PURPOSE: To ensure programme is established to meet quality objectives, to direct and control an organization with regard to quality

RESPONSIBILITY: The Senior Management is responsible for ensuring that quality manual is implemented and maintained.

DEFINITIONS:

Document

Any information that provides direction (e.g. instructions including policy statements, textbooks, reference intervals and their origins, procedures, specifications, calibration tables, charts, posters, notices, memoranda, plans, software, drawings, regulations and standards).

Document Control

A system to regulate the handling and management (including archiving, storing and destruction) of documents containing information that communicates policies, processes, procedures as well as records
Usually pertains to documents that are part of the quality management system.

Policy

Statement describing what is done and why.

Process

Series of inter-related steps involved in an activity or examination that uses resources and is managed to transform inputs into outputs.

Procedure

Written work instructions that specify a way to carry out an examination or step in a process.

Quality Management System

A program developed to support efficient and effective, high quality and appropriate laboratory services (e.g. accurate and precise results, appropriate test selection, timely reporting, correct interpretation of results, clinical usefulness, appropriate

recommendations for further tests). Comprehensive and coordinated efforts (policies, processes and procedures) designed to meet quality objectives, to direct and control an organization with regard to quality. Encompasses quality (management) system, quality assurance and quality control

Quality System
See "Quality Management System."

Quality Manual
A document describing the quality management system

Quality Manager
An individual with delegated responsibility and authority to ensure compliance with the quality management system.

Record
Any information that produces evidence (e.g. requisitions, examination results and reports, instrument printouts, laboratory workbooks and worksheets, accession records, calibration records, quality control records, records of audits, complaints and action taken, external quality assessment records, instrument maintenance records, incident/accident reports, staff training and competency records, personnel records).

SOP
Standard Operating Procedure. See "Procedure".

INSTRUCTIONS:

Quality Manual Basics
The purpose of the quality manual is to:

- Communicate information
- Provide evidence of conformity to the company program requirements
- Share knowledge
- Provide evidence of management's commitment to quality

The following points should be considered when creating a quality manual:

1. It is a document that describes a facility's quality management system through a series of policies.
2. It is the primary documentation of a quality system and must provide a thorough description of the system.
3. The expected length is from 30-70 pages although this could vary depending on the size and scope of the facility, and the amount of information a facility chooses to include.
4. It will usually include management processes, but does not usually include any technical procedures. Procedures are referenced where appropriate.
5. It is a road map to the rest of a company's documentation, and will refer to a myriad of supporting documentation: procedures (work instructions), records, forms, charts, etc.
6. Some of the supporting documentation may be within the manual or included as appendices, but usually it will be kept elsewhere. The quality manual should indicate where supporting documentation can be found.
7. The medium can be either electronic or paper.
8. It must be easy for authorized personnel to update and easy for staff to access.
9. Typically, it is maintained and reviewed by a quality manager.
10. Everyone in the company must be encouraged to provide input into the development of the quality manual.
11. It is essential that the entire staff is familiar with, and understands the contents of the manual and its related documentation

Structure and Contents of the Quality Manual

The exact format, structure and contents of the quality manual are at the discretion of each facility. You have the latitude to design your manual in keeping with your facility's size and complexity. Organize the manual as you wish, but be sure to divide it into manageable sections, and at minimum include the following:

- An introduction (overview of the manual),
- A description of the organization
- A quality policy statement
- A table of contents
- Cross references to other documents
- Definitions and/or glossary of terms
- Proper identification

In developing your quality manual contents, consider that your quality management system must encompass all management activities and processes relating to quality assurance.

- Organization
- Personnel
- Equipment
- purchasing and inventory
- process control (includes validation of processes, internal quality control and external quality assessment)
- documents and records
- information management
- investigation of non-conformities
- assessment (includes the use of quality indicators and internal audits)
- process improvement
- service and satisfaction
- facilities and safety

The Introduction

In the quality manual, there should be an introductory section containing a brief overview of the quality manual and your facility. Consider including the following information:

- The name of the individual who reviewed and approved the quality manual
- The version status, and the date the current version was issued
- The overall scope and use of the manual
- Information about how revisions to the manual will occur
- Distribution information: i.e. internal only, external
- Information about your facility:
    - Name, address, FAX numbers, e-mail contacts etc
    - The scope of examinations offered
    - History
    - Vision, mission statement, values
- Definitions and/or glossary of terms
- A table of contents

The Quality Policy Statement
The purpose of the quality policy statement is to define the intentions and direction of the quality management system. It demonstrates the facility's commitment to quality with clear leadership by top management. This is essential since the leaders shape the culture of the company: their commitment is the key to success.

Example Quality Policy:
Company commits to provide high quality production, that:

- *Meet all customers' requirements; applicable regulatory, statutory and contractual requirements; and relevant national/international standards;*
- *Evaluate and continually improve the effectiveness of the service;*
- *Ensure this policy is communicated to and understood by all employees;*
- *Provide a process for establishment, review and modification of quality objectives;*
- *Review and modify this policy annually for continued suitability.*

Document Control
Quality manual must be considered a controlled document.

Document and Record Control

1. Management shall define, document and maintain a policy, process(es) and procedures to control documents and records. Documents and records may be maintained and stored on any appropriate medium.
2. Authorized documents shall be available at all locations where operations essential to the effective functioning of the laboratory are performed.
3. All documents issued to personnel as part of the quality management system shall be reviewed and approved for use by the manager or designate(s) prior to issue.
4. A list, also referred to as a document control log, that identifies the current valid revisions and their distribution shall be maintained.
5. All documents relevant to the quality management system shall have a unique identification.
6. Documents shall include the date of issue.
7. Documents shall include the edition and/or current revision date and/or revision number.
8. Documents shall designate the number of pages within.
9. Documents shall contain authority for issue.

10. Documents shall contain an electronic identification, if applicable.
11. Document control processes shall be adopted to ensure that obsolete documents are removed and only currently authorized versions of appropriate documents are available for active use at relevant locations.
12. A retention period for superseded documents shall be defined.
13. Retained or archived superceded documents shall be appropriately identified to prevent their inadvertent use.

Maintaining the Manual

Ensure the quality manual:

- Is up-to-date
- Is required reading for all personnel
- Is reviewed annually

1. The quality manual shall be maintained current under the authority of an individual appointed responsible by management (quality manager).
2. The quality manual should be reviewed, signed and dated regularly, and at minimum annually by the quality manager or management.
3. It is advisable to include a "Record of Revisions" page within your quality manual. This could appear in the front material or as an appendix. Alternatively, include a revision history for each individual policy as part of a standard header or footer.
4. If your quality manual is primarily an electronic document wherein uncontrolled printed paper copies may exist, you should consider adding a footer at the bottom of printed pages:

NOTE: *This is a CONTROLLED Document as are all management system files on this server. Any documents appearing in paper form are not controlled and should be checked against the server file version prior to use.*

Notice: *This Document hardcopy must be used for reference purpose only.*
The on-line copy must be used as the current documentation level.
This type of warning reminds personnel to ensure that they are using the most up to date issued copy of any document.

MONITORING:
Regular audits / inspections of manufacturing areas and controls must be in place to ensure that procedures are effective and working.

VERIFICATION AND RECORD KEEPING:
Regular audits / inspections of manufacturing areas and controls must be in place to ensure that procedures are effective and working.
Internal audits records must be completed, which will include:

- non-conformances
- corrective action
- responsibility
- date of completion

RECORDS APPLIED TO THIS PROCEDURE:

- Internal Audit records

DOCUMENTATION RETENTION:
The records applied to this procedure are to be kept on file for a minimum of 3 years.