Accreditation of PT providers – is it worth the money?

Aspects of accreditation from point of view of the providers

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Eurachem Workshop
Portorož, Slovenia, 25-27 Sept. 2005
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A few words about EQUALIS

- National QA organisation for laboratory medicine
  - Project form 1992-95. **Self-financed** limited company 1996
  - 16 staff
  - 14 steering committees with > 80 experts

- PT/EQA schemes
- Calibration services
- Nomenclature & standardisation
- Testing of equipment
- QA projects
- Education and training
Development of EQA activities

![Graph showing the development of EQA activities from 1993 to 2005. The graph compares the number of schemes and accredited schemes over the years.]

- **All schemes**
- **Accredited schemes**
Why accreditation?

- Inside EQUALIS 1997-98...
  - Rapid increase in EQA activities
  - No written procedures for the work
  - Sense of vulnerability

- Outside EQUALIS mid 1990s...
  - Rapid increase in accreditation of Swedish medical laboratories
  - Accreditation of PT providers abroad
  - International debate
  - Information about ILAC work from consultants
The accreditation process

■ 1998: Work started. No existing quality management system to rely on!

■ 2000 & 2001: Pre-assessments → “Need to secure quality and supply of test materials” → contracts

  – “EQAP document” (SWEDAC DOC 04:10)
  – ISO/DIS 13528

■ 2003: Flexible scope
Experience from annual technical assessments 2002-05

- Lead assessor + 3 to 4 experts in team, e.g:
  - 2003: Clinical chemist + food chemist (PT provider) + transfusion medicine specialist + computer expert
  - 2005: Clinical chemist + virologist + civil engineer (EQAS organiser)

- Possibility to influence composition of assessment team

- Duration: 1 day

- Good discussions that stimulate improvements
Audit of subcontractors

- All test materials from subcontractors
- 1-2 audits/year since 2002
- Positive outcome
  - Direct contact with key staff
  - Possibility to study whole manufacturing process
  - Increased understanding of test material limitations
  - Basis for revision of contracts
Is it worth the money?

- Strong trend towards accreditation of EQA schemes*
- Providers’ experience from the accreditation process is positive*
- Small or no increase in fees from accreditation if a QM system is already implemented*

* Eurachem/EQALM survey on accreditation, draft report, Aug. 2005
Is it worth the money for EQUALIS?

- Accreditation a positive experience!
  - Improved general quality of the EQA services,
  - Improved insight into the properties of the test materials and subcontractors’ services,
  - Improved QM system through regular assessment,
  - Ability to meet new requirements related to information security management and IVD

- The cost for accreditation is
  - high since the assessment requires a large team
  - small compared to that for maintaining the QM system
But, it’s a lot of papers!
Structure of quality management system
(September 2005)

- Quality manual (QM)
  - Ch. 1-3: Based on ILAC-G13
  - Ch. 4: Calibration services
  - Ch. 5: Risk management

- 37 standard operating procedures (U)

- 94 work instructions (A)

- 76 contracts (J, K)

- 87 forms (B)

- 2 certificate of analysis (C)

- A fully documented data system, designed for EQUALIS’ needs (D)
Looking to the future...

- New standard ISO/IEC 17011:2004 enables more flexible assessments
  - Longer assessment intervals and smaller assessment teams can reduce costs for accreditation!
  - Smaller teams require assessors with broad competence!
- Our objective is to accredit all schemes, where relevant
- Further development of our QM system is needed