**QUALITY**

**MANUAL**

ISO 15189:2022

<<Comment→ If your country has adopted a different standard code (e.g., UNE-EN ISO 15189:20XX), replace all the “ISO 15189:2022” tags in the documents of the Guide M-15189>>

<<INSERT THE NAME OF YOUR LABORATORY>>

<<Comment → if your Laboratory is part of a larger organization (which performs different activities of examinations), you could insert the internal name of your Laboratory, as convenient>>

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**QM Quality Manual ISO 15189**

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**CONTENTS**

<<Comment → after this document is completed; insert the page number of each chapter and subchapter. These instructions apply to all documents of the Guide M-15189>>

|  |  |
| --- | --- |
| **Section** | **Page** |
| **1. OBJECTIVE AND SCOPE.** |  |
|  **1.1 Objective.** |  |
|  **1.2 Scope.** |  |
| **2. DEFINITIONS AND NOTATIONS.** |  |
|  **2.1 Definitions.** |  |
|  **2.2 Notations.** |  |
| **3. REFERENCES.** |  |
| **4. GENERAL REQUIREMENTS.** |  |
| **4.1 Impartiality.** |  |
| **4.2 Confidentiality.** |  |
| 4.2.1 Management of patient information. |  |
| 4.2.2 Release of confidential information. |  |
| 4.2.3 Responsibility of personnel with confidential information. |  |
| **4.3 Considerations for patients.** |  |
| **5. STRUCTURAL AND GOVERNANCE REQUIREMENTS.** |  |
| **5.1 Legality of the Laboratory.** |  |
| **5.2 Laboratory director.** |  |
| 5.2.1 Laboratory director competence. |  |
| 5.2.2 Laboratory director responsibilities. |  |
| 5.2.3 Delegation of duties or responsibilities. |  |
| **5.3 Laboratory activities.** |  |
| 5.3.1 Scope of activities. |  |
| 5.3.2 Conformance. |  |
| 5.3.3 Advisory. |  |
| **5.4 Organizational structure.** |  |
| 5.4.1 General. |  |
| 5.4.2 Quality management. |  |
| **5.5 Objectives and policies.** |  |
| **5.6 Risk management.** |  |
| **6. RESOURCE REQUIREMENTS.** |  |
| **6.1 General.** |  |
| **6.2 Personnel.** |  |
| 6.2.1 General. |  |
| 6.2.2 Competence. |  |
| 6.2.3 Authorizations for personnel. |  |
| 6.2.4 Continuing education. |  |
| 6.2.5 Personnel procedure. |  |
| **6.3 Facilities and environmental conditions.** |  |
| 6.3.1 Suitability. |  |
| 6.3.2 Control of facilities. |  |
| 6.3.3 Storage facilities. |  |
| 6.3.4 Facilities for personnel. |  |
| 6.3.5 Facilities to collect samples. |  |
| **6.4 Equipment.** |  |
| 6.4.1 General. |  |
| 6.4.2 Requirements. |  |
| 6.4.3 Conformance. |  |
| 6.4.4 User manuals. |  |
| 6.4.5 Maintenance and repair. |  |
| 6.4.6 Adverse incidents. |  |
| 6.4.7 Records. |  |
| **6.5 Equipment calibration and metrological traceability.** |  |
| 6.5.1 General. |  |
| 6.5.2 Equipment calibration procedure. |  |
| 6.5.3 Metrological traceability to the International System of Units. |  |
| **6.6 Reagents and consumables.** |  |
| 6.6.1 General. |  |
| 6.6.2 Receipt and storage. |  |
| 6.6.3 Acceptance testing. |  |
| 6.6.4 Inventory. |  |
| 6.6.5 Instructions for use. |  |
| 6.6.6 Adverse incidents. |  |
| 6.6.7 Records. |  |
| **6.7 Service agreements.** |  |
| 6.7.1 Agreements with Laboratory users. |  |
| 6.7.2 Agreements with POCT operators. |  |
| **6.8 External products and services.** |  |
| 6.8.1 General. |  |
| 6.8.2 Referral laboratories and consultants. |  |
| 6.8.3 Define, review and approval. |  |
| **7. PROCESS REQUIREMENTS.** |  |
| **7.1 General.** |  |
| **7.2 Pre-examination process.** |  |
| 7.2.1 General. |  |
| 7.2.2 Information to patients and users. |  |
| 7.2.3 Requests. |  |
|  7.2.3.1 General. |  |
|  7.2.3.2 Oral requests. |  |
| 7.2.4 Collection and handling of primary samples. |  |
|  7.2.4.1 General. |  |
|  7.2.4.2 Pre-collection activities. |  |
|  7.2.4.3 Patient consent. |  |
|  7.2.4.4 Sample collection activities. |  |
| 7.2.5 Transportation of samples. |  |
| 7.2.6 Reception of samples in the Laboratory. |  |
|  7.2.6.1 Process for reception. |  |
|  7.2.6.2 Exceptions in acceptance of samples. |  |
| 7.2.7 Handling, preparation, and storage of samples. |  |
|  7.2.7.1 Protection of samples. |  |
|  7.2.7.2 Additional examination requests. |  |
|  7.2.7.3 Stability of the samples. |  |
| **7.3 Examination process.** |  |
| 7.3.1 General. |  |
| 7.3.2 Verification of examination methods. |  |
| 7.3.3 Validation of examination methods. |  |
| 7.3.4 Evaluation of measurement uncertainty. |  |
| 7.3.5 Biological reference intervals and limits. |  |
| 7.3.6 Examination procedure. |  |
| 7.3.7 Ensuring the validity of examination results. |  |
|  7.3.7.1 General. |  |
|  7.3.7.2 Internal quality control (IQC). |  |
|  7.3.7.3 External quality assessment (EQA). |  |
|  7.3.7.4 Comparability of examination results. |  |
| **7.4 Post-examination process.** |  |
| 7.4.1 Reporting of results. |  |
|  7.4.1.1 General. |  |
|  7.4.1.2 Review and release of results. |  |
|  7.4.1.3 Reports of critical results. |  |
|  7.4.1.4 Special considerations. |  |
|  7.4.1.5 Automated reporting of results. |  |
|  7.4.1.6 Requirements for result reports. |  |
|  7.4.1.7 Additional information for result reports. |  |
|  7.4.1.8 Amendments to reported results. |  |
| 7.4.2 Post-examination handling of samples. |  |
| **7.5 Nonconforming work.** |  |
| **7.6 Information systems management.** |  |
| 7.6.1 General. |  |
| 7.6.2 Authorities and responsibilities. |  |
| 7.6.3 Information systems. |  |
| 7.6.4 Downtime. |  |
| 7.6.5 Off-site. |  |
| **7.7 Complaints.** |  |
| 7.7.1 Process. |  |
| 7.7.2 Reception of complaints. |  |
| 7.7.3 Resolution of complaints. |  |
| **7.8 Plan for emergency situations.** |  |
| **8. MANAGEMENT SYSTEM REQUIREMENTS.** |  |
| 8.1 General requirements. |  |
| 8.1.1 General. |  |
| 8.1.2 Fulfilment of requirements. |  |
| 8.1.3 Awareness. |  |
| 8.2 Documentation of the management system. |  |
| 8.2.1 Policies and objectives. |  |
| 8.2.2 Content of policies and objectives. |  |
| 8.2.3 Management commitment. |  |
| 8.2.4 Linking of the management system. |  |
| 8.2.5 Access documentation. |  |
| 8.3 Document control. |  |
| 8.3.1 Control. |  |
| 8.3.2 Issuing and updating documents. |  |
| 8.4 Control of records. |  |
| 8.4.1 Creation and readability. |  |
| 8.4.2 Amendments. |  |
| 8.4.3 Retention. |  |
| 8.5 Risks and opportunities. |  |
| 8.5.1 Identification. |  |
| 8.5.2 Actions. |  |
| **8.6 Improvement.** |  |
| 8.6.1 Continual improvement. |  |
| 8.6.2 Feedback. |  |
| **8.7 Nonconformities and corrective actions.** |  |
| 8.7.1 Actions. |  |
| 8.7.2 Effectiveness. |  |
| 8.7.3 Records. |  |
| **8.8 Evaluations.** |  |
| 8.8.1 General. |  |
| 8.8.2 Quality indicators. |  |
| 8.8.3 Internal audits. |  |
|  8.8.3.1 Period. |  |
|  8.8.3.2 Audit program. |  |
| **8.9 Management reviews.** |  |
| 8.9.1 General. |  |
| 8.9.2 Entries of the review. |  |
| 8.9.3 Outputs of the review. |  |
| **9. ANNEX.** |  |
| **9.1 Procedures of the quality management system (see folder PROC)** | --- |
| **9.2 Forms for records of the quality management system (see folder FOR)** | --- |
| **9.3 External documents of the quality management system (see folder EXT)** | --- |
| **9.4 File for Laboratory personnel (see folder PER)** | --- |
| **9.5 File for Laboratory measuring standards and equipment (see folder STD)** | --- |
| **9.6 Documents for legally of the Laboratory (see folder LEG)** | --- |
| **9.7 Records of the quality management system (see folder REC)** | --- |

<<Comment→ table above includes the complete numbering of the ISO 15189 In order to locate easily every requisite in this document (e.g., in the case of an audit).

Section 9 includes a link to the procedures, forms, external documents (e.g., normative standards, accreditation body documents and notifications, etc.), documents for personnel of the Laboratory (e.g. competence evidence), documents for measuring standards and equipment of the Laboratory (e.g. calibration certificates, user manuals, maintenance and failure records, etc.) and records from daily activities of the Laboratory (these are usually handled in additional folders). In the column “Page” insert the page where every item is located in the document (once you fill completely this document). You can add or delete these types of Folders as required>>.

**1. OBJECTIVE AND SCOPE.**

**1.1 Objective.**

The overall objective of this quality manual is to describe the documental structure that follows the Laboratory <<Insert the name of your Laboratory>> to comply with the technical and managerial requirements of the standard ISO 15189:2022 [1] in order to demonstrate that it consistently operates a quality system, it is technically competent, it is impartial, and it is able to generate technically valid results.

**1.2 Scope.**

a) This document applies for all Laboratory personnel, technical and managerial (administrative).

b) This document applies to the services: <<list the general services covered by this quality manual, for example: Microbiology, Hematology, Bacteriology, etc. Or refer to another document>>.

c) This document applies to <<Insert locations where this document applies, for example: Laboratory and/or customer locations and/or other facilities (e.g., sampling), etc.>>.

**2. DEFINITIONS AND NOTATIONS.**

**2.1 Definitions.**

<<Comment→ select, delete, or add as required. The number in brackets “[ ]” indicates the bibliographic reference where this definition was obtained (see section 3)>>

**Audit [2].**

Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

**Bias measurement, bias [1].**

Estimate of a systematic measurement error.

**Biological reference interval reference, reference interval [1].**

Specified interval of the distribution of values taken from a biological reference population.

**Calibration [3].**

Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.

**[…]**

**2.2 Notations.**

For purposes herein, the following considerations are made:

<<Comment→ select, delete, modify or add as required>>

**"Laboratory":** refers to the Laboratory <<Insert the name of your Laboratory>>.

**[…]**

**3. REFERENCES.**

<<Comment→ Select, delete or add as required. These references are recommended, if some are not consulted or purchased, they should be deleted>>

[1] ISO 15189:2022 Medical laboratories - Requirements for quality and competence.

[2] ISO 9000:2015Quality management systems - Fundamentals and vocabulary.

[3] JCGM 200 (VIM): 2012 International vocabulary of metrology - Basic and general concepts and associated terms.

[4] ISO/IEC 17000:2020 Conformity assessment - Vocabulary and general principles.

**[…]**

**4. GENERAL REQUIREMENTS.**

**4.1 Impartiality.**

The Laboratory continuously identifies threats to impartiality of its activities, relationships or relationships among its personnel, using the form <<Insert identification and name of the form, e.g., FOR-02 "Form for threats to impartiality">>. This activity is performed or revised at least once every <<Insert period, for example: 12 months, or sooner if necessary>>, and it is led by <<Insert the name of the position, for example: Quality Manager>> and the technique used for the identification of threats is <<Insert technique to use, for example: Brainstorming>>.

**[…]**

## 5. STRUCTURAL AND GOVERNANCE REQUIREMENTS.

## 5.1 Legality of the Laboratory.

<<Insert the name of your Laboratory or organization to which the Laboratory belongs (if it will acquire the legal responsibility of the Laboratory)>> is a company legally incorporated under national laws, as recorded in the files <<Insert identification registration, incorporation, or similar document>>.

<<Comment → If your Laboratory legally dependents of a larger organization, do this clarification>>

Legal information identifying the Laboratory is:

* Company name: <<Insert the official name of your Laboratory or organization to which your Laboratory belongs>>.
* Legal registration: <<Insert legal registration of your Laboratory or organization to which your Laboratory belongs>>.
* Official address: <<Insert the official address of your Laboratory or organization to which your Laboratory belongs>>.
* Main activities: <<Insert the main activities of your Laboratory and/or organization to which your Laboratory belongs>>.
* Laboratory operation address: <<Insert operation address (if it is different from the official, e.g., temporary address)>>.
* Phone: <<Insert your phone number for Laboratory operations>>.
* Web page: <<Insert the web page of your company>>.
* E-mail: <<Insert your electronic mail for contact>>.

<<Insert the name of your Laboratory>> hereinafter referred as **"Laboratory"** is legally represented by <<Insert the name of the legal representative of your Laboratory>> with professional registration <<Insert number or registration of your legal representative or complementary data, as available>>.

<<Insert an image of the legal registration of your Laboratory (if applicable)>>

The following documents show the legal responsibility of the Laboratory:

<<Comment → Select and adapt those who apply (if possible, all of them)>>

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Description** | **Document** | **Location** |
| 1 | Legal operation | Documents of incorporation | Folder “LEG” |
| 2 | Accounting | Tax payment receipts | Accounting Department |
| 3 | Equipment | Purchase invoices | Folder “STD” |
| 4 | Software  | Purchase invoices | Folder “STD” |
| 5 | Operation authorization | Government authorization | Legal Department |
| 6 | Personnel payments  | Personnel contracts | HR Department |
| 7 | Social Security | Payment receipts | Accounting Department |
| 8 | Normative standards | Purchase invoices | Folder “LEG” |
| 9 | ... | ... | ... |

**[…]**

**6. RESOURCE REQUIREMENTS.**

**6.2 Personnel.**

The Laboratory has enough competent personnel to perform its activities, as indicated in the in the procedure <<Insert identification and name of the procedure, e.g., PROC-04 "Procedure for personnel management and competence">>.

**[…]**

**7. PROCESS REQUIREMENTS.**

**7.1 General.**

The Laboratory has the procedure <<Insert identification and name of the procedure, e.g., PROC-03 "Procedure for risks and opportunities">> to identify, assess and mitigate potential risks to patient care in the pre-examination, examination, and post-examination processes; and to identify opportunities to improve patient care.

**[…]**

**7.2 Pre-examination process.**

The Laboratory has the procedure <<Insert identification and name of the procedure, e.g., PROC-08 "Procedure for pre-examination and samples management">> to describe its activities of pre-examination process.

**[…]**

**7.3.3 Validation of examination methods.**

The Laboratory uses the procedure <<Insert identification and name of the procedure, e.g., PROC-11 "Procedure for validation of examination methods">> to validate its non-standard methods used to perform the examinations, such as: developed methods, methods used outside their intended scope, modified methods, etc.

**[…]**

**8. MANAGEMENT SYSTEM REQUIREMENTS.**

**8.2.1 Policies and objectives.**

The Laboratory has policies and objectives, according to that indicated in the form <<Insert identification and name of the form, e.g., FOR-08 "Form for policies and objectives">>. These are communicated to the personnel through <<Insert instructions to disseminate, for example: meeting, e-mail, memo, etc.>> and its compression is assessed through the survey <<Insert identification and name of the form, e.g., FOR-42 "Form for evaluation of dissemination of the management system">>.

**[…]**

**8.8.2 Quality indicators.**

The Laboratory has the procedure <<Insert identification and name of the procedure, e.g., PROC-19 "Procedure for monitoring quality indicators">> for planning, monitoring and reviewing quality indicators.

**[…]**

**Sample Document**

Purchase the ISO 15189 full Quality Manual Template, Procedures, Forms and Spreadsheets at [www.metrycal.com](http://www.metrycal.com)

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| **Guide for implementing a quality system** **ISO 15189:2022** **for medical laboratories** |
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