

Accreditation of PT providers – is it worth the money?

Aspects of accreditation from point of view of the providers

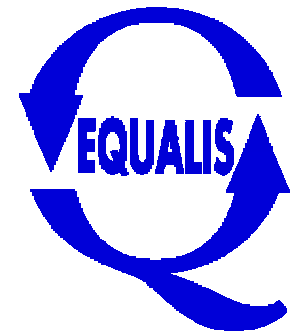
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*Eurachem Workshop
Portorož, Slovenia, 25-27 Sept. 2005*

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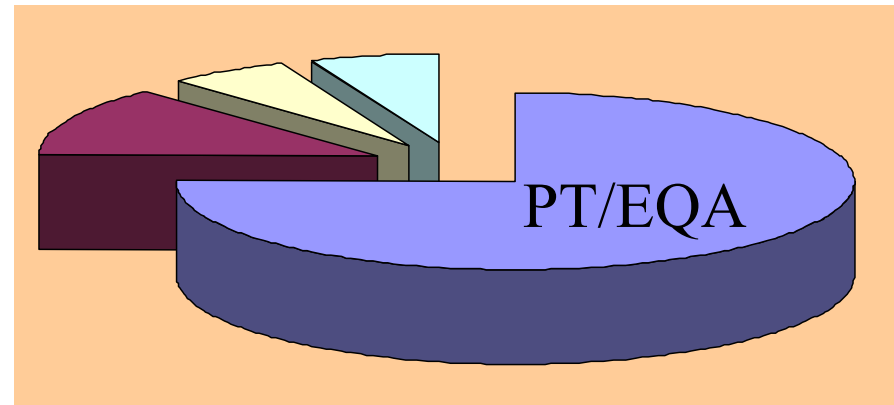
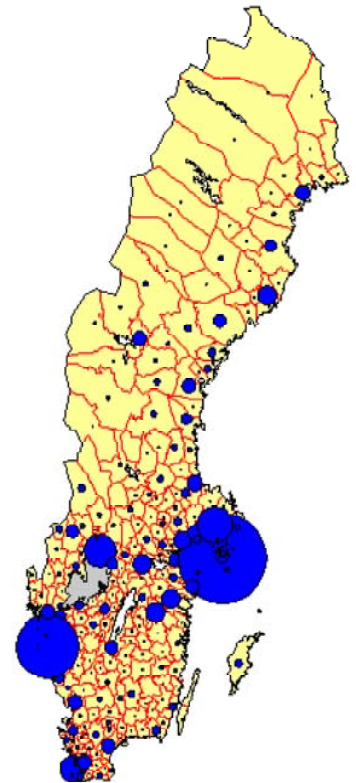


- A few words about EQUALIS
- Background to the accreditation
- Experience from assessments and audits
- Structure of the quality management system
- EQUALIS' conclusions and conclusions from surveys

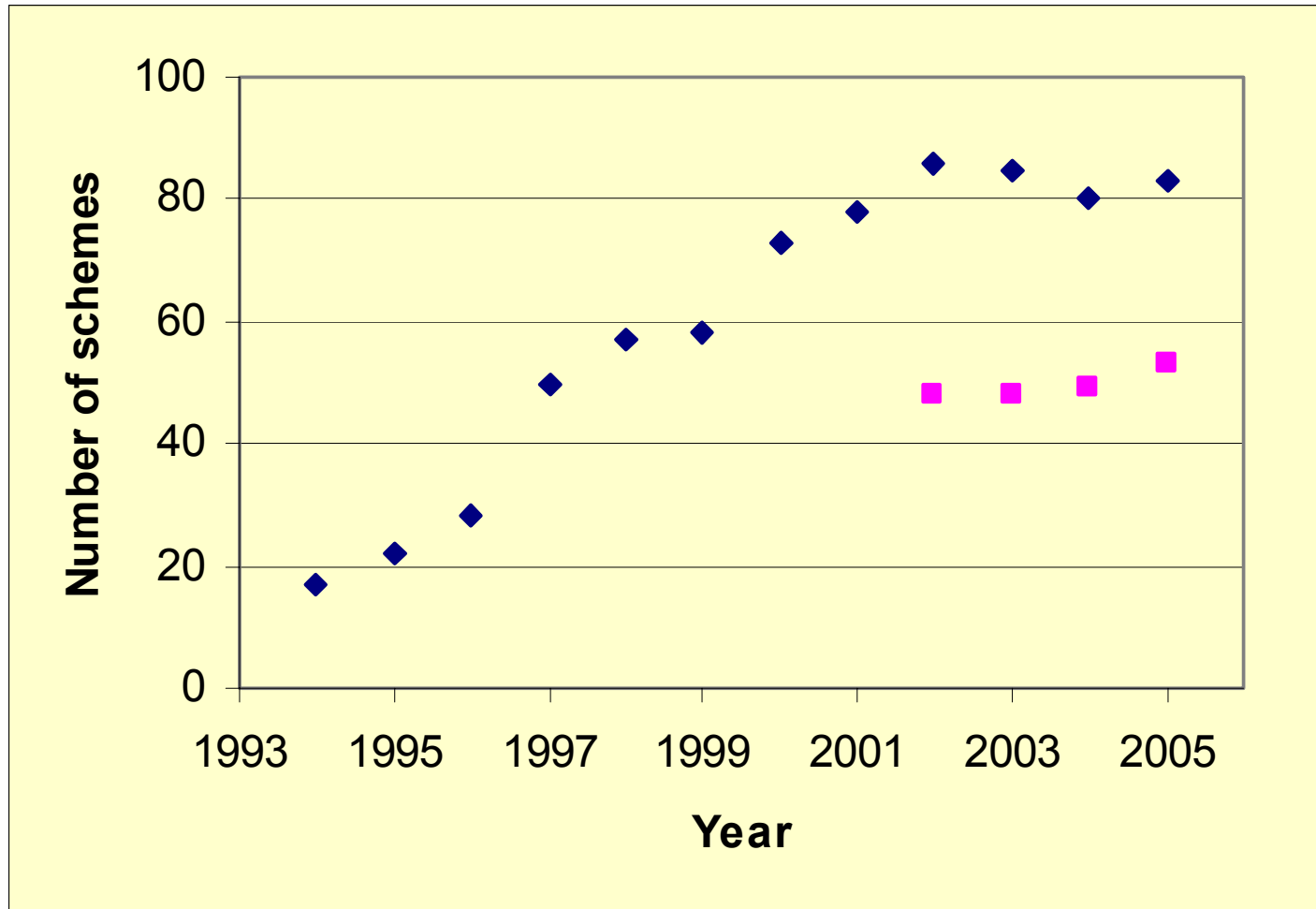


A few words about EQUALIS

- 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

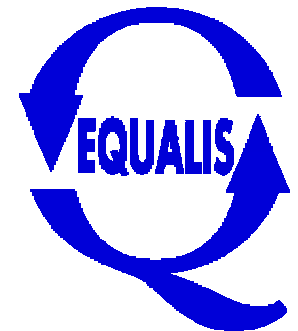


Development of EQA activities



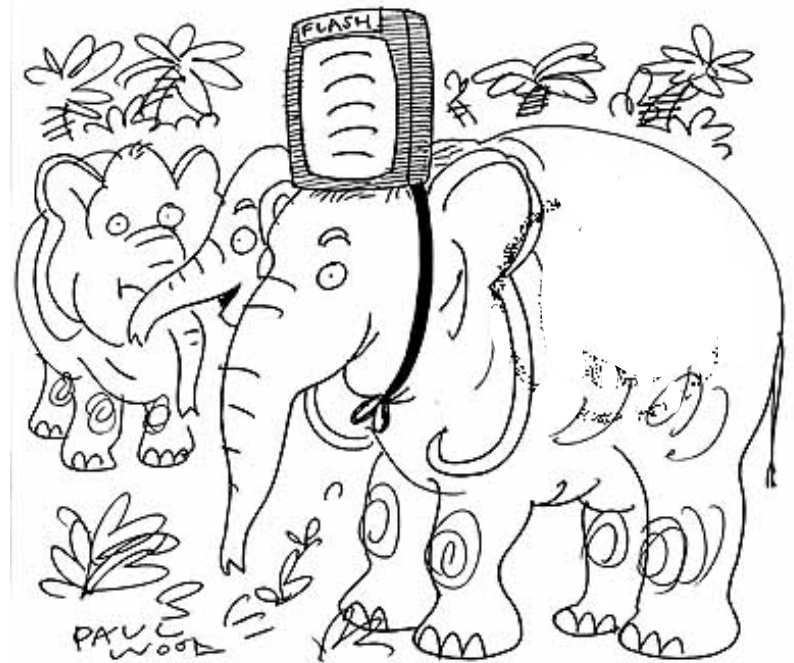
All schemes

Accredited schemes

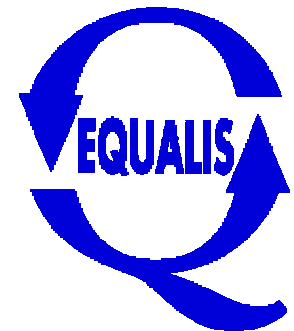


Why accreditation?

- 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



"He's got a photographic memory"



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
- 2002: Accreditation granted. Based on ISO/IEC Guide 43-1, ILAC-G13, ISO/IEC 17025
 - “EQAP document” (SWEDAC DOC 04:10)
 - ISO/DIS 13528
- 2003: Flexible scope



Experience from annual technical assessments 2002-05

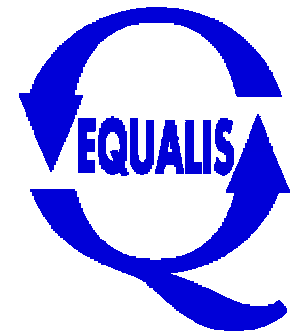


- Lead assessor + 3 to 4 experts in team, e.g:
 - 2003: Clinical chemist + food chemist (PT provider) + transfusion medicine specialist + computer expert
 - 2005: Clinical chemist + virologist + civil engineer (EQAS organiser)
- Possibility to influence composition of assessment team
- Duration: 1 day
- Good discussions that stimulate improvements



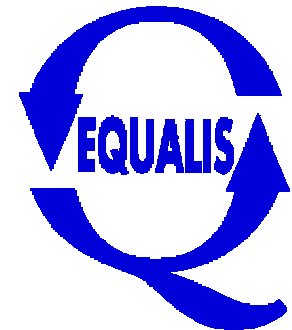
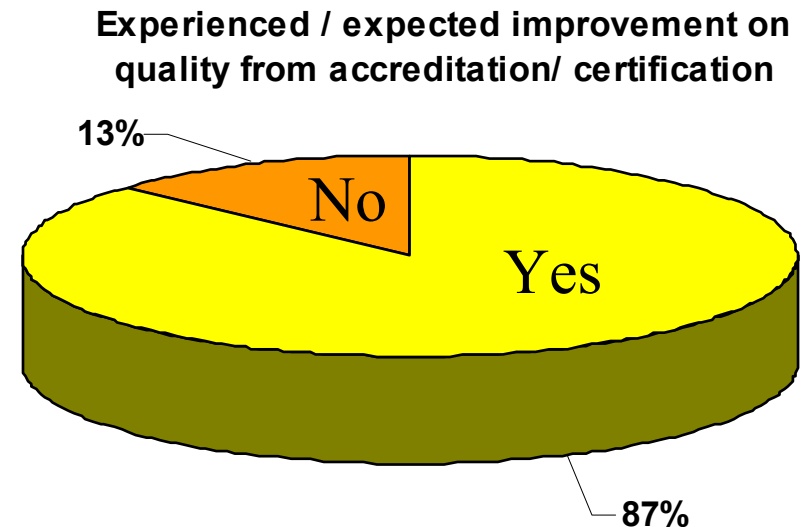
Audit of subcontractors

- 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*

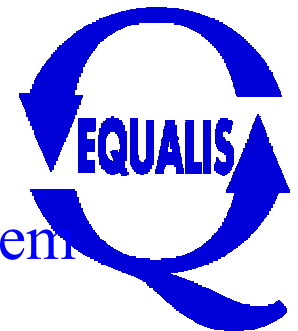


* Eurachem/EQALM survey on accreditation, draft report, Aug. 2005

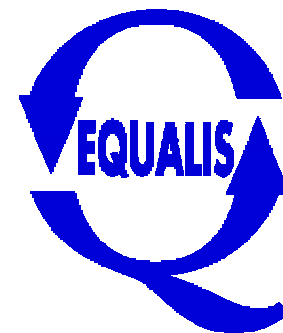
Is it worth the money for EQUALIS?



- 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



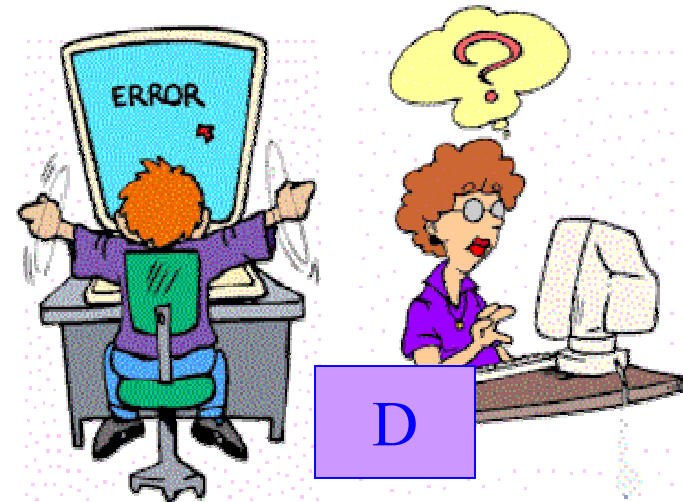
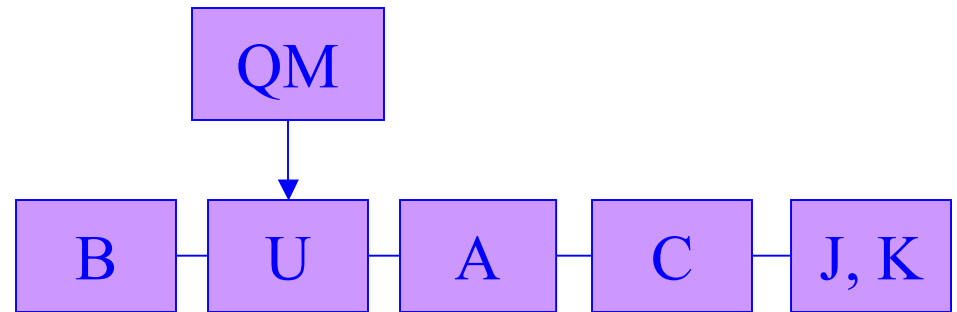
But, it's a lot of papers!



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

