
QSE 3 – Equipment

Key Concepts

This QSE describes the selection, use, maintenance, and monitoring of equipment, including information systems. It also describes the use and testing of alternative systems when primary systems fail.

Key Terms

Backup: Digital data and/or physical storage containing copies of relevant data.

Calibrate: To set or align measurement equipment against a known standard.

Corrective Action: Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.

Critical Equipment/Materials: A piece of equipment or material that can affect the quality of the organization's products.

Data Integrity: The accuracy, completeness, and consistency of information resources.

Equipment: A durable item, instrument, or device used in a process or procedure.

Installation Qualification: Verification that the correct equipment is received and that it is installed according to specifications and the manufacturer's recommendations in an environment suitable for its operation and use.

Operational Qualification: Verification that equipment will function according to the operational specifications provided by the manufacturer.

Performance Qualification: Verification that equipment performs consistently as expected for its intended use in the organization's environment, using the organization's procedures and supplies.

Validation: Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.

Verification: Confirmation by examination and provision of objective evidence that specified requirements have been met.

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Processes for equipment selection, qualification, and maintenance.
- List or tool used for critical equipment identification.
- Equipment calibration and maintenance records, if applicable.
- Equipment qualification records.

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- Manufacturer's written instructions.
 - Records of investigation of equipment malfunction, failure, repair, and requalification, if applicable.
 - Alarm system testing and records of alarm management, if appropriate.
 - Evidence of information system backup and records of testing.
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3.0 Equipment

The organization shall define and control critical equipment.

3.1 Equipment Specifications

Equipment specifications shall be defined before purchase.

3.2 Qualification of Equipment

All critical equipment shall be qualified for its intended use. Equipment shall be requalified, as needed, after repairs and upgrades.

3.2.1 Installation Qualification

Equipment shall be installed per manufacturer specifications.

3.2.2 Operational Qualification

Each piece of equipment and component of an information system shall be verified before actual use.

3.2.3 Performance Qualification

Equipment shall perform as expected for its intended use.

3.3 Use of Equipment

Equipment shall be used in accordance with the manufacturer's written instructions.

3.4 Unique Identification of Equipment

Equipment shall have unique identification.

3.5 Equipment Monitoring and Maintenance

Equipment shall be monitored and maintained in accordance with the manufacturer's written instructions.

3.5.1 Calibration and Accuracy of Equipment

Calibrations and/or adjustments shall be performed using equipment and materials that have adequate accuracy and precision. At a minimum, calibrations and/or adjustments shall be confirmed as described below unless otherwise indicated by the manufacturer:

- 1) Before use.

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- 2) After activities that may affect the calibration.
 - 3) At prescribed intervals.

3.5.1.1 Calibration of equipment shall include details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and specified limitations.

3.5.1.2 Equipment used for calibration, inspection, measuring, and testing shall be certified to meet nationally recognized measurement standards. Certification shall occur before initial use, after repair, and at prescribed intervals. Where no such measurement standards exist, the basis for calibration shall be described and recorded.

3.5.1.3 Equipment shall be safeguarded from adjustments that would invalidate the calibration setting.

 **3.5.2** When equipment is found to be out of calibration or specification, the validity of previous inspection and test results and the conformance of potential affected products or services (including those that have already been released or delivered) shall be verified.

 **3.5.3** The organization shall:

- 1) Define cleaning and sanitization methods and intervals for equipment.
- 2) Ensure that environmental conditions are suitable for the operations, calibrations, inspections, measurements, and tests carried out.
- 3) Remove equipment from service that is malfunctioning/out of service and communicate to appropriate personnel.
- 4) Monitor equipment to ensure that defined parameters are maintained.
- 5) Ensure that the handling, maintenance, and storage of equipment are such that the equipment remains fit for use.
- 6) Ensure that all equipment maintenance and repairs are performed by qualified individuals and in accordance with the manufacturer's recommendations.

3.5.4 Investigation and Follow-up

Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include:

- 1) Assessment of products or services provided since the equipment was last known to be functioning per the manufacturer's written instructions or organization-defined specifications.
- 2) Assessment of the effect on the safety of individuals affected.
- 3) Removal of equipment from service, if indicated.
- 4) Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected, as applicable.