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International Accreditation Service

COURSE HANDBOOK

UNDERSTANDING ISO/IEC 17011:2017

Rev 3

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Chapter 1 - Introduction

1.1 Course Development

This course is based on the requirements of ISO/IEC 17011 and applicable Mutual Recognition requirements. It was originally developed for the APLAC MRA Council's Evaluator Training Working Group and has been delivered to both IAAC and NACLA interested parties.

1.2 Course Description

This course is aimed at accreditation body staff and regulatory agencies:

- Who are new to their positions in the accreditation body, or
- Whose organizations are working with accreditation bodies in the delivery of regulatory oversight, or
- Who wish to become more familiar with the accepted interpretations of the requirements contained within ISO/IEC 17011, and related Mutual Recognition requirements.

This course will provide accreditation body and regulatory staff with the tools; references and methods to better appreciate the requirements contained within ISO/IEC 17011.

1.3 Course Learning Objectives

The course will assist you to:

- **understand** the general international structure for the recognition of accreditation bodies;
- **appreciate** the processes used to recognise the equivalence of accreditations in North America and around the world;
- **understand** the accreditation process requirements in ISO/IEC 17011;
- **practice** the skills of examining ISO/IEC 17011 as regards accreditation process requirements.
- **understand** the personnel requirements in ISO/IEC 17011;
- **practice** the skills of examining ISO/IEC 17011 as regards personnel requirements;
- **understand** the requirements given in ISO/IEC 17011 for demonstrated impartiality;
- **practice** the skills of examining impartiality criteria and making appropriate determinations;
- **understand** the general QMS requirements in ISO/IEC 17011;
- **practice** the skills of examining ISO/IEC 17011 as regards QMS requirements;
- **understand** an AB's obligations for the receipt of a peer evaluation;
- **practice** the planning to receive an evaluation team;
- **understand** the interpretations of ISO/IEC 17011 used by peer evaluators, and
- **practice** the skills of interpreting ISO/IEC 17011 in the manner used by international peer evaluations.

1.4 Learning Approaches

All delegates must read ISO/IEC 17011 and bring this document to the training. The remaining documents in the listing in Section 1.5 are at the discretion of the participant.

At the beginning of the course all delegates will contribute to the learning objectives of the course. At this stage, the delegates will be assigned their work teams. Each team represents a fictitious example accreditation body.

During the two days of the course, delegates will participate in team exercises to practice use of the reference materials during their implementation of 17011-related policies and procedures within their sample applicant accreditation bodies. Outcomes from these exercises and other issues will be discussed by the group as a whole. Some exercises and group discussions will be in the small groups examining the specific examples provided.

Learning and team exercises will involve the use of laptop computers so participants are asked to bring their normal laptop with them. The trainers do not provide laptops. Memory sticks will be used to transfer exercise documentation and files during the training.

During the course, delegates will examine sample observations and develop consensus on how to articulate findings from these observations, based on the reference materials provided.

The last exercise will involve a re-visit to the self-evaluation of the first day. Delegates will quantify their own acquisition of skills and knowledge from this training. Delegates will then be asked to evaluate the delivery of the course and how it met their stated objectives.

1.5 Participant Preparation and Resources

Accreditation Requirements Documents

These documents contain the requirements against which an accreditation body is able to confirm CAB competence in the CAB's desired field of accreditation. Delegates in this training are required to understand the documents related to the accreditation of CABs in their own field of expertise. These documents may not necessarily be discussed during the training, but delegates should be sufficiently familiar with the ones in their field of expertise to discuss their implementation.

- For calibration laboratories, ISO/IEC 17025;
- For testing laboratories, ISO/IEC 17025;
- For clinical laboratories, ISO 15189;
- For inspection bodies, ISO/IEC 17020; ILAC/IAF A4;
- For reference material providers (RMPs), ISO Guide 34 and ISO/IEC 17025 in combination;
- For proficiency testing (PT) providers, ISO/IEC 17043, and
- For product certification bodies, ISO/IEC Guide 65.

Accreditation Body Requirements Documents

Delegates in this training must bring the following documents related to the establishment and maintenance of accreditation body equivalence.

Primary Requirements **(Mandatory)**

ISO/IEC 17011:2017 - *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies.* All delegates must read ISO/IEC 17011 and bring this document to the training. The remaining documents in the listing in Section 1.5 are at the discretion of the participant.

ISO/IEC 17011 is available for sale from the national member body to the ISO or an equivalent reseller having agreement with the ISO or the national member body to the ISO. In the USA, the national member body is ANSI. In Canada, the national member body is the Standards Council of Canada. Both of these organisations have copyright agreements with standards resellers.

Joint ILAC/IAF Policies and Requirements (**Optional** - available from the both the IAF and ILAC websites)

- IAF/ILAC A2 – (Requirements for Evaluation of a Single Accreditation Body)
- IAF/ILAC A3 – (Narrative Framework for Reporting on the Performance of an Accreditation Body)
- ILAC/IAF A5 – (Application of ISO/IEC 17011)

ILAC Policies and Requirements (**Optional** - available from the ILAC website – www.ilac.org)

- ILAC P5 – (MRA Scope and Obligations)
- ILAC P8 – (Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status)
- ILAC P9 – (Policy for Participation in National and International Proficiency Testing Activities
- ILAC P10 – (Policy on Traceability of Measurement Results)
- ILAC P13 – (Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers)
- ILAC P14 – (ILAC Policy for Uncertainty in Calibration)
- ILAC P15 – (Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies)
- ILAC R7 – (Use of the ILAC Mark)

IAF Policies and Requirements (**Optional** - available from the IAF website – www.iaf.nu)

- IAF MD 1 – (Multiple Site Sampling Conducted by a Management System CB)

- IAF MD 3 – (Advanced Surveillance and Recertification Procedures)
- IAF MD 5 – (Duration of QMS and EMS Audits)
- IAF MD 6 – (Application of ISO 14065)
- IAF MD 7 – (Harmonization of Sanctions to be Applied to CABs)
- IAF MD 9 – (Application of ISO/IEC 17021 in Medical Device Quality Management Systems (ISO 13485))
- IAF MD 11 – (Application Of ISO/IEC 17021 For Audits Of Integrated Management Systems)
- IAF MD 12 – (Assessment of Conformity Assessment Bodies with Activities in Multiple Countries)
- IAF MD 14 – (Application of ISO/IEC 17011 in Accrediting 14065)
- IAF MD 15 – (Data to Provide Indicators of MS CB Performance)
- IAF MD 17 – (Witnessing Activities for the Accreditation of Management Systems Certification Bodies)
- IAF MD 18 – (Service Management Sector from ISO/IEC 20000-1)
- IAF MD 20 – (Generic Competence for AB Assessors: Application to ISO/IEC 17011)
- IAF ML 2 – (Use of the IAF Mark)
- IAF PL 1 – (Code of Conduct)
- IAF PL 6 – (MOU)
- IAF PR4 – (MLA Structure Normative Documents)

1.6 Delegate Preparation for this Training

All delegates must have read ISO/IEC 17011:2017 prior to this course.

1.7 Course Outline and Syllabus

This course is delivered in ten parts. The syllabus is as follows.

Day 1

1.7.1 Chapter 1 - Introduction to the Course

- Introduction and delivery of training materials
- Acquisition of delegate objectives
- Completion of self-evaluation on current knowledge

1.7.2 Chapter 2 – Accreditation as Recognition of Competence

- Presentation on the international structure of standardization, including standards development and conformity assessment. How these structures are based on national efforts.
- Presentation on the organisations and processes involved in the national and international recognition of accreditations. The US is not the only nation with more than one accreditation body.

1.7.3 Chapter 3 – Accreditation Processes Requirements in 17011

- Facilitated discussion of ISO/IEC 17011 requirements based on questions presented to the whole group (18 questions). Discussion to cover Clause 7 of ISO/IEC 17011.

1.7.4 Chapter 4 – Accreditation Body Personnel Requirements in 17011

- Facilitated discussion of ISO/IEC 17011 requirements based on questions presented to the whole group (6 questions). Discussion to cover Clause 6 of ISO/IEC 17011.

1.7.5 Chapter 5 – Accreditation Body Risk and Impartiality Requirements in 17011.

- Facilitated discussion of ISO/IEC 17011 requirements based on questions presented to the whole group (15 questions). Discussion to cover Clause 4.4 of ISO/IEC 17011.
- Team exercises on the consideration of risk management
- Team exercises on the examination of situations involving accreditation body impartiality.
- Group discussion on the results of the exercise

Day 2

Review of course objectives with delegates

1.7.6 Chapter 6 – Common Quality System Requirements in 17011

- Facilitated discussion of ISO/IEC 17011 requirements based on questions presented to the whole group (21 questions). Discussion to cover Clause 9 of ISO/IEC 17011.

1.7.7 Chapter 7 – Information and Confidentiality Requirements in 17011

- General discussion of ISO/IEC 17011 requirements based on questions presented to the whole group (8 questions). Discussion to cover Clause 7 of ISO/IEC 17011.

1.7.8 Chapter 8 – Preparing for a Peer Evaluation

- Examination of requirements for an evaluation and the evaluation schedule. Team exercise on scheduling, witnessing and reporting requirements.
- Group discussion on the results of the exercise

End of Day 2

Day 3 – (OPTIONAL DAY BUT IMPORTANT MATERIAL) Note that the material from the third day can replace the discussion in Chapter 8 if the course is only the two-day version. The time will not allow as many scenarios to be discussed, but the understanding of international interpretations is much more important than preparation for an external evaluation.

Review of course objectives with delegates (09:00 – 09:30)

1.7.9 Chapter 9 – Common Interpretations of the Requirements in 17011 (09:30 – 15:30)

- Team exercises in harmonising interpretations of accreditation body requirements from large sample set of peer evaluation findings provided (66 observations). (2½ hours + lunch)
- Group discussion on the solutions from the exercise. (2½ hours)

1.7.10 Chapter 10 - Close out of Delegate Objectives (16:15 – 17:00)

- Review of the attainment of delegate objectives (¼ hour)
- Completion of self-evaluation on current knowledge in comparison with similar self evaluation from first day (¼ hour)
- Delegates evaluate the delivery of the course and how it met their stated objectives. (¼ hour)

End of Day 3

1.8 Participation

During each Chapter, you are encouraged to share information with other delegates, especially those in your team.

The course facilitators will monitor group and team discussions and provide clarification whenever this is needed or requested. Where appropriate, the instructor may also offer comments and suggestions to move the discussion forward.

One of the key aspects of this course is the enhanced level of learning that results from delegate interactions with each other. By sharing ideas, experiences and thoughts relative to the material being presented, delegates will find their learning more effective and interesting.

Delegates should be aware that these courses provide opportunity for delegates to learn from each other – even more than learning from the experts present. Delegates are encouraged to draw from their peers during this course. They are your team's greatest source of knowledge and expertise.

1.9 Course Critique

At the end of the training, your facilitators will ask you to complete a facilitator evaluation form that will be provided to you at the beginning of the training session. It provides your facilitators with a frank set of perceptions from delegates so that training can be amended to improve the material, its delivery, or overall logistics to better meet the needs of future delegates. Please feel free to write your comments on the evaluation form as and when they occur to you.

Chapter 2 – An overview of Peer Body Recognition

2.1 Learning Objectives

Upon completion of this Chapter, you should be able to:

- **understand** the general international structure for the recognition of accreditation bodies, and
- **appreciate** the processes used to recognise the equivalence of accreditations in North America and around the world.

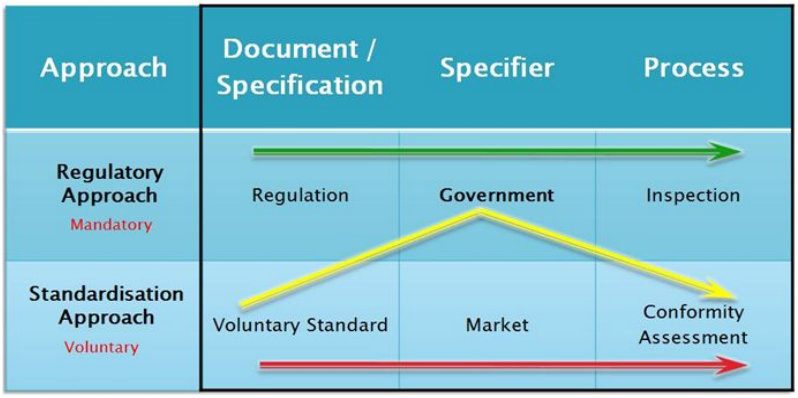
2.2 The Structure of Standardization

2.2.1 From Specification to Competence

There are normally two approaches to determining what requirements must be met, and how they shall be met. The first step is the development of the specification. See the chart below. It shows the differences between the two main approaches used by regulators to execute their primary responsibility, "*protecting the health, welfare and safety"* of citizens within their jurisdiction.

Internationally, the ISO, the IEC, the ITU and other internationally recognised standards development organisations facilitate the development of consensus-based voluntary conformity assessment standards. Within the USA, organisations such as ANSI, ASTM, IEEE, AWWA, and NCSLI, AASHTO, AOAC, ICBO and others also facilitate the development of standards to be applied internationally.

Standards vs Regulations



The green line at the top shows how a government develops a regulation, then specifies its use, and finally enforces it through inspection. An example is the current laboratory-licensing program used by the Ontario Ministry of the Environment, or the US FDA.

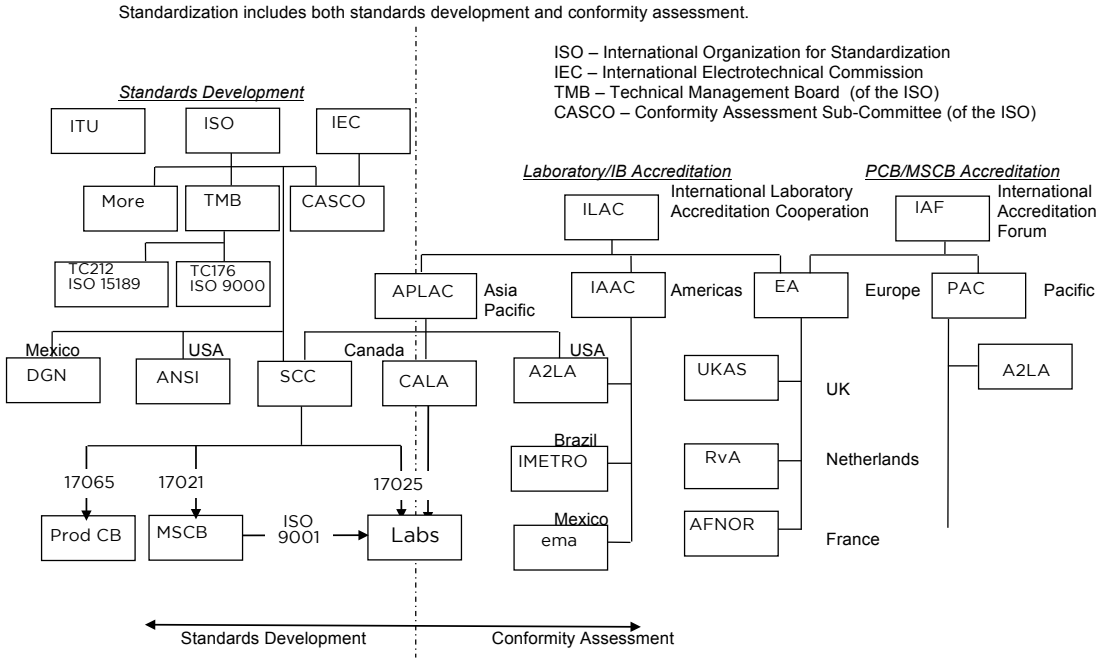
The red line at the bottom is an example of how ISO 9001 and ISO/IEC 17025 are normally delivered without any regulator specification – "by the market, from the market, and for the market". These two standards were developed from within their own communities. Both were developed internationally and included the input of their clients and other stakeholders, including governments. They are delivered using voluntary conformity assessment techniques.

The solid line (green) in the middle represents how a government can specify a voluntary standard. ISO/IEC 17025 and relevant guidelines are delivered today to laboratories, which, if they wish to do business in some specific fields, must meet regulatory requirements for accreditation. These are now part of regulatory tool kits in the protection of the health, welfare and safety of citizens of many nations around the world.

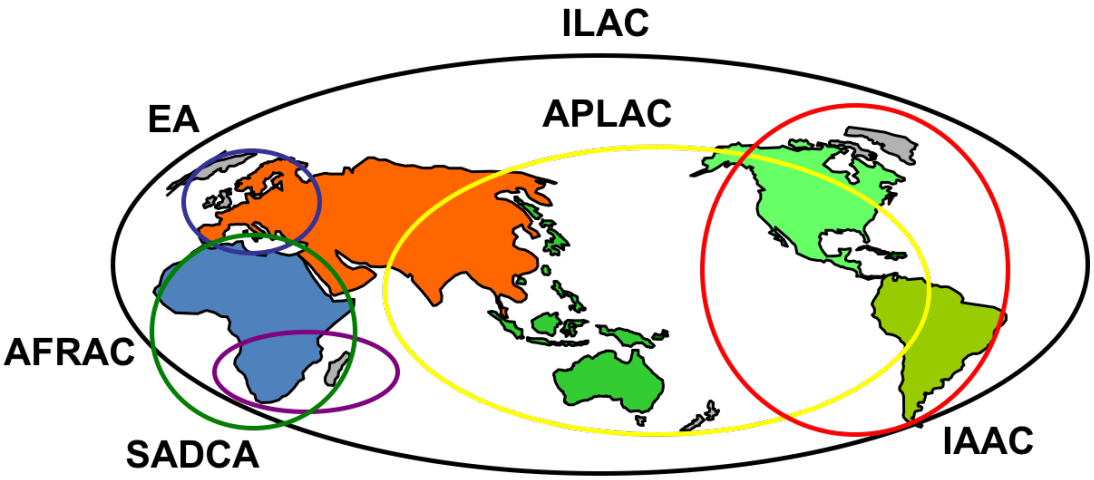
Each of the three components of either type of approach involves:

- writing something that can be used to determine acceptable behaviour (standard or regulation),
- specifying the necessity for this behaviour (the market or some legislation), and
- determining how to evaluate performance against the specification (inspection or conformity assessment).

2.2.2 International Structures of Standards Development and Conformity Assessment



2.2.3 Mutual Recognition of Accreditations



ILAC	**International Laboratory Accreditation Cooperation**
EA	**European co-operation for Accreditation**
APLAC	**Asia Pacific Laboratory Accreditation Cooperation**
IAAC	**Inter-American Accreditation Cooperation**
SADCA	**Southern African Accreditation Cooperation**
AFRAC	**African Accreditation Cooperation**

This diagram shows the coverage of the mutual recognition arrangements made that allows member bodies

2.2.4 Evaluations for Equivalence

Peer evaluations are governed by the following documents:

- IAF/ILAC Evaluation: IAF/ILAC A3
- APLAC Evaluation: APLAC MR001

All of these documents contain definitions on the findings that can be raised during an evaluation and the most common ones (two separate approaches) are shown below. For the purposes of this course, the first one, (ILAC) will be used.

ILAC Evaluation Procedure

Part 3 C: Guidance on Classification of Findings

Finding:	*To be used as a general term*
Non-conformity:	*Finding where the AB does not meet a requirement of the applicable standard (ISO/IEC 17011), its own management system and the Arrangement requirements. The evaluated AB is expected to respond to each non-conformity by taking appropriate corrective action and providing the evaluation team with evidence of effective implementation.*
Concern:	*Finding where the AB's practice may develop into a non-conformity. The evaluated AB is expected to respond to a concern by providing the evaluation team with an appropriate action plan and time schedule for implementation.*

Comment: *Finding about documents or AB's practices with a potential of improvement; but still fulfilling the requirements. The evaluated AB is encouraged to respond to comments.*

2.4 Group Discussion on Equivalence and Recognition

Each group is to consider the number of regulator agencies in the Nation who rely on the receipt of valid test, inspection and certification reports to support either **policy development** or **enforcement**.

2.4.1 How many such agencies / departments exist at national, state, or county level?

National: _____

State: _____

County/City: _____

2.4.2 Each group is to consider the ways and means for each regulatory agency to establish confidence in the results produced by these testing, inspection, and certification bodies. The most common means is regulator inspection and/or third party recognition. Of those listed in question 2.4.1, how many require:

	Nothing	External recognition	Their regulatory evaluation.
National:	_____	_____	_____
State:	_____	_____	_____
County/City:	_____	_____	_____

Each group is to consider the ten most important requirements they perceive as needed in order for a regulatory agency to have confidence in the results produced by these testing, inspection, and certification bodies.

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

Timelines

The group has 30 minutes to discuss the issues listed above and come to consensus on the selections made.

Deliverables

The group should be able to attain consensus on the issues listed above.

Chapter 3 – Accreditation Process Requirements

3.1 Learning Objectives

Upon completion of this Chapter, you should be able to:

- **understand** the accreditation process requirements for accreditation bodies in ISO/IEC 17011;
- **understand** common interpretations of ISO/IEC 17011 with regard to accreditation process requirements, and
- **practice** the skills of examining ISO/IEC 17011 as regards conformance to accreditation process requirements.

3.2 Group Discussion on Accreditation Process Requirements

Tab 2 contains a set of questions in slides that will be presented to the whole group for consideration. Each participant will be asked, as part of a group activity, to vote on the most correct answer while referring to ISO/IEC 17011.

All participants must vote. Any differences of opinion will result in discussion to help clarify issues for the whole group. No one will keep track of the votes, but consensus is a requirement.

If consensus is not attainable (and it may not be attainable in some instances) the training Facilitator will allow the majority to choose the answer.

Sample Documents Provided to Delegates

The slides to be used during this group discussion are contained in Tab 2.

Timelines

The group has two hours to discuss the issues listed above and come to consensus on the selections made.

Deliverables

The group should be able to attain consensus on the issues listed above.

Chapter 4 – Personnel Requirements

4.1 Learning Objectives

Upon completion of this Chapter, you should be able to:

- **understand** the personnel requirements for accreditation bodies in ISO/IEC 17011;
- **understand** common interpretations of ISO/IEC 17011 with regard to personnel requirements, and
- **practice** the skills of examining ISO/IEC 17011 as regards conformance to personnel requirements.

4.2 Group Discussion on Personnel Requirements

Tab 2 contains a set of questions in slides that will be presented to the whole group for consideration. Each participant will be asked, as part of a group activity, to vote on the most correct answer while referring to ISO/IEC 17011.

All participants must vote. Any differences of opinion will result in discussion to help clarify issues for the whole group. No one will keep track of the votes, but consensus is a requirement.

If consensus is not attainable (and it may not be attainable in some instances) the training facilitator will allow the majority to choose the answer.

Sample Documents Provided to Delegates

The slides to be used during this group discussion are contained in Tab 2.

Timelines

The group has one hour to discuss the issues listed above and come to consensus on the selections made.

Deliverables

The group should be able to attain consensus on the issues listed above.

Chapter 5 – Risk and Impartiality Criteria

5.1 Learning Objectives

Upon completion of this Chapter, you should be able to:

- **understand** the requirements given in ISO/IEC 17011 for demonstrated impartiality, and
- **practice** the skills of examining impartiality criteria and making appropriate determinations.

5.2 Group Discussion on Risk Management Requirements

Tab 2 contains a set of questions in slides that will be presented to the whole group for consideration. Each participant will be asked, as part of a group activity, to vote on the most correct answer while referring to ISO/IEC 17011.

All participants must vote. Any differences of opinion will result in discussion to help clarify issues for the whole group. No one will keep track of the votes, but consensus is a requirement.

If consensus is not attainable (and it may not be attainable in some instances) the training facilitator will allow the majority to choose the answer.

Sample Documents Provided to Delegates

The slides to be used during this group discussion are contained in Tab 2.

Timelines

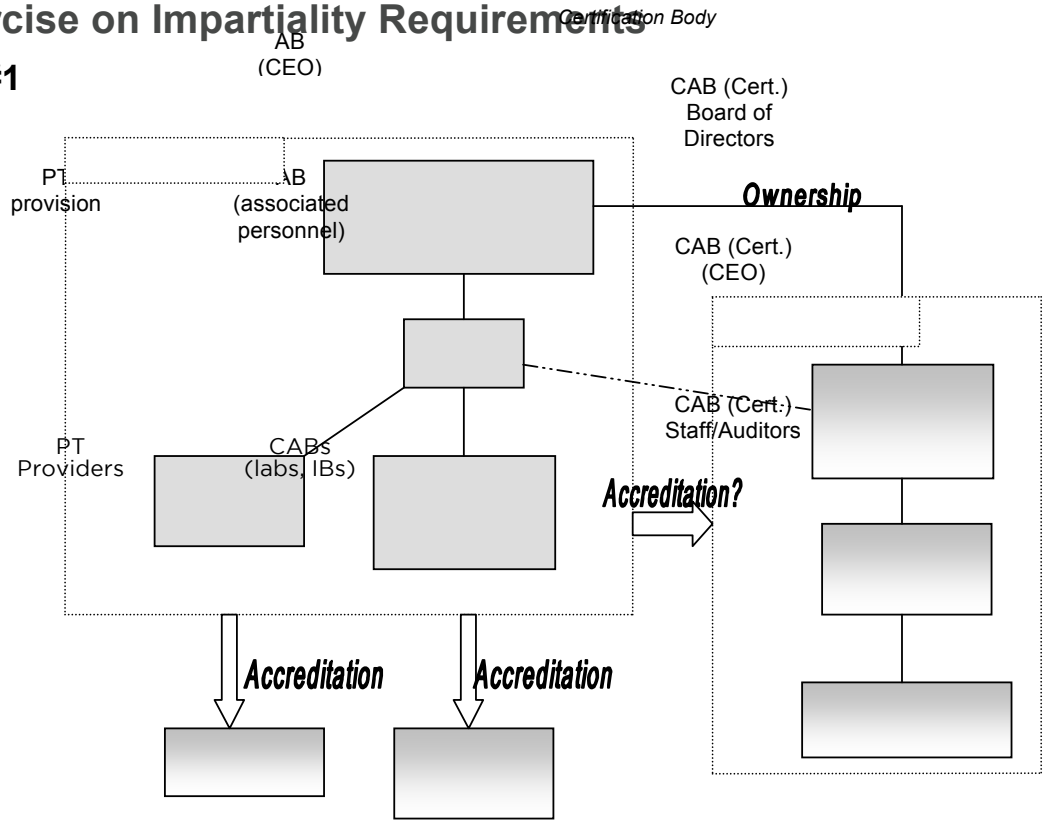
The group has one hour to discuss the issues listed above and come to consensus on the selections made.

Deliverables

The group should be able to attain consensus on the issues listed above.

5.3 Exercise on Impartiality Requirements

Scenario #1



Summary of Situation

An accreditation body (AB) is governed by a Board of Directors appointed by its owners, and has a CEO reporting to it who is responsible for the overall operation of the AB. The AB provides accreditation services (primarily to testing laboratories, calibration laboratories, inspection bodies, PT providers, and reference material producers – but does not accredit certification bodies), PT programmes to the laboratory community, and other activities that are not considered relevant for this exercise.

The Board of Directors also has ownership of a certification body. The certification body has its own, separate Board of Directors appointed by the AB Board of Directors, and its own CEO reporting to the CAB Board.

Questions to answer?

With reference to ISO/IEC 17011…

1. Does the AB structure comply with the Standard?
   - If not, explain why, and give possible actions the AB may take to bring itself into conformity with 17011.
   - If so, explain how the relevant clauses of 17011 have been met by the AB.
   - If undecided, detail additional information the evaluation team should seek in order to make a decision.
2. In terms of 17011, what is the relationship between the AB and the certification body owned by its Board of Directors?
3. If the AB were to accredit the certification body owned by its Board of Directors (either for its certification activities or for another conformity assessment activity), what affect would this have on the relationship between the two bodies? Does it affect your conclusions under 1. and 2. above?

4. If the CEO of the AB were to be appointed to the Board of Directors of the certification body, would this affect your conclusions under 1. and 2., and also 3.?
5. If a member of the certification body is also a member of a decision-making committee, does that still meet the requirements of 4.4 of 17011?

Timelines

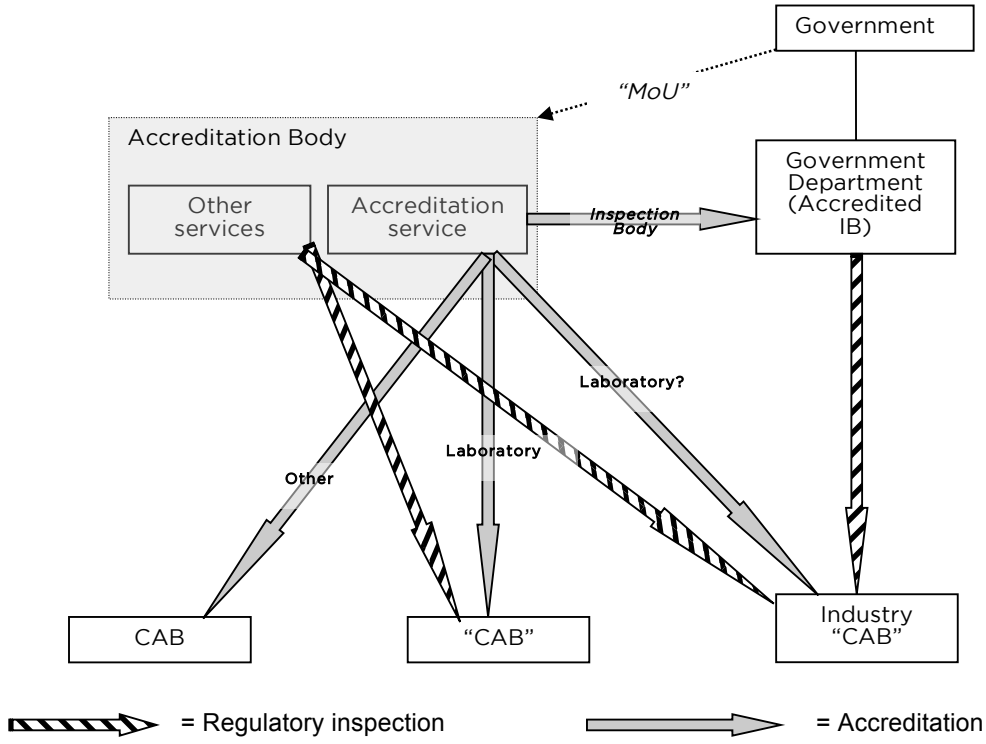
Each team has one hour to deliberate and provide written responses to the questions above.

Teams will gather and present their findings to the whole group. The discussion is anticipated to take one hour and 30 minutes.

Deliverables

Each team is to provide responses, citing the appropriate clauses of ISO/IEC 17011, and their rationale for their responses using the electronic file provided.

Scenario #2



Summary of Situation

The non-governmental accreditation body (AB) offers accreditation services in the areas of laboratory and inspection body accreditation. In addition, it carries out regulatory inspection of organisations under a mandate from Government formalised under a MOU or similar such instrument. The organisations inspected under this mandate may or may not be also accredited by the AB (in this case to ISO/IEC 17025) for similar scopes of activity.

The AB has accredited a government department (as an inspection body to ISO/IEC 17020) to carry out the same types of regulatory inspection (but in a different industry sector) against the same inspection standards that it uses itself in its mandated regulatory inspection role. The accredited government department may inspect the same organisations as the AB inspects (and may also accredit to ISO/IEC 17025).

The regulatory inspection conducted by both the government department and the AB is not considered to be within the definitions of conformity assessment as defined by ISO.

Questions to answer?

With reference to ISO/IEC 17011…

1. Does the situation described comply with the requirements of the Standard?
   - If not, explain why, and give possible actions the AB may take to bring itself into conformity with 17011.
   - If so, explain how the relevant clauses of 17011 have been met by the AB.
   - If undecided, detail additional information the evaluation team should seek in order to make a decision.
2. If the AB was being evaluated for entry into the APLAC MRA for testing and calibration only, how would this affect answer to 1.?
3. How can the AB ensure a balance of interests in their committees dealing with the inspection program?

Timelines

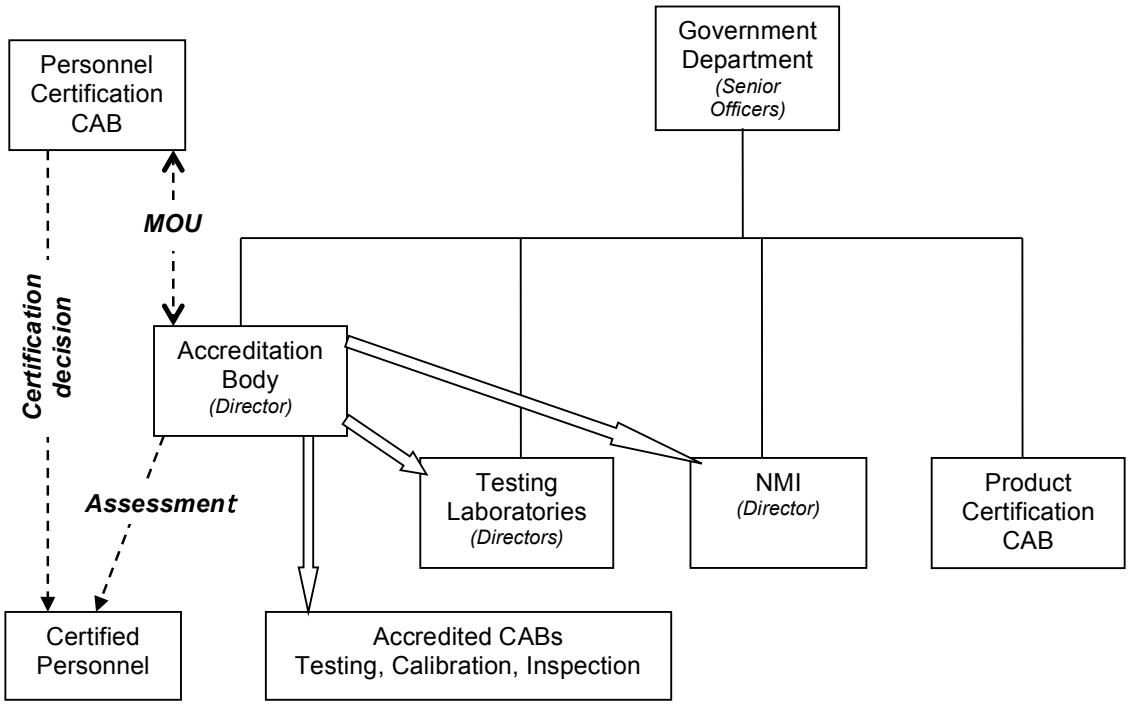
Each team has one hour to deliberate and provide written responses to the questions above.

Teams will gather and present their findings to the whole group. The discussion is anticipated to take one hour and 30 minutes.

Deliverables

Each team is to provide responses, citing the appropriate clauses of ISO/IEC 17011, and their rationale for their responses using the electronic file provided.

Scenario #3



Summary of Situation

The government department consists of several divisions. Among these divisions are an accreditation body (AB), the national measurement institute (NMI), several government testing laboratories, and a product certification body.

The AB (whose senior officer is the Director) accredits testing and calibration laboratories and inspection bodies within industry, including the NMI and the testing laboratory within the government department. In addition, the AB has an arrangement with a separate personnel certification body to carry out audit and surveillance activities on their behalf, i.e. audit and verification activities of certified personnel, which are reported back to the personnel certification body who grants/renews certification of the individual persons.

Questions to answer?

1. With reference to ISO/IEC 17011, identify all activities of the AB that potentially affect impartiality of its accreditations.
2. For each of the activities identified in 1., decide whether the arrangements as described satisfy the requirements of ISO/IEC 17011.
    - If you believe the requirements of the standard are met, give justification along with any assumptions made.
    - If not, explain why with reference to the particular ISO/IEC 17011 clause.
    - If undecided, indicate what further information would be sought to make a decision.
3. How can the AB ensure a balance of interests is represented in its committees?
4. Accreditation decisions are effectively made by external committee members and staff members of the AB who are independent of the assessment process and of the CAB being accredited. However, the accreditation documents (certificates, letters, etc) are formally signed by senior officers of the government department at a level higher than the Director of the AB. These senior officers also have responsibility (both direct and indirect) for the other divisions within the department (including the signing of product certifications).

    How does this situation affect the conclusions made in 2.?

Timelines

Each team has one hour to deliberate and provide written responses to the questions above.

Teams will gather and present their findings to the whole group. The discussion is anticipated to take one hour and 30 minutes.

Deliverables

Each team is to provide responses, citing the appropriate clauses of ISO/IEC 17011, and their rationale for their responses using the electronic file provided.

Timelines

The group has one hour to discuss the issues listed above and come to consensus on the selections made.

Deliverables

The group should be able to attain consensus on the issues listed above.

Chapter 6 – Accreditation Body QMS Requirements

6.1 Learning Objectives

Upon completion of this Chapter, you should be able to:

- **understand** the general QMS requirements for accreditation bodies in ISO/IEC 17011, and
- **understand** common interpretations of ISO/IEC 17011 with regard to general QMS requirements, and
- **practice** the skills of examining ISO/IEC 17011 as regards conformance to general QMS requirements.

6.2 Group Discussion on General QMS Requirements

Tab 2 contains a set of questions in slides that will be presented to the whole group for consideration. Each participant will be asked, as part of a group activity, to vote on the most correct answer while referring to ISO/IEC 17011.

All participants must vote. Any differences of opinion will result in discussion to help clarify issues for the whole group. No one will keep track of the votes, but consensus is a requirement.

If consensus is not attainable (and it may not be attainable in some instances) the training facilitator will allow the majority to choose the answer.

Sample Documents Provided to Delegates

The slides to be used during this group discussion are contained in Tab 2.

Timelines

The group has one and one half hours to discuss the issues listed above and come to consensus on the selections made.

Deliverables

The group should be able to attain consensus on the issues listed above.

Chapter 7 – Information and Confidentiality Criteria

7.1 Learning Objectives

Upon completion of this Chapter, you should be able to:

- **understand** the information and confidentiality requirements for accreditation bodies in ISO/IEC 17011;
- **understand** common interpretations of ISO/IEC 17011 with regard information and confidentiality requirements, and
- **practice** the skills of examining ISO/IEC 17011 with regard to information requirements for recognition of their equivalence mutual recognition arrangements.

7.2 Group Discussion on Information and Confidentiality Requirements

Tab 2 contains a set of questions in slides that will be presented to the whole group for consideration. Each participant will be asked, as part of a group activity, to vote on the most correct answer while referring to ISO/IEC 17011.

All participants must vote. Any differences of opinion will result in discussion to help clarify issues for the whole group. No one will keep track of the votes, but consensus is a requirement.

If consensus is not attainable (and it may not be attainable in some instances) the training facilitator will allow the majority to choose the answer.

Sample Documents Provided to Delegates

The slides to be used during this group discussion are contained in Tab 2.

Timelines

The group has three quarters of one hour to discuss the issues listed above and come to consensus on the selections made.

Deliverables

The group should be able to attain consensus on the issues listed above.

Chapter 8 – Preparing for a Peer Evaluation

(OPTIONAL 3rd DAY BUT IMPORTANT MATERIAL) Note that this material from the second day can be replaced by the discussion in Chapter 9 if the course is only the two-day version. The time will not allow as many scenarios to be discussed, but the understanding of international interpretations is much more important than preparation for an external evaluation.

8.1 Learning Objectives

Upon completion of this Chapter, you should be able to:

- **understand** an AB's obligations for the receipt of a peer evaluation, and
- **practice** the planning to receive an evaluation team;

8.2 Preparing for a Peer Evaluation

IAF/ILAC A2 and APLAC MR 001 governs the conduct of evaluations for single accreditation bodies. These documents contain requirements for the composition and work of evaluation teams and for the body seeking recognition through an evaluation of their equivalence.

All accreditation bodies seeking recognition should be familiar with their applicable MRA document.

The two most significant factors in the successful outcome of an evaluation are:

- The applicant body's interpretation of the requirements for recognition, and
- The evaluation team's ability to obtain sufficient evidence of equivalence.

This chapter deals with the second of these two considerations.

8.3 Team Exercise on the Evaluation Schedule

Each team must now develop a proposed schedule for the evaluation of their accreditation body so that an evaluation team may conclude the successful evaluation of their AB for recognition of their equivalence.

The following conditions apply to this evaluation:

- Your AB seeks recognition for accreditation of testing laboratories, inspection bodies, and product certification bodies.
- Three laboratories, two inspection bodies and one product certification body must be witnessed.
- The evaluation team consists of four persons
- The lead evaluator is competent to evaluate mechanical testing, PT, and electronic calibrations
- One evaluator is competent to evaluate chemistry, microbiology, and other life science testing and inspections, including food.
- One evaluator is competent to evaluate inspection body accreditation.
- One evaluator works for the CPSC.
- One evaluator works for USDA.

Sample Evaluation Plans Provided to Delegates (from IAF/ILAC A2, Part B, Section 3)

Notes: TL = Team Leader, TM = Team Member
copes = laboratories, inspection bodies, product certification bodies, registrars

ABs with single scope

Day	Actions	Evaluators
Day 1	3 hours for preparation with the evaluation team Office, opening meeting, records etc (key issues to be addressed + evaluation plan)	TL + 2 TM
Day 2	Office + witnessing assessments (split evaluation team)	TL + 2 TM
Day 3	Office + witnessing staff + preparation final report + closing meeting	TL + 2 TM
Day 4 morning	Discussing further actions for TMs + departure	TL + 2 TM

ABs with 2 scopes

Day	Actions	Evaluators
Day 1	3 hours for preparation with the evaluation team Office, opening meeting, records etcn(key issues to be addressed + evaluation plan)	TL + 2 TM
Day 2	Office, + preparation for witnessing assessments	TL + 2 TM
Day 3	Office + witnessing staff + witnessing assessments (split evaluation team)	TL + 2 TM
Day 4	Same + preparation final report + closing meeting	TL + 2 TM
Day 5 morning	Discussing further actions for TMs + departure	TL + 2 TM

ABs with 3 scopes

Day	Actions	Evaluators
Sunday	At least 4 hours for preparation with the evaluation team (key issues to be addressed + evaluation plan)	TL + 3 TM
Monday	Office, opening meeting, records etc + preparation for witnessing assessments	TL + 3 TM
Tuesday	Office + witnessing staff + witnessing assessments (split evaluation team)	TL + 3 TM
Wednesday	Office + witnessing staff + vertical audits + witnessing assessments (split evaluation team)	TL + 3 TM
Thursday	Office + witnessing staff + vertical audits (specially directed for confirmation of previous findings + witnessing assessments (split evaluation team)	TL + 3 TM
Friday	Preparation final Report + closing meeting + Discussing further actions for TMs + departure	TL + 3 TM

ABs with full scope

Day	Actions	Evaluators
Sunday	At least 4 hours for preparation with the evaluation team (key issues to be addressed + evaluation plan)	TL + 4 TM
Monday	Office, opening meeting, records etc + preparation for witnessing assessments	TL + 4 TM
Tuesday	Office + witnessing staff + witnessing assessments (split evaluation team)	TL + 4 TM
Wednesday	Office + witnessing staff + vertical audits + witnessing assessments (split evaluation team)	TL + 4 TM
Thursday	Office + witnessing staff + vertical audits (specially directed for confirmation of previous findings + witnessing assessments (split evaluation team)	TL + 4 TM
Friday	Same + preparation final report + closing meeting	TL + 4 TM
Saturday	Discussing further actions for TMs + departure	TL + 4 TM

Sample drawn from APLAC MR001

	Mrs Eve Aluator	*Dr Cal Ibrator*	*A.N Other*	*Ms Nosey Parker*
Sun, dd/mm/yy *15:00hrs*	Evaluation Team meeting	Evaluation Team meeting	Evaluation Team meeting	Evaluation Team meeting
Mon, dd/mm/yy	AB Offices • Introductions • Presentation Commence evaluation **17011 clauses/KPIs/MR-docs** *Detail elements covered*	AB Offices • Introductions • Presentation Commence evaluation **17011 clauses/KPIs/MR-docs** *Detail elements covered*	AB Offices • Introductions • Presentation Commence evaluation **17011 clauses/KPIs/MR-docs** *Detail elements covered*	AB Offices • Introductions • Presentation Commence evaluation **17011 clauses/KPIs/MR-docs** *Detail elements covered*
Evening; 18:00hrs	Evaluation Team meeting	Evaluation Team meeting	Evaluation Team meeting	Evaluation Team meeting
Tues, dd/mm/yy	Travel to assessments Assessment Observation *Detail type of CAB, technical field, type of assessment*	Travel to assessments Assessment Observation *Detail type of CAB, technical field, type of assessment*	Travel to assessments Assessment Observation *Detail type of CAB, technical field, type of assessment*	Travel to assessments Assessment Observation *Detail type of CAB, technical field, type of assessment*
Wed, dd/mm/yy	Assessment Observation *Detail type of CAB, technical field, type of assessment* Travel back to *AB Offices*	Assessment Observation *Detail type of CAB, technical field, type of assessment*	Assessment Observation *Detail type of CAB, technical field, type of assessment*	Assessment Observation *Detail type of CAB, technical field, type of assessment*
Thurs dd/mm/yy	AB Offices Continuation of evaluation of **17011 clauses/KPIs/MR-docs** • Report drafting	Assessment Observation *Detail type of CAB, technical field, type of assessment* Travel back to *AB Offices*	Assessment Observation *Detail type of CAB, technical field, type of assessment* Travel back to *AB Offices*	Assessment Observation *Detail type of CAB, technical field, type of assessment* Travel back to *AB Offices*
Evening 18:00 hrs	Evaluation Team meeting • Report drafting	Evaluation Team meeting • Report drafting	Evaluation Team meeting • Report drafting	Evaluation Team meeting • Report drafting
Fri, dd/mm/yy (a.m.)	AB Offices • Follow-up/completion of issues from Monday and assessments • Report finalisation	AB Offices • Follow-up/completion of issues from Monday and assessments • Report finalisation	AB Offices • Follow-up/completion of issues from Monday and assessments • Report finalisation	AB Offices • Follow-up/completion of issues from Monday and assessments • Report finalisation
(p.m.)	Presentation of evaluation team findings	Presentation of evaluation team findings	Presentation of evaluation team findings	Presentation of evaluation team findings

Question

In preparation of the evaluation, develop team consensus on an evaluation schedule and present it to the facilitator (acting as the principle contact of the body to be evaluated).

Timelines

Each team has one hour and fifteen minutes to deliberate and provide the written proposed evaluation schedule, using the electronic file template provided.

Teams will make their formal presentation of the draft proposed schedule to the group. It is anticipated that this discussion will take one hour.

Deliverables

Each team is to provide a proposed draft schedule, drawn from the appropriate requirements or guidance document, using the electronic file template provided.

Chapter 9 – Interpreting the Requirements of 17011

(OPTIONAL 3rd DAY BUT IMPORTANT MATERIAL) Note that this Chapter 9 material from the third day can replace the discussion in Chapter 8 if the course is only the two-day version. The time will not allow as many scenarios to be discussed, but the understanding of international interpretations is much more important than preparation for an external evaluation.

9.1 Learning Objectives

Upon completion of this Chapter, you should be able to:

- **understand** the interpretations of ISO/IEC 17011 used by peer evaluators;
- **practice** the skills of interpreting ISO/IEC 17011 in the manner used by international peer evaluations.

9.2 Peer Evaluation Procedures

Peer evaluations are governed by the following documents:

- IAF/ILAC Evaluation: IAF/ILAC A2
- APLAC Evaluation: APLAC MR001

These documents contain requirements for the composition and work of the evaluation team and for the body seeking recognition through an evaluation of their equivalence.

The two most significant factors in the successful outcome of an evaluation are:

- The applicant body's interpretation of the requirements for recognition, and
- The evaluation team's ability to obtain sufficient evidence of equivalence.

This Chapter deals with the first of these two considerations.

9.3 Team Exercise on Interpretation of 17011 Requirements

Sample evaluation observations will be allocated to each of the teams for discussion and consideration from the following list of sample observations.

No	Issue	Reference (17011)	Classification (ILAC Anx 5)
1	Accredited product certification bodies do not participate in monitoring the performance of certified products.		
2	Although experts are monitored by staff assessors, the staff assessors themselves are not formally monitored.		
3	Although the accreditation body obtains feedback from the assessed bodies on assessor performance, there is no process for the monitoring of actual performance of assessors. As a result, the accreditation body does not acquire monitoring records of assessor performance.		
4	Although there is a general policy statement and an identification of personnel involved in making accreditation decisions, there is no official procedure for suspension or termination of accreditation.		
5	Appeals process records indicate that appeals decisions are being made by persons who are not independent of the original decisions being appealed.		
6	Assessors are provided assessor assignments based on a low-bid process and are not allowed to extend their assessment charges even when the assessment encounters unforeseen difficulties that require further time to investigate.		

No	Issue	Reference (17011)	Classification (ILAC Anx 5)
7	During the witness of three accreditation bodies, a number of items on the assessment checklist were skipped because of lack of assessor time on site.		
8	In addition to being the sole accreditation decision-maker, the accreditation body's top manager is also responsible to the accreditation body's board of directors for the financial integrity of the accreditation body.		
9	Interested parties within some of the accreditation body's advisory committees have established stringent and prescriptive requirements for the application of section 5.9 of ISO/IEC 17025 and some clauses of 17020. While these requirements have not yet been published, they are being used by assessors.		
10	Interview of working level staff indicate that top management has neither approved nor communicated any of the corporate policies on fees and eligibility requirements for accreditation to staff.		
11	It is not apparent in the management review records whether all inputs to the management review process were considered.		
12	It is not clear where the line for top management is drawn between the accreditation body and its parent body.		
13	Records indicate that the accreditation body's accreditation decision-making council lacks the technical expertise to judge on the appropriateness of findings and CAB responses.		
14	Several applicants were assessed before formally agreeing to the accreditation body terms and conditions or other obligations to the accreditation body as part of their application for accreditation. One two occasions, accredited CABs refused to sign them following accreditation.		
15	Several decisions regarding the scope extensions of accreditation bodies lacked the evidence indicated as necessary within the accreditation body's own procedures, to support these decisions.		
16	Some CABs require a negotiated fee in advance with the accreditation body before it agrees to apply for or renew accreditation		
17	The accreditation body is part of a national regulatory program that also provides accreditation to laboratories that participate in supplier demonstrations of conformance to regulatory requirements. This accreditation body has records that show it fully assesses labs to 17025 but wishes to include its specific requirements on the published scope of accreditation. Such publication is intended to endorse the regulatory program and compliance to its requirements.		
18	The accreditation body allows CABs to make use of the accreditation body logo on their test and certification reports.		
19	The accreditation body allows its CABs to demonstrate traceability of measurement through state metrology laboratories that are not accredited by an ILAC-recognised accreditation body.		
20	The accreditation body appoints technical experts from each of its fields of accreditation to form the body that makes the accreditation decisions. It does not evaluate or monitor them and asserts there is no need to periodically check their technical expertise since they are all recognized as peers in their field.		

No	Issue	Reference (17011)	Classification (ILAC Anx 5)
21	The accreditation body assigns persons responsible for resolving complaints to those involved in the complaint.		
22	The accreditation body conducts annual performance reviews of staff in accordance with best practice in the industry. None of these reviews are based on observed performance as an assessor.		
23	The accreditation body delegates its decision on accreditation to program managers who handle the applications, assign and oversee the assessors, and evaluate the sufficiency of accreditation body corrective actions.		
24	The accreditation body does not control ISO, ILAC or IAF application guidelines/requirements documents in its document control system.		
25	The accreditation body does not distinguish between corrective and remedial action as much of its corrective action records are actually remedial actions to correct nonconformities.		
26	The accreditation body does not provide a list of acceptable PT providers to its inspection bodies and product certification bodies.		
27	The accreditation body formally appoints its decision-making panel (council) from both private industry and public sector bodies. None of the members of this council are assessors.		
28	The accreditation body has a policy for measurement uncertainty for calibration laboratories but has no policies to regarding measurement uncertainty for testing laboratories.		
29	The accreditation body has changed their PT and traceability policies to specify the frequency of both PT and calibration given in national legislation that applies to the heavily regulated nuclear industry and the laboratories that test compliance in that industry.		
30	The accreditation body has issued four certificates of accreditation based on the assessment and decisions of a sub-contracted body.		
31	The accreditation body has neither a policy, nor any procedures, for taking immediate action to suspend accreditation based on major negative findings following assessments of CABs. The accreditation body believes that it must follow “due process” by first proposing to suspend in 30 days to give the opportunity for the CAB to respond.		
32	The accreditation body has neither policies nor procedures to take effective action to prevent misuse of its accreditation symbol.		
33	The accreditation body has never implemented any sanctions on CABs that violate the “without-delay” requirement for reporting major changes.		
34	The accreditation body has not documented a basis for determining the competence of the outside PT providers it recommends to its applicant and accredited CABs.		
35	The accreditation body has not documented an approach for the analysis of assessor competence to govern the selection of the assessors it appoints to its assessment teams.		
36	The accreditation body improved its turn-around times from application to accreditation from 2000 to 2003, but in 2004-05, the times has significantly lengthened in light of major turnover of staff as new staff are not as efficient as the more experienced former staff had been.		

No	Issue	Reference (17011)	Classification (ILAC Anx 5)
37	The accreditation body insisted that follow up of the effectiveness of preventive action was impossible if the problem never occurs in the first place.		
38	The accreditation body itself is not actually a legal entity as it is a program jointly administered by two government departments.		
39	The accreditation body only uses government personnel to assess accredited organisations.		
40	The accreditation body policy and requirements for PT in some specific disciplines does not meet the ILAC-mandated minima. Records indicate that some of the accreditation body's interested parties believe that the ILAC-mandated minima do not make sense for their disciplines.		
41	The accreditation body policy for qualification of assessors includes passing an exam on the knowledge and application of ISO/IEC 17025. The accreditation body does not require any on-site observations, since the accreditation body relies primarily on the qualification processes of other MRA-signatory accreditation bodies. It does not maintain records of such monitoring.		
42	The accreditation body provides fee discounts for CABs in certain fields as an enticement to grow in its newer areas of accreditation.		
43	The accreditation body relies on a sophisticated random sampling plan in performing initial assessments of multi-site CABs, visiting about one-half of the key sites the first year and one-half the second year of accreditation.		
44	The accreditation body requires accredited organisations to draw their traceability of measurement only from the domestic national metrology institute (NMI)		
45	The accreditation body requires assessment staff to complete assessment file preparations for submission to the decision making panel within three weeks of each assessment		
46	The accreditation body staff have limited experience in the operation of an accreditation system. Almost all staff have assumed their appointments within the last 18 months.		
47	The accreditation body subcontracts with "expert" laboratories to carry out assessments of "lower level" laboratories.		
48	The accreditation body subsidizes its annual revenues with grants from the domestic national government.		
49	The accreditation body visits the head office plus two of the four subordinate testing sites listed on the single scope of accreditation every two years.		
50	The accreditation body's related body provides some of its key managerial staff to serve on the accreditation body's policy-making board.		
51	The accreditation body's top manager makes all of the accreditation decisions. This person is also responsible for receiving summary recommendations including information on the resolution of all non-conformities from its technical advisory councils.		
52	The accreditation body's training courses are offered on-site for groups of accreditation bodies from one organization to help them understand and prepare for accreditation.		

No	Issue	Reference (17011)	Classification (ILAC Anx 5)
53	The accreditation process document specifies re-assessments are to be carried out every two years but not to exceed 30 months for any particular cycle. In 11% of the case files examines, the gap was much longer than this.		
54	The content of the accreditation body's assessor training course does not cover flexible scopes and several important assessment techniques.		
55	The domestic NMI does not participate in the CIPM key comparisons.		
56	The evaluation team uncovered records that indicated three accreditations were granted when there was no evidence that some corrective actions have been effectively implemented.		
57	The evaluation team was unable to determine, from available records, the specific technical expertise of accreditation body technical staff and assessors.		
58	The finances available to the accreditation body from government have progressively declined over the last three years. At the same time, government regulation prevents the accreditation body from increasing its costs for services to its accreditation bodies. The accreditation body is now barely covering its costs.		
59	The membership of the policy-making body of the accreditation body does not reflect a balance of the set of those interested parties identified by the accreditation body as important to its operations.		
60	The parent body of the accreditation body supervises the finances and determines the fee schedules for the applicants.		
61	The policy and procedures for avoiding conflicts of interest specifies requirements for some situations, but does not include requirements for the decision-making body members and the objectivity or impartiality of their processes.		
62	The quality manager is the sole person responsible for doing internal audits that are conducted over an annual schedule that covers all areas of the quality system, including the auditing procedures. She is also responsible for implementing any corrective actions required.		
63	The related body (NMI) of the accreditation body had its conformity assessment (calibration) services accredited by the accreditation body itself.		
64	During an assessment, the accreditation body sampling of the inspection body staff did not cover all of the staff and was not representative of all the work for which accreditation was desired.		
65	There is no accreditation body process for ensuring that formerly-accredited CABs stop making reference to their accredited status on each CABs web site.		
66	When asked about how it involved interested parties in policy-making decisions, the accreditation body said it relied on public notices and requests for comments.		

Questions to be considered by each Team

Each team is to review of their evaluation observations and come to consensus on the following:

- What Clause of ISO/IEC 17011 governs the condition under consideration?
- According to IAF/ILAC A3, Part 3 C, how would this observation be classified as a finding?
- What evidence should the applicant AB provide to demonstrate equivalence (conformance) of this condition?

Timelines

Each team has two and one-half hours to deliberate and provide written responses to the questions above, using the electronic files provided.

Teams will gather and present their findings to the whole group. The discussion is anticipated to take two and one-half hours.

Deliverables

Each team is to provide responses, citing the appropriate clauses of ISO/IEC 17011, and their rationale for their responses using the electronic file provided.

Chapter 10 – Quiz and Course Close Out

10.1 Review of Attainment of Delegate Objectives

Delegate objectives garnered during Chapter 1 are examined for attainment.

10.2 Completion of Course Quiz

At the end of the course all delegates will take the end-of-course quiz contained in Tab 5. Each group is to take the quiz together, although each delegate shall provide their own quiz paper to the training facilitator.

10.3 Completion of Delegate Evaluation of the Course

At the end of the course all delegates will evaluate the delivery of the course and how it met their stated objectives.