

(EN 15189, EN 17020, EN17025, RiliBÄK, SLIPTA)



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Setting the Stage

Standardization of (standardized) laboratory methods by internal quality assurance (IQC) and round robin testing (EQA)

standardization of laboratory structures

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

- healthcare must be regulated on the national level and application of international norms contradictory to national regulation
- Technical norms cannot reflect differences between countries
- Aesthetic Surgery services norm (EN 16372) not compliant with national legislation
- In countries without accreditation bodies laboratories can pick foreign accreditation office with less stringent standard (contradiction!)
- application of a certain quality standard in settings with limited resources

Trust



compilation of organizational documents that establishes 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

What makes up a quality management system?

A quality management system consists of policies, procedures, SOPs and records, all of which provide proof of goals, assign responsibility, describe how those responsibilities are performed and provide evidence of compliance

- ISO (International Organization for Standardization) and IEC (International Electrotechnical Commission) form system for worldwide standardization
- National bodies: members of ISO or IEC; participate in development of International Standards through technical committees
- ISO and IEC technical committees collaborate in fields of mutual interest
- Participation of other international organizations, governmental and non-governmental, in liaison with ISO and IEC
- International Standards are drafted in accordance with rules of ISO/IEC Directives
- Draft International Standards are circulated to the national bodies for voting
- 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

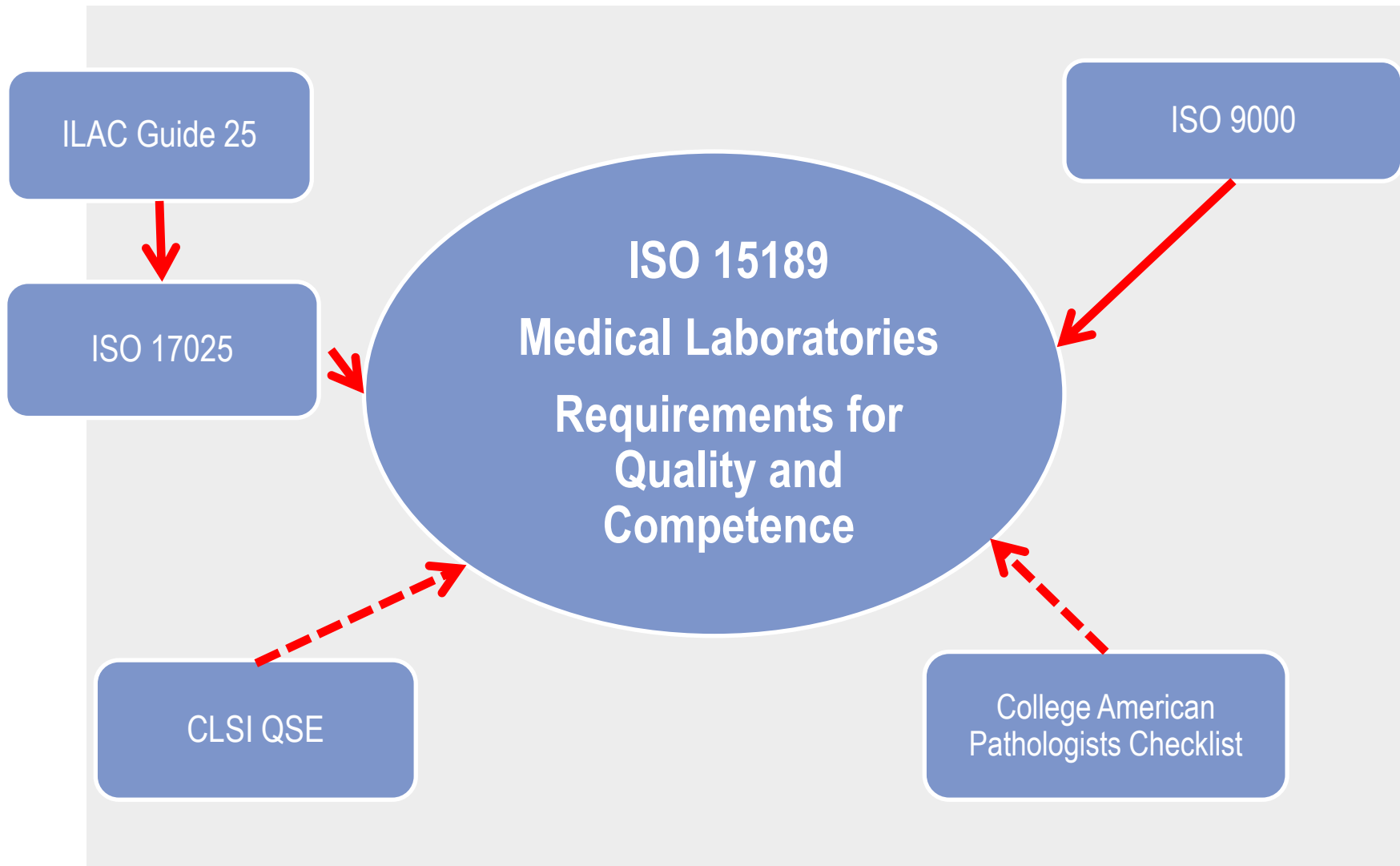
Secretariat Country: United States

Secretariat Organization: CLSI



Number of countries 33 (All continents represented)

Influences in the development of 15189



standard divided into 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**

QMS to safeguard the integrity of patients (indirectly and directly)

BUT: Focus often unclear / intransparent

Focus on analytical techniques (ISO17025; ISO15189)

Competence of examiner is secondary (→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.

What is ISO 15189 and what is its basis?

ISO 15189:2012 is standard that provides specific requirements for quality and competence particular to clinical laboratories

Standard promotes global harmonization of clinical practices

protects the health and safety of patients and healthcare providers, supports efficient exchange of information and protection of data and improves the overall quality of care

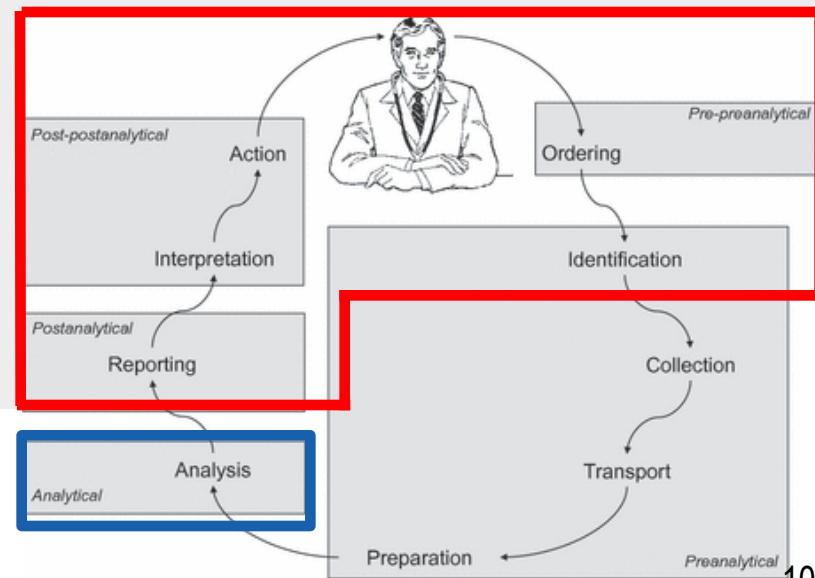
ISO 15189 is used by laboratory customers, regulatory authorities and accreditation bodies to ensure competence

contains increased focus on technical competence, requires mandatory assessment against measurement uncertainty and traceability

Open challenge: management competence

§ 25 Performing and billing for laboratory services (1) The aim of laboratory testing is the **issue of a medical report**. Laboratory services are divided into four parts: 1. **Medical examination decision (ordering)** 2. Pre-analytics, 3. **Laboratory testing under conditions of quality assurance (RiliBÄK)**, 4. **medical assessment of results**

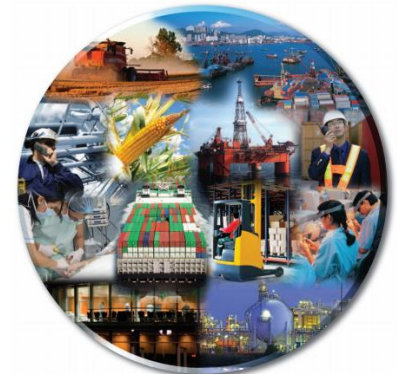
Fees for services in section M GOÄ include the entrance **inspection** of the sample, sample preparation, **testing** (including QA) and the **issuing of the medical report**



- **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



“The best way to find out if you can
trust somebody is to trust them.”

Ernest Hemingway

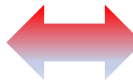
Benefits of standards



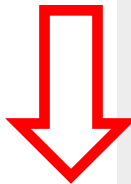
Standard: a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose



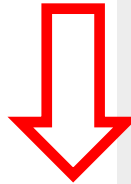
ISO International Standards ensure that products and services are safe, reliable and of good quality



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

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

“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”

BUNDESÄRZTEKAMMER

Bekanntmachungen

Der Vorstand der Bundesärztekammer hat in seiner Sitzung vom 25.09.2015
auf Empfehlung des Wissenschaftlichen Beirats beschlossen:

Stellungnahme der Bundesärztekammer „Normungsvorhaben von Gesundheitsdienstleistungen aus ärztlicher Sicht“

Norms vs. Guidelines

	Norms	Guidelines
Scope	International	National, international
Target	Requirements for technical correct behaviour in most / standardized situations resp. for services (conformity)	Recommendations for physicians and patients for diagnostic and therapeutic procedures for each patient (individually)
Triggers	<ul style="list-style-type: none"> • Need of market • Economic profit 	<ul style="list-style-type: none"> • Improvement of services and information • optimization of patient treatment • education/training • quality assurance
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

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

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

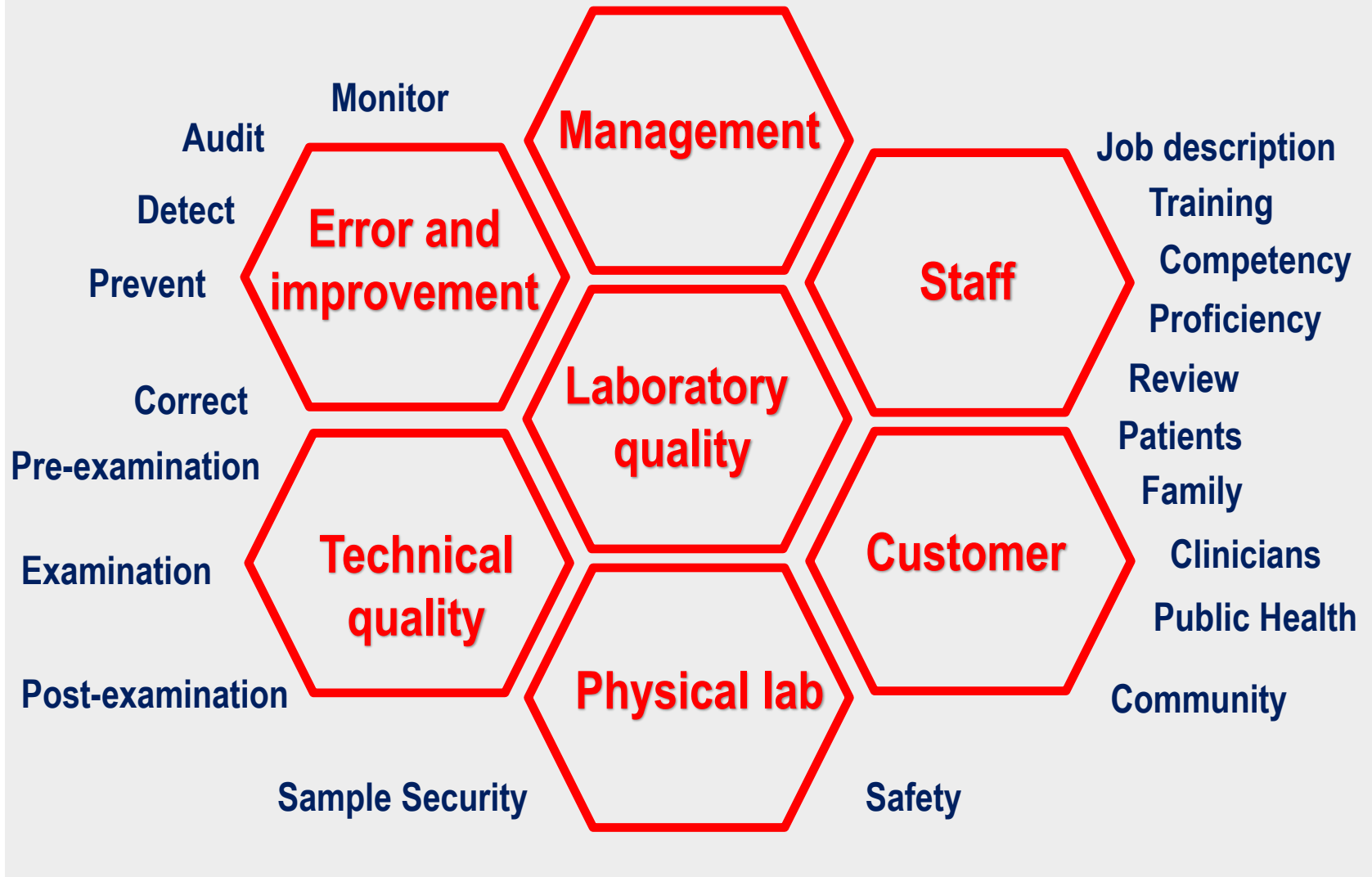
Coverage of legal requirements

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





ISO 17020

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

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

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

In healthcare, following activities are restricted to persons with a permission acc. to § 1 #1: testing in morphologic Hematology, Immunohematology, Hemostaseology, Clinical Chemistry, Microbiology, Parasitology and Immunology including reporting, quality control and technical validation

Excluded from under b - d listed activities are simple clinical-chemical analyses and simple qualitative and semiquantitative analyses of body fluids



Reichsgesetzblatt
Teil I

1939	Ausgegeben zu Berlin, den 20. Februar 1939	Nr. 30
Tag	Inhalt	Seite
17. 2. 39	Gesetz über die berufsmäßige Ausübung der Heilkunde ohne Bestallung (Heilpraktikergesetz)	251
17. 2. 39	Gesetz über die Befolgung der Hochschullehrer (Vierunddreißigste Ergänzung des Befolgungsgesetzes)	252

§ 10 § 9 does not apply to

1. physicians, dentists and **naturopaths/non-medical practitioners/quacksalvers**,
2. Medical laboratory technician students, 5. medical laboratory technicians,
6. Other medical licensed person under direct supervision and responsibility by a person under #1

Guideline of the German Medical Association for Quality Assurance of Medical Laboratory Analyses (Rili-BAEK)



Promulgation of the EU directives on medical products
2002 Medical Devices Marketing Regulations legal obligation to perform regular
quality assurance of medical laboratory analyses

The Rili-BAEK guideline was created in 2004 in cooperation with

- medical research institutions
- Deutsche Krankenhaus Gesellschaft (DKG)
- Kassenärztliche Bundesvereinigung (KBV)
- Dachverband der der Technologen/-innen und Analytiker/-innen in der Medizin Deutschland e.V. (dvta)
- Agencies responsible for monitoring medical product regulations
- Verband der Diagnostikahersteller (VDGH)
- top-level Federal agencies (Physikalisch Technische Bundesanstalt (PTB), Robert Koch Institute (RKI), Paul Ehrlich Institute (PEI))

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



WHO

**GUIDE FOR THE
STEPWISE LABORATORY
IMPROVEMENT
PROCESS TOWARDS
ACCREDITATION IN THE
AFRICAN REGION**

ASLM

AFRICAN SOCIETY FOR LABORATORY MEDICINE



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



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)

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:

No Stars	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
(0 – 150 pts)	(151 – 177 pts)	(178 – 205 pts)	(206 – 232 pts)	(233 – 260 pts)	(261 – 275 pts)
< 55%	55 – 64%	65 – 74%	75 – 84%	85 – 94%	≥95%

Audit Score Sheet	
Section	Total Points
Section 1: Documents & Records	28
Section 2: Management Reviews	14
Section 3: Organization & Personnel	22
Section 4: Client Management & Customer Service	10
Section 5: Equipment	35
Section 6: Evaluation and Audits	15
Section 7: Purchasing & Inventory	24
Section 8: Process Control	32
Section 9: Information Management	21
Section 10: Identification of Non Conformities, Corrective and Preventive Actions	19
Section 11: Occurrence/Incident Management & Process Improvement	12
Section 12: Facilities and Biosafety	43
TOTAL SCORE	275

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.

1.2 Laboratory Quality Manual				
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)			
	Y	P	N	
a) Quality policy statement that includes scope of service, standard of service, measurable objectives of the quality management system, and management commitment to compliance.				

- Rather uniform standards for result quality (round robin testing/EQA, IQC)

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
- **Regulation of healthcare matters not within the scope of ISO and related bodies**
- **Focus of DIN EN ISO 17020 on assessor**

Challenges of accreditation:

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

Outlook / Solutions

- QM systems developed by medical association (e.g. Rilibäk)
- settings with limited resources
- need for stepwise approach in increasing the quality of the laboratory structures
- WHO: “Stepwise Laboratory Improvement Process Towards Accreditation” (SLIPTA)