**Procedure for monitoring the validity of results**

**(IQC, EQA and Comparability)**

<<INSERT THE NAME OF YOUR LABORATORY>>

**CONTROLLED DOCUMENT**

**Autor de documento original: LOGC750219**

**PROC-13 Procedure for monitoring the validity of results**

**(IQC, EQA and Comparability).**

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**Document Changes**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Status** | **Date of issue** | **Revision** | **Description of the performed changes** | **Prepared by** | **Revised by** | **Approved by** |
| Active | YYYY-MM-DD | 0 | None (original version). | AA | BB | CC |
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**1. OBJECTIVE AND SCOPE.**

**1.1 Objective.**

To describe the actions to perform the supervision or monitoring of the validity of examination results, in accordance with the requirements established by the standard ISO 15189:2022 [1].

**1.2 Scope.**

This is document applies to all the Laboratory´s technical personnel.

**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. MONITORING.**

**4.1 Techniques for monitoring.**

The Laboratory monitors the validity of the results of examinations in a planned manner according to the form <<Insert identification and name of the form, e.g., FOR-34 "Form for planning the monitoring of the validity of results">>. The plan is led by the <<Insert responsible function, e.g.: Laboratory Manager>> and review at least every <<Insert period, e.g.: year>>.

The validity of the results of examinations is monitored by two techniques:

1. Internal Quality Control (IQC).
2. External Quality Assessment (EAQ).

These techniques are described in the next sections.

The results of the monitoring are recorded in the form <<Insert identification and name of the form, e.g., FOR-35 "Form for monitoring the validity of results">>.

**[…]**

**4.2 Statistical technique for detecting trends and shifts.**

The following technique is applied to detect trends and shifts and to statistically review the outcomes from monitoring the validity of results for IQC and EAQ:

<<Insert identification and name of the form, e.g., SOFT-06 "Form for statistical detection of trends and shifts from monitoring">>.

In the case that the quality control data analyzed does not meet the predefined criteria, the problem is corrected immediately in a planned manner.

The Laboratory ensures the application of these actions, through <<Insert responsible function, e.g.: the Laboratory Manager>>.

**5. INTERNAL QUALITY CONTROL (IQC).**

a) The Laboratory selects the following appropriate IQC material(s) for control the quality of the examinations:

<<Insert selected IQC materials: … or refer to an inventory list>>.

b) The selection of the IQC material is based on:

**[…]**

**6. EXTERNAL QUALITY ASSESSMENT (EQA).**

a) The Laboratory participates in appropriate EQA programs, by comparison with other laboratories, including POCT methods, as described in the form <<Insert identification and name of the form, e.g., FOR-36 "Form for proficiency test plan">>.

**[…]**

**7. COMPARABILITY OF EXAMINATION RESULTS.**

a) If the Laboratory uses different methods and/or equipment and/or sites for an examination, then a comparability of results for patient samples throughout the clinically significant intervals is performed and record in the form <<Insert identification and name of the form, e.g., FOR-35 "Form for monitoring the validity of results">>.

**[…]**

**8. RESPONSIBILITIES.**

<<Insert responsibilities of key positions, e.g.,>>

<<Comment→ Select, modify, delete or add as required:>>

**8.1 Quality Manager.**

To ensure the application of this document.

**8.2 Laboratory Manager.**

To follow this document.

**8.3 Technician.**

To follow this document as required.

<<Insert other responsibilities>>

**9. RELATED FORMS.**

<<Insert identification and name of the form, e.g., FOR-34 "Form for planning the monitoring of the validity of results">>

<<Insert identification and name of the form, e.g., FOR-35 "Form for monitoring the validity of results">>

<<Insert identification and name of the form, e.g., FOR-36 "Form for proficiency test plan">>

<<Insert identification and name of the form, e.g., SOFT-06 "Form for statistical detection of trends and shifts from monitoring">>

**10. ANNEX.**

<<Insert annexes as required>>

**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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