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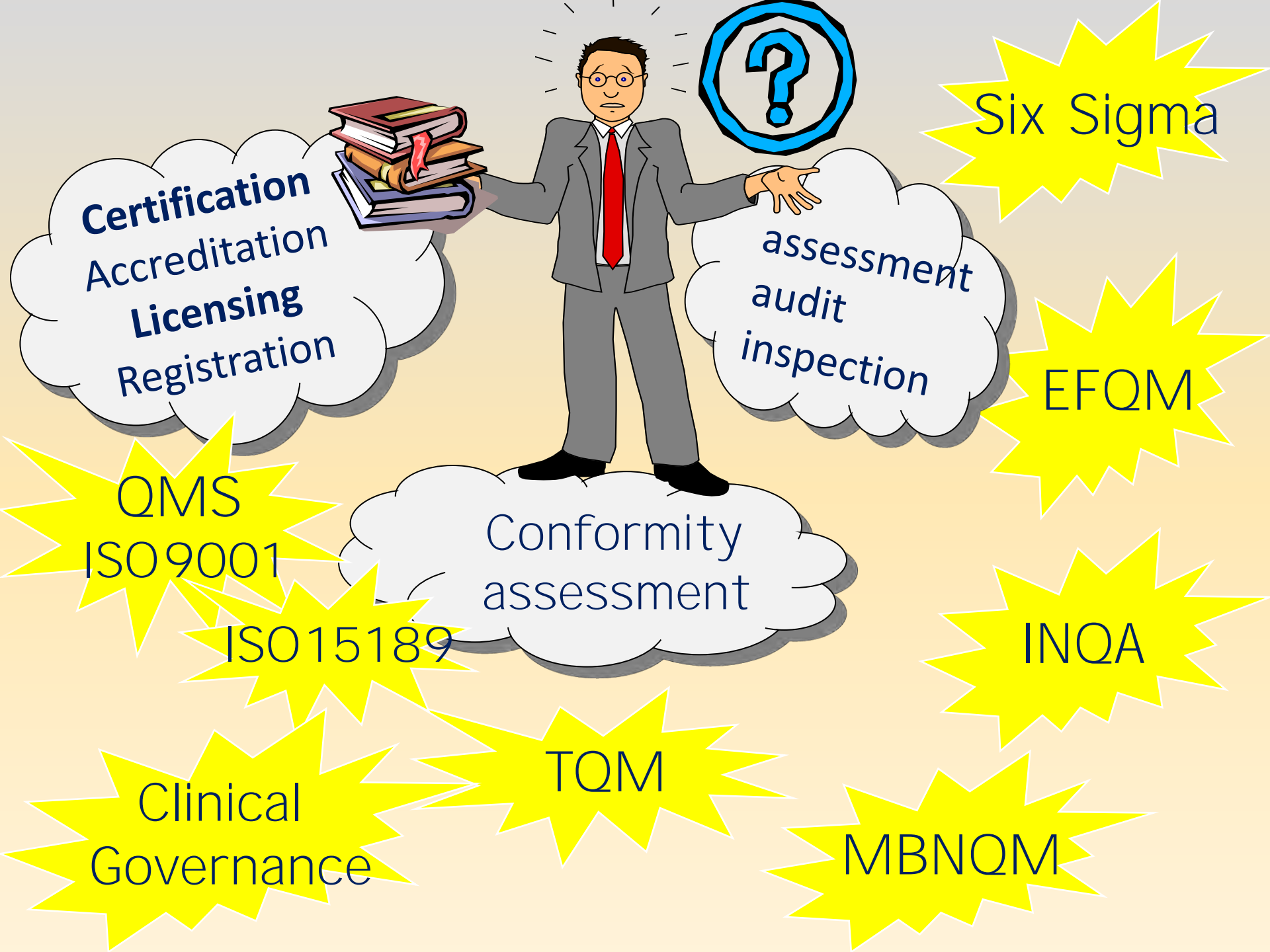
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ارتقاء کیفیت ارائه خدمات
آزمایشگاهی



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Six Sigma

Certification
Accreditation
Licensing
Registration

assessment
audit
inspection

EFQM

Conformity
assessment

INQA

TQM

MBNQM

Clinical
Governance

QMS
ISO 9001

ISO 15189

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ISO 15189 - Medical laboratories

Particular requirements for quality and competence

4 - Management requirements

- 4.1 Organization and management
- 4.2 Quality management system
- 4.3 Document control
- 4.4 Review of contracts
- 4.5 Examination by referral laboratories
- 4.6 External services and supplies
- 4.7 Advisory services
- 4.8 Resolution of complaints
- 4.9 Identification and control of nonconformities
- 4.10 Corrective action
- 4.11 Preventive action
- 4.12 Continual improvement
- 4.13 Quality and technical records
- 4.14 Internal audits
- 4.15 Management review

5 - Technical requirements

- 5.1 Personnel
- 5.2 Accommodation and environmental conditions
- 5.3 Laboratory equipment
- 5.4 Pre-examination procedures
- 5.5 Examination procedures
- 5.6 Assuring the quality of examination procedures
- 5.7 Postexamination procedures
- 5.8 Reporting of results



Some important technical items from other references

- CLSI guidelines CLIA, GP22A, HSA2
- ISO standards ISO 15189, ISO 15190, ISO/TR 10013
- WHO documents
- IATA & UN regulations for transport of infectious substance
- Biosafety in microbiological and Biomedical Laboratories (CDC, NIH).

Training

Lab. Directors

inspectors

Š Training courses were held by
 Š a training team in each university were
 arranged and Cascading training system
 was organized

Capacity building

Š a systematic plan for controlling lab equipment was set
 which has been implemented

Š A website was designed and uploaded

Š Advisory committees were organized

Š EQA programs were expanded

Š potential capacities of Scientific lab. Societies were used

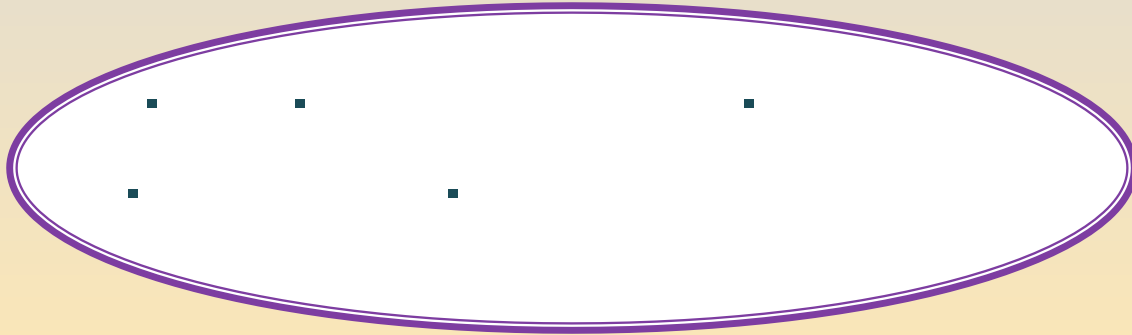
Field Activity

Š Establishing network of universities for audits

Š Organizing Auditor Pool

Š Benchmarking
 getting feed back and assessing the feasibility of standards in

Š Motivating laboratories by giving them Quality Award



**Competency
Assessment**

Accreditation

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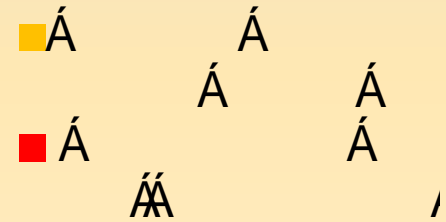
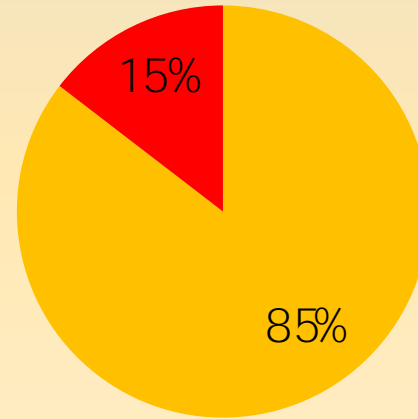
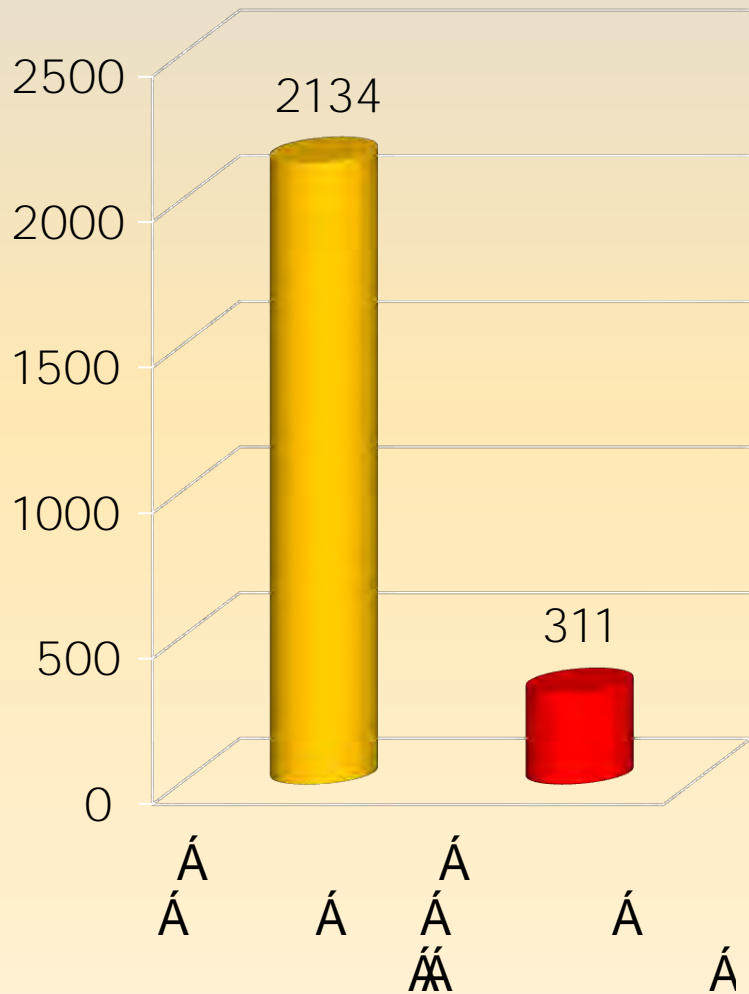
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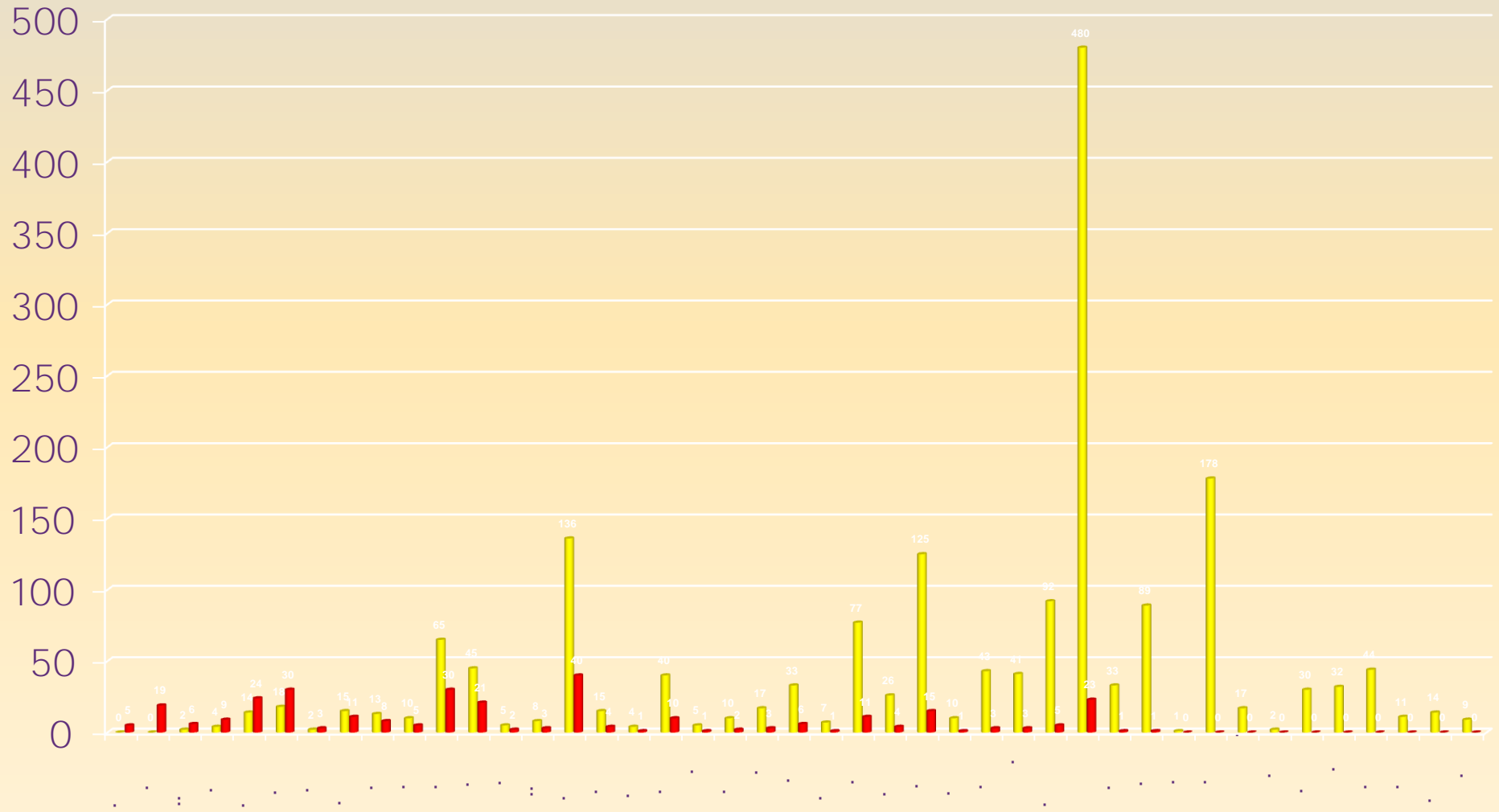
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Accreditation

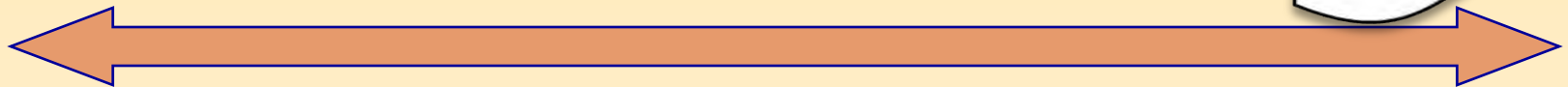
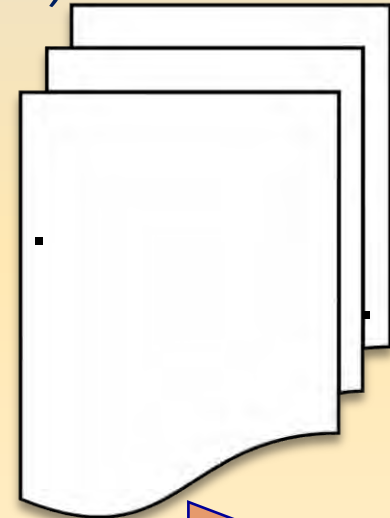
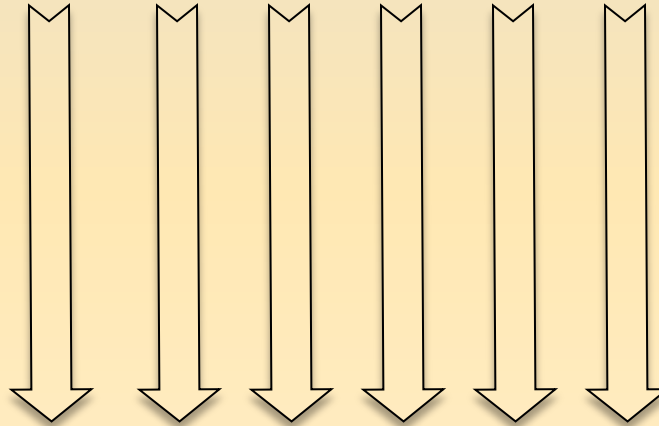
- F 'standard
- G 'Auditor pool
- H 'Accreditation bodies
- I 'User laboratories



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Vertical Standards

(Specific Guideline for subdiscipline\$)



Horizontal Standards

(according to ISO 15189 or National Standards)

G

Auditor pool

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Accreditation bodies



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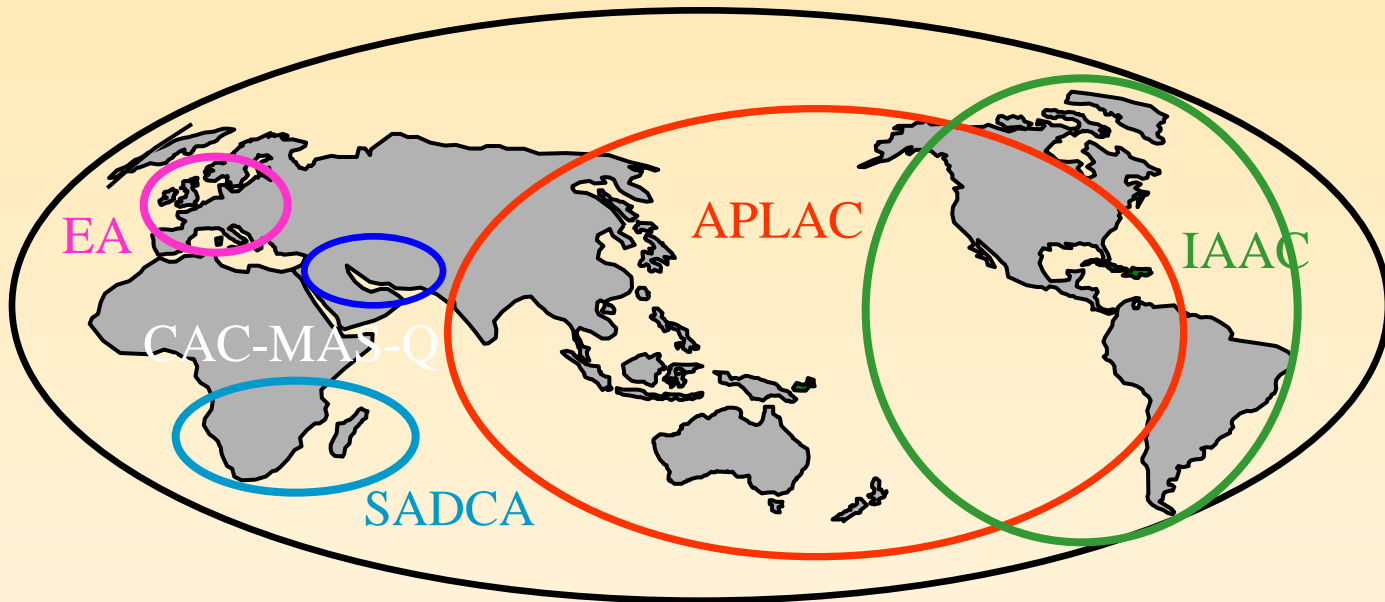
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- Principles
- General Requirements
- Structural Requirements
- Resource Requirements
- Information Requirements
- Process Requirements
- Management System Requirements

ISO/IEC 17011:2004

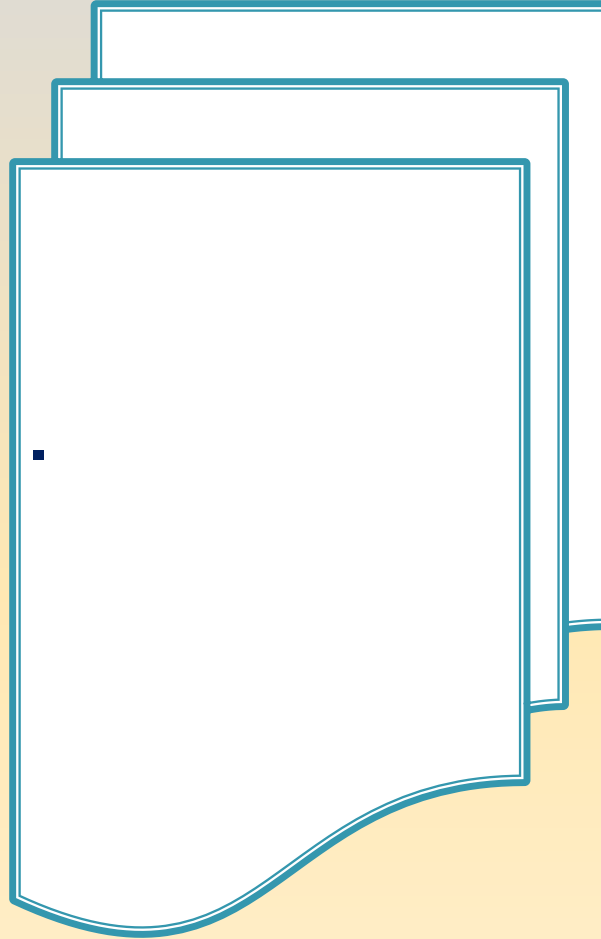
Conformity assessment
General requirements for
accreditation bodies accrediting
conformity assessment bodies

ISO/IEC 17021:2006

Conformity assessment
Requirements for bodies providing
audit and certification of
management systems

ISO/IEC 1701:2004

ISO/IEC 1702:2006



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Assessing laboratory performance

~~Ø~~ On Site Visit

~~Ø~~ EQAS/PT

EQAS /PT

External Quality Assessment / Proficiency Testing

'A program for objectively checking
the performance'

- 3 Allows interlab comparison of performance
- 3 Identifies systematic errors
- 3 Identifies kit/reagent problems
- 3 Identifies training needs
- 3 To ensure the Quality performance of National Health programs
- 3 to verify the epidemics preparedness

Benchmarking p b'pav_ v

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**"It isn't what you find...
it's what you do
about what you find."**

Philip Crosby

