate the underlying cause of a failure. This might involve test personnel not being properly trained in the use of a new instrument.*

Changes identified by the review may be addressed through actions including revisions, additions, or deletions to the quality system documentation.

5.6 In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate, but not be limited to:

a) internal quality control schemes using whenever possible statistical techniques;

b) participation in proficiency testing or other interlaboratory comparisons;

c) regular use of certified reference materials and/or in-house quality control using secondary reference materials;

d) replicate testings using the same or different methods;

e) re-testing of retained items;

f) correlation of results for different characteristics of an item.

A2LA Explanatory Note: *The laboratory should have a systematic quality control program for checking or monitoring the reliability or accuracy of its results for all methods. The particular quality-control schemes and statistical techniques vary greatly with the nature and volume of calibration or testing. Statistical quality-control charts or equivalent tabulations for monitoring accuracy and precision performance should be maintained for quality-control test items such as reference test materials and replicate tests from the same material source as is practicable. The use of reference materials provide for the monitoring of accuracy performance. Replicate testing of duplicate test items provides for the monitoring of precision performance. The retention and re-test of test items may be specified in response to questionable results or complaints. Evaluation of interrelated characteristics of individual test items can aid in detecting errors. More detailed quality control requirements may be specified in program requirements documents (e.g., environmental field of testing). For additional requirements relating to proficiency testing, interlaboratory comparisons and use of reference materials, refer to clauses 4.2 (j) and 5.2 (n) of Guide 25.*

6. Personnel

6.1 The laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

A2LA Explanatory Note: *The appraisal of personnel is a major part of laboratory assessments. This "sufficient personnel" criterion is evaluated based on the range, complexity and frequency of performance of calibrations or tests for which accreditation is sought. For many tests, "sufficient personnel" may mean more than one staff person is involved to assure technical competency. For example, a supervisor exercising technical control may be relatively inexperienced with respect to one facet of the laboratory's work, but another person or persons working in close collaboration with the supervisor may compensate for this inexperience. The accreditation in such a case would be reviewed if there was a major change in either person's duties. The loss of key personnel may affect continuing accreditation. For example, A2LA assessors identify key (or indispensable) staff whose absence would reduce the laboratory's technical competence and may prompt a reassessment before it would be normally scheduled.*

Technical personnel should have demonstrable knowledge and skills to perform calibrations or tests and compute results. They may be asked to demonstrate tests or specific techniques during an assessment.

For each laboratory position, a job description identifying relevant qualifications should be prepared and should also include position title, minimum requirements for the position, responsibilities and reporting relationships, and any supervisory responsibilities (see clause 5.2 e). Any physical condition, such as color blindness, which would limit the capability of a person to perform the assigned task should be identified.

The qualifications and experience required for senior staff are reviewed during the assessment. Factors to be considered include:

- *the number of calibrations or tests for which accreditation is sought;*
- *the technical complexity of the calibrations or tests*
- *the frequency at which specific calibrations or tests are conducted, particularly those calibrations or tests that are judged to be highly experience dependent;*
- *the contact that the senior staff maintains with the development of methodology and adoption of new methodology within the laboratory.*

In all cases senior staff need to demonstrate appropriate understanding of the calibration or test areas in which they exercise supervision.

In assessing qualifications, the balance between relevant academic qualifications and practical calibration or test experience is considered in the light of the range, complexity and accuracy required.

For a laboratory seeking accreditation for a wide range of complex calibrations or tests, senior staff would be expected to have attained a high level of education in the relevant discipline together with sufficient experience in the relevant calibrations or tests.

The senior staff engaged in a limited range of relatively simple calibrations or tests, while holding lesser qualifications, may demonstrate appropriate competence by

having relevant calibration or test experience and demonstrable laboratory management expertise.

More detailed personnel requirements may be specified in program requirements documents (e.g., environmental field of testing).

6.2 The laboratory shall ensure that the training of its personnel is kept up-to-date.

A2LA Explanatory Note: ***Procedures for identifying training needs, for training new technical personnel and for developing and maintaining the expertise of existing technical personnel in new or rarely used techniques should be implemented. The criteria used to assess the competence of trainees should form an integral part of the procedures and be recorded. These procedures should also include the monitoring of the validity of results produced by technical personnel, particularly in the early stages after completion of training in new techniques. As per clause 6.3, records of training and assessments of competence need to be kept.***

6.3 Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.

A2LA Explanatory Note: ***The quality manual should indicate how records covering the education, skills and technical experience of the laboratory personnel are maintained. Personnel records should include, but are not limited to, details of academic and professional qualifications, experience and special abilities, training received, and performance appraisal reports. A list of all tests and calibrations that each staff member has been assessed and found competent to perform should be maintained.***

7. Accommodation and environment

7.1 Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

A2LA Explanatory Note: ***Environmental requirements should be appropriate for the type of work being performed. Calibration or test requirements should be evaluated to determine which environmental factors have an effect on the calibrations or tests being performed. Only the environmental factors which affect the accuracy, stability, or performance of the calibration or test or measurement of test parameters require control. Human factors related to lighting, ventilation and space should be considered with respect to performing the required tasks safely, effectively, and comfortably.***

7.2 The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

A2LA Explanatory Note: ***Environmental factors adversely affecting measurements should be understood, documented (acceptable limits specified) and controlled to the degree necessary so as not to invalidate the results or adversely affect the measurement uncertainty. These requirements also apply to off-site calibration or testing facilities in that care should be taken to monitor, record, and compensate for these***

environmental conditions. Correction factors may be applied to compensate for any out-of-tolerance conditions. Precautions may need to be taken to prevent contamination and degradation of test and measuring equipment. Areas of sample preparation, preconditioning, testing or calibration and storage should be of adequate size and free from degrading factors which might affect the integrity of the samples. Environmental monitoring equipment should be available, calibrated and operating when needed.

7.3 The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

***A2LA Explanatory Note**: Environmental monitoring equipment should be available, calibrated and operating when necessary. Special environmental precautions may be needed for laboratories performing special testing such as microbiological and pathogenic testing and electronic testing where clean rooms are often necessary.*

7.4 There shall be effective separation between neighboring areas when the activities therein are incompatible.

***A2LA Explanatory Note**: Incompatibility of test areas and potential adverse influence, and/or cross-contamination needs to be avoided for certain types of testing (e.g., trace analyses).*

7.5 Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

***A2LA Explanatory Note**: Access control should be compatible with test program requirements as set forth in accreditation and/or regulatory requirements. Uncontrolled access to environmentally controlled areas may have an adverse effect on the quality of measurements being performed. These areas should be identified and procedures established to define controls. Access to areas can be controlled by signs, physical locks, security guards or security access systems.*

7.6 Adequate measures shall be taken to ensure good housekeeping in the laboratory.

***A2LA Explanatory Note**: Poor housekeeping may have an adverse affect on the work being performed so factors such as cleanliness, storage and space should be adequately controlled.*

NOTE - It is the laboratory's responsibility to comply with the relevant health and safety requirements. This aspect, however, is outside the scope of this Guide.

***A2LA Explanatory Note**: The laboratory may need to have a chemical hygiene plan. CFR Part 40, Section 1910.1450 should be consulted. The assessment will determine if responsibilities in this area have been addressed, but will not judge the adequacy of the documentation, because that is a regulatory (e.g., OSHA) responsibility.*

8. Equipment and reference materials

8.1 The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of calibrations and tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this Guide are met.

A2LA Explanatory Note: ***All equipment needed to perform the calibrations or tests must be available during on-site assessment, whether owned, leased, rented, or borrowed. The laboratory should ensure that leased, rented or borrowed equipment meets the applicable requirements, including an assurance that the equipment is adequately calibrated by a calibration service identified and assessed as required by section 15. Each significant item of test equipment (including data processing) and reference materials required to perform the calibrations or tests should be permanently and uniquely identified.***

8.2 All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

A2LA Explanatory Note: ***Maintenance procedures (see clause 5.2 m)) should state in detail:***

- ***how historical maintenance information is kept;***
- ***how an instrument that has been subjected to any influences that might cause doubt as to its integrity is handled;***
- ***how out-of-service-equipment is identified;***
- ***how effects of previous calibrations or tests are determined;***
- ***how operational status is identified; and***
- ***where equipment is held while out of service.***

The treatment of defective equipment, the verification of effective calibration and performance after repair, and the effects of these activities on previously reported test results should be addressed in the quality manual or a standard operating procedure (see clauses 5.2 m) and o) and 13.6).

This requirement implies that an as-found calibration or verification needs to be performed prior to regularly-scheduled calibration or verification. That is, at the time of a regularly-scheduled calibration, a limited verification should be performed prior to any servicing of the equipment.

8.3 Each item of equipment including reference materials shall, when appropriate, be labelled, marked or otherwise identified to indicate its calibration status.

A2LA Explanatory Note: Any item used in the calibration or test process should have its calibration status displayed or be evident to the user. Typical identification status is through the use of calibration labels or "stickers," indicating the type of calibration (limited, special, see report, etc.) and calibration due date. However, other procedures, such as computer systems keyed on instrument serial numbers, may be acceptable as long as the system is well documented, understood by all potential users and effective in removing from service all test equipment in need of calibration. Reference materials should be treated similarly by having their current status (e.g., initials of recipient, dates received and/or prepared and opened and

date of expiration) identified in a manner that will allow a user to determine its validity. A policy or procedure should be available that clearly instructs all users that an instrument or reference material is only considered useable if a valid and current "sticker" is available.

8.4 Records shall be maintained of each major item of equipment and all reference materials significant to the calibrations or tests performed.

The records shall include:

a) the name of the item of equipment;

b) the manufacturer's name, type identification, and serial number or other unique identification;

c) date received and date placed in service;

d) current location, where appropriate;

e) condition when received (e.g. new, used, reconditioned);

f) copy of the manufacturer's instructions, where available;

g) dates and results of calibrations and/or verifications and date of the next calibration and/or verification;

h) details of maintenance carried out to date and planned for the future; and

i) history of any damage, malfunction, modification or repair.

***A2LA Explanatory Note**: Historical files of the calibrations of all equipment should be kept for the same period as the test data containing sufficient information to prove that the equipment was in calibration at the time of use. Other information that may be incorporated into these records includes:*

- *service agents and their contacts;*
- *checking requirements, including the frequencies and checking procedures;*
- *records of in-service checks;*
- *the performance capabilities of the equipment, such as detection limits, stability, repeatability, etc.*
- *traceability path(s);*
- *the identity of staff responsible for monitoring the calibration and maintenance of equipment; and*
- *authorized users.*

9. Measurement traceability and calibration

9.1 All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment.

***A2LA Explanatory Note**: The laboratory calibration system should:*

- *include all items of measuring and testing equipment used;*
- *allow identification of overdue items and removal of such items until corrected (sometimes referred to as a recall system); and*
- *ensure items known to be broken, out of tolerance, or have intermittent problems, etc., are taken out of service. Equipment found to be unstable so its parameters cannot be predicted or equipment otherwise judged to be unreliable should be discarded or rebuilt.*

All procedures for in-house calibration should be documented (including estimation of uncertainties where relevant). These should include acceptance criteria, and corrective action if equipment falls outside these criteria. The personnel responsible for monitoring and for calibration program implementation for each item of equipment should be identified.

9.2 The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available. Calibration certificates shall wherever applicable indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

***A2LA Explanatory Note**: Most items of equipment require the services of a "competent calibration body" to provide the required traceability to national or international standards of measurement. (See A2LA Explanatory Note under clause 15.) To confirm traceability, the calibration body should provide a certificate or report of calibration including all information identified in section 13.2. Certificates or reports should include stated measurement results and associated uncertainties, and the source of traceability (i.e., national or international laboratory or intrinsic standard). To ensure actual traceability, the trail of reference standard verification back to the primary standard at the source (e.g., NIST) should be clear. Actual data on the 'as found' condition of instruments to be calibrated should be recorded and reported to the user laboratory, where it is determined that the instrument is outside of the manufacturer's specifications.*

An intrinsic standard (e.g., Josephson Array Voltage Standard and the Iodine-Stabilized Helium-Neon Laser Length Standard) is based on well-characterized laws of physics, fundamental constants of nature, or invariant properties of materials and make ideal stable, precise, and accurate measurement standards if properly designed, characterized, operated, monitored and maintained. Where intrinsic standards are used, the laboratory should demonstrate by measurement-assurance techniques, interlaboratory comparisons, or other suitable means that its intrinsic-measurement results are correlated with those of national or international standards.

9.3 Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons or proficiency testing.

A2LA Explanatory Note: *Other satisfactory evidence may include:*

- *internationally accepted standard in the field concerned;*
- *suitable reference materials;*
- *ratio or reciprocity-type measurements; or*
- *mutual consent standards which are clearly specified and mutually agreed upon by all parties concerned.*

9.4 Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.

A2LA Explanatory Note: *Generally, a calibration laboratory uses reference standards and working standards with the former providing traceability to a particular source and the latter being used for calibration of equipment. Exceptions to this requirement are possible if it can be shown that the reference standards being used for the calibration of equipment are not degraded in the process. The word 'degraded' applies to loss of accuracy of, damage to, or erratic behavior of the reference standard.*

9.5 Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a program of calibration and verification for reference standards.

A2LA Explanatory Note: *Similar to the requirements for measuring and test equipment of clause 9.1, reference standards also require the services of a "competent calibration body" to provide the required traceability. If a reference standard is calibrated by a national or international standards laboratory, then it is assumed that traceability is fulfilled and that adequate uncertainty is provided. The user should maintain the integrity of these standards through adequate handling, trend and control charts, or other intermediate checks as necessary.*

If a reference standard is calibrated with an intrinsic standard (see A2LA Explanatory Note at clause 9.2.) by the same laboratory, then calibration has to be maintained using appropriate procedures, trend and control charts and uncertainty analysis.

If a reference standard is calibrated by a laboratory not identified as a national- or international-standard laboratory, then that laboratory should be prepared to show adequacy of the calibrations through accreditation by a recognized accrediting body (e.g., A2LA or its MRA partners) or through documentation of the procedures, trend and control charts, uncertainty analysis and proof of traceability.

9.6 Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

A2LA Explanatory Note: *In some cases, special standard and measuring and test equipment require additional checks and verifications in addition to the normal calibrations performed based on the calibration recall system. These checks help in providing trend and control charts to monitor for unacceptable drift. The checks should be scheduled with results recorded.*

9.7 Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

A2LA Explanatory Note: *Many items of equipment used for chemical or equivalent analysis are calibrated or 'standardized' by comparative techniques using reference materials. Where reference materials are used, the laboratory should be able to demonstrate:*

- *that sufficient reference materials are in the laboratory to calibrate the relevant items of equipment over their intended range of use;*
- *that records are kept of the identity and source of each reference material; and*
- *precautions are taken to match the matrices of the reference materials with those encountered in the test samples, or that the laboratory has determined and accounted for the effects of any nonmatching matrices.*

10. Calibration and test methods

10.1 The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

A2LA Explanatory Note: *The system for ensuring that instructions, standards, manuals and reference data are maintained up to date should be part of the document control system and could be an aspect of the management review procedures.*

10.2 The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

A2LA Explanatory Note for Clauses 10. 1 and 10.2: *The use of well-documented procedures is needed in order to maintain consistency of the measurement process when performed at different times and by different operators. For each method, there should be:*

- *clear, unambiguous instructions (the degree of detail may vary depending upon the experience and skill of the operators);*
- *a unique identification in the laboratory;*
- *a date of adoption and amendment;*
- *data on repeatability and reproducibility of the method, together with the number of significant figures to be reported for various measurement ranges; and*
- *the identification of any known limitations of the method, such as applicable concentration ranges, possible interferences, and environmental factors.*

These may be in the form of the published consensus standards or they may be compiled in a procedures manual. In all cases, the methods should be understandable to the operators and the current edition available at the bench level for their use.

Variations in technique may be a significant source of differences in results. When data are reported on a report carrying an A2LA logo, the method cited needs to have been used as written, although deviations for part of the reported data could be acceptable if noted on the report. If the deviations from the standard method relate to all the data reported, the data would be reported on a report which does not carry the logo.

The laboratory should maintain in its literature resources, copies of the applicable consensus standards, regulatory methods, manufacturer's operations manuals for the equipment used and related publications. The laboratory should review newly issued consensus standards and regulatory methods to determine the need to revise laboratory calibration or test procedures.

10.3 Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations or in relevant scientific texts or journals.

***A2LA Explanatory Note**: Where customers have not specified the method, the laboratory should first use methods selected from consensus national and international standards or regulatory methods. If no consensus standards are available, then methods might be found in textbooks, scientific papers, professional journals and research results.*

10.4 Where it is necessary to employ methods that have not been established as standard, these shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports.

***A2LA Explanatory Note**: A2LA considers accreditation of in-house methods where existing standard methods are not suitable. These methods need to be fully documented, should be made available to all interested parties with reasonable conditions, and should have undergone statistical method validation. The method validation is to be documented in the laboratory quality records. Documentation of the validity of the method as established by the laboratory is the primary basis for determining if the method can be included in the scope of accreditation.*

10.5 Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples.

***A2LA Explanatory Note**: The laboratory should use consensus standards for statistical techniques for sampling and reference these techniques in its documented procedures for sampling.*

10.6 Calculations and data transfers shall be subject to appropriate checks.

***A2LA Explanatory Note**: A review of all manual calculations and handwritten data transfers should be done by someone other than the person performing the original work prior to the data being reported to the client. The identity of the person performing these checks should be documented by initials or other suitable means.*

10.7 Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall ensure that:

a) all requirements of this Guide are complied with;

b) computer software is documented and adequate for use;

c) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

d) computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data;

e) it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

A2LA Explanatory Note: *Computers are used in many different aspects of a modern laboratory's business. Section 10.7 is meant to deal with those highly computerized facilities which take a sample or samples and produce data with no manual interaction once the process has started. Some test equipment has as an integral part of its operation a significant computer function. The laboratory buys the computer as an integral part of the test equipment. In this case, the laboratory should have supporting evidence that the capability of the equipment to perform the specific test is within the precision and bias specifications of the test method.*

The laboratory needs to be able to demonstrate that the data generated by the software are equivalent to manually generated data across the full range of the equipment including input and as applicable display and print out. Procedures should address the use of the software, operation of the computerized system, including authorized access to and authorized amendment of computer records. The system should be capable of storing and retrieving all entries of and amendments to the data.

Some laboratories create their own management information systems which integrate data from different instruments, collate it, check it against reference standards, and print it out. In this case, the laboratory should have a system in place to handle computer operations including appropriate organization and management functions, knowledgeable personnel, an appropriate environment, the necessary equipment, the needed software, and procedures for operating the equipment (including data entry and data interpretation), and reporting results coming from the computer equipment. These computerized procedures should be adequate to meet revisions of this standard whenever they apply. Regular back-ups of programs and data should be performed.

Section 10.7 is not meant to address business computer operations such as are used for word processing or for financial reporting.

10.8 Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.

A2LA Explanatory Note: See related sections 14 and 15. These procedures should address:

- *type and extent of control exercised;*
- *specifications for the materials;*
- *verification practices for acceptance of materials;*
- *handling of materials with defined shelf life; and*
- *disposal of unused or out-dated materials.*

The above is similar to the text of clause 4.6 of ISO 9001-1994.

11. Handling of calibration and test items

11.1 The laboratory shall have a documented system for uniquely identifying the items to be calibrated or tested, to ensure that there can be no confusion regarding the identity of such items at any time.

11.2 Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration or test method, shall be recorded. Where there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

11.3 The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item, during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration or test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

11.4 The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

A2LA Explanatory Note for Section 11: When the laboratory has partial or total responsibility for sampling the calibration or test items (referred to simply as the sample), sampling activities should be fully documented as described in section 10 and have the procedures included in the scope of accreditation.

When the laboratory is not responsible for the sampling, the test document should include the identity of the supplier of the sample and other details available, such as source, condition, date, etc. The customer should be consulted for further

instructions if the as-received condition does not meet specifications. Documentation should be maintained in the laboratory quality records. If the method of sampling is not known, the report would simply state, "sample tested as received".

The laboratory should have guidance available for describing the sampling requirements for all test methods where appropriate. These would be available to customers and others who perform the sampling.

Sample retention and storage policies vary individually in light of the types of samples tested, the useful life of the samples, and the likely periods within which a recipient of the results may request a retest. Nonetheless, there should be explicit guidance for each type of sample so that the sample is handled in accordance with test method requirements. These may include chain-of-custody requirements, safeguards against sample tampering and the possible use of the sample as physical evidence for litigation purposes.

12. Records

12.1 The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the calibration certificate, test certificate, or test report for an appropriate period. The records for each calibration and test shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration or testing.

12.2 All records (including those pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client.

A2LA Explanatory Note for Section 12: The laboratory should maintain a record system that will provide a traceable link between the sample as received and the report which is eventually issued on that sample, including all raw test data. This is necessary for both manual and computerized systems. The record system, whether manual or computerized, should include the following information:

- *description of each sample, including its condition;*
- *individual sample identification;*
- *identification of the test method and any deviations and associated quality-control records;*
- *identification of the specific equipment used in the test and associated calibration records;*
- *original test observations (on bench sheets, bound notebooks, etc.);*
- *identification of the person(s) performing the test; and*
- *copy of the test report as issued.*

Original observations should be recorded at the time of the test into bound notebooks, or onto properly designed work sheets. Unbound sheets of paper should be used only if they include information that provides traceability and continuity of the laboratory's activities. Mistakes should never be erased or deleted; they should be noted by drawing a single line through the error and entering the correct value alongside. The work sheets and notebooks should have a place for the initials of the checking officer.

Records retention periods as required by all customers and regulatory agencies should be documented. The security measures taken by the laboratory for the safe archiving of records should also be documented. Records should be retained throughout the time period between assessments as a minimum.

13. Certificates and reports

13.1 The results of each calibration, test, or series of calibrations or tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the calibration or test methods. The results should normally be reported in a calibration certificate, test report or test certificate and should include all the information necessary for the interpretation of the calibration or test results and all information required by the method used.

A2LA Explanatory Note: This is the first clause in which the word "should" instead of "shall" is used. This suggests that there are some circumstances in which calibration or test data do not always result in a report being generated. For example, many captive laboratories provide process-control test data that is continuously recorded and stored as part of process capability records, but the data does not result in the issuance of a separate report. Likewise, measuring and test equipment which is compared and adjusted to a reference material such as a pH meter to a buffer solution may not require a complete report (see also clause 9.2). When a different department outside the control of the laboratory prepares a formal report from laboratory data, the laboratory should provide evidence that these requirements have been communicated to the person in charge of that department.

13.2 Each certificate or report shall include at least the following information:

a) a title, e.g. "Calibration Certificate", "Test Report", or "Test Certificate";

b) name and address of laboratory, and location where the calibration or test was carried out if different from the address of the laboratory;

c) unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;

A2LA Explanatory Note: Each page of the report should carry the identification of the report; pages should be numbered consecutively; and the number of pages should be stated on every page. A unique identification may also be by date, product identification number and lot number, etc. This may not be as effective as a serial number, but it can suffice.

d) name and address of client, where appropriate;

e) description and unambiguous identification of the item calibrated or tested;

f) characterization and condition of the calibration or test item;

g) date of receipt of calibration or test item and date(s) of performance of calibration or test, where appropriate;

h) identification of the calibration or test method used, or unambiguous description of any non-standard method used;

A2LA Explanatory Note: The issue date of the test method should be included in the report.

i) reference to sampling procedure, where relevant;

j) any deviations from, additions to or exclusions from the calibration or test method, and any other information relevant to a specific calibration or test, such as environmental conditions;

k) measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;

l) a statement of the estimated uncertainty of the calibration or test result (where relevant);

> ***A2LA Explanatory Note**: A statement of the estimated uncertainty is relevant for calibration of all reference standards and for most other types of calibrations. It is also relevant when required by clients or regulatory agencies. Laboratories involved in trace analysis have an uncertainty associated with detection limits.*

m) a signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;

> ***A2LA Explanatory Note**: The use of photographic, electronic and mechanical means of reproduction of signatures or names of signers may be acceptable, as long as the user can identify the person taking responsibility for the report and that automated signatures are safeguarded.*

n) where relevant, a statement to the effect that the results relate only to the items calibrated or tested;

o) a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory.

> ***A2LA Explanatory Note**: A2LA accreditation entitles an accredited laboratory to endorse test reports and calibration certificates using the A2LA logo. A2LA strongly encourages the application of the endorsement by a laboratory when its accredited status contributed to its contract for the work. The calibrations or tests reported in this manner need to be performed under the terms of its accreditation and be included in the laboratory's scope of accreditation. In addition, the report or certificate needs to conform to clause 13.2. The A2LA endorsed reports should include the laboratory's accreditation certificate number and a statement similar to the following:*
>
> > ***This laboratory is accredited by the American Association for Laboratory Accreditation (A2LA) and the results shown in this test report [or calibration certificate] have been determined in accordance with the laboratory's terms of accreditation unless stated otherwise in the report.***
>
> ***Endorsed reports containing data from calibrations or tests for which a laboratory is not accredited or which have been undertaken by a subcontractor laboratory that is not accredited need to state that these data are not covered by the laboratory's A2LA accreditation.***
>
> ***Accredited laboratories have the responsibility to ensure that their clients receiving A2LA endorsed reports are aware that products, materials or other items of calibration or test are in no way approved or endorsed by A2LA unless A2LA explicitly permits such endorsement or approval. The A2LA endorsement may be used on reports***

which extend the results on a sample or samples to the properties or qualities of a lot or batch from which the sample was drawn provided that the accredited laboratory's scope of accreditation covers the sampling involved and samples concerned were taken by the staff of the accredited laboratory using an approved sampling procedure (unless provisions of a special program permit otherwise).

A report should not be endorsed if, in addition to the results, it includes any expression of expert opinion as to the serviceability of the sample or batch, or its suitability for a specific purpose or any other statements in amplification of the results other than those referenced above. If a laboratory wishes to issue an endorsed report in these circumstances, any expression of opinion or statements in amplification of the results may be provided in a separate unendorsed document.

Refer to the sections X and XI on laboratory referencing its A2LA-accredited status and misuse of the A2LA logo in Part C of this document for related guidance on advertising accredited status.

13.3 Where the certificate or report contains results of calibrations or tests performed by sub-contractors, these results shall be clearly identified.

A2LA Explanatory Note: Test results provided by subcontracting laboratories are to be clearly indicated as such on the report transmitted to the client. Endorsed reports containing data from calibrations or tests which have been undertaken by a subcontractor laboratory that is not accredited must state that these data are not endorsed by A2LA or covered by the laboratory's A2LA accreditation. See section 14 for the requirements related to subcontracting.

13.4 Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to presentation of the calibration or test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration or test carried out, but the headings shall be standardized as far as possible.

13.5 Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Calibration Certificate [or Test Report or Test Certificate], serial number . . . [or as otherwise identified]", or equivalent form of wording. Such amendments shall meet all the relevant requirements of clause 13.2 of this Guide.

13.6 The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate or amendment to a report or certificate.

A2LA Explanatory Note: The discovery of the reporting of erroneous results to the client is to be followed by a corrected or amended report as expeditiously as possible (see clause 13.5). Clear differentiation between the two reports is to be made so that there will be no mistake as to which report contains the correct results.

The client may be informed of the cause(s) of defective measurement when test report results are adversely affected. This notification can be incorporated in the case narrative portion of the report itself (see clause 5.2 (o)).

13.7 The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of this Guide are met and that confidentiality is preserved.

A2LA Explanatory Note: *The laboratory should have a documented procedure which addresses the reporting of test results by any means including the safeguards used when reporting results to the customer by means other than a paper hard copy.*

Oral transmittal of data is discouraged. Reports by captive laboratories for internal use of a lesser content than is required by clause 13.2 is also discouraged. The development of a complete report format for consistent use in the laboratory is not a difficult exercise. The systematic recording of the data in an orderly fashion may, in the long run, save many an internal project. The above is not intended to suggest that process-control test data recorded as part of the records be put into a report format as well.

14. Sub-contracting of calibration or testing

14.1 Where a laboratory sub-contracts any part of the calibration or testing, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its sub-contractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect to the work being sub-contracted. The laboratory shall advise the client in writing of its intention to sub-contract any portion of the testing to another party.

14.2 The laboratory shall record and retain details of its investigation of the competence and compliance of its sub-contractors and maintain a register of all sub-contracting.

A2LA Explanatory Note for Section 14: *Section 4.1.5 of ISO/IEC Guide 58, "Calibration and testing laboratory accreditation systems -- General requirements for operation and recognition," states:*

> *"4.1.5 The accreditation body shall confine its requirements, assessment and decision on accreditation to those matters specifically related to the scope of the accreditation being considered."*

Therefore, this subcontracting requirement applies only for subcontracting of any part of the tests or calibrations included in a laboratory's Scope of Accreditation.

Laboratories should document their policies and procedures for hiring subcontractors. Accredited laboratories using the services of a subcontracting laboratory are responsible for ensuring to their clients that the subcontracting laboratory has a satisfactory quality system and is competent to perform the required calibrations or tests. Reliance on A2LA-accredited status for the pertinent calibrations or tests is sufficient. When a subcontractor is not accredited by A2LA or other organization using Guide 25, the laboratory should record its assessment of that laboratory's capability to meet Guide 25 requirements on a requirement by requirement basis. Investigations of non-accredited subcontracting laboratories should be done using an audit process similar to its own internal audit system as required by clause 5.3. Even if a laboratory does not plan to subcontract, a policy to that effect should be

documented. It is helpful, however, to have documented procedures for subcontracting in case they are ever needed.

15. Outside support and supplies

15.1 Where the laboratory procures outside services and supplies, other than those referred to in this Guide, in support of calibrations or tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests.

***A2LA Explanatory Note**: The laboratory should identify the inputs to its processes in terms of equipment, materials and services which affect the integrity of its calibrations and tests and develop appropriate specifications and quality control measures.*

Calibration services should be obtained from laboratories accredited to the ISO Guide 25 requirements by A2LA or other accrediting body recognized by A2LA through its mutual recognition agreements. This ensures that traceability to the relevant national or international metrology standards as required by clause 9.2 is authenticated.

Reference material suppliers and all suppliers of outside support services and products should have a registered quality system to one of the ISO 9000 standards.

15.2 Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

***A2LA Explanatory Note**: See related clause 10.8. The procedures for purchasing outside support services or supplies should address:*

- *evaluation and selection of suppliers (i.e., vendors);*
- *type and extent of control exercised;*
- *specifications; and*
- *verification practices for acceptance.*

The above is based upon text of clause 4.6 of ISO 9001-1994.

15.3 The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations or tests.

***A2LA Explanatory Note**: Records should be kept of the different brands and batches of consumables used by the laboratory which might critically affect the test results. The record would show the results of acceptance tests on each new batch of material prior to use.*

Separate records should be kept for each manufacturer supplying major test equipment. These records would include acceptance tests and maintenance history on the equipment.

16. Complaints

16.1 The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

A2LA Explanatory Note: ***Complaints received need not be in writing. Many complaints arrive via telephone or other oral means. A record should be made of the complaint at the time received. They should be assigned immediately to someone for resolution. Guidance should be supplied in the quality manual as to when a conversation becomes recorded as a complaint. All complaints should be concluded and a file should include the substance of the complaint and its resolution. Complaints may be generated by external customers or from within the laboratory's organization. Complaints referred to in this section should not be confused with complaints against quality characteristics of the product or item being tested. These refer to complaints about the laboratory's activities.***

16.2 Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this Guide or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with 5.3 of this Guide.

A2LA Explanatory Note: ***A prompt audit of the quality system should occur when a complaint or any other event suggests a non-compliance with the quality system. The complaints should also be assessed as a group during management reviews of the quality system to see if there are patterns which would indicate a need for improvement in the quality system. Consideration of suitable preventive action should be an integral part of this process.***

PART B

CONDITIONS FOR ACCREDITATION
(based on ISO/IEC Guide 58)

To attain and maintain accreditation, an applicant must agree to:

1) **Afford accommodation and cooperation as is necessary to enable A2LA to verify compliance with the requirements for accreditation including provision for examination of documentation and access to all calibration and testing areas, records and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints;**

2) **Comply at all times with the criteria, requirements (including participation in proficiency testing as required), and conditions for accreditation;**

3) **Claim that it is accredited only in respect of services for which it has been granted accreditation and which are carried out in accordance with these conditions;**

4) **Pay such fees as shall be determined by A2LA;**

5) **Not use its accreditation in such a manner as to bring A2LA into disrepute and not make any statement relevant to its accreditation which A2LA may consider misleading or unauthorized;**

6) **Upon suspension, withdrawal or expiration of its accreditation (however determined) discontinue its use of all advertising matter that contains reference thereto and return any certificates of accreditation to A2LA;**

7) **Not use its accreditation to imply product approval by A2LA unless permitted by a specific program;**

8) **Endeavor to ensure that no certificate or report, nor any part thereof, is used in a misleading manner;**

9) **In making reference to its accreditation status in communication media such as advertising, brochures or other documents, comply with the requirements of A2LA;**

10) **Inform A2LA headquarters without delay and in writing of changes in any aspect of the laboratory's status or operation that affects the laboratory's legal, commercial or organizational status; organization or management (e.g., managerial staff); policies or procedures, where appropriate; premises; personnel, equipment, facilities, working environment or other resources, where significant; authorized signatories; or such other matters that may affect the laboratory's capability, or scope of accredited activities, or compliance with the criteria, requirements and conditions for accreditation;**

11) **Inform A2LA headquarters if the laboratory is denied, has suspended, or loses its accreditation for calibration or testing with any other recognized private or governmental accrediting body and provide an explanation for the reason the accreditation was denied, suspended or lost. Failure to inform A2LA within thirty**

(30) days of the denial, suspension or loss of an accreditation will be grounds for immediate suspension of the laboratory's accreditation; and

12) Carry out any adjustments to its procedures in response to due notice of any intended changes by A2LA to the criteria, requirements, or conditions for accreditation, in such time as in the opinion of A2LA is reasonable.

In order to apply, the applicant laboratory's AUTHORIZED REPRESENTATIVE, must agree to the above conditions for accreditation and must attest that all statements made on their application are correct to the best of their knowledge and belief. An accredited laboratory's AUTHORIZED REPRESENTATIVE is responsible for ensuring that all of the relevant conditions for accreditation are met.

PART C

A2LA ACCREDITATION PROCESS

I. Application

A laboratory applies for accreditation by obtaining the application package from A2LA headquarters and completing appropriate application sheets. All applicants must agree to a set of conditions for accreditation (see Part B of this booklet), pay the appropriate fees set by the A2LA Board of Directors, and provide detailed supporting information on:

- Scope of testing in terms of field(s) of testing, testing technologies, test methods, and relevant standards;
- Organization structure; and
- Proficiency testing.

Accreditation is available for testing laboratories (tests) and calibration laboratories (calibrations). For tests, the scope of accreditation is normally identified in terms of standard test methods prepared by national, international, and professional standards writing bodies. If a laboratory desires accreditation only for a superseded version of a standard test method, the date of the version used is identified in its scope of accreditation. When the date is not identified in their scope of accreditation, laboratories are expected to be competent in the use of the current version within one year of the date of publication of the standard test method. For calibrations, the scope of accreditation is described typically in terms of the measurement parameter, range of measurement and best attainable uncertainties. In some cases, a laboratory's capability will be described in terms of types of tests, testing technologies, or other descriptive text when it is not appropriate or practical to identify specific tests or calibrations.

If a laboratory wishes accreditation for the use of its own methods, then it must provide the following information to the assessor(s) before assessment:

- Origin of method;
- Departures from standard;
- Reasons for and effects of departures; and
- Comparison with the standard methods they replace.

Accreditation will only be granted for tests or types of tests publicly available to all interested laboratories.

II. On-site Assessment

Once the application information is completed and the appropriate fees are paid, A2LA headquarters staff identifies and tentatively assigns one or more assessors to conduct an on-site assessment. Assessors are selected on the basis of their testing or calibration expertise so as to be better able to provide guidance to the laboratories. They do not represent their employers (if so affiliated) while conducting assessments for A2LA. The laboratory has the right to ask for another assessor if it objects to the original assignment. A2LA assessors are drawn from the ranks of the recently retired, consultants, industry, academia, government agencies, and from the laboratory community. Assessors

work under contract to A2LA. Assessments may last from one to several days. More than one assessor may be required.

Assessors are given an assessor guide and checklists to follow in performing an assessment. These documents are intended to ensure that assessments are conducted as uniformly and completely as possible among the assessors and from laboratory to laboratory.

Before the assessment is conducted, the assessor team requests copies of the quality manual and related documentation (i.e., SOPs related to Guide 25 requirements) in order to prepare for the assessment. The quality manual and related documentation must be reviewed by the assessor team before the on-site assessment can begin. This review is done ideally before the assessment is scheduled. Upon review of submitted documentation, the assessor(s) may ask the laboratory to implement corrective action to fill any documentation gaps required by Guide 25 before scheduling the assessment. A pre-assessment visit may be requested by the laboratory as an option at this point to enhance the success of the full assessment.

Prior to scheduling the full assessment, the assessor reviews the draft scope(s) to determine the tests to possibly witness, and checks on the availability of the technical personnel who perform the tests. An assessment agenda is provided by the assessor. The full assessment generally involves:

- An entry briefing with laboratory management;
- Audit of the quality system to verify that it is fully operational and that it conforms to all sections of ISO/IEC Guide 25, including documentation;
- Interviews with technical staff;
- Demonstration of selected tests or calibrations including, as applicable, tests or calibrations at representative field locations;
- Examination of equipment and calibration records;
- A written report of assessor findings; and
- An exit briefing including the specific written identification of any deficiencies.

The objective of an assessment is to establish whether or not a laboratory complies with the A2LA requirements for accreditation and can competently perform the types of tests or calibrations for which accreditation is sought. However, when accreditation is required to demonstrate compliance with additional criteria which may be imposed by other authorities, such as in the case of U.S. EPA, the A2LA assessment will include such additional criteria. Assessors may also provide advice, based on observations or in response to questions, in order to help the laboratory improve its performance.

III. Deficiencies

During the assessment, assessors may observe deficiencies. A deficiency is any nonconformity to accreditation requirements including:

- a laboratory's inability to perform a test or type of test for which it seeks accreditation;

- a laboratory's quality system does not conform to a clause or section of ISO/IEC Guide 25, is not adequately documented, or is not completely operational; or

- laboratory does not conform to any additional requirements of A2LA or specific fields of testing or programs necessary to meet particular needs.

At the conclusion of an assessment, the assessor prepares a report of findings, identifying deficiencies which, in the assessor's judgment, the laboratory must resolve in order to be accredited. The assessor holds an exit briefing with top management of the laboratory, going over the findings and presenting the list of deficiencies (deficiency report). The authorized representative of the laboratory (or designee) is asked to sign the deficiency report to attest that the deficiency report has been reviewed with the assessor. The signature does not imply that the laboratory representative concurs that the individual item(s) constitute a deficiency. The laboratory is requested to respond within one month after the date of the exit briefing detailing either its corrective action or why it does not believe that a deficiency exists. The corrective action response must include a copy of any objective evidence (e.g., calibration certificates, lab procedures, paid invoices, packaging slips and training records) to indicate that the corrective actions have been implemented/completed.

If the laboratory fails to respond in writing within four months after the date of the exit briefing, it may be treated as a new applicant subject to new fees and reassessment should it wish to pursue accreditation after that time.

It is entirely possible that the laboratory will disagree with the findings that one or more items are deficiencies. In that case, the laboratory is requested to explain in its response why it disagrees with the assessor.

A laboratory that fails to respond to all its deficiencies within six months of being assessed shall be subject to being reassessed at its expense. Even if the laboratory responds within six months, A2LA staff has the option to ask for reassessment of a laboratory before an initial accreditation vote is taken based on the amount, extent and nature of the deficiencies. The Accreditation Council panel also has the option to require reassessment of a laboratory before an affirmative accreditation decision can be rendered.

IV. Accreditation Anniversary Date

The anniversary date of a laboratory's accreditation is established 105 to 135 days after the last day of the final on-site assessment before an initial accreditation decision, regardless of the length of time required to correct deficiencies. This date normally remains the same throughout the laboratory's enrollment.

Any extensions to an accreditation beyond the anniversary date must be requested and justified in writing by the laboratory. A2LA does not automatically grant extensions of accreditation. Extensions beyond 90 days are not normally granted.

V. Proficiency Testing

Compliance with the criteria is essential, but may not be sufficient for effectively evaluating laboratory competence. Applicants may be required to participate in relevant and available proficiency testing programs sponsored by A2LA or other organizations administering acceptable proficiency testing programs. Such proficiency testing programs should follow ASTM E1301, a guide for proficiency testing programs.

Proficiency testing is a process for checking actual laboratory testing performance, usually by means of interlaboratory test data comparisons. For many test methods, results from proficiency testing are very good indicators of testing competence. Proficiency testing programs may take many forms and standards for satisfactory performance can vary depending on the field.

An accredited laboratory must participate in method-specific proficiency testing related to its field(s) of accreditation if such programs are available. Requirements for proficiency testing are prescribed by A2LA depending on the applicant laboratory's requested scope of accreditation. Unless otherwise specified in program requirements documents, a laboratory must participate in proficiency testing for one test method on each of their Scopes of Accreditation. Greater participation is encouraged, however. When proficiency testing programs are not available for a specific method, the laboratory should demonstrate proficiency with internal performance-based data.

VI. Accreditation Decisions

Before an accreditation decision ballot is sent to Accreditation Council members, staff shall review the deficiency response, including objective evidence of completed corrective action, for adequacy and completeness. If staff has any doubt about the adequacy or completeness of any part of the deficiency response, the response is submitted to the assessor(s). Since all deficiencies must be resolved before accreditation can be granted, staff shall ask the laboratory for further written response in those cases where staff recognizes that an affirmative vote is not likely because of incomplete corrective action in response to deficiencies or obvious lack of supporting evidence that corrective action has been completely implemented.

Staff selects a "Panel of Three" from the Accreditation Council members for voting. The "Panel of Three" selection takes into account as much as possible each member's technical expertise with the laboratory testing or calibration to be evaluated. The laboratory is consulted about any potential conflicts of interest with the Accreditation Council membership prior to sending their package to the Accreditation Council. At least two affirmative ballots (with no unresolved negative ballots) of the three ballots distributed must be received before accreditation can be granted.

It is the primary responsibility of assessors to judge whether the observed evidence is serious enough to warrant a deficiency. However, the panel members that are asked to vote on an accreditation decision are required to make a judgment whether or not deficiencies still exist based on information contained in the ballot package. Accordingly, panel members can differ with assessor judgments, based upon their interpretation of the criteria for the specific case under question and the supporting evidence available whether a deficiency does or does not exist. Staff attempts to resolve these difference as they arise, but it remains for the panel to make the initial decision.

Staff shall notify the laboratory asking for further written response based on the specific justification for one or more negative votes received from the panel. If further written response still does not satisfy the negative voter(s), a reassessment may be proposed or required. If a reassessment is requested by more than one voter, the laboratory is asked to accept a reassessment. If the laboratory refuses the proposed reassessment, an Accreditation Council appeals panel is balloted (see sections on XII. Adverse Accreditation Decisions and XV. Appeals Procedures below). If two-thirds of those voting (the votes of the initial panel and appeals panel both are included in the

count) agree to a reassessment, accreditation is denied until a reassessment and satisfactory laboratory response(s) to all deficiencies are completed.

If accreditation is granted, the A2LA staff prepares and forwards a certificate and scope of accreditation to the laboratory for each enrolled field of testing and special program. The laboratory should keep its scope of accreditation available to show clients or potential clients the testing technologies and test methods for which it is accredited. A2LA staff also uses the scopes of accreditation to respond to inquiries and to prepare the A2LA Directory. In some cases, such as environmental testing, where a large number of tests need to be identified, a supplemental scope is prepared by staff in cooperation with the laboratory.

VII. Annual Review

Accreditation is for two years. However, after the first year of accreditation, each laboratory must pay annual fees and assessor fees and undergo a one-day surveillance visit by an assessor. This surveillance visit is performed to confirm that the laboratory's quality system and technical capabilities remain in compliance with the accreditation requirements. For subsequent annual reviews occurring after the renewal of accreditation (see Section VIII) each laboratory must pay annual fees and submit updating information on its organization, facilities, key personnel and results of any proficiency testing. Objective evidence of completion of the internal audit and management review is also required. If the renewal laboratory does not promptly provide complete annual review documentation, or significant changes to the facility or organization have occurred, a one-day surveillance visit and payment of the associated assessor fees is required.

VIII. Reassessment and Renewal of Accreditation

A2LA conducts a full on-site reassessment of all accredited laboratories at least every two years. Reassessments are also conducted when evaluations and submissions from the laboratory or its clients indicate significant technical changes in the capability of the laboratory have occurred.

Each accredited laboratory is sent a renewal questionnaire, well in advance of the expiration date of its accreditation, to allow sufficient time to complete the renewal process. A successful on-site reassessment must be completed before accreditation is extended for another two years.

If deficiencies are noted during the renewal assessment, the laboratory is asked to write to A2LA within 30 days after the assessment stating the corrective action taken. All deficiencies must be resolved before accreditation is renewed for another two years.

The renewal decision process is similar to the initial decision process (see section VI. Accreditation Decisions), except as follows:

1) If there are no deficiencies, renewal is automatically processed without an Accreditation Council panel vote.

2) If there are only a few deficiencies of a minor nature (i.e., the non-compliances do not directly affect the integrity of calibration or test results) and there is sufficient objective evidence that the deficiencies have been resolved, the

President may elect to renew accreditation without an Accreditation Council panel vote.

3) If there are major deficiencies (i.e., the non-compliances directly affect the integrity of calibration or test results), the staff advises the laboratory of the required time-frame (normally 30 days) in which to resolve all deficiencies or be subject to further actions leading to suspension or withdrawal of accreditation (see sections XII. Adverse Accreditation Decisions, XIII. Suspension of Accreditation, and XIV. Withdrawal of Accreditation). Several related minor deficiencies or repeat deficiencies from previous assessments may also be considered a major deficiency. In these cases, a ballot of the Accreditation Council panel is conducted using the same voting procedure as for initial accreditation decisions.

IX. Adding to the Scope of Accreditation

A laboratory may request an expansion to its scope of accreditation at any time. Such a request must be submitted in writing to A2LA headquarters. Each request is handled on a case-by-case basis. Unless the previous assessor can verify the competence of the laboratory to perform the additional tests or calibrations, another on-site assessment is normally required. If the additional tests or calibrations require a new technology, another assessment is definitely required.

X. Laboratory Reference to A2LA Accredited Status

Since A2LA laboratory accreditations are issued in a number of fields of testing and testing technologies, it is the ethical responsibility of accredited laboratories to describe their accredited status in a manner that does not imply accreditation in areas that are outside their actual scope of accreditation. This may be accomplished through adherence to the following guidelines:

- Use of the A2LA name and/or logo on general literature such as letterheads and business cards is encouraged; when used in this way, the name or logo shall always be accompanied by at least the word "accredited".

- When the A2LA name and/or logo is used on a business solicitation document such as a proposal or quotation form, the laboratory has the responsibility to distinguish between those proposed tests that fall within the laboratory's scope of accreditation and those that do not. This is done by attaching a copy of its current A2LA Scope of Accreditation sheet and Supplement to the Scope, if appropriate.

- Where test reports are endorsed by a display of the A2LA logo, the field of testing must be stated. On reports where test results are reported that are within the field of testing where accreditation exists but make use of a testing technology that is not included in the scope, this must be so indicated. For example, if a laboratory is accredited in the Environmental Field for only wet chemistry and metals, any gas chromatographic data reported would need to be identified as not covered by the A2LA accreditation. This may be done by placing an asterisk after each such test result with a footnote stating, "This is not covered by our current A2LA accreditation."

- **An accredited laboratory owns the right to release A2LA assessor reports and deficiency reports as long as the reports are reproduced in whole and not in part. A2LA holds this assessment information in confidence unless specifically requested in writing by the accredited laboratory to release this information to another party. Assessment information may be reviewed (but not copied) by external bodies as needed for recognition of the program.**

- **When promoting or providing proof of your accreditation, use the scope(s) of accreditation, as this document details the specific tests and types of tests which are accredited. The certificate is used for display purposes and may also accompany the scope.**

Every circumstance where the principle of accurate representation applies cannot be anticipated and dealt with in this document. Therefore, it is the responsibility of the accredited laboratory not to misrepresent its accredited status under any circumstances. If there are questions, the laboratory should submit intended uses of the logo and/or any other accreditation claims to A2LA Headquarters for advance approval.

XI. Misuse of the A2LA Accreditation Logo

A2LA provides guidance to laboratories attaining accreditation for proper control on the use of its accreditation logo.

Incorrect references to A2LA or misleading use of the accreditation logo found in advertisement, catalogs, etc. shall be dealt with by suitable actions which could include legal or corrective action or publication of the transgression.

In cases of misuse of the accreditation logo by laboratories, A2LA shall take appropriate corrective action, which may include suspension of accreditation.

XII. Adverse Accreditation Decisions

Any decision from an appeals vote which would deny or withdraw a laboratory's complete accreditation, must be agreed upon by a two-thirds vote of those voting from both the initial and appeals panels of the Accreditation Council.

Suspension of all or part of a laboratory's accreditation may be a decision made by either the President or Accreditation Council panel. Suspension actions by the President are generally taken based on failure to comply with the conditions for accreditation (e.g., failure to pay required fees, failure to participate in required proficiency testing, etc.).

In some fields of testing or special programs, failure to meet with the criteria for acceptable proficiency test results can result in automatic enforced withdrawal of accreditation for the test(s) under question. These are identified in the specific requirements for those fields.

See the following sections on XIII. Suspension of Accreditation, XIV. Withdrawal of Accreditation and XV. Appeals Procedures for further details.

XIII. Suspension of Accreditation

The accreditation applicable to a specific laboratory may be suspended upon adequate evidence of:

- non-compliance with the requirements of a nature not requiring immediate withdrawal;
- improper use of the accreditation logo (e.g., misleading prints or advertisements are not solved by suitable retractions and appropriate remedial measures by the laboratory); and
- other deviations from the requirements of the A2LA accreditation program (e.g., failure to pay the required fee or to submit annual review information within 60 calendar days after it is due).

When an accredited laboratory is suspended, A2LA shall confirm an official suspension in a certified letter, return receipt requested, (or equivalent means) to the laboratory's authorized representative, stating:

- the cause;
- the conditions under which the suspension will be lifted;
- that the suspension will be publicized in the A2LA Newsletter and on the Worldwide Web;
- that the suspension is for a temporary period to be determined by the time needed to take corrective action;

- **that, within thirty (30) days of receipt of the notice, the laboratory may submit in person, or in writing, information in opposition to the suspension, including any additional information that raises a genuine dispute over material facts;**

- **that a further review will be conducted to consider such information and a further written notification will be sent to the laboratory by certified mail, return receipt requested, indicating whether the suspension has been terminated, modified, left in force or converted to a withdrawal of accreditation.**

XIV. Withdrawal of Accreditation

A2LA shall withdraw accreditation for any of the following causes:

- **under the relevant provisions for suspension of accreditation;**

- **if surveillance indicates that deficiencies are of a serious nature as judged by the Accreditation Council panel;**

- **when complaints are received relating to one or more of the laboratory's test reports and investigation reveals serious deficiencies in the quality system and/or competence in conducting the specific tests;**

- **if the system rules are changed and the laboratory either will not or cannot ensure conformance to the new requirements;**

- **on any other grounds specifically provided for under these program requirements or formally agreed between A2LA and the laboratory;**

- **when such action is necessary to protect the reputation of A2LA; and**

- **at the formal request of the laboratory.**

When it is proposed to withdraw accreditation, A2LA shall issue a written notice by certified mail, return receipt requested:

- **that withdrawal is being considered;**

- **of the reasons for the proposed withdrawal sufficient to put the laboratory on notice of the cause;**

- **that within thirty (30) days of receipt of the notice, the laboratory may submit in person, or in writing, information in opposition to the withdrawal, including any additional information that raises a genuine dispute over material facts; and**

- **of the effect of proposed withdrawal, including removing the laboratory's name from the A2LA Directory and publicizing the action in the A2LA Newsletter and on the Worldwide Web.**

A laboratory may appeal to A2LA against a decision to withdraw or not to award accreditation.

XV. Appeals Procedure

There are two possible levels that an appeal can reach before being resolved:

1) **Accreditation Council;**
2) **Board of Directors**

The A2LA staff shall advise the applicant in writing of its right to challenge an adverse accreditation decision by the Accreditation Council panel. The appeals policy, including an applicant's right to a hearing, are contained in the A2LA Bylaws.

An appeal shall be lodged no later than thirty (30) days after notification of the decision by forwarding a certified letter to A2LA for timely consideration by the appeals panel of the Accreditation Council.

The decision of the Accreditation Council's appeals group is communicated in writing to the appellant.

If the decision is not favorable to the appellant, the appellant may lodge a further appeal within thirty (30) days of notification by forwarding a certified letter to A2LA for timely consideration by the Board of Directors. This letter shall include appropriate substantiation for the appeal. This letter will be promptly transmitted to the members of the Board of Directors appeals group, the composition of which to be determined taking into account any conflict-of-interest considerations.

The decision of the Board of Directors shall be final and is communicated in writing to the appellant.

XVI. Confidentiality Policy

All information provided by applicants in connection with a request for an application package, an application for accreditation, an assessment or proficiency test is confidential. Such information is examined by a small group of A2LA staff, assessors, and Accreditation Council and external bodies as needed for recognition of the program. All are made aware of its confidentiality. Such information shall not be released unless the applicant provides A2LA permission in writing to do so.

Documents necessary to convey information about accredited laboratories and their scopes of accreditation are not confidential.

In response to a question about whether or not a particular laboratory has applied for accreditation, A2LA simply responds by saying that the laboratory is not accredited. Staff should neither confirm nor deny whether a laboratory has ever applied for accreditation. If the laboratory itself is saying that it has applied for accreditation, it is the laboratory's responsibility to release the information regarding its applicant status. If the caller says that the laboratory claims it applied, staff shall take the name, address and phone number of the laboratory to check to see if the laboratory is misleading the client but staff still will not verify the laboratory's application. Should the laboratory insist that staff verify for a potential client that it has applied to A2LA, staff shall indicate that it has applied only if the laboratory makes such a request to A2LA in writing.

If an inquiry is made about a laboratory whose accreditation has lapsed but is in the renewal process, staff can indicate that the laboratory is not now accredited but is in the process of renewal, if that is the case. If the renewal laboratory's accreditation has lapsed with no indication (return of renewal forms or payment) of pursuit of renewal, staff indicates simply that the laboratory is not accredited.

If A2LA finds that a laboratory is misrepresenting its applicant or accredited status, staff shall treat such information like a complaint by first informing the A2LA President. The President shall determine the appropriate action which would usually involve contacting the laboratory directly about the alleged misrepresentation.

XVII. Conflict of Interest Policy

Since its inception, A2LA has had a policy that actual or apparent conflicts of interest must be avoided as mandated by normal business ethics. Consistent with the principles set forth in ISO/IEC Guide 58, "Calibration and Testing Laboratory Accreditation Systems -- General Requirements for Operation and Recognition," A2LA believes that it is vital that its accreditation services be impartial and objective, uninfluenced by the private interests of individuals acting for A2LA. Accordingly, any person directly involved in actions relating to the A2LA accreditation process shall avoid direct participation in A2LA actions which may involve an actual or apparent conflict of interest.

The Chairman of the Board and the President shall, as promptly as possible, take all possible means to prevent or overcome any such actions that may conceivably be in violation of this policy.

A diagram of the A2LA accreditation process and appeals process is provided on the next two pages.

[Diagram of the Accreditation Process created in Harvard Graphics]

[Diagram of the Appeals Process created in Harvard Graphics]