

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA v.2.0

9. POST-ANALYTICAL PHASE

9.5. INTERPRETATION AND CONSULTATION

AUTHOR	VERSION	APPROVED BY	DATE	

CIRCULATION LIST:	NAME	POSITION

CODE) DOCUMENT: QMM09	(CHAPTER TITLE): POST-	(INSTITUTION): EC4 UNIVERSITY HOSPITAL
(CODE) SECTION: QMM09-S05	ANALYTICAL PHASE	EC4 CLINICAL CHEMISTRY DEPARTMENT
(DATE): 21/10/01	(SECTION TITLE): CONSULTING	
PAGE 2 OF 8		

0. CONTENTS

1. INTRODUCTION

- 1.1. SCOPE
- 1.2. AIMS
- 1.3. PUBLICATION CREDITS
- 1.4. REFERENCES
- 1.5. RELATED DOCUMENTS
- 1.6. ABBREVIATIONS
- 1.7. RELATED DEFINITIONS

2. INTERPRETATIVE REPORTS

3. CONSULTATION SERVICE

4. RESPONSABILITIES ON "ARCHIVING"

5. DOCUMENT MANAGEMENT

6. REVIEW OF DOCUMENTS

AUTHOR	VERSION	APPROVED BY	DATE	

1. INTRODUCTION

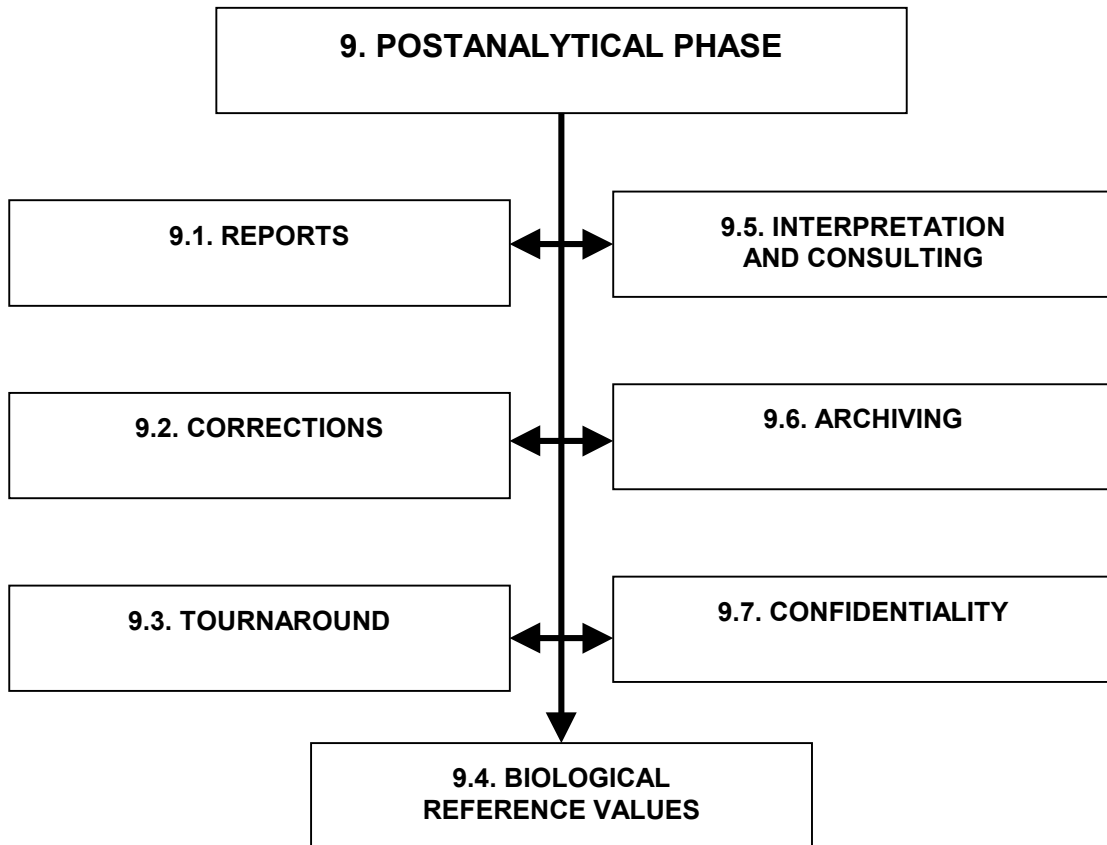
Consultation concerning interpretation of results and advice on further investigation should be available at all times.

There should be regular meetings of professional staff with the clinical staff regarding use of the laboratory and interpretation of results.

The professional staff should participate in clinical rounds for consultation on the interpretation in individual cases.

Professional staff should participate in the medical and clinical audit.

Professional staff should add interpretational remarks to reported results if necessary, e. g. warnings should be added to the report when pathological pitfalls or interfering substances are suspected.



1.1. SCOPE

1.2. AIMS

To fulfil the requirements of the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
4.8. Consultative services and resolution of complaints. 4.8.1. 5.8. Reporting results. 5.8.3. C.6.3. Reports		5.10. Reporting the records. 5.10.5. Opinions and interpretations.

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(CODE) SECTION: QMM09-S05	ANALYTICAL PHASE	EC4 CLINICAL CHEMISTRY DEPARTMENT
(DATE): 21/10/01	(SECTION TITLE): CONSULTING	
PAGE 4 OF 8		

1.3. PUBLICATION CREDITS

EC4 WG

1.4. REFERENCES

1. Jansen RTP, Blaton V, Burnett D, Huisman W, Queralto JM, Zerah 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/DIS 15189 – Quality management in the medical laboratory (December 1998). 4.8.1., 5.8.3., C.6.3.
3. ISO, IEC. General requirements for the competence of calibration and testing and calibration laboratories. DIS 17025. Geneva: ISO, 1998; 5.10.5.
4. Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2nd rev. Ed. Utrecht: NVKC 1996.
5. Burnett D. Understanding accreditation in laboratory medicine. London: Association of Clinical Biochemists, 1996, 170-178.

1.5. RELATED DOCUMENTS

QM 01-04. General information. Clinical advisory services

QM 07-03. Repertoire

MPD 0202-0-0701. Laboratory User's Handbook

MPD 0202-0-0944. Biological Reference Values

1.6. ABBREVIATIONS

1.7. RELATED DEFINITIONS

accuracy The degree of agreement between the result that a test ought to give and that actually obtained. Inaccuracy is expressed as a systematic error. See **accuracy of measurement**.

accuracy of measurement: closeness of the agreement between the result of a measurement and a true value of the measurand (8, definition 3.5). 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".

analytically false negative result: result of a measurement below the limit of detection when the analyte under consideration is present in the sample at a concentration above the limit of detection. NOTE 1: Here, the adjective "negative" is not used in the mathematical sense. NOTE 2: A complementary concept is "analytically true positive result".

analytically false positive result: result of a measurement above the limit of detection when the analyte under consideration is present in the sample at a concentration below the limit of detection. NOTE 1: Here, the adjective "positive" is not used in the mathematical sense. NOTE 2: A complementary concept is "analytically true positive result".

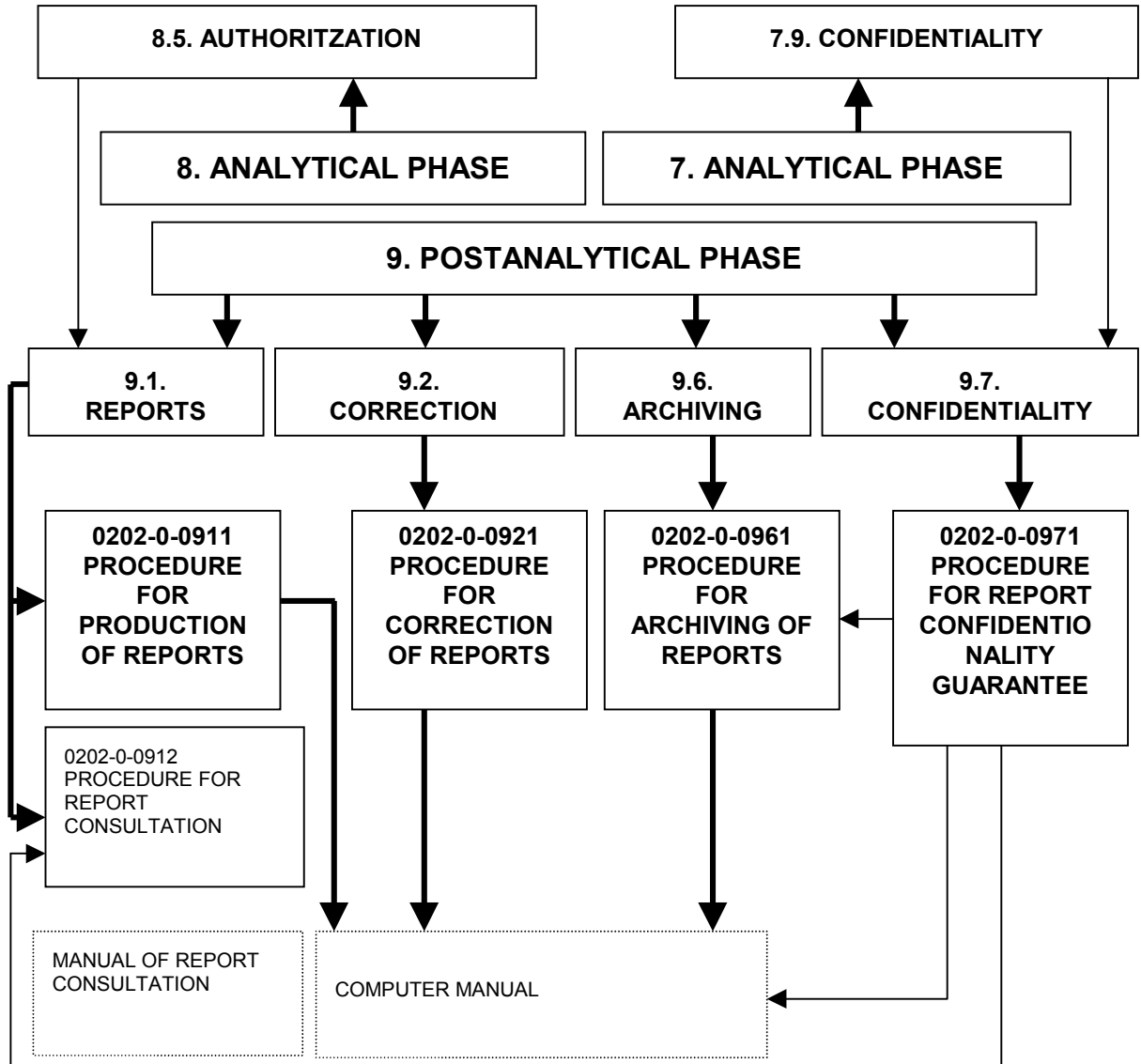
analytical performance characteristic (merit (deprecated)): property in the set of properties that is necessary for assessing the reliability of a measurement procedure and its suitability for any given purpose and where each property can be given an experimentally determined value. EXAMPLES: Analytical sensitivity; repeatability standard deviation; limit of detection.; NOTE: An analytical performance characteristic is a measurable quantity.

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.

error of measurement: result of a measurement minus a true value of the measurand. NOTE 1: To obtain an estimate, a conventional true value of the measurand is substituted for an (unknown) true value. NOTE 2: Error of measurement in a result of a measurement is the sum of random error of measurement and systematic error of measurement. Each type of error may be the outcome of contributions from several sources. These two types cannot

AUTHOR	VERSION	APPROVED BY	DATE	

be separated unless sets of results are available; in that case, the systematic error may be estimated. NOTE 3: The known parts of the systematic error of measurement may be compensated for by applying appropriate corrections or correction factors. NOTE 4: Modern descriptions of uncertainty of measurement avoid the concepts "sources of error" and the (unknown) "systematic error" and "random error"; the respective concepts "sources of uncertainty", "systematic effect" and "random effect" are preferred. The correction for a recognized systematic effect introduces an uncertainty as does the random effects.



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(CODE) SECTION: QMM09-S05	(SECTION TITLE): CONSULTING	EC4 CLINICAL CHEMISTRY DEPARTMENT
(DATE): 21/10/01		
PAGE 6 OF 8		

2. INTERPRETATIVE REPORTS

There is of great importance the quality of reporting and the interpretation of results. In certain disciplines the interpretation of the findings of an investigation *per se*, rather than in relation to a particular clinical setting, are a major part of the report.

The clinician can obtain authoritative advice from the laboratory on:

Suitability of the requested procedure to solve the clinical problem in question	Available in Consultation (see below)
Analytical performance of methods used in the laboratory (precision and accuracy)	Available in Consultation (see below)
Statistical significance of results and their relation to reference ranges	Printed in each report. Printed in the <i>Clinical Chemistry Department User Manual</i> See also: 9.6. Reference values
Scientific basis and the clinical significance of the results	Available in Consultation (see below)

3. CONSULTATION

The consulting service is part of the Clinical Chemistry Department activities (see document *QM 01-04. General information. Clinical advisory services*). This service is available:

All the clinical staff of the parent institution have access to this service, as it is detailed in the document *QM 01-04. General information. Clinical advisory services*, and in the procedures *MPD 0202-0-0701. Laboratory User's Handbook* and *MPD 0202-0-0944. Biological Reference Values List*.

Consultations can be made by telephone or by e-mail

The time schedule, and the phone numbers/addresses of the staff in charge of these services is:

Topic	Responsible	Days	Time available	 
Endocrinology	Dr. X	Monday to Thursday	08.00-14.00	#
General Laboratory	Dr. Z On duty	Monday to Friday	08.00-16.00	#
		Monday to Friday	16.00-08.00	#
		Weekends-Holidays	08.00-08.00	#
Lipidology	Dr. L.	Monday to Friday	09.00-17.00	#
Microbiology	Dr. M. On duty	Monday to Friday	09.00-17.00	#
		Monday to Friday	16.00-08.00	Page: #
		Weekends-Holidays	08.00-08.00	
Proteins	Dr. P Dr. A	Monday to Thursday	08.00-14.00	#
		Tuesday to Thursday	08.00-14.00	#
Toxicology	Dr. Y	Monday to Friday	09.00-17.00	#
...

4. RESPONSABILITIES ON "ARCHIVING"

The production, maintenance and revision of documents concerning the archiving of documents is a duty of the head of each area of the Clinical Chemistry Department.

5. DOCUMENT MANAGEMENT

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EC4 CLINICAL CHEMISTRY DEPARTMENT	(SECTION TITLE): CONSULTING	(CODE) SECTION: QMM09-S05
		(DATE): 21/10/01
PAGE 7 OF 8		

Updated documents concerning the archiving information 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.

6. REVIEW OF DOCUMENTS

Documents concerning the interpretation and consulting activities are revised at least once a year.

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(CODE) SECTION: QMM09-S05	ANALYTICAL PHASE	EC4 CLINICAL CHEMISTRY DEPARTMENT
(DATE): 21/10/01	(SECTION TITLE): CONSULTING	
PAGE 8 OF 8		

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AUTHOR	VERSION	APPROVED BY	DATE	