

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA v.2.0

8. ANALYTICAL PHASE

8.2. CALIBRATION AND TRACEABILITY OF METHODS

AUTHOR	VERSION	APPROVED BY	DATE	

CIRCULATION LIST:	NAME	POSITION

CODE) DOCUMENT: QMM08	(CHAPTER TITLE): ANALYTICAL	(INSTITUTION): EC4 UNIVERSITY HOSPITAL
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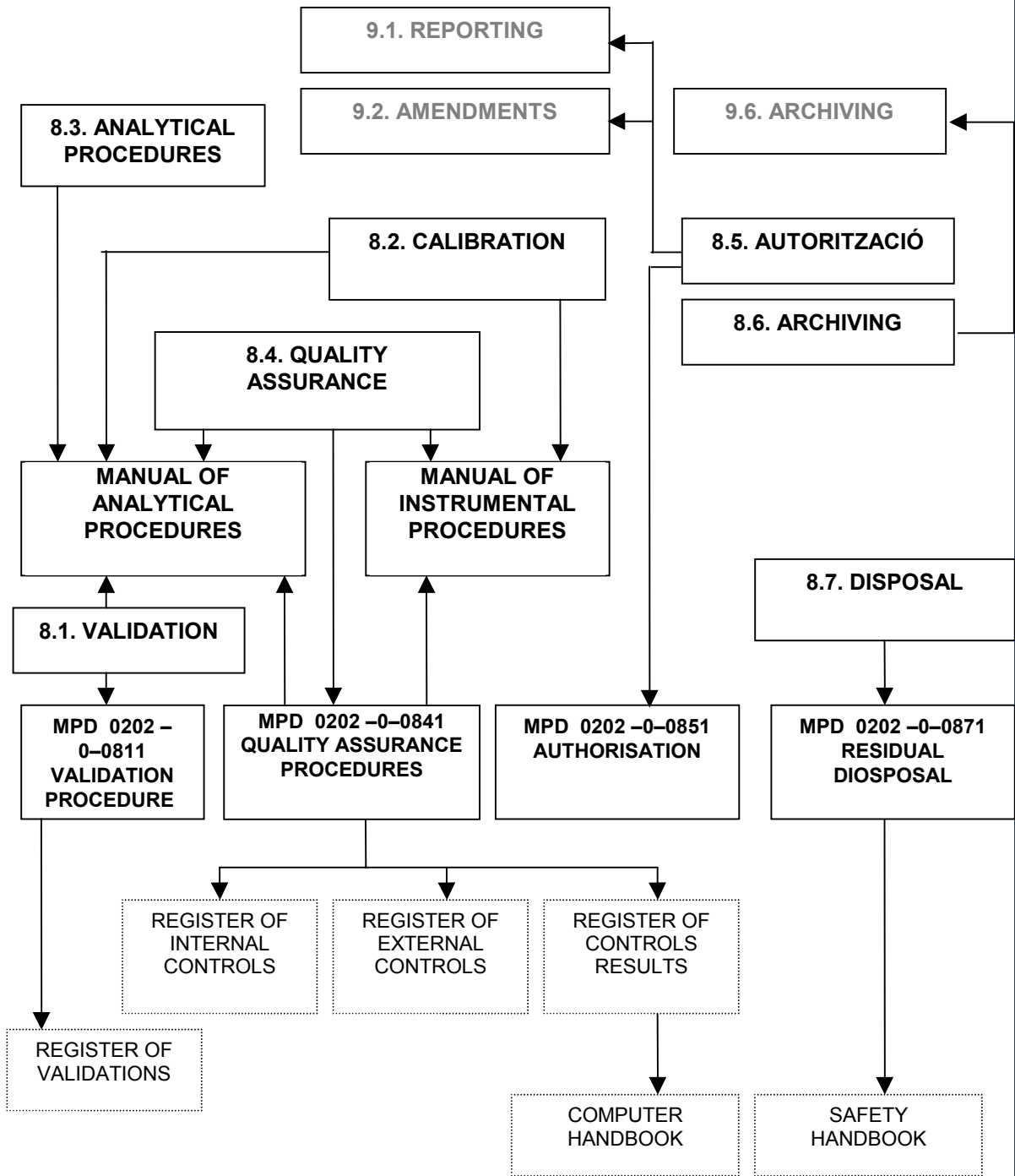
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1. INTRODUCTION

Calibration frequency and calibration method should be stated e. g. in the working procedure.

Calibration materials and their traceability should be stated.

Origin of absorption coefficients, factors and their traceability should be documented.



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1.1. SCOPE

1.2. AIMS

To fulfil the requirements of the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
4.2. Quality management system. 4.2.5.		5.4. Test and calibration methods including sampling 5.4.7. Estimation of uncertainty of measurement. 5.4.7.1.
5.3. Laboratory equipment. 5.3.4.		5.6. Measurement traceability. 5.6.2.1. Calibration.
5.5. Examination procedures. 5.5.3.		5.6. Measurement traceability.. Testing
5.6. Assuring the quality of examination procedures. 5.6.3.		

1.3. PUBLICATION CREDITS

EC4 WG

1.4. REFERENCES

- Jansen RTP, Blaton V, Burnett D, Huismann W, Queraltó JM, Zérah S, Allman B. European Communities Confederation of Clinical Chemistry: Essential criteria for quality systems of medical laboratories. Eur J Clin Chem Clin Biochem 1997; 35(2): 123-132.
- ISO/DIS 15189 – Quality management in the medical laboratory (August 2000). 4.2.5., 5.3.4., 5.3.5., 5.6.3.
- ISO, IEC. General requirements for the competence of calibration and testing and calibration laboratories. DIS 17025. Geneva: ISO, 1998; 5.4.7.1., 5.6.2.1., 5.6.2.2.
- Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2nd rev. Ed. Utrecht: NVKC 1996.

1.5. RELATED DOCUMENTS

QM 08-01. Analytical phase. Validation.

QM 08-03. Analytical phase. Working procedures.

QM 08-04 Analytical phase. Procedures for quality assurance.

QM 09-06. Post analytical phase. Archiving.

MPI 000-3-82015. Procedures for performance checks of pipettes and other volumetric equipment

MPI 000-3-82017. Thermometer recording and calibration procedures

1.6. ABBREVIATIONS

1.7. RELATED DEFINITIONS

biological reference value: value of a measurand in an individual belonging to a defined reference sample group of individuals. NOTE 1: Reference values may have to be classified according to factors of influence such as the diurnal variation, sex, race, or age of the population studied. When applicable, a distribution of values is expressed in term of reference limits (upper and lower). The source of material upon which they are based and the procedure for their determination should be documented. NOTE 2: a biological reference interval usually refers to the central 95-percentile of the distribution of reference values.

central 0,95 - interfractile interval: closed interval of values between the 0,025- and 0,975-fractiles of a set of values. NOTE: If the limits are derived from a sample of values, the employed type of non-parametric or parametric statistics should be indicated.

calibration: the set of operations which establish, under specified conditions, the relationship between values indicated by the analytical instrument and the corresponding known values of an analyte. See **calibration material**.

calibration material: a material of known composition or properties which can be presented to the analytical instrument for calibration purposes.

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calibration sample: the test portion or test solution used for calibration of an analytical procedure. The calibration sample is normally of known weight or volume and is prepared according to specifications.

traceability A property possessed by a test result or measured value of a standard which can be related to a fixed reference by an uninterrupted series of equations whose uncertainty is known.

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2. CALIBRATION

The calibration system is designed and operated in order to (when conceptually applicable) all the measurements performed are traceable to the appropriate standard. The Quality Officer is responsible to guarantee that the calibration programme is performed in the time due and as it is described in the corresponding Operation procedure (see *QM 08-03. Analytical phase. Working procedures*).

Relevant calibration data regarding the various items of laboratory equipment in use is obtained from the manufacturers and kept to hand in the appropriate files. All measuring equipment is labelled or otherwise identified to indicate their calibration status.

2.1. PREVIOUS CALIBRATION

An analytical equipment arrives to the Clinical Chemistry Department calibrated by the manufacturer, when it is possible. Data about these calibrations are recorded in the appropriate registers.

2.2. PERIODICAL CALIBRATION

Equipment is then calibrated in-house by the Laboratory Technicians in accordance with the standard operating procedure, based on the validation report and it is labelled accordingly by the Laboratory Technician performing the calibration. Examples of these procedures are *MPI 000-3-82015. Procedures for performance checks of pipettes and other volumetric equipment*, and *MPI 000-3-82017. Thermometer recording and calibration procedures*.

The calibration data has to meet the specifications contained in test or equipment procedures. Equipment calibrated by external organisations where possible are labelled by the person performing the calibration or by laboratory staff.

Calibration frequencies are indicated in the standard operating procedures.

The period for which calibration data has to be retained is stated in the standard operating procedures for each analyte or instrument.

The calibration system is designed and operated in such a way that (where the concept is applicable), all measurements performed shall be traceable to the appropriate national standard.

Reference standards of measurement, (i.e.: reference thermometers), are stored separately and used only for calibration purposes.

The Quality Manager is responsible for ensuring that the calibration programme is implemented at all times.

The retention time of periodical calibrations is established in the document *QM 09-06. Post analytical phase. Archiving*.

2.3. CALIBRATIONS PERFORMED BY OTHER COMPANY

Wherever possible, the services of an accredited external laboratory are used for calibrations that can not be performed by the Clinical Chemistry Department. In these cases, the analytical equipment is identified and registered the name of the person who has made the calibration. See *QM 08-03. Analytical phase. Working procedures*.

3. TRACEABILITY

The laboratory endeavours to adhere to international standards regarding the traceability of results.

To this end, use is made of certificate reference material and standard reference material as supplied by the National Standards Office and commercial suppliers.

The origin of or traceability to a reference material is stated in standard operating procedures. See *QM 08-03. Analytical phase. Working procedures*.

The laboratory in any case participates in external surveys as a check on the accuracy of its results. See *QM 08-04 Analytical phase. Procedures for quality assurance*.

Further checks are provided by monitoring daily averages and testing reference values by the Batthatarya method.

4. RESPONSIBILITIES ON “CALIBRATION AND TRACEABILITY”

The Director of the Clinical Chemistry Department is the final responsible for the policy and procedures of calibration of analytical equipments from the Clinical Chemistry Department. The Quality Officer is responsible that the calibration programme is performed as it is established in the working procedures.

Writing, reviewing and maintaining the procedures are responsibility of the Quality Officer.

5. DOCUMENT MANAGEMENT

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Updated documents concerning the calibration and traceability are available in the G volume of the LIS.

One copy of these procedures is kept in the Quality System Files. Staff members of the Clinical Chemistry Department receive an update copy as soon as it is available.

6. REVIEW OF DOCUMENTS

Documents concerning the calibration and traceability are revised at least once a year.

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