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
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
Conformity Assessment Infrastructure

- Metrology
- Science and Technology
- Standardization
- Accreditation
- BIPM
- Society
- IEC
- ISO
- IAF
- ILAC

conformity assessment
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
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

Co-operation in Accreditation

World level: ILAC/IAF

Regional level: EA, APLAC/PAC, IAAC

National level: NAB

Conformity Assessment: Accreditation of Laboratories
Hierarchy of Conformity Assessment

Accreditation Body (AB)

Conformity Assessment Bodies

- Laboratory
  - Product, material
    - (product standards, regulatory requirements)
    - ISO/IEC 17025
  - test / calibrate

- Inspection Body
  - Product, process, design, service, plant
    - (Inspection standards, client specifications, regulatory specifications)
  - inspect

- Certification Body
  - System, personnel, product
    - (ISO 9001, ISO 14001, social accountability, product standards)
  - certify
Management Systems Standards
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)

- **Initial audit**: 12 months
- **Surveillance Audits**: 12 months
- **Renewal Audit**: 15 months (5 year cycle)
- **Surveillance audit**: 15 months (3 year cycle)

- Full audit ISO/IEC 17025
- Not full audit ISO/IEC 17025
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 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.