L2 Basic Concepts of Accreditation and Accreditation Process



Objectives

In this lecture we will:

- Discuss the necessary actions to get accreditation
- Speak about the effort necessary
- Try to estimate costs



Definition

Accreditation

Accreditation is a formal declaration by an Accreditation Body, after assessment and confirmation, that a laboratory is effective and competent in meeting the requirements of ISO 17025 to perform tests according to its accredited scope.



Aim of accreditation

- Decision are based on data and information
 - Decisions are made by employers, radiation workers and regulators
 - The data is obtained by testing, inspection or certification (conformity assessment activities)
- A test report or a certificate describes the quality of a product

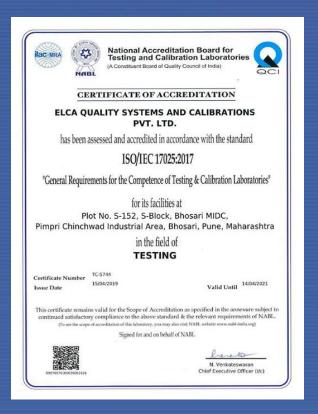


Aim of accreditation

- How do demonstrate the quality of the results of this report?
- A label that adds the dimension of credibility and confidence could do the job. This is the major aim of accreditation, but there is another ...



Typical Certificate and Scope of Accreditation





Accreditation Certificate

Scope of Accreditation



Aim of accreditation



CERTIFICATE OF ACCREDITATION

This is to certify that:

NECSA RADIOANALYSIS

Testing Leberstory No. T0111

is a South African National Accreditation System Accredited Laboratory

for four years commencing July 2005 provided that

all SANAS conditions and requirements are compiled with.

This certificate is valid for:

RADIOACTIVITY ANALYSIS

as per scope on accompanying schedule of accreditation

THE LABORATORY COMPLIES WITH ISO/IEC 17025

While this certificate remains valid,

the Accredited Laboratory named above

is authorised to issue SANAS certificates.

"Recognised as the official national accreditation body by the Department of Trade and Industry of the Republic of South Africa"

This certificate is only valid when accompanied by its schedule of accreditation

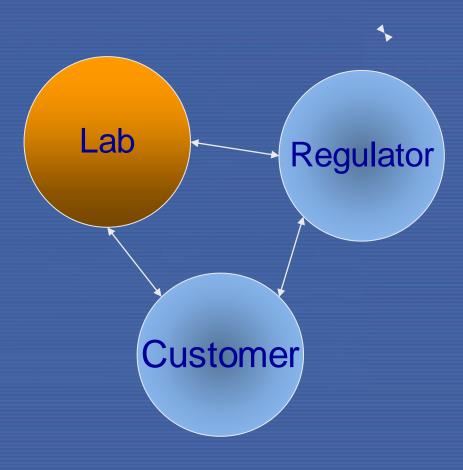


Conformity Assessment Infrastructure

BIPM Metrology Science and Society conformity **Technology** assessment **Standardization Accreditation** trade **IEC** ISO **IAF ILAC**

How Accreditation Helps i. The lab

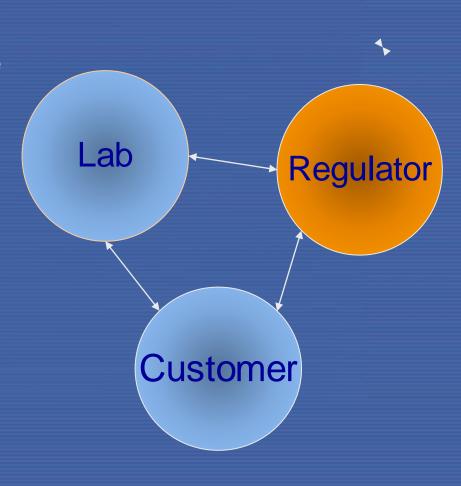
- Marketing tool
- Internal and externally less discussion, more efficiency
- Less complaints, re-analysis & errors internally
- Higher customer satisfaction
- Better knowledge management
- More reports in time
- A more proactive risk-based quality culture, not reactive
- Creating an environment of professionalism and pride
- So, at the end less errors and thus costs





How Accreditation Helps ii. The regulator

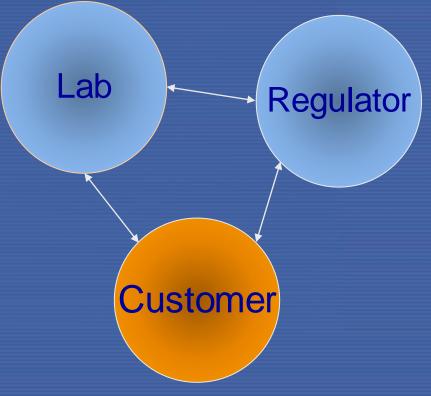
- Reliable testing & calibration services
- Reduce cost of market surveillance and making of regulations
- Self-regulation tool
- Increase transparency, honest competition
- Guaranteed independent service provider
- Better cooperation since competent staff





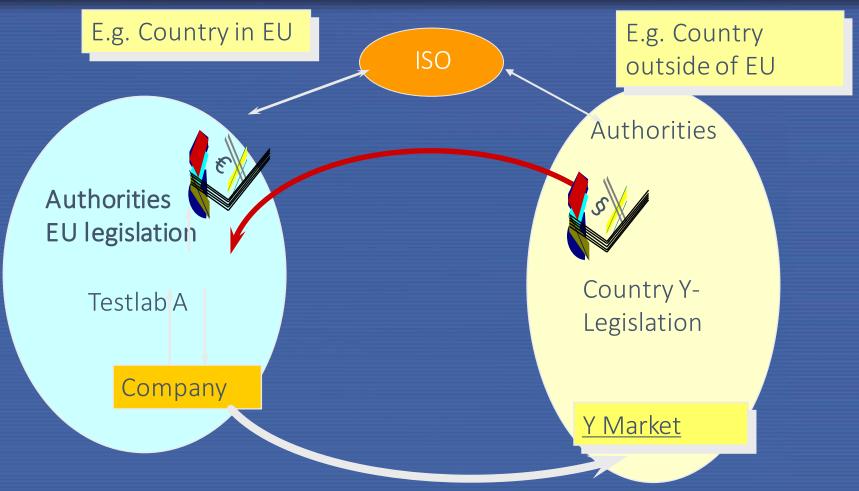
How Accreditation Helps iii. The customer: the employer & radiation worker

- Reduce risk of bad results
- A competent lab with experts in case they have questions – better cooperation
- More comparable results
- Eventually cheaper (?)
- No need to reinvent the wheel, use proven technology (since the aim is technical harmonization)
- Less discussion with regulator
- Acceptable test certificates by other external companies/authorities/countries – One-Stop Testing
- So, in general increasing customer confidence



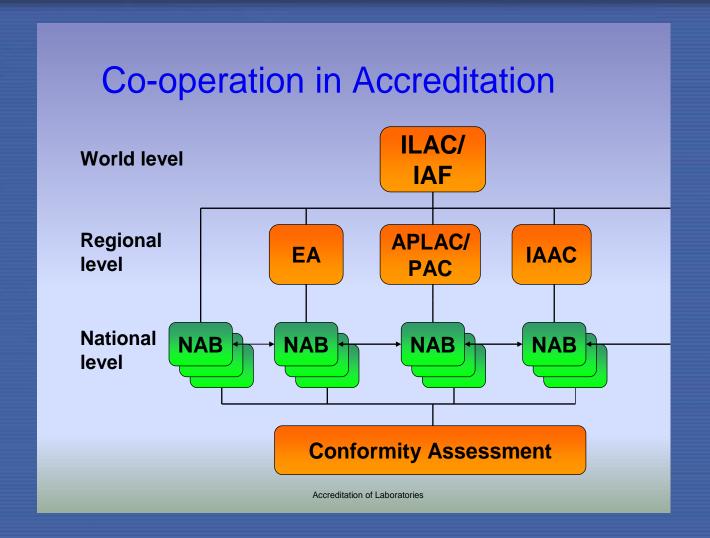


Mutual Recognition and One Stop Testing



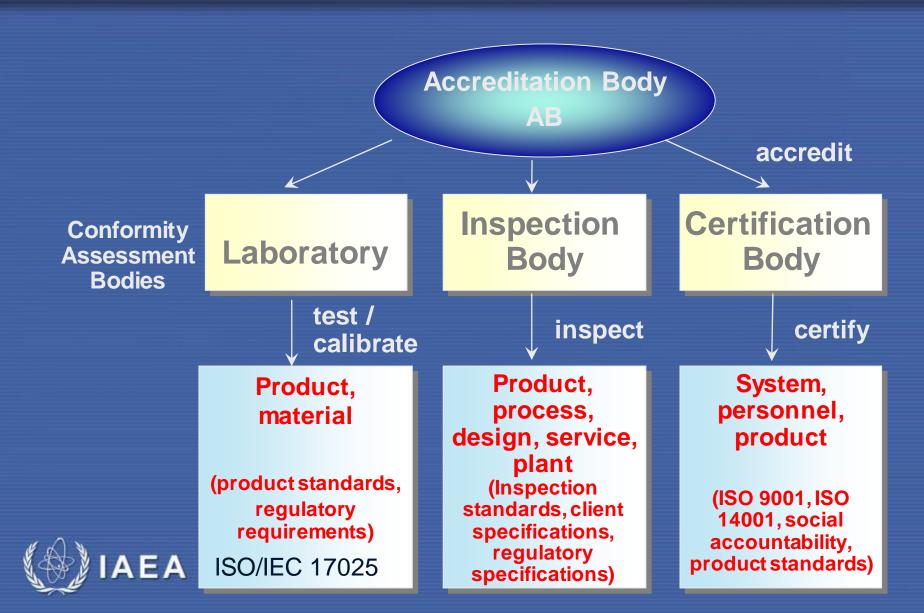
A test report issued by Testlab A under accreditation for a product e.g. free of radioactivity should be accepted in country Y

Only on AB per country: no competition





Hierarchy of Conformity Assessment



Management Systems Standards

Vocabulary and general principles EN ISO/IEC 17000

General requirements for accreditation bodies EN ISO/IEC 17011

certification bodies for:

Requirements for

Supplier's declaration of conformity EN ISO/IEC 17050, Teil 1 und 2

Requirements for proficiency testing EN ISO/IEC 17043 Requirements for testing and calibration laboratories EN ISO/IEC 17025

Requirements for inspection bodies **EN ISO/IEC 17020**

Management systems ISO/IEC 17021

Persons

SO/IEC 17024

services cts, processes, se EN ISO/IEC 17065 Products,

Mutual recognition / Peer assessment EN ISO/IEC 17040, ISO Guide 68



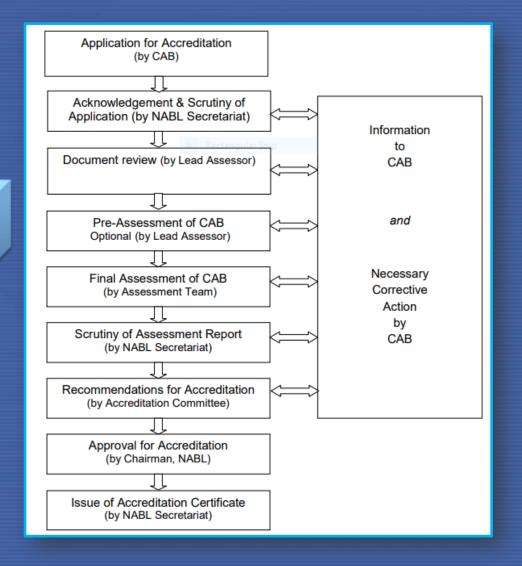
Requirements for the competence of

reference material producers

EN ISO 17034

Flow Diagram of Accreditation Process

Accreditation Process





The way to accreditation

- Decision to go for accreditation define your analysis method, matrix, parameter to be accredited, so define your scope e.g. OSL Dosemeter, Photons, Hp(10) or TLD Dosemeter, Bèta's Hp(0.07)
- Document your lab activities;
- Perform a gap-analysis between your documentation and the standard
- Implement the QM-system;
- Live and improve the system for some time
- Check the system through Internal Audits, Quality Control, ...
- Enhance the system with help of improvement possibilities



After all this, still continuous improvement





Accreditation cycle example (Belgium)



The external audit

- Depending on the size of the organization, the volume of the quality documentation and the amount of accredited test method there will be an number of external auditors assigned to the job.
- The audit may last from one day to several days depending on the volume of documentation and number of methods to check.



Costs

Costs of an accreditation are a sum of different contributions:

- Implementation costs of a QM-system
- Costs of maintenance of the QM-system e.g. internal audits, quality control, intercomparisons, ...
- External audit costs: mainly personnel costs of the external audit team consisting of a lead auditor and one or more technical experts
 - Accreditation bodies very often are state run, where costs will are fixed for a general administration fee, but floating for the audit part depending on the numbers of auditors and the duration of the audit. Mostly the hourly rates are fixed, but will vary depending on an acceptable hourly rate in a country.

