

## Which QMS Standard should be chosen for the structural quality of a medical laboratory?

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<http://www.ifcc.org/ifcc-education-division/emd-committees/c-clm/>

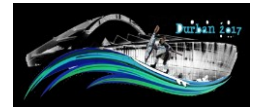
Satellite Educational Workshop on Intelligent Clinical Laboratory Management: Impacts on Quality System Improvement

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## Presentation outline



### standardization of laboratory structures

Several standards for standardization and accreditation of the structural quality developed by medical societies or by ISO and related bodies

- Federal organization of healthcare vs. international norms
- Technical norms and structural differences between countries
- Challenges of technical norms in healthcare
- Uniform performance of accreditation bodies
- application of quality standards in settings with limited resources

## Quality management system (QMS)

compilation of organizational documents establishing policies and procedures to direct and control an organization with regard to quality

relates to general management activities, the provision and management of resources, the pre-examination, examination and post-examination processes and evaluation and continual improvement

captures the requirements of an organization and structurally provides a roadmap that explains **who, what, when, where** and **how** sustainable and repeatable outcomes will be achieved

## Flowchart of compiling a standard

ISO (International Organization for Standardization) and IEC (International Electrotechnical Commission) form system for worldwide standardization

1. National bodies: members of ISO or IEC; participate in development of International Standards through technical committees
2. ISO and IEC technical committees collaborate in fields of mutual interest
3. Participation of other international organizations, governmental and non-governmental, in liaison with ISO and IEC
4. International Standards are drafted in accordance with rules of ISO/IEC Directives
5. Draft International Standards are circulated to the national bodies for voting
6. Publication as International Standard when approval by >75 % of national bodies

## Proposal of new Technical Committee

ISO Committee Name: **ISO TC 212**

Committee Title: **in Vitro diagnostics and Quality**

Secretariat Country: **United States**



Secretariat Organization: **CLSI**

Number of countries: **33** (All continents represented)

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## Influences in the development of 15189



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## Requirements contained within ISO 15189

Five sections:

1. Scope

2. Normative references

3. Terms and conditions

4. Management requirements

## 5. Technical requirements

Contains all requirements for a clinical laboratory's quality management system and the technical requirements used as the basis for confirming a clinical laboratory's competence **to perform specific clinical tests**

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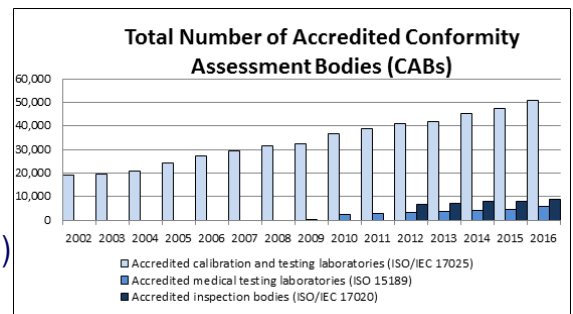
## ISO 9001; 17025; 15189; 17020

QMS to safeguard the integrity of patients

**BUT:** Focus often unclear / intransparent

Focus on analytical techniques (ISO17025; 15189)

**Competence of examiner (ISO 17020)**



*Medicine is not an exact science, and at times requires some educated guesswork on the part of physicians and laboratories, Gary Marchant, a law professor at Arizona State University, told BuzzFeed. "Every time they're wrong, it doesn't mean there should be a lawsuit...But on the other hand, when they clearly haven't lived up to professional expectations, there should be. There's a gray zone, that's a difficult line to draw."*

### A Lawsuit's Potential Impact on Genetic Test Reporting



Case involving misdiagnosis of a genetic variant illuminates inadequacies in genetic testing lab standards.

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Date: MAY.5.2016 // Source: CLN Stat

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## Performance improvement and quality standards

- **ISO15189 centred**
  - Australia: all medical laboratories accredited
    - ISO15189 accreditation linked to medicare benefits
- **National Quality Standard + ISO15189**
  - “Staged approach” in Thailand and Iran
  - GBEA (Guide de bonne exécution des analyses), France
  - RiLiBÄK, Germany
- **National Quality Regulation + ISO15189**
  - USA: Clinical Laboratory Improvement Amendments (CLIA)

Accreditation:  
Facilitating world trade



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## Benefits of standards



Standard: a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose



ISO International Standards ensure that products and services are safe, reliable and of good quality



Standards are strategic tools to reduce costs by minimizing waste and errors and increasing productivity



Standards help companies to access new markets and facilitate free and fair global trade



Government and industries around the world have been using international standards for more than half a century to facilitate trade, establish a technical base for regulation and safeguard consumers

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## Obligation to render medical services in person

In Germany

**Common service law:** „In case of doubt, services have to be performed in person by the party/person obliged to render the service ( § 613 (1) BGB)“

Physician law: § 19 (1) rules of professional conduct

public insurance: § 32 (1) „Zulassungsverordnung für Vertragsärzte“ and § 15 (1) „Bundesmantelvertrag-Ärzte“

### Accreditation of a medical laboratory according to ISO 15189 has to reflect these legal requirements

### Obvious conflict between of universal norm with national law

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## EN 16372 Aesthetic Surgery Services

“The market is already ‘Europeanised’, with patients travelling to other countries to have procedures, where markets are often unregulated and patients are vulnerable to complications.

The standard will help create a level playing field in Europe and ensure that the reputation of competent well-trained surgeons is not compromised at the hands of those who are not fit to practice

- Ethics and marketing
- Consultation procedure
- Competencies
- Management and communication with patients
- Available facilities
- Categorisation and risk level of the procedures”

Source: BSI

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	Norms	Guidelines
Scope	International	National, international
Target	Requirements for technical correct behaviour in most/ standardized situations resp. for services ( <b>conformity</b> )	Recommendations for physicians and patients for diagnostic and therapeutic procedures for each patient ( <b>individually</b> )
Triggers	<ul style="list-style-type: none"> <li>• Need of market</li> <li>• Economic profit</li> </ul>	<ul style="list-style-type: none"> <li>• Improvement of services and information</li> <li>• optimization of patient treatment</li> <li>• education/training</li> <li>• quality assurance</li> </ul>
Participants, representation	Interested parties including industry	Stakeholders, no direct influence of industry
Content based	State of the art knowledge and technology	Evidence-based, independent systematic literature search and evaluation
Decision making	Not defined, dissent not communicated	Consensus decision, communication of consensus strength and dissent
Transparency	Only during development (comments)	High, process publically available
Editorial Independency	No regulations for conflict of interests financial conflicts not exclude	Clear and transparent regulations for conflict of interests, no financial conflicts
Access	Limited, for fee	Unlimited, free, published in the internet

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## Objective: confidence in inspection bodies

conformity with regulations, standards, specifications, inspection schemes or contracts. Inspection includes matters of quantity, quality and **fitness for purpose** of installations or systems in operation

examination of materials, products, installations, plants, processes, work procedures or services, determination of conformity with requirements and reporting of results to clients and authorities

work requires professional judgement in performing inspection, in particular when assessing conformity with general requirements

Inspection activities can overlap with testing and certification activities

**BUT: professional judgement to determine acceptability against general requirements, for which reason inspection body needs necessary competence to perform the task**

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## Definitions of DIN EN ISO 17020

**Product:** result of a process

software (dictionary); hardware (mechanical part); processed materials (lubricant)

In products with elements of different categories, designation depends on dominant element

Products include results of natural processes, such as growth of plants

**Process:** set of interrelated or interacting activities which transforms inputs into outputs

**Service:** result of activity performed at interface between supplier and customer (intangible)

Provision of service can involve activity performed on customer-supplied intangible product (e.g. the income statement needed to prepare a tax return); delivery of intangible product (e.g. the delivery of information in the context of knowledge transmission)

**Impartiality:** presence of objectivity -- conflicts of interest do not exist / are resolved

**terms useful in conveying impartiality:** independence, freedom from conflict of interests, freedom from bias, lack of prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment, balance

## Coverage of legal requirements

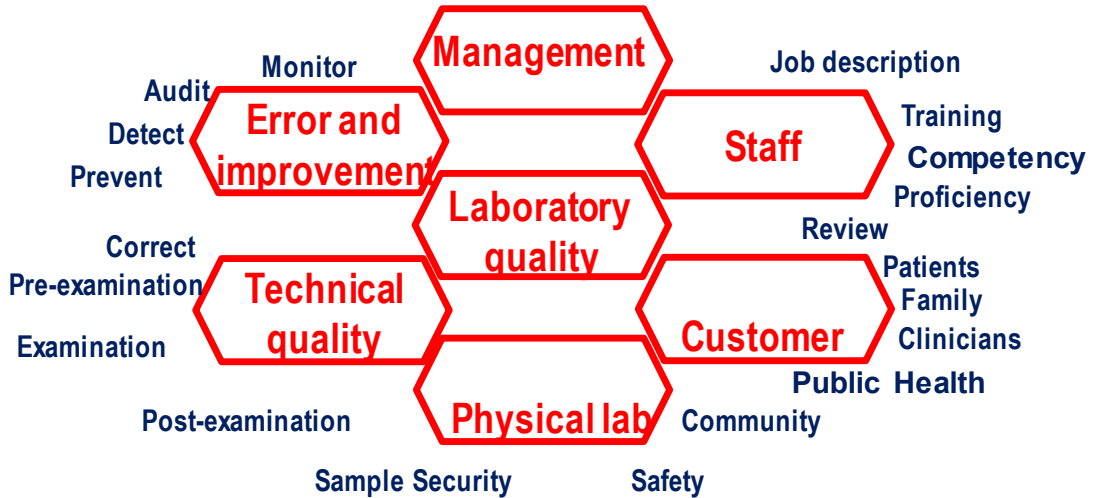
Legal requirements	ISO 17025	ISO 17020
Technical equipment	x	x
Education of personnel	x	x
Professional knowledge	x	x
System knowledge		x
Liability	x	x
Independency		x
Objectivity	x	x
Confidentiality	x	x

**ISO 17020 includes ISO 17025**

**no inclusion of assessment (vs. report) in ISO 17025**



## DIN EN ISO 15189



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## ISO 17020

general criteria are supplemented by a variety of ILAC and IAF/ILAC documents and specific scheme requirements

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## Accreditation of inspection bodies

Most economies with one or more accreditation bodies for the accreditation of inspection bodies to the ISO/IEC 17020 standard

Accreditation bodies are part of government, established by Government, or formally recognised by Government or private entities

ILAC body members provide accreditation services according ISO/IEC 17011 – *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies* ensuring consistent approach to the assessment and accreditation of inspection bodies

ISO/IEC 17020 mandatory for ILAC body members for accreditation of inspection bodies

- validity and appropriateness of inspection methods
- technical competence of staff
- suitability and maintenance of inspection equipment
- where necessary, traceability of measurements
- sampling, handling and identification of inspected items
- quality assurance of inspection data, inspection reports and certificates

### RiliBAEK J Lab Med 2015; 39(1): 26–69

1969/1970 – 2002 legal requirement for *quality control*: **Calibration Act**: Act on Measurement and Calibration

Since 2002, *quality assurance* in medical laboratory tests belongs to **Medical Product Law**

Rili-BAEK issued by the German Medical Association (1971, 1987, 2001, 2008) setting minimum standards for quality assurance in medical laboratories

2008 version of Rili-BAEK: Section A QMS (protection of the patient). Section A applies to *all users* of medical laboratory procedures.

Implementation of Section A of the Rili-BAEK guideline fulfils the statutory rules of a QMS

## Rili-BAEK: Promulgation of EU directives on medical products

### 2002 EU Medical Devices Marketing Regulations

Rili-BAEK guideline was created in 2004 in cooperation with

- medical research institutions
- German hospital Association (DKG)
- National Association of Statutory Health Insurance Physicians (KBV)
- Association of Biotechnologists (dvta)
- Agencies responsible for monitoring medical product regulations
- Association of IVD companies (VDGH)
- top-level Federal agencies (Physikalisch Technische Bundesanstalt (PTB), Robert Koch Institute (RKI), Paul Ehrlich Institute (PEI))

C 173/136

EN

Official Journal of the European Union

13.5.2016

Commission communication in the framework of the implementation of the Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices

(Publication of titles and references of harmonised standards under Union harmonisation legislation)

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## Low Resources: Medical laboratory quality gaps

### Structural issues

weak or little regulatory/quality assurance framework put in place in resource limited settings

in contrast to pharmaceutical products

putting technologists working in the forefront at **unacceptably high risks of occupational infection and patients of wrong reports**

inappropriately equipped/serviced facilities

insufficiently trained/educated personnel, lack of continuous training

### Dilemma

International standards exist but not readily feasible/realistic for many with resource constraints, especially for intermediate/district level laboratories

leaving them an “all or nothing” situation

→ **“staged approach” setting challenging yet achievable milestones to ensure long-term goals are reached**

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### What is the difference between SLIPTA and SLMTA?

#### What is SLMTA?

Strengthening Laboratory Management Toward Accreditation

A task-based training and mentoring tool kit provided to the laboratory personnel in a multi-workshop implementation model. The foundation of this programme is a framework that defines the tasks a laboratory manager must perform in order to deliver quality laboratory services which support optimal patient care. Training activities are designed to enable laboratory managers to accomplish those tasks, using tools and job aides to enhance their management routines. It empowers laboratory managers to initiate immediate laboratory improvement measures, even without additional resources. For more information about SLMTA, please visit [www.SLMTA.org](http://www.SLMTA.org)



#### What is SLIPTA?

Stepwise Laboratory Quality Improvement Process Towards Accreditation

A framework of auditing developed in line with the ISO 15189:2007 Standards and to a certain extent with the 12 Quality System Essentials of the CLSI Laboratory Quality Management System Guidelines. It is used to measure and evaluate the progress of laboratory quality system and award a certificate of recognition (five star levels). It can be used at baseline, during supervision, and for monitoring and evaluation of laboratory progress towards accreditation.



SLMTA	SLIPTA
A toolkit for training and mentoring	A framework for auditing and monitoring
Prepares and supports laboratory quality improvement	Checks and monitors the improvement process using the SLIPTA checklist
Develops work plans and executes improvement projects	Identifies gaps, non-conformities and provides recommendations for corrective actions
Implemented by laboratory personnel (laboratory managers)	Audits performed by ASLM-certified SLIPTA auditors
Graduates on SLMTA and prepares for inspection	Determines star level and provides Certificate of Recognition (1-5 star levels)

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## 2.0 Scope

This checklist specifies requirements for quality and competency aimed to develop and improve laboratory services to raise quality to established national standards. The elements of this checklist are based on ISO standard 15189:2012 (E) and, to a lesser extent, CLSI guideline QMS01-A4; Quality Management System: A Model for Laboratory Services; Approved Guideline – Fourth Edition.

Recognition is provided using a five star tiered approach, based on a bi-annual on-site audit of laboratory operating procedures, practices, and performance. The audit checklist score will correspond to the number of stars awarded to a laboratory in the following manner:

<b>No Stars</b> (0 – 150 pts) < 55%	<b>1 Star</b> (151 – 177 pts) 55 – 64%	<b>2 Stars</b> (178 – 205 pts) 65 – 74%	<b>3 Stars</b> (206 – 232 pts) 75 – 84%	<b>4 Stars</b> (233 – 260 pts) 85 – 94%	<b>5 Stars</b> (261 – 275 pts) ≥95%
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<b>Audit Score Sheet</b>	
Section	Total Points
<b>Section 1:</b> Documents & Records	<b>28</b>
<b>Section 2:</b> Management Reviews	<b>14</b>
<b>Section 3:</b> Organization & Personnel	<b>22</b>
<b>Section 4:</b> Client Management & Customer Service	<b>10</b>
<b>Section 5:</b> Equipment	<b>35</b>
<b>Section 6:</b> Evaluation and Audits	<b>15</b>
<b>Section 7:</b> Purchasing & Inventory	<b>24</b>
<b>Section 8:</b> Process Control	<b>32</b>
<b>Section 9:</b> Information Management	<b>21</b>
<b>Section 10:</b> Identification of Non Conformities, Corrective and Preventive Actions	<b>19</b>
<b>Section 11:</b> Occurrence/Incident Management & Process Improvement	<b>12</b>
<b>Section 12:</b> Facilities and Biosafety	<b>43</b>
<b>TOTAL SCORE</b>	<b>275</b>

ISO15189:2012 Clause 4.1.1.2 "The laboratory or the organization of which the laboratory is a part shall be an entity that can be held legally responsible for its activities. Note: Documentation could be in the form of a National Act, Company registration certificate, License number or Practice number."				
<b>1.2 Laboratory Quality Manual</b>				
Is there a current laboratory quality manual, composed of the quality management system's policies and has the manual content been communicated to, understood and implemented by all staff?	Y	P	N	5
The quality manual includes the following elements:	Tick for each item as Yes (Y), No (N) or Partial (P)			
a) Quality policy statement that includes scope of service, standard of service, measurable objectives of the quality management system, and management commitment to compliance.	Y	P	N	



## Challenges of standards in laboratory medicine



### Standards developed by ISO and related bodies are widely used

- conflict of interest, focus on free trade and consumer rights
- Not reflecting specific situations (national organization of healthcare!)
- Focus of some norms (15189 and 17025) primarily on technical part, 17020 on assessor
- **Regulation of healthcare matters not within the scope of ISO and related bodies**

### Challenges of accreditation:

- Countries without and with several accreditation bodies
- Spending resources for consulting firms instead for the training of the personnel

### Outlook / Solutions

- QM systems developed by medical associations (e.g. Rilibäk)
- settings with limited resources: stepwise approach in increasing the quality WHO: "Stepwise Laboratory Improvement Process Towards Accreditation" (SLIPTA)