Laboratory Quality Management System

Handbook

World Health Organization

Clinical and Laboratory Standards Institute®
WHO Collaborating Center

CDC

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Foreword

Achieving, maintaining and improving accuracy, timeliness and reliability are major challenges for health laboratories. Countries worldwide committed themselves to build national capacities for the detection of, and response to, public health events of international concern when they decided to engage in the International Health Regulations implementation process.

Only sound management of quality in health laboratories will enable countries to produce test results that the international community will trust in cases of international emergency.

This handbook is intended to provide a comprehensive reference on Laboratory Quality Management System for all stakeholders in health laboratory processes, from management, to administration, to bench-work laboratorians.

This handbook covers topics that are essential for quality management of a public health or clinical laboratory. They are based on both **ISO 15189** and **CLSI GP26-A3** documents.

Each topic is discussed in a separate chapter. The chapters follow the framework developed by CLSI and are organized as the "12 Quality System Essentials". A diagram representing these 12 essentials is shown below.

Note:

Health laboratories, in this handbook, is a term that is meant to be inclusive of clinical laboratories, diagnostic laboratories, medical laboratories, public health laboratories, animal and environmental health laboratories or any other laboratories performing testing for the purpose of disease diagnosis, screening, prevention, medical treatment decisions, surveillance or public health. Because all these terms for laboratories are frequently used interchangeably, the terms may likewise be used interchangeably in this handbook.

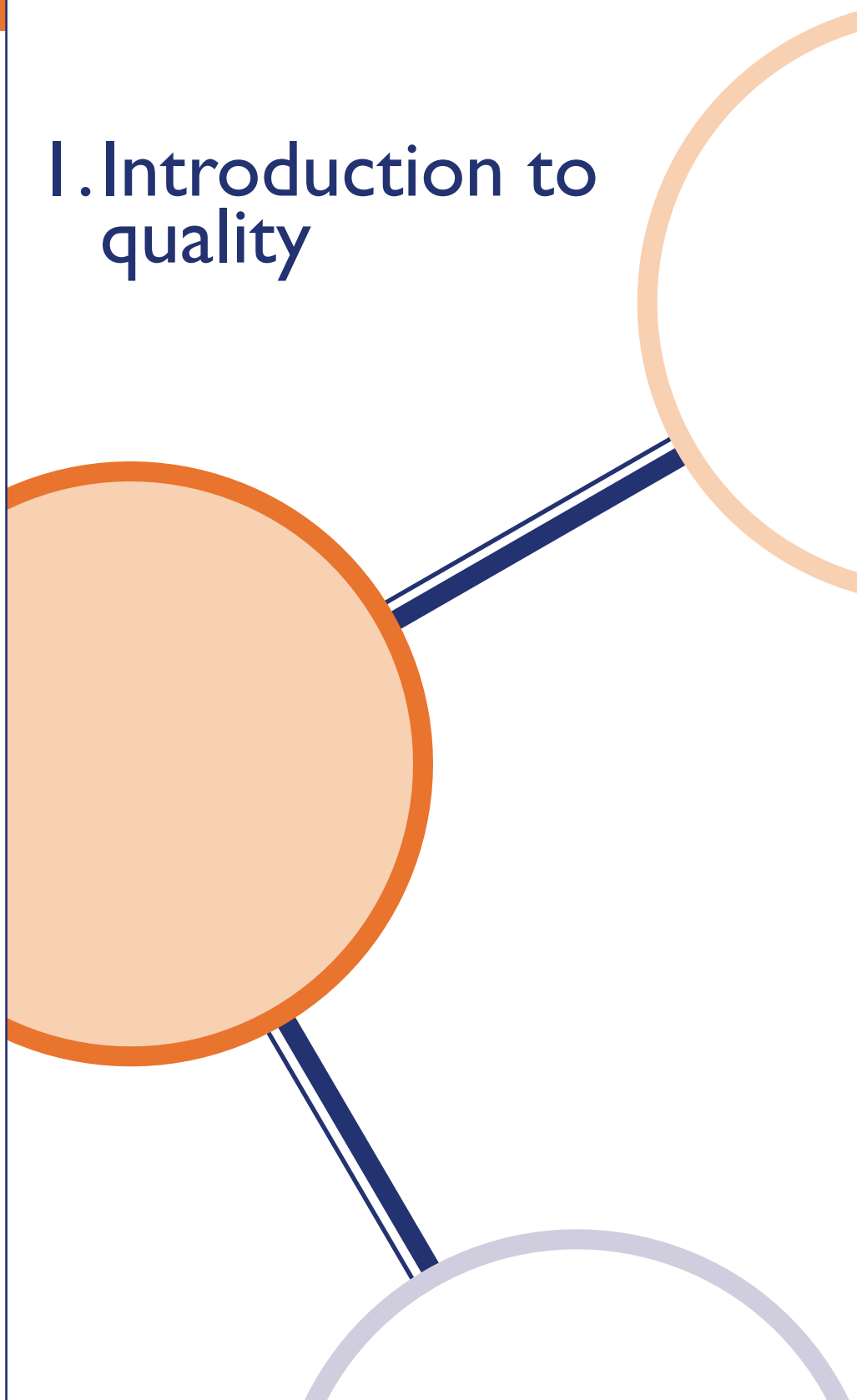
Revision information:

The version 1.1 of the present handbook includes updated Glossary, Acronyms, and References and resources by chapter sections.

Key words

Laboratory quality management system, laboratory quality, laboratory quality systems, laboratory information management, laboratory information system, laboratory documents and records, laboratory quality manual, quality control, laboratory facilities and safety, laboratory equipment, laboratory sample management, laboratory sample transport, laboratory purchasing and inventory, laboratory assessment, laboratory customer service, occurrence management, process improvement, quality essentials, laboratory process control, clinical laboratory, ISO 15189.

1. Introduction to quality



1-1: The importance of laboratory quality

Definition of quality

Laboratory quality can be defined as accuracy, reliability and timeliness of reported test results. The laboratory results must be as accurate as possible, all aspects of the laboratory operations must be reliable, and reporting must be timely in order to be useful in a clinical or public health setting.

Level of accuracy required

When making measurements, there is always some level of inaccuracy. The challenge is to reduce the level of inaccuracy as much as possible, given the limitations of our testing systems. An accuracy level of 99% may at first glance appear acceptable, but the resulting 1% error can become quite large in a system where many events occur, such as laboratory testing.

Negative consequences of laboratory error

Laboratories produce test results that are widely used in clinical and public health settings, and health outcomes depend on the accuracy of the testing and reporting. If inaccurate results are provided, the consequences can be very significant, including:

- unnecessary treatment
- treatment complications
- failure to provide the proper treatment
- delay in correct diagnosis
- additional and unnecessary diagnostic testing.

These consequences result in increased cost in time and personnel effort, and often in poor patient outcomes.

Minimizing laboratory error

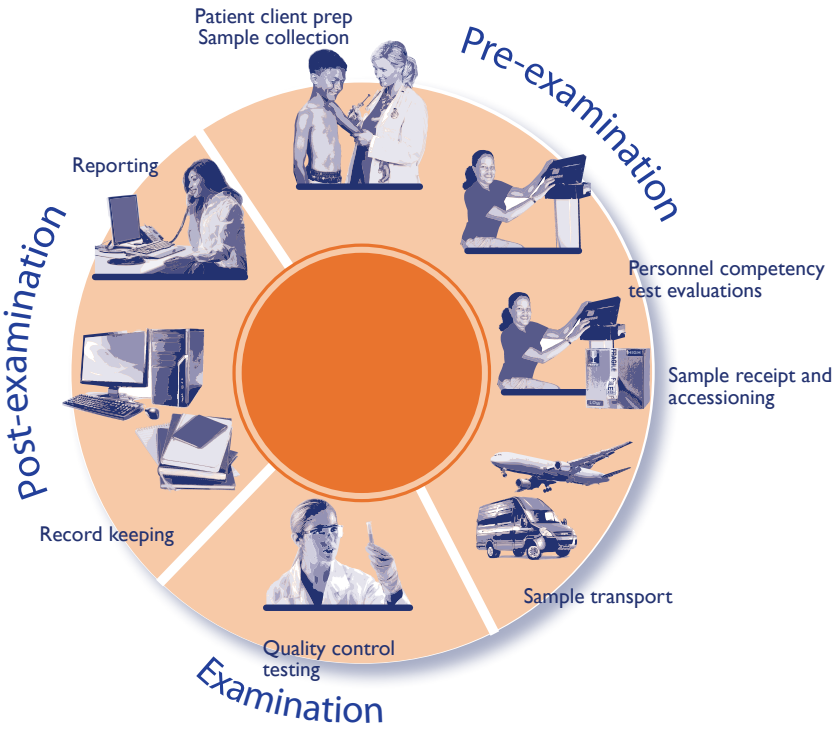
In order to achieve the highest level of accuracy and reliability, it is essential to perform all processes and procedures in the laboratory in the best possible way. The laboratory is a complex system, involving many steps of activity and many people. The complexity of the system requires that many processes and procedures be performed properly. Therefore, the quality management system model, which looks at the entire system, is very important for achieving good laboratory performance.

1-2: Overview of the quality management system

Definition of quality management system

A quality management system can be defined as "coordinated activities to direct and control an organization with regard to quality". This definition is used by the International Organization for Standardization (ISO) and by the Clinical and Laboratory Standards Institute (CLSI). Both groups are internationally recognized laboratory standards organizations, and will be discussed later in this handbook.

In a quality management system, all aspects of the laboratory operation, including the organizational structure, processes and procedures, need to be addressed to assure quality.



Complexity of laboratory processes

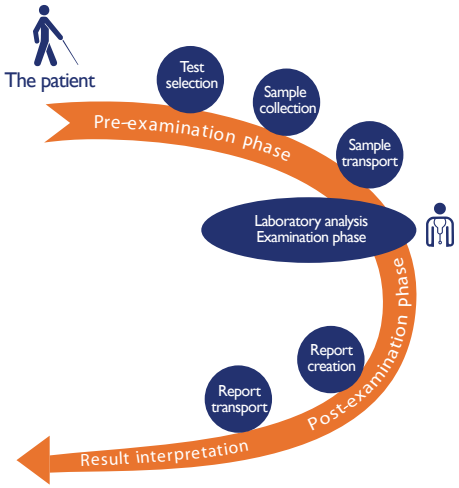
There are many procedures and processes that are performed in the laboratory, and each of these must be carried out correctly in order to assure accuracy and reliability of testing. An error in any part of the cycle can produce a poor laboratory result. A method of detecting errors at each phase of testing is needed if quality is to be assured.

ISO standards group laboratory processes into pre-examination, examination and post-examination categories. Comparable terms in current laboratory use include: pre-analytic, analytic and post-analytic processes; or pre-test, test and post-test processes.

Path of workflow

The entire set of operations that occur in testing is called the **path of workflow**. The path of workflow begins with the patient and ends in reporting and results interpretation, as shown in the figure below.

The concept of the path of workflow is a key to the quality model or the quality management system, and must be considered when developing quality practices. For example, a sample that is damaged or altered as a result of improper collection or transport cannot provide a reliable result. A medical report that is delayed or lost, or poorly written, can negate all the effort of performing the test well.



Quality management system addresses all processes

The complexity of the laboratory system requires that many factors must be addressed to assure quality in the laboratory. Some of these factors include:

- the laboratory environment
- quality control procedures
- communications
- record keeping
- competent and knowledgeable staff
- good-quality reagents and equipment.

1-3: The quality management system model

Overview of the quality management system model

When all of the laboratory procedures and processes are organized into an understandable and workable structure, the opportunity to ensure that all are appropriately managed is increased. The quality model used here organizes all of the laboratory activities into 12 quality system essentials. These quality system essentials are a set of coordinated activities that serve as building blocks for quality management. Each must be addressed if overall laboratory quality improvement is to be achieved. This quality management system model was developed by CLSI,[1] and is fully compatible with ISO standards.[2,3]

Assuring accuracy and reliability throughout the path of workflow depends on good management of all of the quality essentials.

Organization

In order to have a functioning quality management system, the structure and management of the laboratory must be organized so that quality policies can be established and implemented. There must be a strong supporting organizational structure—management commitment is crucial—and there must be a mechanism for implementation and monitoring.

Personnel

The most important laboratory resource is competent, motivated staff. The quality management system addresses many elements of personnel management and oversight, and reminds us of the importance of encouragement and motivation.

Equipment

Many kinds of equipment are used in the laboratory, and each piece of equipment must be functioning properly. Choosing the right equipment, installing it correctly, ensuring that new equipment works properly, and having a system for maintenance are all part of the equipment management programme in a quality management system.

1 CLSI/NCCLS. *A quality management system model for health care; approved guideline—second edition*, CLSI/NCCLS document HS1-A2. Wayne, PA, NCCLS, 2004.

2 ISO 15189:2007. *Medical laboratories–particular requirements for quality and competence*. Geneva: International Organization for Standardization, 2007.

3 ISO 9001:2000. *Quality management systems–requirements*. Geneva: International Organization for Standardization, 2000.

Purchasing and inventory

The management of reagents and supplies in the laboratory is often a challenging task. However, proper management of purchasing and inventory can produce cost savings in addition to ensuring supplies and reagents are available when needed. The procedures that are a part of management of purchasing and inventory are designed to ensure that all reagents and supplies are of good quality, and that they are used and stored in a manner that preserves integrity and reliability.

Process control

Process control is comprised of several factors that are important in ensuring the quality of the laboratory testing processes. These factors include **quality control** for testing, appropriate **management of the sample**, including collection and handling, and **method verification and validation**.

The elements of process control are very familiar to laboratorians; quality control was one of the first quality practices to be used in the laboratory and continues to play a vital role in ensuring accuracy of testing.

Information management

The product of the laboratory is information, primarily in the form of test reporting. Information (data) needs to be carefully managed to ensure accuracy and confidentiality, as well as accessibility to the laboratory staff and to the health care providers. Information may be managed and conveyed with either paper systems or with computers; both will be discussed in the section on information management.

Documents and records

Many of the 12 quality system essentials overlap. A good example is the close relationship between "Documents and records" and "Information management". Documents are needed in the laboratory to inform how to do things, and laboratories always have many documents. Records must be meticulously maintained so as to be accurate and accessible.

Occurrence management

An "occurrence" is an error or an event that should not have happened. A system is needed to detect these problems or occurrences, to handle them properly, and to learn from mistakes and take action so that they do not happen again.

Assessment

The process of assessment is a tool for examining laboratory performance and comparing it to standards, benchmarks or the performance of other laboratories. Assessment may be internal (performed within the laboratory using its own staff) or it may be external (conducted by a group or agency outside the laboratory). Laboratory quality standards are an important part of the assessment process, serving as benchmarks for the laboratory.

Process improvement

The primary goal in a quality management system is continuous improvement of the laboratory processes, and this must be done in a systematic manner. There are a number of tools that are useful for process improvement.

Customer service

The concept of customer service has often been overlooked in laboratory practice. However, it is important to note that the laboratory is a service organization; therefore, it is essential that clients of the laboratory receive what they need. The laboratory should understand who the customers are, and should assess their needs and use customer feedback for making improvements.

Facilities and safety

Many factors must be a part of the quality management of facilities and safety. These include:

- **Security**—which is the process of preventing unwanted risks and hazards from entering the laboratory space.
- **Containment**—which seeks to minimize risks and prevent hazards from leaving the laboratory space and causing harm to the community.
- **Safety**—which includes policies and procedures to prevent harm to workers, visitors and the community.
- **Ergonomics**—which addresses facility and equipment adaptation to allow safe and healthy working conditions at the laboratory site.

Quality management system model

In the quality management system model, all 12 quality system essentials must be addressed to ensure accurate, reliable and timely laboratory results, and to have quality throughout the laboratory operations. It is important to note that the 12 quality system essentials may be implemented in the order that best suits the laboratory. Approaches to implementation will vary with the local situation.

Laboratories not implementing a good quality management system are guaranteed that there will be many errors and problems occurring that may go undetected. Implementing a quality management system may not guarantee an error-free laboratory, but it does yield a high-quality laboratory that detects errors and prevents them from recurring.

1-4: History of laboratory quality management

Definition of quality management

ISO 9000 defines quality management as "coordinated activities to direct and control an organization with regard to quality". This is intimately related to the definition of a quality system—"organizational structure, resources, processes and procedures needed to implement quality management". Quality management concepts in use today had their onset in the 20th century, and are primarily an outgrowth of manufacturing and shop processes.

Principal innovators and their contributions

One of the earliest concepts of the quality management movement was that of quality control of the product. Shewhart developed a method for statistical process control in the 1920s, forming the basis for quality control procedures in the laboratory. Quality control methods were not applied in the laboratory until the 1940s. Other critical thinkers and innovators, including Arman Feigenbaum, Kaoru Ishikawa and Genichi Taguchi, added to the concepts. The most recent method that is of importance to the laboratory is Galvin's work on micro-scale error reduction.

Quality management is not new.

1-5: International laboratory standards

Need for international laboratory standards

A part of quality management is assessment, measuring performance against a standard or benchmark. The concept of quality management requires that standards be set, and again industry has been in the lead.

Important laboratory standards organizations

Using a set of standards established by the United States of America military for the manufacture and production of equipment, the ISO established standards for industrial manufacturing; we know these standards as ISO standards.

ISO

The ISO 9000 documents provide guidance for quality in manufacturing and service industries, and can be broadly applied to many other kinds of organizations. ISO 9001:2000 addresses general quality management system requirements and applies to laboratories. There are two ISO standards that are specific to laboratories:

- ISO 15189:2007. *Medical laboratories—particular requirements for quality and competence*. Geneva: International Organization for Standardization, 2007.
- ISO/IEC 17025:2005. *General requirements for the competence of testing and calibration laboratories*. Geneva: International Organization for Standardization, 2005.

CLSI

Another important international standards organization for laboratories is the Clinical and Laboratory Standards Institute, or CLSI, formerly known as the National Committee for Clinical Laboratory Standards (NCCLS). CLSI uses a consensus process involving many stakeholders for developing standards. CLSI developed the quality management system model used in this handbook. This model is based on 12 quality system essentials, and is fully compatible with ISO laboratory standards.

CLSI has two documents that are very important in the clinical laboratory:

- *A quality management system model for health care; approved guideline—second edition*. CLSI/NCCLS document HS1-A2. Wayne, PA, NCCLS, 2004.
- *Application of a quality management system model for laboratory services; approved guideline—third edition*. CLSI/NCCLS document GP26-A3. Wayne, PA, NCCLS, 2004.

The information in this handbook is based on the CLSI quality management system model and the ISO 15189 standard.

Other standards

There are many other standards organizations, and many examples of laboratory standards. Some countries have established national laboratory quality standards that apply specifically to laboratories within the country. Some laboratory standards apply only to specific areas in the laboratory or only to specific tests. The World Health Organization has established standards for some specific programmes and areas.

1-6: Summary

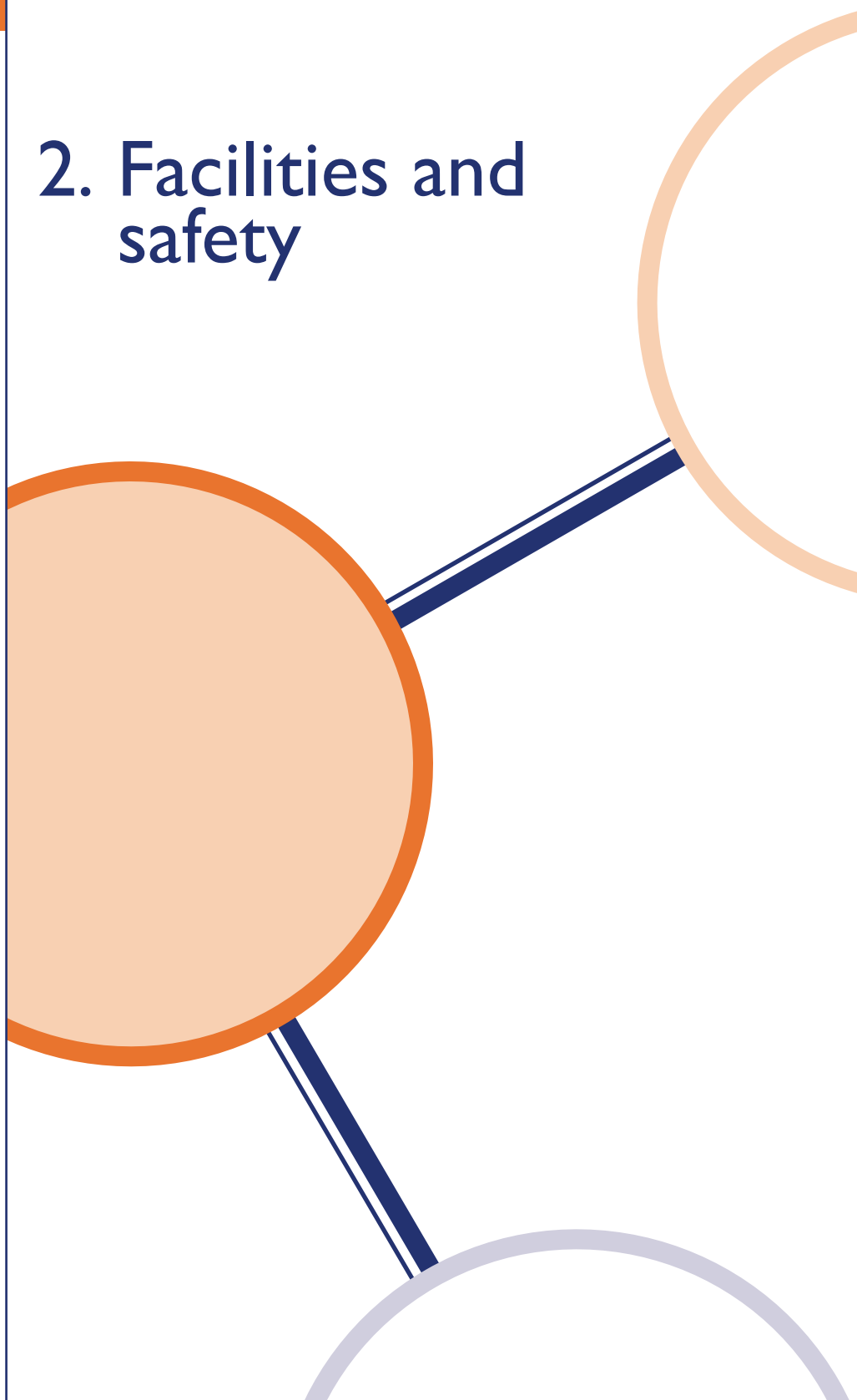
Quality management

Quality management is not new; it grew from the work of innovators who defined quality over a span of 80 years. Quality management is as applicable for the medical laboratory as it is for manufacturing and industry.

Key messages

- A laboratory is a complex system and all aspects must function properly to achieve quality.
- Approaches to implementation will vary with the local situation.
- Start with changes that can be easily accomplished and have the biggest impact.
- Implement in a stepwise process but ultimately, **all quality essentials must be addressed**.

2. Facilities and safety



2-1: Overview

Role in quality management system

The laboratory work space and facilities must be such that the workload can be performed without compromising the quality of work and the safety of the laboratory staff, other health care personnel, patients and the community.

This chapter will describe essential elements for laboratory design and safety that prevent and control exposure to physical, chemical and biological hazards.

This chapter addresses pathogens and chemicals of moderate or low-level risk, rather than highly dangerous substances. As a general rule, all diagnostic laboratories should be designed and organized for biosafety level 2 or above.

Importance of safety

A laboratory safety programme is important in order to protect the lives of employees and patients, to protect laboratory equipment and facilities, and to protect the environment.

Neglecting laboratory safety is very costly. Secondary effects of a laboratory accident are:

- loss of reputation
- loss of customers / loss of income
- negative effect on staff retention
- increased costs—litigation, insurance.

Responsibilities

Ensuring quality and safety during laboratory processes is a major concern for laboratory managers. Often, the laboratories they manage are designed by architects and/or administrators who have little knowledge of specific laboratory needs, making the job of the manager more difficult.

As a **laboratory director**, it is important to:

- actively participate in the design and planning stages of new laboratory facilities;
- assess all potential risks and apply basic concepts of organization in order to provide a proper and safe environment for conducting laboratory activities, including services to patients;
- consider the organization of the laboratory when developing new activities or new diagnostic techniques in the laboratory.

As a **quality manager (or designated safety officer)**, it is necessary to:

- develop a complete and thorough description of basic safety rules and organization, and ensure that personnel are trained in their specific duties when new activities or techniques are introduced into the laboratory;
- know the basics of safety and biosafety management issues when working with chemicals and pathogens of moderate or low level of risk;
- know how to perform an extensive risk assessment when developing new activities in the laboratory;
- conduct laboratory safety audits.

As a **laboratorian,** it is important to:

- be aware of basic safety rules and processes;
- understand the basics of safety and biosafety management issues when working with toxic chemicals, biological samples and physical hazards, and when interacting with patients.

Everyone in the laboratory is responsible for quality and safety.

2-2: Laboratory design

Access

When designing a laboratory or organizing workflow, ensure that patients and patient samples do not have common pathways. Circulation paths should be designed in such a way that contact between the public and biological materials can occur only in the rooms where patient samples are collected. The reception desk where incoming patients register should be located as close as possible to the entry door.

Access to rooms where manipulation or analysis of samples takes place, or where hazardous chemicals or other materials are stored, must be restricted to authorized persons, usually laboratory technical staff and maintenance staff. Restriction of access may be accomplished using signs on doors, locks when appropriate and staff identification badges.

Circulation pathways

To identify where improvements in laboratory design may be needed in order to prevent or reduce risks of cross-contamination, follow the path of the sample as it moves through the laboratory during the pre-examination, examination and post-examination phases of testing. Pathways to assess include:

- Sample collection areas—a laboratory layout with both the reception and the sample collection room located at the entrance saves time and energy.
- Sample processing areas—here, samples are centrifuged as needed, allocated for different examinations and dispersed to the appropriate sections of the laboratory for analysis. If possible, the sample processing area should be separated from, but nearby, the testing areas.
- Start with changes that can be easily accomplished and have the biggest impact.
- Circulation pathways of biological samples between different sections of the laboratory—These pathways should be assessed for the purpose of minimizing contamination risks. If possible, circulation pathways of clean and dirty laboratory materials should never cross, and circulation pathways of contaminated waste should be isolated.
- Post-examination pathways—After the analysis of the samples, the results must be accurately recorded, properly filed, and delivered on time to the right person. Communication systems appropriate to the size and complexity of the laboratory, including the efficient and reliable transferring of messages, should be part of the laboratory design.

For the most efficient design, all related services should be located in close proximity.

2-3: Geographic or spatial organization

Distribution of activities

When organizing laboratory work space, divide the laboratory into areas with different access control in order to separate patients from biological samples. Where samples are actually processed, plan for spatial organization that ensures the best service.

For optimal organization of the laboratory, consider:

- Delineation of laboratory activities—Care should be taken to either group related activities in a single room, or to clearly delineate bench space for specific activities. Measures must be taken to prevent cross-contamination of samples.
- Location of service rooms—Service rooms to accommodate autoclaves, sinks for cleaning glassware, preparation and sterilization of culture media, and so on, should be located in a central area to minimize distances and facilitate circulation paths of materials, samples and goods. A responsible staff member should be designated to oversee cleaning and maintenance of the service rooms.
- Location of activities with specific requirements, such as:
  - molecular biology—needs to be located in a separate space, with at least two rooms, so that preparation of DNA extracts is not performed in the same room as where the subsequent steps (preparation of reagent mixes and DNA amplification) are performed;
  - fluorescence microscopy—requires a dark room with proper ventilation which must not be used for storage of stock materials and other chemicals;
  - ultraviolet illumination systems for DNA gel photography—requires a dark room and appropriate eye protection equipment.

Spatial provision for equipment

The laboratory director and safety officer must consider special needs for equipment when designing laboratory space. Some things to consider are:

- Access to equipment for entry and maintenance—Make sure that there are no physical restrictions for access, such as door and elevator size, that could pose a problem for the delivery and maintenance of new machines and equipment.
- Power supply—Consider the need for a stable power supply for sensitive equipment and a backup power supply or emergency generator for times when the laboratory's primary power source is down.
- Managing disposal of liquids from equipment—Disposal of liquid reagents, by-products and wastes from laboratory equipment and procedures is a major concern for laboratories. When placing equipment in the laboratory, be sure to consider how liquid wastes will be handled. It is important to be aware of, and comply with, local and national requirements for liquid waste disposal, in order to prevent contamination of community sewage systems with pathogens or toxic chemicals.

2-4: Physical aspects of premises and rooms

Facilities

The laboratory must be designed to ensure proper ventilation throughout, with an active ventilation system and adequate space for circulation of people, laboratory carts and trolleys.

Rooms should have a high ceiling to ensure proper ventilation, and walls and ceilings should be painted with washable, glossy paint or coated with a material suitable for cleaning and disinfection. The floor must also be easy to clean and disinfect, and have no edges between the walls and floor.

Work benches

Laboratory work benches should be constructed of materials that are durable and easy to disinfect. If the laboratory's budget allows, ceramic tiles are good materials to use for benchtops, as they are easy to clean and are resistant to deterioration from harsh disinfectants and aggressive cleaning products. However, be aware that the grout between them can sometimes harbour contaminating microorganisms, so must be disinfected regularly.

Wood should not be used, as it is not easy to clean or disinfect, and will deteriorate over time when repeatedly exposed to disinfectants and detergents. Wood also support the growth of contaminants when wet or damaged.

The disadvantage of using steel for benchtops is that steel will rust when washed with chlorine.

It is advisable to organize work benches according to the type of analysis that is performed, with adequate space for benchtop equipment and enough space to place a standard operating procedure while in use and display job aids. In areas where microbiology procedures are performed, work benches should be separated according to the different types of samples or pathogens that are analyzed, in order to minimize risks of cross-contamination.

Cleaning

It is very important that all areas of the laboratory are cleaned and maintained on a regular basis. Examples of areas that need daily attention are:

- Benchtops—clean and disinfect benchtops after completing examinations, and after any spills of samples or reagents. This responsibility is generally assigned to the technical staff performing the tests.
- Floors—these are usually cleaned by cleaning staff, unless restricted access allows only technical staff to disinfect the floors at the end of the day.

Other areas of the laboratory should be scheduled for cleaning on a weekly or monthly basis, depending on laboratory conditions. For example, ceilings and walls may require cleaning weekly, whereas items such as refrigerators and storage areas might be scheduled for a monthly cleaning.

Cleaning and disinfection of laboratory areas should be recorded, including the date and name of the person performing the maintenance.

2-5: Safety management programme

Developing a laboratory safety programme

Often, the responsibility for developing a safety programme and organizing appropriate safety measures for the laboratory is assigned to a laboratory safety officer. In smaller laboratories, the responsibility for laboratory safety may fall to the laboratory manager or even to the quality officer. The steps for designing a safety management programme include:

- developing a manual to provide written procedures for safety and biosafety in the laboratory;
- organizing safety training and exercises that teach staff to be aware of potential hazards and how to apply safety practices and techniques—training should include information about universal precautions, infection control, chemical and radiation safety, how to use personal protective equipment (PPE), how to dispose of hazardous waste, and what to do in case of emergencies;
- setting up a process to conduct risk assessments—this process should include initial risk assessments, as well as ongoing laboratory safety audits to look for potential safety problems.

General safety equipment

The safety officer should be assigned responsibility for ensuring that there is an adequate supply of appropriate equipment for safety and biosafety, such as:

- PPE
- fire extinguishers and fire blankets
- appropriate storage and cabinets for flammable and toxic chemicals
- eye washers and emergency shower
- waste disposal supplies and equipment
- first aid equipment.

Standard safety practices

Policies should be put in place that outline the safety practices to be followed in the laboratory. Standard laboratory safety practices include:

- limiting or restricting access to the laboratory;
- washing hands after handling infectious or hazardous materials and animals, after removing gloves, and before leaving the laboratory;
- prohibiting eating, drinking, smoking, handling contact lenses, and applying cosmetics in work areas;
- prohibiting mouth pipetting;
- using techniques that minimize aerosol or splash production when performing procedures—biosafety cabinets should be used whenever there is a potential for aerosol or splash creation, or when high concentrations or large volumes of infectious agents are used;

- preventing inhalation exposure by using chemical fume hoods or other containment devices for vapours, gases, aerosols, fumes, dusts or powders;
- properly storing chemicals according to recognized compatibilities—chemicals posing special hazards or risks should be limited to the minimum quantities required to meet short-term needs and stored under appropriately safe conditions (i.e. flammables in flammable storage cabinets)—chemicals should not be stored on the floor or in chemical fume hoods;
- securing compressed gas cylinders at all times;
- decontaminating work surfaces daily;
- decontaminating all cultures, stocks and other regulated wastes before disposal via autoclave, chemical disinfection, incinerator or other approved method;
- implementing and maintaining an insect and rodent control programme;
- using PPE such as gloves, masks, goggles, face shields and laboratory coats when working in the laboratory;
- prohibiting sandals and open-toed shoes to be worn while working in the laboratory;
- disposing of chemical, biological and other wastes according to laboratory policies.

Procedures and exercises

Monthly and yearly exercises must be organized for fire drills and laboratory evacuation procedures. This is an occasion for the safety officer to emphasize risks to laboratory staff and to review with them the specific procedures for evacuation, handling of incidents and basic security precautions.

Waste management

Laboratory waste management is a critical issue. All potentially harmful and dangerous materials (including liquids and radioactive materials) must be treated in a specific way before disposing. Separate waste containers should be used depending on the nature of the waste, and must be clearly identified by a colour code. Specific attention should be given to the management of potentially harmful contaminated waste such as sharps, needles or broken glassware. Sharps containers must be available on work benches so they are conveniently accessible to staff.

Internationally recognized labels

Many labels that give warnings and instructions for safety precautions are internationally recognized. A list of websites that provide these labels can be found in the references and resources section.

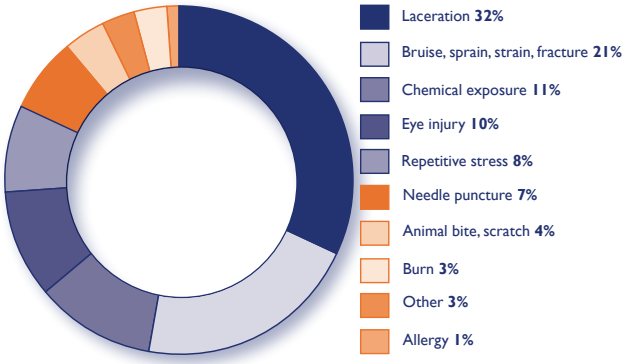
2-6: Identification of risks

Laboratories are hazardous environments

Laboratory workers encounter a significant number of risks, which vary with the types of activities and analyses that are performed.

Risk assessment is compulsory in order for the laboratory director to manage and reduce risks to laboratory employees. Assistance from a safety officer is needed to appreciate potential risks and incorporate appropriate preventive measures. It is important to develop safety procedures that describe what to do in case of accidents, injuries or contamination. In addition, it is important to keep a record of staff exposures to hazards, actions taken when this occurs, and procedures put into place to prevent future occurrences.

The outcome of a study of physical risks encountered by laboratory staff that was conducted by the Howard Hughes Medical Institute Office of Laboratory Safety is shown in the chart. This study only addressed physical risks, but personnel contamination and infection have been reported in many instances, and recent reports on laboratory-acquired infection leading to severe acute respiratory syndrome (SARS) show that the risks are never reduced to zero, even in high-confinement facilities.



Physical hazards

Laboratory equipment is a significant source of potential injury to laboratory staff, thus making training in specific safety procedures imperative. Examples of equipment in which safety training and precautions are important include autoclaves, centrifuges, compressed gas cylinders and fume hoods. Many laboratory instruments pose a danger of electrical shock, and some equipment can emit dangerous microwaves or radiation if not properly used or maintained.

Storage of compressed gases in the laboratory requires precautions unique to the unusual containers in which these materials are kept, and the high pressures they are subject to. Cylinders are kept chained to the wall so that they cannot fall over. The safety cap must be secured over the valve of the cylinder whenever it is moved or taken out of service.

Needles and sharps

Needles, broken glass and other sharps need to be handled and disposed of appropriately to prevent risks of infection to laboratory and housekeeping (custodial) staff. Instructions for proper disposal of sharps are:

- Avoid needle recapping. If recapping is crucial, the correct procedure is for the person doing the recapping to keep one hand behind the back of the needle, and use the other hand to scoop the cover onto the needle.
- Put sharps in a puncture-resistant, leak-proof sharps container. Label the container "Sharps". If the sharps are not biohazardous, deface any biohazard markings or symbols. Seal the container tightly.

Laboratory glassware and plasticware are not considered to be sharps for disposal purposes. Laboratory glassware and plasticware include any item that could puncture regular waste bags and therefore endanger waste handlers. Laboratory glass must be placed in cardboard boxes for safety during transport through the building. Any cardboard box may be used, provided it is sturdy and of a size that will not weigh more than 40 pounds when full.
Contaminated laboratory glass must be appropriately decontaminated prior to disposal.

Never use boxes for the disposal of:

- sharps
- biohazardous materials that have not been autoclaved
- liquid wastes
- chemically contaminated laboratory glassware or plasticware
- chemical containers that cannot be disposed of as regular solid waste.

Chemical hazards

Exposure to toxic chemicals poses a real threat to the health and safety of laboratory staff. There are three main routes by which chemicals enter the body.

- Inhalation—this is the major route of entry when working with solvents; there is great rapidity of absorption when fumes are inhaled.
- Absorption through skin—this may produce systemic poisoning; the condition of the skin determines the rate of absorption. Examples of chemicals with these risks are organic lead, solvents such as xylene and methylene chloride, organophosphate, pesticides and cyanides.
- Ingestion—accidental ingestion is generally due to poor hygiene practices, such as eating or smoking in the laboratory.

To prevent or reduce incidents caused by exposure to toxic chemicals, all chemicals, including solutions and chemicals transferred from their original containers, should be labelled with their common names, concentrations and hazards. Additional information, such as the date received, date opened and date of expiration, should also be recorded.

It is crucial that chemicals are stored properly. Store corrosive, toxic and highly reactive chemicals in a well-ventilated area, and store chemicals that can ignite at room temperature in a flammables cabinet.

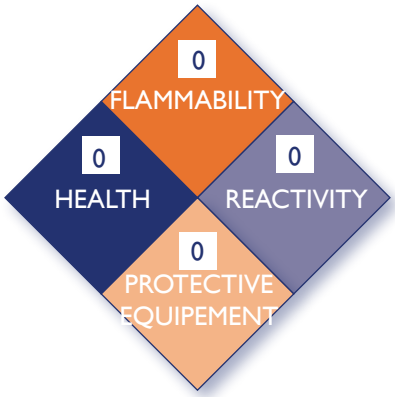
Radiochemicals require special precautions, and dedicated benches with specific bench covers for manipulation of radiolabelled elements are needed. Specific storage areas for radioactive materials are needed. These must provide appropriate protection (Plexiglas™, lead) and specific waste containers, depending on the chemical nature of waste and radioactive elements.

Material safety data sheet

The material safety data sheet (MSDS) is a technical bulletin providing detailed hazard and precautionary information.[1] Businesses are required to provide to their customers the MSDS for all chemicals they manufacture or distribute. Laboratories need to heed precautions listed in the MSDS in order to ensure the chemicals they use are handled and stored safely.

The MSDS provides:

- product information;
- fire and explosion precautions;
- toxicology;
- health effects;
- recommended PPE;
- storage recommendations;
- leaks and spills—recommended actions;
- waste disposal recommendations;
- first aid.



The MSDS should be:

- available to all employees prior to use of hazardous materials;
- kept close to where the hazardous material is used and located.

Biological hazards

Laboratory-acquired infections are not infrequent in medical laboratories. The following tables show the most frequently reported infections acquired in laboratories in the United States of America from 1979 to 1999.[2]

1 ISO 15190:2003. *Medical laboratories—requirements for safety*. Geneva: International Organization for Standardization, 2003.

2 Harding AL, Brandt Byers K. Epidemiology of laboratory-associated infections. In: Fleming, DO, Hunt DL, eds. *Biological safety: principles and practices*. Washington, DC, ASM Press, 2000, 35–54.

Disease or agent	No. of cases
Mycobacterium tuberculosis	223
Q fever	176
Hantavirus	169
Hepatitis B	84
Brucella sp.	81
Salmonella sp.	66
Shigella sp.	56
Hepatitis non-A, non-B	28
Cryptosporidium sp.	27
Total	910

Disease	Probable source	Maximum distance from source	No. infected
Brucellosis	Centrifugation	Basement to 3rd floor	94
Coccidioidomycosis	Culture transfer, solid media	2 building floors	13
Coxsackie virus infection	Spilled tube of infected mouse tissue on floor	5 feet estimated	2
Murine typhus	Intranasal inoculation of mice	6 feet estimated	6
Tularemia	20 petri plates dropped	70 feet	5
Venezuelan encephalitis	9 lyophilized ampoules dropped	4th floor stairs to 3rd or 5th floor	24

Aerosols are the main sources of contamination within diagnostic laboratories; contamination can occur over very long distances. This is why the major target of containment systems is the blockage of aerosol diffusion inside and outside the laboratory. Diagnostic laboratories of physical containment level 2, where activities concern only pathogens of moderate risks, must have appropriate ventilation. Higher containment level laboratories or working cabinets must ensure a continuous inward airflow, as well as absolute filtration of exhausted air, to avoid aerosol dissemination outside the working area or the whole laboratory.[1]

1 Reitman M, Wedum AG. Microbiological safety. *Public Health Reports*, 1956, 71(7):659–665.

2-7: Personal protective equipment

Basic information

The major routes by which laboratory staff acquire work-related infections are:

- percutaneous inoculation
- contact between mucous membranes and contaminated material
- accidental ingestion.

To reduce the risk of these occurrences, it is imperative that staff have access to PPE, be trained in how to properly use it, and habitually use the PPE while working in the laboratory. Approved goggles, face shields, splatter guards, masks, or other eye and face protection should be worn when handling infectious or other hazardous materials outside the biosafety cabinet.

Hand protection

Gloves should be worn in all instances, and should be available to laboratory staff on a routine basis. Effective use of gloves relies on two simple practices.

1. Remove gloves when leaving the working area to prevent contamination of other areas such as the telephone, door handles and pens.
2. Never reuse gloves. Do not attempt to wash or decontaminate gloves—they will develop microcracks, become more porous and lose their protective properties. After use, gloves **must** be disposed of in the contaminated waste.

Face protection

Goggles—The projection of droplets is a frequent occurrence when opening patient sample containers. Protection of eyes with goggles is strongly recommended as a routine procedure to prevent contact with these droplets.

Another way to protect eyes and other mucous membranes from projection is to manipulate the specimen tubes behind a screen (glass or Plexiglas™) or face shield. This equipment should be compulsory when manipulating dangerous liquids, such as liquid nitrogen or some solvents.

Contact lenses do not offer protection from splashes. Additional eye protection must be worn with contact lenses.

Masks—Masks serve as a barrier when splashes or sprays occur. Furthermore, in order to reduce laboratory workers' respiratory exposure to airborne highly dangerous pathogens, it is recommended to use fit-tested particulate respirators with adequate filtering (e.g. EU FFP2, US NIOSH-certified N95) during specimen collection or handling.

Body protection

Laboratory coats are compulsory in all instances in the physical containment level 2 laboratory. Be aware of the composition of fabrics, as some might be highly flammable.

A disposable laboratory coat is compulsory in physical containment level 3 laboratories or in specific instances such as sample collection when highly dangerous pathogens can be involved, such as suspected cases of H5N1 avian influenza or SARS.

2-8: Emergency management and first aid

Emergencies

Laboratories need to have procedures in place for how staff should deal with accidents and emergencies. General written procedures for first aid should be developed and made available to all staff so they know the first things to do, and who to call or notify in case of minor cuts and bruises, major wounds or skin contamination.

Chemical spills

A chemical spill is considered to be **minor** only if the person who spilled it is familiar with the chemical, knows the associated hazards and knows how to clean up the spill safely. The recommended steps for dealing with a minor spill include:

- alert coworkers, then clean up spill;
- follow procedures for disposal of materials used to clean up spill;
- absorb free liquids with an appropriate absorbent, as follows
  - caustic liquids—use polypropylene pads or diatomaceous earth
  - oxidizing acids—use diatomaceous earth
  - mineral acids—use baking soda or polypropylene pads
  - flammable liquids—use polypropylene pads;
- neutralize residues and decontaminate the area.

Anything beyond a minor spill and that requires help from outside of the laboratory group constitutes a **major** spill. Steps to deal with major spills include alerting coworkers, moving to a safe location and calling authorities to report the situation.

Biological spills

When **surfaces are contaminated** by biological spills, the appropriate actions to take are:

1. Define/isolate the contaminated area.
2. Alert coworkers.
3. Put on appropriate PPE.
4. Remove glass/lumps with forceps or scoop.
5. Apply absorbent towel(s) to the spill; remove bulk and reapply if needed.
6. Apply disinfectant to towel surface.
7. Allow adequate contact time (20 minutes).
8. Remove towel, mop up, and clean the surface with alcohol or soap and water.
9. Properly dispose of materials.
10. Notify the supervisor, safety officer, and other appropriate authorities.

Disinfectant: For most spills, use a 1:50 solution (1 g/l chlorine) of household bleach (sodium hypochlorite solution containing 50 g/l chlorine).

For spills containing large amounts of organic material, use a 1:10 solution (5 g/l chlorine) of household bleach, or an approved mycobactericidal.[1] Suggested sources of mycobactericidals are registered with the United States of America Environmental Protection Agency (http://www.epa.gov/oppad001/chemregindex.htm).

Alcohols are not recommended as surface decontaminating agents because they evaporate quickly, thus decreasing contact time.

If **laboratory personnel become contaminated** with biological hazards due to splashes or spills, immediate steps to take include:

1. Clean exposed skin or body surface with soap and water, eyewash (for eye exposures) or saline (for mouth exposures).
2. Apply first aid and treat as an emergency.
3. Notify supervisor, safety officer, or security desk (after hours).
4. Follow appropriate reporting procedures.
5. Report to physician for treatment or counselling.

Laboratory fires

Laboratory personnel need to be alert for conditions that might pose a risk for fires. Keep in mind that liquids with low flash points may ignite if they are near heat sources such as hotplates, steam lines or equipment that might produce a spark or heat.

A small laboratory fire is considered to be one that is extinguishable within 1–2 minutes. The appropriate action to take is to cover the fire with an inverted beaker or wet paper towels. If this fails, use a fire extinguisher. For large fires, call the appropriate local authorities, usually the fire department and the police department.

Laboratories should have the appropriate class of extinguisher for the fire hazards in the laboratory. In general, a class BC or class ABC extinguisher is appropriate. Fire extinguishers must be inspected annually and replaced as needed. Laboratory personnel should be trained in the various classes of fires and basic fire extinguisher use in annual laboratory safety and hazardous waste management training.

All laboratory personnel must learn how to operate a portable fire extinguisher.

1 See World Health Organization. *Laboratory biosafety manual,* 3rd ed. Geneva, WHO, 2004

2-9: Summary

Summary

When designing a laboratory or organizing workflow, ensure that patients and patient samples do not have common pathways. To identify where improvements in laboratory design may be needed in order to prevent or reduce risks of cross-contamination, follow the path of the sample as it moves through the laboratory during the pre-examination, examination and post-examination phases of testing.

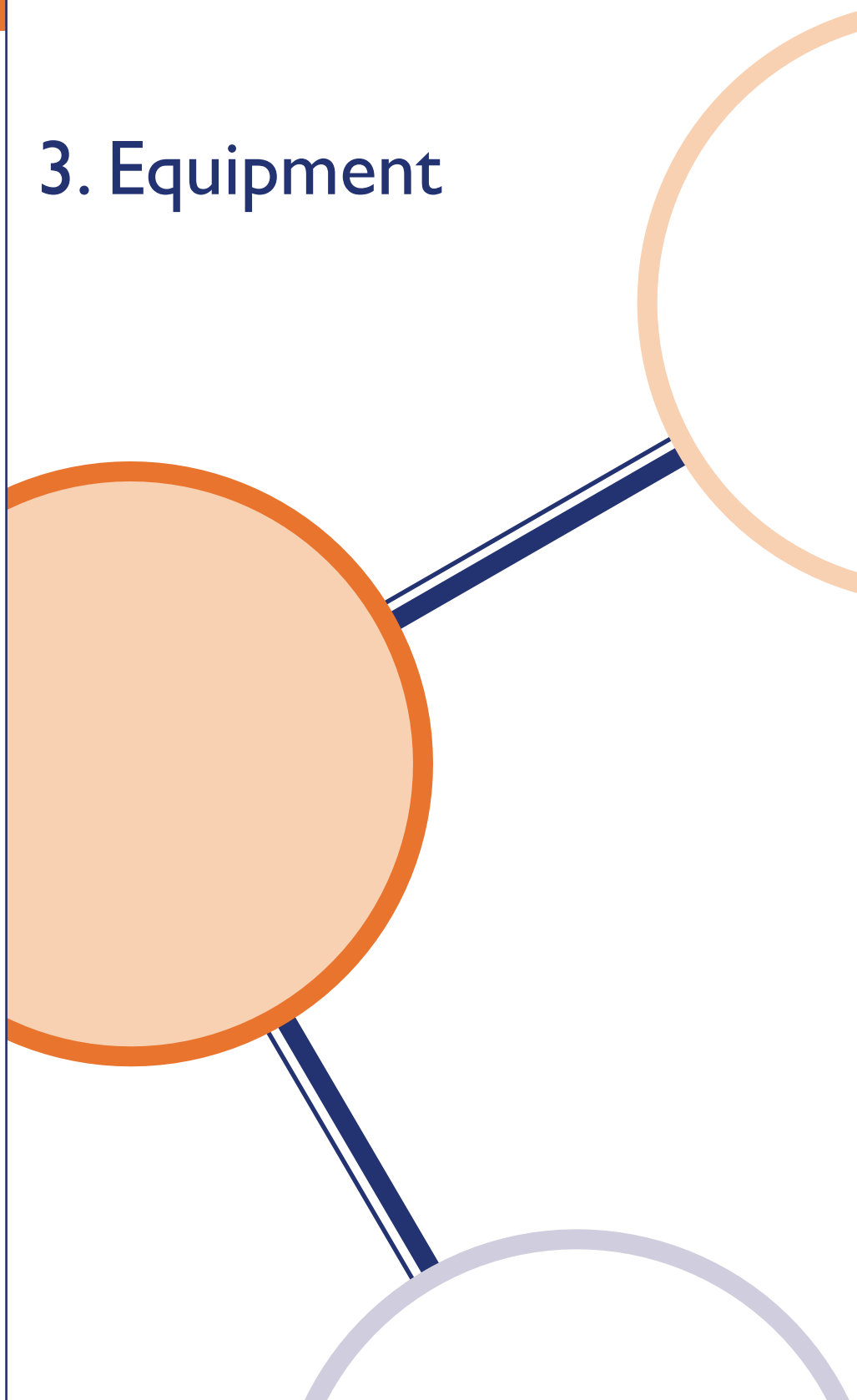
The design of laboratory work areas should ensure proper ventilation and surfaces that can be cleaned and disinfected.

In establishing a safety management programme, it is important to appoint a responsible supervisor. The laboratory should have a safety manual that establishes policy and describes standard procedures for handling safety and emergency issues. Personnel need to be trained in how to apply safety practices and techniques, and to be aware of potential hazards.

Key message

Neglecting laboratory safety is costly. It jeopardizes the lives and health of employees and patients, laboratory reputation, equipment and facilities.

3. Equipment



3-1: Overview

Role in quality management system

Equipment management is one of the essential elements of a quality management system. Proper management of the equipment in the laboratory is necessary to ensure accurate, reliable and timely testing. The benefits of a good equipment management programme are many:

- helps to maintain a high level of boratory performance;
- reduces variation in test results, nd improves the technologist's confidence in the accuracy of testing results;
- lowers repair costs, as fewer repairs will be needed for a well-maintained instrument;
- lengthens instrument life;
- reduces interruption of services due to breakdowns and failures;
- increases safety for workers;
- produces greater customer satisfaction.

Program considerations

A great deal of thought and planning should go into equipment management. As the laboratory puts an equipment management programme in place, the following elements should be considered.

- Selection and purchasing—When obtaining new equipment, what criteria should be used to select equipment? Should equipment be purchased or would it be better to lease?
- Installation—For new equipment, what are the installation requirements and who will install the new instrument?
- Calibration and performance evaluation—What is needed to calibrate the equipment and validate that it is operating correctly? How will these important procedures be conducted for both old and new instruments?
- Maintenance—What maintenance schedule is recommended by the manufacturer? Will the laboratory need additional preventive maintenance procedures? Are current maintenance procedures being conducted properly?
- Troubleshooting—Is there a clear procedure for troubleshooting for each instrument?
- Service and repair—What is the cost? Can the laboratory obtain the necessary service and repair in its geographical area?
- Retiring and disposing of equipment—What must be done to dispose of old equipment when it needs to be replaced?

Oversight

It is the responsibility of the laboratory director to:

- oversee all the equipment management systems in the laboratory;
- ensure that all persons who will be using the instruments have been appropriately trained and understand how to both properly operate the instrument and perform all necessary routine maintenance procedures.

Equipment management responsibility may be specifically assigned to a technologist in the laboratory. In many laboratories, there is a person who has good skills with equipment maintenance and troubleshooting. Giving this person the role of oversight of all equipment is recommended.

Oversight of an equipment management programme includes:

- assigning responsibilities for all activities
- ensuring that all personnel are trained in operation and maintenance
- monitoring the equipment management activities, including
  - reviewing all equipment records routinely
  - updating maintenance procedures as necessary
  - ensuring that all procedures are followed.

Note: day-to-day maintenance should be the responsibility of the technical operator. Everyone who uses the equipment should be trained in calibration and daily maintenance.

3-2: Selecting and acquiring equipment

Selecting equipment

Selecting the best instrument for the laboratory is a very important part of equipment management. Some criteria to consider when selecting laboratory equipment are listed below.

- Why and how will the equipment be used? The instrument should be matched against the service the laboratory provides.
- What are the performance characteristics of the instrument? Is it sufficiently accurate and reproducible to suit the needs of the testing to be done?
- What are the facility requirements, including the requirements for physical space?
- Will the cost of the equipment be within the laboratory's budget?
- Will reagents be readily available?
- Will reagents be provided free of charge for a limited period of time? If so, for how long?
- How easy will it be for staff to operate?
- Will instructions be available in a language that is understood?
- Is there a retailer for the equipment in the country, with available services?
- Does the equipment have a warranty?
- Are there any safety issues to consider?

If the decisions about purchasing are made outside the laboratory (e.g. by a central purchasing body), the laboratory manager should provide information that will support selecting equipment that will best serve the needs of the laboratory. In areas where there are national programmes for purchasing standard equipment, the laboratories of the country should have some input to decisions. In addition, in areas where donors are likely to provide some of the equipment that is used, laboratory management should have input into the choice of equipment. If this is not possible, management should consider declining equipment if it is inappropriate for laboratory needs.

Acquiring equipment

Is it better to purchase or lease equipment? When making this decision, it is a good idea to factor in repair costs. The manufacturer should provide all of the necessary information to operate and maintain equipment. The initial cost of an instrument may seem reasonable, but it may be expensive to repair. Also consider savings that could be negotiated if the laboratory needs more than one piece of equipment.

Before purchasing ask if:

- wiring diagrams, computer software information, a list of parts needed, and an operator's manual are provided;
- the manufacturer will install the equipment and train staff (covering travel expenses as necessary) as part of the purchase price;

- the warranty includes a trial period to verify that the instrument performs as expected;
- the manufacturer's maintenance can be included in the contract and, if so, whether maintenance is provided on a regular basis.

Determine if the laboratory can provide all the necessary physical requirements, such as electricity, water, and space. There must be adequate room to move the equipment into the laboratory; consider door openings and elevator access.

Installing equipment

Before equipment is installed, verify that all physical requirements (electrical, space, doors, ventilation and water supply) have been met.

Other things to consider are:

- The vendor's responsibilities for installation should be confirmed **in** writing prior to beginning the installation process.
- A checklist of the expected performance specifications should be developed, so that performance can be quickly verified as soon as the equipment is installed.

Whenever possible, it is best to have the manufacturer install laboratory equipment; this will likely improve the conditions of the warranty, and also may ensure that the installation is done properly and quickly.

If equipment is installed by the laboratory:

- check that the package contents contain all of the parts;
- make a copy of any software that is part of the system;
- do not allow the equipment to be used before it is completely installed, performance is verified and testing personnel are trained.

3-3: Getting equipment ready for service

After installation

After equipment has been installed, the following details need to be addressed before putting the equipment into service.

- Assign responsibility for performing the maintenance and operation programmes.
- Develop a system for recording the use of parts and supplies (see Chapter 4).
- Implement a written plan for calibration, performance verification, and proper operation of the equipment.
- Establish a scheduled maintenance programme that includes daily, weekly and monthly maintenance tasks.
- Provide training for all operators; only personnel who have been trained specifically to properly use the equipment should be authorized as operators.

Designate those authorized to use the equipment and when it is to be used.

Equipment calibration

Follow the manufacturer's directions carefully when performing the initial calibration of the instrument. It is a good idea to calibrate the instrument with each test run, when first putting it into service. Determine how often the instrument will need to be recalibrated, based on its stability and the manufacturer's recommendation. It may be advantageous to use calibrators provided by or purchased from the manufacturer.

Performance evaluation

Prior to testing patient specimens, it is important to evaluate the performance of new equipment to ensure it is working correctly with respect to accuracy and precision.

In addition, test methods using kits or laboratory instruments need to be evaluated for the ability to detect disease (sensitivity, specificity, positive and negative predictive value) and to determine normal and reportable ranges.

Verification of manufacturers' performance claims—Manufacturers provide performance evaluations for testing methods using their kits or instruments, and include the information in the package inserts or operator's manuals. However, laboratories need to verify the manufacturer's performance claims, and demonstrate they can get the same results using the kits or equipment in their laboratory, with their personnel.

Some of the steps that should be followed to verify performance include:

- testing samples with known values and comparing the results to the expected or certified value;
- if equipment is temperature controlled, establishing the stability and uniformity of the temperature.

Validation of new equipment and associated techniques—If the equipment and associated techniques are new, validation processes will be important. Validation can be carried out by running samples in parallel using both old and new equipment and methods for a period of time to determine that the expected results can be obtained. These validation procedures should be completely recorded.

Function checks

In order to verify that equipment is working according to the manufacturer's specifications, it is necessary to monitor instrument parameters by performing periodic function checks. This should be done before using the instrument initially, then with the frequency recommended by the manufacturer. These function checks should also be done following any instrument repairs. Some examples of function checks are daily monitoring of temperatures and checking the accuracy of wavelength calibration.

3-4: Implementing an equipment maintenance programme

Preventive maintenance

Preventive maintenance includes measures such as systematic and routine cleaning, adjustment and replacement of equipment parts at scheduled intervals. Manufacturers generally recommend a set of equipment maintenance tasks that should be performed at regular intervals: daily, weekly, monthly or yearly. Following these recommendations will ensure that the equipment performs at maximum efficiency and will increase the lifespan of the equipment. This will also help to prevent:

- inaccurate test results due to equipment failure
- delays in reporting results
- low productivity
- large repair costs.

Maintenance plan

A maintenance plan will include preventive maintenance procedures as well as provision for inventory, troubleshooting and repair of equipment. When implementing an equipment maintenance program, some of the initial steps will include:

- assigning responsibility for providing oversight;
- developing written policies and procedures for maintaining equipment, including routine maintenance plans for each piece of equipment that specify the frequency with which all maintenance tasks should be performed;
- developing the format for records, creating logs and forms, and establishing the processes to maintain records;
- training staff on the use and maintenance of the equipment, and ensuring that all staff understand their specific responsibilities.

It is recommended that a label is attached to the instrument indicating when the next maintenance or service should be performed.

Equipment inventory

The laboratory should keep an inventory log of all equipment in the laboratory. The log should be updated with information on new equipment and include documentation of when old equipment is retired. For each piece of equipment, the equipment inventory log should have a record of:

- instrument type, make and model number, and serial number so that any problems can be discussed with the manufacturer;
- date the equipment was purchased, and whether it was purchased new, used or reconditioned;
- manufacturer/vendor contact information;
- presence or absence of documentation, spare parts and maintenance contract;
- warranty's expiration date;
- specific inventory number indicating the year of acquisition (this is especially useful for larger laboratories); for example, use the style "YY-number" (04-001, 04-002, etc.) where "YY-number" equals the last two numbers of the year followed by a number attributed in the year.

An inventory process must be conducted if the laboratory does not have an existing inventory system for equipment. This could be conveniently organized following a model grid, room by room; for example, conduct an inventory of equipment in the reception area, then the sample collection area, the serology testing area, and the parasitology testing area. During the inventory, the condition of the equipment should be documented as functional, partially functional or nonfunctional. Equipment that is not functioning needs to be evaluated as to whether or not it can be repaired. Nonrepairable equipment should be retired, and work should be scheduled for equipment needing repair.

Inventory of spare parts

To ensure that the laboratory does not run out of spare parts, an inventory record of those used most frequently should be kept for each piece of equipment. The record should include:

- part name and number;
- average use of the part, and the minimum to keep on hand;
- cost;
- date when the part is placed into storage and when it is used (in and out stock log);
- quantity of each part remaining in inventory.

3-5: Troubleshooting, servicer repair and retiring equipment

What is the source of the problem?

Problems with equipment may present in many ways. The operator may notice subtle changes such as drift in quality control or calibrator values, or obvious flaws in equipment function. Sometimes, the equipment fails to operate. It is important to teach operators to troubleshoot equipment problems in order to quickly get the equipment functioning and resume testing as rapidly as possible.

When an operator observes instrument drift, it is important to repeat the preventive maintenance procedures as a first step to resolve the problem. If this does not work, proceed with troubleshooting processes.

Troubleshooting

Manufacturers frequently provide a flowchart that can help determine the source of problems. Some of the questions to consider are listed below.

- Is the problem related to a poor sample? Has the sample been collected and stored properly? Are factors such as turbidity or coagulation affecting instrument performance?
- Is there a problem with the reagents? Have they been stored properly, and are they still in date? Have new lot numbers been introduced without updating instrument calibration?
- Is there a problem with the water or electrical supply?
- Is there a problem with the equipment?

Make one change at a time based on symptoms. If the equipment is the problem, review the manufacturer's instructions to verify that all procedures are being followed correctly.

When problems cannot be corrected

If problems cannot be identified and corrected in-house, attempt to find a way to continue testing until the equipment can be repaired. Some ways to achieve this are as follows.

- Arrange to have access to backup instruments. It is often too costly for the laboratory to have its own backup instruments, but sometimes a central stores agency can maintain backup instruments to be shared throughout the local area or country.
- Ask the manufacturer to provide a replacement instrument during repairs.
- Send the samples to a nearby laboratory for testing.

Be sure to notify the appropriate providers that there are problems and that there will probably be delays in completing the testing.

Service and repair

Do not use faulty equipment! Seek help from the manufacturer or other technical expert. Place a note on the equipment so all staff are aware that it is not in use.

Manufacturers may provide service and repair of equipment that is purchased from them. Be sure to set up a procedure for scheduling service that must be periodically performed by the manufacturer. When instruments need repair, remember that some warranties require that repairs be handled only by the manufacturer. Large facilities sometimes have biomedical service technicians in-house who perform equipment maintenance and repair.

Retiring and disposing of equipment

Routine service should be scheduled so as not to interrupt the flow of work.

It is very important to have a policy and procedure for retiring older laboratory equipment. This will usually occur when it is clear that the instrument is not functioning and is not repairable, or when it is outmoded and should be replaced with new equipment.

Once a piece of equipment is fully retired and it has been determined that it has no further use, it should be disposed of in an appropriate manner. This last step is often neglected in laboratories and old equipment accumulates, taking up valuable space and sometimes creating a hazard.

When disposing of equipment, salvage any usable parts, particularly if the equipment is being replaced with another similar one. Then consider any potential biohazards and follow all safety disposal procedures.

3-6: Equipment maintenance documentation

Developing documents and policies for recordkeeping

Equipment documents and records are an essential part of the quality system. The policies and procedures for maintenance should be defined in appropriate documents, and keeping good equipment records will allow for thorough evaluation of any problems that arise (see Chapter 16).

Each major piece of equipment will have its own equipment maintenance document. Smaller, commonly used equipment such as centrifuges and pipettes may be managed with an equipment maintenance document or manual that deals with all such equipment in the laboratory. An equipment maintenance document should include:

- step-by-step instructions for routine maintenance, including frequency of performance and how to keep records of maintenance;
- instructions for carrying out function checks, frequency of performance, and how to record the results;
- directions for calibrating the instrument;
- guide for troubleshooting;
- any required manufacturer's service and repair;
- list of any specific items needed for use and maintenance, such as spare parts.

For major equipment, include identification of the specific instrument and perhaps information on its performance.

Recording maintenance information

Each piece of equipment should have a dedicated logbook documenting all characteristics and maintenance elements, including:

- preventive maintenance activities and schedule;
- recording of function checks and calibration;
- any maintenance performed by the manufacturer;
- full information on any problem that the instrument develops, the subsequent troubleshooting activity and follow-up information regarding resolution of the problem. In recording problems, be sure to record
  - date problem occurred and when equipment was removed from service;
  - reason for breakdown or failure;
  - corrective action taken, including a note about any service provided by the manufacturer;
  - date returned to use;
  - any changes to procedure for maintenance or function checks as a result of the problem.

Some of the tools that are helpful for keeping records of equipment management are:

- charts
- logs
- checklists
- graphs
- service reports.

The logbook should be available for review during the entire life of the equipment.

3-7: Summary

Summary

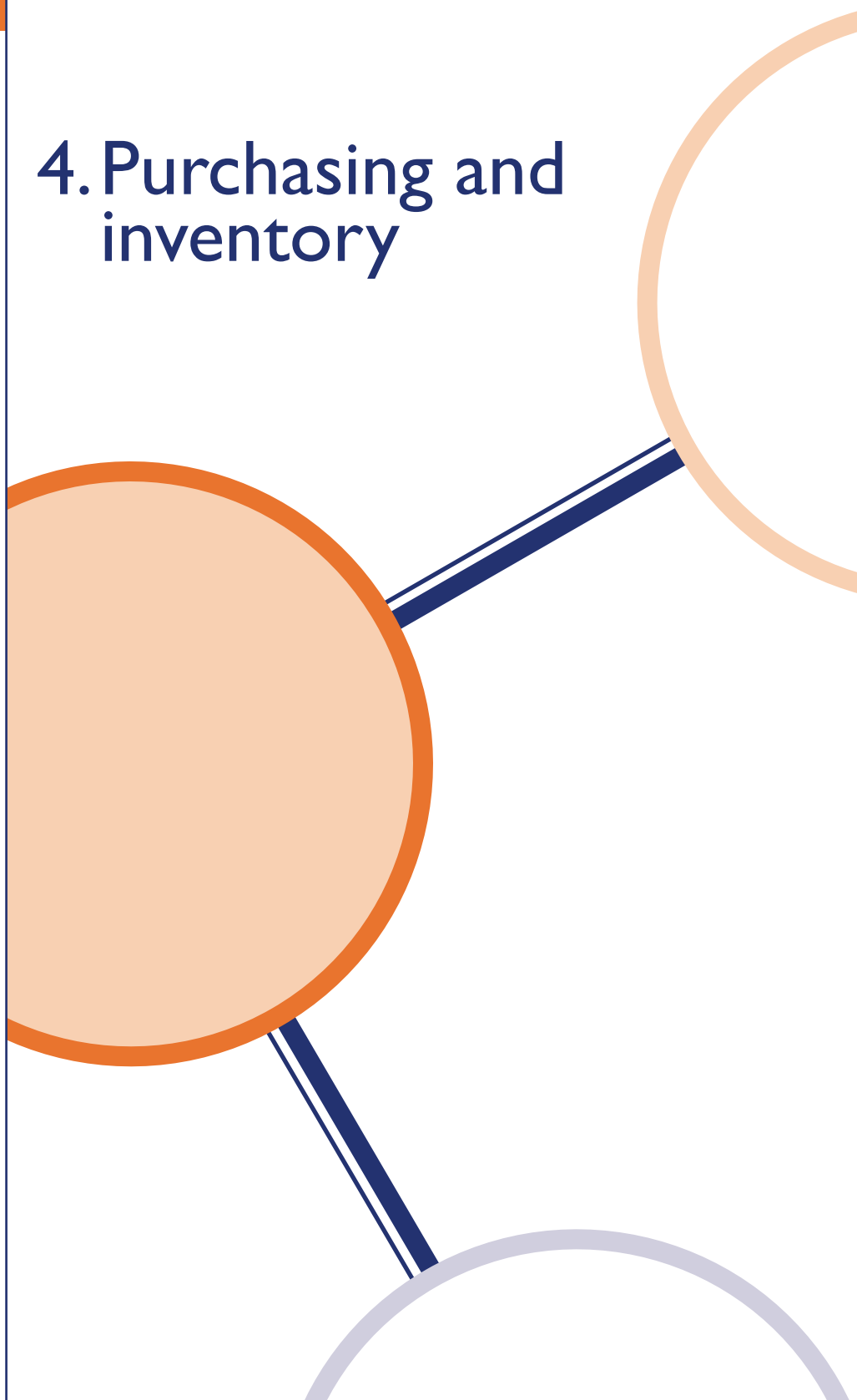
All laboratories should have a well-organized equipment management programme. The programme should address equipment selection, preventive maintenance, and procedures for troubleshooting and repair.

It is essential that good documents and records be maintained. These will include a complete and accurate inventory of all laboratory equipment, documents provided by the manufacturer on operation, maintenance and troubleshooting, and records of all preventive maintenance and repair activities.

Key messages

- A good equipment maintenance programme results in a high level of performance and greater confidence in the reliability of results.
- A significant benefit to the laboratory will be fewer interruptions in test performance, lower repair costs and elimination of premature replacement of equipment.
- Increased safety for laboratory workers will result from well-maintained equipment.

4. Purchasing and inventory



4-1: Overview

Role in quality management system

Purchasing and inventory management is a critical and essential component of the quality management system.

Efficient and cost-effective laboratory operations need the uninterrupted availability of reagents, supplies and services. Inability to test, even for a short time, is very disruptive to clinical care, prevention activities and public health programmes.

Benefits

Careful management of inventory helps to prevent waste, which can occur if reagents and supplies are stored improperly, or if reagents become outdated before they can be used. Establishing a purchasing and inventory management programme will ensure that:

- supplies and reagents are always available when needed;
- high-quality reagents are obtained at an appropriate cost;
- reagents and supplies are not lost due to improper storage, or kept and used beyond expiration.

Considerations

Methods for obtaining reagents and supplies vary considerably between laboratories. Some laboratories may purchase directly but, in many countries, a national procurement system is in place with a central stores area that distributes directly to the laboratories. Also, in many places, donors have a major role in the procurement of supplies and reagents.

The laboratory system for managing the reagents and supplies must take into account these variables.

Challenges

The challenge of inventory management is balancing the availability of supplies and reagents in stock with their expiration dates. The lifespan of reagents can vary from a few weeks to a number of years. It is important to continuously monitor the expiration dates to make sure needed reagents are always on hand and have not expired. However, it is too costly and wasteful to overstock.

Equipment and supplies received or accepted from donors must meet the clients' needs and the operational needs of the laboratory. Managers may sometimes need to refuse donations, but this should be done in a diplomatic way to ensure future offers are not discouraged.

Key components

Successful purchasing and inventory management requires that policies and procedures be established for managing all critical materials and services. Some of the key components to address are:

- vendor/manufacturer qualifications;
- purchase agreements;
- receiving, inspecting, testing, storing, and handling of materials—all purchased material should be inspected and appropriately tested to ensure that specifications are met, and policies should be established for storing and handling materials as they are delivered to the laboratory;
- tracking materials to individual patients—the management system must allow for tracking materials to individual patients; that is, the laboratory should be able to identify specific test materials used for performing tests on any given day, so that if there is a problem with a patient result, the laboratory will know what reagents were used;
- assessing and maintaining inventory;
- controlling expiration periods;
- dispatching supplies to satellite laboratories.

4-2: Purchasing

Selecting vendors

It is very important to set expectations and build and maintain relationships with providers of materials and services. Laboratories that purchase directly should look very carefully at vendors' and manufacturers' qualifications, examining such things as specifications and methods of transport. Laboratories that receive reagents and supplies from a central stores area managed by their government should interact with those managing the central stores area to accomplish these same objectives.

At the outset, the laboratory should:

- define criteria for supplies or materials to be purchased;
- look for the best price, taking into account the qualifications and credibility of the supplier;
- consider the advantages and disadvantages of purchasing "brand name" compared to "generic" products (e.g. is it better to purchase specific pipette tips for a specific pipette, or is it just as effective to use generic pipette tips that cost less?).

It may be useful to seek information from other laboratories when considering quality, reliability of supply, and cost.

It is equally important to evaluate vendors after purchase. Consider such factors as whether the vendor delivered the specified goods, or whether the central procurement body assured that user specifications were met.

Considerations

When setting up procedures for purchasing, there are a number of considerations.

- Understand any local or national government requirements that need to be accommodated in the contracts.
- Negotiate for the best price without undermining quality.
- Carefully review all contracts to make sure the laboratory's requirements are being met. Contracts should clearly address payment mechanisms and provisions to assure reliable availability and delivery of reagents and supplies. Ask if there are penalties for ending a contract.
- Determine how payments will be made, and how the vendor will assure reliable availability and delivery of supplies and reagents.

4-3: Implementing an inventory management programme

Implementation steps

In establishing an inventory control programme there are a number of factors to consider. A system should be designed so that the laboratory can closely monitor the condition of all supplies and reagents, know what quantities are available and be alerted when there is a need to reorder.

The following are important steps for implementation.

- Assign responsibility—without this, nothing may get done.
- Analyze the needs of the laboratory.
- Establish the minimum stock needed for an appropriate time period.
- Develop needed forms and logs.
- Establish a system for receiving, inspecting and storing supplies.
- Maintain an inventory system in all storage areas, and for all reagents and supplies used in the laboratory.

Analyze needs

A laboratory needs a process for analyzing its needs for materials and for determining how many kits for a particular test should be on hand.

The laboratory should make a list of all the tests it performs and identify all the supplies and reagents that are needed for each test. It is wise to use all available information to help estimate the usage of supplies and reagents for the period of time between ordering new materials. The information necessary for analyzing needs includes:

- a complete description of each item used;
- the package count or number of units in which the item is supplied (e.g. a kit can include 12 tests or 100 tests, and pipette tips can be packaged as 100 per box or 1000 per box);
- approximate usage per month (quantification, e.g. 6 boxes used per month);
- the priority or importance level the item has in doing the work of the laboratory (e.g. used every day or only once a month?);
- length of time required to receive a delivery (will the order take a day, week or month to arrive?);
- storage space and conditions (will a bulk order use too much storage space? Does the item require storage in a refrigerator?).

4-4: Quantification

Why?

How can a laboratory determine how much of any particular item to order?

Quantification is a very important process that can help calculate how much is required of any particular item for a given period of time, and it is an essential part of a successful inventory management programme. Accurate quantification will:

- ensure essential supplies will be available when needed
- prevent overstocking, which can lead to wastage of expensive materials.

Quantification provides information for:

- estimating annual budget requirements;
- allowing for better planning;
- making decisions and monitoring performance of the inventory management system.

When?

Quantification is performed when making annual plans for the laboratory and this planning will take into account the usual usage of supplies and reagents.

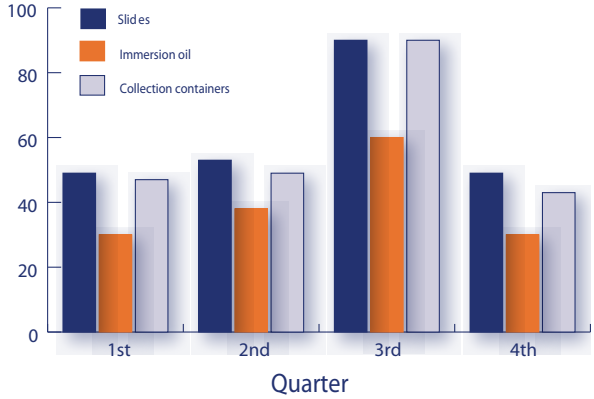
There are times when it is important to consider how new demands on the laboratory will create a need for greater testing volume. This often occurs when new health programmes are being implemented, and in preparation for epidemics, either identified or potential.

How?

The two frequently used methods are consumption-based quantification and morbidity-based quantification.

Consumption-based quantification

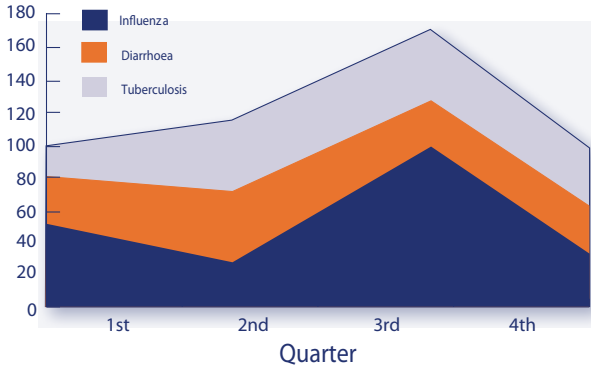
Laboratories most frequently use the consumption-based method, drawing on their experience over time. This method is based on actual consumption, so there are a number of factors to consider. For example, to determine the actual usage, it is important to also estimate how much wastage has occurred and how many expired or spoiled reagents and supplies have been discarded. An example of this type of monitoring is shown below.



For planning, it is a good idea to consider whether any supplies or reagents have been out of stock for more than 15 days during any time of the year. This may mean that supplies are not ordered in sufficient quantities, or that the wastage or expiry is higher than predicted.

Morbidity-based quantification

In using the morbidity-based quantification method (shown below), the laboratory must take into account the actual number of episodes, illnesses and health problems that require laboratory testing. In other words, the laboratory needs to estimate an expected frequency of the disease in question—how many cases will occur per unit of population (per 1000, per 10 000, etc.)? Then, considering how many people the laboratory serves, it can estimate the total number of cases the community might reasonably expect to observe. Using standard guidelines for diagnosis and treatment, and considering how well health care providers adhere to these guidelines, can help to estimate how many laboratory tests will be performed.



A good morbidity-based quantification method is more accurate than the quantification by consumption method, but it depends on accurate data.

4-5: Forms and logs

Developing forms and logs

Developing an appropriate record-keeping system is an important step for inventory management. Good tools for managing the stock include:

- standardized forms
- card systems
- log books.

For any system that is used, the following information should be recorded:

- date reagent or set of supplies are received;
- lot numbers for all supplies, reagents and kits;
- pass or fail acceptance criteria;
- date the lot number or box of supplies was put into service or, if not usable, the date and method of disposition.

Logbook

The stock logbook or card system will provide a way to keep track of all supplies and reagents that are on hand at any given time. In addition to information mentioned above, it is a good idea to record:

- name and signature of the person receiving the materials
- date of receipt
- expiration date
- quantity of the material received
- minimum stock that should be on hand
- current stock balance.

Additional information to record could include:

- shelf number or name
- destination (e.g. to –20 °C freezer to media room).

It is a good idea to keep the stock logbook in the storage area.

4-6: Receipt and storage of supplies

Receiving and inspecting supplies

A system should be established so when supplies are received, personnel know what is expected. All supplies and reagents should be inspected as they arrive in the laboratory to be sure that they are in good condition and to verify that what is received is what was ordered.

In addition, the person receiving supplies should:

- sign their name verifying receipt of goods
- date each item received
- note expiration date
- store new shipment behind existing shipment
- create or update logbook records.

Storage

Storage of reagents and supplies is a very important part of inventory control. Good practices to keep in mind are:

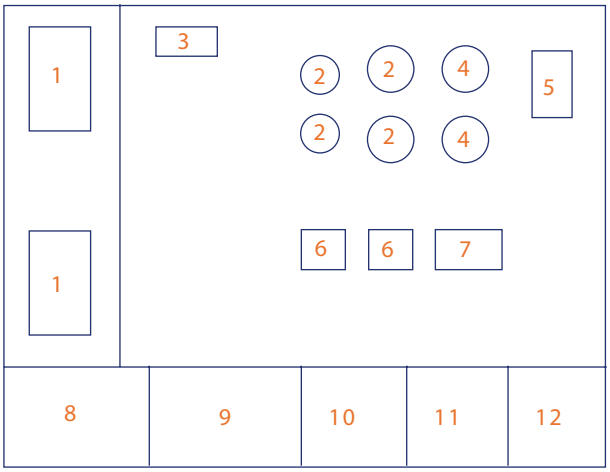
- Keep the storeroom clean, organized and locked to protect the inventory.
- Make sure storage areas are well ventilated and protected from direct sunlight.
- Ensure storage conditions are in accordance with the manufacturer's instructions, paying particular attention to any temperature requirements or other specifications, such as safety requirements.
- Use good shelving strong enough to support items, and organize items carefully on the shelves to prevent movement shifts or falls. Shelves should be attached firmly to support walls to prevent tipping.
- Ensure items are accessible to staff. Sturdy step stools should be available for reaching higher shelves and heavier items should be stored on lower shelves; laboratory staff should not be required to lift heavy items.
- When storing, put the new shipment behind existing materials that are already in the laboratory. Organize the reagents and materials so that the older materials get used first (i.e. items with the first expiry dates are the first used).

Organization of shelves

Labelling shelves is a useful tool for storing inventory and will help to systemize and organize storage space.

- Assign a number (or name) to different areas of the shelves.
- Record in the logbook what shelves are used for which reagents and supplies.

This system helps to avoid "losing" a product, and will save staff time when searching for a product. Even someone who is not familiar with the storeroom can find a product if this system is in place. It is also useful to number cold rooms, refrigerators and freezers for the same purpose. An example of this type of system is shown below.



Labelling reagents

Establishing a system for labelling reagents will be very helpful. It is important to label reagents with the date they are opened and to make sure the expiration date is clearly visible.

4-7: Monitoring inventory

Continuous monitoring of inventory

Procedures should be developed and put in place for continuous monitoring of the inventory. To ensure this is done effectively:

- assign the responsibility for this task to an appropriate person or persons—someone must be in charge;
- be sure that all supplies and reagents in the laboratory are covered by the system and maintain inventory management in all of the storage areas;
- conduct weekly physical counts of reagents and supplies in order to check the system, and as a part of the monitoring process;
- make sure that all records relevant to inventory management are updated and maintained.

Computerized inventory management advantages and drawbacks

In many laboratories, a simple computerized system can be set up for management of inventory. There are many advantages to using a computer. A computer will:

- keep track of the exact number of supplies and reagents on hand, as it can be updated daily;
- allow for good management of expiration dates—the system can be set up to alert when lot numbers are near the expiration date, and therefore use of resources can be optimized;
- generate statistics that will help when planning and making purchases;
- help manage the process for distributing reagents to satellite laboratories;
- ease the burden of inventory management.

Some drawbacks to setting up a computerized system are:

- an on-site computer is needed and it could be expensive to purchase
- staff using the system will need to be trained.

4-8: Summary

Summary

A well-managed laboratory will have a system for inventory maintenance and purchasing. The system will require planning and monitoring to ensure that appropriate quantities of supplies and reagents are always available, and to prevent wastage.

In implementing an inventory management system, the laboratory must assign responsibility for the programme, analyze the needs of the laboratory and establish the minimum stock needed for an appropriate time period. Appropriate logs and forms will be needed, as well as a procedure for receiving, inspecting and storing supplies.

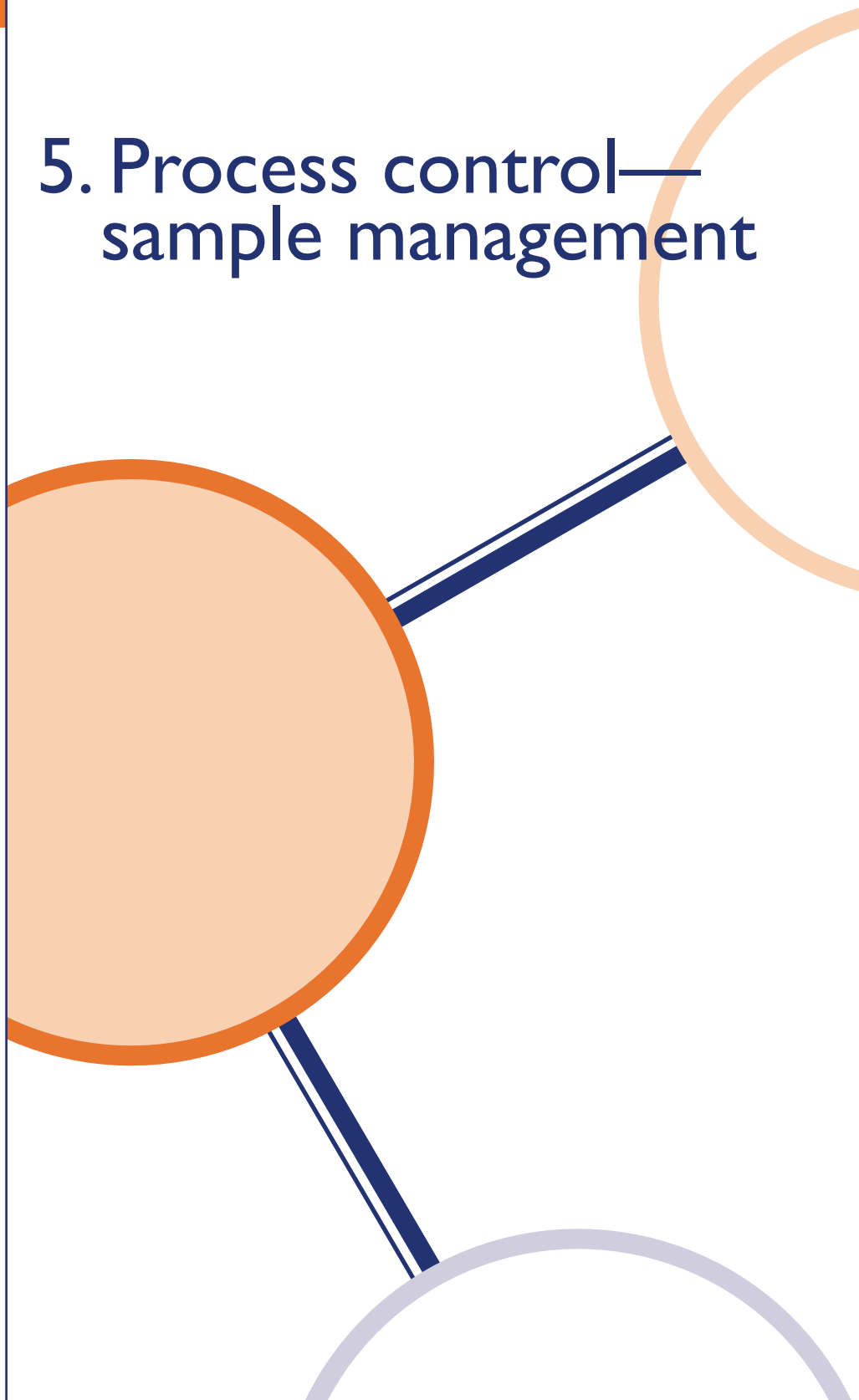
The laboratory will need to maintain an inventory system for all reagents and supplies used in the laboratory; this system must include all areas where reagents and supplies are stored.

Key messages

Properly managing inventory will:

- increase the efficiency and effectiveness of the laboratory, because it will provide an uninterrupted flow of needed materials;
- ensure products are available when they are needed;
- ensure that patient and clinical needs are met.

5. Process control—sample management



5-1: Overview

Role in quality management system

Sample management is a part of process control, one of the essentials of a quality management system.

The quality of the work a laboratory produces is only as good as the quality of the samples it uses for testing. The laboratory must be proactive in ensuring that the samples it receives meet all of the requirements for producing accurate test results.

Sample vs specimen

The International Organization for Standardization (ISO) and Clinical and Laboratory Standards Institute (CLSI) define a sample as "one or more parts taken from a system and intended to provide information on the system" (ISO 15189:2007). The term "specimen" is very commonly used in the laboratory to indicate a sample taken from the human body, but the terminology used throughout ISO documents is "primary sample", or just "sample". In this handbook, the terms "sample" and "specimen" should be considered interchangeable.
It is useful to note that in some of the existing transport regulations, the term "specimen" continues to be used.

Importance of good management

Proper management of samples is critical to the accuracy and reliability of testing, and therefore to the confidence in laboratory diagnosis. Laboratory results influence therapeutic decisions and can have significant impacts on patient care and outcomes. It is important to provide accurate laboratory results in order to ensure good treatment.

Inaccuracies in testing can impact length of hospital stays, as well as hospital and laboratory costs. Inaccuracies can also affect laboratory efficiency, leading to repeat testing with resultant waste of personnel time, supplies and reagents.

Sample management components

Written policies for sample management must be established and reflected in the laboratory handbook. Components to be addressed include:

- information needed on requisitions or forms;
- handling urgent requests;
- collection, labelling, preservation and transport;
- safety practices (leaking or broken containers, contaminated forms, other biohazards);
- evaluating, processing and tracking samples;
- storage, retention and disposal.

5-2: The laboratory handbook

Purpose and distribution

To ensure that all samples are managed properly and that persons collecting samples have the needed information, the laboratory should develop a laboratory handbook. This handbook should be made available at all sample collection areas, including those that are distant from the laboratory.

All laboratory staff should also be familiar with the information in the handbook, and should be able to answer questions about the information included. The laboratory handbook is an important laboratory document. It must be kept up to date and be referenced in the laboratory's quality manual.

Content

Important information that should be included in the laboratory handbook:

- contact names and telephone numbers of key personnel;
- name and address of the laboratory;
- hours of operation of the laboratory;
- list of tests that can be ordered;
- detailed information on sample collection requirements;
- sample transport requirements, if any;
- expected turnaround times;
- description of how urgent requests are handled—this should include a list of what kinds of tests are done on an urgent basis, what are the expected turnaround times, and how to order these tests.

The laboratory should periodically provide training sessions to health care and laboratory personnel who are responsible for the collection of samples.

5-3: Collection and preservation

The laboratory's responsibilites

The collection of appropriate and optimum samples is the responsibility of the laboratory, even though the actual collection process is often carried out by persons who are not part of the laboratory staff. The sample may be collected at the bedside by a nurse if the patient is being managed in a hospital. The health care provider may collect a sample in a clinic setting.

The laboratory can help to ensure good samples by providing collection information to health care personnel at the collection site, making sure that appropriate containers and collection supplies are available, defining a good labelling system and checking all samples carefully when they arrive in the laboratory.

Test requisition

The first step in the process of obtaining the sample is the request for testing. The laboratory must make available a test request form that specifies all the information that will be needed for proper handling and reporting.


Field Data Collection Form

General patient information

Tracking record number:

Date of onset of illness (dd/mm/yyyy):

Clinical specimens

Unique ID No.	Type	Date of collection (dd/mm/yyyy)	Clinical diagnosis	Health status when specimens collected	Remarks

Post mortem-specimens

Date of death (dd/mm/yyyy)

Essential information for the test request form includes:

- patient identification;
- tests requested;
- time and date of the sample collection;
- source of the sample, when appropriate;
- clinical data, when indicated;
- contact information for the health care provider requesting the test.

Sample collection requirements

Collection of samples in the field for epidemiological studies should be accompanied by a form that includes the patient's name, a unique identification number, demographic information and the patient's health status. The additional information is necessary to assist in identifying the source of an infection and finding potential contacts.

Sample collection and preservation will vary, depending on the test and the type of sample to be collected. The laboratory must carefully define a sample collection process for all tests it performs. The following should be considered when preparing instructions.

- **Patient preparation**—Some tests require that the patient be fasting. There may also be special timing issues for tests such as blood glucose, drug levels and hormone tests.

- **Patient identification**—The person collecting the sample must accurately identify the patient. This might be done by questioning the patient, by questioning an accompanying family member, or by the use of an identifying wrist band or other device.
- **Type of sample required**—Blood tests might require serum, plasma or whole blood. Other tests might require urine or saliva. Microbiology testing deals with a variety of sample types, so specific information as to what is required for the test is needed.
- **Type of container**—The container for the sample is often very important, as it will affect volume and any needed additives such as anticoagulants and preservatives. If the container does not control volume, for example as with Vacutainer® tubes, this will need to be clearly specified. Some microbiology samples will require specific transport media to preserve microorganisms.
- **Sample labelling**—All requirements for labelling of the sample at the time of collection will need to be explained in detail in the instructions for collection.
- **Special handling**—Some samples may require special handling, such as immediate refrigeration, protection from light or prompt delivery to the laboratory. Any important safety precautions should be explained.

Patient samples are sometimes collected by the patient themselves; for example, faecal parasitological samples. It is important that the laboratories have set protocols to ensure that appropriate collection kits with instructions for collection, safety precautions and labelling are available for their patients. It is suggested that instructions for the patients be in the languages for the community the laboratory is serving, or presented as simple, easy-to-understand graphics.

Sample labelling

Each sample should be clearly labelled with:

- the patient's first and last name;
- a unique identification number—this might be a hospital number or a number assigned by the laboratory;
- the test that has been requested;
- the time and date of collection;
- the initials of the person collecting the sample.

Outcomes of collection errors

Proper sample collection is an important element for good laboratory practice. Improper collection of samples can lead to poor outcomes, such as:

- delays in reporting test results
- unnecessary redraws/retests
- decreased customer satisfaction
- increased costs
- incorrect diagnosis or treatment
- injury
- death.

5-4: Sample processing

Verification of quality

Once a sample enters the laboratory, there are a number of steps needed prior to testing.

- Verify the sample is properly labelled, adequate in quantity, in good condition and appropriate for the test requested. The test request must be complete and include all necessary information.
- Record sample information into a register or log.
- Enforce procedures for handling suboptimum samples, including sample rejection when necessary.

Rejection of samples

The laboratory should establish rejection criteria and follow them closely. It is sometimes difficult to reject a sample, but remember that a poor sample will not allow for accurate results. It is the responsibility of the laboratory to enforce its policies on sample rejection so that patient care is not compromised.

Management should regularly review the number of rejected samples and reasons for rejections, conduct training on sample collection, and revise written procedures for sample management as needed.

The following are examples of samples that should be rejected:

- unlabelled sample;
- broken or leaking tube/container;
- insufficient patient information;
- sample label and patient name on the test request form do not match;
- haemolysed sample (depending on test requested);
- nonfasting samples, for tests that require fasting;
- sample collected in wrong tube/container (e.g. using the wrong preservative or a nonsterile container);
- inadequate volume for the quantity of preservative;
- insufficient quantity for the test requested;
- prolonged transport time or other poor handling during transport.

Record the reason for rejection in the logbook and include all pertinent information.

When rejecting a sample, it is important to:

- promptly inform the authorized person that the sample is unsuitable for testing;
- request another sample to be collected following procedures outlined in the laboratory handbook;
- retain the rejected sample pending a final decision regarding disposition.

In some circumstances, and after consultation with the requester, it may be necessary to proceed with the testing of a sample that is not optimal.

Register or log

The laboratory should keep a register (log) of all incoming samples. A master register may be kept, or each specialty laboratory may keep its own sample register.

Assign the sample a laboratory identification number—write the number on the sample and the requisition form. If computers are used for reports, enter the information into the computer.

The register should include:
- date and time of collection
- date and time the sample was received in the laboratory
- sample type
- patient name and demographics, as required
- laboratory assigned identification (e.g. number 276_01_06_2009)
- tests to be performed.

Tracking system

The laboratory needs a system to allow for tracking a sample throughout the laboratory from the time it is received until results are reported.
This can be done manually by careful keeping of records as follows.
- Confirm receipt of samples and include date and time.
- Label samples appropriately and keep with the test requisition until laboratory identification is assigned.
- Track aliquots—they should be traceable to the original sample.

If computers are available, maintain a database for tracking. The following information about each sample should be entered into the database:
- identification number
- patient information
- collection date and time
- type of sample (e.g. urine, throat, cerebrospinal fluid for culture)
- tests to be performed
- name of ordering physician (or other health care provider)
- location of patient (e.g. ward, clinic, outpatient)
- diagnostic test results
- time and date results are reported.

Sample handling

Handle all samples as if they are infectious.

5-5: Sample storage, retention and disposal

Sample storage

Written policies should be developed that include:

- description of what samples should be stored;
- retention time;
- location (consider ease of access);
- conditions for storage, such as atmospheric and temperature requirements;
- system for storage organization—one method is to store samples by day of receipt or accession number.

Sample retention

Set a laboratory policy for retention of each type of sample. Some samples can be quickly discarded and others may need to be retained for longer periods. Monitor stored samples and do not keep for longer than necessary, as refrigerator and freezer space may be limited. Sample freeze/thaw cycles must be monitored, as samples may deteriorate under these conditions.

Planning is required for samples that may need long-term storage. An organized, accessible system using computer tracking would be useful for these samples. The inventory of stored samples should be reviewed at specified intervals to determine when they should be discarded.

Sample referral

When referring samples to other laboratories for testing:

- Obtain a laboratory handbook with detailed procedures from each laboratory.
- Ensure the sample is labelled correctly, in the correct container, accompanied by a requisition form that specifies the required test(s) and includes the sending laboratory's contact information.
- Carefully monitor samples that are referred:
  - keep a record of all tests and samples referred, date of referral and name of person referring the test;
  - record and report results received for each referred sample;
  - monitor turnaround times and record any problems encountered.

Sample disposal

The laboratory is responsible for ensuring that disposal of all laboratory waste is handled in a safe manner. To ensure proper disposal of patient samples:

- Develop a policy for sample disposal; apply local as well as country regulations for disposal of medical waste.
- Establish and follow procedures to disinfect samples prior to disposal.

5-6: Sample transport

Need for transport

Frequently, samples are collected outside the laboratory and must be transported for subsequent processing and testing. Transport may be for a short distance, but sometimes a distant clinic or collection site requires the use of vehicles or aeroplanes. In addition, it may be necessary for the laboratory to ship samples to referral laboratories. In all cases, transport must be managed carefully in order to maintain integrity of the sample, giving attention to temperature, preservation needs, special transport containers and time limitations. It is also important to ensure the safety of those handling the material before, during and after transport.

Safety requirements

Laboratories that mail or transport samples by air, sea, rail or road between local, regional and reference laboratories, or between laboratories in other countries, must adhere to a number of regulations. These regulations are designed to deal with transportation accidents and spills, reduce biohazards and keep samples intact for testing.

Regulations

Regulations for transporting samples come from several sources, including:

- national transport regulations;
- International Civil Aviation Organization (ICAO), as conveyed by the International Air Transport Association;
- rail and road traffic agencies;
- postal services.

Private courier companies may have their own requirements.

Compliance with industry standards and regulations is mandatory. Heavy fines may be imposed on personnel who violate these regulations. At risk are the safety of courier, carrier and laboratory personnel, as well as passengers.

The United Nations committee of experts, consisting of voting representatives from over 30 countries and nonvoting advisers from various organizations, makes recommendations for the transport of dangerous goods. Many countries adopt the United Nations regulations in their entirety to stand as their national dangerous goods regulations. Some countries apply variations. National authorities should provide details of their own national requirements.

Classification

Sample transport requirements are based on the category of samples being transported. Infectious substances are classified as Category A or Category B. There is no direct relationship between Risk Groups and Categories A and B.

Category A: Infectious substances capable of causing permanent disability or life-threatening or fatal disease to humans or animals.

These are assigned the following proper shipping name and UN number:
- Infectious substance affecting humans, UN 2814.
- Infectious substance affecting animals only, UN 2900.

Category B: Infectious substances that do not meet the criteria for inclusion in Category A. They are assigned the proper shipping name Biological substance, Category B, and UN number UN 3373.

Medical or clinical wastes that contain infectious substances also need to be classified as Category A or B, depending on the infectious material and whether it is present in the culture.

Exemptions: The United Nations Model Regulations for the Transport of Infectious Substances includes a list of exemptions, which are samples that have a minimal likelihood that pathogens are present. They do not have the same requirements for packaging and shipping as Categories A and B.

Packaging requirements

All three categories of samples have specific packaging instructions and labelling requirements depending on their classification. All potentially hazardous material requires triple packaging.
- The **primary container** is a tube or vial containing the sample; it is made of glass, metal or plastic. It must have a leak-proof seal; if necessary it can be wrapped with waterproof tape. The tube or vial must be labelled with a permanent marker.
- The **secondary container** is a watertight polyethylene box intended to protect the primary container. It is supplied with cardboard or bubble-wrap, or a vial holder in which several primary containers can be placed in order to protect them. Absorbent material (gauze, absorbent paper) must be added in a sufficient quantity to absorb the fluid completely in case of breakage.
- The **outer container** is a strengthened cardboard box used to protect the secondary container. Both the secondary and outer containers are reusable as long as they are intact, but old labels must be removed.

There is specific packaging for samples requiring shipment on dry ice.

Managing sample transport

Ensure that all regulations and requirements are met when transporting samples; be aware of any national requirements that apply to samples transported by hospital or laboratory vehicles.

All personnel who package samples or who drive transport vehicles should be trained in the proper procedures for safety and good maintenance of samples. If ICAO regulations must be met, staff must have specific training in packaging of dangerous goods.

When transporting locally, whether by ambulance, or by clinic or laboratory staff, it is important to maintain sample integrity. Ensure that temperatures are controlled, using ice boxes or air-conditioning, set an acceptable transport time and monitor compliance.

5-7: Summary

Summary

A laboratory handbook describing sample collection and providing testing information must be available to everyone who needs this information.

It is important to have a system for tracking samples as they move through the laboratory.

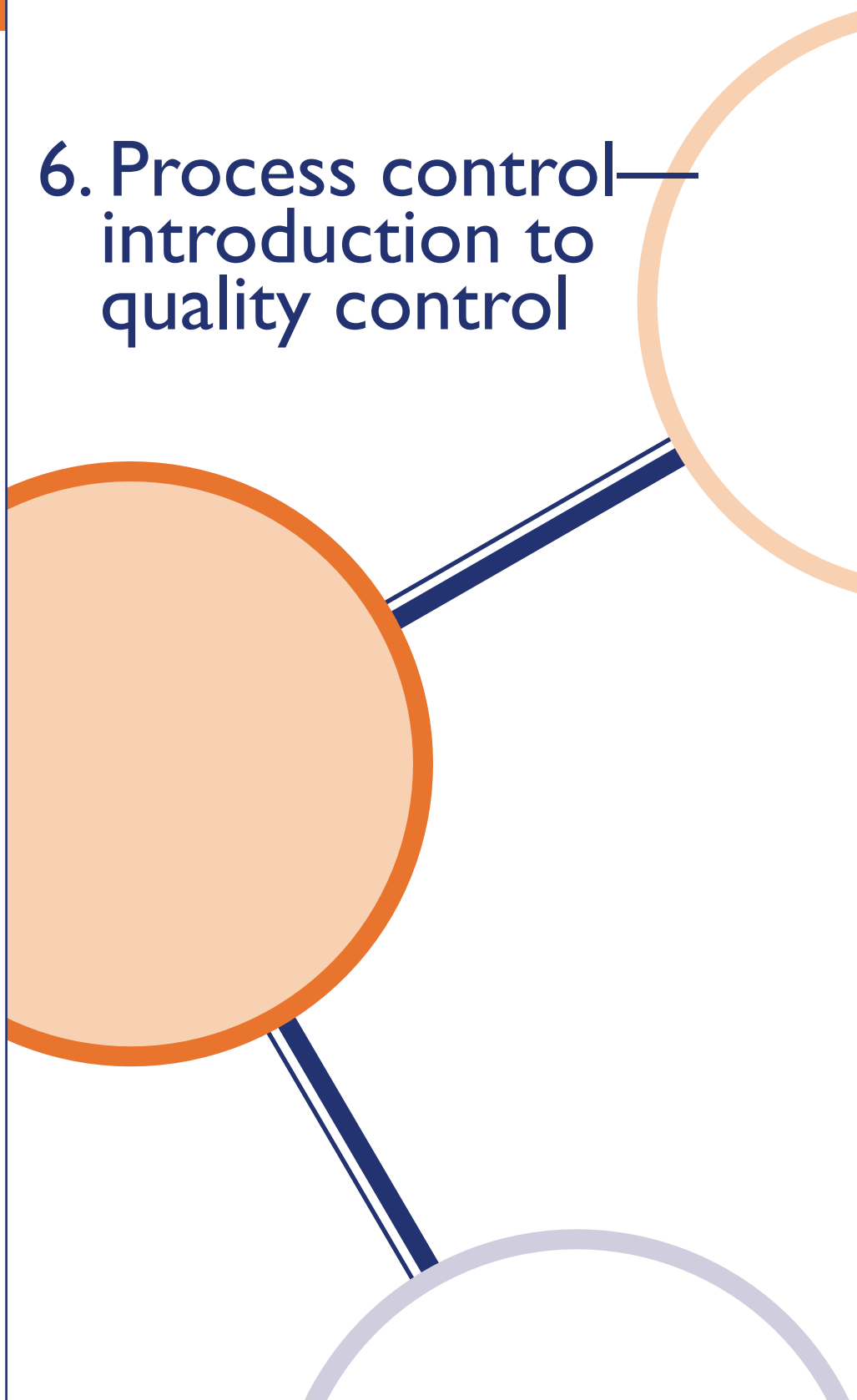
Establish and implement a policy for sample storage and sample disposal.
Maintain sample integrity and assure that all regulations and requirements are met.

It may be useful to appoint someone with oversight responsibilities for sample management.

Key messages

- The laboratory must have good samples in order to ensure accuracy and reliability of testing and confidence in results.
- Sample management directly affects patient care and outcome.

6. Process control—introduction to quality control



6-1: Introduction

Role in quality management system

Process control is an essential element of the quality management system, and refers to control of the activities employed in the handling of samples and examination processes in order to ensure accurate and reliable testing. Sample management, discussed in Chapter 5, and all quality control (QC) processes are a part of process control.

QC monitors activities related to the examination (analytic) phase of testing. The goal of QC is to detect, evaluate, nd correct errors due to test system failure, environmental conditions or operator performance, before patient results are reported.

What is QC?

QC is the part of quality management focused on fulfilling quality requirements (ISO 9000:2000 [3.2.10]). Simply put, it is examining "control" materials of known substances along with patient samples to monitor the accuracy and precision of the complete analytic process. QC is required for accreditation purposes.

In 1981, the World Health Organization (WHO) used the term "internal quality control" (IQC), which it defined as "a set of procedures for continuously assessing laboratory work and the emergent results". The terms QC and IQC are sometimes used interchangeably; cultural setting and country may influence preferences for these terms.

In the past few years, "internal quality control' has become confusing in some settings because of the different meanings that have been associated with the term. Some manufacturers of test kits for qualitative tests have integrated "built-in" controls in the design of their kits, which they sometimes refer to as internal controls. Other manufacturers include their own control materials with the kits they sell and they refer to these as "internal controls", meaning that the materials are meant specifically for that manufacturer's kit. Finally, some people refer to any quality control materials that are used in conjunction with test runs as IQC, as in the 1981 WHO definition.

To avoid confusion, the term "quality control" will be used here to mean use of control materials to monitor the accuracy and precision of all the processes associated with the examination (analytic) phase of testing.

QC for varying methods

Quality control processes vary, depending on whether the laboratory examinations use methods that produce quantitative, qualitative or semiquantitative results. These examinations differ in the following ways.

Quantitative examinations measure the quantity of an analyte present in the sample, and measurements need to be accurate and precise. The measurement produces a numeric value as an end-point, expressed in a particular unit of measurement. For example, the result of a blood glucose test might be reported as 5 mg/dL.

Qualitative examinations are those that measure the presence or absence of a substance, or evaluate cellular characteristics such as morphology. The results are not expressed in numerical terms, but in qualitative terms such as "positive" or "negative"; "reactive" or "nonreactive"; "normal" or "abnormal"; and "growth" or "no growth". Examples of qualitative examinations include microscopic examinations, serologic procedures for presence or absence of antigens and antibodies, and many microbiological procedures.

Semiquantitative examinations are similar to qualitative examinations, in that the results are not expressed in quantitative terms. The difference is that results of these tests are expressed as an **estimate** of how much of the measured substance is present. Results might be expressed in terms such as "trace amount", "moderate amount", or "1+, 2+, or 3+". Examples are urine dipsticks, tablet tests for ketones and some serologic agglutination procedures. In the case of other serologic testing, the result is often expressed as a titre—again involving a number but providing an estimate, rather than an exact amount of the quantity present.

Some microscopic examinations are considered semiquantitative because results are reported as estimates of the number of cells seen per low-power field or high-power field. For example, a urine microscopic examination might report 0–5 red blood cells seen per high-power field.

Because QC processes differ for these various types of examinations, the presentations for QC will be divided into two chapters. Chapter 7 will address QC for quantitative examinations, and Chapter 8 will address QC for qualitative and semiquantitative examinations.

Elements of a QC programme

Regardless of the type of examination that is performed, steps for implementing and maintaining a QC programme include:

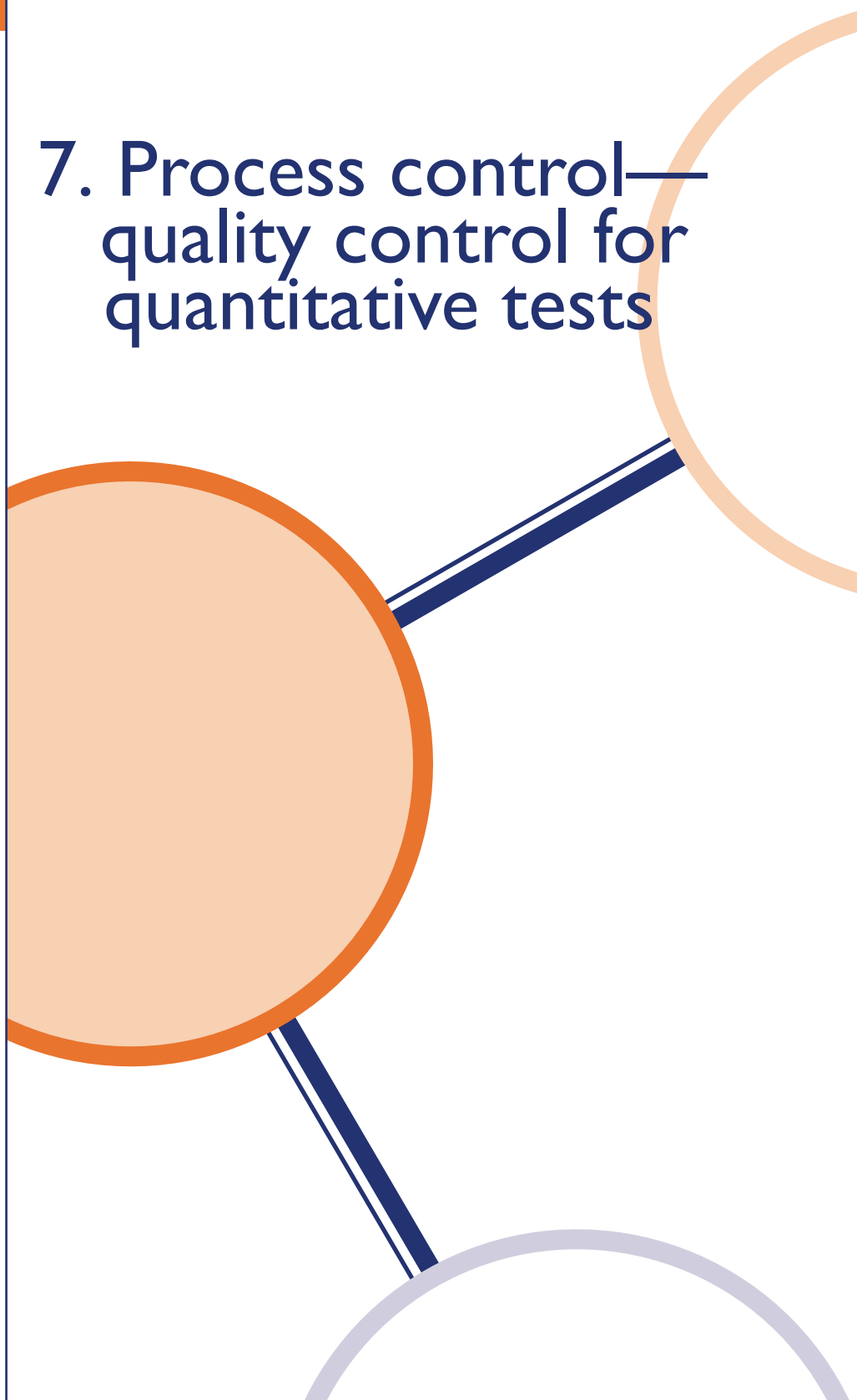
- establishing written policies and procedures, including corrective actions
- training all laboratory staff
- ensuring complete documentation
- reviewing quality control data.

These responsibilities will be described in more detail in Chapters 7 and 8.

Summary

- QC is part of the quality management system and is used to monitor the examination (analytic) phase of testing.
- The goal of QC is to detect, evaluate and correct errors due to test system failure, environmental conditions, or operator performance, before patient results are reported.
- Different QC processes are applied to monitor quantitative, qualitative and semiquantitative tests.

7. Process control—quality control for quantitative tests



7-1: Overview

Role in quality management system

Quality control (QC) is a component of process control, and is an essential element of the quality management system. It monitors the processes related to the examination phase of testing and allows for detecting errors in the testing system. These errors may be due to test system failure, adverse environmental conditions or operator performance. QC gives the laboratory confidence that test results are accurate and reliable before patient results are reported.

This chapter explains how quality control methods are applied to quantitative laboratory examinations.

Overview of the process

Quantitative tests measure the quantity of a substance in a sample, yielding a numeric result. For example, the quantitative test for blood glucose can give a result of 5 mg/dL. Since quantitative tests have numeric values, statistical tests can be applied to the results of QC material to differentiate between test runs that are "in control" and "out of control". This is done by calculating acceptable limits for control material, then testing the control with the patient's samples to see if it falls within established limits.

As a part of the quality management system, the laboratory must establish a QC programme for all quantitative tests. Evaluating each test run in this way allows the laboratory to determine if patient results are accurate and reliable.

Implementation process

The steps for implementing a QC programme are:

- establish policies and procedures
- assign responsibility for monitoring and reviewing
- train all staff in how to properly follow policies and procedures
- select good QC material
- establish control ranges for the selected material
- develop graphs to plot control values—these are called Levey–Jennings charts
- establish a system for monitoring control values
- take immediate corrective action if needed
- maintain records of QC results and any corrective actions taken.

7-2: Control materials

Defining control materials

Controls are substances that contain an established amount of the substance being tested—the analyte. Controls are tested at the same time and in the same way as patient samples. The purpose of the control is to validate the reliability of the test system and evaluate the operator's performance and environmental conditions that might impact results.

Differentiating controls and calibrators

It is important not to confuse calibrators and control materials. Calibrators are solutions with a specified defined concentration that are used to set or calibrate an instrument, kit, or system before testing is begun. Calibrators are often provided by the manufacturer of an instrument. They should not be used as controls since they are used to set the instrument. Calibrators are sometimes called standards, but the term calibrator is preferred. They usually do not have the same consistency as patients' samples.

Characteristics of control materials

It is critical to select the appropriate control materials. Some important characteristics to consider when making the selection are:

- Controls must be appropriate for the targeted diagnostic test—the substance being measured in the test must be present in the control in a measurable form.
- The amount of the analyte present in the controls should be close to the medical decision points of the test; this means that controls should check both low values and high values.
- Controls should have the same matrix as patient samples; this usually means that the controls are serum based, but they may also be based on plasma, urine or other materials.

Because it is more efficient to have controls that last for some months, it is best to obtain control materials in large quantities.

Types and sources of control material

Control materials are available in a variety of forms. They may be frozen, freeze-dried or chemically preserved. The freeze-dried or lyophilized materials must be reconstituted, requiring great care in pipetting in order to ensure the correct concentration of the analyte.

Control materials may be purchased, obtained from a central or reference laboratory, or made in-house by pooling sera from different patients.

Purchased controls may be either assayed or unassayed. Assayed controls have a predetermined target value, established by the manufacturer. When using assayed controls, the laboratory must verify the value using its own methods. Assayed controls are more expensive to purchase than unassayed controls.

When using either unassayed or "in-house" controls, the laboratory must establish the target value of the analyte.

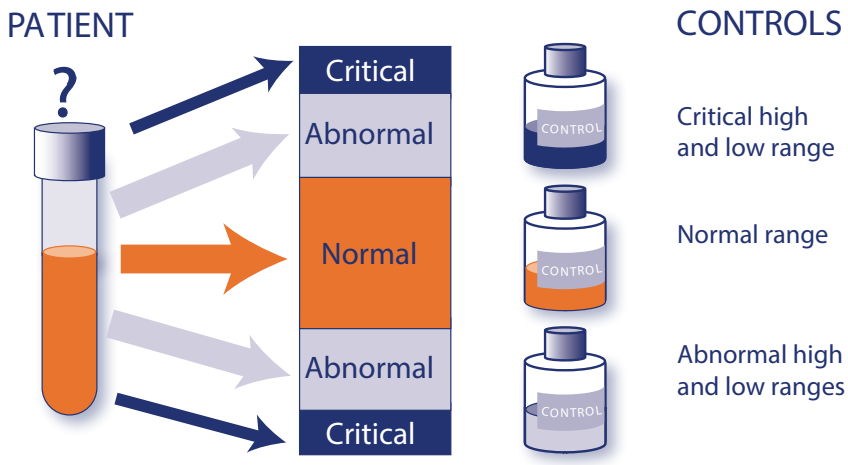
The use of in-house controls requires resources to perform validation and testing steps. An advantage is that the laboratory can produce very large volumes with exact specifications.

Remember that QC materials are usually serum based. Universal precautions should be used when handling.

Choosing controls

When choosing controls for a particular method, select values that cover medical decision points, such as one with a normal value, and one that is either high or low, but in the medically significant range.

Controls are usually available in "high", "normal" and "low" ranges. Shown in the graphic are normal, abnormal high and low, and critical high and low ranges. For some assays, it may be important to include controls with values near the low end of detection.



Preparing and storing control material

When preparing and storing QC materials, it is important to carefully adhere to the manufacturer's instructions for reconstituting and storage. If in-house control material is used, freeze aliquots and place in the freezer so that a small amount can be thawed and used daily. Do not thaw and refreeze control material. Monitor and maintain freezer temperatures to avoid degradation of the analyte in any frozen control material.

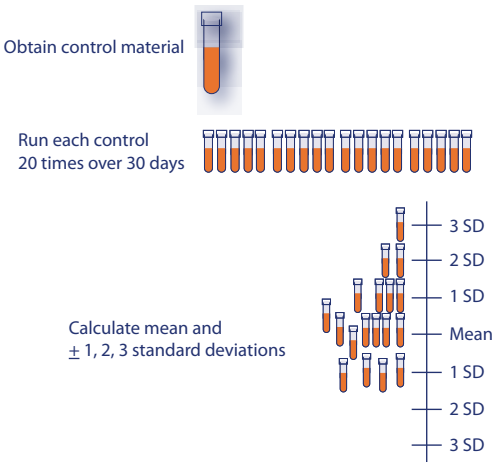
Use a pipette to deliver the exact amount of required diluent to lyophilized controls that must be reconstituted.

7-3: Establishing the value range for the control material

Assaying control over time

Once the appropriate control materials are purchased or prepared, the next step is to determine the range of acceptable values for the control material. This will be used to let the laboratory know if the test run is "in control" or if the control values are not reading properly—"out of control". This is done by assaying the control material repeatedly over time. At least 20 data points must be collected over a 20–30-day period. When collecting this data, be sure to include any procedural variation that occurs in the daily runs; for example, if different testing personnel normally do the analysis, all of them should collect part of the data.

Once the data is collected, the laboratory will need to calculate the mean and standard deviation of the results. A characteristic of repeated measurements is that there is a degree of variation. Variation may be due to operator technique, environmental conditions or the performance characteristics of an instrument. Some variation is normal, even when all of the factors listed above are controlled. The standard deviation gives a measure of the variation. This process is illustrated below.



Characteristics of repeated measures

One of the goals of a QC programme is to differentiate between normal variation and errors.

A few theoretical concepts are important because they are used to establish the normal variability of the test system. QC materials are run to quantify the variability and establish a normal range, and to decrease the risk of error.

The **variability** of repeated measurements will be distributed around a central point or location. This characteristic of repeated measurements is known as **central tendency.**

The three measures of central tendency are:

- **Mode**—the number that occurs most frequently.
- **Median**—the central point of the values when they are arranged in numerical sequence.
- **Mean**—the arithmetic average of results. The mean is the most commonly used measure of central tendency used in laboratory QC.

Statistical notations

Statistical notations are symbols used in mathematical formulas to calculate statistical measures. For this chapter, the symbols that are important to know are:

Σ	the sum of
N	number of data points (results or observations)
X_1	individual result
$X_1 - X_n$	data point 1–n where n is the last result
$\overline{X}$	the symbol for the mean
$\sqrt{}$	the square root of the data.

Mean

The formula for the mean is:

$$\overline{X} = \frac{X_1 + X_2 + X_3 \ldots X_n}{N}$$

As an example of how to calculate a mean, consider enzyme-linked immunosorbent assay (ELISA) testing. The method is to gather data as ratios, add the values and divide by the number of measurements.

Before calculating QC ranges

The purpose of obtaining 20 data points by running the QC sample is to quantify normal variation and establish ranges for QC samples. Use the results of these measurements to establish QC ranges for testing.

If one or two data points appear to be too high or low for the set of data, they should not be included when calculating QC ranges. They are called **"outliers"**.

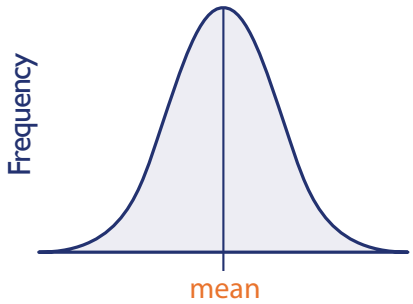
- If there are more than 2 outliers in the 20 data points, there is a problem with the data and it should not be used.
- Identify and resolve the problem and repeat the data collection.

Normal distribution

If many measurements are taken, and the results are plotted on a graph, the values form a bell-shaped curve as the results vary around the mean. This is called a **normal distribution** (also termed Gaussian distribution).

The distribution can be seen if data points are plotted on the x-axis and the frequency with which they occur on the y-axis.

The normal curve shown (right) is really a theoretical curve obtained when a large number of measurements are plotted. It is assumed that the types of measurements used for quantitative QC are normally distributed based on this theory.



Accuracy and precision

If a measurement is repeated many times, the result is a mean that is very close to the true mean.

Accuracy is the closeness of a measurement to its true value.

Precision is the amount of variation in the measurements.

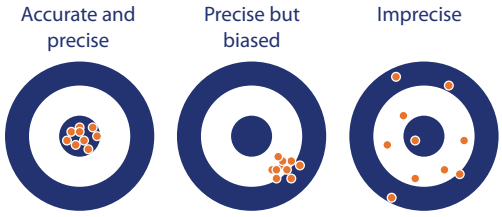
- The less variation a set of measurements has, the more precise it is.
- In more precise measurements, the width of the curve is smaller because the measurements are all closer to the mean.

Bias is the difference between the expectation of a test result and an accepted reference method.
The reliability of a method is judged in terms of accuracy and precision.

Target illustration

A simple way to portray precision and accuracy is to think of a target with a bull's eye. The bull's eye represents the accepted reference value which is the true, unbiased value. If a set of data is clustered around the bull's eye, it is **accurate**.

The closer together the hits are, the more **precise** they are. If most of the hits are in the the bull's eye, as in the figure on the **left**, they are both precise and accurate.



Accurate = precise but not biased

The values in the **middle figure** are precise but not accurate because they are clustered together but not at the bull's eye. The figure on the **right** shows a set of hits that are imprecise.

Measurements can be precise but not accurate if the values are close together but do not hit the bull's eye. These values are said to be **biased**. The middle figure demonstrates a set of precise but biased measurements.

The purpose of quality control is to monitor the accuracy and precision of laboratory assays before releasing patient results.

Measures of variability

The methods used in clinical laboratories may show different variations about the mean; hence, some are more precise than others. To determine the acceptable variation, the laboratory must compute the standard deviation (SD) of the 20 control values. This is important because a characteristic of the normal distribution is that, when measurements are normally distributed:

- 68.3% of the values will fall within –1 SD and +1 SD of the mean
- 95.5% fall within –2 SD and +2 SD
- 99.7% fall between –3 SD and +3 SD of the mean.

Knowing this is true for all normally shaped distributions allows the laboratory to establish ranges for QC material.

Once the mean and SD are computed for a set of measurements, a QC material that is examined along with patients' samples should fall within these ranges.

Standard deviation

SD is a measurement of variation in a set of results. It is very useful to the laboratory in analyzing QC results.

The formula for calculating standard deviation is:

$$SD = \sqrt{\frac{\sum (X_1 - \overline{X})^2}{n-1}}$$

The number of independent data points (values) in a data set are represented by "n". Calculating the mean reduces the number of independent data points to n – 1. Dividing by n –1 reduces bias.

Calculating acceptable limits for the control

The values of the mean, as well as the values of ± 1, 2 and 3 SDs are needed to develop the chart used to plot the daily control values.

- To calculate 2 SDs, multiply the SD by 2 then add and subtract each result from the mean.
- To calculate 3 SDs, multiply the SD by 3, then add and subtract each result from the mean.

For any given data point, 68.3% of values will fall between ± 1 SD, 95.5% between

± 2 SD and 99.7% between ± 3 SD of the mean.

When only one control is used, we consider an examination run to be "in control" if a value is within 2 SD of the mean.

Coefficient of variation

The coefficient of variation (CV) is the SD expressed as a percentage of the mean.

$$CV\ (\%) = \frac{SD}{Mean} \times 100$$

The CV is used to monitor precision. When a laboratory changes from one method of analysis to another, the CV is one of the elements that can be used to compare the precision of the methods. Ideally, the value of the CV should be less than 5%.

7-4: Graphically representing control ranges

Using graphs for analysis and monitoring

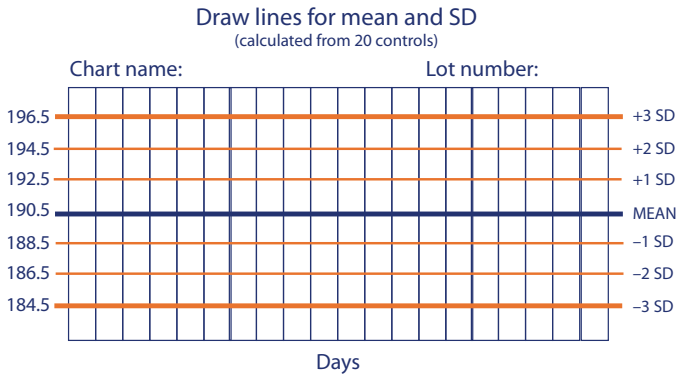
Once the appropriate range of control values has been established, the laboratory will find it very useful to represent the range graphically for the purpose of daily monitoring. The common method for this graphing is the use of Levey–Jennings charts.

Developing data for Levey–Jennings charts

In order to develop Levey–Jennings charts for daily use in the laboratory, the first step is the calculation of the mean and SD of a set of 20 control values as explained in 7-3.

Levey–Jennings chart

A Levey–Jennings chart can then be drawn, showing the mean value as well as ± 1, 2, and 3 SD. The mean is shown by drawing a line horizontally in the middle of the graph and the SD are marked off at appropriate intervals and lines drawn horizontally on the graph, as shown below.



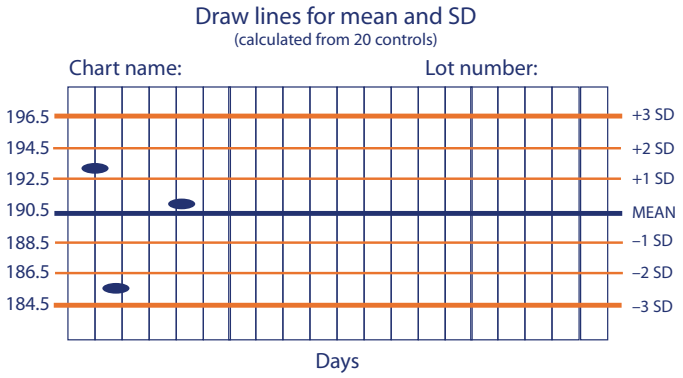
This Levey–Jennings chart was developed using 20 repeated measurements of the control value. In order to use the Levey–Jennings chart to record and monitor daily control values, label the x-axis with days, runs,or other intervals used to run QC. Label the chart with the name of the test and the lot number of the control being used.

7-5: Interpreting quality control data

Plotting control values

A QC sample tested along with patient's samples can now be used to determine if daily runs are "in control". A control sample must be run with each set of patient samples.

Run the control and plot it on the Levey–Jennings chart. If the value is within **±2 SD,** the run can be accepted as **"in-control"**.



The values on the chart are those run on days 1, 2 and 3 after the chart was made. In this case, the second value is "out of control" because it falls outside of 2 SD.

When using only one QC sample, if the value is outside 2 SD, that run is considered "out of control" and the run must be rejected.

Number of controls used

If it is possible to use only one control, choose one with a value that lies within the normal range of the analyte being tested. When evaluating results, accept all runs where the control lies within ±2 SD. Using this system, the correct value will be rejected 4.5% of the time.

In order to improve efficiency and accuracy, a system using two or three controls for each run can be employed. Then another set of rules can be used to avoid rejecting runs that may be acceptable. These rules were applied to laboratory QC by a clinical chemist named James Westgard. This Westgard multirule system requires running two controls of different target values for each set of examinations, developing a Levey–Jennings chart for each, and applying the rules.

The use of three controls with each run gives even higher assurance of accuracy of the test run. When using three controls, choose a low, a normal and a high range value. There are also Westgard rules for a system with three controls.

Detecting error

Errors that occur in the testing process may be either random or systematic.

With random error, there will be a variation in QC results that show no pattern. This type of error generally does not reflect a failure in some part of the testing system, and is therefore not like to reccur. Random error is only a cause for rejection of the test run if it exceeds ±2 SD.

Systematic error is not acceptable, as it indicates some failure in the system that can and should be corrected. Examples of evidence of systematic error include:

- shift—when the control is on the same side of the mean for five consecutive runs;
- trend—when the control is moving in one direction, and appears to be heading toward an out-of-control value.

Even when a control value falls within 2 SD, it can be a cause for concern. Levey–Jennings charts can help distinguish between normal variation and systematic error.

Shifts and trends

Shifts in the mean occur when an **abrupt** change is followed by **six or more** consecutive QC results that fall on one side of the mean, but typically within 95% range as if clustered around a new mean. On the sixth occasion this is called a shift and results are rejected.

Trends occur when values gradually, but continually, move in one direction over six or more analytical runs. Trends may display values across the mean, or they may occur only on one side of the mean. On the sixth occasion, this is determined to be a trend and results are rejected.

The source of the problem must be investigated and corrected before patients' samples are reported.

Measurement uncertainty

As variation occurs in measurements, uncertainty exists as to the true value. Uncertainty represents a range of values in which the true value is reasonably expected to lie. In most situations, measurement uncertainty is estimated at "95% coverage". For most instances, a range of ±2 SD is accepted as measurement uncertainty that is explained by random variation.

But the degree of variation also depends on the method used. Methods that are more precise have less uncertainty because the amount of variation included in the 95% limits is smaller.

Laboratories should strive to use methods that have a high degree of precision, and always follow standard operating procedures.

7-6: Using quality control information

When QC is out of range

When the QC sample that is used in a test run is out of the acceptable range, the run is considered to be "out of control". When this happens, there are several steps that the laboratory must follow.

- The testing process should be stopped and the technologist must immediately try to identify and correct problems.
- Once possible sources of error have been identified and corrections have been made, the control material should be rechecked. If they read correctly, then patient samples, along with another QC specimen, should be repeated. Do not simply repeat the testing without looking for sources of error and taking corrective action.
- Patient results **must not be reported** until the problem is resolved and the controls indicate proper performance.

Problem solving

When attempting to solve QC problems, it is useful to have established policies and procedures for remedial action. Often, manufacturers of either equipment or reagents will provide guidelines that can be helpful. Use any troubleshooting guides that are available.

Possible problems to consider include:

- degradation of reagents or kits
- control material degradation
- operator error
- failure to follow manufacturer's instructions
- an outdated procedure manual
- equipment failure
- calibration error.

7-7: Summary

Summary

A QC programme for quantitative tests is essential to ensuring accuracy and reliability of laboratory testing. The laboratory must establish a QC programme that monitors all quantitative tests. The programme will have written policies and procedures that are followed by all laboratory staff.

The overall responsibility of managing the QC programme is usually assigned to the quality manager, who monitors and reviews all QC data on a regular basis. The recording of the QC data must be complete and easy to access.

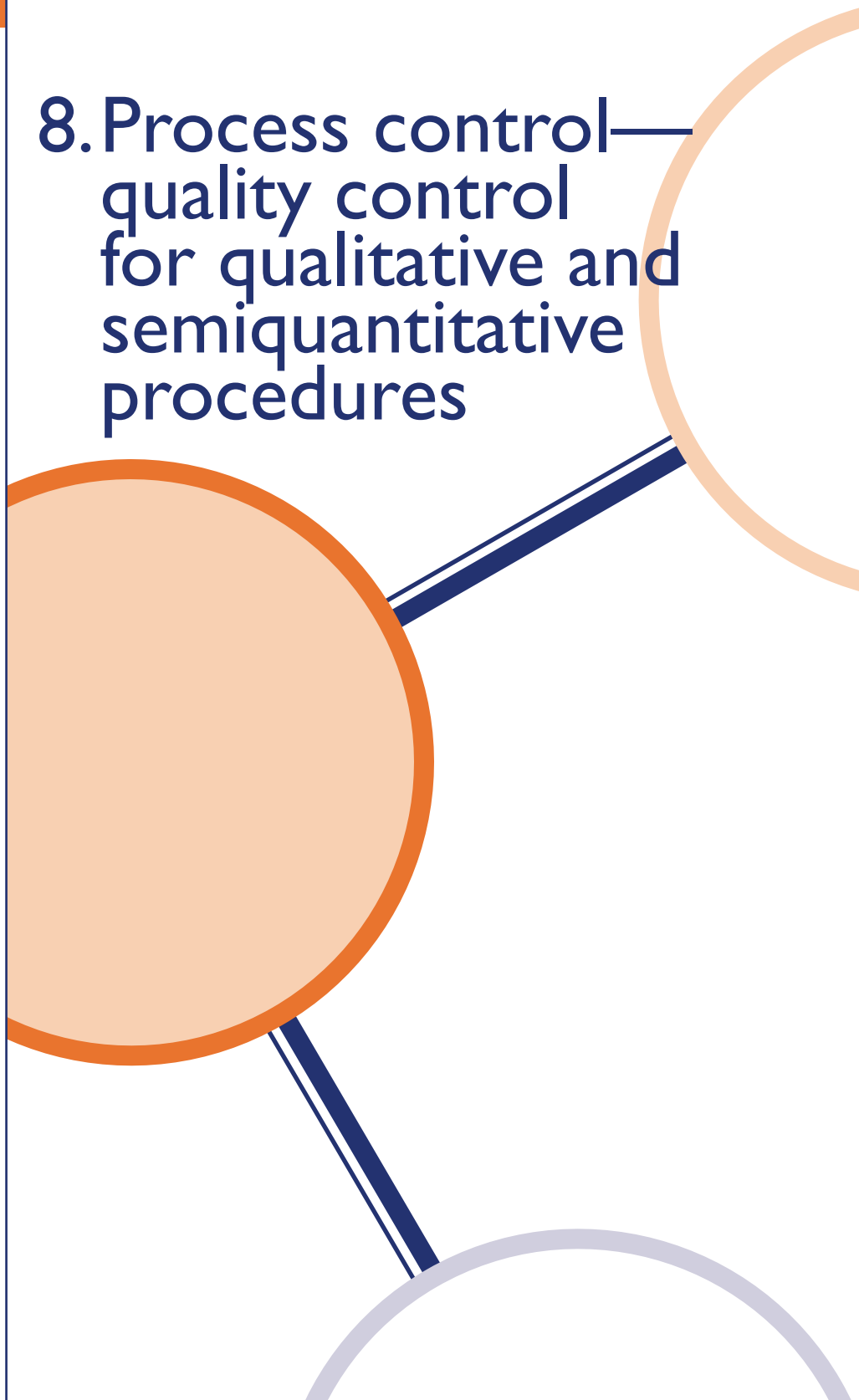
For quantitative testing, statistical analysis can be used for the monitoring process, and the use of Levey–Jennings charts provides a very useful visual tool for this monitoring.

When controls are out of range, corrective action and troubleshooting must be undertaken; the problem must be fixed before reporting patient results. Therefore, good protocols for troubleshooting and corrective action are an important part of the QC process.

Key messages

- A QC programme allows the laboratory to differentiate between normal variation and error.
- The QC programme monitors the accuracy and precision of laboratory assays.
- The results of patient testing should never be released if the QC results for the test run do not meet the laboratory target values.

8. Process control—quality control for qualitative and semiquantitative procedures



8-1: Overview

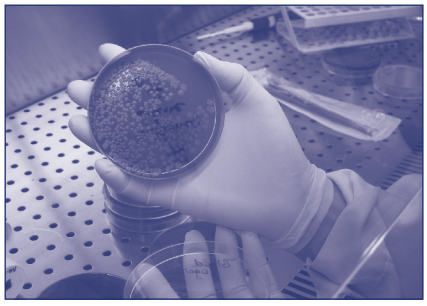
Role in quality management system

Quality control (QC) is a component of process control, which is a major element of the quality management system. It monitors the processes related to the examination phase of testing and allows for detecting errors in the testing system. These errors may be due to test system failure, adverse environmental conditions or operator performance. QC gives the laboratory confidence that test results are accurate and reliable before patient results are reported.

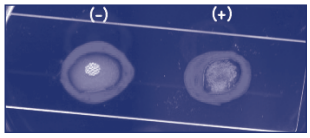
This chapter explains how QC methods are applied to qualitative and semiquantitative laboratory examinations.

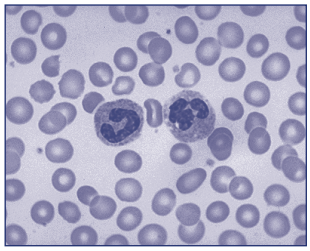
Qualitative and semiquantitative examinations

Qualitative examinations are those that measure the presence or absence of a substance, or evaluate cellular characteristics such as morphology. The results are not expressed in numerical terms, but in descriptive or qualitative terms such as "positive", "negative", "reactive", "nonreactive", "normal" or "abnormal".



Examples of qualitative examinations include microscopic examinations for cell morphology or presence of parasitic organisms, serologic procedures for presence or absence of antigens and antibodies, some microbiological procedures and some molecular techniques.





Semiquantitative examinations are similar to qualitative examinations; testing does not measure the precise

quantity of a substance. The difference is that results of these tests are expressed as an **estimate** of how much of a measured substance is present. This estimate is sometimes reported as a number. Therefore, test results for semiquantitative tests may be shown as "trace amount", "1+, 2+ or 3+", or positive at 1:160 (titre or dilution). Examples of semiquantitative examinations are urine dipsticks, tablet tests for ketones and serological agglutination procedures.

Some microscopic examinations are considered semiquantitative because results are reported as estimates of the number of cells seen per low-power field or high-power field. For example, a urine microscopic examination might report 0–5 red blood cells seen per high-power field.

Important concepts

As with quantitative procedures, it is important to verify that results of qualitative and semiquantitative examinations are correct prior to reporting them to the requesting health care provider.

Conducting QC for many of these tests is not as easily accomplished as with quantitative tests. Therefore, it becomes essential that other processes within the quality system are carefully conducted, in addition to traditional QC methods. Following are some important overarching concepts for quality that apply to qualitative and semiquantitative tests.

- Sample management is important in all laboratory testing. Examinations that are dependent on a viable organism in the sample may need closer monitoring and better communication with nonlaboratory staff (see Chapter 5).
- Dedicated, professional staff who understand the principles of QC are key to quality.
- Incubators, refrigerators, microscopes, autoclaves and other equipment must be maintained and monitored carefully (see Chapter 3).
- Positive and negative controls must be used to monitor the effectiveness of test procedures that use special stains or reagents and tests with end-points such as agglutination, colour change or other non-numeric results.
- Reagents should be stored according to the manufacturer's instructions, labelled with the date they are opened and put into use, and discarded at the expiration date (see Chapter 4).
- Keeping records of all QC processes and corrective actions is necessary for continual improvement of the laboratory quality system (see Chapter 16).
- When problems occur, investigate, correct, and repeat patient testing (see Chapter 14).

If QC results are not what are expected, do not report patient results.

8-2: Quality control materials

Control types

Qualitative and semiquantitative examinations include tests that utilize a variety of control materials. These controls may be built-in (on-board or procedural) controls, traditional controls that mimic patient samples, or stock cultures for use with microbiological examinations.

Built-in controls

Built-in controls are those that are integrated into the design of a test system such as a test kit device. Usually, the device is marked with designated areas where coloured lines, bars or dots should appear to indicate success or failure of positive and negative controls, and these controls are performed automatically with each test. The manufacturer's product instructions may also refer to these as procedural controls, on-board controls or internal controls.

Most built-in controls monitor only a portion of the examination phase, and they vary from one test to another as to what is being monitored. For example, built-in controls for some kits may indicate that all the reagents impregnated into the device are active and working properly, whereas built-in controls for other kits may only indicate that a sample was added and solutions flowed through the device correctly. It is important to carefully read the instructions provided by the manufacturer to understand what the built-in controls monitor, and to determine whether additional controls may be needed.

Examples of test kits with built-in controls are rapid tests that detect the presence of antigens or antibodies, such as those for infectious disease (human immunodeficiency virus [HIV], influenza, lyme disease, streptococcal infection, infectious mononucleosis), drugs of abuse, pregnancy or faecal occult blood.

Even though these built-in controls give some degree of confidence, they do not monitor for all conditions that could affect test results. It is advisable to periodically test traditional control materials that mimic patient samples, for added confidence in the accuracy and reliability of test results.

In some settings, these built-in controls are referred to as internal controls.

Traditional controls

Traditional control materials are made to mimic patient samples and they are tested with the patient samples to evaluate the examination component. Positive controls have known reactivity and negative controls are nonreactive for the analyte being tested. The controls should have the same composition, or matrix, as patient samples, including viscosity, turbidity and colour, in order to properly evaluate the test performance. Control materials are often lyophilized when received, and need to be carefully reconstituted before use. Some manufacturers may provide

these controls with their test kits but, more frequently, they need to be purchased separately.

Traditional controls evaluate the testing process more broadly than built-in controls. They assess the integrity of the entire test system, the suitability of the physical testing environment (temperature, humidity, level workspace), and whether the person conducting the test performs it correctly.

Positive and negative controls are recommended for many qualitative and semiquantitative tests, including some procedures that use special stains or reagents, and tests with end-points such as agglutination or colour change. These controls should generally be used with each test run. Use of controls will also help to validate a new lot number of test kits or reagents, to check on temperatures of storage and testing areas, and to evaluate the process when new testing personnel are carrying out the testing.

Things to keep in mind when using traditional controls for qualitative or semiquantitative tests are:

- test control materials in the same manner as testing patient samples;
- use a positive and negative control, preferably once each day of testing, or at least as often as recommended by the manufacturer;
- choose positive controls that are close to the cut-off value of the test, to be sure the test can detect weak positive reactions;
- for agglutination procedures, include a weak positive control as well as a negative control and a stronger positive control;
- for tests with an extraction phase, such as some rapid group A *Streptococcus* tests, choose controls that are capable of detecting errors in the extraction process.

Stock cultures

QC in microbiology requires use of live control organisms with predictable reactions to verify that stains, reagents and media are working correctly. They must be kept on hand and carefully maintained in the form of stock and working cultures. For each reaction, organisms with both positive and negative results should be tested.

The following organizations offer reference strains, which are available from local distributors:

- American Type Culture Collection (ATCC)
- National Type Culture Collection (NTCC, United Kingdom)
- Pasteur Institute Collection (CIP, France).

Purchased reference strains are usually lyophilized and kept in the refrigerator. Once they are reconstituted, plated and checked for purity, they can be used to make working cultures for quality control.

Some laboratories may choose to use isolates from their own laboratories for QC. If so, they should be monitored closely to verify that reactions tested are sustained over time.

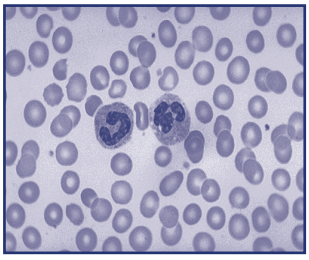
8-3: Quality control of stains

Procedures using stains

In performing many qualitative and semiquantitative procedures, stains are needed for evaluating microscopic morphology of cells, parasites or microbes, or to determine their presence or absence. Stains are used for microscopic procedures that provide information for either preliminary or definitive diagnosis. These are frequent in haematology, urinalysis, cytology, histology, microbiology, parasitology and other laboratory areas.

In microbiology, permanent stains such as acridine orange, trichrome and iron-haematoxylin for faecal parasites, and Giemsa stain for malaria, are frequently used. Gram stains are used for identification of bacteria and yeast from colonies and samples. Acid-fast stains are particularly important for preliminary diagnosis, since growth of mycobacteria takes several weeks. In many sites, *Mycobacterium tuberculosis* (TB) cultures are not available and acid-fast smears will provide the final diagnosis for patients. For wet mounts, iodine solutions are used to detect cysts and eggs in faecal samples, and potassium hydroxide preparations are used to detect fungal elements.

Examination of blood smears requires a stain that allows for clear visualization of red blood cells, white blood cells, platelets and inclusions within cells. Differentiation of cells in blood most frequently employs a Wright stain, and some haematology procedures use special stains to help differentiate infection from leukaemia.



Cytology and histology tests require a wide variety of stains that provide valuable information for diagnosis. Many other stains are available to laboratory staff for special uses.

The common elements for QC are the same: the stains should be prepared and stored properly, and checked to be sure they perform as expected. Remember that many of the microscopic examinations that rely on stains are critical in diagnosis of many diseases.

Stain management

Some stains can be purchased commercially, but others must be prepared by the laboratory, following an established procedure. Once stains are made, their bottles should be labelled with the following information:

- name of the stain
- concentration
- date prepared
- date placed in service
- expiration date/shelf life
- preparer's initials.

It may be useful to keep a logbook for recording information on each stain in use, including the lot number and date received. The expiration date must be noted on the label. Some stains deteriorate and lose their ability to produce the correct reactions.

Stains should be stored at the correct temperature at all times and in an appropriate staining bottle. Some stains must be protected from light. In some cases, working solutions can be made from stock solutions. If so, storage of working solutions should be carefully monitored.

Quality control

Because of their importance, stains should be checked each day of use with positive and negative QC materials, to make sure their reagents are active and they provide the intended results. In most cases, positive and negative controls should be stained with each batch of patients' slides. All QC results must be recorded each time they are run.

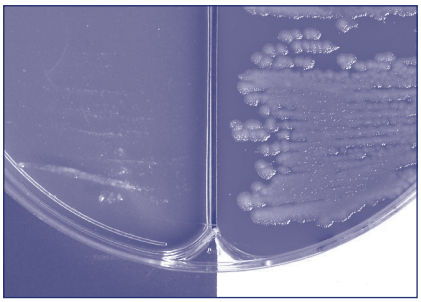
Stains should also be examined to look for precipitation or crystal formation, and to check for bacterial contamination. Careful maintenance and care of the stock and working solutions of stains is an essential component in a system to provide good quality in microscopic examinations.

Be aware that many stains are toxic, therefore, take appropriate safety precautions when working with them.

8-4: Quality control of microbiological media

QC is essential for media

The quality of media used in the microbiology laboratory is crucial to achieving optimal and reliable results. Some media are essential to isolation of microbes, so it is imperative that they function as expected. QC procedures provide the confidence that media has not been contaminated prior to use, and that it supports the growth of the organism with which it was inoculated.



Verifying performance

The performance characteristics of all media used in the laboratory must be verified by the appropriate QC methods. For media that is prepared in-house, this evaluation must be conducted for each batch prepared; for all commercially prepared media, the performance verification will be performed for each new lot number.

In all cases, in-house and purchased media should be carefully checked for:

- sterility—incubate overnight before use
- appearance—check for turbidity, dryness, evenness of layer, abnormal colour
- pH
- ability to support growth—using stock organisms
- ability to yield the appropriate biochemical results—using stock organisms.

Use of control organisms for verification

The laboratory must maintain sufficient stock organisms to check all its media and test systems. Some examples of important stock organisms, and the media checked, include:

- *Escherichia coli* (ATCC 25922): MacConkey or eosin methylene blue (EMB), some antimicrobial susceptibility testing;
- *Staphylococcus aureus* (ATCC 25923): blood agar, mannitol salt and some antimicrobial susceptibility tests;
- *Neisseria gonorrhoeae* (ATCC 49226): chocolate agar and Thayer–Martin agar.

For selective media, inoculate a control organism that should be inhibited as well as one that should grow. Discard any batch of media that does not work as expected.

For differential media, inoculate the media with control organisms that should demonstrate the required reactions. For example, inoculate both lactose-fermenting and non-lactose-fermenting organisms onto EMB or MacConkey agar to verify that the colonies exhibit correct visual appearance.

Note: sheep and horse blood are preferred in preparing media for routine cultures. Blood agar made from human blood should not be used as it will not demonstrate the correct haemolysis pattern for identification of certain organisms, and it may contain inhibitory substances. In addition, human blood can be biohazardous.

In-house media preparation records

It is important to keep careful records for media that is prepared in the laboratory. A logbook should be maintained that records:

- date and preparer's name
- name of the medium, the lot number and manufacturer
- number of prepared plates, tubes, bottles or flasks
- assigned lot and batch numbers
- color, consistency and appearance
- number of plates used for QC
- sterility test results at 24 and 48 hours
- growth test(s)
- pH.

8-5: Summary

Examinations with non-numerical results

Qualitative and semiquantitative examinations are those that give non-numerical results. Qualitative examinations measure the presence or absence of a substance, or evaluate cellular characteristics such as morphology. Semiquantitative examinations provide an estimate of how much of the measured substance is present.

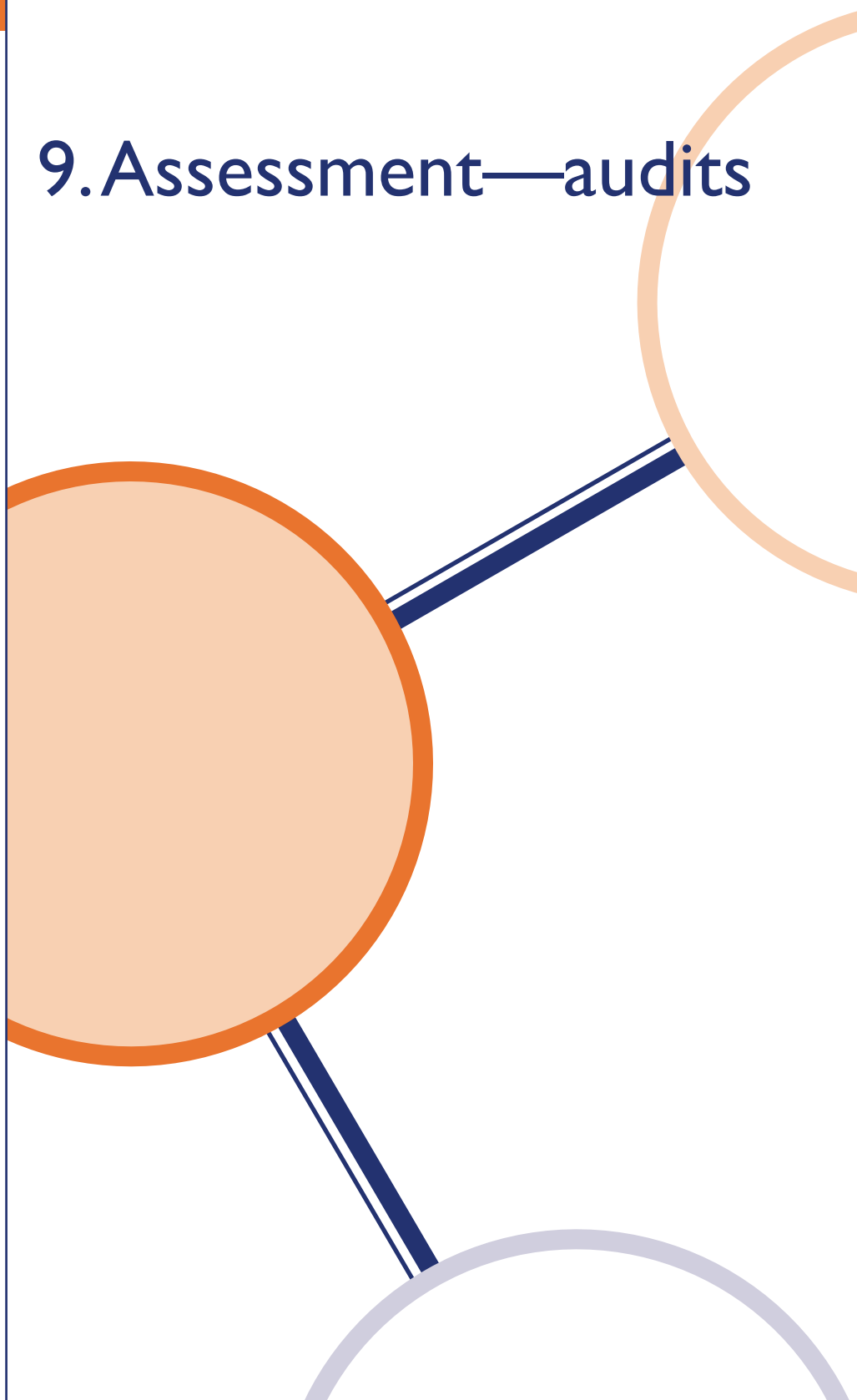
Qualitative and semiquantitative testing must be monitored by QC processes. These processes should use controls that mimic patient samples as much as possible. Quality controls that check kits, reagents, stains and microbiological media and ensure that they work as expected must be used whenever they are available.

The laboratory must establish a QC programme for all of its qualitative and semiquantitative tests. In establishing this programme, set policies, train staff and assign responsibilities, and ensure that all resources needed are available. Make sure that recording of all QC data is complete, and that appropriate review of the information is carried out by the quality manager and the laboratory director.

Key messages

- All staff must follow the QC practices and procedures.
- Always record QC results and any corrective actions that are taken.
- **If QC results are not acceptable, do not report patient results.**

9. Assessment—audits



9-1: Overview

Role in quality management system

Assessment is an important element of the 12 quality system essentials. It is the means for determining the effectiveness of a laboratory's quality management system through internal and external audits, and evaluation of performance in an external quality assessment (EQA) programme. This chapter is focused on descriptions of internal and external audits; EQA will be described in Chapter 10.

What is assessment?

An assessment can be defined as the systematic examination of some part (or sometimes all) of the quality management system to demonstrate to all concerned that the laboratory is meeting regulatory, accreditation and customer requirements. Central-level laboratories are generally familiar with assessment processes, as most will have had some kind of assessment by an external group. However, intermediate or peripheral-level laboratories may not be assessed very often in resource-limited countries.

Accepted standards, whether international, national, local, or standards from accrediting organizations, form the basis for laboratory assessment. In that respect, assessment is interrelated with norms and accreditation (Chapter 11).

In an assessment, someone is asking the following questions:

- What procedures and processes are being followed in the laboratory; what is being done?
- Do the current procedures and processes comply with written policies and procedures? And in fact, are there written policies and procedures?
- Do written policies and procedures comply with standards, regulations, and requirements?

Why perform an assessment?

Assessments are performed in a variety of ways and under a number of different circumstances. The International Organization for Standardization (ISO) standards are very specific about assessment requirements, and the term "audit" is used instead of "assessment". The terms may be considered interchangeable, and local usage will determine the actual terminology required. The ISO definition for audit is a "systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which required criteria are fulfilled."

An assessment, or audit, allows the laboratory to understand how well it is performing when compared to a benchmark or standard. Any gaps or nonconformities in performance can show if the policies and procedures that the laboratory has set require revision or are not being followed.

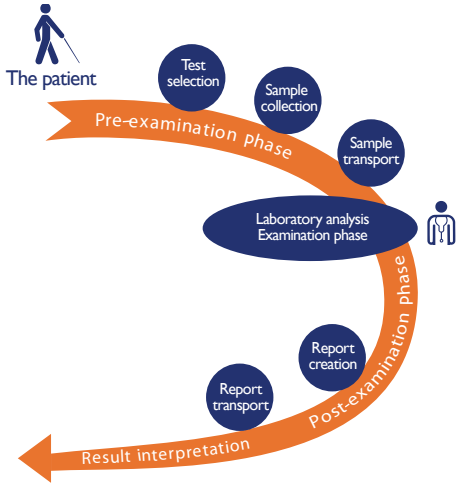
A laboratory needs this information about its performance for:

- planning and implementing the quality system
- monitoring effectiveness of the quality system
- correcting any deficiencies that are identified
- working toward continuous improvement.

External and internal audits

Assessments conducted by groups or agencies from outside the laboratories are called **external audits**. They can include assessments for the purpose of accreditation, certification or licensure.

Another type of assessment that laboratories can utilize is the **internal audit**, where staff working in one area of the laboratory conduct assessments on another area of the same laboratory. This provides information quickly and easily on how the laboratory is performing and whether it is in compliance with policy requirements.



Laboratory path of workflow

Audits should include the evaluation of steps in the whole laboratory path of workflow. They should be able to detect problems throughout the entire process.

Auditing

The value of a well-designed audit is that it will reveal weaknesses in the pre-examination, examination and post-examination phases. During audits, information is gathered about:

- processes and operating procedures
- staff competence and training
- equipment
- environment
- handling of samples
- quality control and verification of results
- recording and reporting practices.

The findings are compared with the laboratory's internal policies and to a standard or external benchmark. Any breakdown in the system or departure from procedures will be identified.

9-2: External audit

External audits

Assessments conducted by groups or agencies from outside the laboratory are called external audits. Some examples of external auditors are described below.

- Health authorities may assess laboratories to evaluate the quality of performance, or compliance with licensing requirements and national regulations. They may also assess as part of a capacity strengthening plan of action, or for public health programme needs.
- Accreditation bodies are organizations that provide accreditation or certification. When a laboratory seeks accreditation, an initial audit will be required to evaluate compliance with standards. In order to maintain accredited status, the accreditation bodies will require periodic audits (see Chapter 11).
- An audit may be requested by major public health programmes, or by agencies that provide funding for programmes. These groups want to ensure that quality standards are being met and that quality practices are in place. International programmes such as the World Health Organization (WHO) Polio Initiative regularly assess disease-specific laboratories according to their own standards with their own checklists; for example, WHO polio laboratory accreditation standard and WHO measles accreditation standard.

Standards

In conducting external audits, the assessors will verify that laboratory policies, processes and procedures are documented and comply with designated standards. Different standards can be used for the assessment processes, ranging from international standards to a locally developed checklist.

Laboratory management must demonstrate to the assessment team that all requirements as laid down in the standard are being followed.

Preparation

When a laboratory undergoes an external audit, the laboratory needs to be fully prepared so that the assessment experience is as easy as possible for both the assessors and the laboratory staff, and so the assessment yields the maximum amount of information.

To be ready for the external audit, it is necessary to:

- plan thoroughly and carefully;
- organize everything ahead of time, including documents and records, to save valuable time during the audit;
- make all staff aware of the audit, and arrange schedules so that all staff needed for the audit will be available.

On occasion, some external audits might occur without prior notification. In this case, the laboratory would not be able to make special preparation, so the laboratory should always be sure its system is operating properly.

Audit report and plan of action

After the audit, the recommendations of the assessors are often presented as a verbal summary to the laboratory management and staff, which are then followed by a thorough written report. After the external audit has been completed the laboratory should:

- review the recommendations of the assessors;
- identify gaps or nonconformities, learning where benchmarks or standards were not fully met;
- plan to correct the nonconformities—this will result in a plan for all needed corrective actions to be taken by the laboratory, which should include a timeline, as well as indicate who is responsible for doing the work;
- record all results and actions taken so that the laboratory has a permanent record of the event—often a written report is useful for preserving all information.

9-3: Internal audit

Purpose

Most technologists in central-level laboratories are relatively familiar with external audits; however, the idea of conducting internal audits might be new to some people.

An internal audit allows the laboratory to look at its own processes. In contrast to external audits, the advantages of internal audits are that laboratories can perform them as frequently as needed, and at very little or no cost. Internal audits should be a part of every laboratory quality system, and are a requirement of ISO standards.[1]

The audits should be conducted regularly and when problems that need to be studied have been identified. For example, internal audits should be performed after receiving a poor performance on a proficiency testing survey, after an increased number of unexpected abnormal results for a particular test, or after an increase in expected turnaround time.

Value of an internal audit

The internal audit is a valuable tool in a quality management system. An internal audit can help the laboratory to:

- prepare for an external audit;
- increase staff awareness of quality system requirements;
- identify the gaps or nonconformities that need to be corrected—the opportunities for improvement;
- understand where preventive or corrective action is needed;
- identify areas where education or training needs to occur;
- determine if the laboratory is meeting its own quality standards.

Internal audit and ISO

ISO standards put much emphasis on internal audits, and for those seeking accreditation under ISO, internal audits are required. ISO requirements state that:

- the laboratory must have an audit programme;
- the auditors should be independent of the activity;
- audits must be documented and reports retained;
- results must be reported to management for review;
- problems identified in the audits must be promptly addressed and appropriate actions taken.

1 ISO 19011:2002. *Guidelines for quality and/or environmental systems auditing*. Geneva, International Organization for Standardization, 2002.

9-4: Internal audit programme

Responsibilities

The laboratory director is responsible for setting overall policies for the internal audit programme. Responsibilities will include assigning authority for the programme (usually to the quality manager) and supporting the corrective action measures that are indicated. It is essential that the laboratory director be fully informed about the results of all internal audits. The quality manager is responsible for organizing and managing the laboratory internal audit programme. This includes setting a timeframe for the audits, choosing and training the auditors, and coordinating the process. The follow-up activities will also usually be the responsibility of the quality manager, and these include managing all corrective action efforts. The quality manager must be sure that laboratory management and the laboratory staff are fully informed about outcomes of the audit.

The commitment of laboratory management and the quality manager will be key to successfully establishing a process for internal audits.

Process

The quality manager or other designated qualified personnel should organize the internal audit following these steps:

- develop a formal plan
- prepare a checklist based on selected guidelines or standards
- meet with all staff and explain the audit process
- select staff to serve as auditors
- collect and analyze information
- share results with staff
- prepare a report
- present the report to management
- retain the report as a permanent laboratory record.

Select areas for audits

In order to facilitate the internal audit process, it is useful to keep it simple. Focus on defined areas of the laboratory activities, identified by issues such as customer complaints or quality control problems. Narrowing the audit to the specific corresponding process will save time and energy. Perform short and frequent audits rather than initiating an annual comprehensive and overwhelming effort.

Establish a schedule

ISO 15189:2007 [4.14.2] states: "The main elements of the quality management system should normally be subject to internal audit once every twelve months". This requirement does not mean that a complete audit needs to be done annually. Rather, it means that over a period of a year, every part of the laboratory should have at least one inspection. Doing a number of small, bench-specific or section-specific audits is much easier than trying to do them all at the same time.

Establish a policy that, at specified intervals, some section of the laboratory or a specific process will have an internal audit. In general, audit regularly and consider three to six-month intervals between audits. If audits reveal specific problems, it may be necessary to include more frequent audits.

Checklists and forms used

When developing checklists for internal audits:

- Take into account any established national policies and standards. For example, most countries have standards for human immunodeficiency virus (HIV) and tuberculosis testing; laboratories conducting this testing need to ensure checklists reflect these standards.
- Ensure checklists are easy to use and include areas for recording information.
- Focus on specific tests or processes; whatever the area of focus, address all areas of the quality system. If auditing enzyme-linked immunosorbent assay (ELISA) tests, consider personnel competency or equipment maintenance, sample handling, and quality control associated with these tests.

Forms will be needed for recording corrective actions and for making reports.

Select auditors

When the laboratory initializes an internal audit programme, selection of auditors is one of the first steps to address. It is very important, and required by ISO standards, that the auditors are independent of the area audited. Some things to consider are:

- The availability of staffing and level of technical expertise—depending on the area for auditing, there might be many kinds of personnel who would be appropriate for conducting the audit; for example, if the laboratory is looking at safety issues, a hospital safety expert, or even a housekeeping expert might be appropriate.
- Whether to hire a consultant—this could still be conducted as an internal audit: the audit is planned by the laboratory itself, without any external constraints, but consultants or peers recruited by the laboratory for this specific audit will help the laboratory staff to conduct it.

Important skills for auditors

Any knowledgeable person in the laboratory can perform internal audits, not just the manager or supervisor.

When deciding the personnel to choose for the audit process, take into account the skills that will be needed for a good result. A good auditor will:

- pay attention to details—for example, check expiry dates, open and inspect refrigerators and storage areas;
- be able to communicate effectively, but also diplomatically—diplomacy is an important skill, since it is easy to imply criticism during an audit process.

The auditors chosen must have the technical skills needed to evaluate the area being audited, and must have a good understanding of the laboratory's quality management system. Some staff may have specialized expertise in a limited area, such as sample transport or housekeeping, but could serve as auditors in these areas. Some in-house training on how to conduct an audit should be provided to those who will serve as auditors.

If auditors are poorly chosen, the audits will be much less effective.

9-5: Actions as result of audit

Audits should lead to actions

Audits should lead to actions—this is why laboratories conduct them, to further the process of continual improvement in the laboratory.

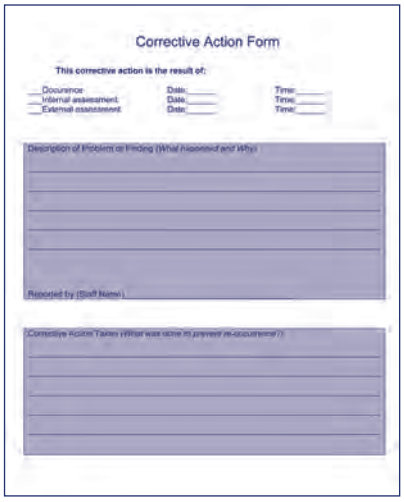
Audits identify opportunities for improvement (OFIs). Both preventive and corrective actions are steps taken to improve a process or to correct a problem.

A record of OFIs should be kept, along with actions that are taken. Preventive and corrective actions should be carried out within an agreed-upon time. Normally the quality manager is responsible for initiating actions.

Problem solving

Sometimes the cause of the problem is not obvious or easily found; in such cases a problem-solving team may be necessary to:

- look for root causes;
- recommend the appropriate corrective action;
- implement the actions decided upon;
- check to see if the corrective actions are effective;
- monitor the procedures over time.

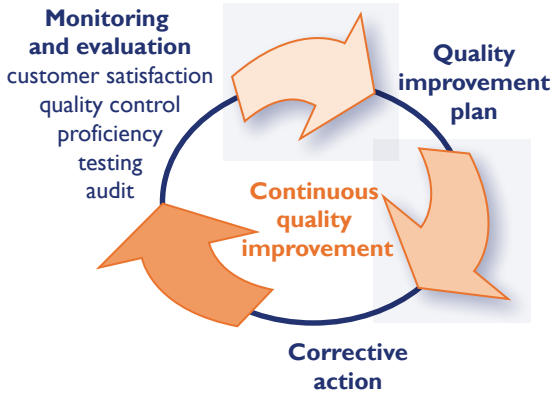

Corrective Action Form

This corrective action is the result of:

All actions and findings from the monitoring should be recorded so the laboratory can learn from its activities.

Continuous monitoring

Continuous monitoring is the key element to success in the quality system. It is through this process that we are able to achieve the continual improvement that is our overall goal.



9-6: Summary

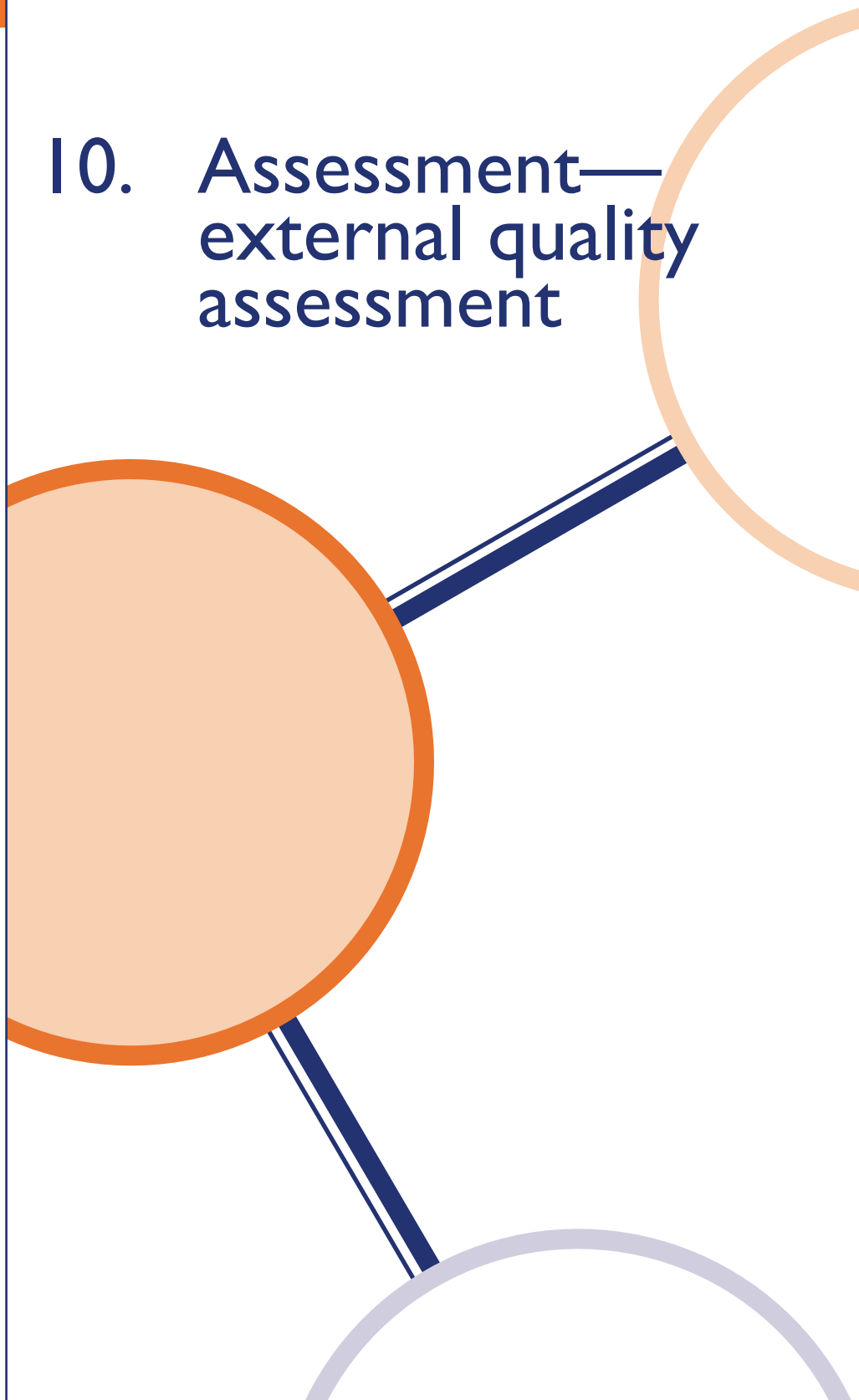
Summary

Assessment is important in monitoring the effectiveness of the laboratory quality management system. Both external and internal audits yield useful information. Audits are used to identify problems in the laboratory, in order to improve processes and procedures. An outcome of assessment is finding root causes of problems and taking corrective actions.

Key messages

- All laboratories should establish an internal audit programme. Conducted on a regular basis, it will provide information for continual improvement.
- Problems become opportunities for improvement.

10. Assessment—external quality assessment



10-1: Overview

Role in quality management system

Assessment is a critical aspect of laboratory quality management, and it can be conducted in several ways. One of the commonly employed assessment methods is that of external quality assessment (EQA).

Definition of EQA

The term EQA is used to describe a method that allows for comparison of a laboratory's testing to a source outside the laboratory. This comparison can be made to the performance of a peer group of laboratories or to the performance of a reference laboratory. The term EQA is sometimes used interchangeably with proficiency testing; however, EQA can also be carried out using other processes.

EQA is here defined as a system for objectively checking the laboratory's performance using an external agency or facility.

Types of EQA

Several EQA methods or processes are commonly used. These include:

1. Proficiency testing—external provider sends unknown samples for testing to a set of laboratories, and the results of all laboratories are analyzed, compared and reported to the laboratories.
2. Rechecking or retesting—slides that have been read are rechecked by a reference laboratory; samples that have been analyzed are retested, allowing for interlaboratory comparison.
3. On-site evaluation—usually done when it is difficult to conduct traditional proficiency testing or to use the rechecking/retesting method.

Another method of interlaboratory comparison is the exchange of samples among a set of laboratories, usually reserved for specialized tests for which no proficiency testing is available. This method is used by very specialized or sophisticated laboratories and therefore will not be further discussed in this chapter.

EQA benefits

Participation in an EQA programme provides valuable data and information, which:

- allows comparison of performance and results among different test sites;
- provides early warning for systematic problems associated with kits or operations;
- provides objective evidence of testing quality;
- indicates areas that need improvement;
- identifies training needs.

EQA helps to ensure customers, such as physicians, patients and health authorities, that the laboratory can produce reliable results.

Individual laboratories can use EQA to identify problems in laboratory practices, allowing for appropriate corrective action. EQA participation will help to evaluate reliability of methods, materials and equipment, and to evaluate and monitor training impact.

For laboratories performing public health–related testing, EQA can help to ensure that results from different laboratories during surveillance activities are comparable. EQA participation is usually required for accreditation. Also, EQA participation creates a network for communication, and can be a good tool for enhancing a national laboratory network. Samples received for EQA testing, as well as the information shared by the EQA provider, are useful for conducting continuing education activities.

Principal characteristics of an EQA scheme

EQA programmes vary, but principal characteristics include the following:

- EQA programmes can either be free of charge or require a fee. Free EQA programmes include those offered by a manufacturer to ensure equipment is working correctly, and those organized by a regional or national programme for quality improvement.
- Some EQA programmes are obligatory, either required by an accrediting body or by law. Others are voluntary, and the quality manager may choose to voluntarily participate in an EQA programme in order to achieve improvement in the quality of the laboratory's performance.
- The EQA programme can be organized at different levels: regional, national or international.
- Individual laboratory results are kept confidential, and generally are only known by the participating laboratory and the EQA provider. A summary is generally provided and allows comparison to the overall group.

- Some EQA schemes may address a single disease; for example, the EQA programme for tuberculosis. Others may address many kinds of laboratory tests, looking at the overall testing performance for microbiology. An example of this multidisease or test programme is the national microbiology EQA in France, which is obligatory.

Successful performance in an EQA programme reflects the effectiveness of the laboratory's quality management, and allows for recognition of laboratory quality by external groups.

EQA is important for improvement of the laboratory quality management system, as it is a measure of laboratory performance.

10-2: Proficiency testing

Definitions

Proficiency testing, or PT, has been in use by laboratories for many years. It is the most commonly employed type of EQA, as it is able to address many laboratory methods. PT is available for most of the commonly performed laboratory tests, and covers a range of chemistry, haematology, microbiology and immunology testing. Most laboratorians are familiar with the PT process, and many laboratories employ some kind of PT.

Standards organizations recognize the importance of this tool, and the following are examples of formal definitions that are in use.

- ISO/IEC Guide 43-1:1997: "Proficiency testing schemes (PTS) are interlaboratory comparisons that are organized regularly to assess the performance of analytical laboratories and the competence of the analytical personnel".
- Clinical and Laboratory Standards Institute: "A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others".

Proficiency testing process

In the PT process, laboratories receive samples from a PT provider. This provider may be an organization (non-profit or for-profit) formed specifically to provide PT. Other providers of PT include central reference laboratories, government health agencies, and manufacturers of kits or instruments.

In a typical PT programme, challenge samples are provided at regular intervals. An optimal frequency will be 3–4 times yearly. If the programme cannot provide challenges with this frequency, the laboratory may be able to seek additional sources.

The laboratories participating in the programme analyze the samples and return their results to the central organization. Results are evaluated and analyzed, and the laboratories are provided with information about their performance and how they compared with other participants. The participating laboratories use the information regarding their performance to make appropriate changes and improvements.

Role of the laboratory

To be successful, PT instructions must be followed carefully, all paper work completed accurately and results submission deadlines met. All PT results, as well as corrective actions, should be recorded and the records maintained for an appropriate period of time.

PT is a tool to measure laboratory performance. Therefore, there must be no difference in the treatment of PT samples and the patient's sample. PT providers make every effort to produce samples that exactly mimic, or closely resemble, usual samples received from patients. PT samples must be processed by normal testing method(s) and involve personnel who routinely perform the testing.

When PT is used for any purpose other than internal quality improvement, the provider or central organization generally prohibits the discussion of results with other laboratories. Some PT organizers send different samples to different groups of laboratories to avoid interlaboratory discussion.

Limitations

PT participation is valuable only if the information received is directed to improvement in the laboratory.

It is important to remember that PT does have some limitations and it is not appropriate to use PT as the only means for evaluating the quality of a laboratory. PT results are affected by variables not related to patient samples, including preparation of the sample, matrix effects, clerical functions, selection of statistical methods of evaluation, and peer group definition. PT will not detect all problems in the laboratory, particularly those that address the pre-examination and post-examination procedures.

A single unacceptable result does not necessarily indicate that a problem exists in the laboratory.

10-3: Other external quality assessment methods

Using other EQA methods

In situations where it is difficult to provide appropriate external samples, or sometimes when normal laboratory quality control methods cannot be applied, other procedures have been developed and used for EQA. The primary examples and their uses are as follows:

- Rechecking/retesting has been used traditionally for EQA for microscopic slides for acid-fast bacilli (AFB), and for human immunodeficiency virus (HIV) rapid testing. It can also be used in other situations, but is not usually employed if traditional PT is feasible.
- On-site evaluation has proven a useful technique for the same situations—AFB examination and HIV rapid testing. It allows for an external evaluation of quality on-site, and can be conducted in conjunction with PT or rechecking/retesting.

These procedures can be time-consuming and costly, and so are used only when there are not good alternatives. It is essential to have a reference laboratory with the capacity to do the repeat testing; the use of a reference laboratory gives assurance that the re-examination process will give a dependable result. The turnaround for the retesting must be accomplished in a timely manner, allowing for immediate corrective actions. In some settings, transport of samples or slides to the reference laboratory will present problems.

Retesting process

This EQA method is used for HIV rapid testing. HIV rapid testing presents some special challenges, because it is often performed outside a traditional laboratory, and by persons who are not trained in laboratory medicine. Additionally, the kits are single use, and cannot be subjected to the usual quality control methods that laboratories employ. Therefore, retesting of some of the samples using a different process such as enzyme immunoassay (EIA) or enzyme-linked immunosorbent assay (ELISA) helps to assess the quality of the original testing.

Characteristically, the retesting is:

- done by a reference laboratory to ensure quality;
- performed on dried blood spots or serum collected at the time of the rapid test performance;
- not performed as a blinded process, as this is unnecessary.

The number of samples retested must provide statistically significant data in order to detect error. This becomes difficult in settings where small numbers of rapid tests are performed. A full discussion of the statistical issues in retesting is found in the Centres for Disease Control and Prevention and World Health Organization *Guidelines for assuring the accuracy and reliability of HIV rapid testing: applying a quality system approach.*

Rechecking process

This method is most commonly used for acid-fast smears; the slides that were read in the original laboratory are "rechecked" in a central or reference laboratory. This allows for the accuracy of the original report to be evaluated, and also allows assessment of the quality of the slide preparation and staining.

The following principles are important when performing recheck procedures:

- The slides for re-examination must be collected randomly. Every effort should be made to avoid systematic sampling bias.
- Rechecking must be based upon statistical considerations. A common method is for the central laboratory to recheck 10% of negative and 100% of positive slides.
- When discrepancies occur, there should be procedures in place to resolve them.
- The outcome of rechecking must be analyzed for effective and timely feedback.

Advantage of performing blind recheck

It is usually recommended that rechecking be done in a blinded fashion, so that the laboratorian performing the retest does not know the original results. In the study carried out by Martinez et al.[1], random blinded rechecking provided more accurate estimates of AFB microscopy results than on the nonrandomly selected, nonblinded smears. This resulted in improved diagnosis and monitoring of treatment response.

On-site evaluation

A periodic visit by evaluators for on-site laboratory assessment is a type of EQA that has been used when other methods of EQA are not feasible or effective. Again, this method has most frequently been employed for assessment of sites performing AFB smears and those performing HIV rapid testing.

On-site evaluation can be a valuable tool to:

- obtain a realistic picture of laboratory practices by observing the laboratory under routine conditions in order to check that it is meeting quality requirements;
- provide information for internal process improvement;
- measure gaps or deficiencies—learn "where we are";
- assist the laboratory in collecting information for planning and implementation of training, monitoring and corrective actions.

On-site evaluation for the purpose of EQA may be conducted by a central reference laboratory or other health authorities. On-site evaluation can be used together with retesting and rechecking schemes to provide more information about performance.

1 Martinez A et al. Evaluation of new external quality assessment guidelines involving random blinded rechecking of acid-fast bacilli smears in a pilot project setting in Mexico. *International Journal of Tuberculosis and Lung Diseases,* 2005,9(3):301–305.

10-4: Comparison of external quality assessment methods

Comparison of some characteristics

Some of the characteristics of PT and rechecking are compared in the table below.

Comparison of proficiency testing (PT) and rechecking/retesting (RC)

Method/characteristics	PT	RC
Interlaboratory comparison	Yes	Yes
Simulated samples	Yes	No
Real samples	Yes/No	Yes
Time and resources needed	Less	More
Analytes evaluated	Many	Few

Summary of comparison

Proficiency testing:

- gives a good, objective measure of the laboratory performance
- can be organized to address most kinds of laboratory testing
- is cost-effective and can therefore be used frequently.

Retesting/rechecking:

- is useful when it is difficult or impossible to prepare samples to test all of the testing process;
- is expensive and uses considerable staff time.

On-site evaluation:

- can give a true picture of a laboratory's overall performance, and offer real-time guidance for improvements that are needed;
- is probably the most costly, requiring staff time, travel time and expenses of those performing the evaluation.

10-5: Managing external quality assessment in the laboratory

Participation in EQA

All laboratories should participate in EQA challenges, and this should include EQA for all testing procedures performed in the laboratory, if possible. The benefits of this participation are considerable, and EQA provides the only means available to a laboratory to ensure that its performance is comparable to that of other laboratories.

For laboratories that are accredited, or that plan to seek accreditation, EQA participation is essential. ISO 15189 addresses EQA requirements for laboratories as follows.

- There is a requirement that the laboratory participate in interlaboratory comparisons.
- Where an established EQA scheme is not available, an alternate EQA mechanism will have to be considered for interlaboratory comparison, such as exchange of samples with other laboratories.
- The laboratory management shall monitor the results of EQA and participate in the implementation of corrective actions.

Management process

When participating in EQA programmes, the laboratory needs to develop a process for the management of the process. A primary objective is to assure that all EQA samples are treated in the same manner as other samples tested. Procedures should be developed that address:

- Handling of samples—These will need to be logged, processed properly and stored as needed for future use.
- Analyses of samples—Consider whether EQA samples can be tested so that staff do not recognize them as different from patient samples (blinded testing).
- Appropriate record keeping—Records of all EQA testing reporting should be maintained over a period of time, so that performance improvement can be measured.
- Investigation of any deficiencies—For any challenges where performance is not acceptable.
- Taking corrective action when performance is not acceptable—The purpose of EQA is to allow for detection of problems in the laboratory, and to therefore provide an opportunity for improvement.
- Communication of outcomes to all laboratory staff and to management.

EQA performance problems

If the laboratory performs poorly on EQA, the problems may lie anywhere along the path of workflow. All aspects of the process will need to be checked. Some examples of problems that may be identified include the following.

Pre-examination:

- The sample may have been compromised during preparation, shipping, or after receipt in the laboratory by improper storage or handling.
- The sample may have been processed or labelled improperly in the laboratory.

Examination:

- The EQA challenge materials may exhibit a matrix effect in the examination system used by the participating laboratory.
- Possible sources of analytical problems include reagents, instruments, test methods, calibrations and calculations. Analytical problems should be investigated to determine whether error is random or systemic.
- Competency of staff will need to be considered and evaluated.

Post-examination:

- The report format can be confusing.
- Interpretation of results can be incorrect.
- Clerical or transcription errors can be sources of error.

Incorrect data captured by the EQA provider is another possible source of error.

10-6: Summary

Summary

EQA is a system for objectively checking the laboratory's performance using an external agency or facility. All laboratories should participate in an EQA process for all tests performed, whenever possible. Accredited laboratories are required to participate in EQA.

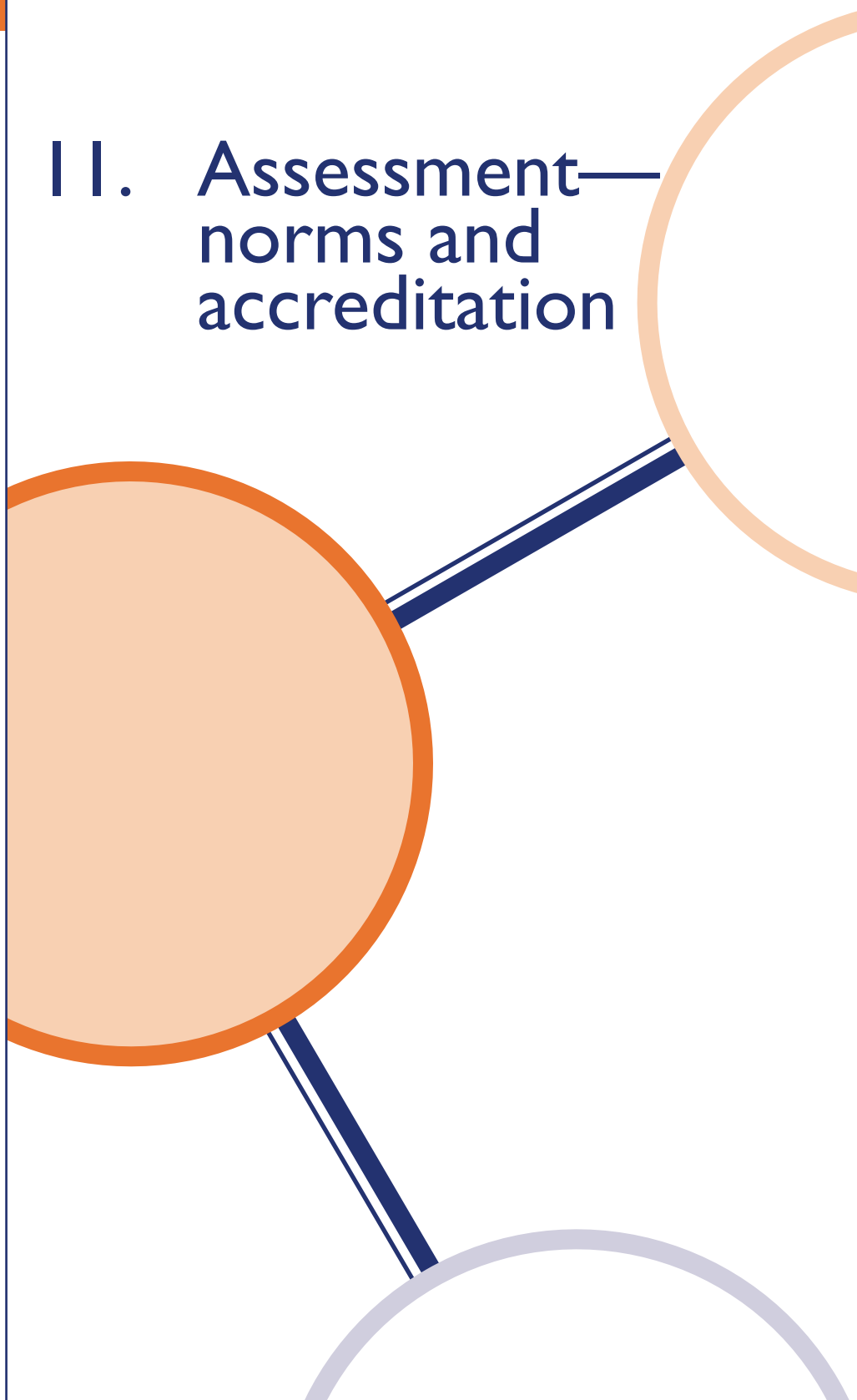
There are several methods for conducting EQA. Traditional PT is available for many tests, is cost-effective and provides useful information. When PT is not practical or does not provide enough information, other methods should be employed.

There must be no difference in the treatment of a PT sample and a patient sample. The normal testing methods must be followed and the procedure must involve personnel who routinely perform the testing.

Key messages

- As EQA uses valuable resources, the laboratory should make the best use possible of its participation in EQA.
- EQA should not be punitive. It should be viewed as educational and used as a tool to help direct improvement efforts in the laboratory.
- EQA is one of the critical elements of a laboratory quality management system.

11. Assessment—norms and accreditation



11-1: Overview

Role in quality management system

Assessment is the means of determining the effectiveness of a laboratory's quality management system. Standards, as well as other normative documents that provide guidelines, form the basis for assessment. They may be developed at international, national or local levels.

Organizations that establish norms or standards, and that provide for accreditation or certification of laboratories, play a vital role in the assessment process.

Overview of the process

An important way for a laboratory to be recognized as delivering accurate and reproducible results is to go through evaluation or assessment processes conducted by a credible, qualified organization. Successful completion of this process gives the laboratory recognition that it is in compliance with the quality standards and norms used for the assessment.

Responsibilities

Laboratory directors need to be aware of the importance of gaining accreditation, certification and licensure, by implementing international or national standards, in line with the scope of laboratory activities and in accordance with national legislation. A major duty of laboratory managers should be to seek information about appropriate norms and standards, and about accreditation and certification processes, so that these can be used to provide better service.

Quality managers must convey to the laboratory staff the need for compliance with standards, whether international or national. The quality officer will explain the process for meeting standards, and will organize and prepare the laboratory for assessments.

Laboratorians must be aware of requirements of the chosen standards, contribute to the development of tasks for meeting standards, be aware of assessment processes and help to assure readiness for assessment processes.

11-2: International standards and standardization bodies

Definitions

Normative document—a document that provides rules, guidelines or characteristics for activities or their results. It covers such documents as standards, technical specifications, codes of practice and regulations.[1]

Standard document—a document established by consensus and approved by a recognized body, that provides for common and repeated use, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.[1]

Regulation—any standard that is mandated by a governmental agency or authoritative body.

Standards may be developed internationally, nationally or locally. Compliance to a standard may be required by government or another authoritative body, or may be voluntary.

Standards developed internationally may have the broadest consensus or agreement, but may be less specific. Standards developed locally may have the highest degree of applicability, but may not be useful for comparison with other regions or countries.

Standardization bodies

Examples of international organizations are given below.

ISO (International Organization for Standardization)

ISO is the world's largest developer and publisher of international standards, and ISO standards are applicable to many kinds of organizations, including clinical and public health laboratories.

ISO is a network of the national standard institutes of 157 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system. It is a nongovernmental organization and it forms a bridge between the public and private sectors. On the one hand, many of its member institutes are part of the governmental structure of their countries or have been mandated by government. However, many members have roots uniquely in the private sector, having been set up by national partnerships of industry associations. Therefore, ISO enables a consensus to be reached on solutions that meet both the requirements of business and the broader needs of society.

The work of preparing standards is conducted by ISO technical committees. Each member body has the right to be represented on the committees. International organizations, both governmental and nongovernmental, also take part in the committee activities. Draft international standards adopted by the technical

1 ISO/IEC Guide 2:1996 (EN 45020:1998) *Standardization and related activities—general vocabulary.* Geneva, International Organization for Standardization, 1996.

committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote.

CLSI (Clinical and Laboratory Standards Institute)

CLSI is a global, non-profit, standards-developing organization that promotes the development and use of voluntary consensus standards and guidelines within the health care community. CLSI documents are developed by experts working on subcommittees or working groups under the direction and supervision of an area committee. Development of CLSI standards is a dynamic process. Each CLSI area committee is committed to producing consensus documents related to a specific discipline, as described in its mission statement.

CEN (European Committee for Standardization)

CEN was founded in 1961 by the national standards bodies in the European Economic Community and associated countries. The general terms include openness, transparency, consensus and integration.

Formal adoption of European Standards is decided by a weighted majority vote of the CEN national members and is binding on all of them. The responsibilities are shared between 30 national members from each country, 7 associate members and 2 counsellors, as well as the CEN Management Centre in Brussels.

WHO (World Health Organization)

WHO has developed several standards for disease-specific diagnostic laboratories. One example is polio, where accreditation is required in order for a laboratory to participate in the Polio Network for Eradication of Poliomyelitis. Seven criteria have been selected, including a minimum activity of 150 samples annually, successful participation in proficiency testing, and accuracy and timeliness of reports of cases to the network.

11-3: National standards and technical guidelines

Country-specific standards

Standards may be developed within a country to apply only to national use. These may be created by governmental organizations, or may also be developed by a recognized body with a specific area or domain for application.

In some instances, national standards have been developed based on an international standard such as ISO, and adapted to the culture and general condition of the country.

Guidelines

Guidelines are developed in a variety of situations. Usually ISO standards need more technical guidance for actual implementation in laboratories and in countries. Several national and international organizations have developed those guidelines.

Another use for guidelines is to address a specific kind of testing or to provide guidance for certain parts of the laboratory. For example, there may be guidelines for performance of human immunodeficiency virus (HIV) rapid testing, or guidelines for obtaining the appropriate biological safety cabinet for the testing being conducted.

Examples

Many national guidelines and standards have been developed. Some examples include the following.

GBEA (Guideline for Good Analysis Performance), France
French legislation created these guidelines to assure the quality of the services offered by French laboratories in 1994. It was revised in 1999 and 2002. All clinical laboratories in France are required by law to comply with GBEA.

BLQS (Bureau of Laboratory Quality Standards), Thailand
The BLQS of the Department of the Medical Sciences has developed national quality standards for health laboratories based on ISO 17025 and ISO 15189. A checklist with 110 items was developed and a stepwise approach was devised. Depending on the score obtained when compared to the checklist, laboratories will be accredited against country-wide national standards, or can apply for the ISO accreditation process.

CLIA (Clinical Laboratory Improvement Amendments of 1988), United States of America

CLIA was mandated by legislation in 1988, and brings all medical laboratory testing in the United States under federal regulation. Quality standards are defined based on the complexity of testing performed. The objective of the CLIA programme is to ensure quality laboratory testing, regardless of where it is performed (e.g. physician's office, hospital laboratory, health clinic, nursing home).

11-4: Certification and accreditation

Applying standards

Standards are used when a laboratory seeks recognition of its ability to use quality practices in carrying out its work. Remember that meeting the standards may be a legal requirement, or may be voluntary. There are three processes that may be used to indicate that the laboratory is complying with defined standards.

- **Certification**—the procedure by which an independent body gives written assurance that a product, process or service conforms to specific requirements.[1] In the certification process, a laboratory is visited by representatives from a certification body. These representatives are looking for evidence of compliance with standards, policies, procedures, requirements, and regulations. Primarily, the inspection team checks for physical presence of texts, procedures and documents.

- **Accreditation**—the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.[2] A laboratory is visited by representatives from an accreditation body who are looking for evidence of compliance with standards, policies, procedures, requirements and regulations, and also observe laboratory staff to ensure that they perform functions and duties correctly and competently.

Accreditation provides a higher level of assurance to those using the laboratory that its testing is reliable and accurate because it includes an evaluation of competency.

- **Licensure**—the granting of ability to practise, usually provided by a local governmental agency. Licensure is usually based on demonstrated knowledge, training and skills.[3] Generally, when laboratory licensure is used, it is a legal requirement for operation.

Elements of accreditation

The accreditation process requires:

- an accreditation body that oversees the assessments and grants accreditation—this body may also set the standards used in the accreditation process;
- standards with which a laboratory must comply in order to gain accreditation;
- knowledgeable assessors or inspectors who seek to establish compliance with the standards by conducting the assessment;
- a user laboratory which is required to, or voluntarily seeks to, comply with the standards by being assessed.

1 ISO/IEC 17000:2004. *Conformity assessment—vocabulary and general principles*. Geneva, International Organization for Standardization, 2004.

2 ISO 15189:2007. *Medical laboratories—particular requirements for quality and competence*. Geneva, International Organization for Standardization, 2007.

3 Wikipedia 2007.

Certification and accreditation bodies

A certification or accreditation body is an organization or agency with the authorized right and authority to inspect a facility, and provide written evidence of its compliance (certification) and competence (accreditation) with a standard.

Certification and accreditation bodies have the following common characteristics:

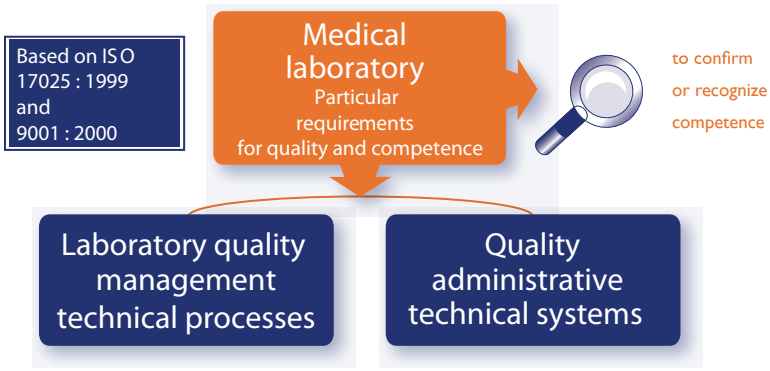
- Approved—accreditation and certification bodies usually require their own accreditation status. This accreditation is commonly performed under the authority of national or international bodies, such as national standards agencies. International accreditation bodies often are accredited to ISO 17011.[1]
- Knowledgeable—these bodies must be knowledgeable and skilled in the content and interpretation of the standards against which they accredit, as well as in the discipline they accredit. An accreditation body team includes both discipline content experts and accreditation requirement experts.
- Standards-based—assessments are always based on established standards.
- Objective—interpretation of competence and skill is based on evidence rather than impression. The inspection teams do not write their own rules, but rather measure compliance with given rules or standards.
- Competent—these organizations ensure that all staff are trained and skilled, and that auditing teams involve members knowledgeable in both technical and quality management information. The bodies maintain competency because of professionalism, and because of the importance of sustaining their own accredited status.

Commonly used standards for accreditation or certification

Standards may be applicable to accreditation or to certification, or they may be regulatory. Some important examples of accreditation standards include ISO 17025 and IS0 15189, both international standards in wide use. ISO 15189 is a preferred standard for medical laboratories because it applies to the total laboratory, regardless which tests it performs, as opposed to ISO 17025, which is designed and intended to be implemented on an individual, test-by-test basis.

ISO 17025 specifies general requirements for competence to carry out tests and/or calibrations, including sampling. It is applicable to testing and calibration laboratories, and can be used for developing quality, administrative, and technical systems that govern operations. It can be used by laboratory clients, regulatory authorities, and accreditation bodies wishing to confirm or recognize competence of laboratories. It does not cover compliance with regulatory and safety requirements.

1 ISO/IEC 17011:2004. *Conformity assessment—general requirements for accreditation bodies accrediting conformity assessment bodies*. Geneva, International Organization for Standardization, 2004.



ISO 15189 is sector specific, meaning that it is designed and intended for use only by medical laboratories. ISO 15189 specifies particular requirements for quality and competence of medical laboratories. It provides guidance for laboratory quality management and technical processes to ensure quality in medical laboratory examinations. ISO 15189 is applicable to all currently recognized disciplines of medical laboratory services, and is based on both ISO 17025 and ISO 9001. It is for use by medical laboratories for developing quality, administrative and technical systems that govern their operations, and is also for use by organizations wishing to confirm or recognize competence of medical laboratories.

11-5: Process of accreditation

The decision to pursue accreditation is not one to be taken lightly or without forethought.

Accreditation visits are expensive, therefore laboratory directors and quality managers must prepare well in advance of the visits to ensure resources are not wasted. Accreditation could begin with one part of the laboratory and then continue with the other sections.

Preparation

Seeking accreditation requires the following:

- Commitment—the path towards meeting standards and recognition is rarely straightforward. When the process becomes difficult, challenging and requires time and effort, it is not uncommon to quit or postpone the process. Once stopped, it becomes very difficult to begin again.
- Planning—the path towards accreditation will take time. Laboratories should organize their staff and time to ensure that the process goes to completion with a minimum of obstruction.
- Knowledge—application of standards requires knowledge of the standards and how to interpret them. If there are no people in the laboratory that have that knowledge, the laboratory may consider sending staff for special training or hiring a consultant.
- Resources—the process to accreditation may require reorganization, restructuring, trained staff or additional equipment. Recognition of potential costs should be considered in the planning phase at the start of the process.

Interpretation of terms

When using standards to prepare for accreditation, keep in mind the following interpretations of terms commonly used in standards.

- Consensus—agreement between delegations representing all the stakeholders concerned—suppliers, users, government regulators and other interest groups. Consensus is not a numeric or majority determination. Consensus represents general agreement in the absence of strong and compelling objection.
- Normative statement—information within a document that is a requirement and essential part of the standard. Includes the word "shall".
- Informative statement—information within a document that is informational only; often it is in the form of a "note". Information may be explanatory or cautionary, or provide an example.
- Compliance—meets both the text and the spirit of a requirement.
- Nonconformity—failure to fulfil the requirements of a specified process, structure or service. May be categorized as major (complete) or minor (partial).
- Verification of conformity—confirmation by examination of evidence.

11-6: Benefits of accreditation

Value of accreditation

It is through the accreditation of third-party evaluators that the laboratory's clients can have confidence that when something is measured, calibrated, inspected, tested or certified, the job has been done competently.

The essential aspect of accreditation is that it promotes confidence in results and services because it is a valid means of verifying claims about quality, performance and reliability. The use of internationally recognized standards as the reference criteria for laboratory accreditation is the key to building trust across borders and promoting best practices worldwide.

Outcomes

The outcomes of accreditation are:

- measurement of the strength and integrity of the quality system
- continual monitoring of the quality system
- recognition for your efforts.

Accredited laboratories tend to perform better on proficiency testing and are more likely to have a working quality management system.

Accreditation as a tool

Accreditation is a valuable tool to determine the effectiveness of the quality management system. However, it is not the ultimate goal. Once accreditation status is obtained, the important challenge will be to maintain that status.

A well-managed laboratory will know that it is meeting its goals. The laboratory should look at accreditation as one form of audit that the quality managed laboratory puts into place to ensure that the system is working properly.

Accreditation status must be renewed regularly and the laboratory challenged each time to maintain and improve the quality level.

11-7: Summary

Summary

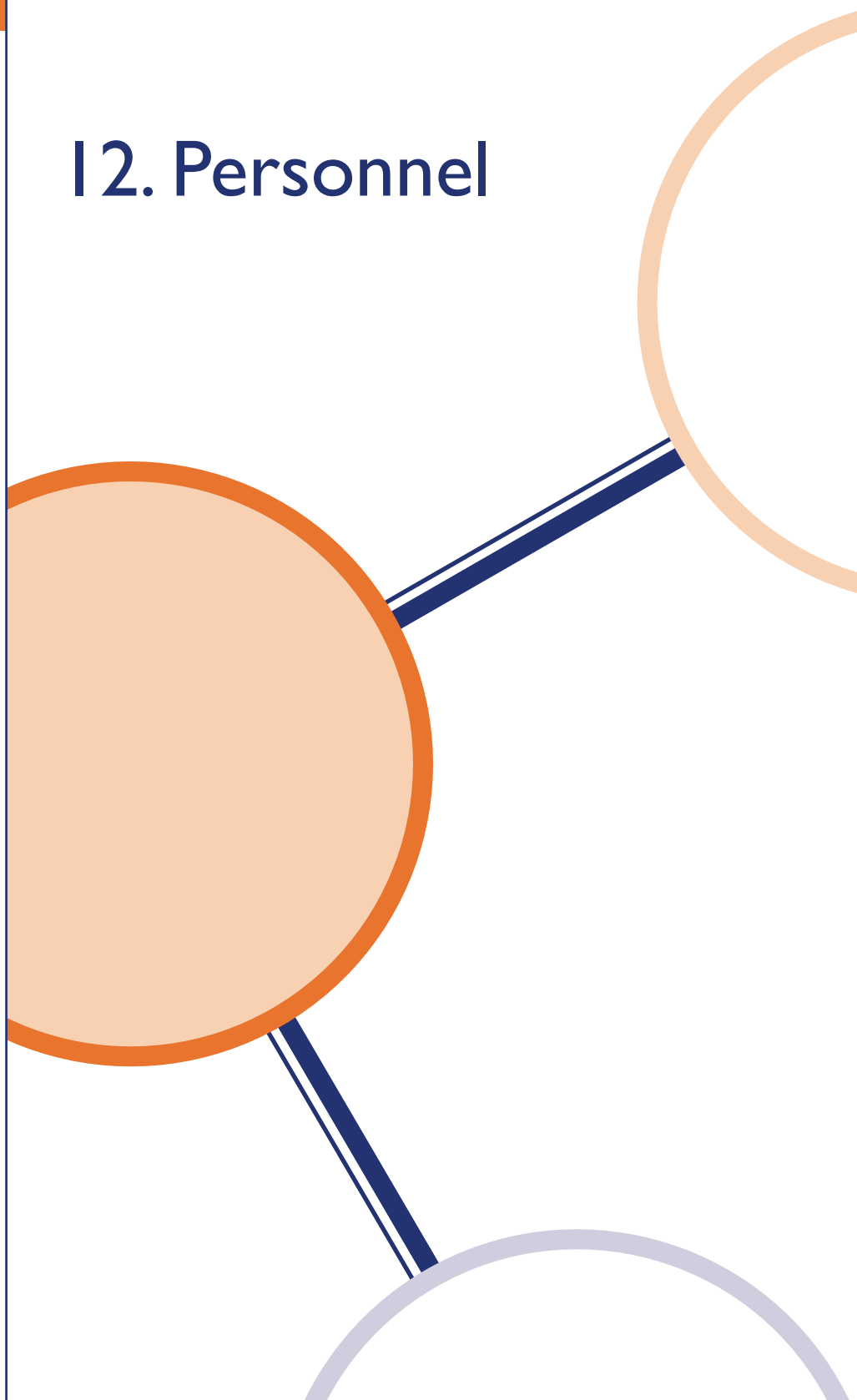
Standards or norms provide guidelines that form the basis for quality practices in the laboratory. They are developed by organizations, often through a consensus process. Accreditation and certification are two processes that can allow for recognition that a laboratory is meeting designated standards.

When a laboratory seeks this recognition, careful planning will be needed to have a successful outcome. An active quality management programme can ensure that a laboratory is in a constant state of "accreditation readiness".

Key message

- Accreditation is an important step in the continual improvement of the quality management system.
- It is an accomplishment to be accredited; it is an achievement to maintain accreditation.

12. Personnel



12-1: Overview

Role in quality management system

Personnel are the most important laboratory resource. Critical to the implementation of the quality management system are people who possess integrity, recognize the importance of their work and participate in continuous improvement. Laboratorians are important partners in health care.

Overview of the process

Recruiting and retaining qualified staff is essential to laboratory quality. Failure to check the education qualifications and references for a new hire can lead to problems in the future.

As a **laboratory director** it is important to:

- Hire an appropriate number of staff to cover workload.
- Verify that items on the job application are correct.
- Develop complete and thorough job descriptions for each employee.
- Train each employee in their specific duties.
- Provide orientation for new employees. Even with a credible background, differences between laboratories are common, so a manager needs to ensure new employees have adequate orientation and training.
- Conduct and record competency assessments on all personnel. It is management's responsibility to verify that trained employees are sufficiently competent to do their work.
- Provide opportunities for continuing education; new techniques or updates for existing methods can be introduced using continuing education courses.
- Conduct annual employee performance appraisals.

As a **quality manager** it is necessary to:

- Provide employees with orientation and training.
- Keep track of employee records and make sure they are confidential.
- Include policies relevant to personnel in the quality manual.

As a **laboratorian** it is important to:
- Participate in training and continuing education opportunities.
- Request training that may be needed as job responsibilities increase.
- Maintain records of personal professional development.

Importance of motivation

Success or failure depends on the knowledge and skills of the people in the laboratory, and their commitment and motivation to perform tasks as described in the job description. Motivated employees are more likely to be committed to their work.

Elements of motivation vary for different people.
- Some people respond to concrete rewards such as bonuses and praise.
- Some people respond best to flexible work schedules that fit their responsibilities to home and children.
- Most people respond to recognition and feeling that they are an integral part of the health care team.

The manager can motivate the team by emphasizing that everyone's job is important; whether it is performing testing, collecting specimens, making reagents or managing the laboratory.

Retention of staff

Migration and turnover of staff have been described as major challenges in many countries. Apart from economic factors, the lack of a good working environment and improper management practices can contribute to loss of staff. A good personnel management programne can contribute to the retention of staff.

12-2: Recruitment and orientation

Personnel qualifications and job description

Management must establish appropriate personnel qualifications for all positions in the laboratory. These should include requirements for education, skills, knowledge and experience. When defining qualifications, keep in mind any special skills and knowledge that are needed, such as language, information technology and biosafety.

Job descriptions give a clear and accurate picture of responsibilities and authorities for each staff position. Job descriptions should:

- lay out all activities and tasks that should be performed;
- specify responsibilities for conducting testing and implementing the quality system (policies and activities);
- reflect the employee's background and training;
- be kept current and be available for all people working in the laboratory.

Job descriptions should be competency based and reflect any skills needed. The requirements for each staff position may vary depending on the size of the laboratory and complexity of testing services offered. For example, in small laboratories with limited personnel, staff may have many responsibilities and perform many tasks, whereas in larger laboratories with more personnel, staff may be more specialized.

Remember, not only are clear job descriptions a guideline, but they can be used to formally assess personnel competency.

Orientation

Orientation is the process of introducing a new staff member to the new work environment and to their specific tasks or duties. Nothing is more frustrating to an employee than not knowing where to find the necessary resources.

Orientation is different from training.

Orientation of laboratory personnel should include the following aspects.

- General orientation—a tour of the workplace and introduction to all management and staff. Information about
  - how the organization fits into the medical community and/or the public health system;
  - key personnel and lines of authority;
  - the laboratory interaction with both users and customers of the laboratory;
  - the policies and procedures regarding facilities and safety.

- Personnel policies
  - ethics
  - confidentiality
  - employee benefits
  - work schedules.
- An employee handbook that outlines the policies of the organization and information about the laboratory quality system.
- A copy of the employee's job description and a detailed review of its contents.
- An overview of standard operating procedures (SOPs).

A checklist that addresses each aspect of the orientation is important. Ask employees to initial and date the checklist to document discussion of each topic.

12-3: Competency and competency assessment

Definitions

Competency is defined as the application of knowledge, skills and behaviours used in performing specific job tasks.[1] Accurate laboratory test results depend on staff being competent in performing a range of procedures that occur throughout the entire examination process.

Competency assessment is defined as any system for measuring and documenting personnel competency. The goal of competency assessment is to identify problems with employee performance and to correct these issues before they affect patient care.

Overview

An initial competency assessment may reveal the need for specific training of the employee. Competency assessment should be conducted at regular intervals during the employee's tenure.

Competency assessments conducted either initially or periodically help to identify or prevent performance problems that may be solved through task-specific training.

Competency assessment methods

Competency assessment methods include the following.

- Direct observation helps identify and prevent any performance problems:
  - The employee's techniques are watched during the examination process, which allows the observer to see if the employee is following the SOP.
  - To avoid subjectivity during a competency assessment, the observer uses a custom-designed checklist; checklists are used when there are specific, observable items, actions or attributes to be observed.

Observation is the most time-consuming way to assess employee competence, but this method is advised when assessing the areas that may have a higher impact on patient care.

- Monitor records (e.g. review worksheets and logs prepared by the employee).
- Review and analyze quality control records and results of proficiency tests performed by the employee being evaluated.
- Retest or recheck results to compare results among personnel; discrepancies should be resolved.
- Assess knowledge or problem-solving skills using case studies. Employees are asked to respond orally or in writing to simulated technical problems.

1 ISO 10015:1999. *Quality management—guidelines for training*. Geneva, International Organization for Standardization, 1999.

Policies and processes

Methods for determining personnel competency may need to be adapted to local customs and concerns.

Policy writing for competency assessment is a critical quality systems issue and is the responsibility of the management. Each policy should be shared with everyone in the laboratory and assessments of all personnel should be documented.

An example of policy for competency assessment is "Every employee shall regularly be assessed for competency for the tasks defined in their job description".

Processes describe how the policy will be enacted. For example, the following questions should be addressed.

- **Who** will conduct assessments? Responsibility for conducting the assessment should be assigned to someone who has previously demonstrated competency in the area to be assessed. The responsible person must document and evaluate the results of the assessment.
- **What** will be assessed? Which job task or tasks and procedure performed in the pre-examination, examination and post-examination testing process will be assessed? Critical competencies for each task should be identified. First-line supervisors should be involved in this step. Examples of critical competencies include
  - patient identification
  - sample collection
  - evaluation of adequacy of samples
  - use of equipment
  - application of quality control procedures
  - interpretation of results.
- **When** will assessments occur (annually or biannually)? It is important to develop a timeline for periodic assessment of each employee. A period of training and then assessment should be implemented for everyone as new procedures and equipment are introduced into the laboratory.

Policies and processes should be reviewed annually and modified when necessary.

Procedures

Procedures describe specifically how each element of the processes will be performed. An employee competency assessment would follow these procedures,

1. The assessor contacts the employee in advance to inform them that the assessment will be done at a prearranged time.
2. The assessment is done while the employee is performing tasks using routine samples.
3. The assessment is done by a specified method previously described and is recorded in a logbook.
4. The results of the assessment are shared with the employee.
5. A remedial action plan is developed defining required retraining. The plan should be written and the manager must ensure that the plan is understood by the employee. The plan should outline specific steps to be taken to resolve or correct the problem with related deadlines. Needed resources should be clearly outlined in the plan. For example, the employee may need an updated version of the SOP.
6. The employee is asked to acknowledge the assessment, related action plan, and reassessment.

If more than one person makes the same error even after training has occurred, consider the root cause of the error, such as equipment malfunction and operating procedure ambiguity.

Competency assessment documentation

Standard forms should be generated in advance and used so all employees are assessed the same way. This will prevent employees from thinking that the assessments are biased.

All competency assessments must be recorded, showing date and results, and should be kept in a place where they remain confidential. These records are part of a laboratory's quality documents, and should be periodically reviewed and used for continuous improvement.

12-4: Training and continuing education

Definitions

Training is a process to provide and develop knowledge, skills, and behaviours to meet requirements. In this context, training is linked to the job description and competency assessment, and addresses identified gaps in specific tasks to be performed by the employee. Competency should be reassessed after any job-specific training.

Retraining is required when competency assessment reveals the need for improving an employee's knowledge and skills.

Cross-training provides an opportunity for staff to acquire skills outside their own discipline. This allows for flexibility in shifting or reassigning personnel whenever needed; this may occur in crisis situations or with absences of staff due to illness or vacation.

Continuing education is an educational programme that brings employees up-to-date in a particular area of knowledge or skills. Since laboratory medicine is constantly changing, keeping current takes effort on the part of both employee and management.

Rationale

Reasons for training and continuing education are to:

- achieve quality practices in the laboratory and produce accurate, reliable and timely test results;
- help staff achieve personal career goals;
- improve the organization's capabilities and achievement of quality objectives.

In laboratory medicine, new testing methodologies and instruments are continuously introduced to the marketplace that could have implications for laboratory testing and improved patient care.

Methods

When planning a training or continuing education activity, consider:

- identification of training needs
- design of training
- provision of training
- evaluation of training results.

Activities can often be organized at low cost, for example:

- starting a journal club;
- starting case study discussion groups;
- watching videotapes and DVDs;
- researching a topic and presenting findings to colleagues;
- using interactive self-study programmes, including e-learning freeware or printed courses;
- collecting and maintaining a set of teaching slides (e.g. haematology and parasitology).

Resources

Local resources—When organizing internal continuing education programmes, local resources available from the health care community should be considered. Some of these resources include:

- quality assurance committee
- clinicians
- nurses
- pathologists
- infection control personnel
- epidemiologists or surveillance officers
- external assessors.

Each of these groups may offer specialized knowledge and experience they can share with laboratory staff. They can be invited to give lectures, lead discussions and exchange information.

External resources—External continuing education programmes can also be presented by topic experts, such as those associated with:

- proficiency testing services
- manufacturers
- scientific societies
- World Health Organization
- United States Centers for Disease Control and Prevention
- nongovernmental organizations.

12-5: Employee performance appraisal

Periodic appraisal

Employees should have a periodic formal appraisal of their overall performance. This is broader than competency assessment and includes the following elements:

- technical competency
- efficiency
- adherence to policies
- observance of safety rules
- communication skills
- customer service
- punctuality
- professional behaviour.

Feedback

Appraisal can affect an employee's morale, motivation and self-esteem, and should be conducted equitably for all employees. People respond to criticism differently, even if delivered tactfully; therefore, consider unique approaches that match personality when counselling employees. Positive feedback, as well as suggestions for improvement, should be provided.

All identified problems should be addressed with the employee when they occur, so that they can correct any issue before the formal evaluation. A periodic appraisal that is part of the employee's record should not have items that were not previously discussed with the employee.

Cause of poor performance

Poor performance may not always be due to technical incompetence. Performance may be affected by:

- distractions—especially personal issues such as a sick child or parent, or financial problems, which can make the employee's concentration difficult;
- excessive workloads that pressure or hurry the employee, which may cause them to inadvertently make errors;
- insufficient initial orientation or training;
- resistance to change—some people may not want to use new procedures ("We've always done it this way, why change?").

The following factors could also contribute to poor results performance.

- Compromised sample—the laboratorian may or may not know that the sample arrived in the wrong preservative or was improperly stored.
- Absence of SOPs or failure to update them—test kits may come with modified manufacturer's instructions, and these modifications need to be reflected in the SOPs.
- Poorly written procedures—including omitting certain steps, the wrong sequence of steps, or incorrect sample or reagent quantities—can cause very serious errors and should always be suspected when several employees obtain erroneous results.
- Job descriptions that are not clear may be a source of error—for example, confusion about who has responsibility for calibrating an instrument could result in the calibration not being done, causing erroneous results.

12-6: Personnel records

Policy

Medical laboratories should maintain employee records that contain information integral to their laboratory-related work. Keep records of positions held and dates for each of these positions. This information is important for calculating employee benefits. All terms and conditions of employment should be a part of the personnel record.

What

Personnel information that the laboratory maintains may differ in different regions and settings. While a complete list of information may include the following, some parts may not be required in all regions and all settings:

- employment details;
- original application and resume;
- tests the employee is authorized to perform;
- conditions of continued employment;
- job description;
- both original and subsequent competency assessments;
- continuing education programmes attended;
- personnel actions—corrective, disciplinary;
- leave records;
- health information, including records of work injury or exposure to occupational hazards, vaccine status, skin tests (if any);
- performance appraisals;
- emergency contact information.

Where

The personnel files should be kept in a secure site to protect confidentiality. Not all information needs to be maintained within the laboratory offices. Some institutions maintain a human resources or personnel department that may be responsible for employee records. Consider what is essential to be maintained in the laboratory itself, such as emergency contact information or job descriptions.

12-7: Summary

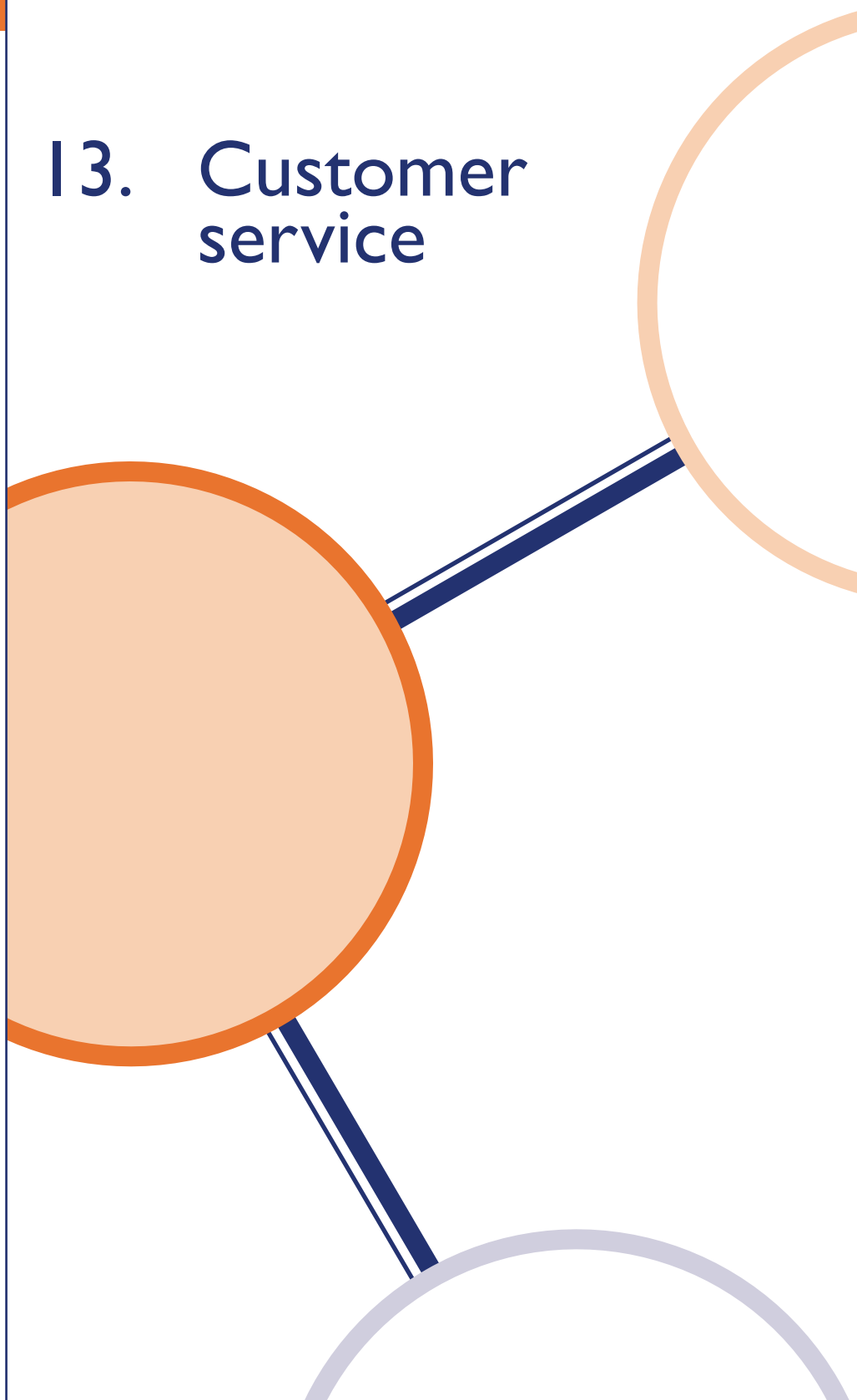
Important principles of personnel management

Management of personnel is critical to the success of a quality management programme. Several elements are important in this management process. Job descriptions should reflect all skills needed and accurately describe tasks, roles, and authorities. The competency of personnel will need to be evaluated at the time of hiring and on a regular, recurring basis. A very important part of the management process is to seek ways to attract qualified personnel, and to provide motivation and appropriate benefits and working conditions so as to retain staff.

Key messages

- Personnel are the most important resource in the laboratory.
- Managers must create an environment that will fully support all laboratory personnel in order to maintain a high quality of laboratory performance.
- Continuing education is vital to personnel competency, but does not need to be expensive. New testing methodologies and instruments are constantly introduced to the marketplace, and employees need to update their knowledge and skills.

13. Customer service



13-1: Overview

Role in quality management system

This chapter will describe basic elements that are essential for developing an effective customer service programme.

Customer satisfaction is a major component of a quality management system, and a significant focus in the International Organization for Standardization (ISO) standards. Ultimately, the laboratory produces a product—the test result—for its customers. If the customer is not well served, the laboratory is not achieving its primary function.

Overview of the process

Philip Crosby defined quality practice as meeting the requirements of the customer. He applied this practice to business and manufacturing, but it is equally important for a medical laboratory. The medical laboratory needs to know who its clients are, and understand clients' needs and requirements.

Medical laboratories have a range of customers including patients, physicians, public health agencies and the community.

Laboratory responsibilities

It is the responsibility of the laboratory director to ensure that the customers' needs are met, and that there is customer satisfaction. The quality manager is responsible for measuring the degree of customer satisfaction, using surveys, indicators and audits to take preventive and corrective action.

All laboratory staff must understand the importance of customer satisfaction. Laboratory personnel must always interact with customers in a way that is appropriate, providing needed information, and being courteous.

Establishing a programme to address customer satisfaction

Seeking customer satisfaction requires the following:

1. Commitment—customer satisfaction is a requirement of several international standards for laboratory quality, but some laboratory staff might consider it secondary to technical competency. Because of the importance of customer satisfaction in a quality system, all staff must be strongly committed to the process.
2. Planning—monitoring takes time and planning to be done properly. Appropriate monitoring tools need to be developed prior to gathering information. Poor planning results in inadequate information and often leads to uninterpretable information.
3. Knowledge—creation of useful monitoring tools requires specific knowledge. If there are not people in the laboratory that have that knowledge, the laboratory may consider sending staff for special training or hiring a consultant.
4. Resources—the process to monitoring does not have to be heavily resourced, but it does take time. Some of that time can be saved by having access to calculators, computers and the internet.

13-2: The laboratory clients—the customers

The laboratory and its clients

The laboratory has many clients and the needs of all must be carefully addressed. A central figure in the client list is the **physician or health care provider**. The initial request for service originates with this person, and the laboratory staff generally identifies the ordering physician as the primary client. Remember that in a hospital setting, the health care provider will be assisted by many other people, including **nurses, medical assistants, phlebotomists, and secretaries or clerks**. These vital hospital personnel should also be considered clients of the laboratory, and their needs must be considered.

Another important client for the laboratory is the **patient**, usually including their **family**. Family members may play a very important role in patient management, and may help with sample collection and transport.

When laboratory testing is being performed to meet a public health need, **public health officials** or workers become clients of the laboratory. The laboratory is a critical partner in surveillance, disease detection and prevention, and other public health programmes. Laboratories need to meet the needs of the public health workers in addressing problems. They sometimes need to share information without compromising the confidentiality of the patient. Specialized laboratories such as food safety or water testing laboratories would have other customers to consider, such as **food producers, manufacturers, or water systems managers**.

The **community** in which a laboratory works also has expectations. The community needs to be assured that the laboratory will not create a risk for workers, visitors or the public.

In many countries, laboratory tests can only be ordered by a licensed health care provider—a physician, nurse or dentist. In some countries, laboratory tests can be ordered by the patient directly without referral from a physician or nurse. Some patients do not have the knowledge or expertise to order the right test or to interpret results. Laboratory personnel may have to provide assistance in test selection and interpretation.

Legal identity

International standards usually require that any laboratory clearly identifies itself to the public, giving assurance that an identified person is in charge and accessible. At a minimum, every laboratory must make public a laboratory name and address, and the name of the director, including relevant contact information.

Physician or health care provider requirements

The health care provider expects to have access to accurate, clinically relevant information that can be understood and used in a timely manner. Health care professionals need assurance of laboratory responsibility throughout the testing process, including pre-examination steps, the testing process itself and the post-examination process.

In the re-examination phase, physicians will be particularly interested in the test menu. They benefit from an accurate collection manual, requisition forms that are complete but user friendly, and a timely delivery system.

For the testing or examination phase, physicians would like to be sure of working with competent personnel. They need to know that the test methods being used have been validated, and that testing is done with good process control and with quality control procedures in place. Appropriate management of all adverse occurrences or errors will significantly affect physician laboratory use.

Patient requirements

The physician looks to the laboratory to do an excellent job in managing the post-examination steps, as these are critical to receiving the results of testing. A solid laboratory information system, a method for results verification, and for delivering timely and interpretable results to the right place, are all important.

The patient expects to receive personal care, keeping in mind comfort and privacy. He or she also expects to be assured that the testing has been done correctly and properly, and provided to the health care provider in a timely manner.

The laboratory actions needed to meet the patient requirements include:

- providing adequate information, both for collection of a specimen, and also information about the laboratory;
- providing good collection facilities;
- having available trained and knowledgeable personnel—personnel should know how to collect a sample properly, and should be trained to be courteous to all patients;
- giving assurance that the laboratory records are maintained properly so that they can be easily retrieved, and also giving assurance of protection of the confidentiality of the records.

Public health requirements

Public health professionals have the same needs as health care providers, requiring that all parts of the pre-examination, examination and post-examination processes are carried out properly. They may need special kinds of information in dealing with an outbreak or epidemic, such as specific collection processes or forms designed for the particular project or investigation. Public health officials will also be particularly concerned with safety issues and containment of infectious material.

Food manufacturers and producers, and water plant managers will need information from the laboratory to help them comply with their specific quality requirements.

Community requirements

The community in which a laboratory does its work expects that dangerous materials will be kept within the confines of the facility, and that the laboratory will protect their own workers from risk. The community should be aware of communicable disease alerts, and surveillance and response activities.

The laboratory is responsible for assuring safety and security, for containment of any infectious materials, for dealing appropriately with waste management, and for following all regulations for the transport of dangerous goods.

Serving all clients well

All clients benefit when a laboratory chooses to put in place a quality system and to seek recognition that it is accredited to the highest standards. This provides assurance that the laboratory is following quality practices, and that the results it produces are accurate and reliable.

Good customer service provides:

- valuable information for best patient care
- valuable information to improve surveillance and other public health actions
- a professional image for the laboratory.

Customer service is an integral part of a quality management system.

13-3: Assessing and monitoring customer satisfaction

Methods for assessment

In order to understand whether client needs are being met, the laboratory will need to employ tools for gaining information. The laboratory needs to actively seek information from customers, rather than just waiting for customers to contact the laboratory with a complaint.

Important information on customer satisfaction may be obtained using:

- complaint monitoring
- quality indicators
- internal audit
- management review
- satisfaction surveys
- interviews and focus groups.

The monitoring of customer service and customer satisfaction is part of the continual improvement performed by the laboratory.

Using assessment methods

When the laboratory is contacted about a problem, this can provide important and helpful information. All such complaints should be thoroughly investigated, and remedial and corrective action taken. However, remember that **received complaints** may reflect only the "tip of the iceberg", because many people do not complain. The laboratory cannot use received complaints as the only means of assessing customer satisfaction.

Quality indicators are an objective measure of laboratory practices.Indicators can be developed that look at complaints, timeliness, patient refusals, and lost or delayed laboratory reports as examples. When these indicators are being monitored, information about customer needs and satisfaction will be acquired.

When the laboratory conducts **internal audits**, some aspects of laboratory practice that affect patient satisfaction can be examined. Examples might include turnaround times—always of great concern to physicians or health care providers.

All findings from these investigations should be very carefully **reviewed by management** and followed up with appropriate action.

13-4: Customer satisfaction surveys

Customer surveys

In order to actively seek information about how clients view the laboratory's service, it will be necessary to conduct surveys (paper-based or electronic) or to use interviews and focus groups. In this way the laboratory can address specific questions to areas of concern, and can look at areas not commonly covered by complaints or internal processes.

ISO standards put a heavy emphasis on the importance of customer satisfaction; customer surveys are required in ISO 9001 standards for quality management systems. Any laboratory that implements a quality management system, whether accredited or not, needs to use some method for surveying clients in order to understand whether needs are being met.

To be successful, **surveys** should be carefully planned and organized. Deciding which clients to ask to participate in a survey is important. Surveying health care practitioners is often easier than surveying patients. Laboratory staff can also be asked to participate in surveys and may offer good suggestions for streamlining operations to improve customer service.

Any survey questionnaire should be pretested for clarity. When developing material, avoid leading and biased questions. Be sure to analyze the results in a timely manner and, when possible, provide some feedback to the group that has been surveyed.

If the survey is to be conducted using **interviews**, the following tips can be helpful.

- Write out all questions in advance, so that everyone is asked the same questions.
- After asking some specific questions about their satisfaction with the laboratory, ask an open-ended question that allows customers to provide honest feedback. For example, ask how the laboratory could improve its service.

Employing **focus groups** can be a very useful technique for gathering information on customer satisfaction. The process of a group discussion will often elicit comments and ideas from all the participants that might not otherwise surface. When conducting focus group discussions, consider the following:

- assemble small groups of 8–10 people
- include people with diverse backgrounds and laboratory needs
- start by asking questions that build trust
- develop a focus group guide for consistency between groups
- ask open-ended questions—not "yes or no" questions.

Summarize verbal responses in a written report that can be used by the laboratory as a tool to improve customer service.

Successful surveys identify opportunities for improvement

When measuring customer satisfaction, whether by survey, indicators or audits, much will be learned when the method is successful. This information and the insights on customer service that it provides can be used to help the laboratory identify opportunities for improvement (OFI). The OFI will lead to preventive and corrective actions.

Information gathering must lead to change in a continual improvement process.

13-5: Summary

Summary

Seeking customer satisfaction requires commitment from the laboratory management and staff. It is important to remember that technical competency is not the only goal for the laboratory.

A programme for addressing customer satisfaction requires good planning, the development of appropriate monitoring tools, and the knowledge to apply the tools to gain usable information.

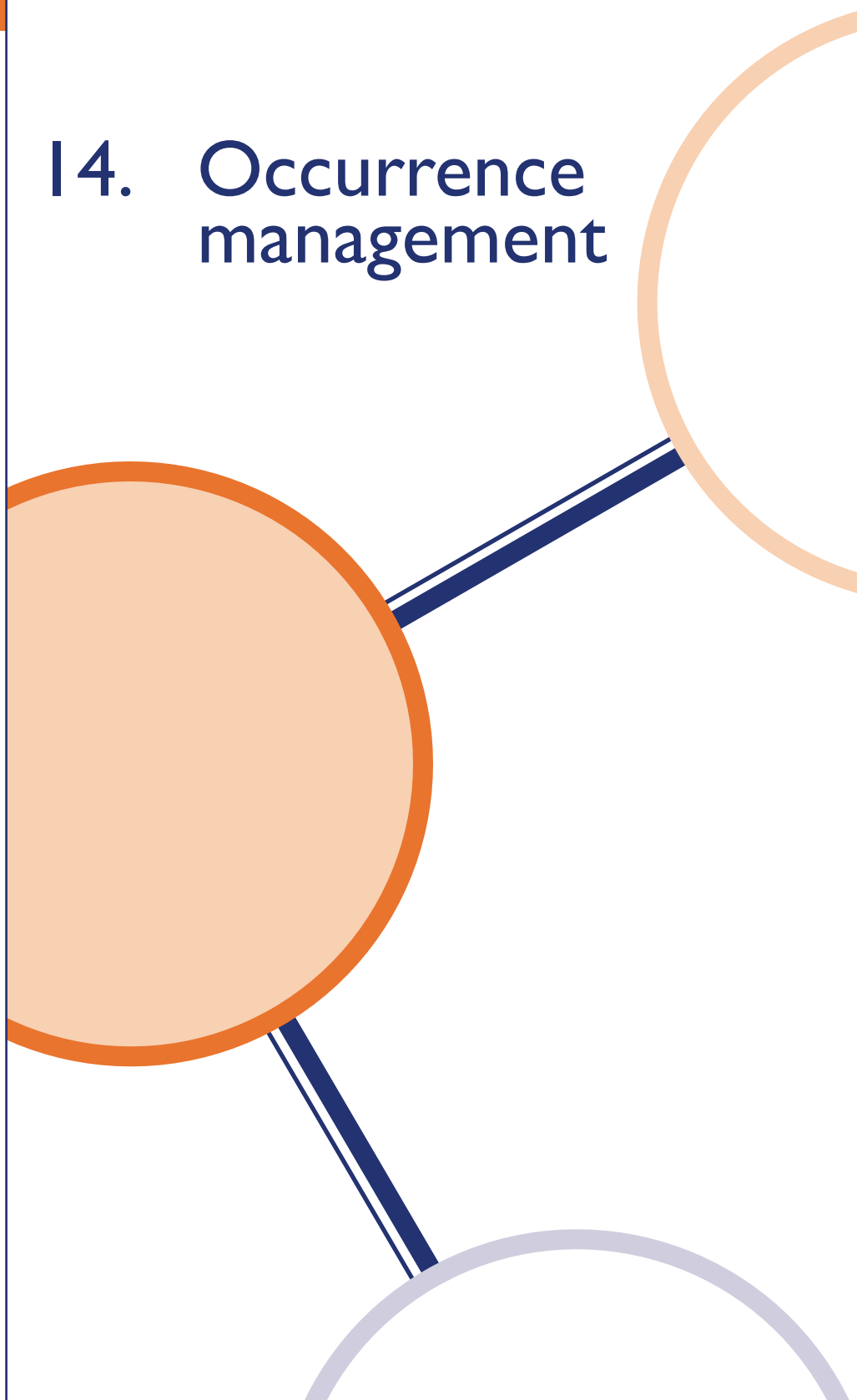
Customers or clients of the laboratory include physicians and other health care providers, hospital and clinic staff, patients and their families, public health officials and the general community.

Monitoring customer satisfaction requires some resources, primarily involving staff time. Managers need to ensure that these resources are available.

Key messages

- Meeting customer needs is a primary goal of the laboratory.
- Everyone in the laboratory is responsible for quality and, therefore, for customer service.
- An active quality management system ensures laboratories meet all client requirements.

14. Occurrence management



14-1: Overview

Role in quality management systems

Occurrence management, or dealing with laboratory errors, is important in ensuring good service from the laboratory. It is one of the 12 quality essentials and must be addressed in laboratory quality management.

This chapter will describe and explain basic elements that are essential for developing an effective occurrence management programme.

Overview of the process

Occurrence management is a central part of continual improvement. It is the process by which errors or near errors (also called near misses) are identified and handled. The goal of an occurrence management programme is to correct the errors in either testing or communication that result from an event, and to change the process so that the error is unlikely to happen again.

Well-managed laboratories will also review their systems and detect process problems that could possibly cause error at some time in the future, allowing for prevention of these errors.

Definition

An occurrence is any event that has a negative impact on an organization, including its personnel, the product of the organization, equipment, or the environment in which it operates. All such events must be addressed in an occurrence management programme.

14-2: Sources and consequences of laboratory error

Causes of laboratory error

Some of the common causes of error in the laboratory are easily identifiable, and are also readily correctable.

For example, some errors may occur because staff are unclear about who is responsible for carrying out a particular task, so it may remain undone. To prevent these types of errors, individual responsibilities must be clearly defined and communicated.

Other errors occur when procedures are not written or followed, and staff are not adequately trained. Written procedures serve as a guide for all staff, and help to ensure that everyone knows what to do. It is essential to ensure that these written procedures are followed correctly. Staff need to be trained in how to conduct the procedures and, if this training is neglected, errors can result.

There are many other sources of error in addition to these, which are frequently observed. While they often occur during pre-examination and post-examination processes, errors can occur throughout the testing process.

Useful studies for understanding sources of laboratory errors include a retrospective data collection that found Australian pathology laboratories had a transcription error rate of up to 39%, and an error rate of up to 26% for analytical results.[1] A report from the College of American Pathologists in collaboration with the Centres for Disease Control and Prevention Outcomes Working Group describes error stratification in the working process for clinical laboratories. In more than 88 000 defects, 41% were observed in the pre-examination phase of testing, 55% in the post-examination phase and only 4% in the examination phase.[2]

Pre-examination errors

Some examples of pre-examination errors that are frequently seen include:

- collecting the wrong sample;
- mislabelling or failing to label the sample;
- storing the sample incorrectly prior to testing, so that the sample deteriorates;
- transporting the sample under conditions that damage the sample or that endanger staff and public safety;
- damaging the reagents or test kits by storing them improperly.

1 Khoury M et al. Error rates in Australian chemical pathology laboratories. *Medical Journal of Australia*, 1996, 165:128–130 (http://www.mja.com.au/public/issues/aug5/khoury/khoury.html).

2 Bonini P et al. Errors in laboratory medicine. *Clinical Chemistry*, 2002, 48:691–698 (http://www.clinchem.org/cgi/content/full/48/5/691).

Examination errors

A list of common errors that occur during the testing process include:

- failing to follow an established algorithm (e.g. for HIV testing);
- reporting of results when the quality control material tests out of range;
- incorrect measuring of the sample or reagents (usually these are dilution or pipetting errors);
- using reagents that have been improperly stored, or after their expiration date.

Post-examination errors

Many of the common laboratory errors occur following the testing of the sample, and some of these may be more difficult to detect. Common examples of these kinds of errors include:

- making a transcription error when preparing the report;
- producing a report that is illegible, usually caused by poor handwriting, but sometimes by damage to the report form;
- sending the report to the wrong location, which often results in complete loss of the report;
- failing to send the report.

Consequences of laboratory error

The laboratory is a critical partner in all health systems, and it must perform its functions well in order to help ensure good outcomes of health programmes and interventions. A failure in the laboratory role can have s significant effect, producing:

- inadequate or inappropriate patient care
- inappropriate public health action
- undetected communicable disease outbreaks
- wasting of resources
- death of an individual.

14-3: Investigation of occurrences

Occurrence cycle includes investigation

A cycle of events reflects the process of occurrence management. When occurrences are found, they must all be investigated to find the causes of the problem. The investigation will help to identify the actions needed to correct the problem and to ensure that it does not occur again. All necessary communication must take place, including informing any health care providers whose clients are affected.

Detecting occurrences

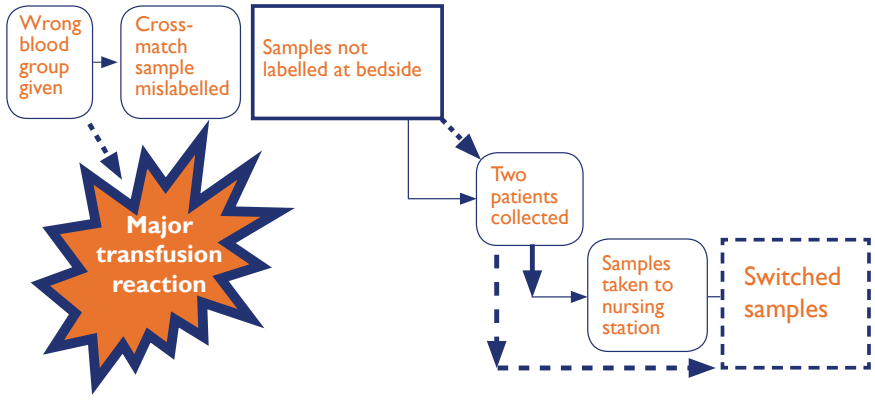
Occurrences are detected through a variety of investigative techniques. Monitoring of complaints and satisfaction surveys will yield much information. Once the laboratory establishes and monitors quality indicators, deficits will be noted. The tools of external assessment, such as proficiency testing, external quality assessment, accreditation and certification processes, will be very useful in occurrence management. A very valuable tool is the internal audit, which can be performed at any time in the laboratory. The laboratory's process improvement efforts will identify opportunities for improvement.

It is the responsibility of management to review all the information that results from use of these tools, and to look for underlying patterns and potential causes for persistent or repeated error.

Investigation involves gathering complete and detailed information about events that led to a problem, and a thorough analysis to determine all the factors that contributed to the problem occurrence.

Root cause analysis

The most aggressive and complete approach to addressing occurrences is to seek the root cause of the problem. This is more than just a thorough examination, but is a planned and organized approach toward finding not only the superficial causes of a problem, but also the deeper or core problems. With some occurrences, they are likely to reccur until such time as the true root causes are discovered and addressed.



14-4: Rectifying and managing occurrences

Correction of occurrences

As a reminder, an occurrence is any event that has a negative impact on an organization, which includes personnel, product, equipment or the environment.

There are several levels of action that may be undertaken to rectify occurrences, including the following.

- Preventive actions involve a planned and organized evaluation of processes and procedures to identify potential error points, so action can be taken to prevent the errors from ever occurring. Preventive actions require planning and team participation.
- Remedial action, or remediation, is the fixing of any consequences that result from an error. For example, if an erroneous result has been reported, it is essential to immediately notify all persons concerned about this error and to provide the correct result.
- Corrective actions address the cause of the error. If a test was done incorrectly, resulting in an incorrect result, corrective actions sort out why the test was not performed properly and steps are taken so that the error does not happen again. As an example, a piece of equipment may have been malfunctioning, and the corrective actions would be to recalibrate, repair or otherwise address the equipment problem.

Occurrence management process

The laboratory should develop a system for prompt investigation of every laboratory problem and error. The management process for dealing with errors or occurrences involves several steps.

1. Establish a process to detect all problems, using the tools that are available. Remember that problems may go undetected unless there is an active system for looking for them.
2. Keep a log of all problem events that records the error, any investigation activities and any actions taken.
3. Investigate the cause of any problem that is detected and carefully analyze the information that is available.
4. Take the necessary action (remedial and corrective)—if the problem is detected before the error actually occurs, take preventive action.
5. Monitor and observe for any recurrence of the original problem, keeping in mind that there may be a systemic problem.
6. Provide information to all those who need it, and to those who are affected by the error.

Responsibilities

The responsibility for monitoring for occurrences belongs to everyone in the laboratory. It is important, however, that someone be designated as the person responsible for marshalling the energies and activities of all staff into an effective management process. In many instances, this is the responsibility of the laboratory director, laboratory manager or quality manager.

14-5: Summary

Summary

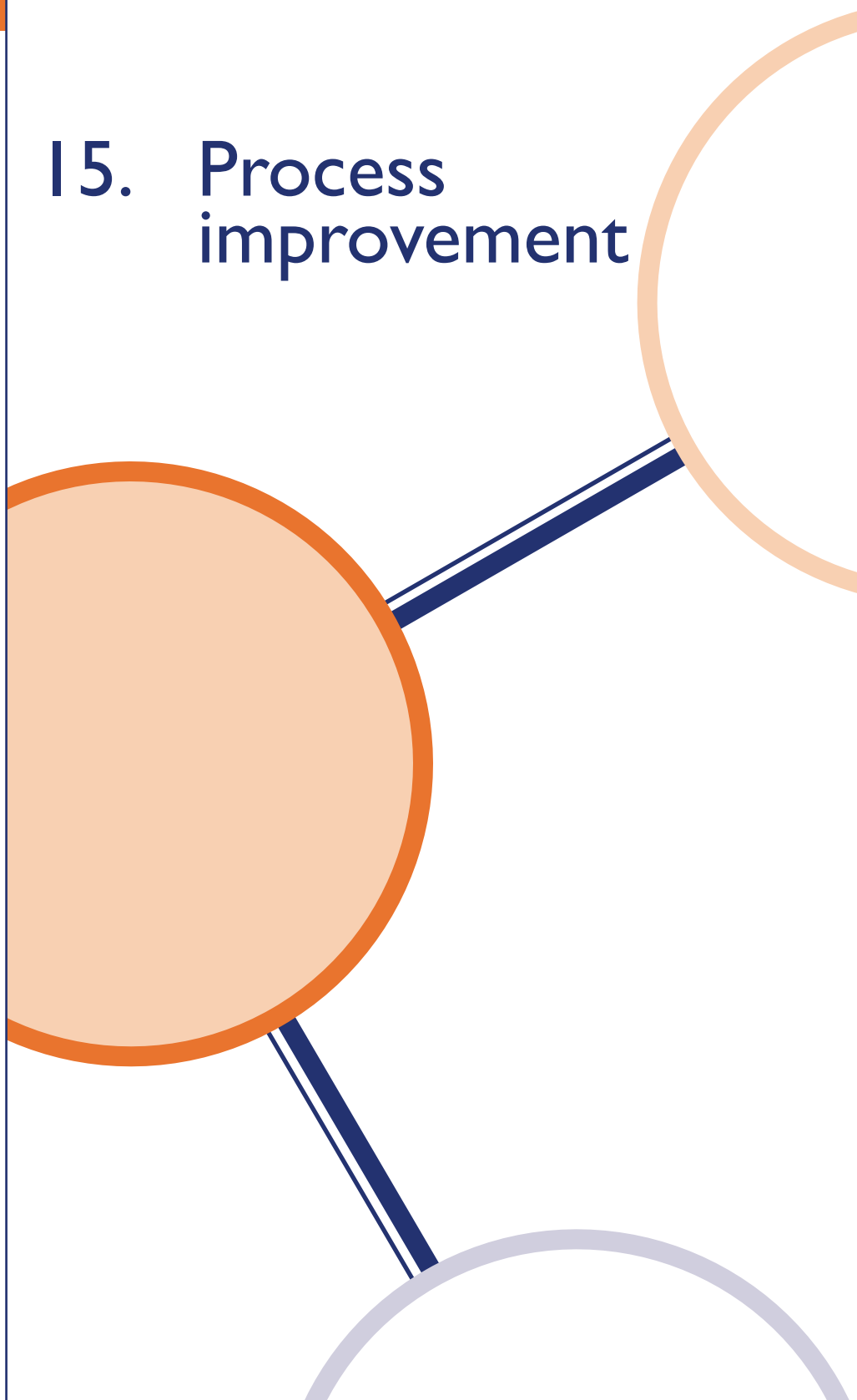
Occurrence management is an integral component of laboratory quality management. It establishes the methods for finding errors and preventing them from occurring again, and also seeks to identify potential errors and prevent them from happening.

The laboratory should employ an active process for occurrence management and take a positive approach. Make an effort to detect problems as early as possible, and then take immediate remedial and corrective action. Be proactive and see opportunities to identify potential error, thus preventing an occurrence. Finally, keep good records of all problems, investigations and actions taken.

Key messages

The difference between a quality-managed laboratory and laboratories with no system in place is that the quality laboratory detects the problem, investigates and takes actions.

15. Process improvement



15-1: Continual improvement concept

Role in quality management system

Process improvement, one of the 12 quality system essentials, establishes a programme for helping to ensure continual improvement in laboratory quality over time. This continual improvement of the laboratory processes is essential in a quality management system.

Historical basis

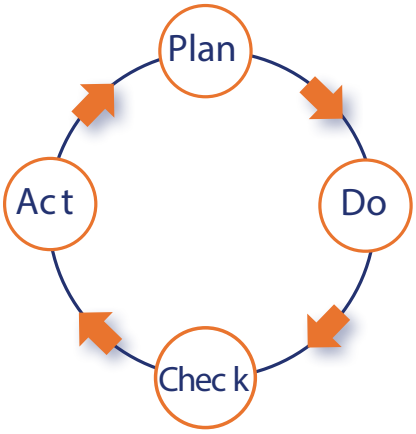
W. Edwards Deming is one of the originators of the concept of continual improvement, the primary goal of a quality management system. Beginning in the 1940s, he worked with manufacturing and industrial processes, and introduced many of the tools used in quality improvement efforts; his ideas and concepts are used today to produce reliable, quality laboratory results. Deming outlined 14 points for quality, many of which can easily be applied to the laboratory. For the purposes of this discussion, two of his points are particularly important:

1. **Create constancy of purpose for improvement**. The message here is that there is a need to be constantly working toward making the process better.
2. **Improve constantly and forever**. This statement points out that continual improvement will always be a goal. Perfection is never achieved, but we try to get as close to it as possible. Process improvement is something that is never finished, but rather continues on "forever".

Deming's PDCA cycle

The Deming Plan-Do-Check-Act (PDCA) cycle shows how to achieve continual improvement in any process.

- **Plan**—identify the problems and the potential sources of system weakness or error. Decide on the steps to be used to gather information. Ask the question, "How can you best assess the current situation and analyze root causes of problem areas?" Using the information that is gathered through these techniques, develop a plan for improvement.
- **Do**—implement whatever plans have been developed—put the plan into action.



- **Check**—this refers to the monitoring process. It will be important to assess the effectiveness of the action taken, using focused review and audit processes. If the system weakness is complex, a pilot study may be needed in order to understand all the complexities. After "checking", revise the plan as required to achieve the improvements needed.
- **Act**—Take any corrective action that is required, and then recheck to be sure that the solution has worked. This cycle is a continuous process, so the laboratory will begin again with a planning process to continue the improvements.

This is the continual improvement process and, in the laboratory, this process is applied to all procedures and processes that are a part of the path of workflow.

ISO process for continual improvement

ISO 15189 [4.12] describes a very similar set of activities for achieving continual improvement in the laboratory. These are outlined as follows:

- identify potential sources of any system weakness or error;
- develop plans to implement improvement;
- implement the plan;
- review the effectiveness of the action through the process of focused review and audit;
- adjust the action plan and modify the system in accordance with the review and audit results.

15-2: Tools for process improvement

What is process improvement?

A process is a series of actions or operations contributing to an end. In every case, inputs (patient samples) are turned into outputs (patient examination results) because some kind of work, activity or function is carried out. Process improvement is a systematic and periodic approach to improving laboratory quality and the inputs and outputs that glue these processes together. It is a way of solving problems. If there is a problem, however hard to describe, one or more processes needs to be improved.

Conventional tools for improvement

Many useful techniques have been developed to use in process improvement, and some have been discussed in other chapters of this handbook. For example, both **internal and external audits** will identify system weaknesses and problem areas. Participation in an **external quality assessment** is another useful tool; it allows for comparing laboratory performance to that of other laboratories.

Management review of all information gathered through these activities should be conducted. In addition, there should be management reviews of the laboratory records on a regular basis; for example, quality control, inventory management and equipment maintenance. These reviews will provide useful information about areas for improvement.

Using information from these reviews and from audits, and through the process of monitoring the organization's customer complaints, worker complaints, errors, near errors or near misses, **opportunities for improvement (OFIs)** will be identified. These OFIs will be the focus for corrective action.

When conducting audits or evaluating laboratory records, it is important to have a goal or standard of performance. Therefore, **quality indicators** will be needed and will have an important role to play.

The plan leads to the goals; OFIs, which are the result of monitoring, lead to the creation of a new plan, with the process leading to continual improvement.

Newer tools

New ideas for tools to use for continual improvement continue to come from the manufacturing industry. Two of these new tools are now being used in laboratory quality improvement.

1. **Lean** is the process of optimizing space, time and activity in order to improve the physical paths of workflow. This tool of industry is applicable to laboratories, and many laboratories are currently engaged in creating a lean system. Lean analysis may lead to revised processes and changes in laboratory floor plans. This should save time and financial resources, as well as help to reduce errors in the path of workflow.
2. **Six Sigma** is also a concept that has come to us from the manufacturing industry. This consists of a formal structure for project planning in order to implement change and improvement. In Six Sigma, the focus is to move toward reducing error to very low levels. The processes that are described in Six Sigma are define, measure, analyze, improve and control. These are similar ideas to those already discussed. The Six Sigma concept applies a very structured method for achieving these processes. (This chapter will not explore Six Sigma in depth; it is included here so that participants will become familiar with the term. See Chapter 15 reference list for sources of Six Sigma information.)

15-3: Quality indicators

Reminder: What is quality?

It is often useful to consider a number of definitions in order to make very clear what is meant by a term such as quality. Philip Crosby, in his essays on quality management from the 1960s, defined quality as "conformance to requirements, not as 'goodness' or 'elegance'".

What is a quality indicator?

Established measures used to determine how well an organization meets needs and operational and performance expectations is a good working explanation of a quality indicator.

Quality indicators are addressed in ISO 9001 and ISO 15189 documents.

ISO 9001 [5.4.1] requires that quality objectives should be measurable. Thus, the objectives or indicators must be quantifiable or otherwise capable of analysis, allowing for an assessment of the success of the quality system.
ISO 9001 [8.4] more specifically requires collecting and analyzing specific information or data upon which one can determine effectiveness and continual improvement. Some of the indicators that are required to be considered include customer satisfaction, conforming to customer requirements for products, counting the number of preventive actions addressed, and ensuring that suppliers are providing materials that will not adversely affect quality.

ISO 15189 [4.12.4] states that the laboratory shall implement quality indicators to systematically monitor and evaluate the laboratory's contribution to patient care. When the programme identifies opportunities for improvement, the laboratory management shall address them, regardless of where they occur. Also, it is stated that laboratory management shall ensure that the medical laboratory participates in quality improvement activities that deal with relevant areas and outcomes of patient care.

Purpose of quality indicators

Quality indicators are information that is measured. The indicators:

- give information about the performance of a process
- determine quality of services
- highlight potential quality concerns
- identify areas that need further study and investigation
- track changes over time.

15-4: Selecting quality indicators

General guidelines

In selecting quality indicators for measuring performance, Mark Graham Brown, a leading expert on performance measurement, suggests the following useful guidelines.[1]

- Fewer are better; that is, do not try to have too many quality indicators, as tracking becomes difficult. Few laboratories can effectively address more than five or six indicators at a single time.
- Link the indicators to the factors needed for success. Choose the quality indicators that relate to areas that need correction in order to achieve good performance; select those that will be most meaningful to the laboratory.
- Measures (indicators) should be based around customer and stakeholder needs.
- Measures should look at all levels of the laboratory; if possible, include indicators that will evaluate function at the top management level, but also flow down to all levels of employees.
- Measures should change as the environment and strategy changes. Do not stick with the same indicators over long periods of time.
- Base the targets and goals for the measures on rational values, rather than values of convenience. They should be established on the basis of research rather than arbitrary estimates.

Developing successful indicators

Quality indicators—also called metrics—are the specific targets that are regularly examined using objective methods, in order to determine if the goals of compliance are being met. When developing quality indicators an organization should ensure the following.

- **Objective**—the indicators must be measurable, and not dependent on subjective judgements. It must be possible to have concrete evidence that the event (or indicator) either occurs or does not, or that the target is clearly met.
- **Methodology available**—be sure that the organization has the tools needed to accomplish the necessary measurements. The laboratory must have the ability to gather the information. If the data or information collection requires special equipment, then make sure the special equipment is available before starting.
- **Limits**—the laboratory will need to know the acceptable value, including the upper and lower range, before starting measurements. Determine in advance the limits of acceptability, and at what point a result causes concern. Also consider what action will be required. For example, how many delayed reports per month would be considered acceptable? How many would be considered as requiring corrective actions? How many would require immediate revision of the action plan?

1 Brown MG. *Baldridge award winning quality: How to interpret the Baldridge criteria for performance excellence.* Milwaukee, ASQ Quality Press, 2006.

- **Interpretation**—decisions must be made as to how indicator information will be interpreted before beginning measurements. Know in advance how to interpret the information that has been collected. For example, if you are monitoring completed requisitions to see if they are correct, you need to know how many samples you have examined, if they have come from multiple sources or all sources, and whether they are for only one type of sample or all sample types.
- **Limitation**—the organization should understand exactly what information is being provided by the indicator, and be clear on what is not being determined by the measurement of a particular indicator. For example, if collecting the number of accidents or errors, do you know if all are being reported?
- **Presentation**—the organization must decide how to present the information in order to fully display its value. Some information is best presented in a table, whereas other information might be best shown by a longitudinal graphic bar or in text. Presentation of information is important when looking for trends that predict future outcome.
- **Action plan**—before beginning the use of an indicator, the laboratory should have some idea of what to do if the indicator shows that there is a problem. Also decide how to collect the information, who will collect it, and how long it will be collected.
- **Exit plan**—because making these measurements takes time and resources, there should be a plan as to when to stop using a particular indicator and replace it with another. Generally, this is done when the original indicator shows that the operation is working and stable.

When developing quality indicators, be sure to engage the bench-level staff—those who do the work have a clear understanding of the tasks and outcomes. The planning process is best done in groups rather than by the quality manager alone. By engaging the people who actually do the work, the opportunity for success improves.

Characteristics of good quality indicators

Good quality indicators (also called metrics) have the following characteristics:

- measurable—the evidence can be gathered and counted;
- achievable—the laboratory has the capability of gathering the evidence it needs;
- interpretable—once it is gathered, the laboratory can make a conclusion about the information that is useful to the laboratory;
- actionable—if the indicator information reports a high or unacceptable level of error, it is possible to do something about the problem identified;
- balanced—consider indicators that examine multiple aspects of the total testing cycle in the pre-examination, examination, and post-examination phases;
- engaging—indicators should examine the work of all staff, not just one group;
- timed—consider indicators with both short-term and long-term implications.

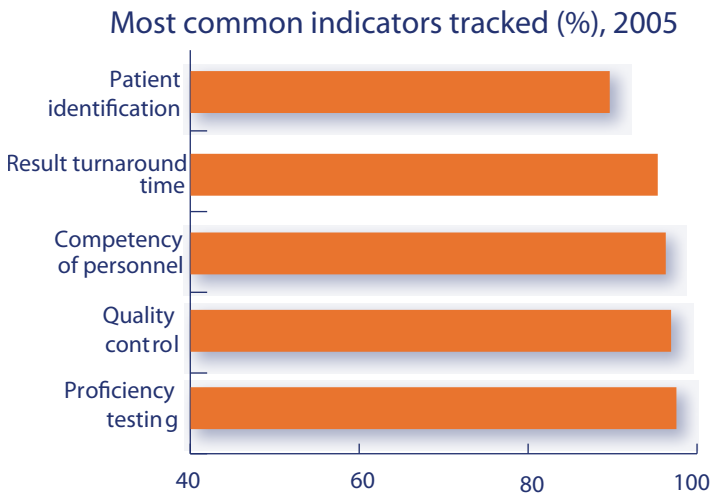
The laboratory produces much information, but all the things that can be measured are not necessarily informative. As an example, a computer can analyze data in a variety of ways, but this does not always mean that the information is useful for continual improvement activities.

Mark Graham Brown warns, "Many organizations spend thousands of hours collecting and interpreting data. However many of these hours are nothing more than wasted time because they analyze the wrong measurements, leading to inaccurate decision making".[1]

Some examples of quality indicators

All laboratories should consider implementing a process for using a set of indicators which cover pre-examination, examination, and post-examination issues, as well as patient care systems.

A 2005 study of medical laboratories carried out in the United States showed the most commonly monitored indicators in use at that time were related to proficiency testing, quality control, personnel competencies, turnaround time, and patient identification and its accuracy.[2]



It is important to note that, ideally, quality indicators used in health care should be linked to patient outcomes. However, this is very difficult with laboratory indicators because patient outcome is dependent upon a complex set of circumstances, including age and underlying illness, stage of illness, stage of diagnosis and stage of therapy. Therefore, laboratories often use quality indicators other than health outcomes of patients.

1 Brown MG. *Using the right metrics to drive world-class performance*. New York, American Management Association, 1996.
2 Hilborne L. Developing a core set of laboratory based quality indicators. Presented at Institute for Quality in Laboratory Medicine Conference, Centers for Disease Control and Prevention, Atlanta, GA United States, 29 April 2005 (http://cdc.confex.com/cdc/qlm2005/techprogram/paper_9086.htm).

15-5: Implementing process improvement

Essentials for implementation

Regardless of the technique used, continual improvement requires action from the people within the organization. Some of the necessary steps are important management roles, and others require the entire laboratory staff for success. These essential factors and steps include:

- Commitment from all levels of the laboratory staff. Improvement requires continual awareness and activity. This is a full-time task and requires dedicated staff time .
- Careful planning so that goals can be achieved. Before action plans are implemented, there is much to consider: root causes of error; risk management; failures, potential failures and near misses; costs, benefits and priorities; and the costs of inaction.
- An organizational structure that supports the improvement activities.
- Leadership—top management must be engaged and supportive.
- Participation and engagement of the people that normally perform the tasks being addressed. These are the staff most likely to know and understand what is done on a regular and daily basis, and without their participation, improvement programmes have little opportunity for lasting success.

Planning for quality improvement

When undertaking and implementing action plans for quality improvement, there are a number of factors to consider.

- What are the root causes of error? In order to correct errors, it is important to identify the root causes, or underlying causes, of the problem.
- How will risk be managed in the laboratory? Risk management takes into account the trade offs between the risk of a problem, and the costs and effort involved in fixing it.
- Failures, potential failures and near misses are categories into which laboratory problems fall. Failures are most commonly identified, as a failure in the system will usually be immediately obvious. Failures need to be addressed as a part of continual improvement. However, a good process improvement programme will try to identify potential failures, which are not so obvious, as well as near misses (those situations where a failure has almost occurred).
- Any process improvement programme must take into account the costs of making changes, the benefits of making the changes and the priorities for action. These decisions relate to the concept of risk management.
- Finally, it is important to consider the cost of inaction, or failure to take action. What will be the cost, in money, time or adverse effects, of not correcting a problem in the laboratory quality system?

Role of leadership

Early on, Deming observed that quality managers working without the clear, active, and open participation of top management cannot succeed in implementing continual improvement. Sustained leadership must come from the top.

Good leadership fosters the culture for improvement, including:

- openness—the process must be understood by all and there must be a recognition that all laboratory staff will have good ideas to help with improvements.
- commitment—it must be clearly communicated that there is support for the process and that improvements will occur.
- opportunity—a good leader will ensure that all staff have the opportunity to participate in the process.

Participation in the process

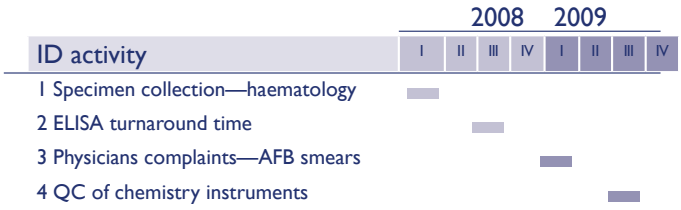
Always remember that top management, quality managers and consultants do not know everything that the bench-level staff know, and often are not aware of all of the staff's tasks. It is vital to engage all bench-level staff in the process improvement programme, as their knowledge and support are also essential. Furthermore, when staff know they can make a difference, they will benefit the laboratory by pointing out potential problems that can be avoided.

Continual improvement requires both leadership and engaged team participation.

Quality improvement activities

The following steps show how to plan quality improvement activities:

- use a timeline and do not take on more than can be accomplished within a timeframe;
- use a team approach, involving bench-level staff;
- use appropriate quality improvement tools;
- implement corrective or preventive actions;
- report quality improvement activities, findings and corrective action progress to management and also to laboratory staff.



If possible, design a study so that results can be statistically measured. Use available information to select a topic for study, for example:

- customers' suggestions or complaints
- identified errors from occurrence management programme
- problems identified in internal audits.

Retiring a quality indicator

Consider as a guideline to have no more than one project every six months.

Use a quality indicator only as long as it provides useful information. Once it is indicating a stable and error-free operation, select a new quality indicator.

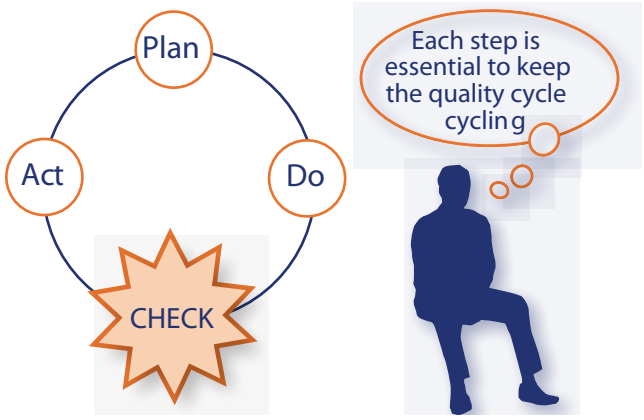
15-6: Summary

Continual improvement

The process for continual improvement includes:

- identification of the problem;
- analysis of the data and the processes;
- determination of the root cause of the problem;
- generation of ideas for solutions.

The quality cycle

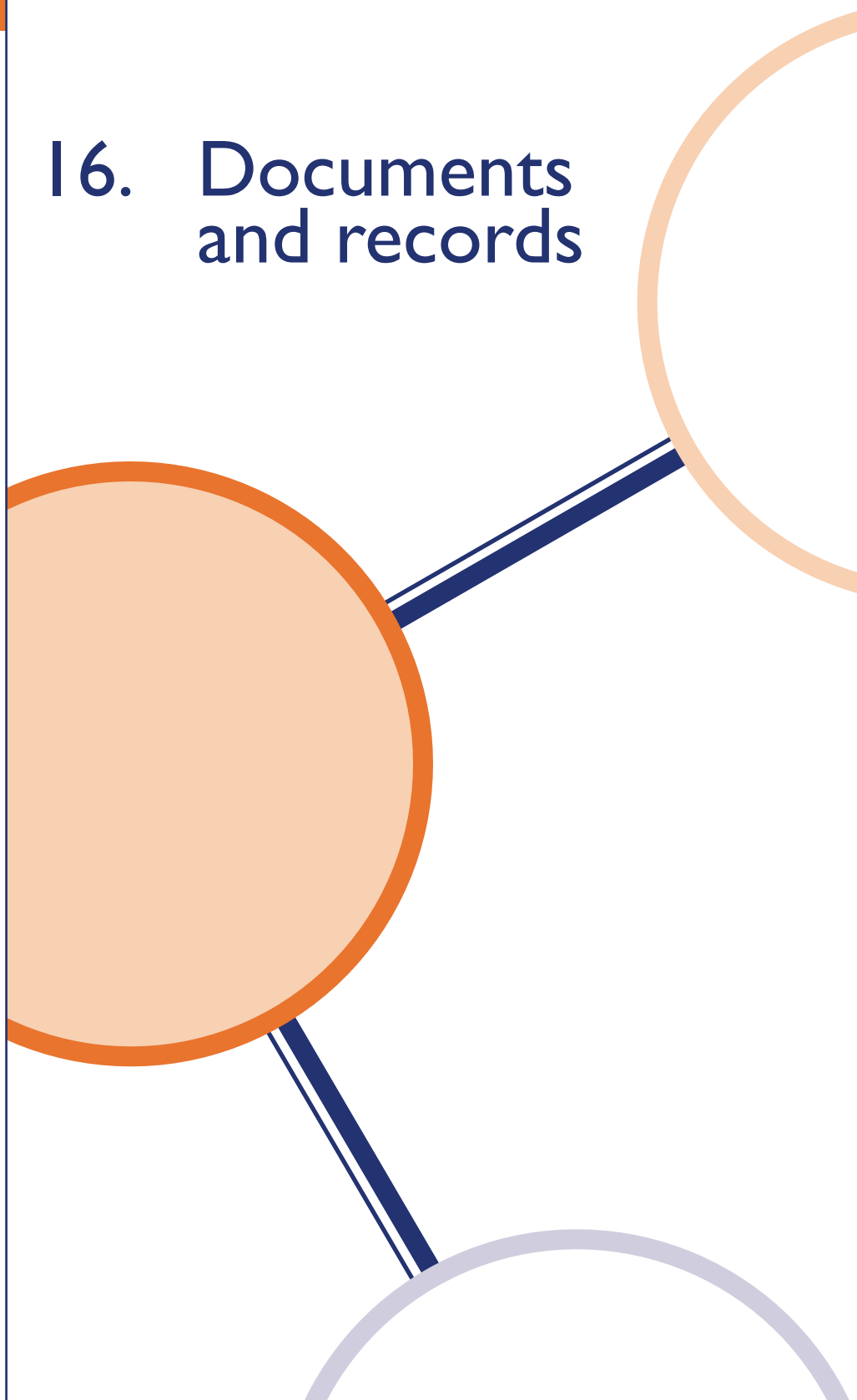


Continual improvement is the core of quality management, but it requires commitment, planning, structure, leadership, participation and engagement.

Key messages

- Quality counts—it is a very important goal for any laboratory.
- Continual improvement is an outcome of an active laboratory quality management system.

16. Documents and records



16-1: Introduction

Role in quality management system

The management of documents and records is one of the 12 essential elements of the quality system. The management system addresses both use and maintenance of documents and records. A major goal of keeping documents and records is to **find information whenever it is needed.**

Documents and records—what are the differences?

Documents provide written information about policies, processes and procedures. Characteristics of documents are that they:

- communicate information to all persons who need it, including laboratory staff, users and laboratory management personnel;
- need to be updated or maintained;
- must be changed when a policy, process or procedure changes;
- establish formats for recording and reporting information by the use of standardized forms—once the forms are used to record information, they become records.

Some examples of documents include a quality manual, standard operating procedures and job aids.

Records are the collected information produced by the laboratory in the process of performing and reporting a laboratory test. Characteristics of records are that they:

- need to be easily retrieved or accessed;
- contain information that is permanent, and does not require updating.

Some examples of records include completed forms, charts, sample logs, patient records, quality control information and patient reports.

Information is the major product of the laboratory, so manage it carefully with a good system for the laboratory's documents and records.

16-2: Overview of documents

Documents include all the written **policies, processes and procedures** of the laboratory. In order to develop laboratory documents, it is important to understand each of these elements and how they relate to each other.

What is a policy?

A policy is "a documented statement of overall intentions and direction defined by those in the organization and endorsed by management".[1] Policies give broad and general direction to the quality system. They:

- tell "what to do", in a broad and general way;
- include a statement of the organizational mission, goals and purpose;
- serve as the framework for the quality system, and should always be specified in the quality manual.

Although there are national policies that affect laboratory operations, each laboratory will develop policies specific to its own operations.

What is a process?

Processes are the steps involved in carrying out quality policies. ISO 9000 [4.3.1][2] defines a process as a "set of interrelated or interacting activities that transform inputs into outputs".

Some examples of laboratory inputs include test requests, samples, and requests for information. Examples of laboratory outputs include laboratory data and reports of results. Using these examples, one process might be how to transform a test request (input) into a test result (output).

Another way of thinking about a process is as **"how it happens".** Processes can generally be represented in a flow chart, with a series of steps to indicate how events should occur over a period of time.

What are procedures?

Procedures are the specific activities of a process (ISO 9000 [3.4]). Procedures are very familiar to laboratorians—a procedure is easily described as the performance of a test.

A procedure tells **"how to do it"**, and shows the step-by-step instructions that laboratory staff should meticulously follow for each activity. The term **standard operating procedure (SOP)** is often used to indicate these detailed instructions on how to do it.

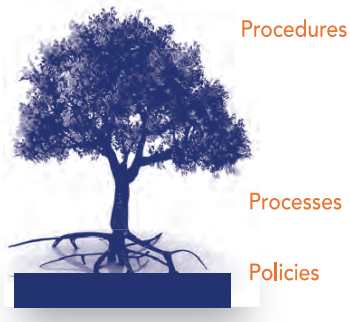
Job aids, or work instructions, are shortened versions of SOPs that can be posted at the bench for easy reference on performing a procedure. They are meant to supplement, not replace, the SOPs.

1 CLSI/NCCLS. *A quality management system model for health care; approved guideline—second edition.* CLSI/NCCLS document HS1-A2. Wayne, PA, NCCLS, 2004.

2 ISO 9000:2005. *Quality management systems—fundamentals and vocabulary.* Geneva, International Organization for Standardization, 2005.

Document hierarchy

A good way to represent the relationship of policies, processes and procedures is as a tree. The policies are represented by the roots, and they form the base for all the other parts. The processes can be viewed as the trunk of the tree, representing a series of steps or flow of actions through the laboratory. The leaves of the tree can be thought of as the procedures; there will be many procedures in the laboratory for accomplishing the activities or the work.



The quality manual is the overall guiding document that defines the quality system through policies established by the laboratory. Next in the hierarchy of documents are the processes, the sets of activities. Procedures either flow from processes, or make up a part of a process; these will generally be described as SOPs. Work instructions or job aids are shortened versions of SOPs. Finally, forms are used to record results; when completed, they become records.

Why are documents important?

Documents are the essential guidelines for all of the laboratory operations. Some of the important documents that every laboratory should have include:

- Quality manual—this is the overall guiding document for the quality system and provides the framework for its design and implementation. A laboratory is required to have a quality manual for ISO accreditation (the quality manual is discussed further in sections 16-3 and 16-4).
- SOPs—SOPs contain step-by-step written instructions for each procedure performed in the laboratory. These instructions are essential to ensure that all procedures are performed consistently by everyone in the laboratory.
- Reference materials—good reference materials are needed in order to find scientific and clinical information about diseases, laboratory methods, and procedures. Sometimes, there are difficult interpretive issues, for which references or textbooks will be needed. As an example, when examining samples microscopically for parasites, photographs and descriptive information can be very helpful.

Written documents are required by formal laboratory standards, including those leading to accreditation. Standards generally require that policies and procedures be written and available. Most inspection or assessment activities include an examination of the laboratory's documents. The documents are an important element on which the laboratory is assessed.

Documents are the communicators of the quality system. All policies, processes and procedures must be written, so that everyone will know the proper procedures and can carry them out. Verbal instructions alone may not be heard, may be misunderstood, are quickly forgotten and are difficult to follow. Everyone, both inside and outside the laboratory, must know exactly what is being done and what should be done at each step. Therefore, all of the guidelines must be written so that they are available and accessible to all who need them.

Documents are a reflection of the laboratory's organization and its quality management. A well-managed laboratory will always have a strong set of documents to guide its work.

A good rule to follow is "Do what you wrote and write what you are doing".

What makes a good document?

Documents communicate what is done in the laboratory. Good documents are:

- written clearly and concisely—it is better to avoid wordy, unnecessary explanations in the documents;
- written in a user-friendly style—it might be helpful to use a standard outline so the general structure will be familiar to staff and easily used by new personnel;
- written so as to be explicit and accurate, reflecting all implemented measures, responsibilities and programmes;
- maintained to ensure that it is always up to date.

Accessibility

The documents needed in the work process must be accessible to all staff. Persons managing samples should have the procedures for sample management directly available to them. Testing personnel will need the SOPs in a convenient place, and perhaps a job aid posted in clear view of the workspace where testing is performed. The testing personnel need immediate access to quality control charts and troubleshooting instructions for equipment. All staff must have access to safety manuals.

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.

16-4: Standard operating procedures (SOPs)

What is an SOP?

SOPs are also documents, and contain written step-by-step instructions that laboratory staff should meticulously follow when performing a procedure. A laboratory will have many SOPs, one for each procedure conducted in the laboratory.

Written SOPs ensure the following.

- Consistency—everyone should perform the tests exactly the same way so that the same result can be expected from all staff. Consistency enables people who use laboratory results to observe changes in a particular patient's results over time. If different laboratories use the same SOPs, comparisons of their results can be made; it should be emphasized that all laboratory staff must follow the SOPs exactly.
- Accuracy—following written procedures helps laboratory staff produce more accurate results than relying on memory alone because they will not forget steps in the process.
- Quality—consistent (reliable) and accurate results are primary goals of the laboratory, and could be considered as the definition of quality in the laboratory.

A good SOP should be:

- detailed, clear and concise, so that staff not normally performing the procedure will be able to do so by following the SOP—all necessary details (e.g. ambient temperature requirements and precise timing instructions) should be included;
- easily understood by new personnel or students in training;
- reviewed and approved by the laboratory management—approval is indicated by a signature and a date (this is important to ensure that the procedures being used for testing in the laboratory are those that are up to date and appropriate);
- updated on a regular basis.

Standardized format

It is a good idea to standardize the formats of SOPs so staff can easily recognize the flow of the information.

Headers are a very important part of the format. Below are examples of two different types of headers that could be used when writing an SOP.

- Complete standardized header—typically the standardized header would appear on the first page of each SOP. The standardized form makes it easy for staff to quickly note the pertinent information.

TLM/MSH Microbiology Department Policy & Procedure Manual	**Policy # MI/RESP/11/v05**	Page 1 of 5
Section: Respiratory Tract Culture Manual	Subject Title: **SPUTUM (Including Endotracheal Tube and Tracheostomy Specimens)**	
Issued by: LABORATORY MANAGER	Original Date: September 25, 2000	
Approved by: Laboratory Director	Revision Date: September 14, 2006	
	Annual Review Date: August 13, 2007	

- Reduced standardized header—this standardized form includes a smaller version of the header that would appear on all pages other than the first.

TLM/MSH Microbiology Department Policy & Procedure Manual	**Policy # MI/RESP/11/v05**	Page 2 of 5
Respiratory Tract Culture Manual		

Preparing SOPs

There are a few things to keep in mind when preparing an SOP. Firstly, it is important to assess the scientific validity of the procedure. Then, when writing the procedure, include all steps and details explaining how to properly perform the procedure. The SOP should refer to any relevant procedures that may be written separately, such as instructions for sample collection or quality control. Finally, a mechanism should be established for keeping SOPs updated.

SOPs should include the following information:

- title—name of test;
- purpose—include information about the test (why it is important, how it is used, and whether it is intended for screening, to diagnose, or to follow treatment and if it is to be used for public health surveillance);
- instructions—detailed information for the entire testing process, including pre-examination, examination and post-examination phases;
- name of the person preparing the SOP;
- signatures of approving officials and dates of approval—it is necessary to follow the laboratory's quality policy and regulatory requirements.

Pre-examination instructions should address sample collection and transport to the laboratory, and conditions needed for proper sample handling. For example, instructions should indicate whether the sample needs a preservative, and whether it should be refrigerated, frozen, or kept at room temperature. Instructions should also reflect laboratory policies for sample labelling, such as requirements to verify more than one type of patient identification, to write the collection date on the sample label, and to make sure all information needed is included on the test request form.

Examination instructions should address the actual step-by-step laboratory procedures to follow and the quality control procedures needed to ensure accuracy and reliability.

Post-examination instructions should provide information on reporting the results, including the unit of measurement to be used, the normal (reference) range, ranges that are life-threatening (sometimes called "panic values") and instructions for how to deal with an urgent report. They should also include references to the published sources of the procedures, including published evidence that the procedures are scientifically valid.

Manufacturer's instructions

The instructions that manufacturers provide in their product inserts tell how to perform the test, but do not include other important information that is specific to laboratory policy, such as how to record results, algorithms outlining the sequence of testing and safety practices. The manufacturer's instructions may describe recommended quality control procedures for the test, but the recommendations may not be as comprehensive as protocols that a laboratory has put into place. **Do not rely solely on manufacturer product inserts for SOPs. Use information from these inserts, but develop SOPs specific to your laboratory.**

What is a job aid?

A job aid is a shortened version of an SOP. It is designed for use directly at the testing site. It should be placed in a visible location, and serves as a reminder of the steps that need to be completed. The job aid and the SOP must include the same instructions. If a job aid is distributed to sources outside the laboratory, ensure that the information illustrated matches that which is instructed in the SOP. External laboratory assessors often check to see if job aids and SOPs are in accordance.

Job aids supplement—not replace—the SOP. They do not include all the details that are provided in the SOP.

16-5: Document control

Purpose of document control

Documents, by definition, require updating. A system must be established for managing them so that current versions are always available. A document control system provides procedures for formatting and maintaining documents and should:

- ensure that the most current version of any document is the one that is in use;
- ensure availability and ease of use when a document is needed;
- provide for the appropriate archiving of documents when they need to be replaced.

Elements of document control

A document control system provides a method for formatting documents so that they are easily managed, and sets up processes for maintaining the inventory of documents. In this system the laboratory will need:

- a uniform format that includes a numbering system, to include a method for identifying the version (date) of the document;
- a process for formal approval of each new document, a distribution plan or list, and a procedure for updating and revising laboratory documents;
- a master log or inventory of all documents of the laboratory;
- a process to ensure that the documents are available to all who need them, including users outside the laboratory;
- a method for archiving documents that become outdated but need to be kept for future reference.

Controlled documents

All documents that are produced by and/or used in the laboratory must be included in the control system. Some important examples include:

- SOPs—these must be up to date, showing the procedures that are in current use and, when work instructions or job aids are used, they must exactly match the SOPs for the tasks described;
- texts, articles and books that are part of the documents referenced in a laboratory;
- documents of external origin, such as instrument service manuals, regulations and standards, and new references (that may change over time).

Developing the document control system

While establishing a document control programme, the following should be considered.

- A system for standardizing the format and/or numbering—it is very useful to have a numbering or coding system that applies to all documents created within the organization. Because documents are "living" and require updating, the numbering system should indicate the document version.
  - One suggestion for a numbering system is to use a letter for the type of document, then an incremented number for each of the documents of this type. All pages of the documents would contain the appropriate number. For example, B1, B2, B3, … for books ; T1, T2, ... for official texts. A location code could be used, and would be useful for the master log or file. For example, "Book number 2, pages 188–200, on bookshelf 1"→ B2, 188–200, BS1.

  - Establishing a document numbering system can be a difficult and time-consuming process. If the laboratory already has an effective system in place, there is no need to change it.
- Approval, distribution and revision process—control of documents requires that they be reviewed on a regular basis, with revision as needed, followed by approval and distribution to those who need them. The review and approval process is generally performed by laboratory management, and approval is indicated by signatures with appropriate dates. Policies for the approval, distribution and revision of documents should be clearly established as a part of the documents and records policy.
- Master log—this will allow the person responsible for document control to know exactly what is in circulation and where copies can be found. The log should be kept up to date at all times.
- Accessibility—the document control plan must provide a process for ensuring that relevant versions of documents are available at the point of use. This may include provision for having current sample collection information available outside the laboratory if collection is performed in other places, such as hospital wards or physician offices.
- System for archiving—remember that archiving old versions of documents will be very important. It is frequently necessary to refer to older versions of documents when researching a problem or when reviewing quality practices. As a part of the distribution process, it will be necessary to collect all old versions of the documents for archiving or destruction.

Implementing document control

When implementing a new document control system, the following steps will be needed.

- Collect, review and update all existing documents and records—usually a laboratory without a document control system will find many outdated documents that will need to be revised.
- Determine additional needs—once all documents have been collected, it should be possible to determine needs for new process or procedure descriptions. If the quality manual has not yet been developed, this should probably be done at that time, as it serves as the framework for all the efforts.
- Develop or obtain examples of documents, including forms and worksheets, if needed—remember that forms of all kinds are documents, but once they have information added they become records. In order to help with formatting, examples from other laboratories or from published materials can be used.
- Involve stakeholders—it is useful when creating documents to be used in the laboratory to involve all staff who will be using them. For documents that will be used outside the laboratory, such as reports, it is very helpful to seek input from those who will use the reports.

Common problems

Some of the common problems found in laboratories that do not have document control systems, or that do not manage their document control systems include:

- Outdated documents in circulation.
- Distribution problems—if multiple copies of documents are dispersed throughout different areas of the laboratory, it will be cumbersome to gather all copies when it is time to update them, and some could be overlooked. For this reason, multiple copies should be avoided. Documents should not be distributed more widely than needed and a record should be kept of where all documents are located.
- Failure to account for documents of external origin—these documents may be forgotten in the management process, but it is important to remember that they may also become outdated and need to be updated.

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).

16-7: Storing documents and records

Where to keep documents and records

Storage must be given careful consideration, as the main goal of documentation is finding the information when it is needed.

Using a paper system

It is important to consider the following when using a paper system for records:

- Permanence—paper records must last for as long as needed. This should be ensured by binding pages together, or using a bound book (log register). Pages should be numbered for easy access, and permanent ink should be used.
- Accessibility—paper systems should be designed so that information can be easily retrieved whenever needed.
- Security—documents and records must be kept in a secure place. Security considerations include maintaining patient confidentiality. Care should be taken to keep documents safe from any environmental hazards such as spills. Consider how records can be protected in the event of fires, floods or other possibilities.
- Traceability—it should be possible to trace a sample throughout all processes in the laboratory, and later to be able to see who collected the sample, who ran the test, and what the quality control results were for the test run, including issuing of the report. This is important in the event there are questions or problems about any reported laboratory result. All records should be signed, dated and reviewed to ensure that this traceability throughout the laboratory has been maintained.

Using an electronic system

Electronic systems have essentially the same requirements as paper systems. However, the methods for meeting these requirements will be different when using computers. The following are factors to consider:

- Permanence—backup systems are essential in case the main system fails. Additionally, regular maintenance of the computer system will help to reduce system failures and loss of data.
- Security—it can be more difficult to assure confidentiality with a computer system, as many people may have access to the data. However, computer access codes can be established to protect the data.
- Traceability—electronic record systems should be designed in a way that allows for tracing the specimen throughout the entire process in the laboratory. Six months after performing an examination, it should be possible to look at the records and determine who collected the specimen and who ran the test.

Record retention

Retention times for records should be determined in each laboratory, based on a number of factors:

- the length of time the laboratory will need to have access to its records;
- government requirements or standards that dictate record retention times;
- whether the laboratory is engaged in ongoing research requiring many years of data;
- the time interval between the laboratory's assessments or audits.

16-8: Summary

Summary

Documents include written policies, processes and procedures, and provide a framework for the quality system. They need to be updated and maintained.

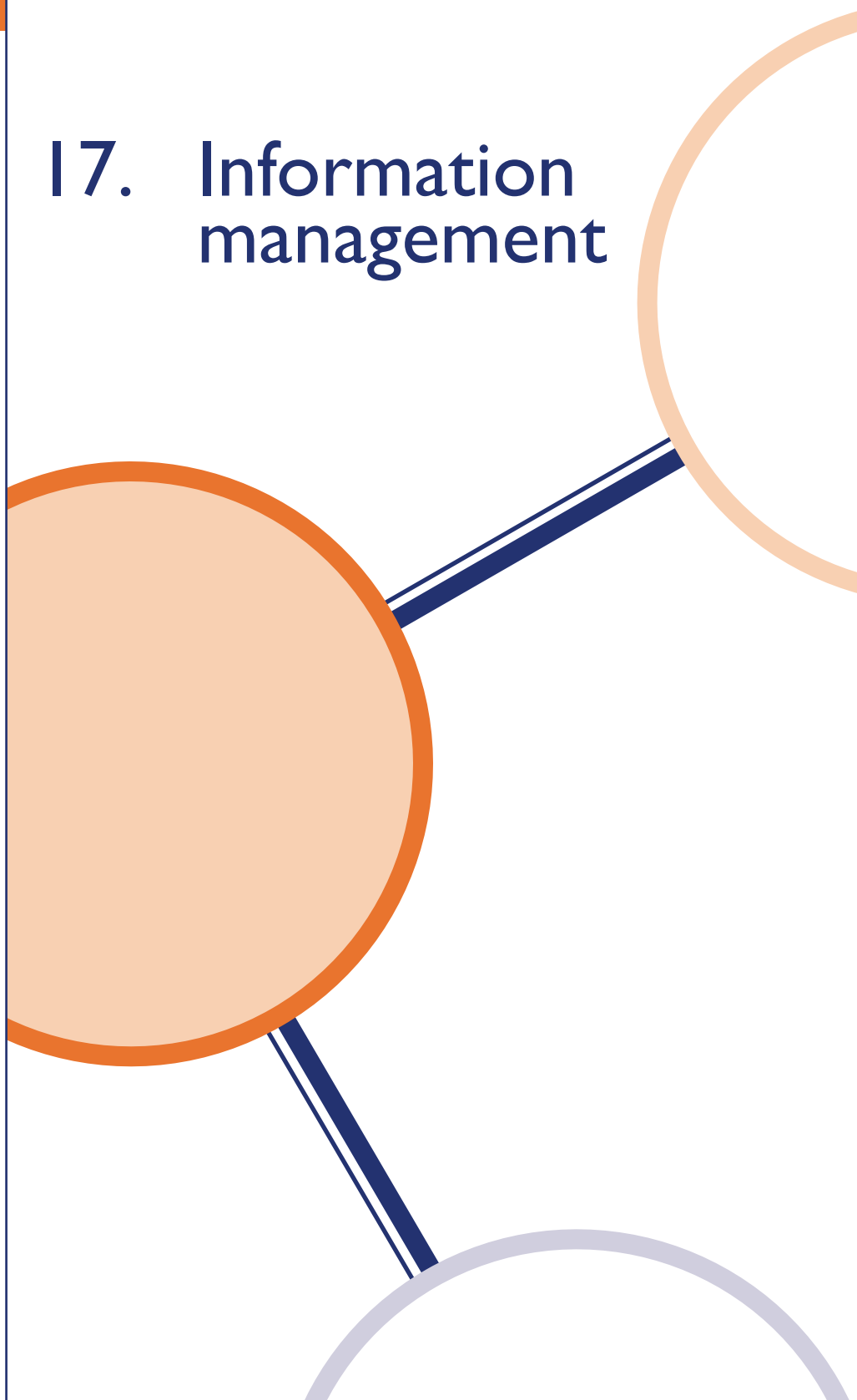
Records include information captured in the process of performing and reporting a laboratory test. This information is permanent and does not require updating.

Having a good document control programme ensures that the most current version of a document is used, and ensures availability and ease of access when a document is needed.

Key messages

- Information is our product.
- Documents are essential for assuring accuracy and consistency in the laboratory.

17. Information management



17-1: Overview

Role in quality management system

Information management is a system that incorporates all the processes needed for effectively managing data—both incoming and outgoing patient information. The information management system may be entirely paper-based, computer-based, or a combination of both. Whatever technology is employed, information management is another of the essentials of a quality system, and is closely related to documents and records (Chapter 16).

Remember that data, and in particular test results, are the final product of the laboratory. Laboratory directors need to ensure that the laboratory has an effective information management system in place in order to achieve accessibility, accuracy, timeliness, security, confidentiality and privacy of patient information.

Important elements

When planning and developing an information management system, whether it is a manual, paper-based system, or an electronic system, there are some important elements to consider:

- unique identifiers for patients and samples
- standardized test request forms (requisitions)
- logs and worksheets
- checking processes to assure accuracy of data recording and transmission
- protection against loss of data
- protection of patient confidentiality and privacy
- effective reporting systems
- effective and timely communication.

17-2: Elements of information management

Unique identifiers

A unique identifier is an important tool for managing information, and careful thought should be given to how best to assign identifiers to patients and samples within the information management system.

Patient identifiers—Sometimes hospitalized patients are assigned a unique identifier upon admission, to be used for the duration of the hospital stay. A patient may get a new number each time they are seen or admitted. In other settings, the unique identifier may be assigned to the patient on a more permanent basis, to be used each time the patient has any health care.

Sample identifiers—Laboratories need to assign unique identifiers to patient samples so they can be tracked throughout the laboratory. The method for generating and assigning unique identifiers within an information management system will depend on many factors. Some commercially available computer systems for laboratories have a numbering system built in to the software. Laboratories using paper-based systems will need to establish their own system.

An example of a simple system for generating unique identifiers is using a number consisting of the year, the month, the day and a four digit number: YYMMDDXXXX. At the beginning of each day, the last four digits will be 0001.

For example, the number 0905130047 can be read 09 05 13 0047, and it would represent sample number 47, received on 13 May 2009.

To avoid confusion or mix-up of samples, use the sample's full identifying number throughout the laboratory. At a minimum, the unique number will need to be used on all aliquots of the sample, on the request form, the laboratory register or log, and the result sheet.

Whatever system a laboratory chooses, unique identifiers should be used to eliminate confusion and mix-up of samples, and make samples and information easier to find.

Test request forms, logs and worksheets

The test request form is where the entire testing process begins, and is important for both paper and electronic systems. To optimize test requests:

- Standardize the test form—the form should indicate all information that needs to be provided when ordering and submitting a test request, and sufficient space for recording the information. ISO 15189 requirements for the request form are addressed in Chapter 16.
- Ensure the request form is completed—when the request form is incomplete, communicate with the requestor to try to secure the needed information. It may become necessary to refuse nonurgent test examination until the form is completed.

Logs that allow for recording data at the time of arrival of the sample in the laboratory are very important, as are worksheets that document which patient samples are being tested during a given procedure. In a paper-based system, this will be a written record, usually in a bound book. For an electronic system, logs and worksheets may be generated from the computer. Thought should be given as to what information should be recorded.

There are certain points in data handling where it is easy for errors to occur, such as during manual transfer of patient data from requisition forms to logs, keyboard electronic entry of data into a computerized information system, or transcription from worksheets to reports. The laboratory should put processes in place to safeguard against errors at these points. Sometimes it may be necessary to adopt formal checking processes to ensure the accuracy of data recording and transmission of handwritten or keyed information.

One example of a simple checking process is to always have two people review data transcription to verify its accuracy. Some computerized systems have electronic checks built into the system that require duplicate entry of data. If these duplicate entries do not match, an error alert is generated to the person entering the data.

Security

It is important to establish a means to protect against loss of data. For paper-based systems, this will involve using safe materials for recording and storing the records properly. For computerized systems, scheduled or regular backup processes become very important.

It is of utmost importance to safeguard a patient's privacy and, in this regard, security measures must be taken to protect the confidentiality of laboratory data. Laboratory directors are responsible for putting policies and procedures in place to ensure confidentiality of patient information is protected.

Reporting systems

The product of a laboratory is the test result or the report. Give sufficient attention to the reporting mechanism to ensure that it is timely, accurate, legible and easily understood.

The report should provide all information needed by the health care provider or the public health official using the data, and include any comments that are appropriate, such as "sample haemolysed" or "repeat sample". It should be verified and signed by the appropriate laboratory staff.

Whether issuing paper-based or computer-based test reports, laboratories must ensure reports arrive on time to the right person. Reports might be delivered by laboratory staff to the hospital ward, by courier or by mail to an off-site facility, or through electronic mechanisms using a sophisticated laboratory information management system. A telephone is often used to give urgent results. A record of the telephone call must be kept and should include the caller's signature, date and time, and whenever possible, the recipient's name. Telephone results should be followed by a written report.

The test result report reflects the laboratory's image to the client, the test requestor, and others who may use or need the report.

Communication considerations

When planning for paper-based or computer-based information systems, be sure to consider the need for a good system for communicating within and external to the laboratory. This is especially important in larger organizations. It may be necessary to devise a system for passing along information between staff covering different shifts or areas of the laboratory, to make sure important details are not overlooked. The laboratory might also need to develop a policy for communicating with its customers, such as health care providers, central reference laboratories and official agencies. The policy should describe what communication channels need to be followed and when, and state who has authority to communicate with the different levels of customers.

Common problems

There are many points where problems can occur when managing laboratory information. The laboratory should carefully consider potential problems and plan on how to avoid them. Some of the most common problems are:

- incomplete data for test interpretation, or insufficient or illegible identification—systems should be designed to minimize this occurrence; for example, when using electronic systems, it is possible to design fields so that if information is missing, data entry cannot be completed;
- forms that are inadequately designed to meet laboratory and client needs;
- standardized forms prepared by others that may not be suitable for all laboratories;
- inability to retrieve data due to poor archiving processes or insufficient backup of computerized information;
- poor data organization, which may hinder later data analysis efforts to meet research or other needs;
- incompatibility between computerized information systems and equipment or other electronic systems, resulting in problems with data transmission.

17-3: Manual, paper-based systems

Developing a manual system

Financial constraints may require that a laboratory use a manual, paper-based system for all its information management. Careful planning, attention to detail nd awareness of problems can allow for the development of a good paper-based system that will provide satisfactory service.

Registers, logs and worksheets

Manual registers, logs and worksheets are widely used, and most laboratorians are very familiar with use of manual systems for managing samples through the laboratory. Even laboratories with some computerization will often have partially or totally handwritten worksheets.

Laboratory registers or sample logs take many forms, and almost all laboratories will have one that has been in use. When reviewing information management needs, consider whether an existing register is satisfactory, or whether it should be redesigned.

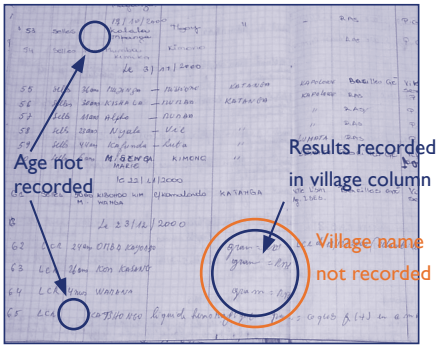
Registers and logs with good design:
- are practical to use and easy to complete
- make it easy to find the data
- make summarizing data and writing reports easier.

The logbook or register can be supplemented by the use of daily logbooks. For example, a separate logbook might be used to keep track of the numbers of patients and samples, or a logbook could be developed that is organized by the type of test. For some specialties such as microbiology or parasitology, a laboratory might decide to keep a specific logbook showing the total number of tests and the percentage of positive results.

Registers and logbooks are unique sources of information for preparing statistics and reports, although they can be more cumbersome to use and less complete than a computerized information system.

Data entry

When using a paper system, it is important to emphasize to staff that all data entry must be complete. A computerized system usually requires that all "essential fields" contain data, but in handwritten records there is no check on this point. An example of a handwritten record book with missing data is shown in the following image.



Legibility

Illegible writing may be a problem, but it must be addressed; emphasize to employees the importance of legibility.

Carefully consider the ease of use and legibility of the final report of results—it is the primary product of the laboratory, so make sure it is done properly and professionally.

Handwritten reports

When handwritten reports are issued, the laboratory needs a copy for its files or archives. Not having an exact copy of the report can lead to later problems, if errors in transcription occur.

It is imperative that the records are kept in a safe place where they can be easily retrieved.

Storing paper-based materials

When storing paper-based materials, keep in mind that the goals are to be able to find a result, trace a sample throughout its pathway in the entire process, and evaluate a problem or an occurrence to find its source.

Some useful rules to think about are:

- keep everything, but develop a system for when and how to discard (for example, after the appropriate established retention time, shred records to maintain patient confidentiality);
- ensure easy access to information by those who need it;
- use a logical system for filing;
- use numbers to help keep things in chronological order.

Paper is fragile and vulnerable to water, fire, humidity and vermin (rodents and insects). Use a storage area that will protect against these elements as much as possible.

17-4: Computerized laboratory information systems

Developing a computerized system

A computerized system for laboratory data is often called a laboratory information management system and is referred to by the acronym LIMS or LIS. The use of a computerized system is becoming more common in laboratories around the world. An appropriately designed and installed LIMS brings accuracy and accessibility to the flow of samples and data in the clinical laboratory.

There are a number of options available to those interested in developing a LIMS. Some laboratories may elect to develop an in-house computer network and use locally developed systems based on commercially available database software, such as Microsoft Access. Others may choose to purchase fully developed laboratory systems, which usually include computers, software and training.

One source of information that may be helpful for planning and implementing a LIMS is the Association for Public Health Laboratories' *Guidebook for implementation of laboratory information systems in resource poor settings*.[1]

Choosing a system

If the decisions about purchasing are made outside the laboratory (e.g. by the information system department), the laboratory director should provide information that will support selecting equipment that will best serve the needs of the laboratory. The most up-to-date hardware or software may not add to the functionality of the laboratory and can end up increasing overhead (e.g. more data handling) in order to use LIMS that have been designed not for the laboratory, but for the accounting or central supplies departments.

A LIMS with flexibility, adaptability, ease of evolution and support, and system speed will most benefit the laboratory. The speed issue is critical, as laboratorians will not use something that is slow or awkward, but if it saves time they will quickly accept the project and aggressively move the process forward.

Advantages of computerized systems

A complete computerized information system will be able to handle all the basic information management needs. A computer system has the capacity to quickly and easily manage, analyze and retrieve data. The computerized system offers some definite advantages over paper-based systems. Some of these advantages are listed below.

- Error reduction—a well-planned computer system, with check systems for errors, will help to alert the user of inconsistencies and reduce the number of errors. It will also provide information that is legible.
- Quality control management—it becomes easy to keep good quality control records, perform analysis on quality control data and generate statistics automatically.

1 Information about this guidebook is available at: http://www.aphl.org/aphlprograms/global/initiatives/Pages/lis.aspx

- Provision of options for data searching—a variety of parameters can be used for data retrieval; it is usually possible to access data by name, by laboratory or patient number, and sometimes by test result or analysis performed. This kind of data searching is almost impossible with paper-based systems.
- Access to patient information—most computer systems allow access to all recent laboratory data for a patient. This is very useful in the process of checking the most recent results against previous data to look for changes, which is a good practice and helps to detect errors. Some computer systems give enough information to determine the admitting diagnosis or access other useful information related to the illness.
- Generate reports—it is easy to generate detailed, legible reports quickly. A LIMS will provide standardized (or customized) reports.
- Ability to track reports—a computer system makes it much easier to track reports, to know when work was finished, who performed the work, when the data was reviewed and when the report was sent.
- Ability to track and analyze trends—the computer and its databases provide very strong search capabilities and, with careful design, it will be possible to retrieve and use large amounts of data effectively to track and analyze trends of various kinds.
- Improved capability for maintaining patient confidentiality—it is often easier to maintain confidentiality of laboratory data when using a computer than when dealing with a handwritten report form, if computer user codes are established to control access to the data.
- Financial management—some systems will allow for financial management; for example, patient billing.
- Integration with sites outside the laboratory—a LIMS can be set up so that data comes into the laboratory system directly from a patient or client registration point. Data can be transmitted to many sites or interfaces as needed. Results can be provided directly to computers accessible to the health care provider or public health official. Computers can handle data entry into a national laboratory database and almost any other data application that is needed.
- Manufacturer-provided training—purchased LIMS often include on-site training for staff. To make the full use of the system, it is essential that either on-site training of all staff, or training at the manufacturer's headquarters, is provided.

Disadvantages

It is important to remember that, in spite of all of the advantages, computers do have disadvantages. Some of these are as follows:

- Training—personnel training is required and, because of the complexity of LIMS, this training can be time-consuming and expensive.
- Time to adapt to a new system—when starting up a computer system, it may seem inconvenient and unwieldy to laboratory staff. Personnel accustomed to manual systems may be challenged by such tasks as correcting errors, and uncertain of how to proceed when encountering situations where a field must be filled in.

- Cost—purchase and maintenance are the most expensive parts of a computerized system, and the costs can be prohibitive in some settings. Additionally, some settings will not have good maintenance that is locally available. Surprisingly, computers use lots of paper, and the cost of materials must be planned for, as this can add up. Also remember that technology changes rapidly, and the life of a computer may not be more than a few years. This might require repurchase of computer equipment periodically in order to remain current and compatible with other systems.
- Physical restrictions—adequate space and dedicated electrical requirements are necessary, as well as placement of the computer away from heat, humidity and dust.
- Need for backup system—all computer information must be carefully backed up. Loss of data due to a damaged disk or system crash cannot be tolerated, and backup systems will be critical.

17-5: Summary

Information management system

Information management is a system that incorporates all the processes needed for effectively managing data—both incoming and outgoing patient information. The system can be entirely paper-based, or it can be partly paper-based with some computer support, or it may be entirely electronic.

For either paper-based or computer systems, unique identifiers for patient samples will be needed. Standardized test request forms, logs and worksheets are also important to both systems. In helping to prevent transcription errors, a checking process is beneficial.

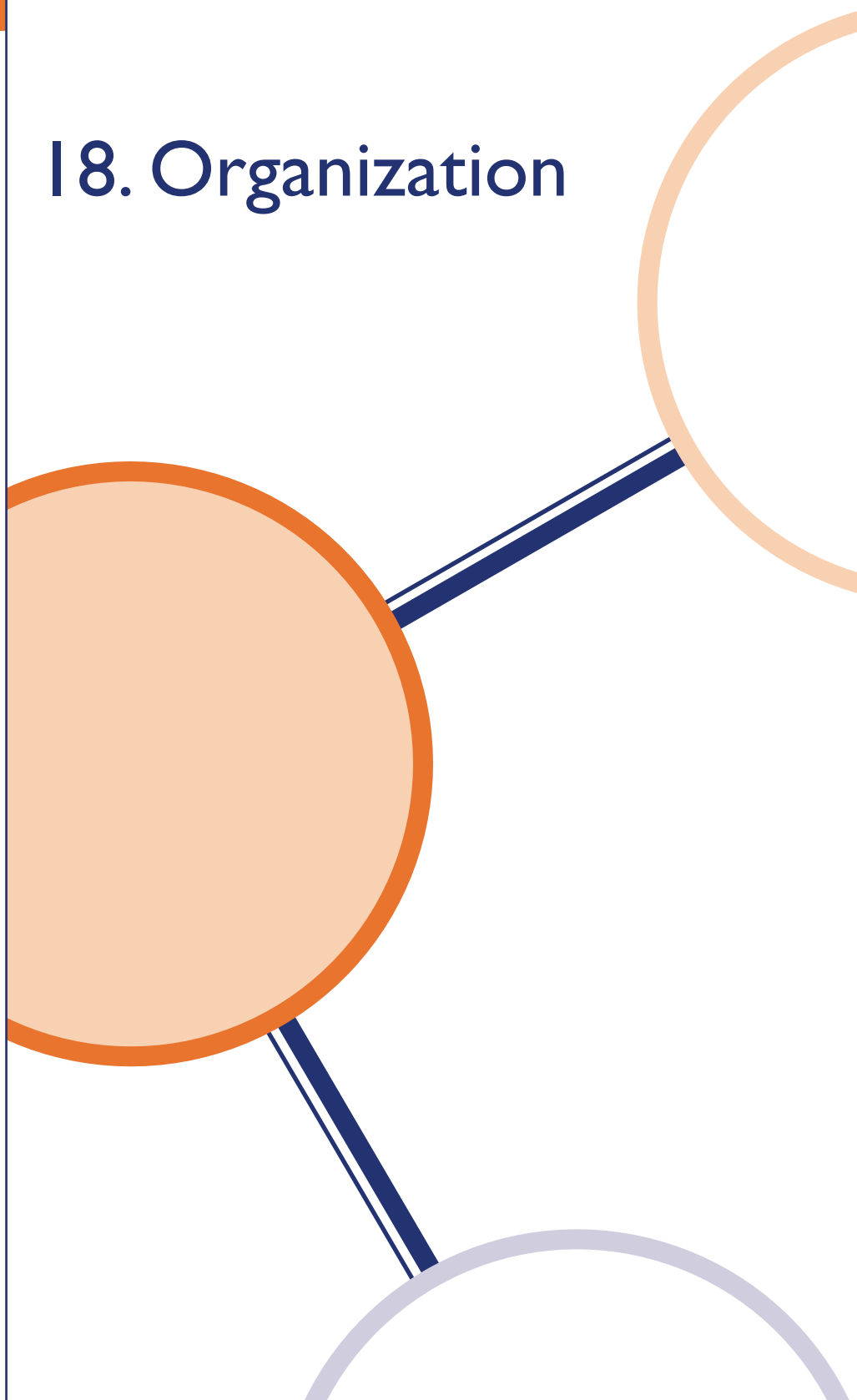
When considering adding a computer-based system to a laboratory, cost is a big factor. In implementation, careful planning and training will help to ensure good results.

Key messages

A good information management system will:

- ensure that all data—the final product of the laboratory—is well managed;
- consider all the ways laboratory data will be used when planning a system;
- ensure the accessibility, accuracy, timeliness and security of data;
- ensure confidentiality and privacy of patient information.

18. Organization



18-1: Organizational requirements for a quality management system

Definition

The term **organization** in the context of a quality management model is used to indicate the management and the supporting organizational structure of the laboratory.

Organization is one of the essential elements of the quality system, and is intimately related to all the other elements in the model.

Characteristics essential to success

The principal element for a successful quality management system is **managerial commitment**.

- Management at all levels must fully support and actively participate in the quality system activities.
- Support should be visible to staff so that there is an understanding of the importance of the effort.
- Without the engagement of management, including the decision-making level of the organization, it will not be possible to put in place the policies and the resources needed to support a laboratory quality management system.

A second vital element is that the **organizational structure** must be designed to ensure that the quality goals of the organization are met.

- The laboratory must be a legally structured entity according to local requirements.
- All the organizational elements required to ensure a properly functioning quality management system must be in place.

Key organizational components

The important organizational requirements for achieving a successful quality system include the following:

- **Leadership**—laboratory leaders must be fully committed to implementation of the system, and these leaders will also need vision, team-building and motivational skills, good communication techniques, and the ability to use resources responsibly.
- **Organizational structure**—the structure of the organization should be clearly defined, and this should be reflected by a functional organizational chart with clear assignment of responsibility.
- **Planning process**—skills for planning are needed, and planning should address a time frame, responsibility for conducting the activities, the availability and use of human resources, management of workflow and financial resources.
- **Implementation**—implementation requires that a number of issues must be addressed by the management staff. These include management of projects and activities, directing resources to accomplish plans, and ensuring that timelines are met and goals achieved.
- **Monitoring**—as components of the quality management system are put in place, processes for monitoring will be needed to ensure that the system is working, and that benchmarks and standards are being met. This element is essential to the primary goal of a quality system, which is **continuous improvement**.

18-2: Management role

Providing leadership

Leadership can be defined in many ways, but it is an important factor in the success of any organization's efforts for improvement.

A good leader will exercise responsible authority. Important roles for a leader include:

- providing vision
- giving a direction for goal-setting
- motivating staff
- providing encouragement.

A strong leader will help staff understand the importance of the task at hand.

Responsibilities of managers

ISO 15189 [4.1.5] states that "Laboratory management shall have responsibility for the design, implementation, maintenance, and improvement of the quality management system".

A quality management system outlines specific responsibilities of managers. Management must be responsible for:

- establishing the policies and processes of the quality system;
- ensuring all policies, processes, procedures, and instructions are documented;
- making sure that all personnel understand documents, instructions, and their duties and responsibilities;
- providing personnel with the appropriate authority and resources to carry out their duties.

Management is charged with providing a quality manual which describes the quality management system. The quality manual is the means by which the policies are established and communicated to the staff and the users of the laboratory.

Laboratory directors have the principal responsibility for setting up an organization that can support the quality system model. They are responsible for developing policies, assigning authority and responsibility to the appropriate persons, ensuring resources and reviewing the organizational aspects of the system for optimal functioning of quality processes. Laboratory directors must ensure that staff follow the quality policies established by the quality manual.

Quality managers assist in developing policies, planning and implementing the quality management system. They are usually responsible for many of the implementing and monitoring processes, and must communicate all aspects of the quality management system processes to the laboratory director or head of the laboratory.

Laboratory staff (laboratorians) are responsible for understanding the organizational structure of the laboratory, including where authority and responsibility are assigned. The laboratory staff will follow all of the quality policies in their daily work routine.

Commitment of management

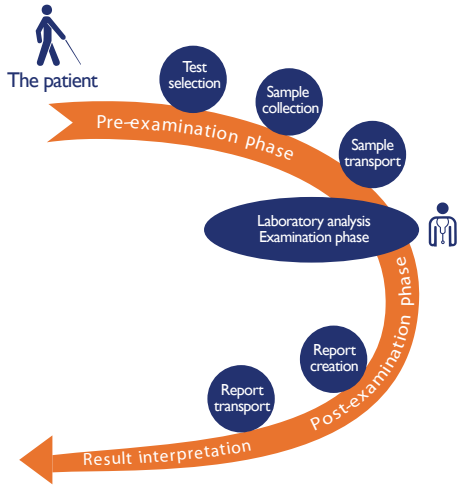
Most critical in beginning any new programme is to seek approval from the top. Management needs to be involved at a sufficiently high level to assure success of the programme. When implementing a quality system, determine what the "sufficiently high level" is; be sure to include those who make decisions as their approval and support is vital. Finally, it is important that laboratory managers communicate their commitment to the entire laboratory staff. Managers must show the way, and encourage and foster the "spirit" of the organization.

18-3: Organizational structure

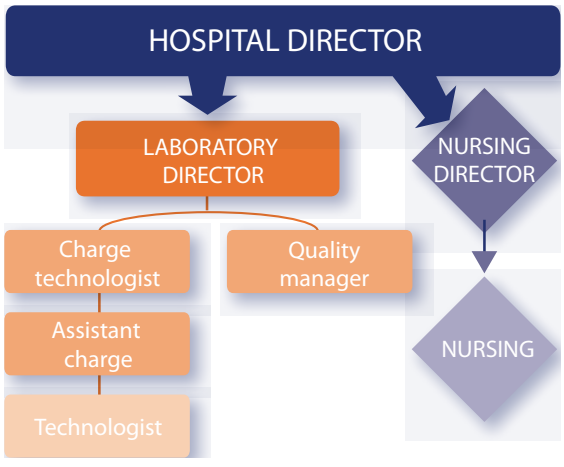
Elements of structure

When considering organizational structure to support a quality management system, a number of elements should be considered:

- The **path of workflow** is the route of a sample through the laboratory, from collection to reporting of a result. The organizational structure of the laboratory must support an optimal path of workflow, by allowing processes that yield efficient sample handling while minimizing error. Considerable attention should be given to the design of this system.



- An accurate and complete organizational chart is necessary. Many problems can be prevented if responsibilities are clearly defined and all members of the laboratory team understand what each is supposed to do.



- A quality management system must have a quality manager.
- Resource allocation must be sufficient to ensure that personnel and infrastructure needs are met.

Quality manager

ISO 15189 [4.1.5 i] states that a laboratory must have a quality manager. The quality manager is the person most directly responsible for ensuring that the quality policies and procedures are carried out.

The quality manager should sit high in the organizational structure; they must be delegated the appropriate responsibility and authority to ensure compliance to the quality system requirements. The quality manager should report directly to the decision maker(s) in the organization.

A very large laboratory may need several quality managers, perhaps one for each section. On the other hand, in a small laboratory this may be a part-time job for a senior technologist, or even a job that is carried out by the laboratory manager.

The quality manager may be assigned many tasks. Some typical responsibilities of the quality manager will include:

- monitoring all aspects of the quality system;
- ensuring staff are following quality policies and procedures;
- regularly reviewing all records; for example, quality control and external quality assessment that are part of the quality system;
- organizing internal audits and coordinating external audits;
- investigating any deficiencies identified in the audit process;
- informing management on all aspects of the quality system monitoring.

18-4: Organizational functions: planning

Approaches to planning

Once management is committed to instituting a quality system in the laboratory, a planning process is needed. Approaches used will vary, depending on many factors in the local situation.

- What quality practices are already in use in the laboratory?
- What is the level of knowledge of current staff?
- What resources will be available?

All elements of the quality system should be included in the planning process. It is not necessary (usually not possible) to implement all parts of the plan at once; a stepwise approach will often be more practical.

In many laboratories, the implementation of a quality system may involve many changes. It is therefore important to keep all staff involved, and to not proceed too rapidly, as personnel may find it difficult to meet the goals and can get discouraged. Communicate with staff frequently, clearly and positively; this will help to keep morale high.

During planning, priority areas will emerge as the bigger problems are identified. It will be important to keep objectives realistic and measurable. Inevitably, there will be some factors that are beyond the control of the laboratory. Recognize these and move on to other factors that can be addressed. If these factors are vital to the ultimate success of the quality programme, then look for ways to influence those who can control them. Always advocate for quality.

Establish a plan

In planning for implementation of a quality system, the first step is to analyze and understand the current practices. A useful way to accomplish this is the technique of **gap analysis**. To conduct a gap analysis:

- use a good quality systems checklist to evaluate the practices in the individual laboratory;
- identify gaps or areas where the laboratory is not using the good laboratory practices required in the quality system.

Using the information provided by the gap analysis, develop a task list of everything needing to be addressed, and then set priorities. In determining priorities, consider first addressing problems that can be easily fixed; this will give some early successes and boost staff morale. Also evaluate what would have the most impact on laboratory quality and give these factors high priority.

Problems commonly identified in laboratories using a gap analysis include:

- test ordering
- sample management
- incompetent technical staff
- quality control
- analytical process
- recording and reporting results
- reagent and equipment management.

The quality system plan

The implementation of a quality system in the laboratory requires a written plan. A written plan makes clear to all staff and all users of the laboratory how the process will proceed. The plan should contain the following components:

- objectives and tasks—what should be done;
- responsibilities—who will get the job done, who will be responsible;
- timeline—when will each task be worked on, when will it be completed;
- budget and resource needs—additional staff, training needs, facilities, equipment, reagents and supplies, quality control materials;
- benchmarks—essential for monitoring progress in implementation.

The written plan should be made available to all laboratory staff, as everyone must understand the plan and the process of implementation.

18-5: Organizational functions: implementation

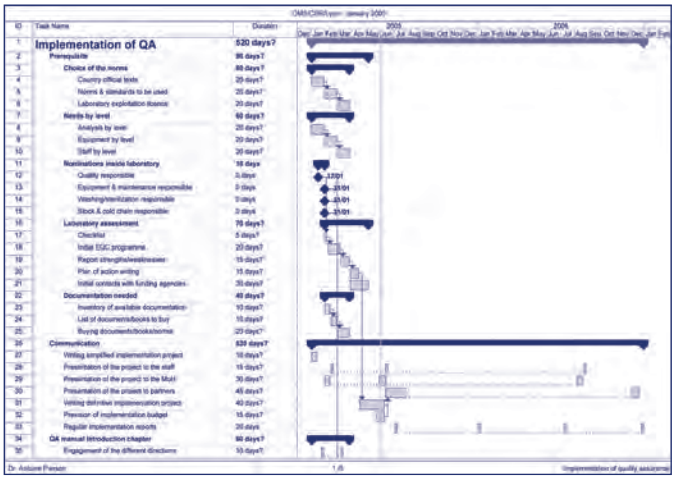
Beginning implementation

Once a plan has been written and agreed upon, implementation will begin. These suggestions will help the laboratory in this process:

- **Commit** from the beginning to complete the project and achieve the established objectives. Go in with a positive attitude.
- **Prepare to implement in stages.** It is important to prevent staff from getting discouraged, so choose manageable "bites" at the beginning. Staggering start dates will also be helpful; use established priorities to determine start dates.
- **Determine resource requirements** early in the process, and secure the necessary resources before starting tasks. If working in a highly resource-limited environment, choose as initial activities those things that can be done with available funds and staff—there are many such activities, such as improving documents, records, or developing up-to-date and improved standard operating procedures.
- **Engage all staff** by communicating effectively. If training is needed to have personnel understand the quality system and its goals, this training should probably be done before starting other tasks.

Following the timeline

As a part of the planning process, the laboratory will have established a timeline for tasks to be performed, including a projected completion date. This timeline is a critical part of the process, as it allows everyone in the laboratory to observe progress. A **Gantt chart** (shown below) is a very useful tool for visually representing the proposed timeline; it shows tasks to be done, with times of beginning and completion.



The timeline should be very carefully prepared, so as to allow appropriate times for completion. Do not let the laboratory staff become overwhelmed with the tasks that need to be accomplished.

Providing resources

During the planning process, all additional resources that are needed will have been identified. As implementation begins, be sure that these resources are in place and available. Several kinds of resources need to be considered:

- all financial requirements— establish a budget;
- personnel needs—are additional laboratory staff required, will training be needed for any of the staff?
- facilities, equipment, supplies, and computer needs.

Monitoring basics

Establishing a system for monitoring quality management is essential in implementing a quality system. It is the monitoring and maintenance part of the effort that will produce the continuous improvement that is the overall goal of a good quality system. Monitoring involves being able to check each part of the system to be sure that the system is working properly.

Establishing a monitoring programme

There are several steps in setting up a programme to monitor compliance to the quality system.

- Assign responsibility for the process. Usually the quality manager will be the person who is primarily responsible for the monitoring programme.
- Develop indicators or benchmarks using the laboratory quality policy. These indicators will be monitored over time.
- Develop a system for the monitoring process; establish time or frequency of checks, decide how the monitoring will be managed.
- Conduct an audit, followed by a management review; these constitute two important tools in monitoring compliance.

Internal audits should be conducted at regular intervals. They are valuable for evaluation, and they are required by ISO 15189.

Management reviews are a particularly valuable component of the monitoring process. It is the responsibility of management to review all appropriate quality systems information, and to look for opportunities for improvement.

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.

18-7: Summary

Steps for organization

As the laboratory moves from intent to action in the development of a quality management system, the major organizational steps will be to assign responsibility for implementation, allocate resources, develop and distribute a quality manual, begin implementation, and monitor compliance with the quality policy and the quality management system requirements.

Successful implementation of a quality management system requires planning, management commitment, understanding the benefits, engaging staff at all levels, setting realistic time frames and looking for ways to continually improve.

Key messages

Remember:

- Quality is not a science; it is a way of thinking.
- Time invested today will help gain quality results, professional and personal satisfaction, and peer recognition.
- Everyone in the laboratory is responsible for quality performance:
  - Laboratory leaders and managers must commit to meeting quality needs.
  - Laboratory personnel must follow all quality assurance procedures and adhere to requirements and standards.

Glossary

A

Accident An undesirable or unfortunate event that occurs unintentionally.

Accreditation Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Reference: ISO 15189:2007.

Accreditation (and certification) body An organization or agency with the authorized right and authority to inspect a facility and provide written evidence of its compliance (certification) and competence (accreditation) with a standard.

Accuracy The closeness of a measurement to its true value.

Analytical phase *See* Examination.

Audit Systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled. Reference: ISO 9000:2005.

B

Benchmark A point of reference or a criterion of quality. A benchmark is intended to serve the user as a guide for measuring optimum performance or to suggest solutions to problems or deficiencies. It implies the best practice.

Bias Difference between the expectation of the test results and an accepted reference value. Reference: ISO 15198:2004.

Biohazard An infectious agent, or part thereof, that presents a real or potential risk to the well-being of humans, animals or plants. It can present a hazard directly through infection or indirectly through the disruption of the environment.

Biological safety cabinet An enclosure in which entry and exhaust air is filtered through a high efficiency particulate air (HEPA) filter to remove any particles from potential aerosols; used to contain a biological hazard, protecting the operator and the environment. Depending on the class of the safety cabinet, it may or may not protect the actual biohazard itself from contamination.

Biological safety levels Also known as physical containment levels:

- **Biological safety level 1** A laboratory that works with agents not known to cause disease in healthy adults; standard microbiological practices apply; no special safety equipment required; sinks required.
- **Biological safety level 2** A laboratory that works with agents associated with human disease; standard microbiological practices apply plus limited access, biohazard signs, sharps precautions and biosafety manual required; biological safety cabinet used for aerosol/splash-generating operations; laboratory coats, gloves, face protection required; contaminated waste is autoclaved. An appropriate ventilation system should be in place.

- **Biological safety level 3** A laboratory that works with agents that may have serious or lethal consequences and with potential for aerosol transmission; biological safety level 2 practices plus controlled access; decontamination of all waste and laboratory clothing before laundering; determination of baseline serums; biological safety cabinet used for all sample manipulations; respiratory protection used as needed; physical separation from access corridors; double-door access; negative airflow into laboratory. The ventilation system must ensure removal of particulates by filtering entry and exhaust air through HEPA filters.
- **Biological safety level 4** A laboratory that works with dangerous or exotic agents of life-threatening nature or unknown risk of transmission; biological safety level 3 practices plus clothing change before entering laboratory; shower required for exit; all materials are decontaminated on exit; positive pressure personnel suit required for entry; separated or isolated building; dedicated air supply and exhaust with HEPA filters; and decontamination systems.

Biosafety The active, assertive, evidence-based process that laboratorians use to prevent microbial contamination, infection or toxic reaction as they actively manipulate live microorganisms or their products, thus protecting themselves, other laboratory staff, the public and the environment.

C

Calibrators Solutions with specified defined concentrations that are used to set or calibrate an instrument, kit or system before testing is begun. Calibrators are often provided by the manufacturer of an instrument.

Certification Procedure by which a third party gives written assurance that a product, process or service conforms to specific requirements. Reference: ISO/IEC 17000:2004.

Certification (and accreditation) body An organization or agency with the authorized right and authority to inspect a facility and provide written evidence of its compliance (certification) and competence (accreditation) with a standard.

Checklist A list used to ensure all important steps or actions in an operation have been taken. Checklists contain items important or relevant to an issue or situation.

Coefficient of variation (CV) The standard deviation (SD) expressed as a percentage of the mean.

Competence Demonstrated ability to apply knowledge and skills. Reference: 19011:2002.

Compliance An affirmative indication or judgement that the supplier of a product or service has met the requirements of the relevant specifications, contract or regulation; also the state of meeting the requirements. Meets both the text and the spirit of a requirement.

Confidentiality Pertains to the disclosure of personal information in a relationship of trust, with the expectation that it will not be divulged to others in ways that are inconsistent with the original disclosure.

Consensus General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments. Reference: ISO/IEC Guide2:2004.

Continual/continuous improvement The cornerstone of quality management systems; allows the laboratory to gain insights from setting objectives, monitoring through audit and management review, addressing complaints and nonconformities, and performing client satisfaction surveys. A recurring activity to increase the ability to fulfill requirements. Includes the steps Plan, Do, Check, Act.

Continuous quality improvement A philosophy and attitude for analyzing capabilities and processes and improving them repeatedly to achieve the objective of customer satisfaction.

Control chart A chart with upper and lower control limits on which values of some statistical measure for a series of samples or subgroups are plotted. The chart frequently shows a central line to help detect a trend of plotted values toward either control limit.

Control material Substance, material or article used to verify the performance characteristics of an in vitro diagnostic medical device. Reference: ISO 15198:2004.

Controlled documentation A system for maintaining and ensuring the proper use of time-sensitive or version-sensitive documents.

Correction Action to eliminate a detected nonconformity.

Customer Organization or person that receives a product or service from a supplier organization.

Customer satisfaction Customer's perception of the degree to which the customer's requirements have been fulfilled. It can vary from high satisfaction to low satisfaction. If customers believe that you have met their requirements, they experience high satisfaction. If they believe that you have not met their requirements, they experience low satisfaction.

D

Deming cycle for continuous improvement A visualization of the continuous quality improvement process usually consisting of four points—Plan, Do, Check, Act—linked by quarter circles. The cycle was first developed by Dr Walter A Shewhart, but was popularized in Japan in the 1950s by Dr W Edwards Deming.

Deming's 14 principles The foundation of Deming's philosophy. The points are a blend of leadership, management theory and statistical concepts that highlight the responsibilities of management while enhancing the capacities of employees.

Document Information and its supporting medium; digital or physical. The International Organization for Standardization (ISO) identifies five types of documents: specifications, quality manuals, quality plans, records and procedure documents. *See* Normative document and Standard document.

Documentation Written material defining the process to be followed.

E

Error A deviation from truth, accuracy or correctness; a mistake; a failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim.

Event An occurrence of some importance and frequently having an antecedent cause.

Examination 1. Activities and steps related to performing laboratory examinations. 2. Set of operations having the object of determining the value or characteristics of a property. In some disciplines (e.g. microbiology) an examination is the total activity of a number of tests, observations or measurements. Reference: ISO 15189:2007. 3. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing. Also referred to as an analytical phase. *See* Pre-examination and Post-examination.

External quality assessment (EQA) A system for objectively checking the laboratory's performance using an external agency or facility.

F

False negative In the case of a clinical microbiology test, a negative test result for a person who is actually infected.

False positive In the case of a clinical microbiology test, a positive test result for a person who is actually not infected.

Flowchart A graphical representation of the flow of a process. A useful way to examine how various steps in a process relate to each other, to define the boundaries of the process, to identify customer and supplier relationships in a process, to verify or form the appropriate team, to create common understanding of the process flow, to determine the current best method of performing the process, and to identify redundancy, unnecessary complexity and inefficiency in a process.

Form Forms are the blank pages or computer screens, labels, or tags on which data, information, or results are recorded. After data, information, or results are entered onto a form, screen, label, or tag, it becomes a record.

G

Gantt chart A very useful tool for visually representing the proposed time line: it shows tasks to be done, with times of beginning and completion.

Gap analysis Planning tool used to compare the present/current state with the future desired state. Basis for development of action plans to address high-priority gaps.

I

Incident An individual occurrence of brief duration or secondary importance.

Incident report A document, usually confidential, describing any accident or deviation from policies or orders involving a patient, employee, visitor, or student on the premises of a health care facility.

Indicators Established measures used to determine how well an organization is meeting its customers' needs, as well as other operational and financial performance expectations.

Infrastructure System of facilities, equipment and services needed for the operation of an organization. Reference: ISO 9000:2005.

Informative statement Information within a document that is informational only; often it is in the form of a "note". Information may be explanatory or cautionary, or provide an example.

Inspection Examination of a product, process, service, or installation or their design and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements. Reference: ISO/IEC 17020:2012.

Internal audit An audit carried out by the laboratory personnel who examine the elements of a quality management system in their laboratory in order to evaluate how well these elements comply with quality system requirements.

ISO standards A set of international standards providing guidance for quality in the manufacturing and service industries; developed by the International Organization for Standardization (ISO) to help companies effectively document the quality system elements to be implemented to maintain an efficient quality system. The standards, initially published in 1947, are not specific to any particular industry, product or service; they are broadly applicable to many kinds of organizations.

ISO 9001:2008 The most important and internationally well-recognized series of standards for quality management are referred to as the ISO 9000 series or family. It includes a series of policy statements.

ISO 15189:2007 Standard for medical laboratories; a series of policy statements.

• L

Laboratory director Person(s) with responsibility for, and authority over, a laboratory. Reference: ISO 15189:2007.

Laboratory manager Person(s) who manage the activities of a laboratory headed by a laboratory director.

Laboratorian Person who works in a laboratory and is trained to perform laboratory procedures.

Lean A system of methods that emphasize identifying and eliminating all non-value-adding activities. Tools include S5—sort, set, shine, standardize, sustain—and CANDO—clearing up, arranging, neatness, discipline, ongoing improvement. An English phrase coined to summarize Japanese manufacturing techniques (specifically, the Toyota production system).

Licensure Granting of permission by a competent authority (usually a government agency) to an organization or individual to engage in a practice or activity.

• M

Management Coordinated activities to direct and control an organization. Reference: ISO 9000:2005.

Management review Evaluation of the overall performance of an organization's quality management system and identification of improvement opportunities. These reviews are carried out by the organization's top managers and are done on a regular basis.

Material safety data sheet (MSDS) Technical bulletin providing detailed hazard and precautionary information.

Metric A measurement for standard of quality for comparing different items or time periods—you can't improve what you can't measure. Decision makers examine the outcomes of various measured processes and strategies and track the results to guide the company and provide feedback.

N

Nonconformity Non-fulfilment of a requirement. Reference: ISO 9000:2005.

Normative document A document that provides rules, guidelines or characteristics for activities or their results. It covers such documents as standards, technical specifications, codes of practice and regulations.

Normative statement Information within a document that is a required and essential part of the standard. Includes the word "shall".

O

Occurrence An event, accident or circumstance that happened without intent, volition or plan.

Occurrence management A central part of continual improvement; the process by which errors or near errors (also called near misses) are identified and handled.

Organization Group of people and facilities with an arrangement of responsibilities, authorities and relationships. Reference: ISO 9000:2005.

Organizational chart Defines the working structure for the organization; organizes jobs along lines of authority; defines reporting structure and span of control; defines authority to make decisions and accountability for results; works together with job descriptions to define the working structure of the organization.

Organizational structure The pattern of responsibilities, authorities and relationships that control how people perform their functions and govern how they interact with one another.

P

Path of workflow (clinical laboratory) Sequential processes in pre-examination, examination and post-examination clinical laboratory activities that transform a physician's order into laboratory information.

PDCA Plan, Do, Check, Act (quality improvement tool). A checklist of the four stages which you must go through to get from "problem faced" to "problem solved". See Deming cycle for continuous improvement.

Policy An overarching plan (direction) for achieving an organization's goals.

Post-examination (also post-analytical phase) Processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results, and storage of samples after the examinations. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing.

Precision Closeness of agreement between quantity values obtained by replicate measurements of a quantity, under specified conditions. *See* Quantitative examination.

Pre-examination (also pre-analytical phase) Steps, in chronological order from the clinician's request, including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the examination phase begins. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing.

Preventive action Plan steps that are taken to remove the causes of potential nonconformities or to make quality improvements. Preventive actions address potential problems, ones that have not yet occurred. In general, the preventive action process can be thought of as a risk analysis process.

Problem solving The act of defining a problem; determining the cause of the problem; identifying, prioritizing and selecting alternatives for a solution; and implementing a solution.

Process The use of resources to transform inputs into outputs. In every case, inputs are turned into outputs because some kind of work, activity, or function is carried out.

Process control Concerns monitoring all operations of the laboratory.

Process improvement Process management focused on reducing variation and improving process effectiveness and efficiency. Reference: ISO 3534-2:2006.

Product Result of a process; may be services, software, hardware or processed materials, or a combination thereof.

Proficiency testing 1. ISO Guide: 43 (EA-2/03): Proficiency testing schemes are interlaboratory comparisons that are organized regularly to assess the performance of analytical laboratories and the competence of the analytical personnel. 2. CLSI definition: "A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others". *See* External quality assessment.

Project Unique process, consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost and resources. Reference: ISO 9000:2005.

Q

Qualitative examination Measurement of the presence or absence of a

substance, or evaluation of cellular characteristics such as morphology. The results are not expressed in numerical terms, but in qualitative terms such as "positive" or "negative"; "reactive" or "nonreactive"; "normal" or "abnormal"; and "growth" or "no growth".

Quality Degree to which a set of inherent characteristics fulfils requirements. Reference: ISO 9000:2005.

Quality assurance A planned and systematic set of quality activities focused on providing confidence that quality requirements will be fulfilled.

Quality audit (also quality assessment or conformity assessment) A systematic and independent examination and evaluation to determine whether quality activities and results comply with planned arrangements, and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Quality control A set of activities or techniques whose purpose is to ensure that all quality requirements are being met. Simply put, it is examining "control" materials of known substances along with patient samples to monitor the accuracy and precision of the complete examination process.

Quality improvement Part of quality management focused on increasing the ability to fulfil quality requirements. Reference: ISO 9000:2005.

Quality indicator Established measure used to determine how well an organization meets needs and operational and performance expectations.

Quality management Coordinated activities that managers carry out in an effort to implement their quality policy. These activities include quality planning, quality control, quality assurance and quality improvement. *See* Quality system essentials.

Quality management standards (such as ISO 9001:2008 and ISO 15189:2007) A series of policy statements. Required statements include the term "shall". Full compliance with the standard requires that all "shall" statements are implemented. Were the laboratory to be inspected to ensure compliance with the standard, the auditor or inspector would expect to see evidence that each required policy was being met. "Shall" statements are often supplemented by notes or comments that often contain examples or statements using the term "should". These statements are intended to give guidance on what would be considered as reasonable activities, content or structure to demonstrate that the "shall" statement is being followed. The organization is not required to meet all the comments, suggestions or recommendations included within these notes or commentary.

Quality management system Coordinated activities to direct and control an organization with regard to quality.

Quality manual Document specifying the quality management system of an organization. Reference: ISO 9000:2005.

Quality plan Document specifying which procedures and associated resources shall be applied, by whom, and when, to a specific project, product, process or contract. Reference: ISO 9000:2005.

Quality policy Overall intentions and direction of an organization related to quality as formally expressed by top management. Reference: ISO 9000:2005.

Quality record Objective evidence which shows how well a quality requirement is being met or how well a quality process is performing. It always documents what has happened in the past.

Quality system The defined organizational structure, responsibilities, processes, procedures and resources for implementing and coordinating the quality assurance and quality control activities.

Quality system audit A documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the quality system are suitable and have been developed, documented and effectively implemented in accordance with specified requirements.

Quality system essentials The necessary infrastructure or foundational building blocks in any organization that need to be in place and functioning effectively in order to support the organization's work operations so that they proceed smoothly. *See* Quality management. CLSI developed the quality management framework and organized the topics as the "12 Quality System Essentials" based on both ISO 15189 and CLSI GP26-A3 documents.

Quality system review A formal evaluation by management of the status and adequacy of the quality system in relation to quality policy and/or new objectives resulting from changing circumstances.

Quality tools The diagrams, charts, techniques and methods that, step by step, accomplish the work of quality improvement.

Quantification A process for calculating how much is required of any particular item for a given period of time.

Quantitative examination Measures the quantity of an analyte present in the sample. The measurement produces a numeric value as an end-point, expressed in a particular unit of measurement.

• R

Record Document stating results achieved or providing evidence of activities performed. Reference: ISO 9000:2005. Information captured on worksheets, forms and charts.

Referral laboratory External laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure (Reference: ISO 15189:2007), or for testing not performed in the originating laboratory.

Regulation Any standard that is mandated by a governmental agency or authoritative body.

Requirement A need, expectation or obligation. It can be stated or implied by an organization, its customers or other interested parties. There are many types of requirements; some of these include quality requirements, customer requirements, management requirements and product requirements.

Risk The combination of severity of harm and probability of occurrence of that harm.

Risk analysis The systematic use of available information to identify hazards and estimate the risk.

Risk assessment Identifying potential failure modes, determining severity of consequences, identifying existing controls, determining probabilities of occurrence and detection, and evaluating risks to identify essential control points.

Risk management The identification, analysis and economic control of those risks which can threaten the assets or earnings of an enterprise.

Root cause A factor that caused a nonconformity and should be permanently eliminated through process improvement.

Root cause analysis A tool designed to help identify not only what and how an event occurred, but also why it happened.

S

Safety Those processes implemented to protect laboratory workers, visitors, the public and environment.

Sample (also specimen) One or more parts taken from a system and intended to provide information on the system, often to serve as a basis for decision on the system or its production. Reference: ISO 15189:2007.

Semiquantitative examination Test whose results are expressed as an estimate of how much of the measured substance is present.

SI units Modernized metric system, called SI from the French name, *le Système International d'Unités*.

Six Sigma A quality process that measures defects in parts per million; stands for six standard deviations (sigma is the Greek letter "s" used to represent standard deviation in statistics) from the mean. Six Sigma methodology provides the techniques and tools to improve the capability and reduce the defects in any process by constantly reviewing and retuning the process.

Specimen *See* Sample.

Standard document A document established by consensus and approved by a recognized body that provides, for common and repeated use, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

Statistical tools Methods and techniques used to generate, analyze, interpret and present data.

Supplier Organization or person that provides a product or service.

Survey The act of examining a process or of questioning a selected sample of individuals to obtain data about a process, product or service.

T

Task A specific, definable activity to perform an assigned piece of work, often finished within a certain time.

Team A group of individuals organized to work together to accomplish a specific objective.

Test Determination of one or more characteristics according to a procedure. Reference: ISO 9000:2005.

Traceability Ability to trace the history, application or location of that which is under consideration.

Turnaround time Length of time that a sample's final result may be issued to the ordering physician.

U

Universal precautions An approach to infection control in which all human blood and certain human body fluids are treated as if known to be infectious.

V

Validation Confirmation, through provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. Reference: ISO 15198:2004.

Verification Confirmation, through provision of objective evidence, that specified requirements have been fulfilled. Reference: ISO 15198:2004.

Verification of conformity Confirmation, by examination of evidence, that a product, process or service fulfils specified requirements.

Vision An overarching statement of the way an organization wants to be; an ideal state of being at a future point.

W

Waste Any activity that consumes resources and produces no added value to the product or service a customer receives.

Work environment All the factors that influence work; these include social, cultural, psychological, physical and environmental conditions. The term work environment includes lighting, temperature, and noise factors, as well a well as the whole range of ergonomic influences. It also includes things like supervisory practices, as well as reward and recognition programmes. All of these things influence how work is performed.

Acronyms

• A

AFB acid-fast bacilli

ANSI American National Standards Institute

ASQ American Society for Quality

• C

CDC Centers for Disease Control and Prevention (United States of America)

CEN Comité Européen de Normalisation (European Committee for Standardization)

CLIA Clinical Laboratory Improvement Amendments (United States, 1988)

CLSI Clinical and Laboratory Standards Institute (Wayne, Pennsylvania, United States of America), uses a consensus process to develop standards

CLSI GP26-A3 *Application of a quality management system model for laboratory services* (quality document)

CLSI HS1 *A quality management system model for health care* (quality document)

• D

DNA deoxyribonucleic acid

• E

ELISA enzyme-linked immunosorbent assay

EQA external quality assessment

H

HIV human immunodeficiency virus

I

IATA International Air Transport Association

IEC International Electrotechnical Commission. IEC is the world's leading organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

ISO International Organization for Standardization

L

LIMS laboratory information management system

M

MSDS material safety data sheet

N

NCCLS National Committee for Clinical Laboratory Standards (former name of Clinical and Laboratory Standards Institute)

P

PDCA Plan, Do, Check, Act (quality improvement tool)

PT proficiency testing

Q

QC quality control

S

SD standard deviation

W

WHO World Health Organization

References and resources by chapter

There are two International Organization for Standardization (ISO) standards that are specific to laboratories and the Clinical and Laboratory Standards Institute (CLSI) has two documents that are very important in the clinical laboratory. These four documents are referred to throughout each of the 18 chapters and are therefore not cited in the individual chapters listed below.

- ISO 15189:2007. *Medical laboratories—Particular requirements for quality and competence*. Geneva, International Organization for Standardization, 2007.
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• Flowchart for Classification of Infectious Agents for Transport;

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• Packaging and Labeling of Exempt Substances;

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