

Mandatory accreditation of Medical labs in France: Benchmark for the EU countries?

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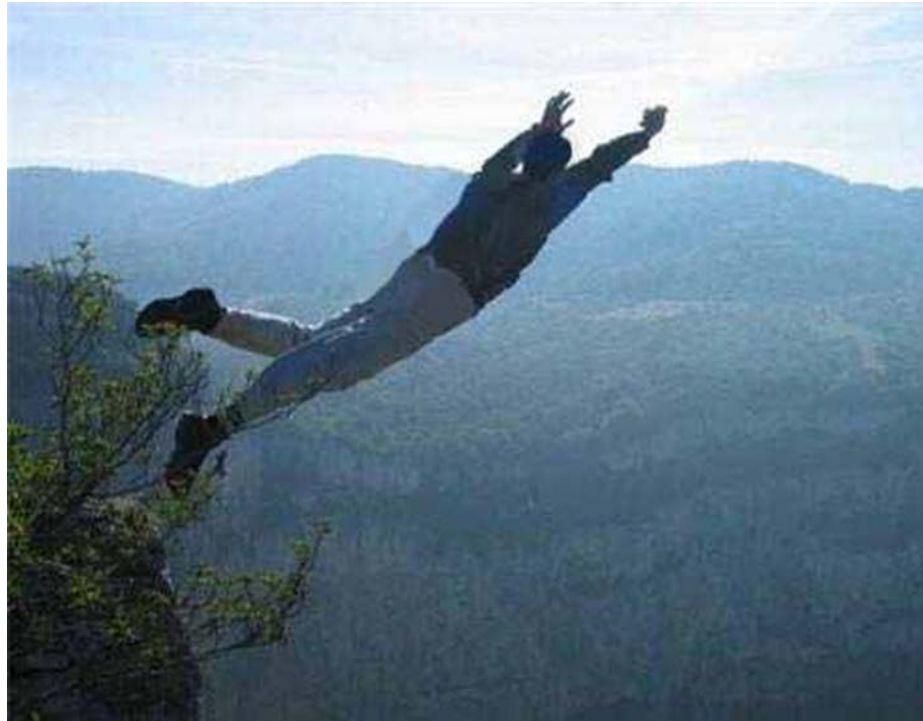
SFBC Accreditation WG chairman

EFLM A/ISO WG chairman

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QUALITY IN LABORATORY MANAGEMENT IN EUROPE:
IMPACT OF FUTURE TRENDS ON LABS DAILY ROUTINE
Euromedlab - Paris – 24/06/2015

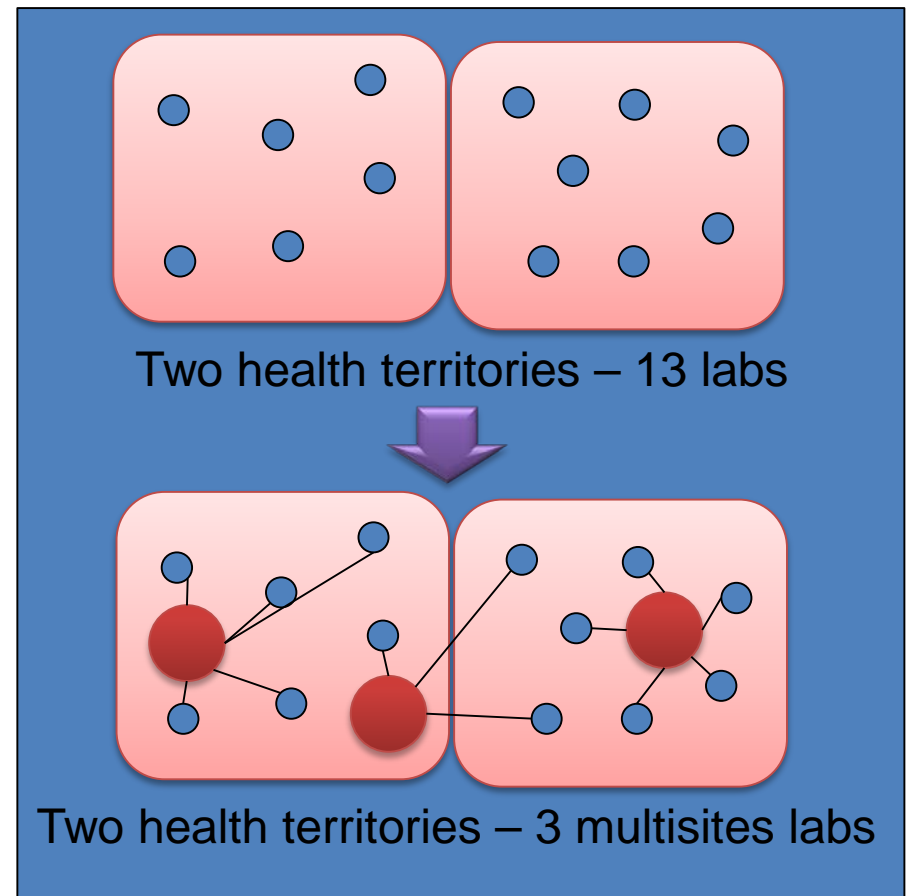


WHY SHOULD WE WORK FOR ISO 15189/22870 ACCREDITATION?

2010-2013

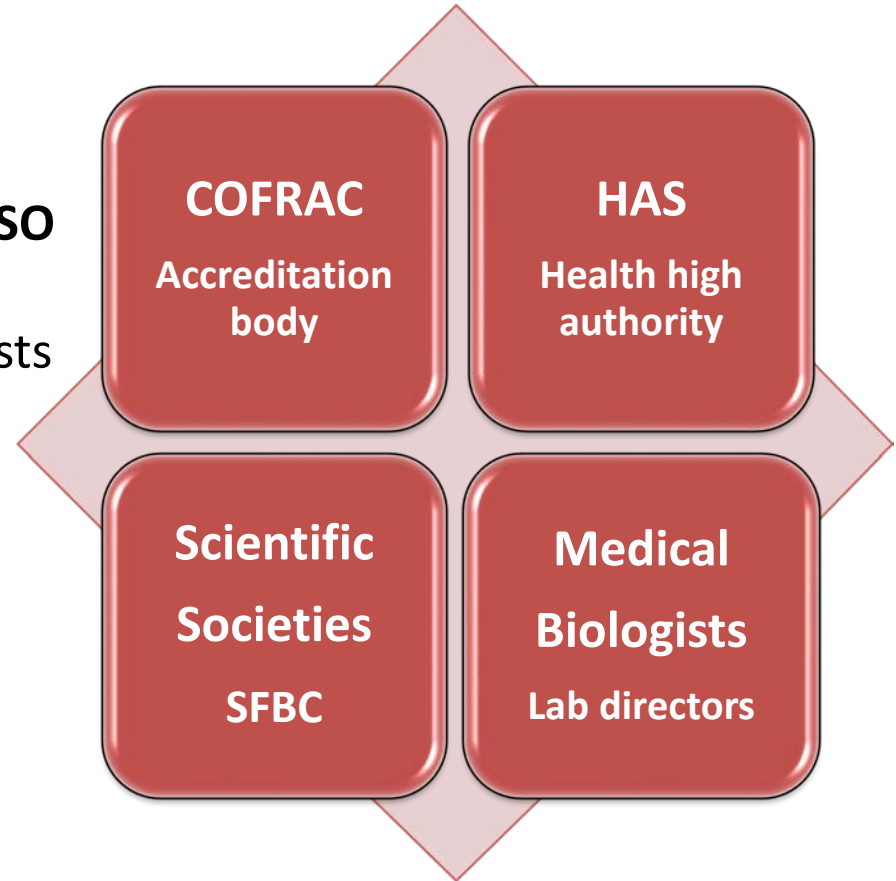
French reform of Medical Biology

- Harmonization of private and public practices
- Choice of “medical” biology vs. “industrial” biology (examination vs. analysis)
- Reorganization of territorial distribution : multisites labs with proximity medicalized antennas
- Proven quality by **mandatory accreditation**



French accreditation project

- **Who?** All biologists in public and privates medical biology Labs
- **What?** New regulation for Medical Biology : **mandatory accreditation using NF EN ISO 15189 and NF EN ISO 22870**
- **Where?** In all medical labs for all tests performed
- **When?** 2013 to prove the initial engagement – 2020 to complete achievement
- **Why?** Proven quality, international recognition, increase in biology “medicalization”
- **How?**
Working hard, **now and together**



Role of National Societies

Example - Guidelines for accreditation of medical laboratories – Vol.1-3

- SFBC WG ALBM
 - Published in Ann. Biol. Clin.
 - Now in French (in English?)
 - Scope: all requirements of the two standards 15189 and 22870
- Agreement of accreditation body COFRAC
- Consensus work from specialists in laboratory medicine
 - Volume 1: preanalytical – analytical
 - Volume 2: postanalytical – POCT
 - Volume 3: quality management, support processes



Why not only revise our national standard?

	GBEA	ISO Accreditation 15189 – 22870
Quality aspects	Directive approach	Process approach
	Technical requirements	QMS + technical requirements = competence
Quality Management	No	Yes
Recognition	National	International MLA EA ILAC
Evaluation	Inspection	Double audit quality + technical (peers)
Organism	Government DDRASS	Unique national accreditation body COFRAC

What is the gold standard?

15189/22870: the magical numbers

- **Many common points**
 - Quality management system near from ISO 9001 standard
 - Technical requirements near from ISO 17025 standard
- **15189 Specificities for Medical Biology**
 - Explicitly treats the **3 phases** of the examination process and particularly of pre and post-examination phases
 - Verification of result quality (specific technical requirements)
 - Affects many responsibilities to the lab director (specialist in LM)
 - Also includes requirements about medical tests selection and advisory services
- **22870 Specificities for POCT**
 - Operators not under the lab authority
 - Physicians and nurses involvement in QMS
 - ISO 22870 is a good complement of ISO 15189

It is the Law!

MINISTÈRE DE LA SANTÉ ET DES SPORTS

Arrêté du 5 août 2010 fixant les références des normes d'accréditation applicables aux laboratoires de biologie médicale

NOR : SASP1016668A

La ministre de l'économie, de l'industrie et de l'emploi, la ministre de la santé et des sports et le ministre auprès de la ministre de l'économie, de l'industrie et de l'emploi, chargé de l'industrie,

Vu le code de la santé publique, notamment son article L. 6221-2 ;

Vu le code de la sécurité sociale, notamment son article L. 161-37 ;

Vu la loi n° 2008-776 du 4 août 2008 relative à la modernisation de l'économie, notamment son article 137 ;

Vu l'ordonnance n° 2010-49 du 13 janvier 2010 relative à la biologie médicale ;

Vu le décret n° 2008-1401 du 19 décembre 2008 relatif à l'accréditation et à l'évaluation de conformité pris en application de l'article 137 de la loi n° 2008-776 du 4 août 2008 de modernisation de l'économie ;

Vu l'avis de la Haute Autorité de santé en date du 27 avril 2010,

Arrêtent :

Art. 1^{er}. – Les normes d'accréditation en vigueur applicables aux laboratoires de biologie médicale prévues à l'article L. 6221-2 sont :

1° La norme NF EN ISO 15 189 pour les activités et examens mentionnés à l'article L. 6221-1 ;

2° La norme NF EN ISO 22 870 pour les examens de biologie médicale mentionnés à l'article L. 6211-18.

Art. 2. – Pour les structures mentionnées aux articles L. 6221-12 et L. 6221-13 du code de la santé publique, au titre des examens ou activités désignés aux mêmes articles, les normes d'accréditation sont les normes déterminées à l'article 1^{er}.

Art. 3. – Le présent arrêté sera publié au *Journal officiel* de la République française.

Fait à Paris, le 5 août 2010.

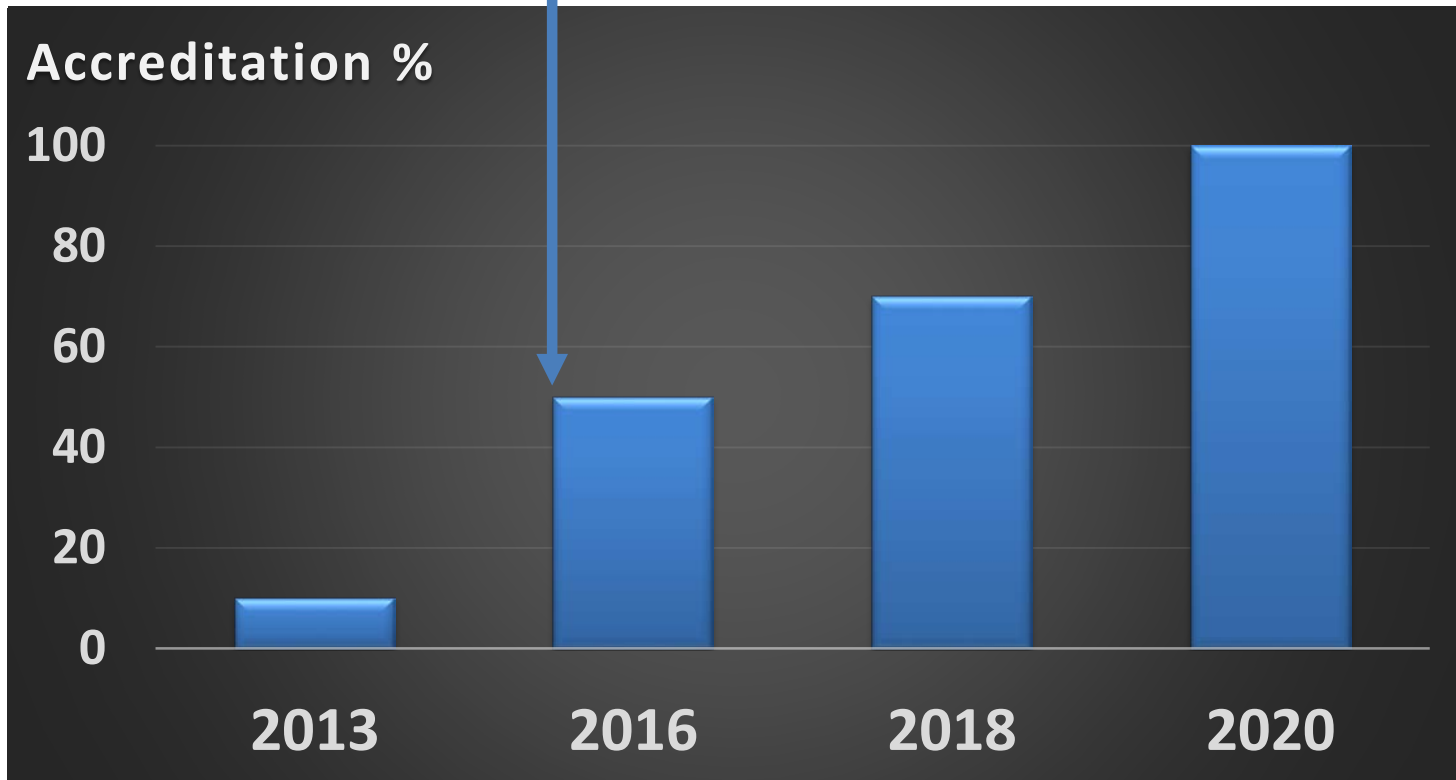
La ministre de la santé et des sports,
ROSELYNE BACHELOT-NARQUIN

*La ministre de l'économie,
de l'industrie et de l'emploi,*
CHRISTINE LAGARDE

Accreditation agenda (POCT included)



All tests families



Towards complete accreditation of all French labs ...

- Accredited labs in **2010** using 17025 or 15189 standards : about 180
 - Few changes since 2000
 - Less than 10 in public hospitals (15189)
 - Incomplete scope
 - 22870 : 0 in 2010
- **Current dynamics**
 - About 300 in 2013, 450 sites + 400 in progress
 - 22870 : 2 in 2013, perhaps 5 in 2014
 - Labs involvement linked to **mandatory constraint**
 - **Evolution of structures** – marked decrease in the number of labs with creation of multisites labs
 - From 5000 in 2007 to 1200 in 2013 (target around 800)

Is it possible to reach 100%?

- **Key factors for success**

- Find about 500 technical assessors (now <200)
- Use 100% flexible scope
- To follow a continuous managed progression from 2013 to 2020
- To exclude new innovative tests during clinical assessment
- To be attractive for labs which achieve 100% goal before the deadline (facilitated site opening)



The circle quadrature



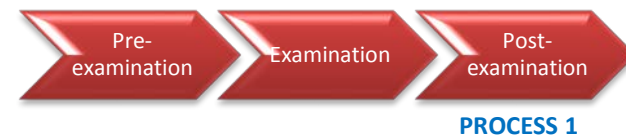
- Needs to improve and prove Lab **quality**
 - Patients and physicians **increased needs** for healthcare
 - Increased needs for LM in medicine practice
 - Accreditation is the best way to prove lab competence
- **AND** increase Lab **efficiency**
 - Increase in health costs
 - Financial constraints – management of expenses
 - Declining medical demography
 - Increased lab activity with decreased expenses

WHY IT COULD APPEAR AS DIFFICULT TO DO?

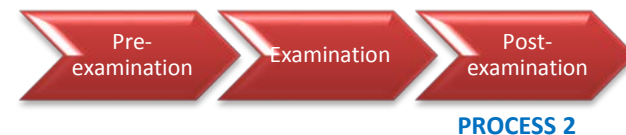
Main issues (1) - Parallel organizations

University hospitals in 2010

- Multiple processes
 - Historic wish to control process from A to Z
- Complexity of global structure
 - Heterogeneous organizations
- Discrepancies between quality management systems
- Processes outside laboratory
 - Sample collection
 - Support processes



Biochemistry



Hematology



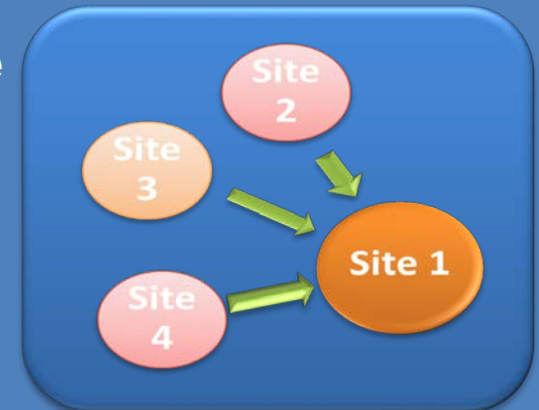
Microbiology

Main issues (2) - Multisites labs

- Rule: only one multisites lab in one hospital or hospital group
- Accreditation consequences
 - 1 responsible
 - Multisites quality management
 - Homogenization of pre-examination procedures

Territorial multisite laboratory

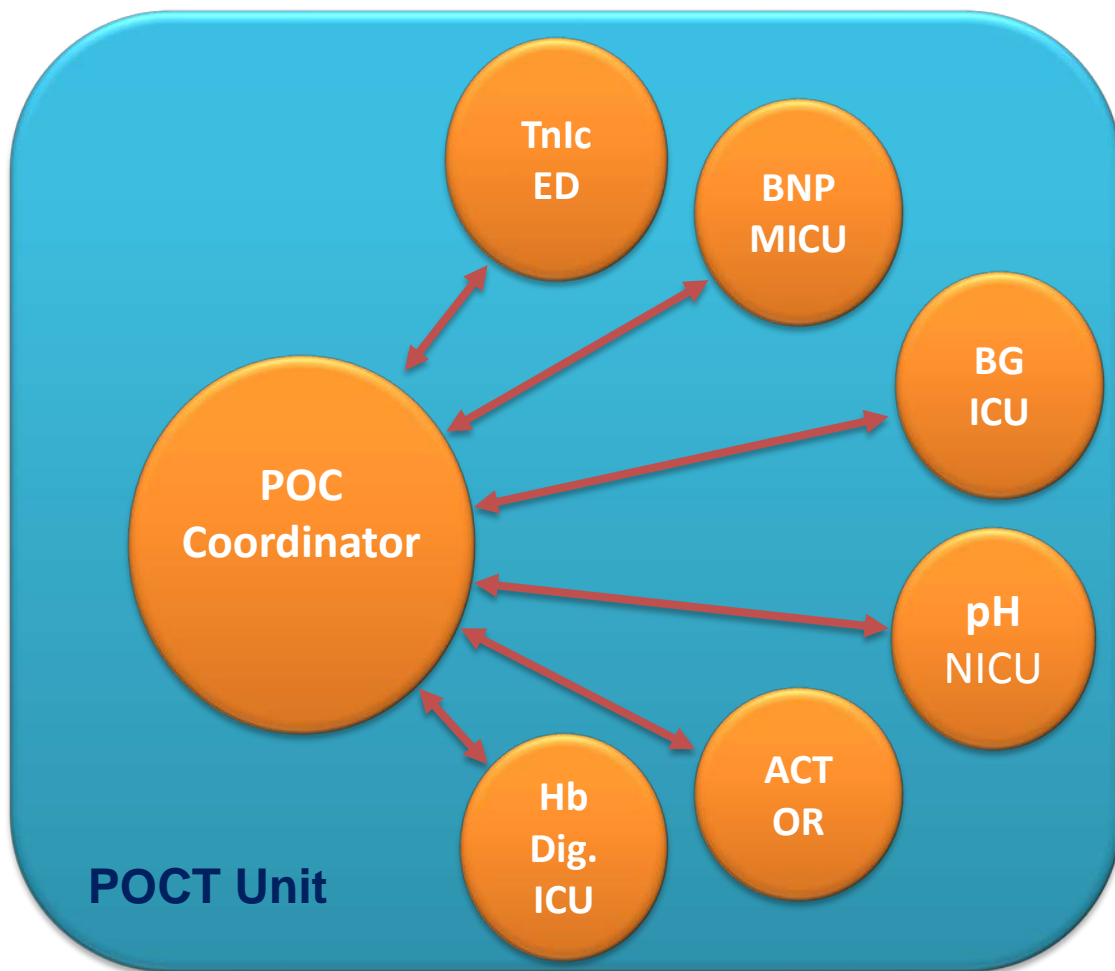
« Star » model with unique central lab



« Network » model with multiple connected labs



Main issues (3) - POCT



- POCT under lab responsibility
- From 15189 to 22870
- Objectives
 - Remote control
 - Training-Habilitation
 - *A posteriori* biological validation
 - Unified procedures
 - One POC coordinator
- **Mandatory accreditation**
NF ISO EN 22870

Difficult but not impossible

- Medical Biology and finally all medicine is going towards proven quality and accreditation all around the world
- We all must go ahead one day
- **BUT**
 - Changes leads to “resistance to change”
 - Professionals think they work well and do not feel the need to prove it
 - So, it was necessary in France to make the process mandatory to create dynamics and control the agenda
 - It is a first step prior to convince lab people that advantages will come back to the lab after achievement of accreditation process (simplified organization)

And now, what do we do ?

- The question is **not** now for us:
 - WHY** should we work for an ISO 15189 lab accreditation?
- **BUT**
 - HOW** to manage quickly the lab ISO accreditation process?

A goal: to provide a medical service

- **Accreditation process**
 - Proven quality with international reference
 - Optimization of Lab organization
 - Initial quality over costs following by increased lab efficiency
 - Management by quality
 - Patient safety and care in first line: added value of LM
- And parallel/anticipated **restructuring** to make it possible
 - **Reduced number** of lab structures and generalization of the multisites lab models (“star” model and “network” model)
 - **Develop medicalization** of clinical biology vs. excessive industrialization:
 - Effective medical presence on each site
 - Prescription adjustment, advisory services
 - Medicalized management of test ordering to manage health expenses
 - **Maintain patient and clinician proximity vs.** lab excessive consolidation:
 - Better definition of the role of proximity lab (stat biology)
 - Quality management of pre and post analytical phases
 - Define the possible role of POCT to achieve medical needs under the lab responsibility

Questions

- **WHY should we work for an ISO 15189/22870 accreditation?**
 - To prove our competency to our customers (patients and clinicians) and to our “bank” (Social Security)
 - To have a chance to solve the quality/efficiency equation in the competitive National and European context
- **WHY should we work for a MANDATORY ISO 15189/22870 accreditation?**
 - To “boost” the lab consolidation process
 - Because the voluntary process has failed before
 - Increase of new accredited labs since 2013 is more than during 10 previous years

Conclusions

- Is accreditation process needed to give to the patient a good care quality?
 - Probably **no**
- Is accreditation process lead to an improvement in lab organization and patient care quality?
 - Probably **yes**
- Is regulation (by law in France) needed to quickly progress in the accreditation process?
 - Clearly **yes in the French context**

Perspectives

- Mandatory ISO accreditation of all French labs in the next 5 years is a big challenge
- Many European countries have the same goal with or without mandation
 - To be discussed in the next presentation from EFLM WG survey
- Laboratory quality management is heard as
 - An heavy new constraint
 - An indirect restructuration tool
- But **it is also**
 - A very efficient lab management tool (management by quality)
 - A federative project for all the laboratory team
 - A necessary way for our medical specialty to “survive” in this “global” context

