

Accreditation in Czech Republic

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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
- Imaging 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

Regulation through quality

- Quality monitoring
- Accreditation, certification, TQM, ISO,..
- Patients rights
- Standard operation processes
- Standards of health care quality

Quality in the health care

The level of excellence 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 EFCC

- **Improvement of quality system in laboratory 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 authoritative body gives formal recognition that a body or person is competent to carry out specific tasks

Independent process

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

Accreditation of laboratories

- **Accreditation according to ISO 15189 – clinical laboratory**

Widely accepted in medical laboratory community

Available for 5 years

Accreditation in Czech Republic history

- The first meeting foccusing on QMS and clinical labs accreditation was in 2000.
- Discussion - way of implemenatation QMS
 - Certification ISO 9001
 - Accreditation ISO 17 025
(from 2003)
 - National standards

Accreditation of laboratories

- Many discussion about QMS and accreditation
- The first laboratories started accreditation according ISO 17025 as calibration laboratories – „pioneers labs“

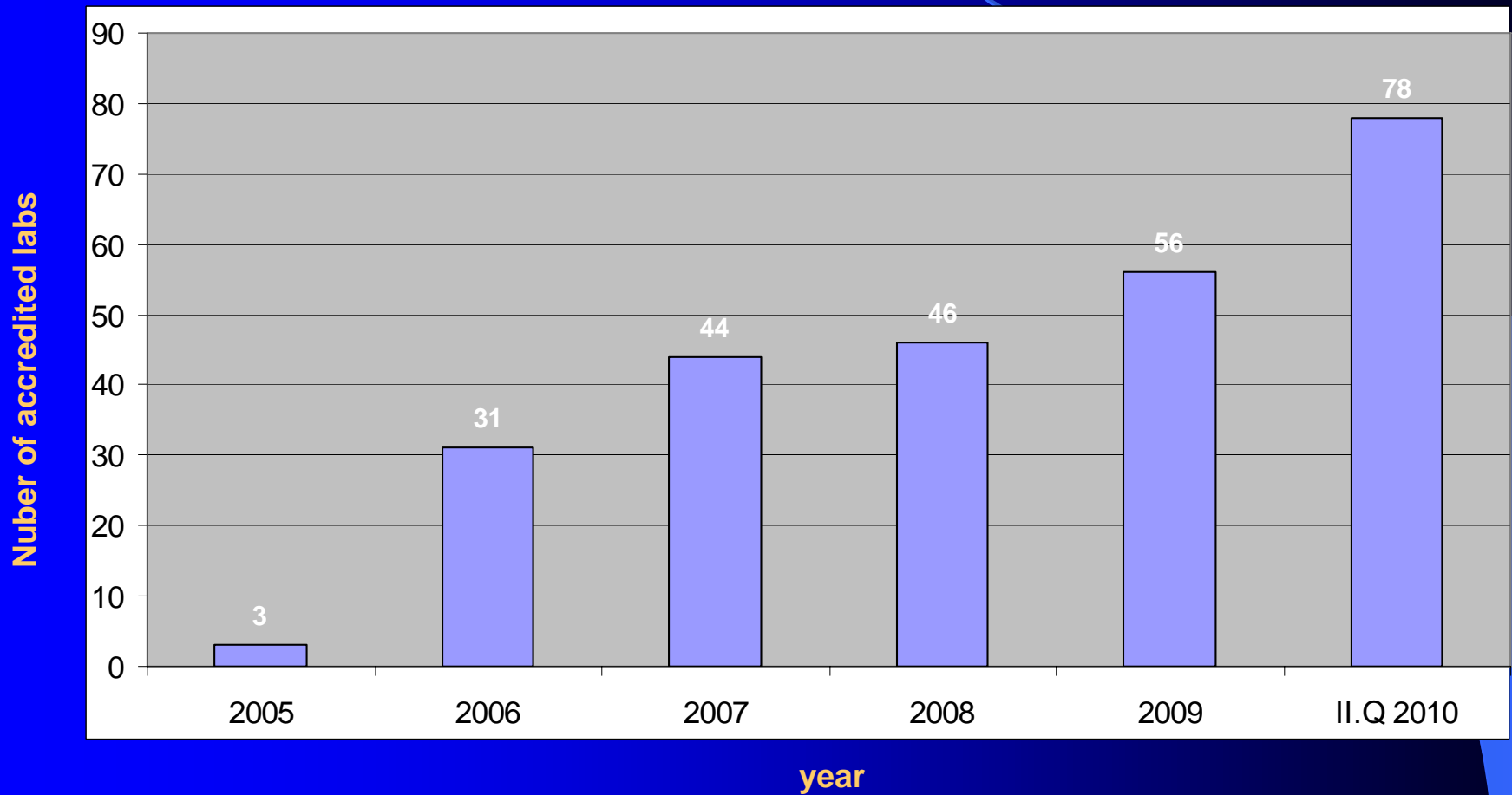
Czech Institute of Accreditation

- National standards – professional society set up standards incorporated requirements from ISO 15189, ISO 9001 and ISQ – *NACCL*

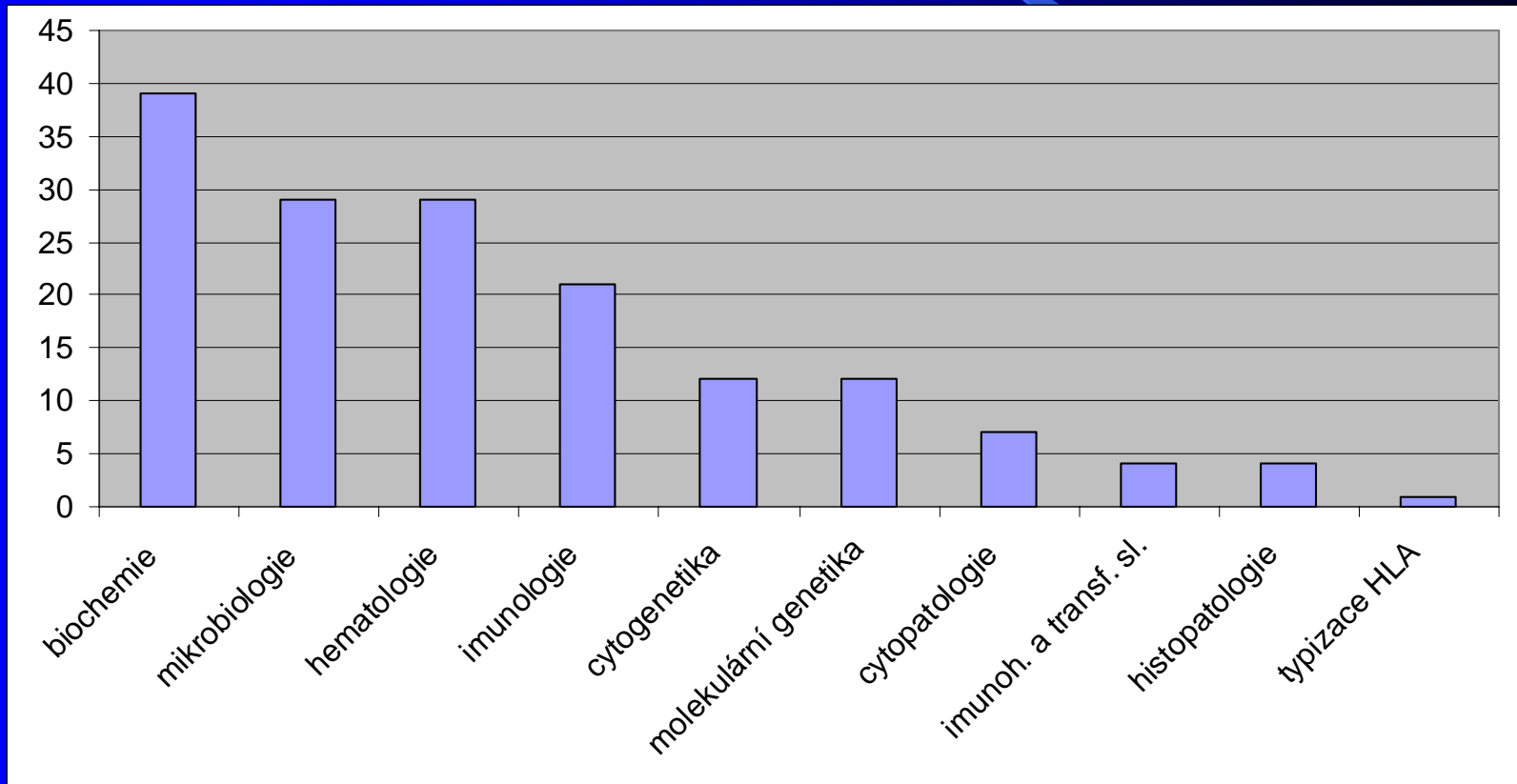
Czech Institute of Accreditation

- Accreditation of clinical labs is provided
Czech Institute of Accreditation
- ISO 15189 preferable
- National accreditation body
- Expert committee for clinical labs
 - Experts from professional societies
 - Cooperation with professional societies

Number of accredited labs



Accredited labs (78) - specialization



Czech Institute of Accreditation – situation

- Increasing number of accredited labs
- 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

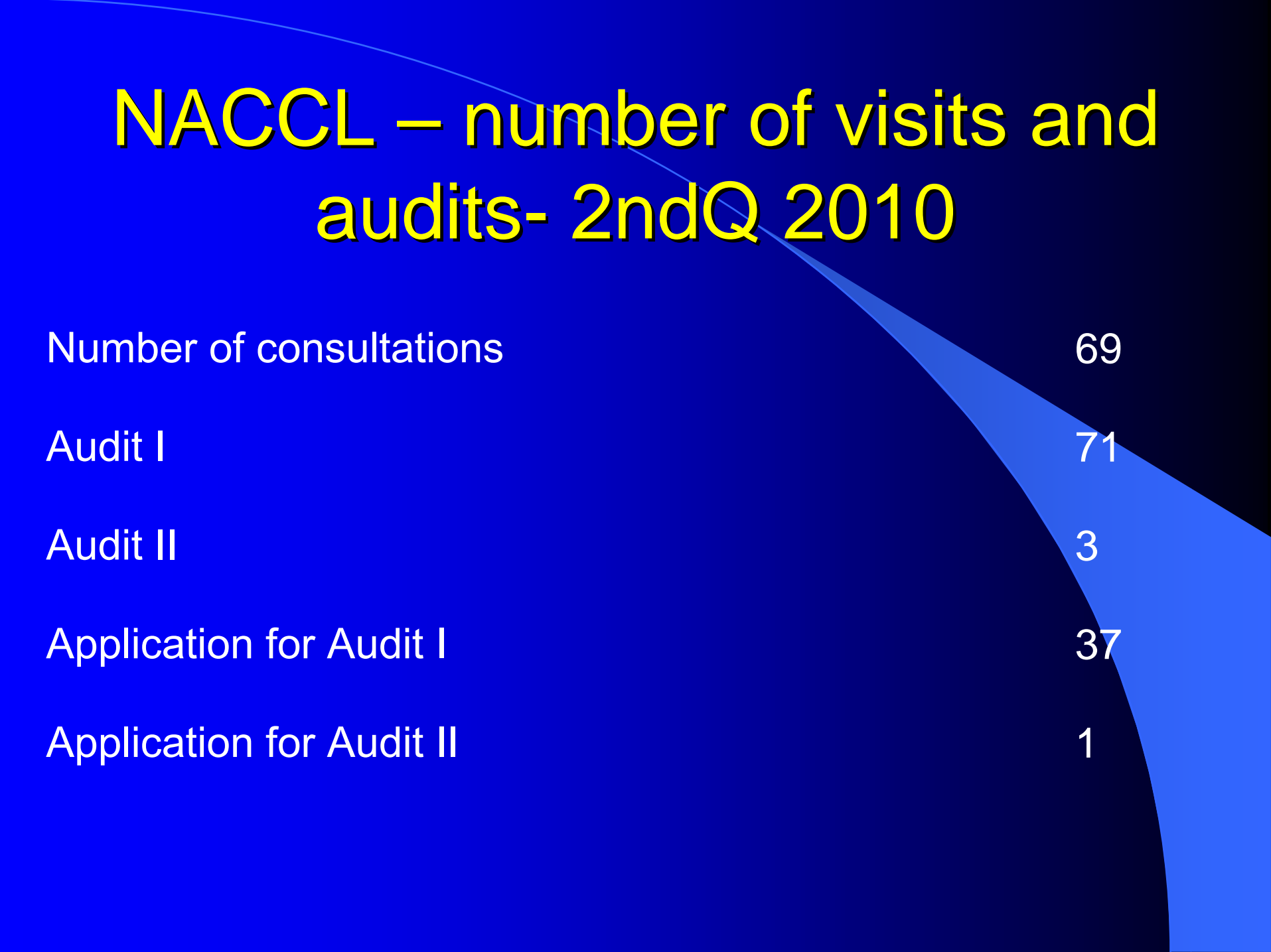
National Authorization Centre of Clinical Laboratories- NACCL

- Established by professional societies
- Unit of Czech Medical Association
- The first idea – accreditation organ
- National standards – from ISO 15189
- Now, not accreditation body but agency
 - Lab education of QMS
 - Preparation of lab for accreditaion

National Authorization Centre of Clinical Laboratories

- Assessors are laboratory specialists
- Basic principle – education
- Increasing number of experts and training
- Services
 - Registration
 - Consultation
 - Audit I – basic requirement
 - Audit II – „70%-80%“ requirements from ISO 15189

NACCL – number of visits and audits- 2ndQ 2010



Number of consultations	69
Audit I	71
Audit II	3
Application for Audit I	37
Application for Audit II	1

NACCL – number of visits and audits- 2ndQ 2010

Speciality	Audit	Registration
Clinical biochemistry	45	108
Mikrobiology	11	46
Immunology	8	30
Toxicology	0	2
Nuclear medicine	4	8
Genetic	1	8
Cytology	12	19
Hematology	26	64
Pathology	5	7
Transfussion medicine	7	14

Accreditation

- **Basic principle**
 - Voluntary
- **Health insurance company**
 - All inhabitants are insured
 - Contract
 - Participation on EQA
 - **Implementation of QMS**
 - ISO 9001 ?
 - **ISO 15189**
 - **Audit NACCL**



ISO 9001

**National
System**

ISO 17025

ISO 15189

Reason why accredited

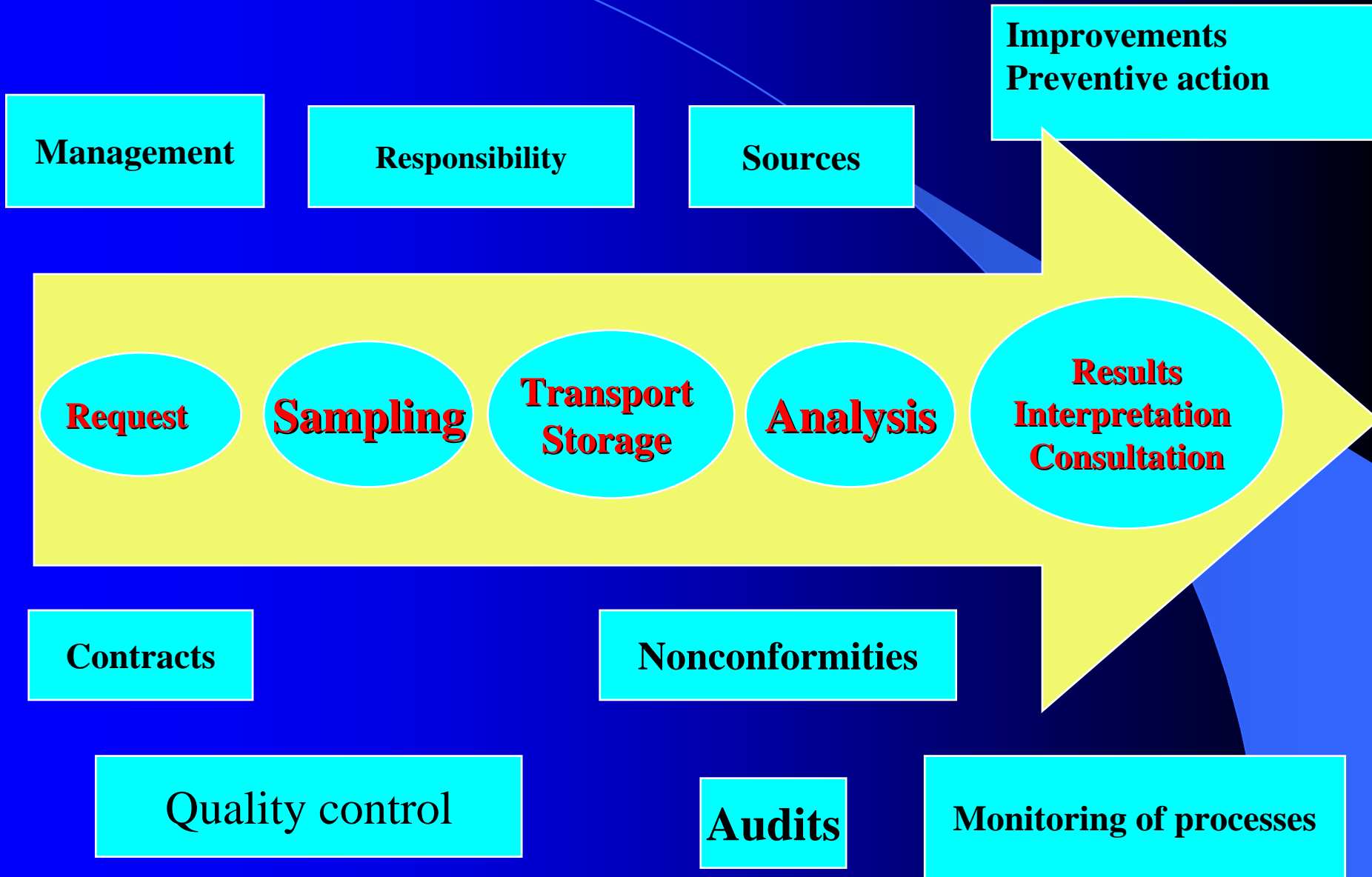
Our aims

- **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**

Preparation for accreditation

- Builging 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**

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Benefites and negation of accreditation

Benefits

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

Negations

- Investment expenses
 - Education QMS
 - Calibration
 - Control materials
 - Validation
- Expenses with accreditation
- Time consuming process

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

Accreditation is instrumentality and not aim

**Quality system is about people, with people
and for people**

**Thank you for your
attention**

