

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA v.2.0

7. PREANALYTICAL PHASE

7.2. CONSULTATION AND EFFICACY

AUTHOR	VERSION	APPROVED BY	DATE	

CIRCULATION LIST:	NAME	POSITION

CODE) DOCUMENT: QMM07	(CHAPTER TITLE): PRE-ANALYTICAL	(INSTITUTION): EC4 UNIVERSITY HOSPITAL
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1. INTRODUCTION

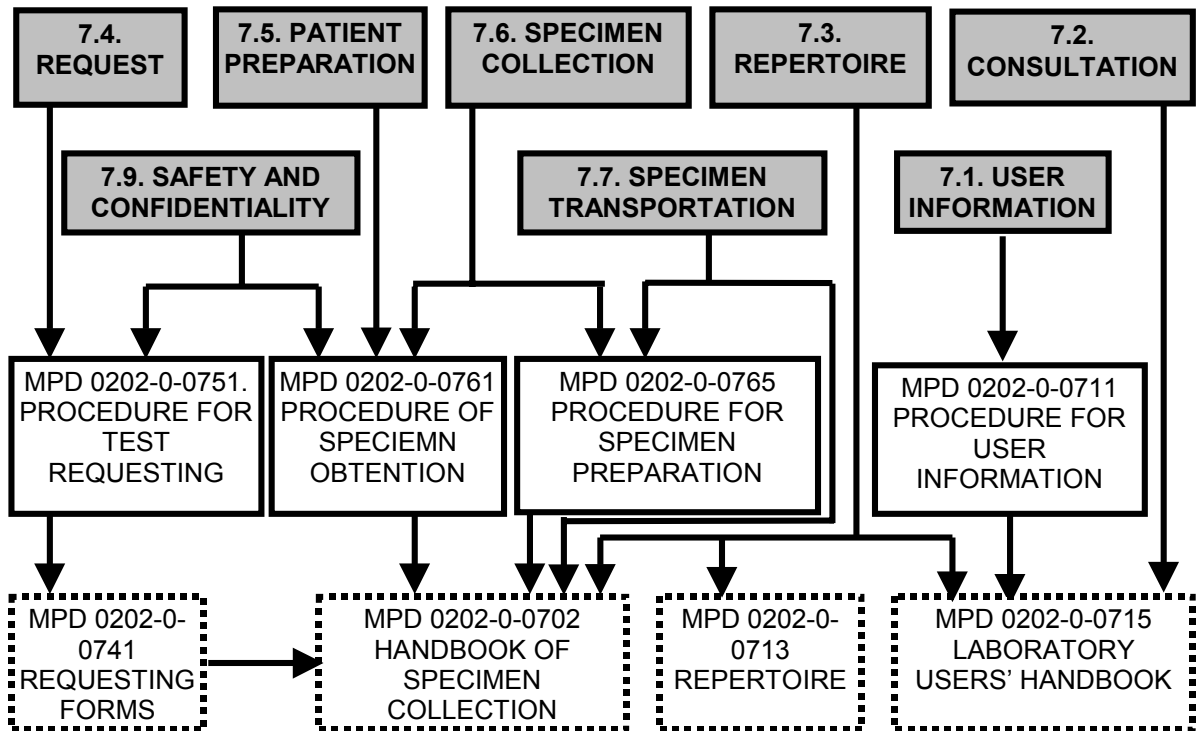
Consultation concerning efficacy of tests, repeat frequency and required type of specimen should be available at all times.

There should be regular meetings of professional staff with the clinical staff regarding the use of the laboratory, and for the purpose of consultation on scientific matters.

The professional staff should participate in clinical rounds, enabling consultation on efficacy in individual cases as well as in general.

The consultation function should be part of the medical audit.

1.1. SCOPE



1.2. AIMS

To fulfil the requirements of the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
.8. Advisory services and resolution of complaints. 4.8.1.	7.2. Client related process. 7.2.2. Review of product requirements.	
5.1. Technical requirements. Personnel. 5.1.4. (a)	7.3. Design and development	

1.3. PUBLICATION CREDITS

EC4 WG

1.4. REFERENCES

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1. 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.
2. ISO/TC 212/WG 1., Quality management in the clinical laboratory. Revised ISO/CD 15189, Quality management in the medical laboratory (December 1998). 4.7.1., 5.1.4. (a).
3. ISO.DIS Quality management systems – Requirements. ISO 9000. Geneva: ISO, 2000. 7.2.2., 7.3.
4. Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2nd rev. Ed. Utrecht: NVKC 1996.

1.5. RELATED DOCUMENTS

MPD 0202-0-0702 Handbook of specimen collection

MPD 0202-0-0715 Laboratory User's Handbook

1.6. ABBREVIATIONS

1.7. RELATED DEFINITIONS

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2. CONSULTATION SERVICES


Consultation services provided by the Clinical Chemistry Department include:

- appropriate test
- required type of specimen, timing, patient preparation, etc
- repeat frequency
- efficacy and interpretation of tests results
- turnaround time
- complementary and additional testing

3. AVAILABILITY OF CONSULTATION SERVICES


3.1. ON DUTY STAFF

Professional staffs on duty are available 24 hours. For contact:

				@
Clinical Chemistry	STAT laboratory	Dr. On duty	0011	duty@clin.chem.ec4h.eu

3.2. SPECIALISED CONSULTATION

Consultation services are available at normal working hours:

				@
Biochemistry	Toxicology	Dr. ABC	1234	ABC@clin.chem.ec4h.eu
	Endocrinology	Dr. DEF	5678	DEF@clin.chem.ec4h.eu
	Tumour markers	Dr. GHI	9012	GHI@clin.chem.ec4h.eu

Haematology
...

4. PROCEDURES FOR CONSULTATION SERVICES

4.1. MEETINGS WITH CLINICAL STAFF

There should be regular meetings of professional staff with the clinical staff regarding the use of the laboratory, and for the purpose of consultation on scientific matters.

4.2. PARTICIPATION IN CLINICAL GROUNDS

The professional staff should participate in clinical rounds, enabling consultation on efficacy in individual cases as well as in general.

5. AUDIT OF CONSULTATION SERVICES

The consultation services are part of the medical audit.

6. RESPONSABILITIES ON "CONSULTATION"

The Director of the Clinical Chemistry Department is responsible of the consultation policy with laboratory services users.

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The writing, revision and maintenance of documents concerning the consultation by users is responsibility of the Quality Officer.

Facilities for consultation services are included in the handbooks: *MPD 0202-0-0702 Handbook of specimen collection* and *MPD 0202-0-0715 Laboratory users' handbook*. Writing and maintaining both documents are responsibilities of the Quality Officer.

7. DOCUMENT MANAGEMENT

Updated documents concerning the consultation services users are available in the document 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 consultation services are revised at least once a year.

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