16-6: Overview of records

Importance of records

Remember that records are laboratory information, either written by hand or computer-printed. They are permanent, and are not revised or modified. They should be complete, legible and carefully maintained, as they are used for many purposes, such as:

- Continuous monitoring—without access to all the data collected as a part of a quality system process, continuous monitoring cannot be accomplished.
- Tracking of samples—well-kept records allow for tracking of samples throughout the entire testing process; this is essential for troubleshooting, looking for sources of error in testing and investigating identified errors.
- Evaluating problems—well-kept equipment records will allow for thorough evaluation of any problems that arise.
- Management—good records serve as a very important management tool.

Never change a record. If new information needs to be added to a record, it should be noted as an addition, with a date, and signature or initials.

Examples of laboratory records

Many kinds of records are produced in a laboratory. Some examples include:

- sample logbook, registers;
- laboratory workbooks or worksheets;
- instrument printouts—maintenance records;
- quality control data;
- external quality assessent or proficiency testing records;
- patient test reports;
- personnel records;
- results of internal and external audits;
- continuous improvement projects;
- incident reports;
- user surveys and customer feedback;
- critical communications (e.g. letters from regulatory agencies, government or administrative offices within the health care system).

A method to record any information that must be kept should be established. The following type of records could be easily forgotten.

- Information on the management and handling of rejected samples.
- Data needed on any sample referred to another laboratory; to include when the sample was transported, where it was sent and when the report was issued. The sample should be able to be tracked throughout the referral process.

- Information about adverse occurrences or problems. Include all information that is pertinent, such as the results of any investigation of the problem (see Chapter 14).
- Inventory and storage records. These help keep track of reagents and supplies; (see Chapter 4).
- Equipment records.

Test report contents

Test reports should be designed so that all information that is needed by the laboratory, the laboratory users, and for any accreditation requirement, is included. The following is a list of test report contents required by ISO 15189:

- identification of test;
- identification of laboratory;
- unique identification and location of patient, where possible, and destination of the report;
- name and address of requestor;
- date and time of collection, and time of receipt in laboratory;
- date and time of release of report;
- primary sample type;
- results reported in SI units or units traceable to SI units, where applicable;
- biological reference intervals, where applicable;
- interpretation of results, where appropriate;
- applicable comments relating to quality or adequacy of sample, methodology limitations or other issues that affect interpretation;
- identification and signature of the person authorizing release of the report;
- if relevant, notation of original and corrected results.

Many of the items listed above are used by laboratories for their report forms. Some may be used less often, depending on the test and the context. For some tests, the report form may also need to include the patient's gender, as well as the date of birth (or age).