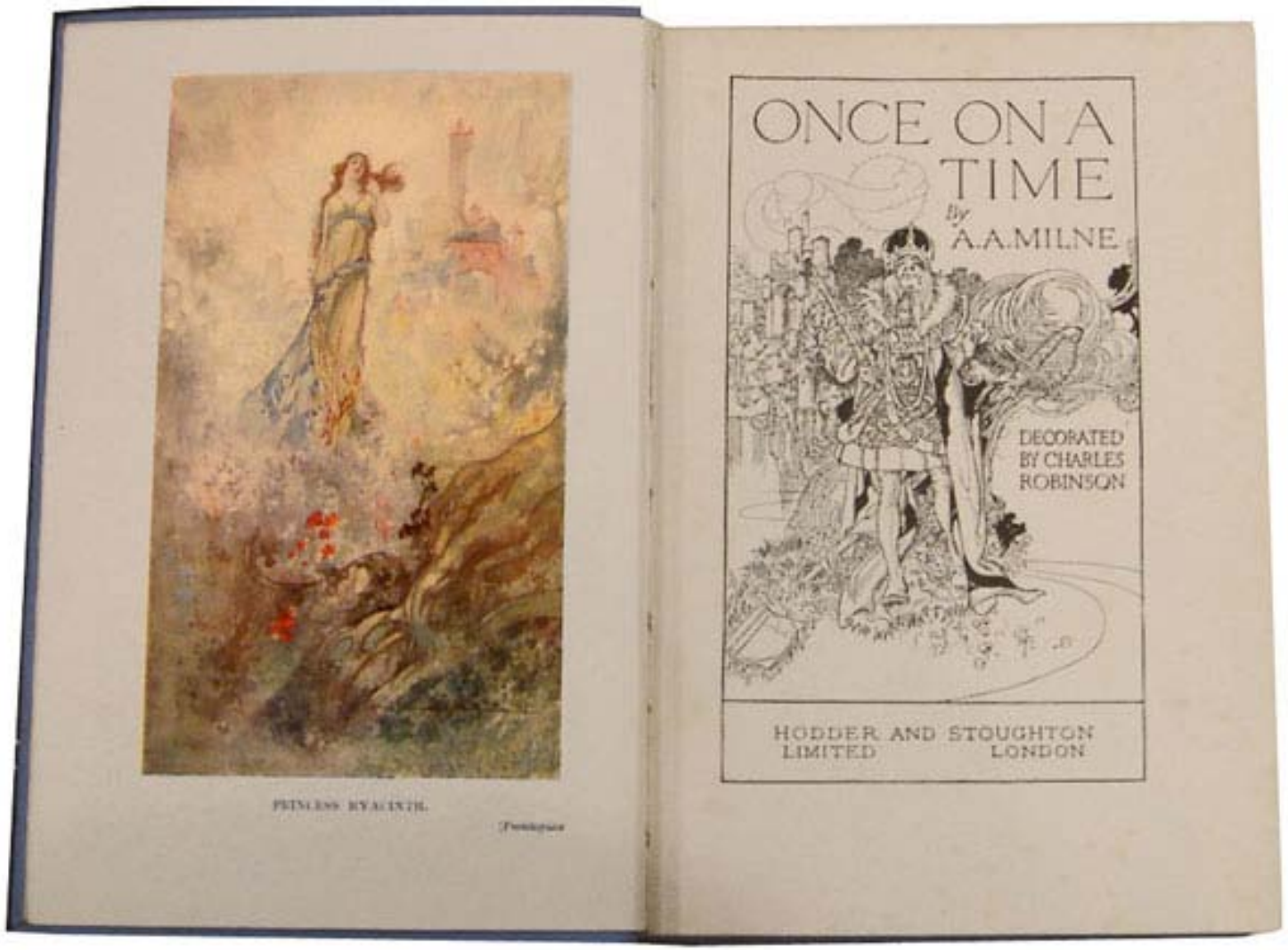
Lessons learned; Mistakes made

- **Accrediting a medical genetics laboratory**
  - Molecular genetics + Cytogenetics
  - 2003: ISO 17025
  - 2007: + ISO 15189
  - 2008: Reaccreditation
    + 2 new laboratories

  - *ESHRE, Royal Society of Medicine, 22-23/3/2010*

2001: First there was...

But then…


ONCE ON A TIME
By
A.A.MILNE
DECORATED BY CHARLES ROBINSON
HODDER AND STOUGHTON LIMITED
LONDON

What is Quality in the laboratory?

International Organization for Standardization

"Degree to which a set of inherent characteristic fulfils requirements"

ISO 9000 2000

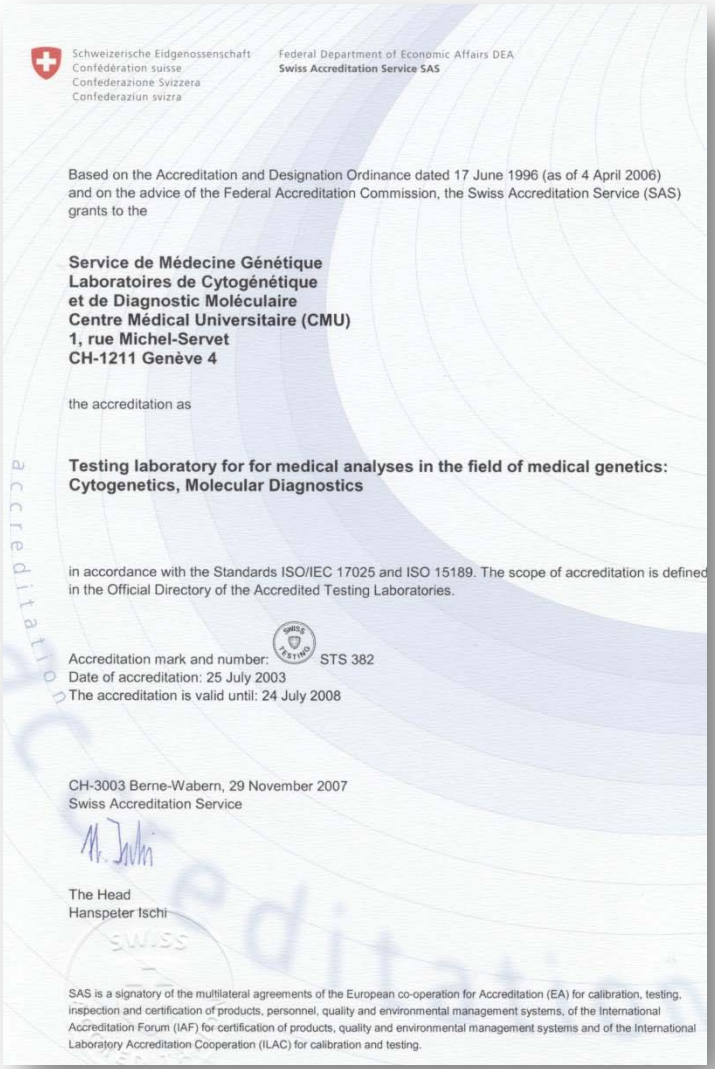
"Quality in a service or product is not what you put into it; it is what the customer gets out of it"

Peter Drucker

"Quality means doing it right when no-one's watching"

Henry Ford

And now



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Economic Affairs DEA
Swiss Accreditation Service SAS

Based on the Accreditation and Designation Ordinance dated 17 June 1996 (as of 4 April 2006) and on the advice of the Federal Accreditation Commission, the Swiss Accreditation Service (SAS) grants to the

Service de Médecine Génétique
Laboratoires de Cytogénétique
et de Diagnostic Moléculaire
Centre Médical Universitaire (CMU)
1, rue Michel-Servet
CH-1211 Genève 4

the accreditation as

Testing laboratory for for medical analyses in the field of medical genetics: Cytogenetics, Molecular Diagnostics

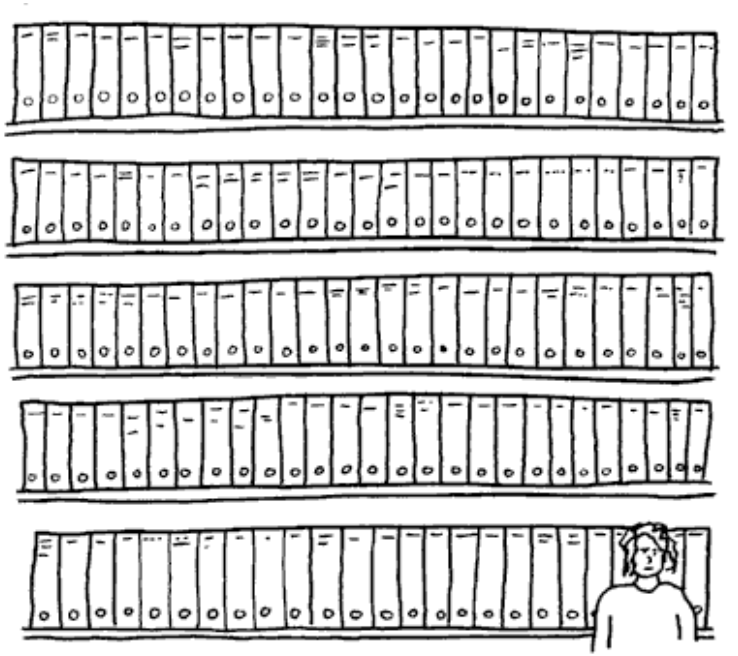
in accordance with the Standards ISO/IEC 17025 and ISO 15189. The scope of accreditation is defined in the Official Directory of the Accredited Testing Laboratories.

Accreditation mark and number: STS 382
Date of accreditation: 25 July 2003
The accreditation is valid until: 24 July 2008

CH-3003 Berne-Wabern, 29 November 2007
Swiss Accreditation Service

The Head
Hanspeter Ischi

SAS is a signatory of the multilateral agreements of the European co-operation for Accreditation (EA) for calibration, testing, inspection and certification of products, personnel, quality and environmental management systems, of the International Accreditation Forum (IAF) for certification of products, quality and environmental management systems and of the International Laboratory Accreditation Cooperation (ILAC) for calibration and testing.



The Geneva experience 2002-2010

- **Negatives**
  - 1 very tough year
  - Cost
    - Equipment
    - 1 WTE (whole-time equivalent)
  - Continuous work load
    - + 5-10% per person (2-4 hours/week)
  - Development slowed (but...)

- **Positives**
  - Lower risk of error
    - Traceability
    - More foolproof systems
  - Development improved
  - Equipment better maintained and followed
  - Training improved
  - Responsibilities better defined
    - Efficiency
    - Satisfaction
    - Harmony
  - Reputation (competitivity)
    - Client confidence
    - Client education
  - And – the tests work better !

People

1. Motivation
2. Tasks
3. Competence

The aim is improvement for our patients, not blame for our colleagues

People

- **Include everybody…**
  - From the beginning
  - Educate everybody
    - Study the standard!
  - Motivate everybody
    - Management
    - Administration
    - Lab directors
    - Technical staff
    - Secretaries
    - …
- **Define responsibilities**
  - Define and assign tasks
  - Organize teams
  - Employ if necessary
    - To go from nothing to audit in 1 year :
    - 1 WTE,
    - +10-20% for existing staff

Be realistic

- **Do not aim for perfection:**

“Striving for excellence motivates you; striving for perfection is demoralizing”

Documents


How many more documents do you think we need to create?
Records

Quality Manual and related documents

- There are a lot of documents and procedures!
- Before writing:
  - **Look** at other quality systems and QMs (or follow a workshop!)
  - **Plan** all the sections
  - **Define** a document management system
  - Decide on **software** support
  - Buy **computers** if necessary

8.3.2003

Make the documents useful and usable

- **Before you write any document, ask :**
  - **What** is the purpose of this document?
  - **Who** is going to use the document?
    - *If there is no user, it is useless*
  - **If** this document were not created, what would be the risk?
  - Are we **only** filling out the form because we believe that we have to?
    - *If so: don't!*

Be sufficient

- QMS: must cover all processes related to your testing
  - Accreditation
    = attestation that you "**fulfill the requirements** of ISO15189"

- **Be concise**

  - Try to keep documents to one or two pages (at least at the beginning)
  - Refine the document further when it no longer meets the need
  - Each use of a document is a chance to "put it on a diet"
    - *Something useless? Remove it…*

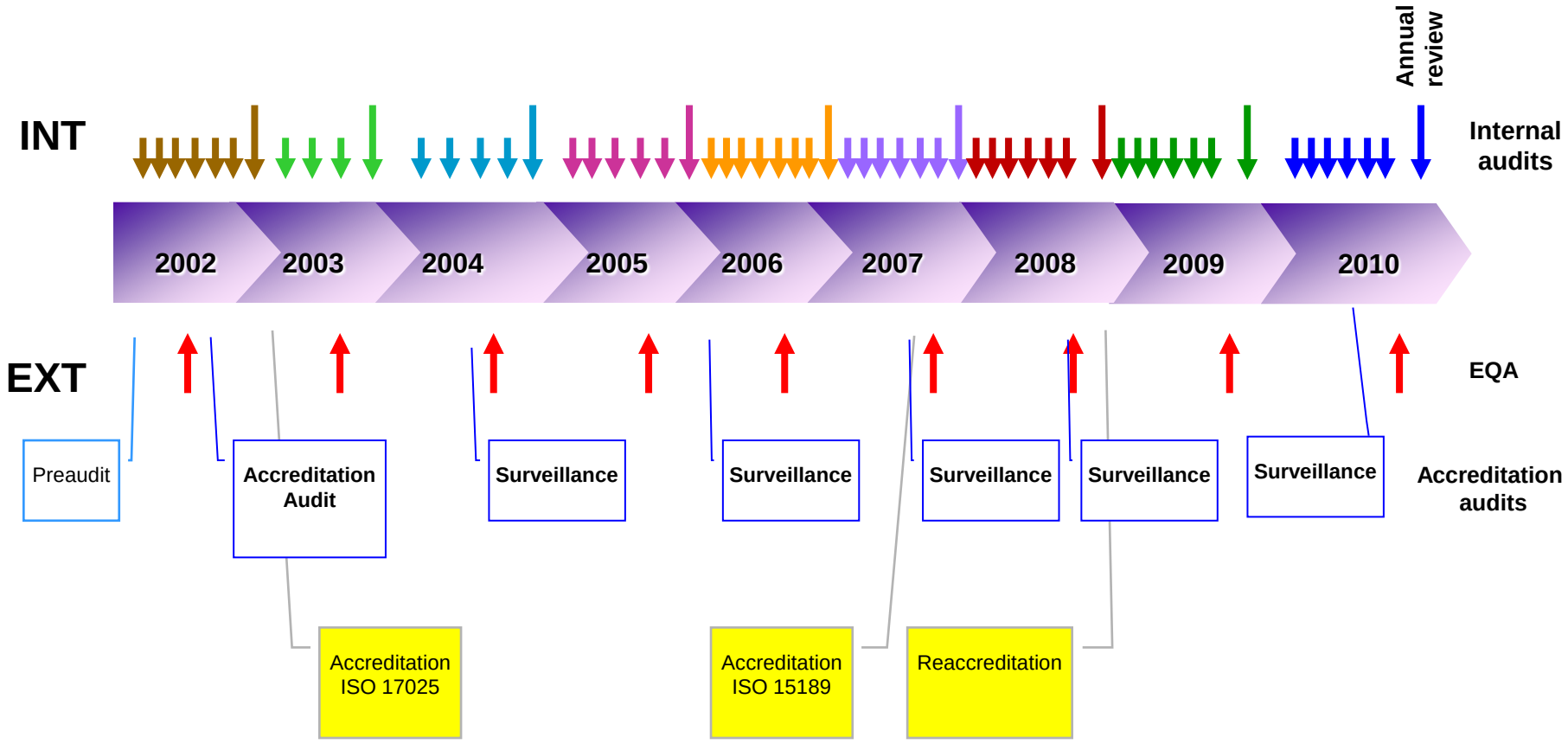
Be precise

- **But not too precise**
  - *Write what you do – do what you write*
    - If you incubate 10-20 minutes, do not write 15 minutes
    - If you store “in the fridge”, do not write “at 4°C” (unless you can prove all the fridges are at 4°C…)
    - centrifugation, incubation, electrophoresis, …
  - Be pragmatic: Useful?  Useless?

Write everything – but only once!

- **Plan to make changes easy**
  - In SOPs, use general terms
    - TaqPol, agarose, PCR machine
    - Define these specifically in separate documents,
      "List of standard reagents"
      "List of equipment" …
  - write "sequence" or "run on gel"
    - And define these in separate "technical SOPs" (standard operating procedures)
  - Geneva: ~100 disease-specific SOPs
    - But 1 for DNA preparation, 1 for sequencing, 1 for gels, …

Assessing the quality system

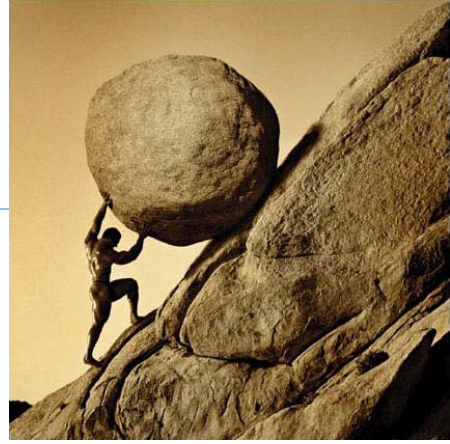


Surveillance / accreditation audits

Geneva Non-conformities, 2003-2008

1. Update the organigramme
2. Control, modification and traceability of electronic lists
   eg Excel or Access
3. Clarify handling of samples for research projects
4. Guarantee that an initial qualification is performed when installing a new instrument.
5. Evaluate all equipment & reagent suppliers
6. Establish SOPs for Genescan & Genotyper software
7. If limitations are identified by EQA: update the SOPs
8. Establish a training programme for new secretaries
9. Document the cleaning of the labs (esp. radioactivity).
10. Simplify recording non-conformities.
11. Clearly define procedures for approving documents.
12. Clearly document the technical competence of personnel.
13. Indicate the precise date at which a person becomes competent for a technique (day not month).
14. Indicate which reagents can be used beyond their validity date.
15. Establish a procedure concerning reagents and solutions which can be used after the expiry date.
16. Introduce documentation of checks of
    1) the pH meter,
    2) the heating plate for slides.
17. For PCR-based tests, install physical separation between pre and post, with a unidirectional flow and a change of lab coat.
18. Document the requirements for patient samples (pre-analytical).
19. Define situations where “urgent sample” rules are applied
20. Define criteria that identify urgent samples
21. Define when the prescriber is informed about extra tests

NC: continuous improvement



2003 Clearly **document the technical competence** of personnel.

2005 Indicate the **precise date at which a person becomes competent** for a technique (day not month).

2003 Indicate which reagents can be used **beyond their validity date.**

2005 **Establish a detailed procedure** concerning reagents and solutions which can be used after the validity date.

2006 Define situations where **“urgent sample” rules** are applied

2007 Define criteria that **identify** urgent samples

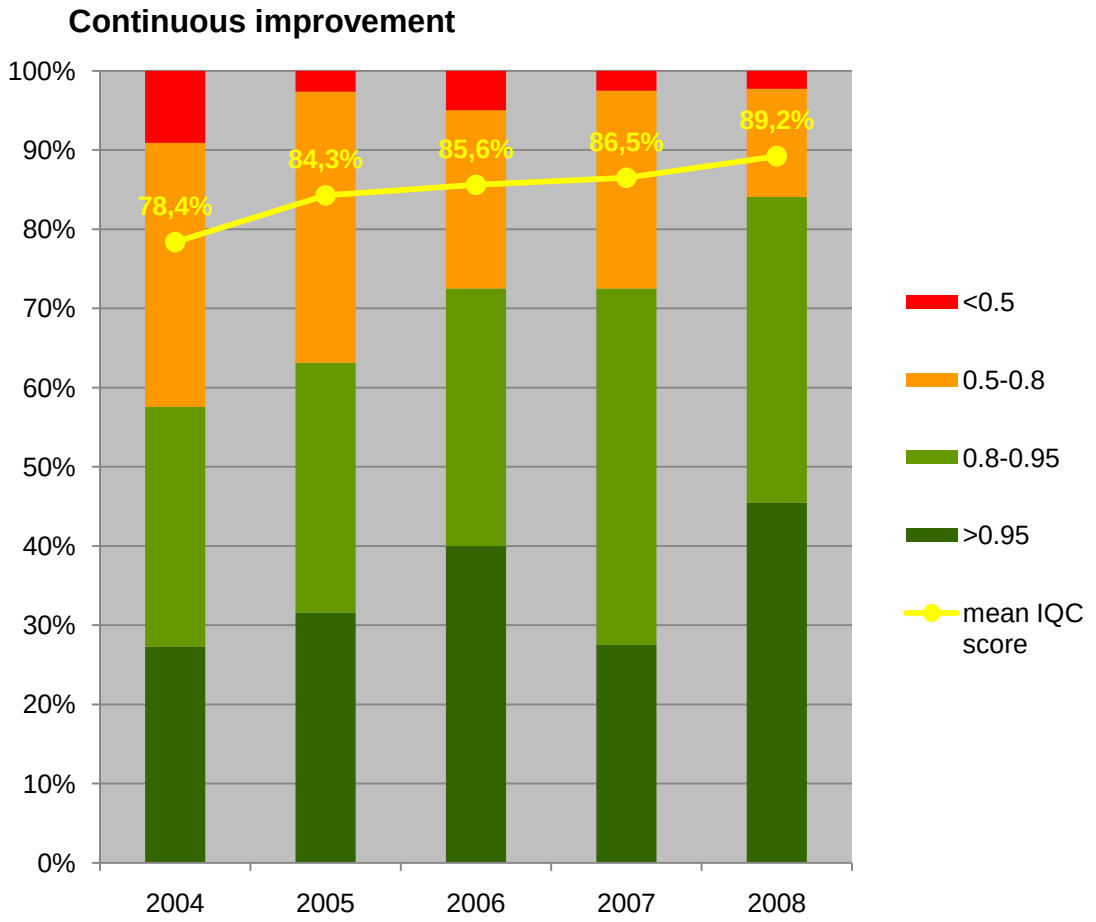
“The tests work better” ?

- IQC Score :
- for each test,
- for each patient:
  - 1 = complete first time
  - 0 = something redone
- 5 people, >100 tests
  - Southern, PCR, sequencing, MLPA, Real-time, …

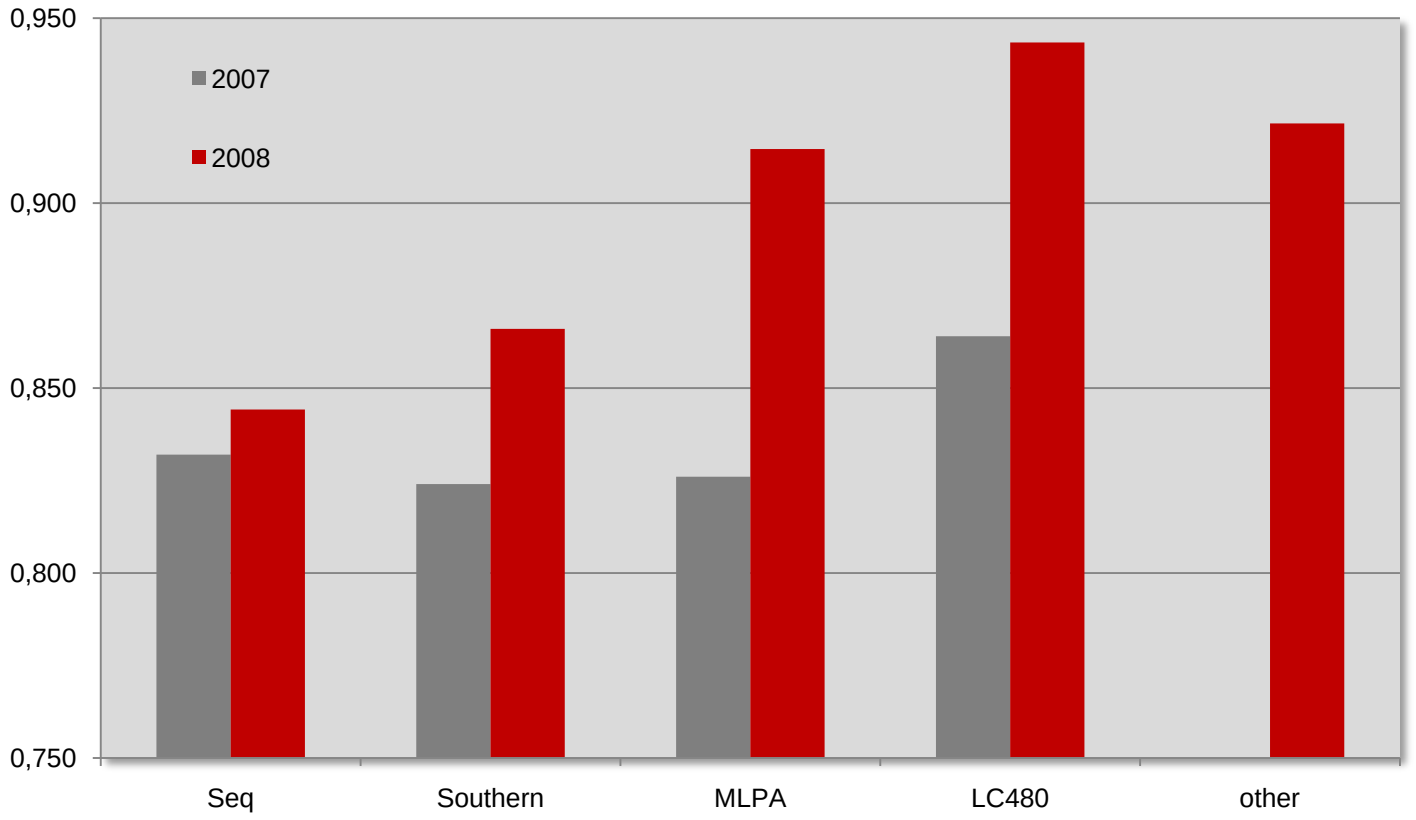
Isab2008	PCR		Southern		Seq	
	1	0	1	0	1	0
Amyloidosis	*11*	*1*			*1111 1211 111*	*11*
F8			*1111 1311 1*		*1111 1111 1111*	*11*

Quality indicators

	mean	*≤ 0.8*
2004	**0.78**	**45%** *15/33*
2005	**0.84**	**37%** *14/38*
2006	**0.86**	**30%** *12/40*
2007	**0.87**	**28%** *11/40*
2008	**0.89**	**16%** *7/44*



IP per technique



Start with what? (MAM personal opinion)

- **Get a copy of ISO 15189**
- **Sign up for EQA**
  - **Or organize inter-lab comparisons**
- **Consider training &/or peer networks**
- Write
  - SOPs, including IQC
  - Equipment folders
    - Fridges, freezers, incubators
  - First draft of scope (organic document)
- Define and start to apply:
  - Validation of new tests
  - Training procedures
  - Documentation of competence
  - Recording complaints and feedback
- Internal audits?
  - 1) “vertical”;
  - 2) “witness”
- Management Review?

Accreditation Workshops 2005-2009

- **~350 participants**
  - ~1/4 participate in several workshops
  - >150 institutions from 40 countries (32 in Europe)
- **20 workshops**
  - Accreditation case studies
  - Validation
  - IQC, EQA and MR
  - Internal audit
  - Motivation & change
  - IT support
  - National workshops (BE, CH, NED, FR)
  - *Ateliers francophones*
- Round tables (ESHG);
  Quality & Laboratory Symposium
- **2010**
  - Beginners' guide to accreditation (UK, SI)
  - *Atelier d'initiation* (FR)
  - Managing the human side of change (BE)
  - Validation of diagnostic tests (SE)
  - Internal audit (SE)
  - Case studies (ESHG SE)
- Report on workshops:
  Guidance document for preparing for accreditation

Athens, Barcelona, Basel, Berlin, Birmingham, Leiden, Leuven, Nice, Oxford, Prague, Vienna, ….

Start with what? (MAM personal opinion)

- Get a copy of ISO 15189
- Sign up for EQA
  - Or organize inter-lab comparisons
- Consider training / peer networks
- Write
  - SOPs, including IQC
  - Equipment folders
    - Things that measure
    - Things that heat/cool
    - Things that move
  - First draft of scope
    - organic document
- Define and start to apply:
  - Validation of new tests
  - Training procedures
  - Documentation of competence
  - Recording complaints and feedback
- Internal audits?
  - 1) “vertical”
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  - **Training improved**
  - **Responsibilities better defined**
    - Efficiency
    - Satisfaction
    - Harmony
  - **International reputation** (competitivity)
    - Client confidence
    - Client education
  - **The tests work better !**

People make success:

Pleasure in the job puts perfection in the work

Aristotle