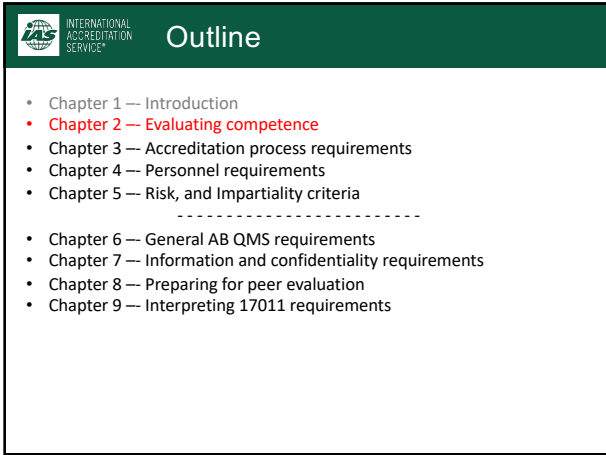
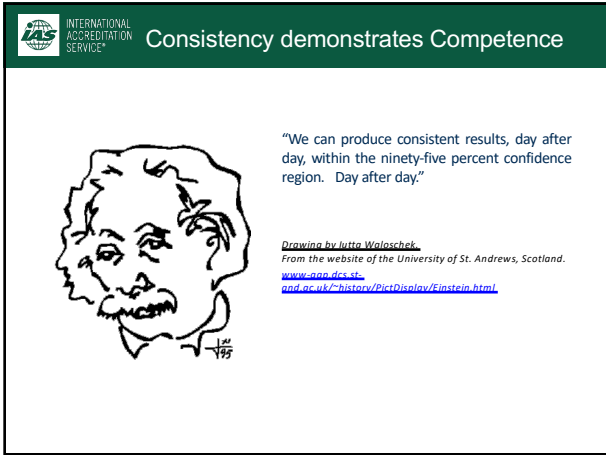




1



2



3



Description of the Perfect CAB

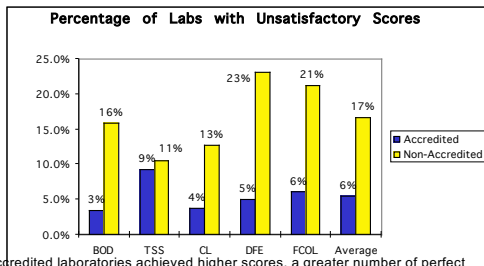
“An organisation that produces consistent results, day after day after day after day..... at specified uncertainties within the 95% confidence region.”

- Sounds boring to the marketing types but not to lab people.
- It is about the science
- It is about consistency
- It is about technical competence

4



Impact of Demonstrated Competence Proof is in PT Scores.



Accredited laboratories achieved higher scores, a greater number of perfect scores, and fewer unsatisfactory scores in each of the five parameters. See www.cala.ca/perfaced-2001.pdf.

5



Competence Components

The Lab/IB/CB (CAB) with:

- The People with the Skills and Knowledge
- The Environment with the Facilities and Equipment
- The Quality Control, and
- The Procedures

All aimed at producing valid results.

6



INTERNATIONAL ACCREDITATION SERVICE

Competence for a Lab or IB

Ask CAB clients and regulators which is most important:

- A. CABs conform to an international standard
- B. CABs are competent
- C. CABs produce valid (correct) results

They will respond in this priority:

- 1. Correct results
- 2. Competence
- 3. Conformance to a standard

7



INTERNATIONAL ACCREDITATION SERVICE

Competence for a CB

Ask CB clients and regulators which is most important:

- A. CBs conform to an international standard
- B. CBs are competent
- C. CBs produce valid (impartial) results

They will respond in this priority:

- 1. Correct results by an impartial body
- 2. Competence
- 3. Conformance to a standard

8



INTERNATIONAL ACCREDITATION SERVICE

Competence

- CAB clients and regulators want labs to be correct and that it is telling them the truth. They want to trust that **both** of these conditions exist whenever one of them produces a result. Instead of facing all of the CABs and asking them if (and how) they would do this, many have come to trust an organisation whose recognition of the CAB indicates that both conditions are being met.
- That type of organisation is a recognised accreditation body.

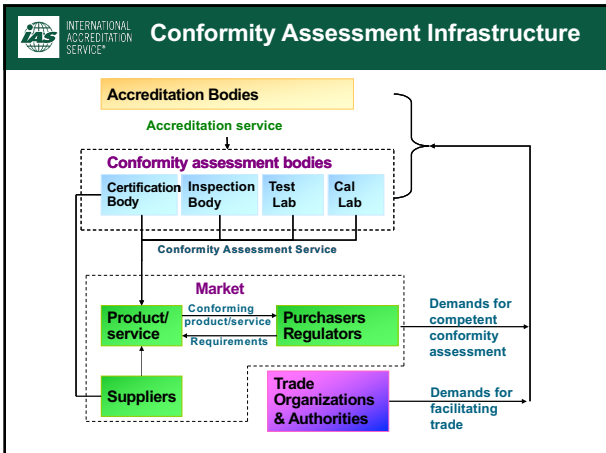
9

Standards vs Regulations

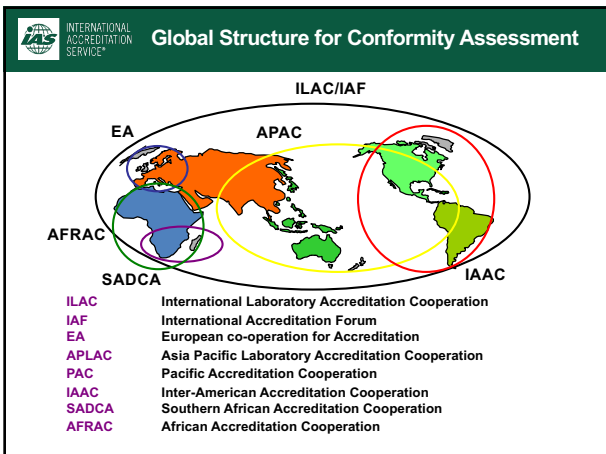
Approach	Document/Specification (What is it?)	Specifier (Who wants it?)	Process (How do they get it?)
(1) Regulatory Approach (Mandatory)	Regulation	Government	Inspection
(2) Standardisation Approach (Voluntary)	Voluntary Standard	Market	Conformity Assessment

- Red** = Govt Regulation, ENFORCED by Inspectors through INSPECTION
- FDA Lab Licensing Fail to comply? Jail or fines
- Black** = Govt Regulation, MONITORED through Audits for CONFORMANCE
- Most Lab Accreditation Fail to conform? Lose registration
- Blue** = Market Demand, MONITORED through Assessments for COMPETENCE
- ISO 9000. Fail to demonstrate competence? Lose accreditation

10



11



12



INTERNATIONAL ACCREDITATION SERVICE™

ILAC Findings

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.

13



INTERNATIONAL ACCREDITATION SERVICE™

ILAC Findings

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.

14



INTERNATIONAL ACCREDITATION SERVICE™

Changes in Definitions 17011:2017

- "accreditation certificate" removed
- notes under "appeal" removed
- "expert" changed to "technical expert" and does not assess independently.
- "extending accreditation" better defined
- "lead assessor" changed to "team leader"
- "surveillance" removed and included in "assessment"
- "remote assessment" added
- "assessment techniques" added

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Changes in Definitions 17011:2017

- “conformity assessment activity” added
- “assessment programme” added
- “accreditation process” added
- “accreditation activity” added
- “accreditation decision” added
- “granting accreditation” added
- “accreditation scheme” added
- “assessment plan” added
- “accreditation body personnel” added
- “maintaining accreditation” added
- “reassessment” added

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Rationale for Accreditation

1. There is 1 question in this Chapter.
2. **What does the standard require?**
3. Participants select their own answers.
4. The whole group is balloted for the most appropriate response.
5. [Clapping indicates a correctly answered question. Buzzer indicates an incorrectly answered question.](#)
6. The citation from the standard is displayed next to the most correct answer.
7. The quiz then advances to the next question.

Press

Continue

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Rationale for Accreditation

Introduction

Accreditation is primarily to provide customer service to CABs:

- A. [TRUE](#)
- B. [FALSE](#)
- C. [NOT APPLICABLE](#)

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