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| **Training/competency requirements** |
| Acknowledgment required by all manufacturing and quality staff |

# Purpose

This procedure outlines the process of procurement, qualification, commissioning and ongoing maintenance of equipment.

# Scope

This procedure applies to all staff involved in validation, qualification, use and maintenance of equipment. This procedure ensures documented ongoing operational fitness of equipment and its reliable performance in the facility.

# Definitions

|  |  |
| --- | --- |
| Installation Qualification (IQ) | The process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification usually defined by the manufacturer.. |
| Operational Qualification (OQ) | The process of obtaining and documenting evidence that installed equipment operates in accordance with its operational procedures. |
| Performance Qualification (PQ) | The process of obtaining and documenting evidence that installed operational equipment performs effectively within limits set by approved manufacturing processes. |
| SE | Service Engineer |
| SR | Service Report (may also be referred to as repair report) |
| PM | Production Manager |
| QM | Quality Manager |

# Responsibilities

|  |  |
| --- | --- |
| Quality Manager | Evaluate critical service suppliers. Review and approve equipment qualification, validation protocol. Equipment failure impact assessment as part of OI |
| Production Manager | Manage equipment procurement. Review and approve equipment qualification, validation protocol and report, equipment repair, modification or relocation and SR. Set up service contracts with service providers. Ensure that maintenance and calibration is carried out as planned. |
| All staff | Perform equipment management procedure as per instructions contained herein. Report of any equipment breakdowns or deviations to PM and QUALITY MANAGER. |

# Documents

## *Insert list of referenced documents here*

# Equipment and Materials

Not applicable.

# Equipment Management Procedures

All equipment is purchased or acquired according to the purchasing/procurement policy.

Equipment qualification including IQ, OQ and PQ is performed on each new piece of equipment. In addition, all equipment requires requalification following repair, modification, or following relocation for non-portable equipment.

All equipment used in the manufacturing process is subject to an initial validation following predefined and approved validation protocols. The validation protocol ensures that equipment is suitable for use in the intended way in a given process. Validation must be performed for each new piece of equipment acquired by the facility. Validation may not be required when acquiring an additional piece of equipment of the same model and from the same supplier/manufacturer, however, however full qualification and commissioning is required. Refer to Validation SOP for details.

Equipment is formally commissioned as fit for use following review by the Production Manager and the Quality Manager of the validation and/or qualification documentation.

## Equipment Register

Details of all equipment are recorded on the equipment register and include but are not limited to:

* equipment type / description
* asset and serial number
* manufacturer, supplier and model
* date commissioned
* categorise portable, movable or stationery equipment
* service contact details
* regular maintenance frequency
* preventative maintenance frequency
* next scheduled service due date
* operational status

Details are obtained from visual inspection of equipment, the manual or in consultation with manufacturer or supplier.

## Equipment Qualification

For each item of equipment, qualification must be performed according to approved protocols, and the results recorded in qualification documentation. Qualification protocols should be prepared for each equipment type with the protocol being reused for each item of that type and model that is installed. IQ and OQ demonstrate that the equipment is installed and operates as intended by the manufacturer. For some items of equipment IQ/OQ is the only qualification required.

PQ demonstrates that the equipment is functioning correctly within the process by testing the output from the process.

### Installation Qualification IQ

IQ is performed to check if the equipment is installed correctly and according to manufacturer’s specifications. IQ also ensures that all required supporting services are available and connected correctly. Specific IQ requirements may vary from one piece of equipment to another and may be specified by the manufacturer. In general to perform IQ, check that the equipment:

* is received in good condition and is not damaged
* is received with all ordered parts and components, including operating manuals, if applicable
* is located appropriately (eg. levelled, on supported bench, close to power, data port or other required utility)
* complies with facility requirements (eg does not pose OH&S issues)
* has an asset number assigned and attached if applicable
* is installed with and according to the equipment user’s manual (if applicable).
* has been electrically tested and tagged (if applicable)
* has been connected to the appropriate utilities (eg water or carbon dioxide gas)

Any additional, equipment specific, IQ requirements should be defined in consultation with the manufacturer or supplier.

### Operational Qualification OQ

OQ is performed to check if the equipment consistently operates as specified by the manufacturer within established limits and to demonstrate conformity with the functional requirements. Equipment checks and tests must cover the full intended operating range and include the upper and lower operating limits (if applicable). OQ also includes testing the effectiveness of any safety devices (if present) in relation to OH&S. OQ requirements may vary from one piece of equipment to the other and may be specified by the manufacturer. In general to perform OQ, check that the equipment:

* meets the equipment specification
* starts-up and shuts down
* correctly operates throughout all operating ranges including timers, gauges, alarms or other settings
* control systems operate as intended
* complies with relevant regulations
* does not pose an OH&S risk
* performs any additional, equipment specific requirements (in consultation with the manufacturer)
* OQ allows preparation and finalisation of operating, calibration and maintenance SOPs for the equipment.
* OQ also determines if operator training is required before use of the equipment.

### Performance Qualification PQ

PQ is generally only required where the functioning of the equipment impacts on the performance of the manufacturing process or has a potential impact on product quality. The necessity of a PQ step must be determined for each type of equipment and the rationale recorded in the initial validation report. PQ usually follows OQ and it is used to verify acceptable equipment performance in intended processes over the full range of expected operating conditions. PQ requirements vary between different equipment but also vary between different processes. Each time a change in the process is introduced or a new process is developed, PQ must be developed following validation to ensure continuing correct performance of the equipment.

For new equipment type or model and new or changed processes, the PQ is part of the process validation. The validation protocol for the new or changed process includes criteria that need to be met for the equipment used in the process. These criteria defined in the validation process may be defined as PQ criteria to be used in formal initial and subsequent equipment qualification.

## Equipment Commissioning

This flowchart outlines the equipment commissioning process.



### New Equipment Qualification and Commissioning

This procedure relates to new equipment acquired for the first time

1. Add equipment details to the equipment register
2. Complete the “Do not Operate” tag and attach to the equipment
3. Ensure IQ and OQ is performed in line with manufacturer’s recommendations
4. Review the IQ/OQ report in consultation with the PM
5. Ensure the checks and tests in the report meet the acceptance criteria
6. Ensure report certifies that the equipment is signed and dated and fit for use
7. Prepare a validation protocol.
8. Send it for review to Production Manager and Quality Manager to obtain approval
9. Complete the validation process and ensure validation acceptance criteria are met (refer to the validation procedure for details)
10. Prepare a qualification form including using the Equipment Qualification Template and define IQ, OQ and PQ specifications.
11. Prepare validation report
12. Forward validation report to PM and QM for review to obtain approval
13. Prepare equipment SOP, equipment qualification form (IQ/OQ/PQ), cleaning and maintenance form(s) if required in accordance with the validation report.
14. Obtain external document number(s) for the technical manual and any additional associated documents.
15. Prepare cleaning and maintenance schedule and maintenance contracts following warranty expiration date.
16. Complete the IQ, OQ and PQ on the qualification form as per validation guidelines and obtain commissioning approval from PM and QM.
17. File all documentation in the relevant equipment folder
18. Update Equipment Maintenance Log.
19. Remove “Do not Operate” tag, equipment is commissioned for use

### Additional Equipment Qualification and Commissioning

This section relates to each additional piece of equipment of the same type and model that has been previously installed and validated.

1. Add equipment details to the equipment register
2. Tag equipment with “Do not Operate” tag
3. Ensure IQ/OQ/PQ is performed
4. Evaluate IQ/OQ/PQ results against acceptance criteria
5. Complete the qualification form and obtain commissioning approval from PM and QM.
6. File all documentation in the relevant equipment folder
7. Update Equipment Maintenance Log.
8. Remove “Do not Operate” tag, equipment is commissioned for use

### Equipment Qualification and Commissioning Following Repair, Modification or Relocation

If equipment stops operating as intended, is modified or relocated (for non portable item):

1. Complete the “Do not Operate” tag and attach to the equipment
2. Update Equipment Maintenance Log
3. Complete first section of Repair, Relocation or Modification form and inform the PM
4. Following repair, modification or relocation decide whether PQ and re-commissioning is required in consultation with PM and QM. Document rationale on the Repair, Relocation or Modification form. (Essentially, if the repair activity included any parameters that may directly affect the quality of the product re-commissioning is required.)
5. Ensure IQ/OQ/PQ is performed if applicable
6. Evaluate IQ/OQ/PQ results against acceptance criteria
7. Complete the qualification form and obtain and obtain commissioning approval from PM and QM
8. File all documentation in the equipment folder
9. Update Equipment Maintenance Log.
10. Remove “Do not Operate” tag, equipment is commissioned for use

## Calibration & Maintenance

Calibration and maintenance must be performed at regular intervals to ensure equipment performs as expected. Equipment specific calibration and maintenance requirements are established in consultation with the manufacturer and are outlined in the initial validation report. These requirements usually follow manufacturer’s recommendations but may include additional or modified specifications as per validation report. Most equipment usually has preventive maintenance established by the manufacturer or authorised service provider. The following rules apply to all equipment with preventive maintenance schedules:

* Preventive maintenance reports must include all adjustments and replacements details and all checks and tests performed.
* Any testing or reference equipment used by service engineer must have current certification of accuracy such as NATA. The report must be reviewed and approved by the PM or delegate.
* The report must have a statement that the equipment is fit for use signed by the service engineer and by PM or delegate.
* If equipment does not meet the checks acceptance criteria equipment is immediately removed from service and repair organised.

## Repair

When equipment is faulty:

1. Attach a completed “Do Not Use” tag on the equipment briefly describing the fault, sign and date.
2. Quarantine any product which may have been affected by the equipment failure and notify the QM.
3. Raise an OI and notify the QM as product quality and safety or the accuracy of test results may have been compromised
4. Complete first section of Repair, Relocation or Modification form and inform the PM.
5. Organise repair with the PM or delegate
6. Following repair record details of repair and details about the condition of the equipment after repair on Repair, Relocation or Modification form or attach a SR.
7. The equipment must be deemed fit for use and the form and/or report must be signed by the SE.
8. Review details of repair on the form, attached service report if applicable and decide if re-commissioning is required in consultation with PM. Any decision and rationale is recorded on Repair, Modification or Relocation form.

## Cleaning

Cleaning instructions are included in the relevant equipment specific SOP which describes the use & maintenance of that equipment. It includes cleaning frequency, specific cleaning agent requirements if applicable, and cleaning methods. If there is no requirement for equipment specific cleaning, then at a minimum, weekly surface cleaning is performed and recorded on Weekly Cleaning Record.

## De-commissioning of equipment

At the end of the useful life of an item of equipment it must be demonstrated that the equipment was operating correctly before being disposed of in accordance with Equipment: Medical Equipment Management policy. Record the disposal date and fate of the equipment in the equipment register.

# Change Log

|  |  |  |
| --- | --- | --- |
| Version No: | Change: Summarise changes from the previous version of document. | Effective Date |
|  |  |  |

# End of Document