GUIDELINES ON TRAINING COURSE FOR ASSESSORS

PURPOSE

This document provides guidance to APLAC members on the suggested content of a training course for lead assessors of laboratories. The objectives of the course are set out on page 4.

AUTHORSHIP

This publication has been written by the APLAC Training Committee.

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FURTHER INFORMATION

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CONTENTS

1. INTRODUCTION

1.1 The competence of assessors underpins the credibility of a laboratory accreditation scheme. It is thus essential that laboratory assessors, in addition to possessing the required professional knowledge and experience, are adequately trained in the accreditation criteria and assessment techniques. The purpose of this document is to provide a detailed syllabus for training of laboratory assessors. It describes the topics considered to be essential to laboratory assessor training courses.

1.2 The main objective of a laboratory assessor training course is to train assessors to perform laboratory assessments in accordance with the requirements of ISO/IEC Guide 58 and using ISO/IEC 17025 as criteria. At the end of this training course, successful participants will be able to:

(a) identify the principles and techniques of assessment, and apply this acquired knowledge in the conduct of assessments;

(b) identify the management requirements of ISO/IEC 17025, and apply these requirements to the assessment of management systems in testing and calibration laboratories;

(c) identify the general technical requirements of ISO/IEC 17025, and apply these requirements to the assessment of the technical competence of testing and calibration laboratories within their area of professional technical expertise; and

(d) plan, organise and conduct assessments of laboratories against these requirements in accordance with the procedures of the local laboratory accreditation body.

1.3 In order to achieve this objective, assessors should be familiar with the following:

(a) Meaning of laboratory accreditation;

(b) International dimension of laboratory accreditation;

(c) Accreditation criteria and their interpretations;

(d) Accreditation body operation and regulations;

(e) Accreditation process and assessment techniques;

1.4 The programme detailed below generally follows the guidelines given in ILAC-G3: *1994 Guidelines for Training Courses for Assessors Used by Laboratory Accreditation Schemes*.

1.5 Successful completion of this course should be regarded as meeting the training requirement of lead assessors as specified in ILAC-G11:1998 *ILAC Guidelines on Assessor Qualification and Competence*. However, in order to be qualified as a lead assessor, other criteria given in ILAC-G11 have to be fulfilled such as assessment experience, education and professional qualifications.

2. TIME ALLOCATION

2.1 The total duration of the course should be 40 hours spread over 5 or 5 1/2 days. Course time is allotted according to the following schedule.

Topics	Time allotted, hours
Introduction to course arrangements and introduction of participants and tutors	1
Introduction to laboratory accreditation and international dimension of laboratory accreditation	2
Accreditation criteria and their interpretations – management requirements	4
Accreditation criteria and their interpretations – technical requirements	12
Accreditation body operation and regulations	2
Accreditation process	8
Assessment techniques and people skills	8
Written examination	3
Total	**40**

2.2 The course may be split into several courses but the whole syllabus should be covered and the time allotted to each topic should be in reasonable agreement with the time specified in the above table.

3. EVALUATION OF PERFORMANCE OF PARTICIPANTS

3.1 The performance of each participant should be evaluated. The evaluation is normally done by continuous monitoring and a written examination. The body providing the course should have procedures for the evaluation of the performance of participants. Marking schemes and procedures for the written examination should be available.

3.2 It is expected that participants should obtain a satisfactory overall score before they could be regarded as having successfully completed the course. An example of the structure of a suitable examination is given in Annex VI.

4. NUMBER OF PARTICIPANTS

In order to provide sufficient opportunities for the participants to be involved in the discussions and allow effective evaluation of the performance of the participants, the number of participants should preferably be about 20.

5. EXERCISES

Some examples of class exercises are also included in Annexes II to V. The body providing the training could use these examples to design its own training course materials. It is however recognised that, due to cultural differences, the class exercises may have to be amended to suit the local culture.

6. DETAILS OF COURSE CONTENTS

6.1 Introduction to Laboratory Accreditation

The following topics should be covered:

(a) Definition of laboratory accreditation (according to ISO/IEC Guide 2): a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Differences between certification and accreditation should be highlighted, e.g. certification is the procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements. Information given in ILAC-I2 *Testing, Quality Assurance, Certification and Accreditation* should be mentioned.

(b) Who grants accreditation, i.e. what is an accreditation body? Third party who has the authority, i.e. governments, non-government professional institutions, specific legislation conferring the authority to the accreditation body, etc. The international standard for the operation of an accreditation body, i.e. ISO/IEC Guide 58, should be mentioned here.

(c) According to this definition, what are the requirements for accreditation? Depending on the purpose of accreditation, they may be based on published criteria such as OECD Principles of GLP, ISO/IEC 17025 or set out in specific pieces of legislation, etc. Basic quality control and assurance concepts should be mentioned.

(d) Who are the stakeholders of accreditation bodies? The laboratories and their clients, the regulatory authorities, manufacturers, buyers, etc. What are their needs and how to satisfy these needs? Types of laboratory – testing, calibration, R&D laboratories, and 1st, 2nd and 3rd party laboratories. Legal status of laboratories and relationship between laboratories and accreditation bodies should be discussed.

(e) ILAC-G11:1998 ILAC *Guidelines on Assessor Qualification and Competence* should be explained. The role of an assessor is to assess the laboratory's conformance to ISO/IEC 17025. The key tasks of assessors are the evaluation of staff competence, technical validity of methods, equipment, accommodation, materials, test results, etc. Accreditation requirements should be interpreted based on satisfying the needs of the stakeholders.

(f) The benefits of accreditation should be explained, e.g. acceptance of reports, declaration of conformance to international standard, fulfilment of legislation requirements, etc.

6.2 International Dimension of Laboratory Accreditation

The following topics should be covered:

(a) ISO/CASCO : what it is and how it works.

(b) World Trade Organisation and Agreement on Technical Barriers to Trade (TBT). How laboratory accreditation can facilitate free trade. The information given in ILAC-I3 *The Role of Testing and Laboratory Accreditation in International Trade* should be mentioned here.

(c) International development of laboratory accreditation : past, present and future. Co-operation of laboratory accreditation bodies : ILAC, APLAC, IAAC, EA, etc. Harmonisation of assessment procedures. Introduction of ISO/IEC Guide 58 and ILAC-S2 ILAC *Rules* should be mentioned here.

(d) Who accredits the accreditors? Peer evaluations and MRAs. ILAC-G1 *Guidelines for Establishment and Review of Mutual Recognition Agreements* and APLAC MR001 *Procedures for Establishing and Maintaining Mutual Recognition Agreements Amongst Accreditation Bodies* should be mentioned here. The frameworks of APLAC multilateral MRA and the ILAC global Arrangement should also be given.

6.3 Accreditation Criteria and Their Interpretations

6.3.1 This part deals mainly with the requirements stipulated in ISO/IEC 17025. It should start with a general introduction to the history of the development of ISO/IEC 17025 – from ISO/IEC Guide 25 to ISO/IEC 17025 followed by an overall view of the standard. Then discussion should go into the detailed requirements. ISO/IEC 17025 should be explained clause by clause with special emphasis placed on the interpretations and amplifications of the requirements by ILAC/APLAC as given in various ILAC and APLAC publications such as

- ILAC Guidance to the application of ISO/IEC 17025
- ILAC-G2 Traceability of Measurements
- ILAC-G5 Guidelines for Calibration and Maintenance of Test and Measuring Equipment

and other relevant APLAC documents.

6.3.2 Each of the following clauses of ISO/IEC 17025 should be explained in detail with illustrative examples and exercises where necessary.

(a) Management requirements

. Organisation
. Quality system
. Document control
. Review of requests, tenders and contracts
. Subcontracting of tests and calibrations
. Purchasing services and supplies
. Service to the client
. Complaints
. Control of non-conforming testing and/or calibration work
. Corrective action
. Preventive action

. Control of records
. Internal audits
. Management reviews

(b) Technical requirements

. General
. Personnel
. Accommodation and environmental conditions
. Test and calibration methods and method validation
. Equipment
. Measurement traceability
. Sampling
. Handling of test and calibration items
. Assuring the quality of test and calibration results
. Reporting the results

6.3.3 Selections of the following exercises should be given:

(a) Exercises on "Assessment of Quality Manual" should be given. Findings to be presented by one member from each group. A quality manual should be studied individually by each group member. The exercises should include requirements regarding document control, contract review, corrective and preventive actions, subcontracting, control of non-conforming testing and/or calibration work, control of records, internal audits and management reviews, etc. Non-compliance as well as compliance with the requirements of ISO/IEC 17025 should be included in the "Quality Manual" and attendees should be required to identify to which clauses of ISO/IEC 17025 they relate. An example of this exercise is given in Annex II.

(b) Individual exercises on the identification of non-compliance as well as classification of observations to non-compliance and recommendation using fictitious scenarios. The exercises should include such requirements as measurement traceability, measurement uncertainty, opinions on reports, method validation, etc. Examples of such exercises are given in Annexes III and IV.

(c) An exercise on deciding the acceptability of calibration certificates. See the example in Annex IV.

6.3.4 Special emphasis should be given to the following aspects:

(a) *Quality system model*, i.e. clause 4 Management Requirements of ISO/IEC 17025. Cross references to ISO 9001/2 should be given here. Differences between certification and accreditation should be reiterated. The importance of and requirement for a quality manual should be given. A specimen of a typical quality manual should be used as a means to illustrate various requirements.

(b) *Measurement Traceability* : an explanation should be given of the definition, means to achieve traceability, concept of metrological quality, international standards of measurements, transfer standards, reference standards and reference materials. The importance of equipment calibration and traceability of calibration

to international standard of measurements/SI units should be emphasized. APLAC-EA Policy on Traceability of Measurements or the ILAC Policy on Traceability of Measurement should be explained.

(c) *Measurement Uncertainty* : an introduction to ISO Guide to Expression of Uncertainty in Measurement should be given here. ILAC-G8 *Guidelines on assessment and reporting of compliance with specification* should be mentioned here. A brief introduction to EURACHEM/CITAC Guide *Quantifying Uncertainty in Analytical Measurement* should be given.

(d) *Method validation* : the different requirements for standard and non-standard methods should be highlighted. A brief discussion of EURACHEM Guide *The Fitness for Purpose of Analytical Methods – A Laboratory Guide to Method Validation and Related Topics* should be held.

(e) *Opinions and interpretations* : the accreditation body's policy on the accreditation of professional judgement should be given. The extent to which an accreditation body covers professional judgement should be explained, e.g. predictive opinions versus opinions based on objective facts, etc.

(f) The concept of "fitness for purpose" rather than "pursuit of perfection" should be stressed. Emphasis should be given to the fact that quality assurance is always a balance of risk, cost and technical possibilities.

(g) The focus of assessment as assessment of competence rather than just compliance with standard should be stressed, particularly for technical aspects.

6.3.5 Specific criteria of the accreditation body for the interpretations and amplifications of the ISO/IEC 17025 requirements should be referred to and explained.

6.4 Accreditation Body Operation and Regulations

6.4.1 This part provides a detailed description of the accreditation body's operation, structure and regulations. A brief description of the procedure for accreditation should be given here. Emphasis should be placed on the following aspects:

(a) The structure, operation and regulations of the accreditation body should be explained. Rules and structures of various committees should be given.

(b) Legal liability of assessors : Information given in ILAC-11: 1994 *Legal Liability in Testing* should be briefly mentioned.

(c) Regulations governing the use of the accreditation body mark including requirements for test reports/certificates bearing the accreditation body mark should be explained. Recommendations given in ILAC-G14 *Guidelines for the Use of Accreditation Body Logos and for Claims of Accreditation Status* should also be

explained. Examples of uses and abuses of accreditation marks/status should be given.

(d) Rules for granting, maintaining, extending, reducing, suspending and withdrawing accreditation: Requirements and recommendations given in ISO/IEC Guide 58 and ILAC-G10 *Harmonised Procedures for Surveillance and Reassessment of Accredited Laboratories* should be explained.

(e) Proficiency testing: The importance of and requirement for participation in suitable proficiency testing activities should be explained. An outline if ISO/IEC Guides 43-1 and 43-2 should be given. Actions taken by the laboratories and accreditation bodies in cases of unsatisfactory performance in proficiency testing programmes should be described.

6.4.2 Syndicate exercises on the abuse of accreditation marks/status should be given. Cases of abuse should be studied by the members. Discussions should be held and comments from the floor should be invited after presentations given by each syndicate.

6.5 Accreditation Process and Assessment Techniques

6.5.1 Accreditation process

Clause 6 of ISO/IEC Guide 58 should be explained, i.e. application for accreditation, assessment, assessment report, decision on accreditation and granting of accreditation. Then details of the assessment procedure should be given, including:

(a) Application; appointment of lead assessor

(b) Examination of quality manual and scope of accreditation

(c) Preliminary reports to laboratory

(d) Pre-assessment visits and reports

(e) Composition, selection and appointment of assessment team

(f) Preparation for assessment, e.g. briefing notes

(g) Conduct of assessments : opening meeting, examination of records, observation of laboratory practices, interviews of laboratory staff, recording of findings, exit meeting, and reporting of findings.

(h) Post-assessment activities : evaluation of corrective actions by documentation review, follow-up visits; notification of granting/reaffirmation/extension of accreditation, and terms for accreditation.

6.5.2 Assessment techniques

Different techniques for each of the above assessment steps should be given. The discussions should cover the following topics:

(a) factors to be considered when selecting assessors

(b) information to be included in briefing notes

(c) review of documentation

(d) pre-assessment meeting of assessors

(e) sharing of responsibility of amongst assessors

(f) techniques, and items to be covered in opening and exit meetings

(g) items to be examined for evaluating compliance with ISO/IEC 17025

(h) use of vertical and horizontal audit techniques

(i) techniques for recording of findings : use of accreditation body checklists and record forms

(j) classification of findings/observations as non-compliance/s and recommendation/s

6.5.3 People skills

(a) questioning and communication techniques for assessments

(b) attributes of a good assessor : reference to ISO 10011-1, -2 and -3 (and ISO/CD.1 19011 Guidelines on Quality and Environmental Auditing)

(c) human aspects of assessment, and interpersonal skills

(d) personality types

(e) learning preferences

(f) leadership skills

6.5.4 Selections of the following exercises should be given:

(a) Exercises on describing findings in writing and classifying them as observations or non-comformities. The adequacy of evidence should be discussed. Examples of the exercises are given in Annex V.

(b) Syndicate exercises on dummy assessments based on a fictitious scenario. The exercises should include at least two parts. The first part provides an opportunity for the participants to practise assessment techniques, i.e. questioning and listening techniques and other information gathering techniques. Techniques to avoid

escalation of conflict should be included in this part. The second part provides an opportunity to practise the techniques for recording and reporting assessment findings.

(c) A syndicate exercise on scope of accreditation – fictitious observations to be used to illustrate the point of irrelevant findings outside the scope of accreditation.

(d) Role-plays on signatory interviews, entry and exit interviews. Participants should be divided into three groups – the first and second groups act as the laboratory personnel and the assessment team respectively. The third group is asked to give comments on the performance of the roles. The findings for the dummy assessments can be used in this exercise. Agreement on scope of accreditation should be included as one of the items to be covered.

7. ACKNOWLEDGEMENTS

Exercises and an example of the structure of an examination given in the Annexes II to VI are kindly contributed by A2LA, IANZ and NATA.

ANNEX I

ILAC GUIDANCE DOCUMENTS

The following is a list of ILAC guidance documents that contain useful information on laboratory assessment and accreditation. References should be made to these documents when preparing training courses.

ILAC G1: 1994	*Guidelines for the Establishment and Review of Mutual Recognition Agreements*
ILAC G2: 1994	*Traceability of Measurements*
ILAC G3: 1994	*Guidelines for Training Courses for Assessors*
ILAC G4: 1994	*Guidelines on Scopes of Accreditation*
ILAC G5: 1994	*Calibration and Maintenance of Test and Measuring Equipment*
ILAC G6: 1994	*Guidance under ISO/IEC Guide 25 for Laboratories Performing Sampling*
ILAC G7: 1994	*Accreditation Requirements and Operating Criteria for Horseracing Laboratories*
ILAC G8: 1996	*Guidelines on Assessment and Reporting of Compliance with Specification*
ILAC G9: 1996	*Guidelines for the Selection and Use of Certified Reference Materials*
ILAC G10: 1996	*Harmonised Procedures for Surveillance & Reassessment of Accredited Laboratories*
ILAC G11: 1998	*Guidelines on Assessor Qualification and Competence*
ILAC G12: 2000	*Guidelines for the Requirements for the Competence of Reference Materials Producers*
ILAC G13: 2000	*Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes*
ILAC G14: 2000	*Guidelines for the Use of Accreditation Body Logos and for Claims of Accreditation Status*
ILAC Guidance Document	*Guidance for Accreditation to ISO/IEC 17025*
ILAC I1:1994	*Legal Liability in Testing*
ILAC I2:1994	*Testing, Quality Assurance, Certification and Accreditation*
ILAC I3: 1996	*The Role of Testing and Accreditation in International Trade*
ILAC-S2: 1998	*Rules*

ANNEX II

QUALITY MANUAL REVIEW EXERCISE

Purpose:

To give students practical experience in reviewing a quality manual against ISO/IEC 17025.

Instructions:

Each group of approximately five students should review the quality against the criteria as found in ISO/IEC 17025. Each group should prepare a checklist covering each major section of ISO/IEC 17025 (Section 4, section 5, etc.), and the corresponding area in which the quality manual addresses the requirements as found in 4.2. After completion of the exercise, each group will be assigned several major sections on which to present their findings to the class. Each group will choose a presenter, and then write their findings on an overhead transparency. The presenter will be allotted ten minutes to address the findings of the group.

Goals:

Gauge public speaking skills
Practical knowledge in quality manual review
Understand the different ways that a quality manual may be constructed and still meet the requirements

General time allotted:

2.0 hours to review manual
0.5 hours to prepare presentations
0.5 hours to present findings

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TopNotch Quality Manual

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QUALITY POLICY

1.1. Topnotch Laboratory, its management and employees, shall provide testing and calibration services that:

1.1.1. Conform to customers' legitimate needs, requirements, and intended use;

1.1.2. Are consistent with the highest level of service and quality in the industry;

1.1.3. Comply with applicable government standards and regulations;

1.1.4. Are in accordance with current laboratory accreditation standards; and

1.1.5. Are in accordance with this quality manual and all supporting documentation.

Signed

Albert Alpha
Topnotch Vice President
Date:

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CONTRACT REVIEW

2. The Vice-president is responsible for coordinating a comprehensive testing plan for all work performed on behalf of clients

2.1. The Vice-president shall review all incoming orders to determine that:

2.2. The laboratory has the technical skills to perform the work

2.3. The laboratory has all necessary equipment, supplies and staff to perform the work

2.4. The client has fully specified the testing to be performed, and that this testing is appropriate for the samples received

2.5. If the laboratory has full capabilities to perform the work, the Vice-President shall sign the Incoming Test Sample form (Form 219) to indicate that the review has been performed.

2.6. This form shall be placed in the Traveler folder that accompanies each item through its life in the lab.

2.7. If the laboratory does not have the capability to perform the testing, whether due to technical difficulty, or lack of staff or equipment, the Vice-President shall notify the client. A record of the notification shall also be placed in the Traveler folder.

2.8. Should the Vice-President decide to subcontract the work, the work shall only be placed with accredited facilities. A record of the certificate and scope of accreditation for each subcontractor shall be available in the purchasing department.

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OVERVIEW AND MAINTENANCE OF QUALITY DOCUMENTATION

3. This "TopNotch Quality Manual" is maintained up to date under the responsibility of the technical manager.

3.1. The Vice President shall approve all revisions to this manual

3.2. All documentation, including this manual shall be controlled and shall not be reproduced without the written approval of the quality manager. Any reproductions shall follow the issuance procedure as listed below in section 2.8.

3.3. The quality manager maintains a database of all controlled documents, including personnel responsible for approval.

3.4. All updates and additions to the quality documentation shall be issued under the format described in LP4.3.

3.5. In the case that an update requires the quality manual or any other related manual to be repaginated, those repaginated pages with no other substantive changes shall be reproduced in the master copies of the manuals only. There will be no re-issue or revision numbers change to these pages.

3.6. Prior to issuance, the appropriate personnel must approve all pages of documents.

3.7. Upon issue, the document control database is updated to include:

3.7.1. Person receiving the issue

3.7.2. Document Control No.

3.7.3. Title of document

3.7.4. Revision No.

3.7.5. Revision Date

3.8. When a document is revised, the quality manager shall consult the document control database, and print a listing of all current holders of this document.

3.9. The quality manager shall ensure that all obsolete documents and copies of these documents are removed from the work premises.

3.10. One copy of each obsolete document shall be marked to preclude its use, and stored for a period of five years

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STAFF RESPONSIBILITIES

4. The President of the Laboratory is ultimately responsible for the quality of all laboratory-testing services. She obtains the financial resources needed.

4.1. The Vice President shall be responsible for planning and organizing the technical resources necessary to provide quality testing and calibration services including the coordination of a comprehensive quality program for all section functions from testing of samples to transmission of reports to Topnotch customers (See section 14: Contracts). The Vice President shall possess sufficient organizational freedom and authority to carry out this task. For the purposes of this manual, the Vice-President is designated as the Quality Manager. The Vice-President shall

4.2. The Physicist shall approve all mechanical and non-destructive test procedures, and serves as the Technical Manager for the non-destructive test methods.

4.3. The Metrologist shall approve all external and internal calibration procedures, and serves as the Technical Manager of the calibration test methods.

4.4. The Metallurgist shall approve all metallurgical procedures, and serves as the technical manager for the metallurgical test methods.

4.5. The Lab Supervisor shall instruct all Technicians to follow applicable policies, procedures, and work instructions relevant to their area of work.

4.6. The Technicians shall do as instructed.

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STAFF SELECTION

5. TopNotch Laboratory management shall ensure that staff is properly recruited, selected, trained, and encouraged to continually improve their performance to meet both professional and laboratory goals and objectives.

5.1. Staff selection shall be based upon defined prerequisites and qualifications for carrying out each job. Selection shall be made on the basis of the applicant who has the best combination of qualifications, skills, seniority, demonstrated ability, work record and potential to carry out the particular job. A job description shall be documented for each position of the laboratory. These position descriptions are kept in the Position Description manual held by the personnel department.

5.2. Staff selection shall be based upon defined prerequisites and qualifications for carrying out each job. Selection shall be made on the basis of the applicant who has the best combination of qualifications, skills, seniority, demonstrated ability, work record and potential to carry out the particular job. A job description shall be documented for each position of the laboratory. These position descriptions are kept in the Position Description manual held by the personnel department.

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STAFF TRAINING

6. The purpose of training is to identify, familiarize and attain proficiency against the defined policies and procedures relevant to each job. All employees shall read and understand the relevant sections of this manual and related documented quality policies and procedures. For the Technicians, this includes the sample flow, Methods Manual, and in-place data recording and reporting.

6.1. The training mechanism and policy introduction shall be the responsibility of the Lab Supervisor after general orientation of policies by the Administrative Assistant.

6.2. The Lab Supervisor shall train employees in their charge primarily through informal apprenticeship as follows:

6.2.1. A general orientation and familiarization with facility layout, equipment identification, location and use.

6.2.2. Introduction to in-place forms, worksheets, and reporting procedures.

6.2.3. Method identification and procedures introduction.

6.2.4. General philosophy including levels of uncertainty to be achieved.

6.3. The Lab Supervisor shall record completion of a probationary period (usually 90 days) evaluating and rating employee progress in attaining proficiency for each job task/test assigned. The record shall include dates when proficiency to perform tasks/tests without direct supervision or oversight is established.

6.4. Assuming the selection process succeeded in obtaining employees with the requisite technical knowledge and background, training shall concentrate on familiarizing the employees with laboratory-developed written and oral procedures and reporting protocols.

6.5. Performance appraisals shall be held after the first 90 days for new employees and annually thereafter. The emphasis of such appraisals is on identification of further training needs, employee improvement, and resolution of shortcomings or misunderstandings between performance objectives and actual performance.

6.6. All training procedures on technical operation of the laboratory shall be consistent with applicable standard methodology as defined in but not limited to:

6.6.1. ASTM, ASME, SAE, and ISO standards

6.6.2. Customer generated standards and specifications

6.6.3. Equipment supplier recommended methods

6.6.4. Published and acceptable scientific literature sources

6.6.5. TopNotch Laboratory defined or standardized procedures and methods

6.7. When appropriate, employees are encouraged to participate in offsite training through professional seminars, equipment and software user training programs, as well as college credit courses.

6.8. A record of all training is shall be maintained by the personnel department.

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EQUIPMENT

7. The Metrologist maintains a list of all equipment.

7.1. Equipment shall be appropriately controlled with labels indicating serial number, file reference, and calibration status.

7.2. Defective equipment shall be labelled as such with a red tag. Do not use defective or uncalibrated equipment without permission of the Lab Supervisor.

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CALIBRATION

8. The frequencies specified in the tables maintained in the Calibration and Maintenance Manual by the Metrologist are minimums for equipment in continual use. Equipment or ranges not used during the specified verification intervals need not be verified until before the next time used. Equipment used often must be verified at the designated intervals. Equipment seldom used may be calibrated or verified at intervals longer than stated, only upon permission of the Lab Supervisor. Such deviations must be recorded and explained and the equipment shall be so identified and tagged.

8.1. Calibration frequency intervals are subject to adjustment depending upon historical performance. If changes greater than three sigma are noted at current calibration frequency intervals, then the intervals shall be shortened to maintain in-tolerance requirements.

8.2. Measuring equipment and reference standards used for calibration shall be more accurate than the test equipment or instrument being calibrated and have documented and authenticated traceability to the appropriate National Institute of Standards and Technology (NIST) standards or other acceptable national or international standards. Procedures outlining the proper selection and use of reference standards for all measuring equipment can be found in the Calibration and Maintenance Manual.

8.3. A label or tag shall be affixed to each piece of equipment or equipment container or holder as practical. Each label or tag shall include the following information:

8.3.1. Identification number and name;

8.3.2. Date of last calibration;

8.3.3. Due date of next calibration;

8.3.4. Initials/name of calibrating personnel or calibration service firm.

8.4. Equipment or ranges not conforming to minimum accuracy requirements (as specified in the calibration table) shall be taken out of service and so labelled until a recalibration shows satisfactory operation.

8.5. All equipment calibration and operational in-house checks shall follow procedures. All equipment calibrated by an outside service shall be required to provide adequate documentation of the calibration status of the equipment before and after service, with reference data authenticating traceability to NIST standards as applicable.

8.6. New equipment shall be calibrated before use. Modified or repaired equipment shall be verified for calibration over the operational or use range and recalibrated if necessary.

8.7. All calibrations and verification protocols shall be performed using methods and standards defined by applicable national and international standards bodies such as ASTM, ISO, etc. or by acceptable vendor methodology with traceability to NIST standards.

8.8. All procedures shall be strictly followed with no variation unless so authorized by the Lab Supervisor.

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TEST & CALIBRATION PROCEDURES

9. All tests and calibrations shall be performed strictly in accordance with the Methods Manual (number 6).

9.1. The Methods Manual is kept in the lab area.

9.2. The Lab Supervisor shall ensure that it is up to date and that obsolete copies are removed from use.

9.3. The Metrologist, Metallurgist and Physicist shall approve all methods within their respective areas and approve all deviations.

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SAMPLE HANDLING

10. Samples are received by the Lab Supervisor who assigns a Technician as lead analyst for the test or calibration.

10.1. Samples are uniquely numbered using the date "960501-001" "960501-002", etc.

10.2. The login computer generates the ID, which gets affixed to the sample.

10.3. Samples are prepared according to the method in the Methods Manual (number 6).

10.4. When a customer requests a procedure for which there is no method in the Methods Manual, it is up to the Lab Supervisor whether or not to handle the work and create a new or "non-standard" method. The Lab Supervisor shall consult the professional in charge of the technology involved. A record shall be maintained of non-standard tests performed.

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SUPPORT AND SUPPLIES

11. The Purchasing Manual (number 16) contains procedures to be used when requesting, ordering and receiving supplies.

11.1. The purchasing department maintains a list of all approved suppliers, and a record of their investigation of the suppliers' quality.

11.2. Only approved suppliers are to be used for the purchase of materials in the laboratories.

Revision Date: 4/1/96 Prepared By:

Revision No: 3 Approved By:

HANDLING COMPLAINTS

12. Complaints are defined as any situation that casts doubt on the laboratory's compliance with its own documented policies or procedures.

12.1. Any personnel my record a complaint from a client or any other source, using the Complaint Database system.

12.2. The complaint database record shall contain:

12.2.1. Name and address of complainant (when available);

12.2.2. Substance of complaint;

12.2.3. Date of complaint.

12.3. The quality manager shall review all entries into the complaint database, and assign the appropriate person to address the complaint. The assignment shall be entered into the database.

12.4. The assigned personnel shall investigate the complaint, and shall enter all pertinent information into the database.

12.5. The area of complaint shall be audited in accordance with section 12 of this manual, and all information shall be entered into the database.

12.6. A complaint is not resolved until full investigation is complete, and either:

12.6.1. Corrective action has been verified; or

12.6.2. Complaint has been deemed invalid when evaluated against the quality system.

12.7. The quality manager shall enter resolution date and all details of the resolution into the database only.

12.8. If the complaint concerns test data for clients, the quality manager shall ensure that:

12.8.1. The effect of the complaint is evaluated to determine whether it casts doubt on the correctness or validity of the test data;

12.8.2. The client is contacted immediately should the test data be affected. A record of the contact shall be maintained in the Traveler file;

12.8.3. All other testing of the same nature is halted until the root cause of the failure is identified; and

12.8.4. Any other affected clients are notified.

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INTERNAL AUDITS

13. The Vice President shall be responsible for arranging audits carried out by an audit team from an outside agency, or by trained in-house personnel independent of the areas to be audited.

13.1. The audit team shall use the applicable quality system checklist as a guide to performing the audit and use this manual and related quality system documentation to establish the criteria for determining the degree of conformance to quality manual requirements.

13.2. The steps to be followed in performing an internal audit are:

13.2.1. Notification of audit dates to all involved

13.2.2. Entry briefing to management of each area to be audited

13.2.3. Performance of the audit: interview staff, examine records, complete applicable checklists, draft a report, etc.

13.2.4. Exit briefing summarizing findings;

13.2.5. Follow up to determine if deficiencies identified during the audit are corrected.

13.3. The Vice President shall be responsible for initiating and documenting any "Corrective Action Requests" made necessary as a result of the audit.

13.4. Top management shall review the results of all audits so that any needed changes to the quality system can be recognized and adopted expeditiously.

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MANAGEMENT REVIEWS

14. The Vice President shall be responsible for convening management reviews with, at a minimum, the Lab Supervisor and Administrative Assistant serving as recording secretary.

14.1. This management team shall consider results of audits, complaints, preventive action requests, and opportunities to expand business and other factors in doing reviews.

14.2. The Vice President shall be responsible for initiating and documenting any "Action Requests" made necessary as a result of the review.

14.3. All staff are encouraged to submit Form 309 Preventive Action Request whenever they discover an area where an improvement to the system can be made to prevent errors form occurring.

ANNEX III

EXERCISES ON ISO/IEC 17025 REQUIREMENTS

ISO 17025 Scenarios:

Each of the scenarios represents what an assessor might see at a laboratory during an assessment. The job of the attendees is to relate each scenario to a specific clause or sub-clause in the standard (for example, if the scenario represents a situation about retention of obsolete documents for knowledge preservation purposes, the correct response would be found in 4.3).

In groups of two, the students will address each scenario by finding the closest relation in the standard. In many cases more than one answer may be correct. The students should identify one clause that most specifically addresses the scenario, and then, time permitting, find one or two others. The students should not go to extremes.

Goals of exercise:

Ensure students familiarize themselves with the clauses in the standard
Give students practical examples on how the standard relates to laboratory situations
Prepare the groundwork for writing deficiencies

General time allotted for exercise:

Students working in groups: 1 hour
Instructor-student review of exercise: 1 hour

Group Exercise

ISO/IEC 17025 APPLIED

It is not enough to merely know what ISO/IEC 17025 says. The real test for anyone with responsibility for assessing a laboratory is to be able to apply the clauses to real life situations.

In the pages that follow, are listed 30 brief scenarios, based on real life situations. You should now go through these scenarios and identify directly along side each scenario the clauses in ISO/IEC 17025 that you think would apply to the situation described. In doing this, please keep in mind that:

a. You should only identify the clauses in ISO/IEC 17025 which apply to the situations, not the deficiencies.

b. In many of the scenarios, more than one clause may apply. Try to identify the important clauses without going to extremes.

Scenario	Clause(s)
1. When questioned about training records, the laboratory manager replied that the company's procedure required that the Personnel Department hold all training records.	
2. Because of the nature of its work, many of the test methods in use in the laboratory had been developed in-house from methods published in technical journals. Records of the development and validation of these test methods were maintained in the laboratory's technical library.	
3. The laboratory manager claimed that it was unrealistic to require a documented procedure for handling customer complaints: in his words "Every complaint is different and anyway, on the rare occasions when one of our customers does question a result, I always investigate the matter personally".	
4. The laboratory's internal audit procedures required each section leader to conduct a partial audit of another section of the laboratory every month. The audit schedule ensured that a different element of the quality system was addressed on each occasion.	
5. In the scenario immediately above, the results of each audit were summarized by the Quality Manager and placed on the agenda for discussion at the monthly meetings of the laboratory's management.	
6. During an assessment, the laboratory manager acknowledged that sensors in an automated testing machine were suffering from an intermittent fault: until the problem was fixed, all testing personnel had been warned to watch carefully for any anomalous readings obtained during these tests.	

Scenario		Clause(s)
7.	The laboratory has developed a set of procedures intended to initiate a preventive action, but these procedures seem to only address problems after they occur.	
8.	During the audit, the assessor observed that there were several outdated copies of procedures stored in the laboratory. These procedures contained no evident mark to signify that they were outdated copies. When questioned about the outdated procedures, the lab manager stated that the procedures were part of the historical record.	
9.	A laboratory undertaking pesticide residue determinations began to find abnormally high results in test samples, control samples and blanks. The laboratory manager discovered that pesticides were being stored in another section of the building, which shared the same air conditioning system.	
10.	In a diamond-grading laboratory, the assessor noticed clusters of jewellery grade diamonds set out on the workbenches without any accompanying identification of their source, mass or number. The laboratory manager claimed that this wasn't a problem because most of his customers were "regulars" and it was his business to know which diamonds belonged to whom.	
11.	A large geochemical assay laboratory, whose clients included a number of mineral exploration companies, recently hired a retired geologist as a part-time assistant quality control officer. The laboratory's recruitment procedures failed to reveal that this geologist was also working as a part-time consultant to one of these exploration companies.	
12.	In a manufacturing company, every piece of equipment and machinery in use has been assigned a "plant number" and full details of its acquisition, history and maintenance are retained in a register held by the Factory Manager. Major items of equipment located in the laboratory are included in this register.	
13.	In a laboratory handling potentially pathogenic materials the assessor noted that a label affixed to a biohazard cabinet indicated that the cabinet was last serviced and tested nearly three years ago. The laboratory manager claimed that the cabinet had been serviced and tested several times since then but couldn't explain the absence of labels confirming this.	

Scenario	Clause(s)
14. In the quality control laboratory of a company manufacturing agricultural chemicals. There were no documented methods for many of the simple physical tests being performed daily (density, viscosity, moisture content, etc). An assessment revealed that the technicians performing these physical tests were making simple obvious errors in laboratory testing techniques needed for the proper performance of these tests.	
15. For reasons of safety and liability, the laboratory has designed a viewing room to allow clients to monitor the conduct of their testing without going onto the shop floor.	
16. Every thermometer in the laboratory had a small strip of paper, glued to the top of the stem, on which was written its serial number and the date of its most recent calibration.	
17. During the assessment of a laboratory undertaking tensile tests on steels, the calibrated micrometer used to measure test piece diameters had to be retrieved from the Maintenance Workshop.... One of the mechanics on the night shift had "borrowed" a micrometer from the laboratory because his own micrometer had been damaged.	
18. One year, while the laboratory manager was away on her annual vacation, the laboratory received a request for a series of tests well outside the scope of its accreditation. One of the section leaders had to telephone the laboratory manager for a decision on what to do because nobody in the laboratory knew exactly how to deal with such a situation.	
19. When questioned about procedures for purchasing chemicals and consumables, the laboratory manager eventually found in his filing cabinet a list of the suppliers he normally used, but admitted that the list hadn't been updated for some time and didn't cover all of the materials currently being purchased for the laboratory.	
20. The laboratory manager wanted clarification on the need to separate the functions of "technical manager" and "quality manager"; the total staff of her laboratory was only five people and there was no one apart from herself to whom she could assign the quality management responsibility.	
21. Because of problems with its compression-testing machine, a commercial testing laboratory was sending its clients' concrete test cylinders across to a nearby concrete producer's quality control laboratory. The laboratory manager admitted that he didn't know whether the laboratory was accredited but he knew some of the people who worked there and they seemed knowledgeable enough.	

Scenario	Clause(s)
22. When this laboratory manager was questioned further, he admitted that he hadn't given any thought to advising his clients of this arrangement, and that he had been reporting the results as if they had been obtained in his own laboratory.	
23. As this assessment continued, the assessors asked the technician to measure the dimensions of the six cylinders he was about to cap in preparation for the compression tests.... three of the six cylinders were found to be outside the specified tolerance. The technician said that he didn't think it was his responsibility to check the dimensions of any cylinders that were made and provided by the client.	
24. During a preliminary visit to the laboratory, an assessor saw a number of cardboard boxes containing laboratory records stacked in a stairwell at one end of the building; the stairwell was one of the designated emergency exits.	
25. When asked about what happens to test items after testing is complete, the laboratory manager explained that it all depends on the circumstances.... some customers usually wanted their test items returned, but in most cases the items were kept for a few months and then discarded as the storage areas filled up.	
26. The company's offer of an early retirement package has been accepted by seven of the nine professionally qualified scientists in the laboratory, including the Chief Chemist and the Chief Microbiologist. All seven of these people will retire within the next three months.	
27. The laboratory's proving ring, sent out to an external accredited lab for its scheduled recalibration, has just been returned uncalibrated: the accompanying letter from the calibration lab described the proving ring as having been "irretrievably damaged by misuse and neglect" and recommended that it be immediately withdrawn from service and replaced. Purchased only five years ago, this proving ring had been used for in-house calibrations of the laboratory's five universal testing machines.	
28. The laboratory manager agreed that interlaboratory programs were valuable, but her experience was that a good internal quality control program incorporating frequent use of certified reference materials was equally necessary.	
29. Although the quality manual contained a comprehensive chart depicting the key functional positions within the organization, no position descriptions had been prepared because it was felt that the job titles were largely self-explanatory.	

Scenario	Clause(s)
30. As the assessor reviewed the laboratory's file for Client A, he noted that the lab had received a contract from the client, but there was no record that the client's requirements had been reviewed.	

ANNEX IV

EXECRISES ON ISO/IEC 17025 REQUIREMENTS

Exercise 1

Purpose

This exercise is designed to raise the awareness of course participants on the importance of ensuring that Technical Managers (by whatever title) have a clear understanding of the wider scientific aspects of the work they are doing and that they are not merely following published test methods that they do not really understand.

It emphasizes that accreditation is an evaluation of competence and not merely checking that laboratories are following procedures.

Signatory / Key Technical Manager Appraisal

1 Read the scenario below
2 List the additional questions you would ask and additional information you would need, if any, to determine the competence of the applicant.
3 Would you grant signatory approval on the information given? Why? Why not?
4 How/when will you tell him whether he has been successful in gaining signatory approval or not?

Be prepared to report back your findings

Scenario

The proposed signatory has been with the organisation for about one year.

He is conducting testing for protein in meat products using the Kjeldahl method which determines organic nitrogen. This result must be multiplied by a factor to determine protein (and lean meat) content in the product. Some meat products (e.g. sausages) contain wheat flour, which also contains protein but the factor for wheat flour is different.

You are interviewing the applicant and discover the following.

1 He has a chemistry qualification from the local Polytechnic.
2 He worked for two years in a water-testing laboratory before joining this laboratory.
3 The method was well established by his predecessor before he joined the organisation.
4 He is not aware of any validation data but he thinks the last interlaboratory comparison program result (last year) was OK.
5 He now does a duplicate once a month because at his previous water laboratory they told him it was a good idea. He does not do anything if the duplicates are rather far apart as he has no standard for acceptance.
6 He does neither blanks nor a reference material such as nicotinic acid. The laboratory does not appear to have any reference amino acids.
7 He does know that the potassium sulphate will elevate the boiling point but does not know why they use a mercury catalyst rather than a copper one.
8 He does not know why the method multiplies his nitrogen answer by 6.25 except that that is what they have always done.
9 The method is in their test methods manual and he thinks it was originally based on AOAC but he has not checked.

10 Last month he did a split sample with his supervisor and they got results that were 5% of the result apart. The supervisor thought that was OK.
11 The methods manual quotes an uncertainty but he does not know where it came from nor how it was calculated.
12 He is familiar with the Quality Management Systems elements of ISO/IEC 17025 and has already updated their manual to fulfil the requirements of the new standard.
13 He signs out the test results after his supervisor has checked them.

Exercise 2

Purpose

The first part is to make participants more aware that contract review has wider implications than simply checking that the resources (staff, equipment, materials, methods) are available. ISO/IEC 17025 requires laboratories to understand the requirements of customers. Note that "requirements" may be very different from "wants" and the standard says requirements. In the exercise, business requirements and wider implications of accepting work need to be considered.

The second part of the exercise is to give participants an opportunity to **assess** a contract review which has been done by someone else but where they are now familiar with the scenario.

Review of Requests, Tenders and contracts

2a	1	Read the scenario below
	2	List the issues you will need to cover in the contract review
	3	Conduct and record the contract review
2b	1	Exchange your contract review with another group
	2	Assess the contract review for compliance with ISO/IEC 17025 including technical validity assuming you know the scenario

Be prepared to report back your findings

Scenario

In line with its quality objective to increase turnover of the laboratory by attracting further external work, XYZ Laboratories Ltd responds to a telephone request from a new external client. The client wishes XYZ Laboratories to conduct a series of tests on imported product that is similar to, but not directly in competition with, product manufactured by the laboratory's parent company XYZ Manufacturing Ltd.

XYZ Laboratories Ltd has the physical capability to conduct many of the tests requested. However, two of the more critical tests requested will require the acquisition by XYZ Laboratories Ltd of an expensive load cell which will extend the working range of one item of test equipment.

Although the volume of tests initially requested by the new client is relatively small, the client has indicated that, should the imported product find a market niche, future testing requirements could be very large and may exceed the entire existing workload of XYZ Laboratories Ltd.

NOTE: Neither XYZ Laboratories nor its parent company, XYZ Manufacturing Ltd have had any previous business dealings with the new client requesting this testing.

Exercise 3

Purpose

Participants will gain experience in assessing the adequacy of a presented record of method validation and in listing additional steps that they would expect to be done to fulfil the requirements of competence and compliance with ISO/IEC 17025.

This is a new element in the standard which makes it equivalent to ISO 9001 and assessors will need to understand how it applies for the discipline they are assessing.

Method Validation

1 Read the scenario below
2 List the additional things which could have been done to validate this method
3 Was there sufficient validation for acceptance in terms of the requirements of ISO/IEC 17025. (Note also clause 4.4 of ISO 9001 if available)

Be prepared to report back your findings

Scenario

The laboratory analyses food and soil samples for heavy metals such as lead, zinc, copper, arsenic, antimony. The conventional, standard method which is used involves firstly a perchloric acid digestion and then a determination by ICP/MS. The perchloric acid digest is tedious (four hours) and dangerous (accumulated perchloric acid can explode in the stack of the fume-cupboard and has been known to kill technicians).

The laboratory has been working on a new digest method involving placing the sample in a sealed glass container, filling it with oxygen, igniting the sample and dissolving up the ash in dilute acid. The method is clean and fast (3 minutes).

The laboratory obtained a milk powder sample for use during the method validation. They found that about two grams of milk powder could be digested in a one litre container and that after some trials with location of the sample on a stand in the container they could get a clean digest. The ICP/MS part of the test remained unchanged.

After many trials they settled on the best arrangements and had records to show that over 20 milk powder samples analysed by this method gave results identical (within ±3 %) to the standard perchloric acid method.

The dairy industry requires all samples to be analysed using Dairy Board test methods. Most environmental engineers require all soil samples to be analysed using EPA test methods. Both of these methods specify perchloric acid digest.

Based on the above work the laboratory is seeking extension of its accreditation for this new method for dairy products and soils.

Exercise 4

Purpose

This exercise has two different sections.

The first is to raise participants' awareness of the different sorts of calibration certificates that they will be presented with by a laboratory to demonstrate its measurement traceability. Some of the certificates presented will be inadequate in that they are either from an ISO 9002 certified laboratory or they are manufacturers' declarations. Assessors must be able to quickly identify which are acceptable.

The second section emphasises that measurement traceability for many testing laboratories cannot be back to SI units but rather to reference materials. It illustrates the difficulty testing laboratories will have in obtaining good certified reference materials and requires them to think about the technical validity of this home-made material as a reference material for calibrating equipment.

Measurement Traceability

3.1 a Study the example calibration certificates attached.
b Discuss which ones are acceptable, in terms of traceability of measurement, for a testing laboratory to use.

3.2 a Read the scenario
b Is the material described a suitable reference material for the laboratory to calibrate its GC/MS? If not, what else could the laboratory do?
c What happens to the reported test result if the reference material contains 10% of inorganic impurities.

Be prepared to report back your findings

Scenario

The laboratory analyses food products and waters for traces of pesticides to ensure that samples comply with regulatory requirements.

Methiocarb is one of the pesticides to be analysed but the laboratory was not able to obtain a "pure" "reference" sample of methiocarb from its supplier for calibrating its equipment.

The laboratory obtained some commercial Mesurol orchard spray concentrate, the active ingredient of which is methiocarb.

After some column chromatography clean-up followed by three re-crystallisations the laboratory obtained clean white crystals of methiocarb. The melting point was only two degrees lower that that quoted in the texts.

The laboratory ran the sample through its high resolution MS and the sample appeared to be clean. It then sent a portion to the local university for an NMR and again the sample appeared to be clean.

This material was then used as primary reference material for the calibration of the GC/MS which it was using to analyse food and water extracts.

Exercise 5

Purpose

The first part of the exercise is to encourage participants to work out ways of estimating uncertainty in their field of expertise. It is hoped that where their field usually says "it can't be done in our field" they will think laterally to come up with at least something which can be done and the sort of data needed to do it.

The second part of the exercise is for the trainee assessors to assess what someone else (equivalent to a laboratory) has done to estimate uncertainty and to make a decision on its adequacy.

Uncertainty of Measurement

5a	1	Work alone
	2	Read the examples below and select one you understand best
	3	Prepare a description of how you will estimate the uncertainty for this measurement. What tests will you need to obtain sufficient data? What data will you need?
5b	1	Pass all your answers to another group
	2	Assess each uncertainty plan for compliance with ISO/IEC 17025. Did they take individual contributions into account? Did they cover uncertainties back to sample receipt at the laboratory? Would they have made a "reasonable estimation"?

Be prepared to report back a summary of your discussions

Examples

1 Testing water for fluoride

2 NDT testing of welded joints

3 Cervical screening test for cancer cells

4 EMC test of appliance for transmitted radiation

5 Strength test for concrete blocks

6 DNA paternity test

7 Calibration of mercury in glass thermometer

8 Moisture test for wool

9 Chloride in thermal insulating material

10 Ultrasound scan for deep vein blood clots in patient's leg

11 Strength test for crash helmets

12 Measurement of gauge block

13 Leakage test for window in aluminium frame

14 Lead in paint on child's toy

ANNEX V

EXERCISE ON REPORTING OF FINDINGS

Described on the following pages are four incidents which occurred during the assessment of a laboratory. Consider carefully the information and evidence given about each incident.

* **If you consider that there is sufficient evidence of a nonconformity against one of the requirements of ISO/IEC 17025:**

  - indicate this on the associated report form by a (✓) in the Nonconformity box on the first line of the form;
  - write a statement expressing the nonconformity in the Statement section of the report form and, in the box provided, indicate the appropriate clause of ISO/IEC 17025; and
  - in the Evidence section of the form, quote the evidence on which you made your decision.

* **If you do not consider that there is sufficient evidence of a nonconformity against any of the requirements of ISO/IEC 17025:**

  - indicate this on the associated form by a (✓) in the Observation box on the first line of the form;
  - write a statement explaining your reasons for this decision in the Statement section of the report form; and
  - in the Evidence section of the form, describe what further investigations you would undertake in order to get the evidence you need to decide whether it is a conformity or a nonconformity.

Incident 5.01

During an examination of the laboratory's test method manual, the assessor found five test methods (TM.09, TM.16, TM.17, TM.21 and TM.22) which did not show any date of issue or authorisation and were not cross-referenced to any standard method.

The laboratory manager explained that these methods had been developed in the laboratory many years ago, but there were no records available to show whether or not they had been validated.

All other test methods in the manual showed a date of issue, an authorising signature and a cross-reference to a standard (ASTM or ISO) test method.

Decision: **Nonconformity** ☐ **Observation** ☐

Statement:

.... ISO/IEC 17025 ☐

Evidence:

Incident 5.02

When examining the laboratory workbooks, the assessor found that a group of five test results, originally obtained by technician **ABC**, had been crossed out and corrected by another person with the initials **XYZ**.

The Laboratory Manager explained that **XYZ** was the Supervisor of the section in which **ABC** worked, and the items were probably re-tested by **XYZ** because of some doubts about the correctness of **ABC**'s results.

The test items concerned were numbered 5760 ➔ 5764. The items were originally tested by ABC on 17 March 2000; the corrections made by XYZ were dated 24 March 2000.

Decision: **Nonconformity** ☐ **Observation** ☐

Statement:

.... ISO/IEC 17025 ☐

Evidence:

Incident 5.03

On a workbench in the sample preparation room, the assessor noticed a technician using an old electronic balance on which is a label with the words *"Not Calibrated"*. The assessor recorded the serial number (Serial. No. 916725) of the balance for later investigation.

When examining the laboratory's equipment records, the assessor discovered that this balance was shown on the list of testing equipment as *"Withdrawn from use - Not to be calibrated"*.

The Laboratory Manager told the assessors that this balance was not used for any accurate work and the technician was probably using it for a task which did not require accurate weighing.

Decision: **Nonconformity** ☐ **Observation** ☐

Statement:

.... ISO/IEC 17025 ☐

Evidence:

Incident 5.04

The door to one of the special purpose rooms in the laboratory was marked ***"CLEAN ROOM"*** and had a printed sign stating ***"IMPORTANT*** - Protective head caps, shoe coverings and dust-free laboratory coats must be worn in this room".

The Laboratory Manager explained to the assessment team that the tests conducted in this room required a dust-free environment and it was for this reason that testing staff were required to wear the head caps, shoe coverings and dust-free coats.

When they entered the room, the assessors noted that 3 of the 5 testing staff working in the room were not wearing head caps or shoe coverings.

Decision: **Nonconformity** ☐ **Observation** ☐

Statement:

.... ISO/IEC 17025 ☐

Evidence:

ANNEX VI

RECOMMENDED CONTENT, STRUCTURE AND CONDITIONS OF EXAM

Duration : 2.5 hours

Participants may have a clean copy of ISO/IEC 17025 to refer to.

Content and Structure :

1.	Short questions or questions with multiple choice answers relating to assessment process and assessment technique with one or two questions on accreditation and mutual recognition.	15 marks
2.	Questions on ISO/IEC 17025 and a requirement to indicate the clause and sub-clause relevant to their answer. These do not just require reciting of the words of the standard but require some lateral thinking.	25 marks
3.	Questions where descriptions or lists are required for each answer. Again the relevant 17025 clause must be quoted and again some lateral thinking is required.	40 marks
4.	This section relates to the on-site assessment. Process lists are required and then two "incidents during assessment" are reported and the student is required to state how they would handle this and to record any Corrective Action Requests they would issue and to rate the seriousness of any nonconformances. Several blank CAR forms are provided.	20 marks