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ATLAS Project
ISO 15189 Accreditation Support Course

Basic knowledge of ISO 15189
– Quality Management System –

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Welcome to Japan

Cherry blossoms and Mt. Fuji in my hometown, Yokohama

Tokyo Station near my office in the evening

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Member of ATLAS Project

Mr. Seki has managed quality assurance for over 30 years while serving at Health Sciences Research Institute, Inc. His areas of specialty are quality management, clinical chemistry, and medical statistics.

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What is Standardization?

At a restaurant, cooking methods vary from person to person and the taste of food is not constant.

The activity of preparing materials using a defined method and setting specific standards for providing services is called “standardization”.

A document describing a standardized process is called a “standard”.

Organizations Promoting Standardization

- Representative organizations promoting international standardization include the ISO (International Organization for Standardization), which deals with products and services, and the IEC (International Electrotechnical Commission), which deals with standardization in the fields of electrical and electronic technology.
- As of January 2018, 162 organizations were members of the ISO. In Japan, the JISC (Japanese Industrial Standards Committee), a council established by the Ministry of Economy, Trade and Industry, is a member of the ISO.

Practical Example

1. Product compatibility: Unify the shape and dimensions of products such as prepaid cards (JIS X 6311) and credit cards (ISO/IEC 7810).
2. Accurate information transmission: Emergency exits (ISO 6309), tsunami danger areas (ISO 20712-1).
3. Ensuring and improving consumer safety: Durability of automobile tires (ISO 10191), structure of disposable lighters (JIS S 4801).
4. Improving operational and production efficiency: standardizing design and parts.
5. Reducing and controlling environmental load: ISO 14001 for environmental management.

Relationship Between Classification of Standards And Regulations

Optional Standard ： A standard that is either based or not based on the standard

- International Standard: ISO, IEC
- Regional Standard : CEN (European Committee for Standardization), CENELEC (European Committee for Electrotechnical Standards)
- National Standard : ANSI (American National Standards Institute), JIS (Japanese Industrial Standards)
- Industry (body) Standard

Relationship Between Classification of Standards And Regulations

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Mandatory standard : The reference standard content is enforceable by law.

- Fire Service Act (JIS K 2265, …)
- Building Standards Law (JIS A 3301, JIS A 4201, JIS 3302, ...)
- Personal Information Protection Law (JIS Q 15001)

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ISO and Technical Committee (TC)

- In recent years, the globalization of medical care has advanced, and patients and medical examinees receive high-quality medical services in their own country as well as across national borders. With the movement of patients and examinees around the world, establishment of international standards is becoming widespread in the medical field.
- Based on these movements, the TC 212 "Clinical Examination and *In Vitro* Diagnostic Examination System" was established within ISO in 1995.
- In Japan, the secretariat heads the Japanese Industrial Standards Committee (JISC) and Japanese Committee for Clinical Laboratory Standards (JCCLS) under the Ministry of Economy, Trade and Industry (METI).

ISO / TC212 Activities

- WG1 : Quality and competence in the medical laboratory
- WG2 : Reference systems
- WG3 : *In vitro* diagnostic products
- WG4 : Microbiology and molecular diagnostics
- WG5 : Laboratory biorisk management

TC 212 member countries include P-members (Participating countries, 39 countries) and O-members (Observing countries, 20 countries) and many international standards have been created and issued in collaboration with related organizations such as EC, CASCO, and APLAC.

Medical Technical Committees

- ISO TC 272 Forensic Science
- ISO TC 210 Quality Management and Corresponding General Aspects of Medical Devices
- ISO TC 276 Biotechnology

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1. What are ISO standards?
2. Essence of ISO 15189
3. Quality Management System of laboratory services
4. Implementation of ISO 15189

Scope

- This International Standard specifies requirements for quality and competence in medical laboratories.
- Medical laboratories can use this standard to develop quality management systems and assess their own competence. It can also be used to confirm or recognize the competence of medical laboratories by laboratory customers, regulating authorities, and accreditation bodies.
- International, national, or regional regulations or requirements may apply to specific topics covered in this International Standard.

Medical Laboratory Services

- Medical laboratory services are essential to patient care and therefore must be available to meet the needs of all patients and clinical personnel responsible for patient care.
- Services include arranging for examination requests, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent interpretation, reporting and advice, and considerations of safety and ethics in medical laboratory work.

Essence of ISO 15189

- Although this International Standard is intended for use throughout the currently-recognized disciplines of medical laboratory services, those working in other services and disciplines, such as clinical physiology, medical imaging, and medical physics, may also find this information useful and appropriate.
- In addition, bodies engaged in recognizing the competence of medical laboratories can use this International Standard as a basis for their activities.
- If a laboratory seeks accreditation, it should select an accrediting body that operates in accordance with ISO/IEC 17011 and takes into account the specific requirements of medical laboratories.

Major Tests Performed In Health And Medical Fields

Specimen Test	General (urine, feces, etc.)	Qualitative (urine/feces), Scatoloscopy, Basic analysis for punctatum
	Hematology	Blood count / Blood cell morphology test, Thrombus
	Biochemistry	Biochemistry, Isozyme, Immunochemistry, Tumor marker
	Immunology	Immunochemistry, Immunohematology, Infectious disease
	Microbiology	Microscopic examination of stained film (general bacteria)
	Gene-related/Chromosome test	Somatic gene test, Chromosome, Germline gene test
	Pathology	Preparation for Histodiagnosis, Cytodiagnosis, Pathological diagnosis
Biopsy	Physiology	Respiratory function test (Spirography), Electrocardiogram
	Imaging tests	Ultrasonography, MRI, PET

Requirements

- This International Standard is not intended for the purpose of certification; however, a medical laboratory's fulfilment of the requirements of this International Standard means that the laboratory meets both the management system requirements and technical competence requirements to consistently deliver technically valid results.
- The management system requirements in Clause 4 are written in a language relevant to a medical laboratory's operations and meet the principles of ISO 9001:2008, *Quality management systems — Requirements*, and are aligned with its pertinent requirements (Joint IAF-ILAC-ISO Communiqué issued in 2009).
- Clause 5 is based upon ISO/IEC 17025, requirements for technical to medical laboratories.

Difference between "accreditation" and "certification"

- It is optional for the laboratory to choose ISO 9001 "**certification**" or ISO 15189 or ISO/IEC 17025 accreditation.
- If certified by 9001, the clinical laboratory is guaranteed to develop a QMS but does not demonstrate the technical competence to perform clinical tests.
- In contrast, ISO 15189 or ISO/IEC 17025 includes the requirements of QMS specified in ISO 9001 "**certification**", and "**certification**" by this standard is an addition to the construction of QMS by the clinical laboratory. It shows that the laboratory can submit accurate and reasonable results.
- Therefore, because of the role of clinical laboratories, it is internationally common to obtain ISO 15189 or ISO/IEC 17025 "**accreditation**" rather than "**certification**".

Revision of ISO 15189

- At the ISO/TC212 general meeting held in Seoul in October 2018, the revision of ISO 5189: 2012 was resolved with a plan to proceed with the revision work over 48 months using the composition of ISO/IEC 17025: 2017 as a revision guide.
- It is scheduled to be published by March 2022, latest. After that, there will be a minimum transition period of two years from the 2012 edition to the 2022 edition.
- As of February, there are 229 ISO 15189: 2012 accredited laboratories.

ISO 15189 System Review Plan

Description	Target date	Limit date	Started	Status
New project approved			2018-08-24	CLOSED
New project registered in TC/SC work program			2018-11-09	CLOSED
Committee draft (CD) registered			2021-01-08	CURRENT
DIS registered	2021-06-25	2021-08-24		AWAITING
Final text received or FDIS registered for formal approval	2022-02-25			AWAITING
International Standard published	2022-06-25	2022-08-24		AWAITING

ISO 15189 Revised Content

- This revision will align the structure with ISO/IEC 17025: 2017 “General requirements for the capacity of laboratories and calibration laboratories”.
- It also introduces a process approach and concept based on risk management, which are the basic principles of ISO 9001: 2015 "Quality Management System-Requirements".
- The annex includes additional requirements for POCT, including POCT governance, quality assurance programs, training programs, reagents and consumables, and management of results.
- Supportive standards for POCT is ISO 22870 Point-of-testing (POCT) – Requirements for quality and competence.

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Foreword

- To develop an organization that is resistant to internal and external changes, a well-managed system must be established.
- To this end, there are many ISO standards related to management, such as ISO 15189 (Medical laboratory - Requirements for quality and competence), ISO 9001 (Quality Management System - Requirements), ISO 14001 (Environmental Management Systems - Requirements with guidance for use), and ISO 27001 (Information Technology - Security Techniques - Information Security Management Systems - Requirements Information Security Management System ISMS), being developed.
- These are collectively named as Management System Standards (MSSs).
- There is a strong demand from the industry for better consistency across these MSSs. As a result, management requirements are becoming common and are being used as global management tools.

Quality Concept

- **Quality Control** is part of “quality management that focuses on meeting the accuracy requirements of inspection data”. Management means controlling and maintaining the status quo.
- **Statistical Quality Control** refers to “control by $\bar{x}$-R chart” using quality control materials.
- **Quality Assurance** is “a part of quality management that focuses on giving confidence that quality requirements are met.” This involves managing the pre-examination, examination, and post-examination processes.
- **Quality Management System (QMS)** is “a system of activities that sets policies and goals to direct and manage quality, and is coordinated to achieve those goals.”

Process of Specimen Examination

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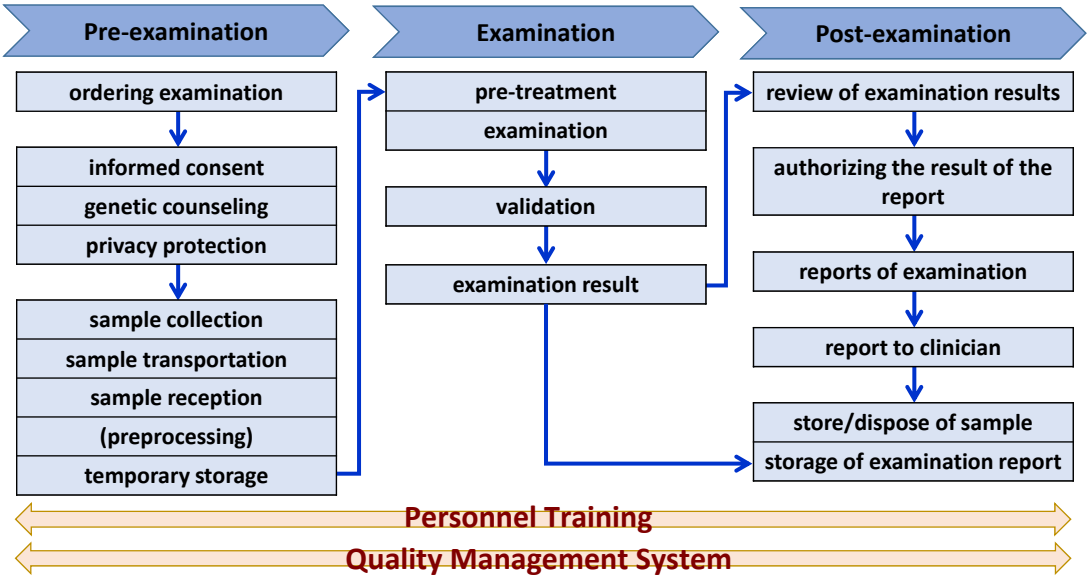

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We Developed A QMS, But Why Can't We Manage It?

Although many institutions have developed a QMS, they have not been able to manage and operate it usefully. By considering the causes of this, you will learn how to approach QMS in the future.

Cause:

1. Obtaining certification was the first goal. At the time of obtaining ISO 15189 certification, everyone participated, but a sense of ownership was lacking.
2. Personnel do not voluntarily practice ISO requirements.
3. Prior to acquiring certification, a management document was created that did not match the actual conditions of the laboratory.
4. Through education and training, relevant personnel were not informed of the latest version of all management documents.

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5. Human resource development has not been sufficiently implemented in line with the education program according to the job level.
6. Internal audits are conducted by inexperienced personnel who do not fully understand the contents of the ISO 15189 standard.
7. From the management review, continuous improvements in specific quality indicators of the policies and goals set by the laboratory have not been formulated into an action plan.
8. Insufficient methods for corrective and preventive actions for incidents/accidents, internal quality control, and nonconformity from external quality control surveys. There is no mechanism to immediately improve the process in which the problem occurred.
9. There is no system in place for managers to monitor the work progress of all the staff.

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Points to Consider:

How to communicate the need to develop a quality management system (QMS) with all clinical laboratory personnel?

Why do clinical laboratories need a QMS?

1. Learn the concept of QMS and process of considering how to manage the quality status of work as a mechanism of effectively carrying out the work.
2. Importantly, grasp the issues in the QMS and quality status (operation/management status) of operations and make improvements.
3. Ultimately, communication with all lab personnel that consistent protocol use enables QMS implementation in the laboratory from the bottom-up is necessary.

To Meet The Needs of Clinicians (Customer Satisfaction)

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1. Clarify request information (requirements) to ensure proper examination and interpretation of results for examination requests from clinicians.
2. Have the competence and resources available to meet this requirement.
3. Determine an appropriate inspection procedure that meets the needs of the customer.
4. Depending on the laboratory, secure an appropriate contract laboratory and consultant.

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Confirm The Concept of QMS

- Setting up a QMS in a clinical laboratory is a way to prevent fluctuations in the process, right from the request for an examination to the reporting of the result, from having a significant impact on quality. Further, if a problem is observed, a QMS can help us take corrective action.
- Maintaining the integrity of pre-examination, examination, and post-examination processes enables high-quality patient care.

To Provide Customers With Accurate and Reliable Examination Results

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The establishment, operational management, evaluation, and improvement of the QMS are essential for ensuring the consistent quality of appropriate inspections.

1. Development tools : ISO 15189, CAP, IQCP, JCQHC
2. Process operation management : pre-examination, examination, and post-examination processes
3. Ensuring the quality of examination results : Verification of inspection process by internal quality control and external quality control (proficiency test, PT) and internal audits
4. QMS improvement : corrective actions, preventive actions, continual improvements

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Results of Developing A QMS For The Laboratory

1. Quality Assurance :

   Quality Assurance of pre-examination, examination, and post-examination processes can be established.

2. Personnel :

   Human resource development can be achieved through frequent educational programs.

3. Management :

   Organization, document management, corrective/preventive action, internal audit, management review, reduction of errors, and establishment of recurrence prevention maintain the integrity of laboratory services.

4. Technical Aspect :

   Accurate inspection and accurate examination result reporting lead to cost reduction through improvements in technology, such as reducing re-examination rates, shortening the turnaround time, reducing the number of complaints, and PT evaluation result.

"Standards have become
the common language of the world"

"Without standards,
there can be no improvement"