

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA

10. EVALUATION OF THE QUALITY SYSTEM

10.2. INTERNAL AND EXTERNAL COMPLAINS

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1. INTRODUCTION

There should be a low threshold system for reporting internal (from within the laboratory) (near) accidents, complaints and ideas.

Internal (near) accidents, complaints and ideas should be registered.

External (from outside the laboratory) accidents, near accidents and complaints should be registered.

Internal and external complaints and ideas should be discussed in staff meetings and the actions taken should be documented.

Professional staff should decide whether reported (near) accidents should lead to the immediate introduction of new measures in the laboratory organization or the consultation procedure.

1.1. SCOPE

1.2. AIMS

To fulfil the requirements of the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
4.7. Consultative services and resolution of complains. 4.7.2.	7.2. Client related process. 7.2.3. Communications with clients.	4.8. Complaints
4.11. Internal audits. 4.11.1. to 4.11.3.	8.2. Measurement and monitoring. 8.2.1. Client satisfaction	
4.12. Management review. 4.12.1 and 4.12.3.	8.3. Control of non-conformities	
5.1. Personnel. 5.1.4. .(p)		

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 clinical laboratory. Revised ISO/CD 15189, Quality management in the medical laboratory (December 1998), 4.7.2., 4.11.1., 4.11.2., 4.11.3., 4.12.1., 4.12.3., 5.1.4.(p).
- ISO.DIS Quality management systems – Requirements. ISO 9000. Geneva: ISO, 2000; 7.2.3., 8.2.1., 8.3.
- ISO, IEC. General requirements for the competence of calibration and testing and calibration laboratories. DIS 17025. Geneva: ISO, 1998; 4.8.
- Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2nd rev. Ed. Utrecht: NVKC 1996.

1.5. RELATED DOCUMENTS

10.2.1. Form for record complains and non conformities.

10.2.2. Hospital procedures for complaints and errors.

1.6. ABBREVIATIONS

1.7. RELATED DEFINITIONS

conformity: fulfilment by a product, process or service of specified requirements.

mistake (blunder): Unauthorized departure from the prescribed measurement procedure. NOTE: The mistake can take the form of an omission or an incorrect action and may be due to insufficient understanding, perception, interpretation, judgement, or attention. This is to be distinguished from error of measurement.

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non-conformity: non-fulfilment of a specified requiremen.

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

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2. REGISTRATION OF COMPLAINTS AND NON CONFORMITIES

2.1. INTRODUCTION

In order to monitor the quality of laboratory operations, a record of errors non conformities and complaints (incidents) is kept. This systematic registration of complaints and non conformities enables appropriate action to be taken to improve the quality of laboratory operations. Quality improvement is more important than the apportionment of blame for particular errors.

The occurrence of a complaint or nonconformity indicates that a customer (a patient, hospital department or doctor) or member of staff is dissatisfied, and/or that there is something wrong with the standard operating procedures or the attitude or performance of at least one member of staff.

Arrangements are also in place for the systematic collation and assessment of suggestions for the improvement of procedures.

2.2. HOSPITAL PROCEDURES

There are three hospital-wide procedures for the registration and handling of complaints and non conformities which of course also apply in the laboratory.

These are as follows:

1. The patients' complaint procedure
2. The faults, accidents and near-accidents procedure
3. The staff complaint procedure

These procedures cover most of the relatively serious complaints and errors. Copies of the procedures can be found in the document *10.2.2. Hospital procedures for complaints and errors*.

2.3. LABORATORY PROCEDURES

In addition to the hospital-wide procedures covering more serious incidents, a number of systems are in place to record less serious occurrences within the laboratory:

1. an internal error registration system, mainly for recording errors in the performance of tests
2. a register for staff complaints regarding incidents involving the laboratory
3. a register for externally originated complaints regarding incidents involving the laboratory (complaints originating outside are recorded separately from those made by laboratory staff)
4. a register for suggestions regarding the improvement of procedures

Specimens of the forms used for each register are contained in the document *10.2.1. Form for recording complaints and non conformities*. The differences between these registers are apparent from forms used for each.

Completed forms are submitted to the Laboratory Supervisor. All forms are retained by the Laboratory Supervisor in ring binders. Copies of the forms are kept by:

- the Laboratory Supervisor
- the Quality Officer
- the Clinical Chemists

2.4. COMPLAINTS MADE BY TELEPHONE

If a complaint is made by telephone, the complainant is if possible put through to the Laboratory Supervisor or a Clinical Chemist, who completes the appropriate form immediately after taking the call.

3. HANDLING OF COMPLAINTS AND NON CONFORMITIES

Serious complaints made by patients or staff and faults, accidents and near-accidents reports are handled in accordance with the relevant hospital procedure.

Internal errors in the performance of tests are corrected immediately and, if the Clinical Chemist considers it necessary, the doctor in charge of the case is contacted. These immediate responses are recorded on the form.

The error is then discussed with the person or persons involved straightaway.

When a complaint is made regarding an incident involving the laboratory, the urgency of the matter is considered by the

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Laboratory Supervisor, who then takes immediate corrective action, if necessary in consultation with the Clinical Chemist.

Generally speaking, information regarding such incidents is collated by the person who receives the complaint and recorded on the form or appended to it.

At least once a month, all errors and complaints are reviewed by the quality Officer, the Clinical Chemists and the Laboratory Supervisor at their regular work discussion meeting.

At this meeting, the need for procedural revisions is considered. Any corrective action decided upon is recorded on the form.

The system may be summarized as follows:

- the responsible officer (the Laboratory Supervisor or Clinical Chemist) collates information regarding the incident and records it on the form or in an appendix
- in urgent cases, the responsible officer takes immediate corrective action and if necessary discusses this with one of the (other) Clinical Chemists
- the action taken is recorded on the form.
- the form is forwarded to or retained by the Laboratory Supervisor
- a complaint registration number is allocated and the documentation filed under the appropriate heading in a complaint file.
- for reasons of confidentiality, the complaint files are stored in a locked cupboard by the Laboratory Supervisor
- The Quality Officer has access to the data
- Once a month, all errors and complaints are reviewed and the need for procedural revisions is considered.

4. EVALUATION OF COMPLAINTS AND SUGGESTIONS

All complaints and suggestions are considered by Clinical Chemists and Laboratory Technicians at their work discussion meetings.

Once every six months, all the errors and complaints in each category are reviewed by the Quality Officer, Laboratory Supervisor and Clinical Chemists with a view to identifying any patterns not apparent when the separate incidents were dealt with.

Following this review, any necessary procedural revisions are made or the matter discussed with the person or persons concerned. The outcome of the review is briefly minuted.

Another matter addressed at the meeting is the effectiveness of any corrective action previously taken, such as the revision of procedures or the instruction of staff.

To this end, each corrective act listed in the minutes of the previous meeting is reviewed. If the frequency of a particular error makes review after six months impractical, review is postponed to a later date.

The Laboratory Supervisor and Clinical Chemists also discuss suggestions for the improvement of standard operating procedures.

Suggestions which are considered practical and likely to be effective are taken up; procedures are duly revised and the new versions introduced.

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