

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA v.2.0

9. POST-ANALYTICAL PHASE

9.3. TURNAROUND TIME

AUTHOR	VERSION	APPROVED BY	DATE	

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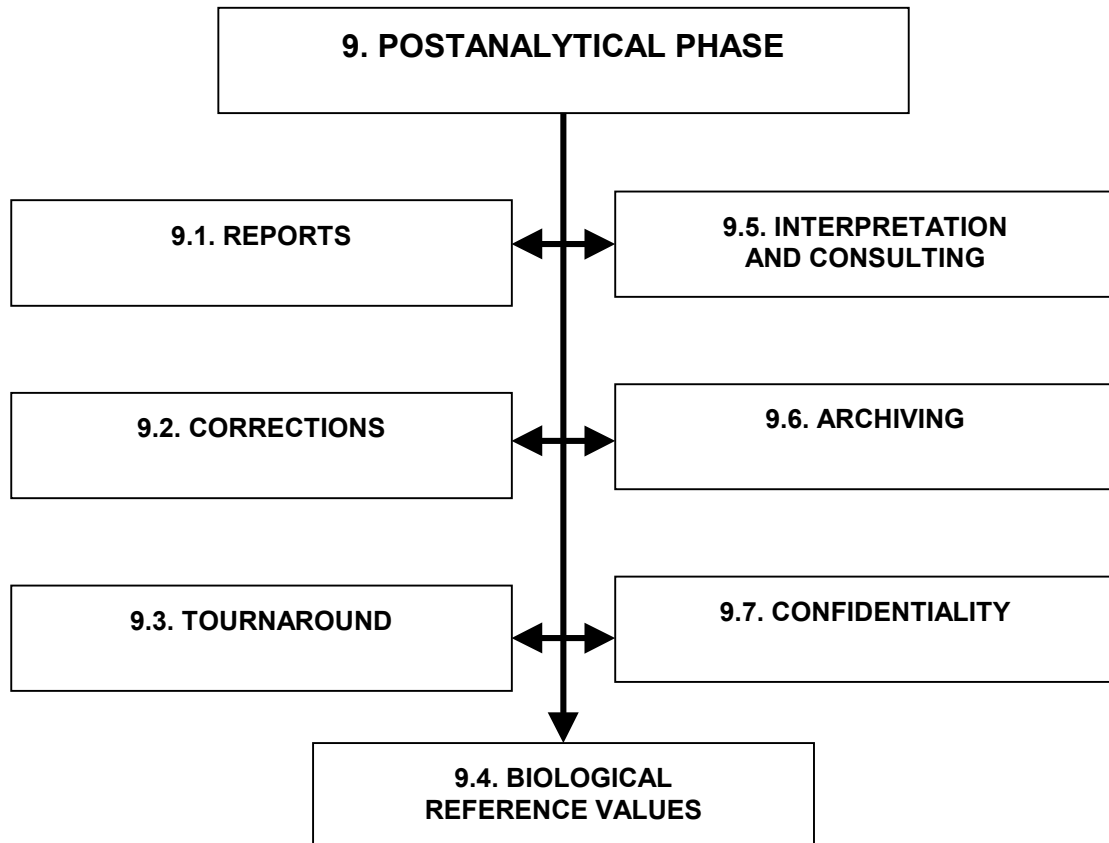
1. INTRODUCTION

The requesting physician should be familiar with the normal reporting time for assays.

Turnaround times for stat and routine tests should be audited regularly.

The turnaround time for assays sent to other laboratories should be known and checked.

Turnaround times should be part of the medical audit.



1.1 SCOPE

1.2. AIMS

To fulfil the requirements in the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
5.8. Reporting results. 5.8.7.	7.1. Planning of realisation process 7.5. Product and services operations. 7.5.4. Product conservation	

1.3. PUBLICATION CREDITS

EC4 WG

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1.4. REFERENCES

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/DIS 15189 – Quality management in the medical laboratory (December 1998). 5.8.7.
3. ISO.DIS Quality management systems – Requirements. ISO 9000. Geneva: ISO, 2000., 7.1., 7.5.4.
4. Jansen RTP, Bank CMC, Huisman W, Penders T.J. NVKC Model quality manual. 2nd rev. Ed. Utrecht: NVKC 1996.

1.5. RELATED DOCUMENTS

QM 07-03. Preanalytical phase. Repertoire

QM 09-01. Postanalytical phase. Reporting

MPD 0202-0-0911 Procedure of report production and issuing

MPD 0202-0-0701. Laboratory user's handbook

Laboratory specimen obtention handbook.

1.6. ABBREVIATIONS

LIS: Laboratory information system.

1.7. RELATED DEFINITIONS

reference measurement laboratory: laboratory that performs reference measurement procedures and provides results with stated uncertainties (see: **subcontractor**)

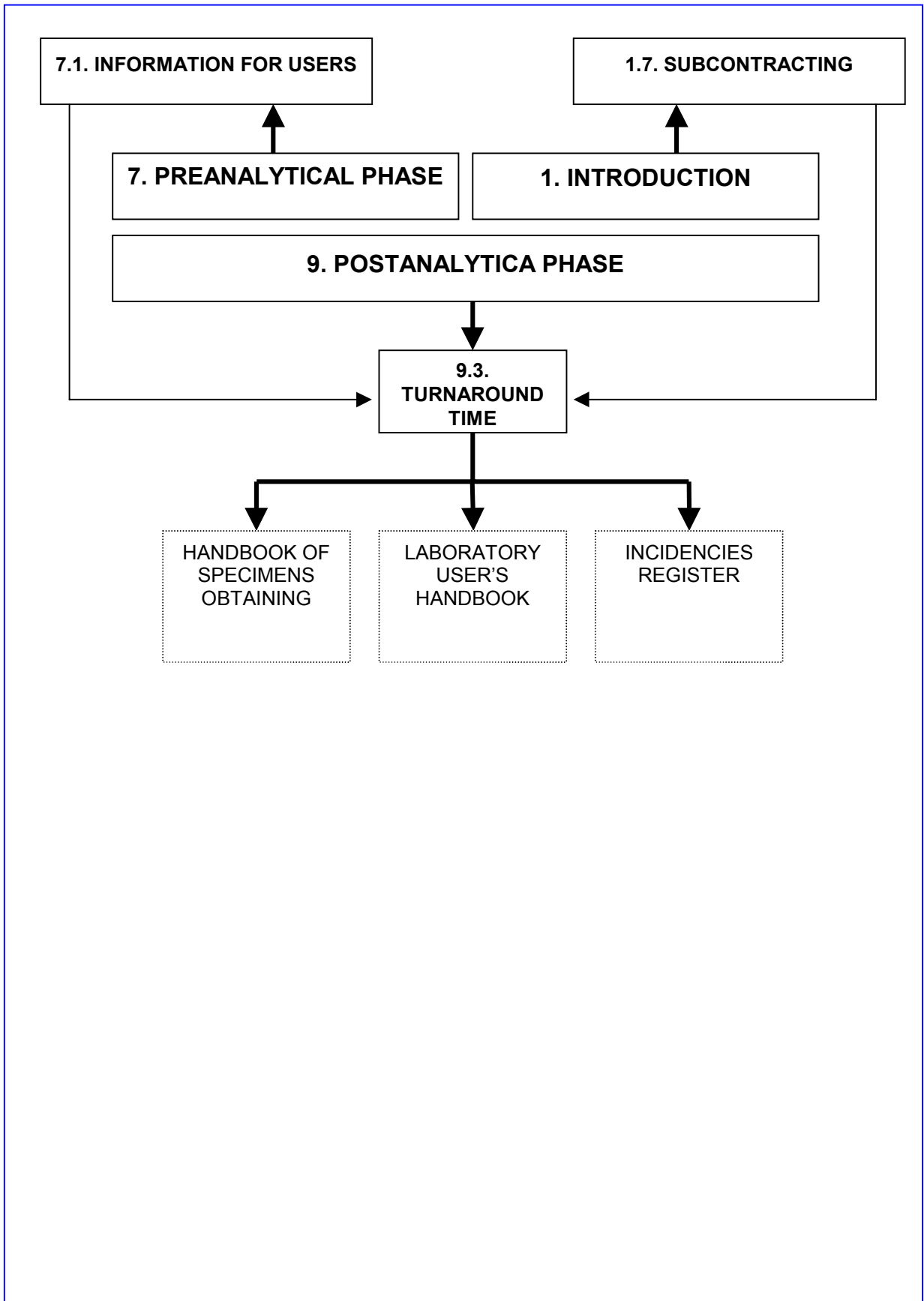
referral laboratory laboratory organization to which a sample is submitted for an examination procedure and report (see: **subcontractor**)

subcontractor: laboratories to which specialised or infrequently requested assays are sent (see **reference measurement laboratory, referral laboratory, reference measurement laboratory**)

turnaround time: interval between collection of the primary sample either by laboratory personnel or receipt from an external source and the reporting of results to the requesting health care provider (time from sample to report) or interval between receipt of the request and the reporting of results to the requesting health provider (time from request to report).

user: the clinician or other health care worker who requests examination of a sample by a medical laboratory.

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2. TURNAROUND TIME

The results of in-patient and outpatient tests are reported as they become available using the procedures detailed in *QM 09-01. Postanalytical phase. Reporting and MPD 0202-0-0911 Procedure of report production and issuing.*

The results of tests requested by general practitioners or other external service users are reported on a daily basis.

The documents: *MPD 0202-0-0701. Laboratory user's handbook* and *Laboratory specimen obtaining handbook*, which are distribute to all users of analytical services, include the turnaround time.

2.1. STAT ASSAYS

The documents: *MPD 0202-0-0701. Laboratory user's handbook* and *Laboratory specimen obtaining handbook* contain details about updated data about turnaround time of stat assays.

As a genera rule, the stat assay turnaround time is less than one hour.

When there is not possible to fulfil the established turnaround time, the Clinical Chemist responsible informs the requesting clinician and the reason is recorded in the incidence register:

system	analyte	turnaround time	comments
Serum	Glucose	1 hour	
Whole blood	pH	15 minutes	
Urine	Benzodiazepines	1 hour	Qualitative result. For quantification see "routine assays"
...

2.2. ROUTINE ASSAYS

The documents: *MPD 0202-0-0701. Laboratory user's handbook* and *Laboratory specimen obtaining handbook* contain details about updated data about turnaround time of routine assays.

As a genera rule, the stat assay turnaround time is between 1 and 15 days.

When there is not possible to fulfil the established turnaround time, the Clinical Chemist responsible informs the requesting clinician and the reason is recorded in the incidence register.

system	analyte	turnaround time		comments
		In-patients	Out-patients	
Serum	Glucose	12 hour	24 hours	
Whole blood	pH	15 minutes	(not appropriate)	
Urine	Benzodiazepines	3 days	4 days	Referred to external laboratory
...

2.3. REFERRED ASSAYS

The turnaround time for assays referred to a subcontractor are known, published in the *MPD 0202-0-0701. Laboratory user's handbook* and checked periodically.

The knowledge of the turnaround time is a condition necessary to subcontract a referral laboratory. If the referral laboratory does not fulfil the scheduled turnaround time without plausible explanation, subcontracting can be cancelled.

When the turnaround time is not fulfilled it is recorded in the incidence register.

3. AUDIT

Turnaround times for STAT, routine and referred assays are audited every 6 months.

Turnaround times are part of the medical audit.

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4. RESPONSABILITIES ON “TURNAROUND”

The establishment of turnaround times is a duty of the Clinical Chemistry Department Director, in agreement with the heads of each area of the Department. The production, maintenance and revision of documents concerning the turnaround time is a duty of the head of each area of the Clinical Chemistry Department.

5. DOCUMENT MANAGEMENT

Updated documents concerning the turnaround time 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.

Clinical staff periodically receive an update list of the turnaround time. This list is also available in the Clinical Chemistry Department web pages.

6. REVIEW OF DOCUMENTS

Documents concerning the turnaround time are revised at least once a year.

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