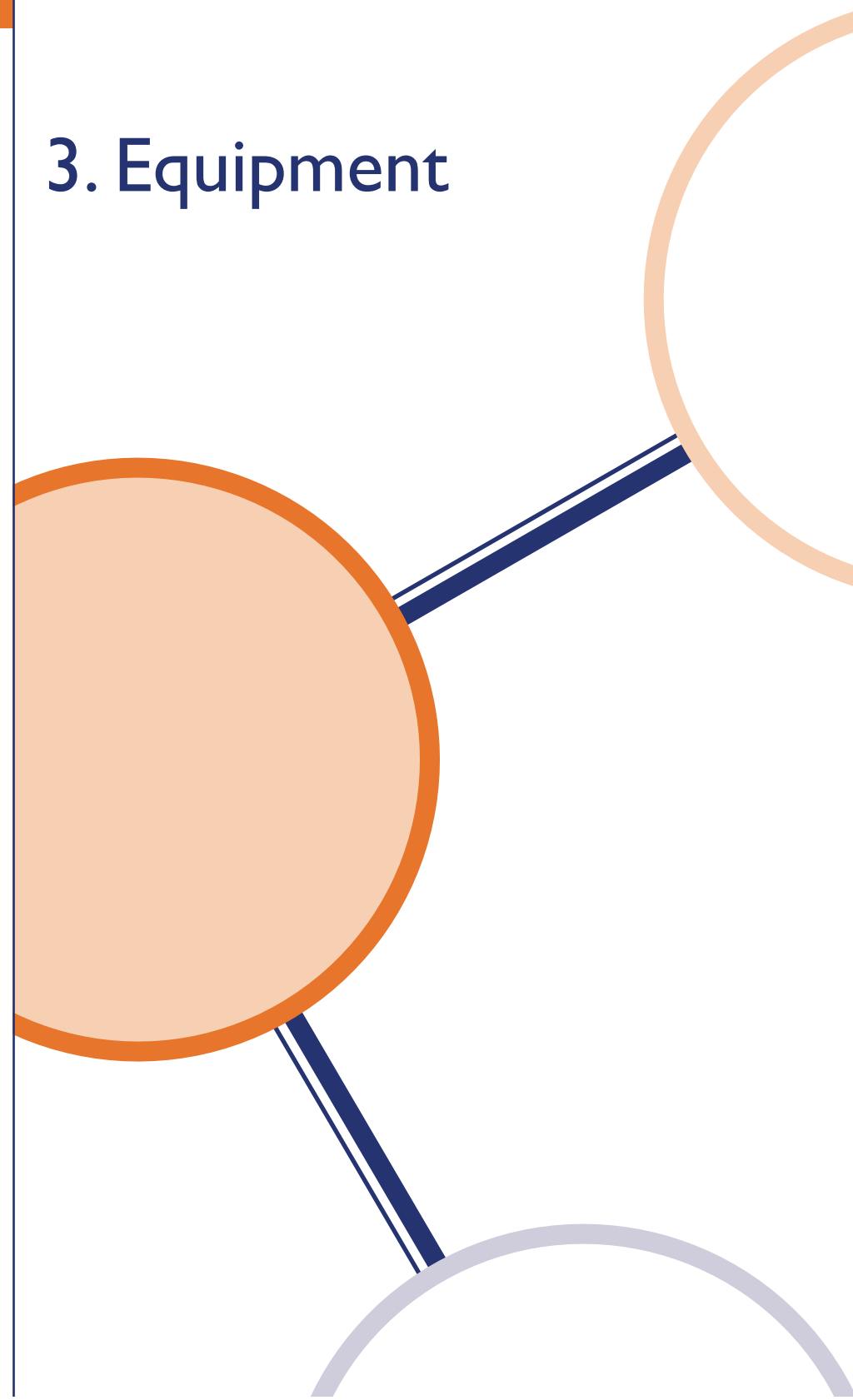
3. Equipment



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, and 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.

Programme 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.

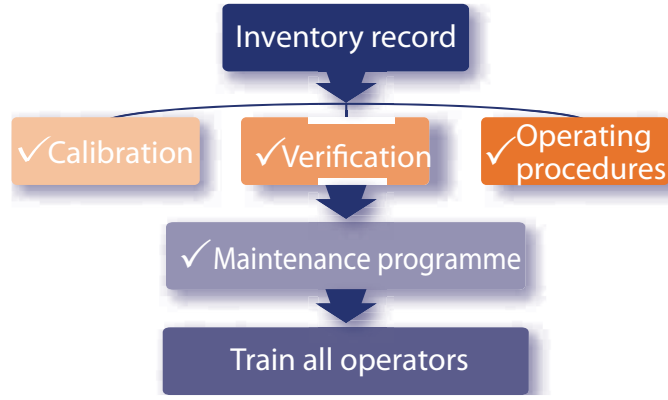
3-3: Getting equipment ready for service

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 programme, 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.

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

Retiring and disposing of equipment

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.