



GUIDELINES ON TRAINING COURSES FOR ASSESSORS

PURPOSE

This document provides guidance to APLAC members on the suggested content of training courses for assessors of laboratories, inspection bodies, reference material producers and proficiency testing providers. The objectives of the courses are set out on page 4.

AUTHORSHIP

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1. INTRODUCTION

- 1.1 The competence of assessors underpins the credibility of conformity assessment body (CAB) accreditation schemes. It is thus essential that 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 assessors for laboratories, inspection bodies, reference material producers (RMP), and proficiency testing providers (PTP). It describes the topics considered to be essential to assessor training courses.
- 1.2 The main objective of an assessor training course is to train assessors to perform assessments in accordance with the requirements of ISO/IEC 17011 and applicable standards. At the end of a 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 the primary accreditation criteria, and apply these requirements to the assessment of management systems in laboratories, inspection bodies, RMPs, or PTPs;
 - (c) Identify the general technical requirements of the primary accreditation criteria documents and apply these requirements to the assessment of the technical competence of laboratories, inspection bodies, RMPs, or PTPs within their area of professional technical expertise, including where applicable, the statistical requirements for RMPs and PTPs; and
 - (d) Plan, organise and conduct assessments of laboratories, inspection bodies, RMPs and PTPs against these requirements and in accordance with the procedures of the accreditation body.
- 1.3 In order to achieve this objective, assessors should be familiar with the following:
- (a) Meaning of accreditation of CABs;
 - (b) International dimension of accreditation of CABs;
 - (c) Accreditation criteria and their interpretations;
 - (d) Accreditation body operation and regulations;
 - (e) Accreditation process and assessment techniques;
 - (f) Where appropriate, applicable statistical techniques and methods for estimation of uncertainty of measurement.
- 1.4 A list of ILAC and APLAC documents that contain useful information on laboratory, inspection body, RMP and PTP assessment and accreditation has been provided in ANNEX 1. References should be made to these documents when preparing training courses.
- 1.5 The programme detailed below generally follows the guidelines given in *ILAC G3: Guidelines for Training Courses for Assessors*.
- 1.6 Successful completion of this course should be regarded as meeting the training requirement for assessors as specified in *ILAC G11: ILAC Guidelines on Qualifications*

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and Competence of Assessors and Technical Experts. 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 working experience.

- 1.7 It is common that qualified technical assessors for specific areas may not possess the appropriate statistical expertise in ISO 13528 for PTPs or ISO Guide 35 for RMPs. It is the responsibility of the accreditation body to recruit assessors with the appropriate expertise and to ensure that the required expertise is available within the assessment team to properly assess the ability of a CAB to evaluate homogeneity, stability, and to effectively assign PT or RM property values. It should however be noted that attendance at training courses may not be sufficient to obtain the necessary expertise in statistical techniques required for assessing a RMP or PTP when such competencies are required.
- 1.8 A PTP/RMP may not necessarily be a laboratory or have in-house laboratory facilities, yet the laboratory it employed for the production and characterization of the PT items or RM has to be competent to perform the related tasks. Hence, assessors for RMPs need to have knowledge of ISO/IEC 17025 or ISO 15189 for medical field as a foundation before completing training on ISO Guide 34. Since a RMP is expected to conduct all testing and calibration in support of the production of reference materials in compliance with the requirements of ISO/IEC 17025 or for tests performed in the medical field, in compliance with the requirements of ISO 15189, it is desirable that a candidate RMP assessor have prior experience in ISO/IEC 17025 and/or ISO 15189 assessments before becoming an RMP assessor. Hence a bridging approach to RMP assessor training may be most effective.
- 1.9 Similarly, assessors for PTPs need to have knowledge of ISO/IEC 17025 or ISO 15189 before completing training on ISO/IEC 17043 since the preparation and determination of the characteristics and assigned values of the PT items rely much on the competency of the PTP's laboratory. Accredited laboratories in the relevant field meeting the requirements of ISO/IEC 17025 or ISO 15189 are generally accepted as meeting the relevant competency requirements. However, obtaining accreditation is not a mandatory requirement for laboratories employed by a PTP to prepare the PT items. It is therefore desirable that a candidate PTP assessor also has prior knowledge of ISO/IEC 17025 or ISO 15189 so as to be conversant with the requirements of a competent laboratory.
- 1.10 It is essential that the assessment team for PTPs has knowledge of appropriate statistics used for operating proficiency testing activities, and the assessment team for RMPs has corresponding knowledge for certification of certified reference materials, making reference to the relevant ISO standards on statistics such as ISO 13528 for PTPs or ISO Guide 35 for RMPs or other relevant alternatives. It is recognized that the statistical requirements are not specified in detail in the relevant ISO documents, but understanding the requirements of the documents and the relevant alternatives may provide positive insight.

2. TIME ALLOCATION

- 2.1 The total duration of the course will depend upon the objectives set and whether or not there is required self-study to be completed in advance. For the training of assessors for laboratories, a course of 36 - 40 hours, at least for the training of lead assessors, is strongly recommended, and if they are also trained as either RMP/PTP assessors, an additional day (6-8 hours) of training on the respective accreditation criteria is recommended if they already have basic statistical competence; and where necessary, a further additional day (6-8 hours) of statistical training respectively for PTP or RMP assessors. An example of course time allocation based on the assumption of 8 hours per day is as follows:

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Topics		Time allotted, hours
For Basic Assessor Skills		
Introduction to accreditation of CABs and international dimension of accreditation		2
Accreditation criteria and their interpretations – quality management system requirements		6
Accreditation criteria and their interpretations – technical requirements		16
Accreditation body operation and regulations		1
Accreditation processes and ISO/IEC 17011		7
Assessment techniques and people skills		5
Subtotal (For laboratory assessor)		37
For Laboratory Assessors who demonstrate competence		
Assessment of RMPs, including brief introduction to ISO Guide 35 or equivalent (applicable only to RMP assessor training courses)		8
Subtotal (For laboratory assessor also trained as RMP assessor)		45
Assessment of PTPs and use of ISO 13528 or equivalent (applicable only to PTP assessor training courses)		8
Subtotal (For laboratory assessor also trained as PTP assessor)		45
For Assessors already with basic statistical competence		
Applicable statistics for RMP (including requirements of ISO Guide 35 or equivalent) [Optional for RMP assessors]		8
Applicable statistics for PTP (including requirements of ISO 13528 or equivalent) [Optional for PTP assessors]		8
Subtotal (With statistical training for <u>PTP or RMP</u> assessors)		53
Subtotal (With statistical training for assessors for <u>both PTP and RMP</u>)		61
Written examination		3
Total	Laboratory assessors	40
	Assessors for Lab + RMP or Lab + PTP	48
	Assessors for Lab + PTP + RMP	56
	With additional statistical training for either RMP or PTP assessors already having basic statistical competence	56
	With additional statistical training for RMP + PTP assessors already having basic statistical competence	64

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- 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 recommended in the above table. It should be noted the recommended time allocation for each topic provided above is based on an 8-hour day, and they may be adjusted according to the course objectives and participant's experience as needed.

Candidate RMP or PTP assessors could be trained on laboratory assessments by courses based on the guidelines for laboratory assessors. Upon completion of the laboratory assessor training course, the candidate may attend respective specific training courses for RMP assessors or for PTP assessors, each of which should be at least one day (6-8 hours) in duration and covers the topics on accreditation criteria for RMPs/PTPs and the differences between laboratory assessments and RMP/PTP assessments. On top of these RMP/PTP accreditation criteria trainings, a separate training course on relevant statistics used in organising proficiency testing activities (such as ISO 13528 or equivalent) or in producing certified reference materials (such as ISO Guide 35 or equivalent), with duration no less than one day (6-8 hours) may also be attended by candidate PTP/RMP assessors nominated by accreditation bodies as potential assessors for assessing RMP/PTP where statistical expertise is required.

3. EVALUATION OF PERFORMANCE OF PARTICIPANTS AND EXAMINATION

- 3.1 The performance of each participant should be evaluated. The evaluation is normally done by continuous monitoring during the course and from the results of the written examination. The body providing the course should have procedures for the evaluation of the performance of participants.
- 3.2 An example of the structure of a suitable examination is given in Annex 2. Marking schemes for the written examination should provide consistency from class to class.
- 3.3 It is expected that participants should obtain a satisfactory overall score, which can be determined by the accreditation body and agreed with the course provider, before they may be regarded as having successfully completed the course.

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 time allocated for should be reasonable in relation to the number of participants. The number of participants of the assessor training course should be limited to 20 unless additional time is allocated.

5. DETAILS OF COURSE CONTENTS

5.1 Introduction to Laboratory, Inspection Body, RMP, or PTP Accreditation

The following topics should be covered:

- (a) **Basic quality concepts:** quality, quality management, quality assurance, quality control and quality improvement, should be introduced.
- (b) **Stakeholders** of accreditation bodies and their accredited laboratories or inspection bodies or reference material producers or proficiency testing providers – customers of CABs, regulatory authorities, manufacturers, buyers, users of products inspected or tested, etc. Understanding their needs and satisfying these needs.
- (c) **Accreditation and certification (according to ISO/IEC 17000)** - their definitions and differences in their emphasis.

- (d) **The accreditation body** - Definition and the international standard for the operation of an accreditation body, i.e. ISO/IEC 17011.
- (e) **The requirements for accreditation in ISO documents** such as ISO/IEC 17025, ISO 15189, ISO/IEC 17020, ISO Guide 34 and ISO/IEC 17043 as accreditation requirements. In addition, application documents, accreditation body rules or specific pieces of legislation, etc. may be included in accreditation requirements.

Specific criteria of the accreditation body for the interpretations and amplifications of the ISO/IEC 17025 and/or ISO 15189, ISO/IEC 17020, ISO Guide 34 or ISO/IEC 17043 requirements, should be mentioned. Where applicable, the relevant statistical techniques referred in ISO 13528 and/or ISO Guide 35 (or other equivalent references) should be explained.

The availability and role of relevant ILAC and APLAC requirement and guidance documents should be given.

- (f) **Types of CABs** including laboratories (testing, calibration, medical, reference, material characterisation, or R & D laboratories, and 1st, 2nd, and 3rd party laboratories), inspection bodies (Type A, B, or C), reference material producers (RMPs), proficiency testing providers (PTPs) and their interrelationships; certification bodies for management systems, personnel and products, should be explained.

Legal status of CABs, conflicts of interest / impartiality and relationship between CABs and accreditation bodies should be discussed.

The conformity assessment structure from government through accreditation bodies and conformity assessment bodies to end users of products and services should be introduced.

5.2 International Dimension of Accreditation

The following topics should be covered:

- (a) ISO, its functions and the work of the relevant committees (e.g. CASCO, REMCO and ISO TC 212).
- (b) World Trade Organisation and Agreement on Technical Barriers to Trade (TBT). How laboratory or inspection body accreditation can facilitate free trade.
- (c) International development of accreditation of CABs: past, present and future. Co-operation of accreditation bodies: ILAC, APLAC, EA, IAAC, IAF, PAC, etc. Harmonisation of assessment procedures. Introduction of ISO/IEC 17011 and *ILAC R2: ILAC Rules* may be mentioned here.
- (d) Who accredits the accreditors? Peer evaluations and MRAs. *IAF/ILAC A2: IAF/ILAC MRAs: Requirements for Evaluation of a Single Accreditation Body* and *APLAC MR 001: Procedures for Establishing and Maintaining the APLAC Mutual Recognition Arrangement Among Accreditation Bodies* should be mentioned here. The frameworks of APLAC multilateral MRA and the ILAC global arrangement should also be given.
- (e) The benefits of accreditation should be explained, e.g. assurance of competence, international acceptance of reports, declaration of conformance to international standard, fulfilment of legal requirements, etc.

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5.3 Accreditation Criteria and Their Interpretations – Quality Management System Requirements

- 5.3.1 This topic deals mainly with the quality management system (QMS) requirements stipulated in ISO/IEC 17025 and/or ISO 15189 or ISO/IEC 17020. RMP and PTP assessors will be trained as laboratory assessors (ISO/IEC 17025 and/or ISO15189) in this part of the course. The quality management system specific for RMPs or for PTPs will be covered in a bridging course.
- 5.3.2 This part should start with a general introduction to the history of the development of the relevant standard followed by an overall view of the standard.
- 5.3.3 The discussion should go into the detailed quality management system requirements. ISO/IEC 17025 and/or ISO 15189 or ISO/IEC 17020 QMS elements 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:

IAF/ILAC: A4 Guidance on Application of ISO/IEC 17020

APLAC TC 002: Internal Audits for Laboratories and Inspection Bodies

APLAC TC 003: Management Review for Laboratories and Inspection Bodies

- 5.3.4 Each of the management requirements in the respective primary accreditation criteria documents should be explained in detail with illustrative examples and exercises where necessary.

5.4 Accreditation Criteria and Their Interpretations – Technical Requirements for Laboratories

This part deals mainly with the technical requirements for laboratories stipulated in the respective primary accreditation criteria documents:

- ISO/IEC 17025 and/or ISO 15189 and/or ISO 15195: Laboratory medicine - Requirements for reference measurement laboratories

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.

The focus of assessment as assessment of competence rather than just conformity with requirements should be stressed, particularly for technical aspects.

- 5.4.1 Discussion should go into the detailed technical requirements. Each technical element 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-P9: ILAC Policy for Participation in Proficiency Testing Activities*

- *ILAC-P10: ILAC Policy on Traceability of Measurement Results*

- *APLAC TC 004: Method of Stating Test and Calibration Results and Compliance with Specification*

- *APLAC TC 005: Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing*

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- *APLAC TC 007: Guidelines for Food Testing Laboratories*
- *APLAC TC 012: Guidelines for Acceptability of Chemical Reference Materials and Commercial Chemicals for Calibration of Equipment Used in Chemical Testing*
- *ILAC G24: Guidelines for the Determination of Calibration Intervals of Measuring Instruments*

As this part is for laboratory assessors, *APLAC TC 008: Guidelines on the Approach to the Assessment of Reference Material Producers and the Resulting Scope of Accreditation* should be mentioned without going into the details.

5.4.2 Each of the following clauses from ISO/IEC 17025 and/or ISO 15189 should be explained in detail with illustrative examples and exercises where necessary.

- (a) Personnel
- (b) Additional qualifications for opinions and interpretations
- (c) Training and link with human resource management
- (d) Job descriptions
- (e) Qualifications, training and competency records
- (f) Accommodation and environmental conditions
- (g) Purchasing services and supplies
- (h) Equipment (and reagents and consumables for medical laboratories)
- (i) Identifying and understanding the requirements of the laboratory's customers (all interested parties)
- (j) Review of requests, tenders, contracts and service agreement and test/calibration method selection
- (k) Subcontracting or referring of tests and calibrations
- (l) Sampling: Sampling should cover sampling procedures and plans, their relationship to uncertainty of results or interpretations.
- (m) Pre-examination processes for medical laboratories: The special requirements of ISO 15189 for sample collection manuals.
- (n) Handling of test and calibration items
- (o) Test and calibration methods and 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. For medical laboratories, extent of evaluation of examination procedures or verification of *in vitro* medical devices *to confirm that they are suitable for the intended use should be discussed.*
- (p) Metrological traceability of measurement results: An explanation should be given of the definition, means to achieve metrological traceability, concept of metrological

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- quality, international standards of measurements, transfer standards, reference standards and reference materials, including traceability of empirical methods to reference materials and to the defined method. An introduction to ISO17511 which describes the metrological traceability chain and calibration hierarchy of the reference materials and reference measurement procedures used in laboratory medicine should be given.
- (q) Uncertainty of measurement: An introduction to *ISO Guide to Expression of Uncertainty in Measurement (GUM)* and *ILAC P14 ILAC Policy for Uncertainty in Calibration* along with a brief introduction to the approaches in *EURACHEM/CITAC Guide Quantifying Uncertainty in Analytical Measurement* and *APLAC TC 005* should be given. The application of uncertainty of measurement in medical testing should be explained and the work of the Joint Committee on Traceability in Laboratory Medicine (JCTLM) should be mentioned.
 - (r) Compliance with specification and relationship to uncertainty of measurement and level of confidence (APLAC TC 004)
 - (s) Quality control - ensuring the quality of test and calibration results (linking clauses 5.9 and 5.4.7.1 of ISO/IEC 17025; and clause 5.6 of ISO 15189 with this topic)
 - (t) Proficiency testing / inter-laboratory comparisons: The importance of and requirement for participation in suitable proficiency testing activities should be explained. An outline of ISO/IEC 17043 should be given. Actions taken by the laboratories and accreditation bodies in cases of unsatisfactory performance in proficiency testing programmes should be described.
 - (u) Post-examination processes (for medical laboratories)
 - (v) Reporting the results and uncertainties where required
 - (w) Laboratory information management (for medical laboratories)
 - (x) 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. ISO 15189 requirements for interpretation of test/examination results should be emphasised where relevant.

5.5 Accreditation Criteria and Their Interpretations – Technical Requirements for Inspection Bodies

5.5.1 This part deals mainly with the technical requirements stipulated in ISO/IEC 17020.

5.5.2 Discussion should go into the detailed technical requirements. ISO/IEC 17020 technical elements 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:

- *IAF/ILAC A4: Guidance on the Application of ISO/IEC 17020*
- *ILAC P10: ILAC Policy on Traceability of Measurement Results*
- *ILAC P9: ILAC Policy for Participation in Proficiency Testing Activities*
- *APLAC TC 006: Guidance Notes on ISO/IEC 17020*

5.5.3 Each of the following clauses from ISO/IEC 17020 should be explained in detail with illustrative examples and exercises where necessary.

- (a) What is inspection?
- (b) Administrative requirements
- (c) Scope of inspection body
- (d) Independence – type a, b and c inspection bodies
- (e) External documents and product standards
- (f) Personnel
- (g) Inspector management and competence
- (h) Job descriptions
- (i) Training, supervision and monitoring and link with human resource management
- (j) Qualifications, training and competency records
- (k) Equipment management and calibration
- (l) “Calibration and traceability” of inspection result
- (m) Purchasing
- (n) Contract review and subcontracting
- (o) Handling items for inspection
- (p) Inspection methods
- (q) Quality control and “proficiency testing”
- (r) Technical records
- (s) Reporting
- (t) Complaints and appeals
- (u) Health and safety of inspectors

5.6 Accreditation Criteria and Their Interpretations – Technical Requirements for Reference Material Producers

5.6.1 The accreditation criteria for RMPs is ISO Guide 34 which has incorporated the technical requirements expected of a competent laboratory producing the reference material, if a RMP assessor is not yet a laboratory assessor, the person should undergo and pass a training course for laboratory assessors before attending this bridging course for RMP assessors.

5.6.2 Documents to be included in RMP assessor training course are ISO Guides 30, 31, 34 and 35 as well as APLAC TC 008 and various ILAC guidance and procedure documents including ILAC P10. Assessor checklists, if used by the accreditation body, the accreditation body documents and the standard application documents should also be part

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of the course. The document should be provided well in advance of the course and the course should include the inter-relationships between various documents.

- 5.6.3 The major differences between a laboratory assessment and a RMP assessment summarised in the following table should be emphasized in the RMP assessor training course. For RMP, in addition to the technical requirements of a laboratory meeting the ISO/IEC 17025 requirements or ISO 15189 requirements for medical testing, relevant requirements for the following should be included:
- a. Design, production, handling, and shipping of reference materials;
 - b. Characterization of certified properties;
 - c. Homogeneity, including uncertainty of unit differences;
 - d. Effects of transport of reference materials (also called short term stability);
 - e. Long term stability of certified property values;
 - f. Uncertainty of property values, including the uncertainty of characterization, inhomogeneity, transport, and long term stability.
- 5.6.4 One of the key issues of RMP assessments is the way in which the RMP meets the relevant requirements of ISO/IEC 17025 or ISO 15189 for medical field, for testing and calibration activities of the RMP. Applicable requirements depend on how the RMP operates, in particular, the relationship between the RMP and its subcontractors with respect to various tasks of the production process. Trainees should be informed of the various approaches given in APLAC TC 008.

5.7 Accreditation Criteria and Their Interpretations – Technical Requirements for Proficiency Testing Providers

- 5.7.1 Although it is not a requirement that the laboratory or contracted laboratory of a PTP to be accredited, it is preferable that a PTP assessor is also a laboratory assessor with prior knowledge and experience in applying ISO/IEC 17025 or ISO 15189 to laboratory operation. An overall introduction to the requirements of ISO/IEC 17025 or ISO 15189 applicable to the competency assessment of the laboratory of a proficiency testing provider should be explained. Application and relevance of statistical techniques in organising proficiency testing activities and in determining assigned values of PT items as described in ISO 13528 or other relevant alternative reference should be included.
- 5.7.2 Aspects to be considered when designing a proficiency testing scheme, including the production, handling and shipping of proficiency testing items, statistical considerations, items expected in a proficiency testing plan and instructions to be provided to participants should be mentioned.
- 5.7.3 Competency of the laboratory in conducting homogeneity and stability study on PT items and applying appropriate statistics to determine the assigned values and the suitability of the PT items should be emphasised. The importance of maintaining participants' confidentiality throughout data handling and processing should be mentioned. Where applicable, competency of other contractors (e.g. for distribution of PT items or for data entry and processing) should also be established.
- 5.7.4 Content of a proficiency testing report is usually more complicated than a test or calibration report and the expected contents of a proficiency testing report should be explained. Various methods for establishing the assigned value, estimation of the associated uncertainty of the assigned value, statistical measures for evaluation of performance, summary statistics for different methods and various considerations should be discussed.

Key Differences between Laboratory and RMP/PTP Assessments

Assessment Processes	Laboratory	Reference Material Producer	Proficiency Testing Provider
Accreditation Standards	ISO/IEC 17025 Or ISO 15189 (for medical laboratory)	ISO Guides 30, 34, 31, 35 ISO/IEC 17025 or ISO 15189 (for medical laboratory) The complexity of the requirements and the interrelationships, results in significant planning needed up front. Results in frequent communications between team members during the conduct of the assessment. Statistical methods where applicable	ISO/IEC 17043, ISO 13528 ISO/IEC 17025 or ISO 15189 (for medical laboratory) The complexity of the requirements and the interrelationships, results in significant planning needed up front. Results in frequent communications between team members during the conduct of the assessment. Statistical methods where applicable
Scopes	Contains Tests Methods / Calibrations	Types of RMs / CRMs ranges	Types of PT items, Test performance under evaluation
Scope of Assessment Activity	Lab is often limited to one or two rooms and a few personnel	RMP is full manufacturing facilities, storage, laboratory, packaging and potentially a large number of staff.	PTP is laboratory producing and characterising the PT items, storage, packaging, distribution, data entry and analysis, report preparation, potentially a large number of staff; and where possible, some subcontracting activities.
Assessor (s)	Often solo and sometimes team	Frequently team assessment	Frequently team assessment
Review Application and supporting documents	Review Scope of Accreditation QM and SOPs Technical SOPs Subcontractor arrangements	Review Scope of Accreditation QM and SOPs Technical SOPs Laboratory support Subcontractor arrangements	Review Scope of Accreditation QM and SOPs Technical SOPs Laboratory support Subcontractor arrangements

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Assessment Processes	Laboratory	Reference Material Producer	Proficiency Testing Provider
Assessor Contacts Applicant	Currency of documents Request technical SOPs Facility layout Work shifts Branch facilities Satellite locations	Currency of documents Request technical SOPs Facility layout Work shifts Branch facilities Satellite locations Laboratory support Subcontractor arrangements Statistical methods where applicable	Currency of documents Request technical SOPs Facility layout Work shifts Branch facilities Satellite locations Laboratory support Subcontractor arrangements Statistical methods where applicable
Prior Document Review	Report to the applicant in writing of gaps, or revisions needed in management system documentation Prepare questions by reviewing previous assessment report and corrective actions, PT data. Request technical methods/SOPs if needed.	Report to the applicant in writing of gaps, or revisions needed in management system documentation Prepare questions by reviewing previous assessment report and corrective actions, PT data. Request technical methods/SOPs if needed.	Report to the applicant in writing of gaps, or revisions needed in management system documentation Prepare questions by reviewing previous assessment report and corrective actions, PT data. Request technical methods/SOPs if needed.
Prepare agenda	Usually straight forward agenda covering management system/testing	More complex- more likely chance of team assessment	More complex- more likely chance of team assessment

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Assessment Processes	Laboratory	Reference Material Producer	Proficiency Testing Provider
On-site assessment	<p>Entry briefing / tour facilities – gain understanding of work flow.</p> <p>Consideration for safety precautions Environment (i.e. clean rooms)</p>	<p>Entry briefing / tour facilities – gain understanding of work flow.</p> <p>Consideration for safety precautions Environment (i.e. clean rooms)</p> <p>Note when certain manufacturing processes or analyses are schedule to occur – schedule to witness/evaluate.</p> <p>Have RMP explain work flow/production process to team to help aid in efficiency of assessment.</p>	<p>Entry briefing / tour facilities – gain understanding of work flow.</p> <p>Consideration for safety precautions Environment (i.e. clean rooms)</p> <p>Note when certain processes of a PT round or analyses are schedule to occur – schedule to witness/evaluate.</p> <p>Have PTP explain work flow/production process to team to help aid in efficiency of assessment.</p>
On-site assessment technical	Observe Testing and/or Calibration	<p>Observe Testing and/or Calibration when possible however the frequency of the use of test methods may be weeks or years so it may not be practical to observe processes.</p> <p>Demonstration of competence will be through records. Conduct vertical audits.</p> <p>Evaluation of statistical processes</p>	<p>Observe Testing and/or Calibration when possible however the frequency of a PT may be infrequent so it may not be practical to observe processes.</p> <p>Demonstration of competence will be through records. Conduct vertical audits.</p> <p>Evaluation of statistical processes</p>
Assessment team Interactions within team	Solo – none Team-at least once a day	At least once a day but normally more frequent	At least once a day but normally more frequent
Reports	<p>Testing or calibration reports</p> <p>-ISO/IEC 17025 cl. 5.10</p> <p>ISO 15189 cl. 5.8.2 and 5.8.3</p>	Certificates to ISO Guide 31	PT reports at different stages including interim and final reports – ISO/IEC 17043 cl. 4.8
End result/product	Test or calibration result	RM/CRM production	PT schemes offered for participation

5.8 Accreditation Body Operation and Regulations

5.8.1 Describe 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. Rules and structures of various committees should be given. Linkage with the clauses of ISO/IEC 17011 should be covered.
- (b) Regulations governing the use of the accreditation body symbol including requirements for reports/certificates bearing the accreditation body symbol should be explained. Recommendations given in *ILAC P8: ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories* should also be explained. Examples of uses and abuses of accreditation symbols/status should be discussed.
- (c) Rules for granting, maintaining, extending, reducing, suspending and withdrawing accreditation: Requirements and recommendations given in ISO/IEC 17011 should be explained.
- (d) Proficiency testing participation requirements of the accreditation body should be outlined along with requirements for follow-up of outlier results. *ILAC P9: ILAC Policy for Participation in Proficiency Testing Activities* should be briefly introduced; and,
- (e) Requirements that the accreditation body has to ensure that the scope of testing is appropriately covered (e.g., where relevant, statistical methods applied and statistical expertise on the assessment team for RMPs and PTPs).

5.9 Accreditation Processes and Assessment Techniques

5.9.1. Overall

ILAC G11: ILAC Guidelines on Qualifications and Competence of Assessors and Technical Experts should be explained. The role of an assessor is to assess the CAB's competence and its conformance to ISO/IEC 17025 and/or ISO 15189 or ISO/IEC 17020 or ISO Guide 34 or ISO/IEC 17043. The key tasks of assessors are the evaluation of staff competence, technical validity of methods, equipment, accommodation, materials, test/calibration/inspection results, statistical methods, etc. Accreditation requirements should be interpreted based on first understanding and then satisfying the needs of the various stakeholders.

5.9.2. Accreditation processes

Clause 7 of ISO/IEC 17011 should be explained, i.e. criteria for accreditation, application for accreditation, assessment, analysis of findings and assessment report, decision on accreditation and granting of accreditation. Then details of the assessment procedure should be given, including:

- (a) Application
- (b) Appointment of lead assessor

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- (c) Pre-assessment visit and report
- (d) Examination of quality manual, other documents and selected records
- (e) Preliminary report to laboratory or organisation
- (f) Composition, selection and appointment of assessment team to ensure that the required competencies are covered
- (g) Preparation for assessment, e.g. briefing notes
- (h) Conduct of assessment: opening meeting, examination of records, observation of CAB's practices, interviews of staff/signatories, recording of findings, analysis of findings, preparation of report or summary, exit meeting and reporting of findings.
- (i) Post-assessment activities: evaluation of corrective actions by review of information supplied or by follow-up visits; notification of granting/reaffirmation/extension of accreditation, and scope of accreditation.

5.9.3. Assessment techniques

Techniques for 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 amongst assessors
- (f) Items to be covered in opening and exit meetings
- (g) Items of ISO/IEC 17025 and/or ISO 15189, or ISO/IEC 17020 or ISO Guide 34 or ISO/IEC 17043 to be examined for evaluating competence, technical validity and management system conformity
- (h) The assessment trail (vertical or horizontal)
- (i) Techniques for recording of findings: use of accreditation body checklists and record forms
- (j) Classification of findings/observations as nonconformities (major and minor) and recommendations
- (k) Handling competence and technical validity decisions which may be more subjective

5.9.4. People skills

- (a) Questioning and communication techniques for assessments
- (b) Attributes of a good assessor – refer to ISO 19011 Guidelines on Quality and Environmental Auditing

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- (c) Human aspects of assessment, and interpersonal skills
- (d) Personality types
- (e) Learning preferences
- (f) Leadership skills

6. **EXERCISES**

6.1.1 Some examples of class exercises are given in “Members Only” area on APLAC website. The body providing the training could use some of these examples to design its own training course materials. It is, however, recognised that, due to cultural differences and time restraints, the class exercises may have to be amended to suit the local situation.

6.1.2 Selections from the following exercises should be given:

- (a) Assessment of Quality Manual: Each group member would study a model “quality manual” which contains nonconformities as well as conformities with the requirements of ISO/IEC 17025, ISO 15189, ISO/IEC 17020, ISO Guide 34 and ISO/IEC 17043. Attendees should be required to identify to which clauses of accreditation criteria documents the nonconformities relate.
- (b) Statistical techniques (where relevant) from ISO Guide 35 and/or ISO 13528 (or equivalent); suggest exercises in homogeneity evaluation, stability testing, and determining the assigned value and its uncertainty; suggest also (for RMP) design and review of interlaboratory testing data.
- (c) Scenarios: Identifying nonconformity as well as the classification of observations into nonconformity and recommendation using the fictitious scenarios. The relevant clause(s) of the standard may also be identified during this exercise.
- (d) Individual exercises on specific elements of the laboratory standard such as:
 - Goals and objectives
 - Job descriptions
 - Contract review
 - Method validation
 - Metrological traceability of Measurement – Acceptability of example calibration certificates
 - Uncertainty components
 - Level of confidence that results comply with specification (using Student-*t* tables)
 - Information from interviewing signatories
 - Use of accreditation body symbol on reports
 - Personality types
 - Types of questions
- (e) Describing findings in writing and classifying them as observations or nonconformities (major or minor). The adequacy of evidence should be discussed.
- (f) Individual exercises on specific elements of the inspection body standard such as:
 - Goals and objectives
 - Job descriptions

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- Traceability of Measurement – Acceptability of example calibration certificates
 - Scenario to identify Type A, B or C
 - Document control / availability of product standard/specification
 - Developing a checklist for monitoring inspectors
 - Information from interviewing signatories
 - Use of accreditation body symbol on reports
 - Personality types
 - Types of questions
- (g) Individual exercises on specific elements of RMP standard such as:
- Characterization of property values;
 - Homogeneity
 - Transportation (short term stability);
 - Stability;
 - Uncertainty.
- (h) Individual exercises on specific elements of PTP standard such as:
- Planning of proficiency testing
 - Homogeneity and stability
 - Assigned value determination, including uncertainty and traceability
 - Operation of proficiency testing schemes
- (i) A role-play of part of an assessment based on a fictitious scenario. This gives 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.
- (j) A role-play on signatory interview, or leading an entry or exit meeting. One member of the group could report on the performance of the “assessor”.

7. ACKNOWLEDGEMENTS

The example of the structure of an examination given in Annex 2 and exercises uploaded in the “Members Only” area on the APLAC website are kindly contributed by A2LA, CALA, CNAS, HKAS, IANZ and NATA.

ANNEX 1**ILAC AND APLAC DOCUMENTS**

There are a number of useful references available on the respective websites of ILAC (www.ilac.org) and APLAC (www.aplac.org) to which references should be made when preparing training courses.

For ILAC Documents, the **Guidance Series (G Series)** documents are for accreditation bodies and accredited organisations. These guidance documents may provide information on the interpretation of accreditation criteria for specific applications. Documents of the **Procedural Series (P Series)** are procedural and policy publications for the operation of the ILAC Arrangement, and which form part of the criteria for ILAC Arrangement evaluations.

For APLAC Documents, documents related to training and produced by the training committee are placed under the **TR series**. Documents to provide guidance on application of accreditation criteria are produced by the technical committee and are placed under the **TC series**. Some examples are

APLAC TC 004: Method of Stating Test and Calibration Results and Compliance with Specification

APLAC TC 005: Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing

APLAC TC 006: Guidance Notes on ISO/IEC 17020

APLAC TC 008: APLAC Requirements for and Guidance on the Accreditation of a Reference Material Producer and the Resulting Scope of Accreditation

APLAC TC 009: APLAC Guidance on Assessing Laboratories and Inspection Bodies to meet Foreign Regulatory Requirements

APLAC TC 010: General Information on Uncertainty of Measurement

APLAC TC013: Guidance for the assessment, reassessment, and surveillance of "key activities" at laboratories with multiple locations

**RECOMMENDED CONTENT, STRUCTURE
AND CONDITIONS OF EXAMINATION**

Duration : 3 hours

Participants may have a clean copy of ISO/IEC 17025 or ISO 15189 or ISO/IEC 17020 or ISO/IEC 17043 as relevant 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 or ISO 15189 or ISO/IEC 17020 or ISO/IEC 17043 and a requirement to indicate the clause and sub-clause relevant to the answer. These should not just require reciting of the words of the standard but should require some lateral thinking.	25 marks
3.	Questions where descriptions or lists are required for each answer. Again the relevant ISO/IEC 17025 or ISO 15189 or ISO/IEC 17020 or ISO/IEC 17043 clauses must be quoted and again some lateral thinking is required.	40 marks
4.	This section relates to the on-site assessment. Some questions may require lists of the steps of an accreditation process. Some may describe incidents/findings during assessment and the student is required to state how they would handle this, to record any nonconformities / corrective action requests(CAR) they would issue, to rate the seriousness of any nonconformity and to list the relevant clause of the standard or other accreditation requirement. Several blank CAR forms could be provided. One incident may relate to more than one CAR.	20 marks

A separate examination may be needed for the bridging course for RMP or for PTP assessors. This could be an 1-hour examination and consist of short questions aimed at assessing the understanding of the trainee of ISO Guide 34 or ISO/IEC 17043 requirements and how a RMP/PTP should be assessed.