

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA v.2.0

## 8. ANALYTICAL PHASE

### 8.4. QUALITY CONTROL AND ASSESSEMENT

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CIRCULATION LIST:	NAME	POSITION

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<b>(DATE): 21/10/01</b>	<b>(SECTION TITLE): QUALITY</b>	
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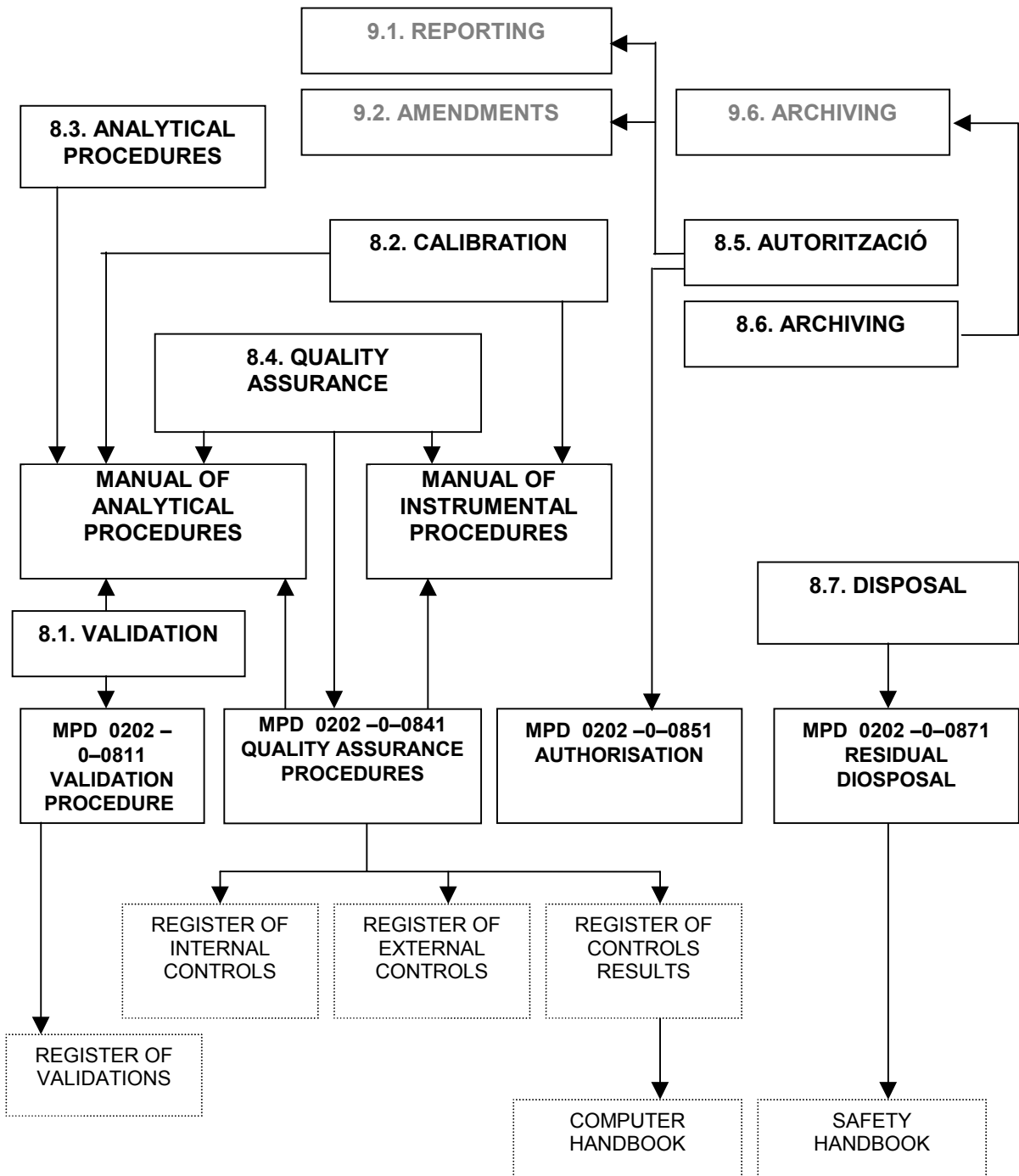
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## 1. INTRODUCTION

There should be a system of internal quality control.

Criteria against which analytical processes (measurement and also observation) are judged should be stated, for



example, in the working procedures.

Such criteria should preferably be based on biological variance.

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Internal quality control results should be checked and kept at the bench where the relevant working procedures are performed.

The laboratory should take part in valid external quality assessment schemes (EQAS), preferably those organized by the profession, and covering the repertoire.

Internal quality control results, also from near patient or point of care testing equipment, and EQAS results should be regularly evaluated in technical staff meetings, and actions taken should be documented.

### 1.1. SCOPE

### 1.2. AIMS

To fulfil the requirements of the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
5.6. Assuring the quality of examination procedures. 5.6.1. to 5.6.7	7.1. Planning of realisation process 7.5. Production and services operations. 7.5.1. Control of operations; 8.1. 8.2. Measurement and monitoring. 8.2.2. Internal audit; 8.2.4. Product measurement and monitoring	5.6. Measurement traceability. 5.6.2.2. Testing 5.9. Assuring the quality of test and calibration results

### 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/TC 212/WG 1. Quality management in the medical laboratory (August 2000). 5.6.1. – 5.6.7.
- ISO/DIS Quality management systems – Requirements. ISO 9000. Geneva: ISO, 2000. 7.1., 7.5.1., 8.2.2., 8.2.4.
- ISO, IEC. General requirements for the competence of calibration and testing and calibration laboratories. DIS 17025. Geneva: ISO, 1998. 5.6.2.2., 5.9.
- Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2<sup>nd</sup> rev. Ed. Utrecht: NVKC 1996.

### 1.5. RELATED DOCUMENTS

QM 09-06. Post analytical phase. Archiving

MPD 0202 –0–0841 Quality assurance

Register of quality assurance programmes

Handbook of Laboratory Information System

### 1.6. ABBREVIATIONS

**EQAS:** External Quality Assessment Schemes

### 1.7. RELATED DEFINITIONS

**accuracy of measurement:** closeness of the agreement between the result of a measurement and a true value of the measurand. NOTE 1: The term accuracy is also applied to sets of results of measurements and to measurement procedures. NOTE 2: The concept accuracy of measurement is described by trueness of measurement and precision of measurement. Thus, accuracy is not a synonym for trueness or for precision. NOTE 3: The concept, accuracy, relates to a combination of systematic effects and random effects that contribute individual components of error of measurement. NOTE 4: Accuracy cannot be given a numerical value, but can be expressed on an ordinal scale such as (poor, fair, good). NOTE 5: substitutes the concept "true value" by "accepted reference value".

**analytical specificity:** A term which expresses qualitatively the extent to which other substances interfere with the

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determination of a substance according to a given procedure. Specific is considered to be the ultimate of selective, meaning that no interferences are supposed to occur.

**analytical sensitivity:** The slope of the calibration curve. If the curve is in fact a 'curve', rather than a straight line, then course sensitivity will be a function of analyte concentration or amount. If sensitivity is to be a unique performance characteristic.

**bias of measurements (bias; inaccuracy (deprecated))** difference between the expectation of the results of measurement and a true value of the measurand,. NOTE 1: Bias of measurements is equal to the systematic error of measurement that may be composed of one or more systematic error components. Its value is unknown. NOTE 2: An estimator is the "sample bias of measurements" that is the difference between the average and a conventional true value (or accepted reference value. NOTE 3: ISO defines bias as the difference between the expectation of the results and an accepted reference value (the latter including true value, assigned value, certified value, consensus value, and (when such are not available) the expectation itself).

**control chart** chart, with upper and or lower control limits, on which values of some statistical measure for a series of samples or subgroups are plotted, usually in time or sample number order. NOTE 1: The chart frequently shows a central line to assist detection of a trend of plotted values toward either control limit. NOTE 2: In some control charts, the control limits are based on the within-sample or within-subgroup data plotted on the chart; in others, the control limits are based on adopted measurement standard values or specified values applicable to the statistical measures plotted on the chart.

**imprecision of measurements:** dispersion of independent results of measurements obtained under specified conditions. NOTE 1: Imprecision of measurements, when applied to sets of results of measurements, depends solely on the dispersion of random error of measurement and does not relate to a true value of the measurable quantity. NOTE 2: Imprecision is usually expressed numerically as the repeatability standard deviation, an intermediate precision standard deviation, or a reproducibility standard deviation of the results of measurements. NOTE 3: Imprecision can be expressed on an ordinal scale such as (small, medium, large); NOTE 4: Imprecision is the inverse of precision of measurements.

**inaccuracy of measurement:** discrepancy between the result of a measurement and a true value of a measurand. NOTE 1: Inaccuracy of measurement, when applied to sets of results, describes a combination of systematic effects and random effects that contribute individual components of error of measurement. NOTE 2: Inaccuracy is related to uncertainty of measurement. NOTE 3: Inaccuracy can be measured on an ordinal scale such as (small, medium, large). NOTE 4: Inaccuracy is the inverse of accuracy of measurement; the latter concept is preferred.

**internal quality control:** operational techniques and activities within a laboratory that are used to fulfil requirements for quality. NOTE 1: In the clinical laboratory, internal quality control is aimed both at monitoring a process to assess whether results of measurement are reliable enough to be released and at eliminating causes of unsatisfactory performance at relevant stages of the quality loop. NOTE 2: Internal quality control in the broad sense applies to all steps of activity for production of results of measurement, from assessing clinical needs, via collection of sample, and measurement of a measurable quantity to reporting of result.

**laboratory proficiency testing (external quality assessment):** determination of laboratory measurement performance by means of inter-laboratory measurement comparisons. NOTE 1: Here, this concept is distinguished from two other types of inter-laboratory study: method-performance study and material-certification study. NOTE 2: The term "external quality assessment" (EQA) is sometimes preferred if proficiency testing is thought to convey an unintended impression of an official regulatory function.

**measurand:** particular quantity subject to measurement. EXAMPLE Vapour pressure of a given sample of water at 20 °C. NOTE The specification of a measurand may require statements about other quantities such as time, temperature and pressure.

**quality assurance:** all the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality. NOTE: There may be both internal and external purposes for quality assurance: (a) internal quality control: within an organization, provides confidence to the laboratory management; (b) external quality assessment: in contractual or other situations provides confidence to the customers or others.

**repeatability** precision under circumstances which are as consistent as possible (same laboratory, laboratory technician, run, etc.). The standard deviation can be calculated from independent analysis results obtained using identical material or from independent duplicate analyses using different materials.

**repeatability conditions** conditions where independent results of measurement are obtained with the same measurement procedure on the same measurand by the same measuring system, used under the same conditions, at the same location over a short period of time.

**repeatability of results of measurements** closeness of the agreement between the results of successive measurements of the same measurand carried out under repeatability conditions. NOTE: Repeatability of results of measurements can be measured on an ordinal scale such as (low, medium, high). It is inversely expressed in terms of the dispersion of the results of measurements, usually as the repeatability standard deviation.

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**reproducibility:** precision under variable circumstances. A statement of reproducibility must indicate the nature of the circumstances in question. EXAMPLE: different laboratories, days/weeks or laboratory technicians etc.

**reproducibility of results of measurements** closeness of the agreement between the results of measurements of the same measurand carried out under the changed conditions of measurement that must be specified. NOTE 1: A valid statement of reproducibility of results of measurements requires specification of the conditions changed. The changed conditions may include: principle of measurement, method of measurement, observer, measuring system, calibration material, location, conditions of use of measuring system, time. NOTE 2: In ISO the concept "reproducibility conditions" is defined with the principle and method of measurement kept constant. NOTE 3: Reproducibility of results of measurements can be measured on an ordinal scale such as (low, medium, high). It is inversely expressed in terms of the dispersion of the results of measurements, for example as the reproducibility standard deviation. NOTE 4: Results of measurements are here usually understood to be corrected results of measurements.

**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. INTERNAL QUALITY CONTROL

There is a system of internal quality control covering all the Clinical Chemistry Department assays.

Criteria against which analytical processes (measurement and also observation) are judged are stated in the standard operating procedures. Such criteria are based, when it is possible, on biological variance or in the state of the art.

Internal quality control results are checked and kept at the bench where the relevant working procedures are performed.

The *MPD 0202 –0–0841 Quality assurance* gives details about the method to perform internal and external quality assessment.

Quality Assurance results are recorded in the appropriate Registers and retained according the document *QM 09-06. Post analytical phase. Archiving.*

The Quality Manager has the responsibility to day to day working quality assessment.

## 3. EXTERNAL QUALITY CONTROL

The Clinical Chemistry Department takes part in valid external quality assessment schemes (EQAS), preferably those organized by the profession, and covering all the repertoire.

There is a register (*Register of quality assurance programmes*) which include the name of manufacturer, number of materials involved and scheme of control.

When there is no external programs, the Clinical Chemistry Department develop mechanism for assessing the bias of analytical methods, as inter laboratory comparisons, etc.

## 4. POINT OF CARE QUALITY ASSESSMENT

The Clinical Chemistry Department has the responsibility for quality control of all point of care assays in the Hospital.

## 5. QUALITY CONTROL DATA ASSESSMENT

Internal quality control results, also from near patient or point of care testing equipment, and EQAS results are regularly evaluated in technical staff meetings, and actions taken should be documented. See the *MPD 0202 –0–0841 Quality assurance* for details.

## 6. RESPONSIBILITIES ON “ANALYTICAL QUALITY CONTROL ASSESSEMENT”

The Director of the Clinical Chemistry Department is the final responsible for the policy and procedure for quality assessment of all the analytical procedures used in the Department, guaranteeing that analytical procedures performs appropriately to the purpose which they are used. The technical performance of quality assessment programs are responsibility of technical staff. The supervision of the results is responsibility of the Head of the laboratory area. The Quality Officer is responsible of the assessment of all the quality assurance program.

The performances of the analytical tests are established by the Director of the Department and the Head of each laboratory area.

Writing, reviewing and maintaining the documents and procedures concerning quality assurance is responsibility of the Quality Officer.

## 7. DOCUMENT MANAGEMENT

Updated documents concerning the method validation 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.

Data concerning quality assessment is available in the workplace where it was produced. Members of the Quality Committee has access to these data.

## 8. REVIEW OF DOCUMENTS

Documents concerning the method validation are revised at least once a year.

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