White Paper

Management of Equipment in an ISO/IEC 17025:2017 Accredited Laboratory
Part 2: Equipment Lifecycle Models

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1 Introduction

ISO/IEC 17025:2017 General requirements for the Competence of Testing and Calibration Laboratories[1] is an international quality assurance scheme for ensuring the quality of testing and calibration operations and competency of those that carry out those activities. The goal of the ISO/IEC 17025 International Standard is the facilitate the global recognition of testing and calibration results, by serving as a framework of requirements for individual testing and calibration laboratories to construct a quality management system appropriate to their needs.

The first paper[2] in this series discussed the classification of laboratory equipment into different categories. The categories were either based on the use of the equipment or on the equipment's complexity. These are summarised in **Table 1.**

Table 1: Equipment Classifications

Level	Quality Criticality	Measuring Equipment	Analytical Equipment	Software
1	Quality Critical	Reference Standards	Non – Measurement	Infrastructure
2	Quality Non – Critical	Non – Adjustable	Adjustable Non – Computerised	Firmware
3	Non – Critical	Adjustable Non – Computerised	Computerised	Non – Customised
4		Computerised	Networked	Customised
5		Networked	Bespoke	Bespoke
6		Bespoke		

Clause 6.4 of the ISO/IEC 17025 International Standard addresses the requirements for laboratory equipment, including measuring instruments. This Clause requires laboratory measuring instruments to be suitable for purpose and to conform to preestablished specifications from the time it enters service until the time it is decommissioned at the end of its useful life. One way of achieving this is to adopt a life cycle management model approach, with milestones at key points, corresponding to key events, on the instrument's lifecycle.

The benefits of implementing life cycle management model are:

1. Appropriate specifications for the equipment are established prior to procurement
2. Equipment is demonstrably suitable for its purpose before it is used to perform any testing or calibrations
3. The equipment is calibrated and maintained to ensure it continues to be suitable for its purpose
4. Evidence is continually created to demonstrate the equipment continues to be suitable for purpose, and any performance deterioration is quickly detected and corrected.
5. The performance of the equipment is periodically reviewed to detect any long-term trends in performance, and to ensure the equipment always conforms to current requirements
6. The performance at the end of the equipment's life is confirmed to meet established requirements.
7. All equipment is managed in a consistent manner
8. The model is designed to ensure equipment is demonstrably suitable for purpose throughout its entire life

Implementing such a lifecycle into a laboratory's quality management system requires that the model must be clearly defined and will require appropriate procedures to be established to provide instructions on how to perform the associated management tasks in a consistent manner. This paper will discuss the structure of a suitable lifecycle, together with the content of the content of the procedures required to manage it.

2 Equipment Life Cycle

The equipment life cycle shown in **Figure 1** is designed to ensure laboratory equipment is both suitable for its purpose and continues to provide valid results throughout its entire lifetime.

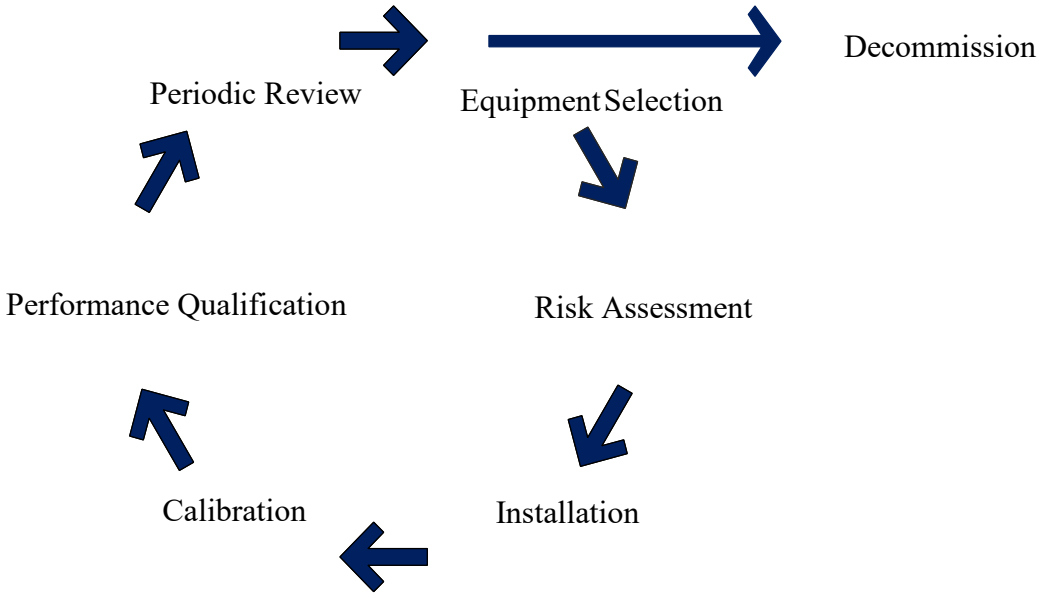

Figure: 1 Equipment Qualification Life Cycle

The management lifecycle consists of the following key points:

1. The cycle starts with equipment selection which entails identifying the user, functional and operational requirements for the equipment, and an assessment of the supplier.
2. Following selection of the equipment an assessment of the risks associated with a failure of the equipment's key functions. The information obtained from this risk assessment will be used identify activities required to mitigate those risks.
3. Installation qualification entails ensuring the equipment was delivered as ordered, the location where the equipment will be used is suitable and the key functions of the equipment work.
4. Calibration entails referencing the signal from the equipment to recognised metrological standards
5. Performance qualification consists of the daily and periodic checks undertaken to provide evidence the equipment is performing correctly.
6. Periodic review entails reviewing the records that are created during the use of the equipment to detect any trends or deterioration in performance. If the periodic review, or if at any time, a need to upgrade the instrument is identified, the process of selection, risk assessment. Installation, and calibration will start again.
7. Decommissioning entails ensuring the equipment is still within calibration since its previous calibration, all the records are accounted for and the equipment is cleaned and decontaminated.

3 Defining and Documenting the Equipment Management Lifecycle Model

The lifecycle model can be defined by describing each key point. This would usually be presented in the laboratory's quality manual. The details of each key event should be explained in the respective procedure. It is recommended the following procedures are implemented.

1. Selection and Installation of Laboratory Equipment
2. Calibration and Preventative Maintenance
3. Periodic Review of Laboratory Equipment
4. Decommissioning of Laboratory Equipment

It may be possible to combine all these individual procedures into a single procedure, however, this will usually result in an exceedingly long procedure. As users will seldom need to use all these processes at the same time, the author does not advocate this approach.

4 Selection and Installation of Laboratory Equipment

As selection and installation of laboratory equipment usually occur together these two key events can be conveniently combined into a single procedure.

4.1 Selection and Installation Planning

A project to select and install more complicated laboratory instruments should usually start with a project plan. The purpose of the project plan to

1. Decide on the strategy for qualification
2. Identify the activities that will be carried to qualify the instrument
3. Assign roles and responsibilities
4. Determine a timeline for the activities
5. Determine the resources required to deliver the project
6. Identify what records need to be created to evidence the instrument conforms to appropriate specifications
7. Define how to handle deviations from the plan in the event of unforeseen events
8. Develop contingency plans in the event the instrument does not deliver as expected

The benefits of creating a project plan are:

1. Everyone involved in the project understands what is expected
2. Management can approve and buy into the plan
3. Management knows what resources are required and can assign those resources as required
4. Management knows how long it will take to deliver the projects, and can plan laboratory operations accordingly
5. Management can see that there is a contingency plan available
6. The accreditation body or regulatory authorities can readily see adequate planning and thought has be invested into the selection, installation and demonstrating the instrument meets appropriate specifications and is suitable for purpose

A project plan may not be required for some categories of equipment. For example, analytical equipment assigned to category 1 and measuring equipment assigned to categories 1 and 2 would probably not require a detailed project plan. However, as the complexity of the

equipment increases a project plan becomes more important and is expected by the regulatory authorities and accreditation bodies.

4.1.1 Documenting the Plan

The records created during the planning phase will be used to communicate requirements to management and all those concerned. In addition, the records created will serve as a record of the management approval. It is suggested the records should be in the form of a single document containing the following information:

4.1.1.1 Introduction

This should contain a description of what is to be qualified and the purpose of the document,

4.1.1.2 Scope

This should define the scope of the plan, what is included and what is not included together with justification.

4.1.1.3 Users

Identify the individuals that will be using the instrument and list the names of the users together with any access privileges.

4.1.1.4 Regulations, Policies, Standards and Procedures

Compile a complete list of regulations, policies, standards, and procedures which the instrument must conform to. This will serve as a reference point during the selection and installation of the equipment.

4.1.1.5 Strategy

Discuss the overall strategy that will be followed during selection and installation, including reference to any laboratory policies and SOPs and industry practices. For example

4.1.1.6 Roles and Responsibilities

Define the responsibilities users, owner, vendor, other departments (IT, Validation, Quality Assurance etc)

4.1.1.7 Equipment Categories

Document the assigned categories with appropriate justification.

4.1.1.8 Deliverables

This should include the

1. Records that need to be created.
2. procedures that may be impacted by the new instrument and need to be reviewed and amended if required.
3. Procedures requiring creation, review, or amendment

This also needs to include responsibilities for preparing, reviewing, and approving these documents.

4.1.1.9 Timeline

A timetable of events should be established, this can be presented either in tabular form or using a Gant Chart.

4.1.1.10 System Security
Discuss the steps to be taken to ensure the security of the system.

4.1.1.11 Contingency Plan
The contingency plan is what are you going to do if the equipment fails to meet the specifications. With a new instrument from a major supplier this happens extremely rarely. Such an event should be carefully investigated with the aim of identifying the root cause and determining an appropriate course of action.

4.1.1.12 Deviation Handling
The handling of deviations should be described in laboratory policies and procedures. It has been the author's practice to provide detailed instructions in the documents associated with the installation, calibration, review and decommission of the equipment (since that is when the deviations will occur). In the planning document the author has limited this section to defining what a deviation is for the purposes of the project, commenting that instructions for handling deviations will be provided in the respective document and making a reference to the respective to that document

4.1.1.13 Glossary
A list of terms used together with definitions should be included.

4.2 Equipment Selection
The selection of a laboratory instrument is a key phase in the lifecycle management of laboratory equipment. Clause 6.4.4 requires that equipment conforms to specified requirements. Without those requirements being clearly defined it is not possible to determine if the equipment is suitable for purpose. Errors in the selection process can result in an instrument that is deficient in some functionality which can present enormous technical, compliance and business issues. It is therefore critical to invest sufficient resources into the selection process and create at set of requirements that truly meet the laboratory's needs.

The purpose of the selection phase is to:
1. Define the user, functional, and operational requirements of the instrument and to ensure the instrument selected is of the correct type and will have the appropriate functionality
2. Document the decision process for the selection of the instrument and supplier
3. Ensure the selected supplier can meet company qualification and support criteria

Instrument selection is best developed by a multi-disciplinary team comprising of several laboratory personnel and expertise, as applicable, from information technology, engineering, validation, and quality assurance. Outside consultants can also be involved, if needed to ensure that all required specifications are included. The outputs from the selection phase are:
1. User requirement specification (URS) – The purpose of the URS is to define what the user wants to do with the equipment. This should be written by typical users, and should include:
    i. A description of the intended use of the results of the tests carried out using the equipment or a description of the potential use of instruments calibrated by the equipment. This information can come from the laboratory's scope of accreditation and other sources.
    ii. A description of the use of the equipment – What types of samples, testing, or calibrations will be carried out with the equipment?

iii. A description of the operational environment – This should include a discussion of the regulatory or accreditation environment, as well of the use environment. This should include any attributes required to conform with regulatory or accreditation requirements, as well as the use environment.
iv. A list of what the user requires – This should include such things as the software that should be installed on the computer, computer security requirements particularly if the equipment will be networked.

2. Functional requirement specification (FRS) defines the functionality the equipment must have to be able to perform its assigned tasks, defined in the URS, and to comply with regulatory, accreditation, and laboratory requirements. The FRS will be created from the URS and the knowledge and experience of users. In addition, all the major manufactures publish detailed equipment function documents and performance specifications, which can be used as a guide. The author, however, does not advocate simply stating that the manufactures specifications shall be used as the official FRS. The functional requirements specification must consider the laboratory's specific requirements. Simply using the manufactures specification will not achieve this and may lead to much unnecessary work during the installation phase.

3. Operational requirements define what the equipment must be able to do, and the limits it must be able achieve, to fulfil its intended purpose. These will often define the accuracy and/or uncertainty that may be achieved by the equipment and may be set by industry guidelines or national and international standards. These requirements will be used when installing, calibrating, and maintaining the equipment to determine that the equipment is suitable for purpose. When consider such operational requirements it is necessary to
   i. Consider the requirements of the user of the results will need to meet their requirements.
   ii. Set the limits sufficiently broad so the equipment can routinely conform to them when being calibrated. However, limits set too stringently can result regular calibration failures
   iii. Not set the limit so broad as to be meaningless

4. Vendor Approval (VA) The selection and approval of the vendor will be controlled by the laboratory's control of external providers procedures, however, when procuring new laboratory equipment documented evidence needs to establish that the:

1. Instrument was designed, developed, and manufactured under a documented quality management system
2. Instrument was tested to a documented protocol that is traceable to design and requirement specifications
3. Vendor can help with instrument installation, qualification, trouble shooting, maintenance and repair in a timely manner
4. Vendor can provide satisfactory after sales service
5. Vendor operates a customer feedback system
6. Vendor operates a change control system
7. Vendor will permit an audit if one is required

The extent of vendor qualification will vary depending on several factors, such as

1. The level of compliance risk associated with the instrument
2. The level of knowledge and experience the vendor has with the sector(s) the laboratory operates in

3. The vendor's quality management system
4. The laboratory's experience with the vendor

Depending on the situation VA can range from obtaining documented evidence of an established quality management system, to carrying out a full on-site audit. In practice the extent of VA will lay somewhere between these two extremes. A major instrument supplier with significant experience in the sector(s) the laboratory operates in, will unlikely require a full on-site audit unless performance issues are encountered.

The procedure discussing the selection of laboratory equipment needs to specify the format the URS, FRS Operational, and vendor requirements should be presented in. The level of detail need for a specific instrument will depend on its use and complexity. The equipment classifications discussed in the previous paper[2] in this series can be used to establish requirements for different categories.

4.3 Equipment Installation

The equipment installation phase entails the following activities:

1. Confirming the delivered items conform with those ordered on the purchase order.
2. Confirming all documentation, operator manuals, certificates, software licences and authentication or activation codes are present, documented and achieved.
3. Confirming the selected environment meets the manufactures specifications.
4. Confirming all the individual components and accessories are correctly assembled.
5. Confirming all required software is correctly installed and configured.
6. The instrument is registered in the laboratory equipment database and laboratory asset numbers are assigned, if applicable.
7. Establishing the systems required to ensure the equipment is constantly operating in accordance with the requirements established in the User, functional and operational specifications.

Prior to the arrival of the instrument on site it is important to consider the environment where the instrument will be installed. This includes ensuring there is sufficient space to site the instrument, including sufficient room to allow personnel to work around it, and all the required utilities are available and able to support the new equipment. This includes ensuring there are enough power sockets and the electric circuits have sufficient capacity to meet the new equipment's requirements. Consideration may also need to be given to the availability of network sockets. The procedure for installing new equipment should explain how these checks should be recorded.

When the equipment arrives on site the hardware, software, spare parts, consumables, accessories and documentation will need checking to conform that the correct items have been delivered, delivery is complete and undamaged, and all documentation, including operating and service manuals, licences, and certificates are present. A list all hardware, including description, manufacturer, part number, serial number, and firmware version needs to be made to identify and record the equipment.

Prior to installing the new equipment make sure it has been electrically tested and conforms to all safety requirements. Once the new equipment and computer software has been installed, the entire equipment needs to be checked for correct installation, this needs to include all anti-virus, firewall and application software. The level of testing will depend on the use and complexity of the equipment. The equipment classifications discussed in the

previous paper[2] in this series can be used to establish requirements for different categories. The procedure for installing new equipment should provide instruction for determining the extent of testing for a specific instrument. This procedure also needs to provide instructions on how the installation shall be recorded. The level of detail that should be recorded will depend on the use and complexity of the equipment, and the equipment classifications discussed in the previous paper[2], in this series, can be used to establish requirements for different categories.

The systems that will ensure the equipment is constantly conforming to specifications also need to be established during the installation of new equipment. This needs to include:

1. Issuing a logbook – A logbook is a means of recording the equipment's calibrations, maintenance, repair, and change of consumable parts. This can be in any appropriate format, including: a physical book, a folder on a computer network or a database
2. Scheduling of calibration and maintenance – This needs to include entering the new equipment into the calibration plan and establishing contracts.
3. Training – If training is required this need to be arranged and scheduled
4. Procedures – Any new procedures that need to be created, approved, and distributed
5. Change Control – This is the process of evaluating the potential impact of changes made to equipment and ensuring the necessary controls are implemented to maintain the equipment in a calibrated state.

The procedure addressing the selection and installation of equipment will also need to provide instructions on how to document instructions for performing an equipment installation and how to record the installation. The following outline is for a combined set of installation instructions and records

1. **Purpose:** Record the purpose of the document
2. **Scope:** Define what is covered and what is not covered by the document.
3. **Responsibilities:** Define who is responsible for doing what
4. **Identification of Personnel Involved:** Table the following information:
    i. Name
    ii. Job Title
    iii. Affiliation
    iv. Role
    v. Signatures and initials.
5. **Documentation of the Site of Installation Record the following information:**

Location

    i. Room No. / Bench No.
    ii. Required Bench/Floor Area
    iii. Available Bench/Floor Area

    Electricity supply

    i. Record the required number of power sockets and total current requirement
    ii. Record available circuit numbers, number of available sockets, circuit rating, current load, and available current

    Network Sockets

    i. Record the required number of network sockets
    ii. Record the reference numbers of the available sockets and socket(s) record

6. **Reconciliation of Deliveries**
    i. Record and check the part number(s) of each item match the part number on the Purchase Order and on supplier's Delivery Note

ii. Record and check the serial number(s) on each item agree with the serial number on supplier's Delivery Note
iii. Inspect each item for damage and record condition
iv. Inspect any tilt indicators, confirm they are all present and intact, and do not show the package has been tilted

7. **Reconciliation of software, documentation, cables, manuals, spare parts, and consumables.** Compile a list of all items together with respective part numbers and document presence and are undamaged.
8. **Documentation of the Equipment** Record the following information:
   i. Manufacturer
   ii. Actual part number
   iii. Serial number
   iv. Firmware version
   v. Laboratory asset number of the hardware components
9. **Documentation of computer hardware**
   i. Record the following information relating to the computer and monitor:
      a. manufacturer
      b. model
      c. serial number
      d. laboratory instrument No.
   ii. Record the following information
      a. Actual processor type and speed
      b. RAM type and size
      c. Graphics adaptor type
      d. Hard disk size and partitions
      e. LAN Interface model identity
      f. Pointing device
      g. Optical drive type

   Determine that the components conform to specification established in the design qualification
10. **Installation, configuration, and documentation of software** This section is used to record the configuration of the software. This can include:
    i. User accounts
    ii. Electronic signatures (format)
    iii. Passwords (password expiry and complexity requirements)
11. **A list of all installed software** Record the following information about each software package included: -
    i. Description
    ii. Software name
    iii. Version No.
    iv. Location
    v. Licence No.
    vi. Activation code
12. **Clock Configuration** Provide instructions on how to configure the computer clock and record the following information.
    i. Time Zone
    ii. Daylight saving (Yes/No)
    iii. Time server address
13. **Installation Testing** Provide instructions on how to test the equipment has been correctly installed. Including testing of:

i. Key equipment functions
ii. Logon/Logoff
iii. Security features
iv. Audit trail features

14. **Equipment Logbook**
    Confirm an equipment Logbook has been Issued and record logbook number and date of issue.
15. **QMS Procedures**
    Record QMS Procedures numbers and Titles
16. **Routine Preventative Maintenance (PM) and Calibration**
    Record Calibration and Preventative Maintenance (PM) has been scheduled and any contracts have been established.
17. **Training**
    Record all training necessary to use the new equipment
18. **Change Control (CC)**
    Describe change control procedures

Appendices, containing:

1. Manufacturer's hardware installation instructions
2. Manufacturer's software installation, configuration, and verification instructions
3. Finance authorisation
4. Purchase order
5. Supplier's delivery note, or waybill
6. Laboratory instrument number request form(s)
7. Copies of installation engineer's training certificates
8. Copies of calibration certificates
9. Conformance certificates (e.g. CE marking)
10. Supporting documentation created during installation

5 Risk Assessment

Clause 8.5 of the ISO/IEC 17025:2017 International Standard requires laboratories to consider the risks associated with its operations. This includes those presented by laboratory equipment. Assessing the risks associated with laboratory equipment also allows for development of mitigation of those risks to be implemented during installation, calibration, and daily use (performance qualification) of the equipment. The procedures for assessing the risks associated with laboratory equipment should be the same as those associated with all aspects of the laboratory's activities.

Although not required by the ISO/IEC 17025:2017 International Standard, use of one of the risk assessment tools provides for such assessment to be made in a consistent manner. As the assessment tools allow for considerable customisation to meet the requirements of the user, a procedure should be implemented to provide instructions on how to carryout an assessment. Some assessment tools require the level of risk to be assigned to a category (such as high, medium, and low) or assigned a numerical value depending upon the severity of the consequences associated with the respective risk. To help users to consistently assign categories, or numerical values, in a consistent manner, laboratories should establish criteria for assigning categories, or numerical values. The procedure should also explain the records to be retained

6 Calibration and Preventative Maintenance

Clause 6.4.7 of the ISO/IEC 17025:2017 International Standard requires laboratories to establish a calibration program. Laboratory equipment needs to be calibrated at a frequency that is sufficient to maintain confidence in the calibrated status of the equipment. The frequency of calibration should be consummate with the risk associated with the equipment. This will usually be dependent on the use of the equipment and its frequency of use. The previous paper[2] in this series discussed the concept of quality criticality, advocating applying the following levels to laboratory equipment

1. Quality Critical is all equipment used to make measurements, that were either directly, or incorporated into results that were, reported to customers.
2. Quality Non – Critical is all equipment that although not used to make measurements which are either reported, or incorporated in to results that are reported, to the customer, but is used to assure the quality of such measurements or results.
3. Non – Critical is all equipment not used to make measurements or produce results that are reported to the customer, nor used to assure the quality of the results that are reported to the customer.

This classification is useful when making decisions regarding the interval between calibrations. As equipment assigned to the quality critical category is used to make measurements, that are either directly, or incorporated into results that are, reported to customers, it will usually present a greater risk than equipment assigned to the quality non – critical category. Equipment assigned to the quality critical category should be calibrated more frequently than equipment assigned to the quality non – critical category. As equipment assigned to the non – critical is not used to make measurements or produce results that are reported to the customer, nor used to assure the quality of the results that are reported to the customer, it need not be calibrated.

The frequency of use is the other key criterion used to determine frequency of calibration. Equipment with moving parts, used daily to make measurements that are either directly, or incorporated into results, that are reported to customers should usually be calibrated at intervals not exceeding twelve months. However, the actual frequency should be determined from an assessment of how long it could reasonably be expected to remain within the established specification. In addition, to periodic calibration, equipment needs to be calibrated as follows:

1. Following initial installation of equipment
2. Prior to, if possible, and after repair of the equipment
3. Prior to and after relocation of static equipment
4. If there is reason to doubt the validity of the calibration

The parameters that will be calibrated, together with their respective specifications should be established as operational requirements during the selection phase. The parameters to be calibrated should be discussed in the equipment procedure required by Clause 6.4.3.

Preventative maintenance (PM) should, at least, be carried out in accordance with the manufacturer's recommendations. If preventative maintenance may affect the calibration status of equipment, the calibration needs to be performed both before, to provide evidence that the instrument was operating within specifications prior to the PM being carried out, and after preventative maintenance has been carried out.

7 Performance Qualification

Performance qualification (PQ) can be considered as documented evidence that provides a high level of confidence the equipment is consistently performing to prescribed criteria. Performance qualification consists of periodic, often daily, checks on equipment that creates evidence the instrument conforms to predetermined criteria. Examples of these checks include checking:

1. The balance readout when a specific weight is loaded
2. The output intensity and stability a UV spectrophotometer lamp
3. Conductivity and total organic carbon content of purified water

The periodic checks need to be discussed in the procedure required by Clause 6.4.3. This also needs to provide instructions on how to perform these checks and the results of these checks. The valuable results of performing periodic checks are that they provide prewarning of a possible instrument failure and provide evidence of acceptable previous performance should the instrument be damaged or fail a calibration. Thus, reducing the need to perform retests or recalibrations in the event of instrument damage or calibration failure.

8 Periodic Review

The purpose of carryout periodic reviews is to:

1. Create evidence that provides a high degree of assurance that the equipment continues to function in accordance with appropriate, predetermined, criteria.
2. Ensure the instrument conforms to current requirements and expectations, which may have changed since the installation of the equipment
3. Detect any trends in performance.
4. Detect any deterioration in performance.
5. Implement any necessary remedial action

Periodic reviews need to also consider new requirements, expectations, and guidelines that are currently being developed and need to consider and trends in nonconformities reported by the accreditation bodies and, where appropriate regulatory authorities. For example, the warning letters, on relevant topics, issued by the United States Food and Drug Administration and published on the FDA.gov website. As these can be expected to be incorporated into new accreditation body expectations.

The laboratory will need to identify what records should be included in the review. This will usually include, as appropriate:

1. Maintenance, qualification, and calibration records
2. Malfunction and repair records
3. Records for routine replacement of parts, such as lamps and pump pistons
4. Deviation reports
5. Training records
6. Change control and configuration management
7. Backup and archive records

The laboratory will also need to determine how to record each review which will be in some kind of report. The following is a suggested content:

1. Identification of the equipment being reviewed
2. Responsibilities: Define who is responsible for doing what
3. Identification of personnel involved

4. Detailed instructions on how to perform the review
5. Review findings
6. Conclusions and recommendations
7. Instructions on how to handle non-conformances and deviations

9 Decommissioning

When it is time to remove the equipment from service careful consideration needs to be given to the decommissioning process, several issues need to be addressed. The most important of these, from the compliance perspective, is the need to demonstrate that the instrument was still calibrated and suitable for purpose from the time of its last calibration up to the time it was last used. Other aspects that need to be addressed are:

1. Ensuring that all instrument records are accounted for and archived
2. Ensuring that all service contracts are cancelled
3. Ensuring that the instrument scheduling is cancelled in the validation master plan
4. The instrument is thoroughly cleaned, and any contamination removed

The qualification status of the equipment can be confirmed by performing a final as is calibration on the instrument; if the equipment passes this it can be concluded that the instrument was still performing to its established specification up to the time of that final calibration. In the event the instrument fails, or it is not possible to calibrate the equipment due to no repairable damage, the event needs to be treated as a nonconformity and an investigation initiated to determine the impact on any measurements that were made using that instrument.

The procedure for decommissioning equipment needs to provide instructions for recording the decommissioning activities which will be in some kind of report. The following is a suggested content:

1. Purpose Define the purpose of the report:
2. Responsibilities: Define who is responsible for doing what
3. Copy of calibration protocol or calibration instructions
4. Summary of test results, together with acceptance criteria and a statement of out come
5. Conformation that all records associated with the equipment have been accounted for and archived.
6. Conformation that all service contracts have been cancelled
7. Conformation that the equipment scheduling is cancelled in the validation master plan.
8. Confirmation that the equipment has been thoroughly cleaned and all contamination removed.
9. Instructions on how to handle non-conformances and deviation

10 References

1. ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories. International Organisation for Standardisation, Geneva, 2017
2. D. Trew, Management of Equipment in an ISO/IEC 17025:2017, Accredited Laboratory Part 1. Classifications of Laboratory Equipment.