Accreditation of clinical laboratories in Europe: - benefits and negation

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Vilnius May 12, 2012

Trends in medicine

- Early detection, diagnosis
- Algorythm of treatment and diagnostic strategy
- Molecular medicine
- Immunomodulation and Immmunotherapy
- Stem cells
- Nanotechnolgy
- Tailored medicine – personalised medicine
- Biotechnologies – new drugs, etc.

- **Quality management systém**
- **Patients safety**

New trends in laboratory medicine in the 21st century

- Laboratory automation, robotics
- Consolidation of laboratories
- Integrated organisation of an IT network
- Accreditation of laboratories
- Molecular diagnostics
  - DNA microarray – chips
  - Proteomics
  - Pharmacogenetics
- POCT
- Immaging analysis
- Patient ID –barr-coding

Regulation in the health sector

- Regulation through quality
- Regulation of prices
- Regulation of the market structure
- Regulation by determining the basic health care services
- Regulation of capacity
- Public opinion, lobby, PR

Quality in the health care

The level of excelence of the health care provided in relation to the current level of knowledge and technical development.

Customer orientation.

Basic requirements and criteria for laboratories from client's perspective

- Availability
- Comprehensiveness
- Fast response
- Reliability and accuracy
- Information and consultation
- Analysis of complaints and claims

IFCC and EFLM

- Improvement of quality system in laborartory medicine – priority
- ISO 15189
- WG – ISO CEN – coordination of activities
  - Development and amendments to ISO 15189
- WG – Accreditation
  - Harmonisation of the analytical process
  - Definition of the key criteria
  - Cooperation with the European Accreditation

Accreditation

Accreditation – procedure by which an autoritative body gives formal recognition that a body or person is competent to carry out specific tasks

Independend process

Interest of society – high level of competence – personal and technical in health care provideres including labs

Accreditation and certification laboratories II

- **Accreditation according to ISO 15189 – clinical laboratory**
  - approx. 80 % similarity to ISO 17025
  - version 2007, new version 2012 ??
- **Accreditation according to ISO 17025 – testing laboratory**
- **Accreditation according to ISO 15195 – reference laboratory**

Accreditation and certification

Difference accreditation and certification

CERTIFICATION

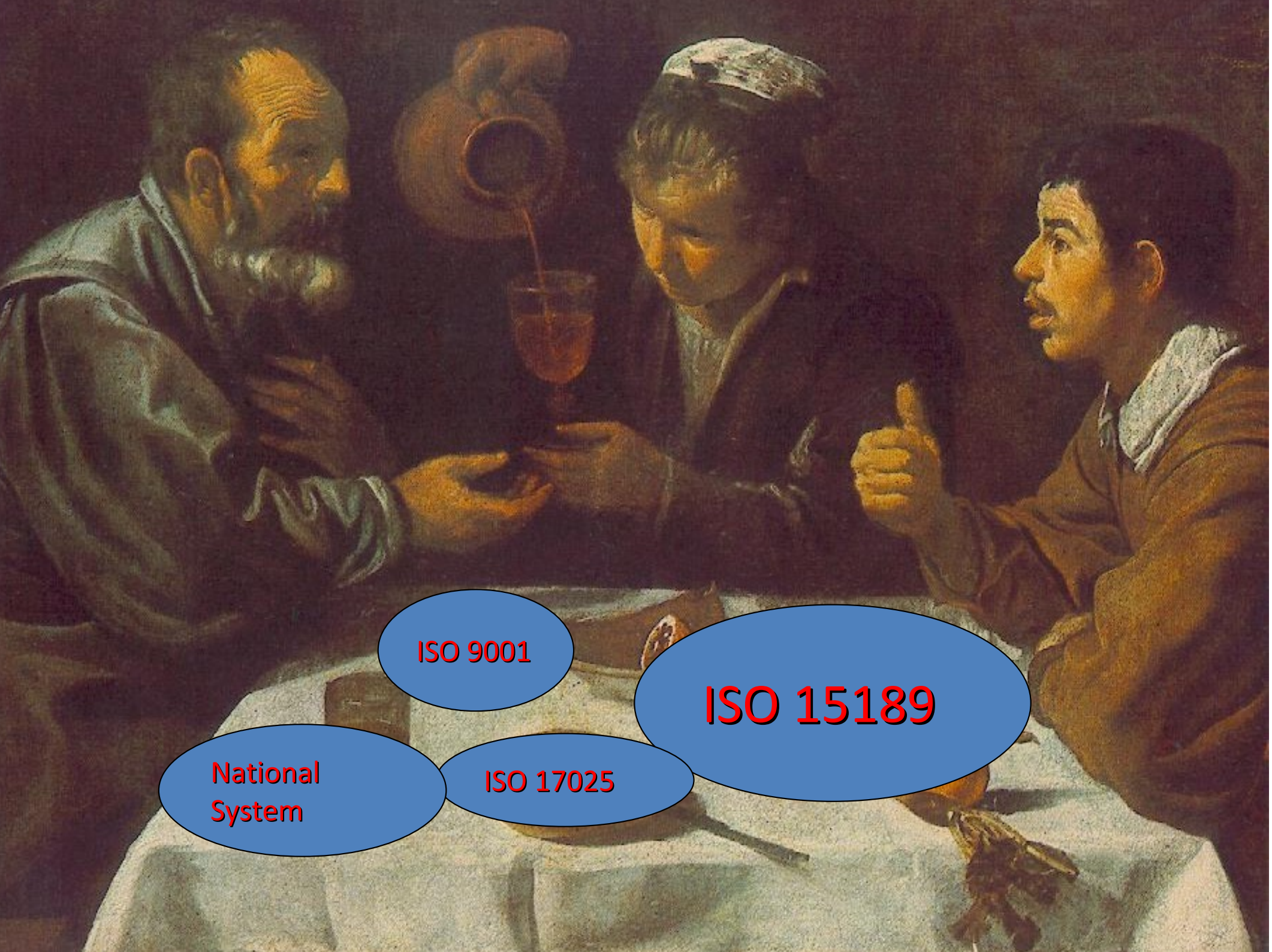
*"Procedure by which a **third party** gives written assurance that a product, process or service conforms to specific requirements".*

- Each country has **multiple** certification bodies.
- Example of certification bodies: AENOR, AFNOR, BVQI, CERMET, IQNet, TüV, …
- = requirements for a quality management system (only)
- ISO 9001

ACCREDITATION

*"Procedure by which an **authoritative body** gives formal recognition that a body or person is competent to carry out specific tasks".*

- There is only **one** recognized national accreditation body in each country.
- Example of accreditation body: CIA in Czech Republic
- = requirements for a quality management system + requirements regarding technical & analytical competence
- ISO 17025 and ISO 15189


ISO 9001
ISO 15189
National System
ISO 17025

Accreditation of laboratories

- Accreditation according to ISO 15189 – clinical laboratory

Widely accepted in medical laboratory comunity

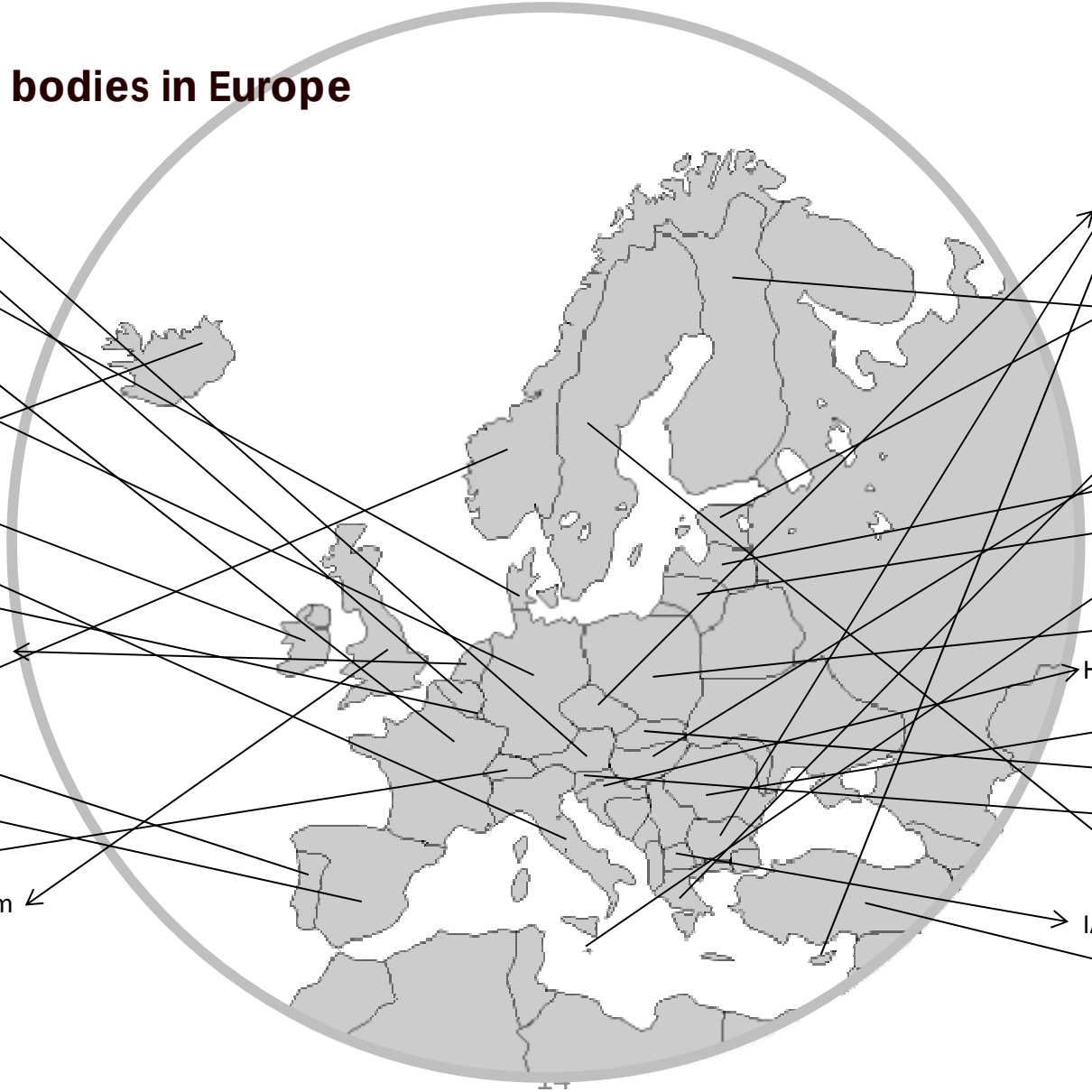
Available for more then 7 years

Why accreditation?

- Accreditation is a good way to demonstrate **competence of the laboratory**
- Accreditation is a tool **to recognize laboratories world-wide**
- In some countries accreditation is **mandatory** or will be mandatory in the future
- Accreditation and the linked periodical audits are a **stimulant** for keeping the quality system alive

Accreditation bodies in Europe

Accreditation bodies in Europe



BMWA – Austria
BELAC – Belgium
DANAK – Denmark
COFRAC – France
DACH – Germany
ISAC – Iceland
INAB – Ireland
SINAL – Italy
ILNAS – Luxemburg
RvA – The Netherlands
NA – Norway
IPAC – Portugal
ENAC – Spain
SAS – Switzerland
UKAS – United Kingdom

BAS – Bulgaria
CYS-CYSAB – Cyprus
CAI – Czech Republic
EAK – Estonia
FINAS – Finland
ESYD – Greece
NAT – Hungary
LATAK – Latvia
LA – Lithuania
NAB-MALTA – Malta
PCA – Poland
HAA – Republic of Croatia
RENAR – Romania
SNAS – Slovakia
SA – Slovenia
SWEDAC – Sweden
IARM – FYR of Macedonia
TURKAK – Turkey

National acreditation body– conformity assessment „ISO 17011“

OPIS

Ministerstvo průmyslu a obchodu

Č.j.: 49493/10/05300/01000

PID: MIPOX01JQBKJ

V Praze dne 20 dubna 2011

Rozhodnutí č. 4 / 2011

ministra průmyslu a obchodu,

kterým se schvaluje změna zakládací listiny Českého institutu pro akreditaci, o. p. s.

Článek 1

Za účelem splnění povinnosti uložené zakladateli obecně prospěšné společnosti v čl. II bodu 1 zákona č. 231/2010 Sb., kterým se mění zákon č. 248/1995 Sb., o obecně prospěšných společnostech a o změně a doplnění některých zákonů, ve znění pozdějších předpisů, jako osoba oprávněná jednat v této záležitosti jménem zakladatele – České republiky podle § 7 odst. 1 zákona č. 219/2000 Sb., o majetku České republiky a jejím vystupování v právních vztazích, ve znění pozdějších předpisů, tímto

s c h v a l u j i

následující

úplné znění

zakládací listiny obecně prospěšné společnosti
Český institut pro akreditaci, o. p. s.,

vyhotovené notářským zápisem ze dne 13.2.1998 pod č.j. N 60/98 – NZ 52/98, ve znění dodatků č.I až IX a ve znění úprav v souladu s čl. II odst. 1 zákona č. 231/2010 Sb., kterým se mění zákon č. 248/1995 Sb., o obecně prospěšných společnostech a o změně a doplnění některých zákonů, ve znění pozdějších předpisů:

International Organization for Standardization

International Standards for Business, Government and Society

Home | Products | Standards development | News and media | About ISO | For ISO Memb

Products › ISO Standards › By TC › CASCO Committee on conformity assessment

- ISO Store
- ISO Standards
  - By ICS
  - By TC
  - How to use the ISO Catalogue
  - Standards in action
  - Management and leadership standards
  - The ISO portfolio
  - FAQs
  - Country codes (ISO 3166/MA)
  - Directory of aerospace standards
- Publications and e-products
- ISO Concept Database (ISO/CDB)
- Copyright

ISO/IEC 17011:2004

Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies

Media and price

Language	Format	Add to basket
English	PDF (660 kB)	CHF 108,00
English	Paper	CHF 108,00
French	PDF (794 kB)	CHF 108,00
French	Paper	CHF 108,00
Spanish*	PDF (277 kB)	CHF 108,00
Spanish*	Paper	CHF 108,00

* Official ISO translation

General information

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TC/SC: CASCO	

Abstract

ISO/IEC 17011:2004 specifies general requirements for accreditation bodies assessing and accrediting conformity assessment bodies (CABs). It is also appropriate as a requirements document for the peer evaluation process for mutual recognition arrangements between accreditation bodies.

Accreditation bodies operating in accordance with ISO/IEC 17011:2004 do not have to offer accreditation to all types of CABs.

For the purposes of ISO/IEC 17011:2004, CABs are organizations providing the

www.cai.cz;

www.iso.org/iso/catalogue_detail?csnumber=29332

EA survey
October 2011

Standards used for accreditation

Accreditation body/Country	Standard
BELGIUM (BELAC)	ISO 15189 & ISO/IEC 17025
CYPRUS (CYS-CYSAB)	ISO 15189
CZECH REPUBLIC (CAI)	ISO 15189 & ISO/IEC 17025
DENMARK (DANAK)	ISO 15189 & ISO/IEC 17025
ESTONIA (EAK)	ISO 15189 & ISO/IEC 17025
FINLAND (FINAS)	ISO 15189 & ISO/IEC 17025
FRANCE (COFRAC)	ISO 15189 & ISO/IEC 17025 ISO 228570 (until nov 2013)
GERMANY (DAKKS)	ISO 15189 ISO 17020 in Anatomical Pathology
GREECE (ESYD)	ISO 15189 & ISO/IEC 17025
IRELAND (INAB)	ISO 15189 & ISO/IEC 17025
LATVIA	ISO 15189
MALTA (NAB-MALTA)	ISO 15189
NETHERLANDS (RVA)	ISO 15189
NORWAY (NA)	ISO 15189 & ISO/IEC 17025
PORTUGAL (IPAC)	ISO 15189 & ISO/IEC 17025
REPUBLIC OF CROATIA (HAA)	ISO 15189
SERBIA (ATC)	ISO 15189 & ISO/IEC 17025
SPAIN (ENAC)	ISO 15189
SWITZERLAND (SAS)	ISO 15189 & ISO/IEC 17025
TURKEY (TURKAK)	ISO 15189
UKAS	ISO 15189

Accreditation mandatory

Accreditation body/Country	Mandatory
BELGIUM	**YES, only for labs molecular biology (oncology and virology)**
CYPRUS (CYS-CYSAB)	NO
CZECH REPUBLIC (CAI)	NO
DENMARK (DANAK)	NO
ESTONIA (EAK)	NO
FINLAND (FINAS)	NO
FRANCE (COFRAC)	**YES. All medical labs, for all sites, for all activities .** **Deadline: 1st November 2016**
GERMANY (DAKKS)	NO- Only for **newborn screening**
GREECE (ESYD)	NO
IRELAND (INAB)	NO
LATVIA (LATAK)	**YES, for hospital laboratories. In force from 2012.01.01**
MALTA (NAB-MALTA)	NO
NETHERLANDS (RVA)	NO
NORWAY (NA)	NO
PORTUGAL (IPAC)	NO
REPUBLIC OF CROATIA (HAA)	NO
SERBIA (ATC)	NO; Law on Protection against ionizing Radiation and Nuclear Safety; Department of antirabic Protection
SPAIN (ENAC)	NO
SWITZERLAND (SAS)	NO.Comment: There are less inspections in human genetics laboratories from other governmental bodies, when accredited.
TURKEY (TURKAK)	NO
UK (UKAS)	NO

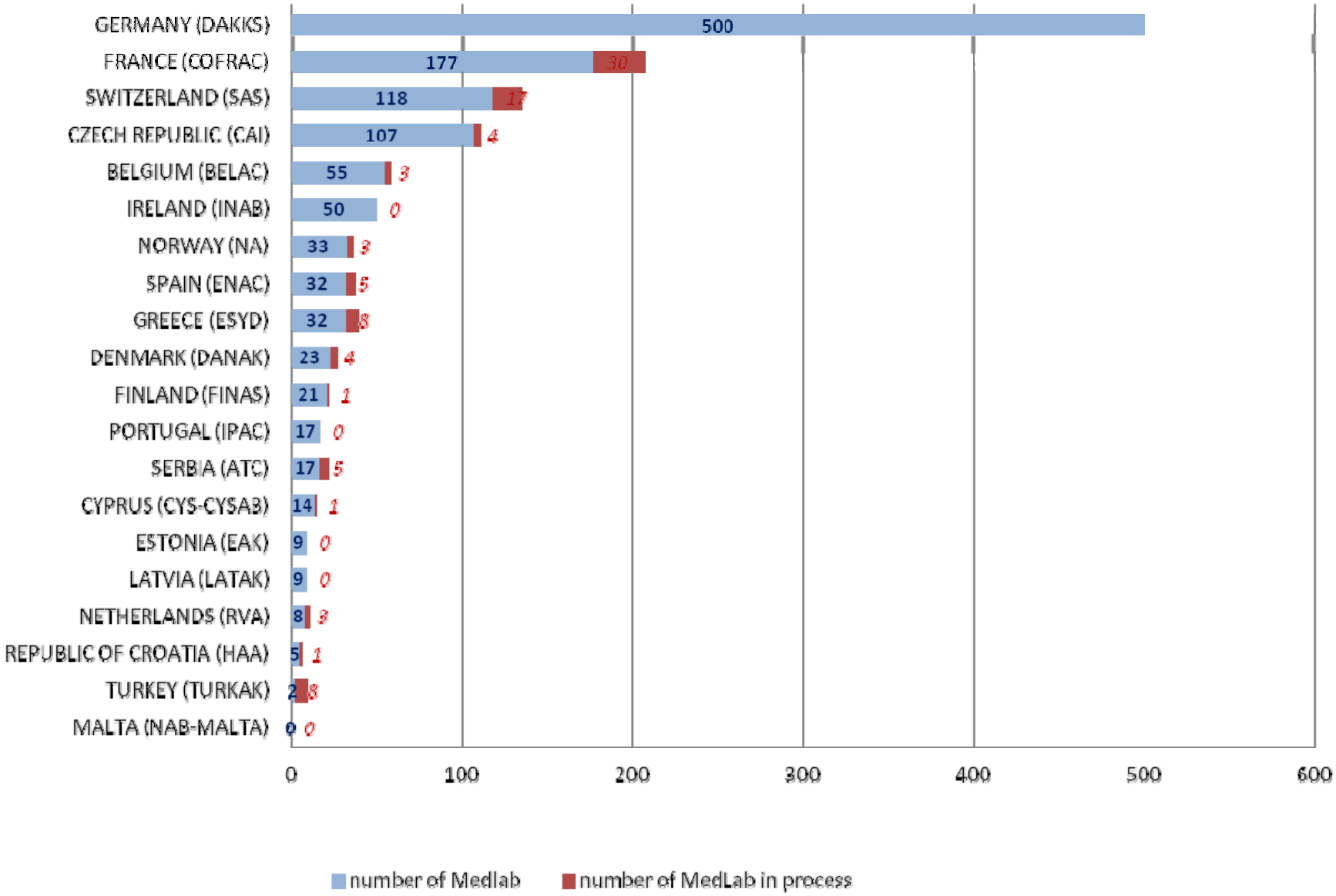
Legal requirements for medical laboratories

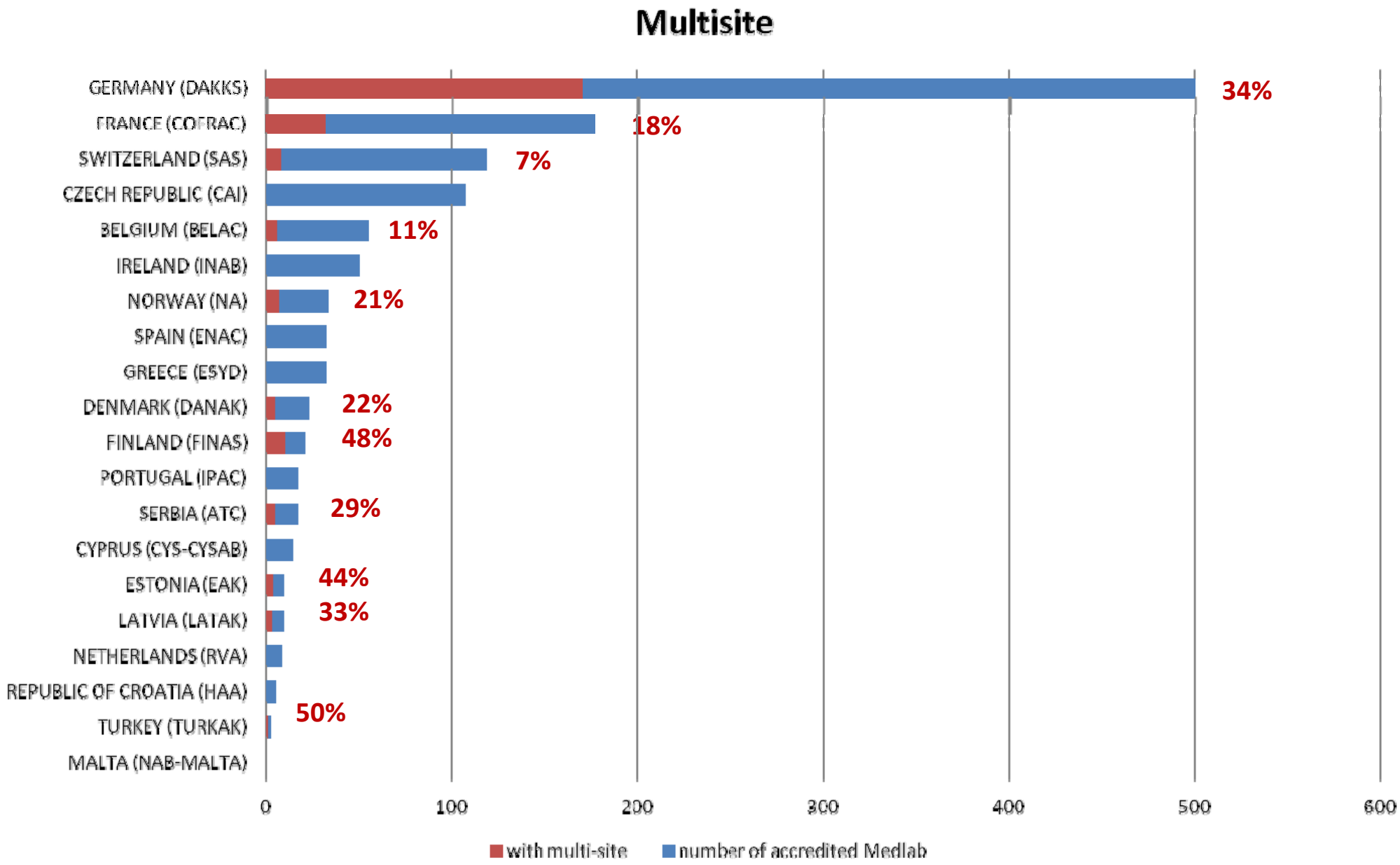
Accreditation body/Country	Legal requirements
BELGIUM	Yes and they need to work against the so called 'praktijkrichtlijn' which is actually a light version of ISO 15189
CYPRUS (CYS-CYSAB)	NO- (Law hazardous wastes; quality and safety of human tissue cells). Law 132/1988 (Registration of Medical Laboratories)
CZECH REPUBLIC (CAI)	NO
DENMARK (DANAK)	-
ESTONIA (EAK)	-
FINLAND (FINAS)	Clinical microbiology laboratories, which are dealing with infectious diseases Yes, they need a licence from authorities
FRANCE (COFRAC)	There are legal requirements regarding good laboratory practices that laboratories have to fulfill (ex : subcontracting, pre-analytical requirements, quality controls, interpretations…) and also specific legal requirements (ex : diploma, specific agreement, validation of the results, geographical requirements for a multi-sites lab, …).
GERMANY (DAKKS)	**YES**. laboratories have to fulfill the "guidelines of German Medical Association". This guideline contains requirements for quality-management-system and for internal and external quality control.
GREECE (ESYD)	**YES**.
IRELAND (INAB)	-
LATVIA (LATAK)	YES. If not accredited, requirements in accordance to 15189.
MALTA (NAB-MALTA)	**YES**. There is a system of licensing which is administered by the Ministry responsible for Health Services. The Ministry has established basic application and license conditions.
NETHERLANDS (RVA)	NO: Legionella in water, semenbanking, donorlab's , paternity testing
NORWAY (NA)	Yes – in some technical fields (e.g. blood banks)
PORTUGAL (IPAC)	YES
REPUBLIC OF CROATIA (HAA)	NO
SERBIA (ATC)	The Ministry of Health requires the healthcare facilities to be authorised to perform healthcare services . (together with other regulations)
SPAIN (ENAC)	**YES**. clinical labs have to fulfill specific requirements for their authorization granted by regional healthcare authorities
SWITZERLAND (SAS)	Yes, there are several legal requirements
TURKEY (TURKAK)	YES (license)

Legal requirements for sampling sites

Accreditation body/Country	Legal requirements
BELGIUM	-
CYPRUS (CYS-CYSAB)	NO; Yes, referring to the responsibility and training of blood taking
CZECH REPUBLIC (CAI)	NO
DENMARK (DANAK)	-
ESTONIA (EAK)	-
FINLAND (FINAS)	NO
FRANCE (COFRAC)	There are specific requirements for sampling sites: when the sampling site is not a part of the laboratory (nurses), a contract has to define the relationship between nurses and the lab own staff. When the sampling site is a part of the laboratory, a medical biologist has to work on a sampling site when receiving patients
GERMANY (DAKKS)	There are not sampling sites in Germany
GREECE (ESYD)	-
IRELAND (INAB)	n/a
LATVIA (LATAK)	NO
MALTA (NAB-MALTA)	NO. The NAB-MALTA is not aware of any such requirements.
NETHERLANDS (RVA)	NO
NORWAY (NA)	NO
PORTUGAL (IPAC)	**YES**
REPUBLIC OF CROATIA (HAA)	NO
SERBIA (ATC)	-
SPAIN (ENAC)	**YES.** Units for collection of biological samples must be authorized by regional healthcare authorities. For this authorization the unit must be linked to a medical laboratory which takes the responsibility for the whole process.
SWITZERLAND (SAS)	NO
TURKEY (TURKAK)	NO
UKAS	NO

Accredited & in process Medlabs




Multisite
GERMANY (DAKKS)
FRANCE (COFRAC)
SWITZERLAND (SAS)
CZECH REPUBLIC (CAI)
BELGIUM (BELAC)
IRELAND (INAB)
NORWAY (NA)
SPAIN (ENAC)
GREECE (ESYD)
DENMARK (DANAK)
FINLAND (FINAS)
PORTUGAL (IPAC)
SERBIA (ATC)
CYPRUS (CYS-CYSAB)
ESTONIA (EAK)
LATVIA (LATAK)
NETHERLANDS (RVA)
REPUBLIC OF CROATIA (HAA)
TURKEY (TURKAK)
MALTA (NAB-MALTA)
34%
18%
7%
11%
21%
22%
48%
29%
44%
33%
50%
0
100
200
300
400
500
600
with multi-site
number of accredited Medlab

Scope of accreditation

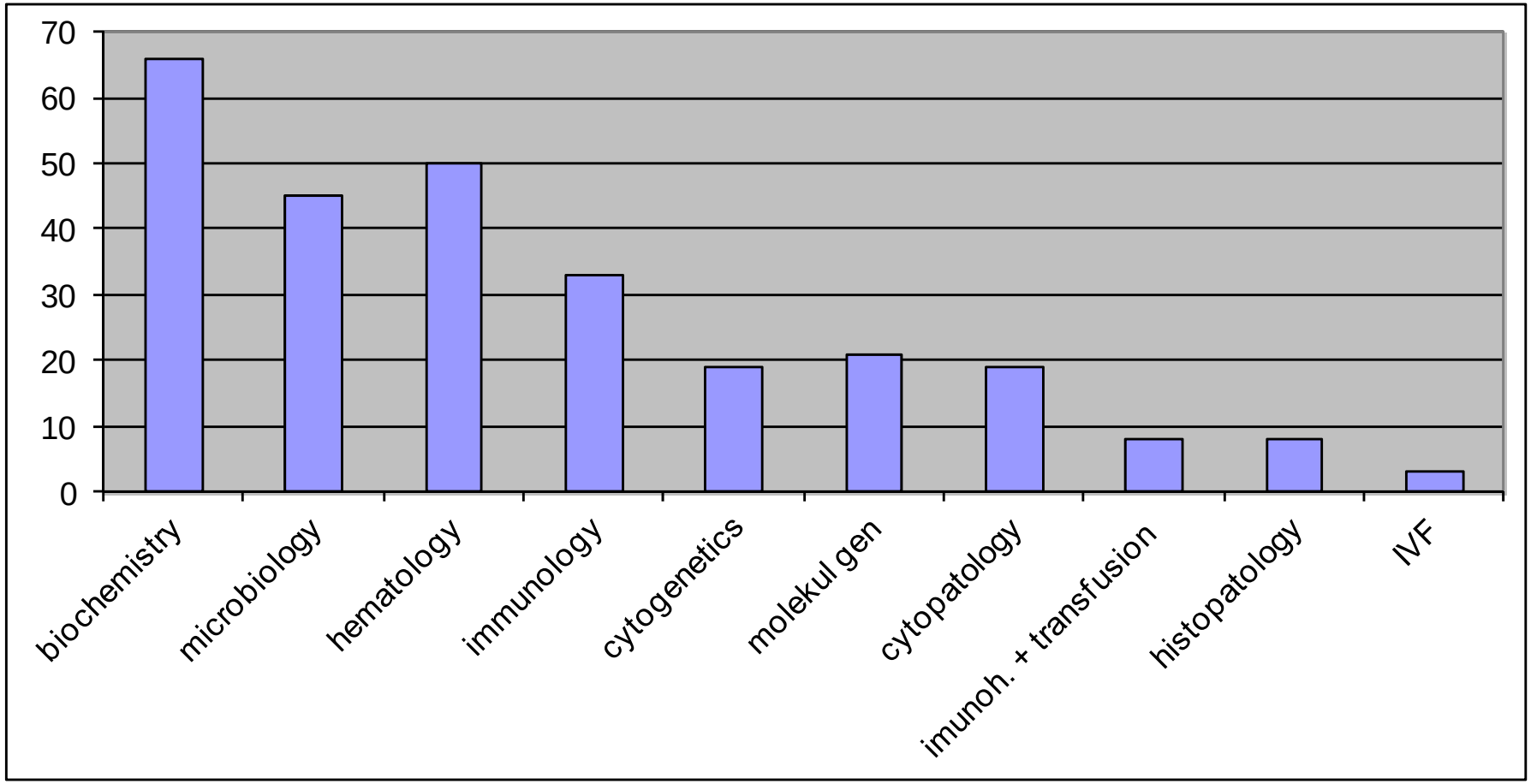
90-100% of AB	50-90% of AB	<50% of AB	Other medical areas
Clinical Chemistry Clinical Microbiology Haematology Immunology	Immunohematology Parasitology Clinical Toxicology Pharmacology Anatomical Pathology (Cytology and Histopathology) Molecular genetics Cytogenetics	Histocompatibility Point of care	Imaging Radiotoxicology Biological dosimetry Spermiology Clinical embriology IVF Pathology : -Molecular pathology - In-situ techniques Anticoagulation centers Sampling Forensic Testing Clinical physiology Nuclear medicine Clinical neurophysiology

POCT accrediting AB
GERMANY (DAKKS)
FRANCE (COFRAC)
IRELAND (INAB)
NETHERLANDS (RVA)
DENMARK (DANAK)
SPAIN (ENAC)
BELGIUM (BELAC)

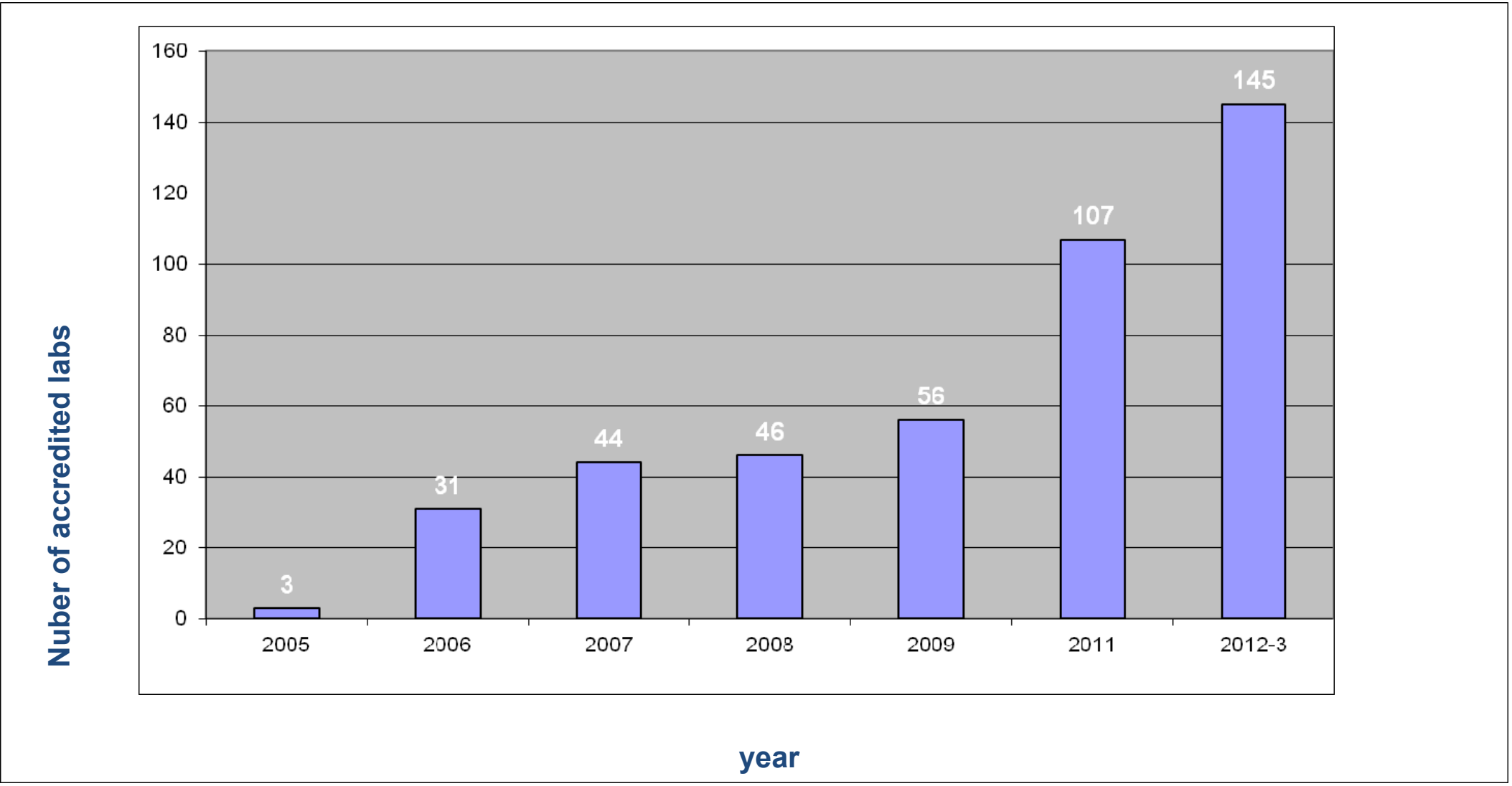
Czech Republic
Czech Institute of Accreditation

- Increasing number of accredited labs
- Accreditation - mandatory for genetic testing from 2012 by new health care law
- Requirements of healths insurance companies
- Training of experts
- Assessors are laboratory specialists and experts of QMS
- Increasing of number of experts
  - New area – in vitro fertilization labs

Accredited labs (145) – specialization (272)



Number of accredited labs
136 -15189 + 9 -17025



Reason why accredited
Our aims

- **Improve quality of our services**
- **High standard of services for clients – patients, physicians**
- **Interest of management – institute and hospital**
- **Better documentation of processes and responsibilities**
- **Somebody should start…**

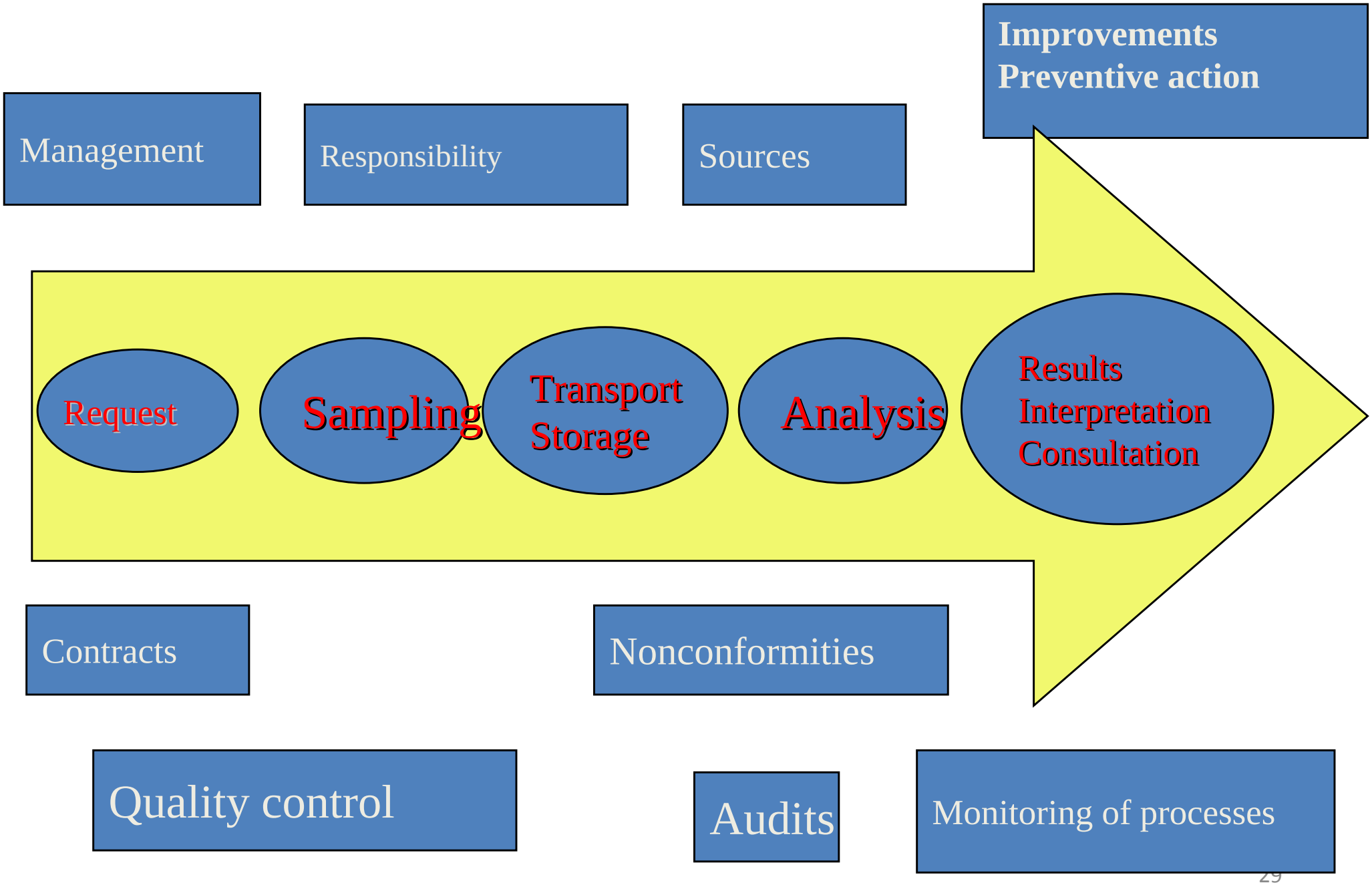
History

- 2001 – decission – start of accreditation
- 2004 - ISO 17025 – was established
- 2006 – ISO 15 189 and ISO 15189 was done
- 2012 – reaccreditation

Preparation for accreditation

- Builiging the team – education
- Select methods
- Analytical processes
- Metrology system
- Processess map
- Definition and structure of documents
- Quality manual
- Conflict of interest
- SOPs

Processes map



Accreditation …

Do the right things right
Describe how you do it
Do the things how you describe
All evaluate

Do the right things right
Describe how you do it
Do the things how you describe
All evaluate

Do the right things right
Describe how you do it
Do the things how you describe
All evaluate

Main areas of quality improvement in laboratory medicine

- Reduction of errors in the pre-analytical processes
- Facilitation of accurate and rapid diagnostics
- Participation in acceleration and efficiency of treatment
- Facilitation of personalised medicine development
- High quality of processes with continuous improvement

Laboratory services will be the centre of attention regarding quality due to their wide ranging impact on the care for patients.

Accreditation is not about who is the best, but who have system of standard procedures

ACCREDITATION IS INSTRUMENTALITY AND NOT AIM

Quality system = never ending story

Maintenance and improvment of system is ambitious story

Quality system is about people, with people and for people

Benefites and negation of accreditation

Benefits

- Standardization of processes
- Demonstrability od results
- Personal policy
- Evaluation of suppliers
- Prestigious
- Better communication with partners

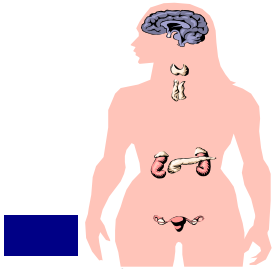
Negations

- Investment expences
  - Education QMS
  - Calibration
  - Control materials
  - Validation
- Expences with accreditation
- Time consuming process

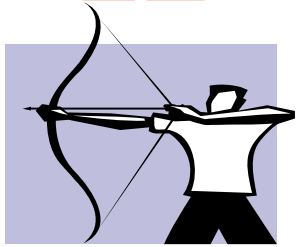
- Better profit from health insurance company or payers ??

Accredited lab

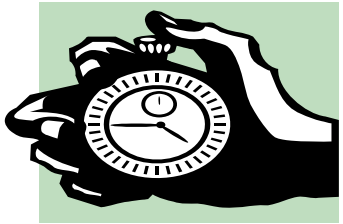
„Right“ patient



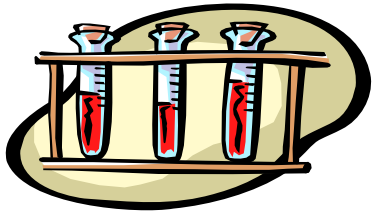
„Right“ diagnostic test



„Right“ time



„Right“ process



Aitäh – Ačiū - Paldies