

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA v.2.0

8. ANALYTICAL PHASE

8.7. DISPOSAL OF SPECIMENS AND WASTE MATERIAL

AUTHOR	VERSION	APPROVED BY	DATE	

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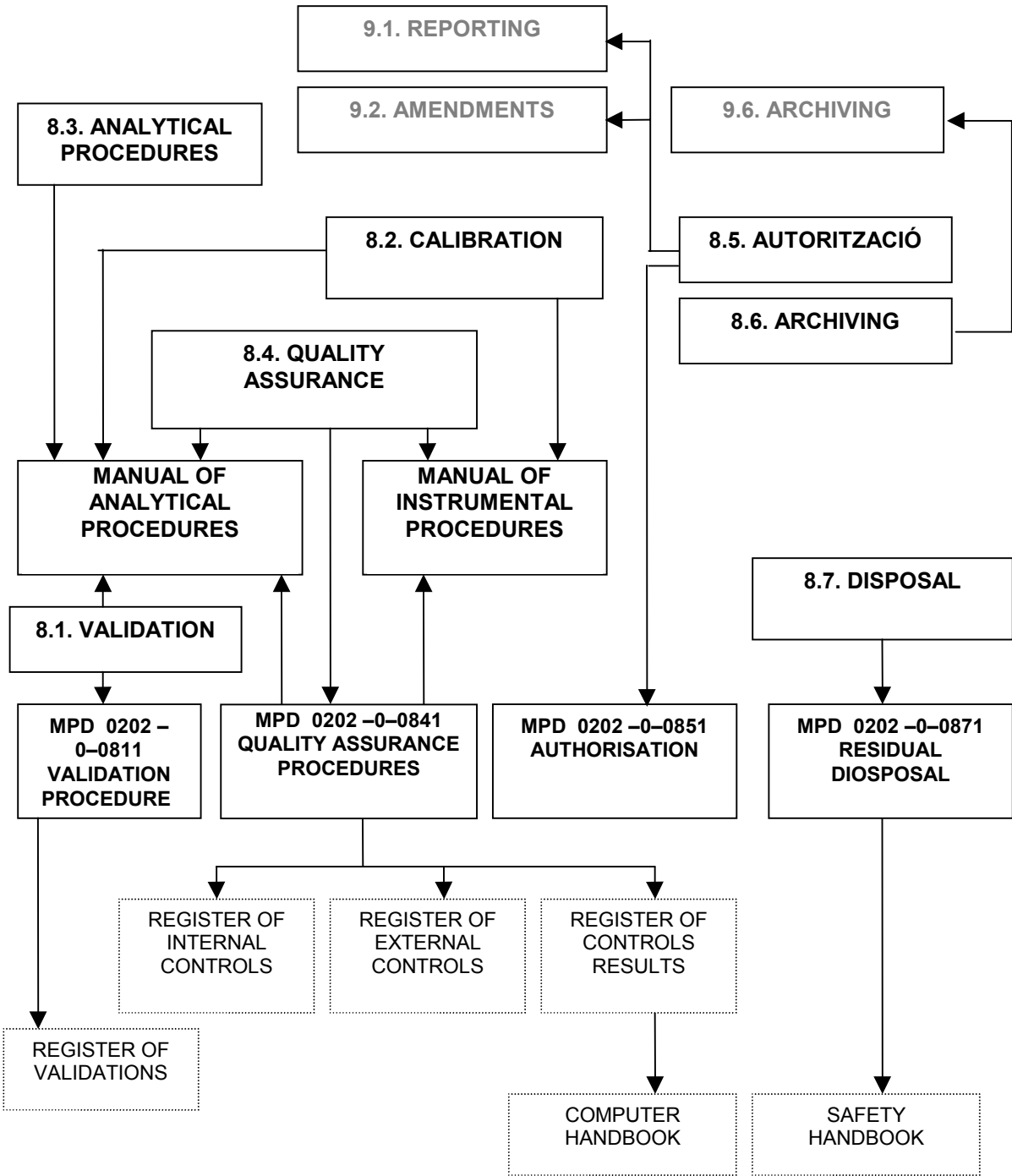
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1. INTRODUCTION

Patient material should be considered and treated as potentially infectious.

Specimens, needles and blood-contaminated disposable should be disposed of in special containers and be treated as infectious waste.



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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
5.7. Post-examination procedure. 5.7.3.		

1.3. PUBLICATION CREDITS

EC4 WG

1.4. REFERENCES

- Jansen RTP, Blaton V, Burnett D, Huisman 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 (Ugust 2000). 5.7.3
- ISO/TC 212/WG 1., Quality management in the clinical laboratory. Revised ISO/CD 15189, Quality management in the medical laboratory (December 1998). 5.4.2.(c)., 5.7.3.
- Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2nd rev. Ed. Utrecht: NVKC 1996.

1.5. RELATED DOCUMENTS

QM 09-06. Post analytical phase. Archiving.

MPD 0202 –0–0871. Waste disposal

Safety Handbook

1.6. ABBREVIATIONS

1.7. RELATED DEFINITIONS

sample: one or more parts taken from a system and intended to provide information on the system, often to serve as a basis for a decision on the system or its production. EXAMPLES: A volume of serum taken from a larger volume of serum; a simple random subset of measured values of a measurable quantity taken from a set of such values. NOTE 1: The single part forming a cohesive entity and taken from one place and at one time is also called a "sampling unit" or an "item". NOTE 2: Unless otherwise specified, the sample is assumed to be representative of a "static system", that is a system having no appreciable change in relevant measurable quantities during the time of consideration. NOTE 3: When a "dynamic system" is concerned, as is often the case in the clinical laboratory sciences, the calendar time of sampling is a mandatory item of specification to the system of interest. Such a special type of sample has been called a "**specimen**", but this term is not used here. The term specimen has also been used in laboratory medicine as a synonym for a sample, as defined here, of biological origin, or for an entire macroscopic parasite. NOTE 4: The system from which a sample is taken may not be of the same type as that of the measurand. EXAMPLE: A given blood sample may serve for measurement of pH in plasma and haemoglobin concentration) in erythrocytes. NOTE 5: The definition given above covers a sample from any type of system. ISO gives two definitions that apply more to data and materials respectively. (a) sample: One or more sampling units taken from a population and intended to provide information on the population; (b) sample: Representative quantity of material extracted from a batch of reference material). NOTE 6: In some countries the term specimen is used for primary sample (or a subsample of it) which is the sample prepared for sending to or as received by the laboratory and intended for measurement.

specimen: in some countries the term specimen is used for primary sample.

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2. SPECIMENS

Specimens from patients are considered and treated as potentially infectious.

After the retaining period established in the document *QM 09-06. Post analytical phase. Archiving.*, there are removed according the procedure *MPD 0202 –0–0871. Waste disposal*, where it is described how the different specimens are disposed taking into account the personnel and environment safety. Other items developed in this procedure are:

- (a) disposal classification;
- (b) local and national regulations applicable;
- (c) containers (number, localization, marks, etc.);
- (d) specific treatments according analyzers or instruments;
- (e) steps in waste disposal;
- (f) other considerations.

Waste Co. is contracted for specimen waste disposing.

3. GLASSWARE

Special precautions are taken when glass material is used, cleaned or stored. Details are given in the *Safety Handbook* and in the procedure *MPD 0202 –0–0871. Waste disposal*.

4. WASTE MATERIAL

Needles and blood-contaminated disposable should be disposed of in special containers and be treated as infectious waste.

Waste Co. is contracted for waste disposing.

Details concerning the criteria in waste disposal are included in the procedure *MPD 0202 –0–0871. Waste disposal*

5. RADIOACTIVE WASTE

The management of radioactive material is described in the *Safety Handbook*.

6. RESPONSIBILITIES ON “WASTE DISPOSAL”

The Director of the Clinical Chemistry Department is responsible of the policy and procedures for an efficient and safe disposal of all the biological material.

Writing, reviewing and maintaining the documents related to waste disposal are responsibility of the Quality Officer.

7. DOCUMENT MANAGEMENT

Updated documents concerning the archiving of laboratory waste disposal documents 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.

8. REVIEW OF DOCUMENTS

Documents concerning the laboratory waste disposal documents are revised at least once a year.

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