ACKNOWLEDGMENT:
These materials were developed and presented by Kenneth N. Parson under contract to the National Institute of Standards and Technology.

COURSE OBJECTIVE

The objective of this course is to expand on the knowledge and understanding of the laboratory accreditation process for those who are already involved in laboratory accreditation in one form or another. A comparison of the differences between ISO/IEC Guide 25 and its replacement, Final Draft International Standard (FDIS) 17025 is a primary part of the course. The transition to an International Standard will require that everyone involved in accreditation understand how to interpret and apply the requirements of this new Standard. Through active participation course participants will gain a better understanding of the accreditation process and related standards.

TABLE OF CONTENTS:

INTRODUCTION

At best, this matter of accreditation can be rather confusing. What is accreditation? And, why is it becoming a topic of such keen interest to many throughout the world? This handbook along with material presented in the course are designed to provide the participant with a better understanding of accreditation and the factors that influence the accreditation process. The material is divided into three major parts:

1-STANDARDS AND GUIDES. The identification of major international documents, a review of their purpose and how they relate to the accreditation of calibration and testing laboratories. This section of the handbook includes a comparison of the existing ISO/IEC Guide 25, General requirements for the competence of calibration and testing laboratories and ISO/IEC Final Draft International Standard (FDIS) 17025, General requirements for the competence of testing and calibration laboratories. It is expected that ISO/IEC FDIS 17025 will soon replace ISO/IEC Guide 25 and will then be known as ISO 17025. When this occurs, accrediting bodies and laboratories will be expected to realign their management and quality systems to satisfy the new requirements. Persons who are currently qualified as laboratory assessors will need to be re-qualified and become proficient in assessing to this new set of requirements.

2-THE ASSESSMENT PROCESS. An introduction to the primary elements of ISO/IEC Guide 25 and the new Standard, ISO/IEC FDIS 17025. This section also presents information on how assessors are selected by an accrediting agency, how assessors are assigned to a project and how the assessment process is carried out.

3-LABORATORY PREPARATION. The ability of a laboratory to apply for and receive accreditation in the shortest possible time with the least amount of effort and cost will depend on how well the laboratory prepares for the event. The information presented in this section deals with some factors a laboratory should consider before making application to an accrediting agency.

Before we get into a detailed discussion of the assessment process and how a laboratory should prepare for accreditation we need to be sure we recognize and understand the nature of the international standards and guides that influence the field of accreditation. There is a principal organization and a series of international standards that have a relationship to ISO/IEC Guide 25 that should be addressed. The following is a brief introduction to the International Organization for Standardization (ISO) and the ISO 9000 series of Standards.

For brevity, from this point on ISO/IEC Guide 25 will be referred to simply as Guide 25, or, the Guide, and ISO/IEC FDIS 17025 as the Standard or 17025.

PART 1
(2) STANDARDS AND GUIDES

International Organization for Standardization (ISO) (3)

ISO is a worldwide federation of national standards bodies. ISO technical committees prepare international standards. Each member organization interested in a subject for whom a technical committee has been established has the right to be represented on the committee. Other international organizations, governmental and non-governmental in liaison with ISO and IEC also, take part in the work. ISO works closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization. ISO is headquartered in Geneva, Switzerland.

Documentation Relevant to Accreditation (4)

There are many standards and guides available through ISO. Only those most closely related to accreditation are identified here. The function of laboratories and how they operate is an integral element of quality. It is therefore important to understand how the work of laboratories as imposed by Guide 25 fits into the overall scheme of quality management as imposed by ISO 9000.

ISO 9000 Series - International Standards for Quality Management (5)

The management and control of inspection, measuring and test equipment is an important consideration in the quality assurance process. Requirements for the control, calibration and maintenance of these devices are addressed in the ISO 9000 series of documents and therefore, have a relationship to the requirements imposed by Guide 25. The ISO 9000 series of International Standards for Quality Management are currently covered in 4 documents, which include:

> ISO 9001, Quality systems - Model for quality assurance in design/development, production, installation and servicing
>
> *For use when conformance to specified requirements is to be assured by the supplier during several stages which may include design/development, production, installation and servicing.* ***Clause 4.11*** *deals with requirements for Inspection, Measuring, and Test Equipment.*
>
> ISO 9002, Quality systems - Model for quality assurance in production and installation
>
> *For use when conformance to specified requirements is to be assured by the supplier during production and installation.* ***Clause 4.11*** *of this document deals with requirements for Inspection, Measuring, and Test Equipment.*

ISO 9003, Quality systems - Model for quality assurance in final inspection and test. *For use when conformance to specified requirements is to be assured by the supplier solely at final inspection and test.* ***Clause 4.11*** *deals with requirements for Inspection, Measuring, and Test Equipment.*

ISO 9004, Quality management and quality system elements - Guidelines

Used for internal quality management purposes. ***Clause 13*** *deals with the Control of measuring and test equipment.*

Quality–Functional Terms (6)

There are terms frequently associated with the word quality that we tend to use when we talk about a "quality system" a "quality manual" and "quality management." I think of the word quality system as being composed of those processes that take place within an organization that enables it to effectively accomplish its purpose. An organization usually produces some form of product or provides a service. A quality manual identifies and documents all the significant processes involved in producing a quality product or service. Quality management is the activity of assuring that processes in the system are identified in the quality manual are well documented, understood and implemented by those assigned to the processes.

ISO 9000-Quality System (7)

There are 20 parts in the ISO 9000 series that basically identify a quality system. Part 4.11, Control of inspection, measuring and test equipment is the most directly related to the requirements of Guide 25. Although there are similarities between the subjects listed in ISO 9000 and Guide 25 there is a difference as to how these parts of a quality system are applied. In most cases, the ISO 9000 quality system requirements are focused on organizations that manufacture a product or provide a service. Maintenance, care and control of test equipment within an organization is considered an essential part of the organizations quality system. However, ISO 9000 does not address the requirements for the operation of a laboratory or verification of a laboratory's technical competence. Herein lies the major difference between the quality requirements of ISO 9000 and those of Guide 25.

ISO 9000/Guide 25 Relationship (8)

ISO 9000 imposes requirements for operating a quality system in an organization while Guide 25 is more specific to the requirements for operating a laboratory and verifying a laboratory's technical competence to perform calibration or tests.

Certification versus Accreditation (9)

Certification. ISO 9000 deals with standards for Quality Management. The primary focus is on the principles of quality assurance. Does a company applying for "Certification" to one of the 9000 series of International Standards have a documented quality system in place and is the system being complied with? Persons selected for this type of audit process are skilled in the field of quality assurance and usually have a sound knowledge in auditing methods and techniques. These persons do not, per se, have to be experts in the type of work or services being provided by the company they will be auditing. Working for a "Registrar", (a certifying agency) these auditors conduct audits. Where the company has a quality system that meets the 9000 requirements the company will receive a "Certificate" from the certifying agency. This certificate will attest to the fact the company has been audited and found to be in compliance with the appropriate 9000 series Standard.

Accreditation. Guide 25 deals with a calibration or testing laboratory's technical competence and its ability to comply with specific standards, test methods or approved procedures. Also the application of Guide 25 requirements to assure the validity of a laboratory's test data. Just as with the 9000 series requirements, a laboratory must have a quality system in-place and the laboratory must be in compliance with that system. Persons selected for this type of auditing must be considered technically competent in the area of laboratory operations and have laboratory experience. They must be skilled in laboratory management and quality assurance techniques as they apply to laboratories. Technical experts must also have extensive knowledge and skills in the science of metrology and their field of measurement technology.

ISO/IEC Guide 25 General Requirements for the Competence of Calibration and Testing Laboratories (10)

The third and current edition of Guide 25 was drawn up by the ISO Council Committee on Conformity Assessment (CASCO) in response to a request arising from the International Laboratory Accreditation Conference held in Auckland, New Zealand on 17-21 October 1988. The revised Guide was approved by the International Electrotechnical Commission (IEC) Council in October 1990 and by the ISO Council in December 1990.

This document has been used as a basis for the assessment of laboratories by many countries since it was approved for use in 1990. Accrediting bodies, laboratory assessors and calibration and testing laboratories have recognized this Guide as the document that defines the general requirements for the competence of calibration and testing laboratories.

Guide 25 Scope (11)

Guide 25 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.

Additional requirements and information which have to be disclosed for assessing competency 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. Guide 25 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.

ISO 9000/Guide 25 Comparison (12 and 13)

Using ISO 9001 as an example. In addition to the first three subjects, Scope, Normative references and Terms and definitions, there are 20 subjects that are addressed as requirements. In Guide 25, the first three subjects are basically the same, Scope, References and Definitions and then contain 13 subjects addressed as requirements. Management and quality systems are specifically identified as primary subjects in these two documents. Beyond that there is no direct correlation between the requirements contained in these documents. Many times, a specific requirement contained in ISO 9001 will appear as a subordinate requirement within one of the main subjects in Guide 25. As an example, 4.14 Corrective and preventative action is identified in ISO 9001 as a main subject but in Guide 25 it is addressed subparagraph 5.2 o). The point is that in both documents the principal elements of quality are addressed but not necessarily in the same way. Guide 25 focuses on laboratory accommodation and environment, traceability unique to the measurement and calibration, calibration test methods, certificates and reports and a focus on complaint procedures.

ISO/IEC FDIS 17025 General Requirements for the Competence of Testing and Calibration Laboratories (14)

This is the document that will soon replace ISO/IEC Guide 25. It is now in the final draft form and will soon be voted on for acceptance by members of ISO. Once accepted it will become the International Standard and will invoke the general requirements for the competence of testing and calibration laboratories.

General Information (15–17)

ISO Standards and Guides are revised on a five-year cycle. Revision to Guide 25 started in 1995. Project assigned to ISO/CASCO Working Group 10. There were many revisions. A decision was made to publish as a Standard. A meeting was held at the National Institute of Standards and Technology (NIST) in November 1998. Numerous comments were considered. The team developed a consensus of comments. They forwarded 11 general and 125 specific comments to ANSI/ICAC for voting. A second meeting occurred in Geneva on February 1999. At that meeting all comments on the then DIS 17025 were considered with most accepted. At this point the document became known as Final Draft International Standard (FDIS) 17025. The team was then disbanded until the next revision is needed. Expect ISO/IEC 17025 to be approved by end of September 1999. Anticipate ISO/IEC 17025 will be published by end of 1999 or early in 2000.

FDIS 17025 Contents (18 and 19)

Scope, Normative references and Terms and definitions make up the first three sections of the Standard. Requirements are now divided into two sections; Section 4 Management requirements and Section 5, Technical requirements. This reorganization of the material represents one of the more significant changes between Guide 25 and 17025. Table 1 listed in the Appendix shows how the requirements are organized in 17025 in regards to Management and Technical requirements. The third column in the table shows how the technical requirements are listed in Guide 25. This table is only presented to show the relationship and arrangement of subject titles between the two documents. In 17025 there are now 14 Management subjects and 10 Technical subjects for a total of 24. In Guide 25 there are 13 related requirement clauses (4–16) as listed in table 1.

FDIS 17025 Scope (20)

This is a summary of the contents of the Scope as provided in 17025. It specifies the general requirements for competence. Applicable to all organizations performing test or calibrations. 17025 is applicable to all laboratories regardless of size. To be used by laboratories, accrediting bodies and others concerned with laboratory competence.

There are two statements that are important to keep in mind:

Regarding "notes". Paragraph 1.3 states that notes given in the Standard are for clarification of text, examples and guidance. It goes on to say that notes do not contain requirements and do not form an integral part of the Standard

ISO 9001 and 9002. Paragraph 1.5 states that if laboratories comply with 17025 they will operate a quality system for their activities that also meets the requirements of ISO 9001:1994 and ISO 9002:1994. The last sentence states that 17025 covers several technical competence requirements that are not covered by ISO 9001:1994 and ISO9002: 1994.

These statements are new and more focused than the Scope statements in Guide 25. We can expect that it will take time for those involved in the accreditation process to fully understand what the implications are concerning a laboratories operation of a quality system that also meets the requirements of ISO 9001 and 9002. The statement that 17025 covers several technical competence requirements beyond ISO 9001 and 2 will need to be clarified through some form of matrix that will show where 17025 exceeds the ISO 9001 and 9002 requirements.

FDIS 17025 to Guide 25 Comparison (21 and 37)

There are several significant changes that have taken place with the transition from Guide 25 to 17025. Table 2 in the Appendix is arranged to show how subject matter in the two documents is related. This information is also covered in slides 21 through 37.

<u>ISO/IEC Guide 58: 1993</u> Calibration and Testing Laboratory Accreditation Systems-General Requirements for Operation and Recognition (38)

This document identifies the requirements for the operation of a system for accrediting calibration and testing laboratories. It is one of the basic requirements documents used for the development of Mutual Recognition Agreements (MRA) between accreditation bodies. Accreditation granted to a laboratory by an organization complying with the requirements of Guide 58 and agreed to through an MRA may be recognized at the national/international level. Many people do not realize that Guide 58 requirements are very similar to those imposed on laboratories through Guide 25. Guide 58 requires that an accrediting body meet basically the same organization and management requirements as Guide 25. Each accrediting body must also have a documented quality system, address the qualification of its personnel, have contracting arrangements, maintain records, have a documented accreditation process, sub-contracting arrangements and assessment reports. The philosophy of the concept of international standardization requires that all participants (not just laboratories) be accountable and responsive to applicable requirements as imposed by the system of international standards.

PART-2
(39)THE ASSESSMENT PROCESS

This section covers some terms related to the assessment process and how the Guide is organized. An explanation of 12 steps in the assessment process is presented, followed by a discussion of desirable qualifications and traits for assessors.

It is important to understand that the material presented in the following sections of this handbook are based on methods and procedures used by the National Voluntary Laboratory Accreditation Program (NVLAP), a part of the United States, National Institute of Standards and Technology (NIST). Each accrediting body must determine how it wishes to manage the accreditation process. Assessors who have been found to be technically competent and selected to participate in this activity must understand and agree to perform this work in accordance with the accreditation requirements established by their accrediting body.

Related Terms (40)

There are three key terms that relate to the assessment process. They are Adequacy, Compliance and Technical Competence.

Adequacy of documentation is the first step in the assessment process. A laboratory assessor must first review the laboratory's application and quality manual. The effort here is to determine if these documents adequately address and satisfy all the requirements imposed by the accrediting body and Guide 25. At this point in the assessment, attention should be focused on the laboratory's organization, management and quality system. Detailed information regarding each clause in Guide 25 is covered along with some techniques for accomplishing document review a very important part of the assessment process.

Compliance to documentation is the second step in the assessment process and is accomplished as part of the on-site visit. Assessors must determine if laboratory personnel are complying with policy and procedures as set forth in the laboratory's quality manual.

Technical competence**.** This activity is also accomplished as part of the on-site visit. Assessors who are recognized as technical experts in the fields of calibration or testing which the laboratory is seeking accreditation will verify that laboratory personnel are able to demonstrate technical competence by performing calibration or testing operations.

How Guide 25 is Organized

The Guide is divided into 16 clauses. The first three are introductory and include the **Scope** of the Guide, a list of **References**, and a list of relevant **Definitions.** Although these issues are important, the actual requirements a laboratory must satisfy are detailed in

the remaining 13 clauses, 4 through 16. In the following, each clause is identified by number and title followed by a brief explanation about the content of the clause. This information gives only a brief summary statement about the nature of the requirements contained in each clause. These statements are provided to acquaint the reader with the characteristics and properties of the Guide. This information must not be used as a substitute for the actual requirements stated in Guide 25. Clause 4 through 16 of the Guide concentrates on requirements for laboratory accreditation. They are:

Clause 4, Organization and Management

There are 11 requirements imposed by this clause. In brief, these requirements state:

The legal identity of the laboratory, organizational structure, authority, responsibility and resources, moral issues of integrity, independent judgement, freedom from commercial, financial or other pressures, and ways to protect clients' confidential information and proprietary rights.

Clause 5, Quality System, Audit and Review

There are 30 requirements imposed by this clause. In brief, these requirements state:

The need to establish and maintain a documented quality system, a statement of the laboratory's policy and operational procedures to meet requirements of the Guide, and procedures that cover the objectives and commitment by top management. Addressed also are, organizational relationships, document control procedures, job descriptions, approved signatories, traceability, scope of work, calibration or test procedures used, handling procedures, measurement equipment and standards used, inter-laboratory comparisons, feedback, corrective action and departures from procedures. During the first phase of the assessment process, the assessor's attention is primarily focused on these areas of organization, management and the quality system.

Clause 6, Personnel

There are three requirements imposed in this clause. These requirements state:

Laboratories shall have sufficient personnel with the education, training, and technical knowledge and experience needed for their assigned duties. Training of personnel must be kept up to date and records of relevant qualifications, training, skills and experience shall be maintained.

Clause 7, Accommodation and Environment

There are six requirements imposed in this clause. These requirements state:

Laboratory energy sources, lighting, heating and ventilation within the laboratory as well as at sites other than the permanent laboratory premises. Procedures are required for monitoring, controlling and recording environmental conditions. There must be effective separation between neighboring areas when activities are incompatible. The laboratory shall have access to controlled areas, and adequate measures taken to ensure good housekeeping.

Clause 8, Equipment and Reference Materials

There are 13 requirements imposed in this clause. These requirements state:

The laboratory shall be furnished with all equipment required to perform assigned calibration and test workload. Each item of equipment must be maintained, identified, and labeled for calibration status. Records shall be maintained concerning equipment condition and status.

Clause 9, Measurement Traceability and Calibration

There are seven requirements imposed in this clause. These requirements state:

That any equipment having an effect on the accuracy or validity of calibrations shall be calibrated before being put into service. Measurements shall be traceable to national standards. Calibration certificates and reports shall include measurement results and associated uncertainties. Where traceability is not applicable, the laboratory shall participate in a suitable interlaboratory comparison process or, proficiency test program. Laboratory standards are to be used for calibration only and must be calibrated by a body that can provide traceability to a national standard. Equipment shall be subject to in-service checks and reference materials must also be traceable.

Clause 10, Calibration and Test Methods

There are 12 requirements imposed in this clause. These requirements state:

The laboratory shall have documented instructions on the use of equipment. Reference data relevant to calibration shall be kept up-to-date. The laboratory shall use appropriate methods and procedures including sampling techniques, handling, transportation, storage and the preparation of equipment. Procedures shall also be documented for the estimation of uncertainty of measurement, and the analysis of data. Where methods are not specified, the laboratory shall select methods published in international or national standards, or reputable technical organizations or scientific texts or journals. When establish standards or methods are not used, they shall be subject to agreement with the client. Sampling methods shall be documented and include statistical techniques for the selection of samples. Calculations shall be subject to appropriate checks.

Use of computer or automated equipment for capture, processing or manipulation of data shall be subject to Guide 25 requirements and must be complied with. Software must be documented and adequate to protect the integrity of data. Computer equipment shall be maintained and procedures for the security of data, unauthorized access and the amendment of computer records shall be documented. There shall also be documented procedures for the purchase, reception and storage of consumable materials used for technical operation of the laboratory. Note - This last requirement is closely related to clause 15, Outside support services and supplies.

Clause 11, Handling of Calibration and Test Items

There are four requirements imposed by this clause. These requirements state:

The laboratory shall have a system for uniquely identifying items to be calibrated. The laboratory shall also employ methods to determine the "as received condition" of equipment, procedures for notifying the client and receive instructions from the client when equipment does not conform to requirements. The laboratory shall also have procedures to avoid deterioration or damage to equipment, including the appropriate environment, storage and security arrangements to protect the condition and integrity of equipment. There shall be documented procedures for the receipt, retention and safe disposal of equipment and provisions to protect the laboratory.

Clause 12, Records

There are two requirements imposed by this clause. These requirements state:

The laboratory shall maintain a record system. Records (including those listed in 8.4 records for equipment) certificates and reports shall be stored safely, held secure and in confidence to the client.

Clause 13, Certificates and Reports

There are 21 requirements imposed by this clause. These requirements state:

Results of calibration or test shall be reported accurately, clearly, unambiguously and objectively to instructions specified in the calibration or test method. Reports shall include all the information necessary for the interpretation of the calibration results and all information required by the method used. There are 15 entries that are required on each certificate or report. These entries are listed as, a) through o) under clause 13.2. There are also requirements concerning the results of any calibration or tests performed by a sub-contractor. Reports should be carefully arranged and designed to have a standard heading but also designed to accommodate the particular type of calibration or test being reported. There are also specific requirements for making any amendment to these certificates and reports. The laboratory shall also have procedures to notify the client whenever conditions cast doubt on the validity of results. There shall also be procedures that ensure

that the requirements of Guide 25 are met and confidentiality preserved whenever, calibration or test results are transmitted by telephone, telex, facsimile or other electronic or electromagnetic means.

Clause 14, Sub-Contracting of Calibration or Testing

There are two requirements imposed by this clause. These requirements state:

Sub-contracting must be arranged with a laboratory that complies with the requirements of Guide 25. The laboratory must be able to demonstrate that its sub-contractor is competent and complies with the same criteria of competence as the laboratory in respect to the work being sub-contracted, advise the client in writing of its intent to sub-contract any portion of the testing to another party. Record and retain details of investigation of the competence of sub-contractors and maintain a register of all sub-contractors.

Clause 15, Outside Support Services and Supplies

There are three requirements imposed by this clause. These requirements states

The laboratory shall use of only outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests. The laboratory shall ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specification concerned.

Clause 16, Complaints

There are two requirements imposed by this clause. These requirements states:

The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. Records for all complaints and actions taken by the laboratory shall be maintained. Where doubts are raised concerning laboratory compliance, the laboratory shall ensure those areas of activity are promptly audited to clause 5.3 of Guide 25.

Nature of the Assessment Process (41)

Table 3 identifies four major events that normally occur during the assessment process including steps within each event. The two key events are, step 6, the Report on Documentation and step 12, the Final Report.

Each step in the process is described below:

Step 1 - Receive Offer

As a qualified assessor, recognized by the accrediting agency, you will be contacted to determine if you are available and wish to participate in this assignment. You will be briefed on the nature of the assignment and advised of the location and estimated level of effort that will be involved.

Step 2 - Estimate Effort

Once you agree to accept the offer, the accrediting agency will send you the application along with the laboratory's quality manual and any other related material. Based on this material and the information provided during step 1 regarding the level of effort, you will begin to estimate the amount of labor and other direct costs it will require for you to accomplish this assignment.

Step 3 - Make Bid

You will be expected to submit your bid to the accrediting agency in such a way that all costs are identified. The most important element of the bid will be your estimate of the number of hours it will take you to evaluate and report on the laboratory's documentation and the labor involved in your part of the on-site assessment. Labor cost is based on the agreed to hourly rate established by the accrediting agency. You will also need to estimate other direct costs such as your per-diem, lodging, meals, airline, and rental car costs and miscellaneous costs such as telephone, Fax, and Express mail. Once you have prepared your estimate and reviewed it carefully, submit your bid. Depending on the country and arrangements with the accrediting agency this bid process may not focus on the monetary issue of pay for assessors but still identifies the costs involved for travel and per-diem.

Step 4 - Receive Award

Once the accrediting agency has accepted your bid you will be notified. Prior to the award, the accrediting agency will submit your name and biography to the laboratory for their information and for the opportunity to decline your services if for any reason they feel that is necessary, such as a possible conflict of interest. Normally you will be given some form of authorization to proceed at this time.

Step 5 - Document Review

At this point the actual assessment begins. This process is covered in detail later in the Handbook.

Step 6 - Issue Report

When documentation assessment is completed you will be expected to formulate your conclusions in a written report submitted to the laboratory. This report will address the adequacy of the laboratory's documentation and its compliance with Guide 25

requirements. Where deficiencies are noted, you will notify the laboratory to respond to the report and advise you as to what action the laboratory intends to take to correct the deficiencies.

Step 7 - Receive Response

You will review the laboratory's response to your report to determine if the proposed action taken or to be taken by the laboratory will satisfy the requirements. If the response is satisfactory, you will begin scheduling arrangements for the on-site visit.

Step 8 - Schedule On-Site

Arrangements for the on-site visit involve coordination between all parties involved. Both the assessors and laboratory management staff must be satisfied all issues have been resolved resulting from the document review and both parties are reasonably confident the on-site can proceed without any major problems. The accrediting agency must also be advised to take into account any changes that might be involved in the nature of the assessment or changes in the level of effort. These issues must be addressed and resolved between the accrediting agency and the laboratory before the on-site visit is started.

Step 9 - Entrance Meeting

The on-site is by far, the most complex part of the assessment process. As the Lead Assessor, you will be the principle spokesperson for the assessment team. With that in mind, you will need to think about how you will conduct your part of this very important meeting.

Step 10 - Conduct Assessment

Time management is the key to conducting the assessment. You must have a plan of action. How will the on-site assessment proceed? How will you divide the work so all elements of the assessment can be accomplished in a very short period of time?

Step 11 - Exit Brief

The exit brief is probably the most critical event in the assessment processes. You and your team have just completed an extensive assessment of the laboratory and must now compile your thoughts and formulate a sound logical presentation of your findings. You have only a few hours to compile your findings and to prepare for the exit brief. You can expect company executives, the head of quality assurance and other departments and members of the laboratory staff to attend this meeting. They will have a keen interest in what you have to say. You and your team will be expected to provide a written report to the members of this meeting at its conclusion.

Step 12 - Final Report

The results of the overall assessment are included in your final report to the accrediting agency. Normally, the accrediting agency will have standard forms that are used to make this report. You will be asked whether the laboratory is considered competent for accreditation in the areas requested. You will also be asked what deficiencies, if any remain and what follow up corrective action is required. If the laboratory is not found competent, you will be expected to state your reasons why another on-site will be required. Depending on your arrangements with the accrediting agency, you will file your claim for services rendered or transact some form of acknowledgment that the assignment has been completed.

Qualifications and Personal Traits (42)

Much of the success of the accreditation process will depend on the performance of those persons assigned to carry out the assessment process. Qualification and the demeanor of assessors during the assessment process are very important.

Technical Competence is the most distinguishing qualification required for persons involved in the assessment of calibration and testing laboratories. Just as laboratories must be technically competent, so must the assessors. To do an effective job, you must have an in-depth understanding of how a laboratory functions and if you are a technical expert you must have formal as well as practical knowledge and experience in the field of measurements you have been selected to assess.

As an administrator you should possess good leadership qualities, be able to work independently but yet be able to motivate others. You should also have the ability and desire to organize, plan and coordinate projects, set goals, meet schedules and have the confidence to make decisions.

As a person you should have a good attitude, be committed to the work, have a respect for yourself and everyone involved in the project. You should be able to control your emotions and not let your personal feelings interfere with your work. Your personal character and appearance are important too.

As an assessor, you should be a good observer and a good listener, a good note taker. You need the power of deductive reasoning, analytical and objective so you are able to see and distinguish important issues from those of little significance. You should be able to write well.

Sequence of Events (43)

Calibration and testing laboratories make their application for accreditation to an accrediting agency. Based on the number of measurement parameters the laboratory

wishes to be accredited in, the accrediting agency evaluates the application and estimates the number of assessors needed and the time required to perform the overall assessment, in particular, the time to conduct the on-site assessment. Once the accrediting agency has evaluated these requirements, the selection of assessors begins. This selection is predicated on the fact the accrediting agency is drawing on a pool of fully qualified, technically competent assessors. The assessment team is composed of a lead assessor along with as many technical experts as needed to carry out the assessment.

Regardless of how the accrediting agency selects and employ's assessors, the events described below are important and should be take into account. In the NVLAP approach to the assessment process, there are 12 basic steps. These steps proceed through the following sequence of events. They are:

1. Pre-arrangements and the selection of assessors (steps 1 through 4).

2. Familiarization and evaluation of the adequacy of the laboratory's documentation (steps 5 through 7).

3. The on-site visit to assess the laboratory's compliance to documented procedures and technical competence (steps 8 through 10)

4. Drawing conclusions and making the final report (steps 11 and 12).

These are the events you as an assessor will probably experience. These steps may vary depending on the procedures set up by the accrediting agency for which you will work but will probably follow this outline. The emphasis in handbook is based on the role of the lead assessor but all assessors will generally be expected to follow the same steps.

Document Review (44) + (45 and 46)

The material in this section covers the review and assessment of a laboratory's application, quality manual and other related material. The review of a laboratory's application and quality manual, in particular as it relates to the laboratory's organization and management and how its quality system works, is the first step in the assessment process. We will consider how one might determine if these documents are adequate and meet the requirements of Guide 25. This assessment activity would be nearly impossible to accomplish if the assessor did not have a sound understanding and insight into the nature of the requirements imposed by Guide 25.

As an assessor begins to evaluate a laboratory's application and quality manual, the assessor must think in terms of the overall assessment process. There are two phases involved in the assessment leading to accreditation.

During the first phase, the assessor becomes acquainted with the laboratory through its application and the information contained in the laboratory quality manual (described

earlier in step 5). These documents provide an insight into the organization of the laboratory. The quality manual should define the quality system in detail and document the procedures employed by the laboratory to control all calibration and test processes required by Guide 25. It should also show how the laboratory is organized, how the laboratory controls documentation, where the laboratory fits in a larger organization or company or if it operates as an independent organization. The quality manual should also provide information about the laboratory's measurement capabilities. The application should provide information about the size and layout of the laboratory, and include a list of laboratory standards and related equipment used.

While the lead assessor is involved in the review of the laboratory's organization and management structure and the content of its quality manual, other assessors referred to as "technical experts" begin to examine information concerning the technical capabilities of the laboratory. Technical experts are experts in a field of measurement generally with many years of experience in their field of work. Many times, lead assessors are those with several years' experience operating laboratories with extensive knowledge in the organization and management of laboratories and quality assurance techniques as they apply to laboratories.

Getting Started (47)

Now that you have been given the assignment to assess a laboratory, the first order of business is to make contact with the designated laboratory point of contact and your assigned team members. This is an important first step. You need to establish a professional but cordial relationship with these personnel. Much of the success of your efforts will depend on your management abilities, your interpersonal skills and your ability to establish a sound working relationship with everyone involved. You will need to get your team organized, reach an understanding as to how you will operate, how you will exchange information and who will talk with the laboratory representative regarding various matters. For example, most of the coordination and reports regarding laboratory organization and quality procedures as well as the arrangements for the on-site visit will be discussed between the lead assessor and the laboratory point of contact. Technical experts will talk with the laboratory point of contact and with technical specialists within the laboratory on technical issues regarding specific measurement processes. The lead assessor must be careful not to interfere in these technical discussions unless there is some compelling reason to do so. Technical experts should also not interfere in those activities normally performed by the lead assessor. Mutual respect and consideration are essential elements of the process.

Familiarization (48)

Read all the material that has been provided. As you review these documents make note of anything that stands out, is unusual in your opinion or catches your eye. Did the laboratory provide a response to all the information requested in the application? Is the information provided adequate? What information, if any, is missing? Did you notice any

conflicting statements or ambiguities? Do not try to analyze the information at this point. You are simply getting acquainted with the material and formulating a general opinion about what you see in terms of organization and content. If necessary reread all of the material or review parts you do not understand or are unclear. If you need clarification, call the laboratory point of contact and discuss the issue.

Checklists (49)

Checklists are normally designed by accrediting bodies and provided to assessors so the assessors can perform a systematic evaluation of the laboratory and to record the results of the assessment.

Personal Computer (PC) (50)

A personal computer will be of great help during the assessment process. Ideally the checklist should be loaded into the PC. As you begin to evaluate the documentation, you will use the PC formatted checklist to record your commentary in a systematic, step by step manner.

Evaluation and Analysis

The evaluation and analysis process is not simple. You may have to search throughout the laboratory's documentation to find a statement or process that satisfies the requirement in question. There are occasions when more than one statement or process addresses the same requirement and times where you will find conflicts. To a degree, there is some overlap or repetitive statements in the Guide. As an example, much of the material presented under clause 5, Quality system, audit and review, will also be addressed in some form within other clauses. You will need to understand these relationships and deal with them in context.

Classify your Findings (51)

You will need to establish a method for classifying your findings or you may be assigned these categories by your accrediting agency. An example of three simple categories that can be used are:

1. S - In your judgement, the Guide 25 requirement has been fully addressed and is satisfactory in regard to the approach used. You may or may not be required to state how you came to this conclusion by the accrediting agency. However, for your own record keeping and for recall later in the assessment process you may wish to annotate how you came to this conclusion by simply referring to where this material is located in the laboratory's documentation along with a few simple notes if needed.

2. C - A comment or concern you have regarding any issue where you feel it is important to convey this information to the laboratory. It is important here to avoid telling the

laboratory how to "do" a process but that you see some element of the process missing or out of order or what ever other concern you might have. This is another positive trait of the assessment process. If presented properly and in the right context, it gives the laboratory a "heads-up" on a possible flaw or weakness that the laboratory can now consider and possibly incorporate into their system.

3. D - A deficiency. You have determined the laboratory has not addressed a Guide 25 requirement or you feel that the approach taken does not satisfy the requirement. This is where your "technical competence" becomes important. You must establish and articulate a sound rational argument as to why you believe there is a deficiency. Your credibility as an assessor in the view of the laboratory, your peers, and the accrediting agency will be at stake. Your ability to recognize and clearly present a sound argument as to why a requirement has not been satisfied is the essence of your credibility as an assessor.

Where to Start? (52)

Start at the beginning, organization and management, clause 4.1. It states that the laboratory shall be legally identifiable. In this same clause, it goes on to say the laboratory shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the requirements of this Guide. You have already encountered two requirements.

You must find tangible evidence that the laboratory has made a statement about its legal identity. If you can not locate this information, you must identify this as a deficiency. If you do locate the information but feel it is too vague or ambiguous, you should make a comment about your concern. If you find the statement and it is clear and well stated, you will determine it to be satisfactory and mark it (S) and go on to the next requirement. The second requirement necessitates that the laboratory be organized and shall operate in such a way that its permanent, temporary, and mobile facilities meet the requirements of the Guide. In this case you will need to keep in mind that the requirement is not only imposed on the permanent laboratory facilities but also any temporary or mobile facilities. You will have to keep this in mind as you evaluate the documentation. If you encounter any information indicating the laboratory provides temporary or mobile service you will have to determine if the laboratory is complying with the requirements of the Guide. Controlling processes in temporary locations or in mobile units will require special attention to such things as controlling and monitoring environment, and protecting measurement or test standards. Has the laboratory taken these issues into account? Are these processes documented? Are they adequate?

Each requirement is unique and contributes to the overall performance and control of an organized and managed laboratory. The point is to understand the requirement, how it relates to other requirements and how it fits into the overall scheme of things. Then you must figure out what you will expect to see in the laboratory's documentation that will convince you that the requirement has been adequately addressed.

Issue Report (53)

There are many requirements in the Guide that can not be properly evaluated during the document review phase of the assessment process. Many requirements can only be evaluated during the on-site visit. In this initial report, you will primarily address the results of your review of the laboratory's application and organization and management and its quality system as defined in the laboratory quality manual. There is no reason to consider scheduling an on-site visit until documentation is determined to be adequate.

It is a good practice to provide both your team members and your point of contact at the accrediting agency with a draft copy of your report and proposed cover letter. Ask them to review the report and advise you of any concerns or thoughts they may have so you can take these into account before issuing the report. You may also consider sending a final draft of your report to the laboratory for an informal review and comment before sending the official report. This gives the laboratory the opportunity to point out or clarify a statement that may be inherently incorrect in your report. It is much better to discover and resolve this type of issue before the report is official. It is also a courtesy to the laboratory.

In your cover letter you will ask the laboratory to respond to any deficiencies noted in the report. These deficiencies must be acknowledged and the laboratory must determine and specify what corrective action will be taken or reasonably planned for. Once you have received a reply from the laboratory and you, your team members, the laboratory and the accrediting agency are satisfied with the response, you are ready to prepare for the on-site visit.

Preparing for the On-Site (54)

Planning, coordination, and time management, are key elements of an on-site visit. This section explains how to prepare for and coordinate an on-site visit. It will also explain how to conduct the entrance meeting, do the assessment, consolidate data, compile results, present your findings at the closing meeting and complete and submit your final report.

Readiness (55)

The decision to commence with the on-site visit should be based on the collective agreement of all parties concerned. Laboratory management must feel confident the laboratory is ready to demonstrate its compliance and technical competence to the Guide 25 requirements. Technical experts assigned to the project must also be satisfied that the laboratory is technically capable of performing selected measurements over the range and to the uncertainties specified in the application for accreditation.

Scheduling (56)

The lead assessor through counsel with the technical experts and discussions with the laboratory management coordinates a date for the on-site visit. The lead assessor will also notify the accrediting agency that preparations are under way for the on-site.

Logistics (57)

Travel plans, flight arrangements (if necessary), lodging, rental cars, dates of arrival must be discussed and coordinated so all team members will arrive and be able to assemble at a pre-arranged time before the on-site starts. It is important for the team to get organized and make any final arrangements or adjustments to the plan of action before arriving at the laboratory. This activity can be relatively simple if only 2 or 3 persons are involved. If the team is made up of several assessors then more attention will be needed to organize and prepare for the visit.

Arrival (58)

Be on time. Laboratory personnel will be expecting you and will have arranged for your visit. This is a very important event in the overall assessment process. It is the time of first impressions and a time to get acquainted. Do not confuse this activity with the entry briefing which, is a more formal and focused event.

Code of Conduct (59)

You and your team are guests at the laboratory. It is very important that all members of your team understand and comply with all operating procedures imposed by the laboratory. You will be assigned space to assemble your team and accomplish your work. The use of phones, copying equipment or any other devices must only be done as arranged with the laboratory. You and your team members may be required to wear an identification badge and it is not uncommon to be assigned an escort as you go into various areas throughout the laboratory facilities. You will need to know and comply with the laboratory schedule for coffee and lunch breaks, and starting and quitting times for personnel within the laboratory.

Entry Briefing (60)

The primary purpose of the entry briefing involves the formal introduction of you and your team members to the laboratory staff. It covers a review the scope and objectives of the assessment. It provides the opportunity to establish ground rules for conduct of the assessment, arrange time and location for periodic meetings with laboratory management and to establish the date, time and location for the closing meeting and to clarify or answer any questions or concerns.

The Assessment Process (61)

Have a plan of action and try to follow it. Be sure you and your team are prepared to review requirements covered in clause 4 through 16 of Guide 25.

Organization and management and Quality system, audit and review, Clause 4 and 5. This will be an extension of the assessment of the adequacy of laboratory documentation. Primarily the assessor doing this part of the assessment will determine if laboratory personnel are in fact complying with the procedures documented in the quality manual as promulgated by laboratory management. This part of the assessment will go beyond those areas examined during the first review of the laboratory's documentation.

Personnel, clause 6. You will need to examine training records. Examine records for key personnel and some of the technicians. Are the records in good order? Are the maintained and up-to-date? Is there a record of on-the-job or currency training? Is there evidence of a reasonable level of training for all job disciplines? Are there qualification requirements listed for each job description? Technical assessors may be asked for their opinion on the qualifications of technical personnel and whether their performance appears to be consistent with their record of training and experience.

Accommodation and environment, clause 7. Examine these requirements from two points of view. Are these requirements documented and are they being complied with? Select a procedure and make observations. Are personnel performing the process as documented? Are accommodations and environmental conditions satisfactory to meet the requirements of the measurements being performed? Are instruments being used to measure environmental conditions? Are these instruments calibrated? Are they traceable? Are conditions within environmental limits? Does the laboratory have procedures that describe what to do when environmental limits are exceeded? Conclusions reached should take these considerations into account.

Equipment and reference material, clause 8. Technical assessors should examine calibration or test procedures being used including the list of required standards. From this review they can determine if the laboratory has all the standards and ancillary equipment needed. The matter of how equipment is identified, labeled and tracked and how records are kept is part of the management and quality assurance process. The question to consider is whether or not these processes as documented are being complied with?

Measurement traceability and calibration, clause 9. Technical requirements for achieving traceability, control and use of standards and reporting of measurement results are primarily of a technical nature. The technical assessor will need to examine certificates and test reports for technical content. Laboratory record keeping procedures should also be examined to determine if Guide 25 requirements are being complied with. The requirement for equipment to be calibrated before being put into service is more of a quality system requirement. Both technical and quality factors should be considered.

Calibration and test methods, clause 10. Most of these requirements are related to the quality system. They address requirements for procedures that support the actual measurement process. Evidence that these procedures are documented and being complied with will require the attention of all auditors on the team. This work will need to be divided between the assessors so all elements are covered but without duplication.

Handling of calibration and test items, clause 11. These requirements are also related to the quality system. Are there laboratory procedures documented that satisfy these requirements? Select one or two of the processes and make observations to determine compliance.

Records, clause 12. Although there are only two requirements in this clause, record keeping is a very important part of the laboratory's work. It is the historical evidence of the work accomplished by the laboratory and yet, there is a tendency for this to be a weak area. Many times procedures regarding records are not well designed or documented. There also seems to be a natural aversion to recording data for historical purposes and a lack of effort to verify the information recorded is complete and correct. These procedures need to be examined closely to ensure the record system is of reasonable design, addresses all the requirements and that there is evidence the records are complete and correct.

Certificates and reports, clause 13. In reality, this is part of the record keeping process. However, because of the technical nature of these documents concerning traceability, the recording of measured values, environmental conditions and the uncertainty statement, they are unique. They represent a record of the results of a calibration or make a statement about the measured characteristics of a standard. Users of these reports must rely on the information presented in these reports to satisfactorily accomplish their work. As a result there are 21 specific requirements imposed on these documents. It states that these reports must be reported accurately, clearly, unambiguously and objectively. You will need to examine several reports closely to verify all requirements are covered and reported correctly.

Sub-Contracting of calibration or testing, clause 14. This clause relates to a situation where the accredited laboratory providing calibration support to a client and elects to contract with another laboratory to perform some portion of the calibration. This situation might occur when the laboratory's measurement system is not functioning, a laboratory standard is not available, there is a lack of qualified personnel to perform the calibration or test, or the laboratory is overloaded with work. If you find the laboratory enters into such an arrangement, you will need to determine if the laboratory has documented procedures to cover this type of situation. The laboratory must have documented evidence to demonstrate that the laboratory providing these sub-contracted services are competent and comply with the same criteria of competence as the laboratory in respect to the work being sub-contracted and that the client has been advised in writing. The simplest solution for the laboratory is to select an accredited laboratory to provide the

sub-contracted service if at all possible. When it is not possible to use an accredited laboratory, the burden of verifying competence will rest with the laboratory wishing to obtain sub-contracted services.

Outside support services and supplies, clause 15. This clause tends to emphasize supplies and consumables but the words "outside support services" includes arrangements the laboratory has with other laboratories to calibrate or certify the laboratory's reference standards. There must be evidence laboratories providing this level of service are of adequate quality to sustain confidence in the laboratory's calibrations or tests. This requirement may be difficult to achieve because many higher level laboratories have not yet been accredited to the Guide. It will be up to the accrediting agency to clarify and provide guidance on this issue.

Complaints, clause 16. Generally in the past, calibration and testing laboratories have not employed or participated in a complaint system. Many participate in some form of trouble or failure reporting system that relates to non-conformance but not really a complaint system. You will need to determine if the laboratory has a documented complaint system. Does the system cover Guide 25 requirements? How does the laboratory recognize a complaint and how is it documented? How is a complaint processed? Who does the evaluation? How does the laboratory find the root cause? How are complaints cataloged? How is trend analysis accomplished, and what are the reporting requirements to management?

Technical assessment. Depending on the type of calibration or testing involved, the technical assessor may have prearranged with the laboratory to conduct certain calibrations or tests. In other cases, the technical expert may observe scheduled work In progress. Although this work can be very complex, there are basic questions that will need to be answered. Does the laboratory have the necessary laboratory standards and ancillary equipment needed to perform the calibration or test? Is the laboratory environment being controlled and monitored to the extent necessary to perform the measurements or tests? Are laboratory personnel using documented, up-to-date procedures to carry out the process and are the methods and techniques employed consistent with the measurements or tests being made? Is there evidence of measurement traceability? Does the laboratory employ sound technical methods for establishing measurement uncertainty? And, is there evidence laboratory personnel are qualified and technically competent to control the measurement or test process?

Evaluation and Analysis (62)

Throughout the assessment you need to keep the following thought in your mind, is the process being assessed under control? It is just as important to take note of compliance as well as noncompliance. This will be of value when you make your overall summary report .Be sure to quantify your observations.

Progress Meetings (63)

As you and your team members proceed with the assessment it will be important to meet once or twice a day to discuss your progress and to determine if there are any significant problems being encountered. Information exchanged during these meetings will be used as appropriate during daily discussions with laboratory management. As time goes on these meeting must become more focused on areas of weakness or non-compliance. Gradually this information will be refined and clarified and will begin to form the basis for your presentation at the exit briefing and will become a part of the final report.

Compiling Results (64)

You and your team members must meet the challenge of finalizing your report. You must consider all the information and data collected by your team. The team will need to sort through all this information. Set aside any preliminary observations or findings that at this point you collectively feel are not relevant. Identify each deficiency and relate it to a Guide 25 requirement and clearly state why you believe it is a deficiency. There must be compelling, objective evidence to support your claim. If you can not state your claim then you can not call it a deficiency. This is where the technical ability of you and your team members really comes into play. If you have presented a sound argument supported by facts you will find that laboratory management will accept and support your claim.

Each deficiency should be documented separately. Relate each deficiency to the specific Guide 25 requirement and present your argument as to why the laboratory is not satisfying the requirement. Do this for every deficiency. These deficiency reports along with a copy of the completed checklist become the documented results of the on-site visit.

Using the information contained in the checklist along with the deficiency reports, a brief summary report that addresses each of the technical clauses (4 through16) should be developed. In this overall assessment you should take the opportunity to identify how well the laboratory is performing. You may also include comments or suggestions you feel may be beneficial. However, be very careful that these comments or suggestions are not offensive to the laboratory management. Use good judgement whenever you decide to offer suggestion. Do not get into the mode of a consultant, it is counter productive and not considered ethical. This summary report should be complementary and supportive of the efforts of the laboratory to achieve a higher level of performance. You must also state how many deficiencies were found in each area and what corrective action has been decided upon.

The Exit Brief (65)

There are many ways this meeting could be handled. In my experience I have found the following procedure to work well. Be sure you and your team are all present and ready for the briefing. Be sure all the principals are present and ready to receive your briefing.

Make your opening remarks and explain how you plan to present the material. At this point, I find it best to have each team member talk about their part of the assessment and their conclusions. Because these people are considered as technical experts, it is best to let them address technical issues relative to their area of expertise. After the technical areas have been discussed, you should offer laboratory management the opportunity to respond to the briefing and to ask for any clarification. Once these matters have been addressed it will be time to close the meeting.

Final Report (66)

The original report should be signed and dated by both parties and copied in sufficient quantities for all concerned. The report along, with any supporting material, will be forwarded to the accrediting agency along with your recommendations.

PART - 3
(67)LABORATORY PREPARATION

The goal of achieving accreditation is much like the goal of a high jumper wanting to clear the bar at a higher level. There must first be a reason why this new goal is worth achieving and then there must be a commitment to the task. It will take time and practice. New techniques may be needed and there will be failures in the beginning or along the way. Without a goal and strong commitment it will be difficult to successfully compete at this new level of performance.

Explore the Possibilities (68)

Look into the future. Where will your laboratory be in three to five years? Changes are taking place, more companies are considering ISO 9000 certification and laboratories are applying for accreditation to Guide 25. Can you ignore these changes? How competitive will your laboratory be in the future if you do not take action to become accredited? Now is the time to consider your options.

Prepare a Quality Manual (69)

This documentation must reflect the philosophy and culture of your laboratory. Do not try to use an off-the-shelf quality manual. Copies of an outline for a quality manual are available and can be very helpful in formatting your own manual. The reason this is so important is that you and your staff will be expected to comply with the procedures contained in your quality manual and this will be verified during the on-site visit. If you document processes in the way you and your staff accomplish the work then compliance will come naturally.

There is no exact way to prepare a quality manual. It should reflect the way your laboratory operates. It must, however, address every requirement contained in Guide 25 and include or identify where your "how to" procedures are located.

Do not try to re-invent the wheel. Use whatever procedures you have as a starting point. Even if you do not have a procedure, write down how you carry out the activity and then verify it works as you have described the process.

Personnel (Training) (70)

Personnel are the most important element within a laboratory. Without knowledgeable personnel neither a laboratory nor any other organization can function well. The finest laboratory facilities with the best laboratory standard equipment and procedures are not of much value without competent personnel. Without skill and knowledge to make fine music, what good is a musical instrument? The same applies to laboratory instrumentation, what good is it without the skill and knowledge to make good measurements?

Laboratory management personnel must have the training and experience in management and quality assurance systems needed for the effective control over laboratory operations. Laboratory technicians need the skill and training necessary to demonstrate their ability and technical competency to make laboratory measurements.

Keep good training records and try to maintain an active training program for all laboratory personnel.

Knowledge of Measurement Traceability (71)

One of the most important functions performed by a laboratory involves measurement traceability. A laboratory must have documented evidence that measurements made by the laboratory can be traced to a national standard. The laboratory must keep records that can demonstrate that measurement traceability has been achieved. Traceability is a part of the laboratory's record keeping process. I refer to this as a "paper" trace. It documents what laboratory standards were used during the calibration, the date the calibration was performed, identification of the instrument being calibrated or tested, the name of the technician along with all relevant calibration data. I use the term "technical" trace to define the technical data contained on a Certificate or Report of Calibration or test as issued by a higher level laboratory for the laboratory standard used during the calibration or test process. In this case, the technician must be sure the information on the Certificate or Report is complete. The technician must have the technical knowledge to interpret and apply the technical information on the report to the calibration or test process being undertaken.

Measurement Uncertainty (72)

A few years ago we used the term accuracy instead of uncertainty. Measurement uncertainty is an expression of the doubt we have in the quality of the measurement result. Many laboratories have not developed a good understanding of measurement uncertainty. Laboratories that perform calibrations at a level below a standards or secondary laboratory tend to calibrate equipment within a four to one test accuracy ratio. This is an acceptable practice and has been used by laboratories in the military as well as in industry. However, based on the requirements in Guide 25, a laboratory is expected to have sufficient knowledge of measurement uncertainty for the level of calibration being performed. When the on-site assessment is conducted, the technical expert chosen to evaluate the technical competence of your laboratory personnel will expect that these individuals will be able to demonstrate a working knowledge of measurement uncertainty within the level of calibration being performed. There are many training courses now available on the subject of measurement uncertainty. Gaining some knowledge in this area will be necessary for any laboratory pursuing accreditation.

Complaint Process (73)

Recognizing complaints and deciding how to deal with them is part of a quality system. Most laboratories have not developed a functional complaint process. Clause 16 of Guide 25 addresses the need for a complaint system. To be accredited, a laboratory must have a documented procedure for dealing with complaints. If a laboratory is part of a company that provides some product or service, the laboratory may be required to participate in the company complaint system as part of the company quality system. If the primary business of the company is calibration laboratory services, a complaint system will need to be developed.

Record Keeping (74)

This is the essence of the calibration process. A laboratory may calibrate equipment and place labels on the equipment as a quality indicator but the records that document the history of the equipment is vital to the integrity of the equipment. Records contain performance data including the number of times the instrument was received with out of tolerance conditions noted, types of failures, rejections, repair part replacement, and calibration data including a record of traceability. Any laboratory wishing to be accredited must have well documented records and recording keeping procedures. The retention time for records is also important.

Good Housekeeping (75)

The very nature of work accomplished in laboratories makes it important that a housekeeping routine be established and faithfully carried out in a laboratory. It does not take long for workbenches to become cluttered with test leads, accessories, procedures and operation and maintenance manuals, and tools. Remember you can only make a first impression once. How your laboratory and laboratory standards are maintained will have an effect on technical assessors as well as your customers.

Scope of Accreditation (76)

Deciding what areas to be accredited in can be a rather complicated process. You really need to give this much thought. What is your rationale for choosing certain measurement parameters? What are the benefits to be derived? Do you feel confident your laboratory can perform well in the parameters chosen? What will it cost to prepare and how long will it take? These are just of few of the questions you need to answer before you make your application for accreditation.

Dress Rehearsal (77)

Do your own evaluation of your laboratory. Just as they do in the theater, do a dress rehearsal. Find out how well your laboratory can do and identify those areas that need work and take appropriate corrective action before the on-site visit is scheduled. It will be

far better if you can resolve any problems before the visit instead of these problems being formally documented during the on-site.

Make your Application (78)

The subjects discussed in this section should help a laboratory prepare for the accreditation process. **Read and re-read** Guide 25 as you prepare. Be sure you have addressed all the requirements in the Guide. Even if you feel a certain requirement does not apply to your laboratory, address the issue and state why the requirement does not apply. Be sure you **have well documented, "how to" procedures** that tell how your laboratory accomplishes a process in support of each Guide 25 requirement. If you will consider matters such these, you should be ready to submit your application to the accrediting agency

APPENDIX:

TABLES AND DIAGRAMS

The tables and diagrams presented here are referenced in the text of the Handbook. The page number where the subject matter is discussed in the Handbook is identified next to the table of diagram number.

Table 1 (Page 7)
FDIS 17025 Contents

17025	**17025**	**Guide 25**
Section 4 Management requirements	**Section 5 Technical requirements**	**Requirements**
4.1 Organization and management	5.1 General	4. Organization and management
4.2 Quality system	5.2 Personnel	5. Quality systems, audit and review
4.3 Document control	5.3 Accommodations and environmental conditions	6. Personnel
4.4 Review of requests, tenders and contracts	5.4 Testing and calibration methods and method validation	7. Accommodation and environment
4.5 Sub-contracting of tests and calibrations	5.5 Equipment	8. Equipment and reference materials
4.6 Purchasing services and supplies	5.6 Measurement traceability	9. Measurement traceability
4.7 Service to the clients	5.7 Sampling	10. Calibration and test methods
4.8 Complaints	5.8 Handling of test and calibration items	11. Handling of calibration and test items
4.9 Control of nonconforming testing and/or calibration work	5.9 Assuring the quality of test and calibration results	12. Records
4.10 Corrective action	5.10 Reporting the results	13. Certificates and reports
4.11 Preventative action		14. Sub-contracting of calibration and testing
4.12 Control of records		15. Outside support services and supplies
4.13 Internal audits		16. Complaints
4.14 Management reviews		

Table 2 (Page 7)
FDIS 17025 to Guide 25 Comparison

ISO/IEC 17025	ISO/IEC Guide 25
There is no section in 17025 that is equivalent to Section 5.2 in Guide 25.	Section 5.2 a) through s) lists subjects that must be addressed in the quality manual
Annex A is cross referenced to ISO 9001:1994 and ISO 9002:1994	There is no Annex nor any cross reference to ISO 9001 or 2 contained in Guide 15.
Annex B is guidance regarding interpretation of ISO/IEC 17025 for specific applications	There is no Annex nor any interpretation of Guide 25 for specific applications
Bibliography of publications has been included	There is no bibliography contained in Guide 25
Document control has been expanded to three major sections with more "how to" procedures included 4.3.1 defines documents to be controlled 4.3.2 document approval and issue 4.3.3 documentation of changes	Documentation control is a one line entry in Clause 5.1
Section 4.4, Review of request, tender or contract, expanded to a major section with detail as to what is expected 4.4.1 describes process which laboratory must follow 4.4.2 records 4.4.3 subcontracted work 4.4.4 and 5 deviations, contract modifications	Review of new work is the related subject and is a one line entry in Clause 5.2 i)
Section 4.9, Control of nonconforming testing and/or calibration work. Expanded to a major section with detail on: • Policy and procedures required • Evaluation of significance of nonconformance • Remedial actions taken • Client notified, work recalled	A single statement in Clause 5.2 p). "Arrangements for exceptionally permitting departures for documented policies or procedures."
Section 4.10, Corrective action. Presents the concept of cause analysis, identification of potential corrective actions, monitoring the results of corrective actions and special audits • Root cause analysis • Implementation of actions	A single statement in Clause 5.2 o) regarding feedback and corrective action

• Monitoring, additional audits	
ISO/IEC 17025	**ISO/IEC Guide 25**
Section 4.11, Preventative action. Introduces a new concept from ISO 9000. • Proactive versus reaction • Trend analysis • Risk assessment • Opportunities for improvement • Action plans • Assessment of effectiveness	The subject of Preventative action is not addressed
Section 4.12, Records. Adds requirement to identify and properly retain quality records as well as technical records as required by Guide 25 • Procedures required • Security • Backup	Clause 12, Records is focused mostly on calibration and test records and that they must be stored, held secure and in confidence to the client
Section 5. Technical requirements. Not significantly different from Guide 25 • Separates testing from calibration laboratories in areas of traceability and reporting requirements	No significant comment.
Section 5.2, Personnel. Expanded to 5 paragraphs with more detail in • Management responsibilities • Policies and procedures to identify training needs • Supervision of staff undergoing training	Clause 6, Personnel states that a laboratory must have sufficient personnel with, education, training, technical knowledge and experience. Ensure that training is kept up to date and records shall be maintained
Section 5.4, Test and calibration methods and method validation. Adds sampling but is not significantly different from Guide 25 requirements. Detail on validation of test methods, and estimation of measurement uncertainty is also provided. • Testing laboratories are expected to be able to estimate uncertainty when appropriate	Calibration and test methods, Clause 10 is fairly comprehensive and is addressed within eight sub-paragraphs.

ISO/IEC 17025	ISO/IEC Guide 25
Section 5.6, Measurement traceability. • Requires an established program of calibration for test and measurement equipment • Requires testing and calibration laboratories to be traceable to SI, intrinsic standards related to SI, certified reference materials, or consensus standards • Interlaboratory comparisons if possible	Measurement traceability and calibration, Clause 9 is fairly comprehensive and covers the subject in seven sub-paragraphs.
Section 5.7, Sampling. A new section which requires a sampling plan and documentation of results • Applies when sampling is done prior to testing of calibration • Proper statistical methods must be used • Procedures for generation/maintenance of records	Sampling, brief statement in Clause 10.5 contains a brief statement concerning sampling.
Section 5.9, Assuring the quality of test and calibration results. A new section based on the section in ANSI/NCSL Z 540-1 (5.6a through e) that speaks of ways to ensure quality of measurement	Ensuring the quality of results provided. Addressed in Clause 5.6
Section 5.10, Reporting the results. • Separates testing and calibration • Adds sampling, opinions and interpretations. Not significantly different from Guide 25 plus ANSI/NCSL Z 540 additions in the areas of traceability and uncertainty • Basis for opinions and interpretations must be documented and clearly identifiable in the test report	Clause 13, Certificates and reports is very detailed concerning the information that must be on a Certificate of Report of calibration

Table 3 (Page 15)

A-Planning: 1. Receive offer 2. Estimate effort 3. Make bid 4. Receive award	**C-On-Site Visit:** 8. Schedule on-site 9. Entrance meeting 10. Conduct assessment
B-Familiarization: 5. Document review ***6 .Issue report*** 7. Receive response	**D-Conclusions and Reports:** 11. Exit brief ***12. Final report***