16-3: The quality manual

What is a quality manual?

The quality manual is a document that describes the quality management system of an organization (ISO 15189). Its purpose is to:

- clearly communicate information
- serve as a framework for meeting quality system requirements
- convey managerial commitment to the quality system.

As the quality manual is an important guide or roadmap, all persons in the laboratory should be instructed on its use and application. The manual must be kept up to date, and responsibility for the updating should be assigned.

Writing a quality manual

Although ISO 15189 standards require that laboratories have a quality manual, the style and structure are not specified. There is considerable flexibility in how to prepare it, and a laboratory can construct the manual so that it is most useful and suited to the needs of the laboratory and its customers.

When writing a quality manual, it is a good idea to use a steering committee. Because the quality manual needs to be tailored to the specific needs of the laboratory, each facility should carefully consider how to best involve those who are needed. Involve the policy makers for the laboratory. It is also essential to involve the bench technologists, to take advantage of their expertise and get their buy-in.

The quality manual should state policies for each of the twelve essentials of the quality system. Also describe how all the related quality processes occur, and make note of all versions of procedures (SOPs) and where they are located. For example, SOPs are a part of the overall quality system. Although there are usually too many to include directly in the quality manual, the manual should specify that SOPs be developed and indicate that they be compiled in the SOP manual.

Key points

The key points to remember about the quality manual are:

- there is only one official version
- the quality manual is never finished—it is always being improved
- it should be read, understood and accepted by everyone
- it should be written in clear, easily understood language
- the quality manual should be dated and signed by the management.

Developing a quality manual is a very big job, but it is also very rewarding and useful for the laboratory.

18-6: The laboratory quality manual

Definition

The quality manual is a document which fully describes the quality management system of an organization. It is key to the process, serving as a guide for the entire system. The manual will clearly lay out the quality policies, and will describe the structure of the other laboratory documents.

In a laboratory that is implementing a quality management system, there must be a quality manual. However, there is considerable flexibility in how to prepare it, and a laboratory can construct the manual so that it is most useful and suited to the local need (see Chapter 16 for additional information).

ISO 15189 [4.2.4] requires that laboratories have a quality manual, although style and structure are not specified.

Writing a quality manual

The purpose of a quality manual is to clearly communicate information, and to serve as a framework or roadmap for meeting quality system requirements. The manual is the responsibility of laboratory management, and thus conveys managerial commitment to quality and to the quality management system.

The manual should contain the following:

- All quality policies of the laboratory—these should address all 12 essential elements of the quality system.
- A reference to all processes and procedures—for example, standard operating procedures (SOPs) are a part of the overall quality system. There are usually too many to include directly in the quality manual, but the manual should say that all procedures must have an SOP and that these can be found in the SOP manual.
- A table of contents—ISO 15189 provides a suggested table of contents, and this includes a description of the laboratory, staff education and training policies, and all the other elements of a quality management system (e.g. documents and records).

Maintaining and using the quality manual

The quality manual is the framework for the entire quality management system, therefore it must always be correct and up to date. The laboratory will need to establish a process to ensure this. The following steps offer suggestions for developing, maintaining and using the quality manual.

- When the quality manual is written and prepared, it must be approved by the head of the laboratory. In some laboratories, approval by another appropriate person, such as the quality manager, might also be required. This approval should be indicated by having official signatures and dates of signing recorded in the manual itself.

- A process or system for updating needs to be established. This system should specify the frequency for reviewing the manual, assign responsibility for updating to someone (usually the quality manager), and define how changes in the manual will be incorporated and documented. Changes to the quality manual will need to be approved; approval should be indicated by having signatures of the person(s) with authority to make changes, and the date of the change, recorded in the manual.

- Instruction on use of the manual should be provided to all laboratory staff; laboratory personnel must understand that the policies detailed in the quality manual are always to be followed.