

# Auditing a Calibration, Preventative Maintenance & Housekeeping System

## Goals

**When you have completed this unit, you should be able to:**

- Perform an audit of a calibration, preventive maintenance, and housekeeping system
- Use a range of tools and information, including the contents of this unit and the internet to support the audit of a calibration, preventive maintenance and housekeeping system
- Understand and apply appropriate GMP standards/regulations to an audit of a calibration, preventive maintenance and housekeeping system
- Recognize compliance or non-compliance of calibration, preventive maintenance and housekeeping systems to applicable regulations

## Definitions

**Adjustment:** The adjustment of an instrument to improve accuracy so it shows the correct value. It is recommended to calibrate before and after adjustment. See also calibration.

**As found:** The condition or status of equipment, instrumentation or systems prior to calibration or maintenance activities.

**As left:** The condition or status of equipment, instrumentation or systems following calibration or maintenance activities.

**Calibration:** The ICH definition is: "The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standard over an appropriate range of measurements." A shorter definition is: "Calibration shows the error an instrument has when compared to a known standard.". See also adjustment.

**Critical item:** Items which have been assessed to impact on product quality, safety and efficacy or otherwise present an unacceptable hazard if the equipment or its protective system should fail and where failure or malfunction could lead to danger to life, significant harm to any person or to the environment.

**Housekeeping:** Those activities designed to keep a facility in a clean, sanitary and well-maintained condition.

**Inventory:** the list of equipment for a facility, organized in a convenient hierarchy, with equipment identified at the level at which the maintenance history will be documented and maintained.

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other means. If an external contractor is performing calibration work for the site, the contractor must work with the Site Engineering and Maintenance group. Site personnel should also review and approve the calibration documentation and/or records generated by the contractor in order to ensure that jobs have been completed per established procedures and that equipment is within established tolerances.

If possible, calibration should be performed in a calibration laboratory, free of conditions that may impact calibration such as:

- Ø Vibration
- Ø Variable line –voltage
- Ø Dust
- Ø Fumes
- Ø Extreme temperature ranges or other environmental extremes that could impact equipment functionality

All calibration work must be recorded. Calibration records normally contain the following information:

Equipment/Instrument Name and ID #
PMS Number _____
Date calibration performed: _____
Date of next calibration: _____
As-found readings: _____
As- left readings _____
Description of work performed: _____ _____
Test equipment (incl. certificates as appropriate) and standard used: _____ _____
Procedure used: _____
Additional documentation required to interpret the results _____
signed by _____ (Person performing work)
Approval of records to assess any SHE or product implications following any adjustments.

Calibration records should be kept in a secure document filing and archive system. Calibration data should be reviewed for trends. All work performed on equipment or instruments should be documented and use traceable standards. Computer systems for scheduling, tracking, and reporting of calibration and preventive maintenance jobs should be developed and implemented to defined quality standards with appropriate qualification performed.

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disinfected and/or sterilized where appropriate, before processing recommences if the required standards of cleanliness and/or asepsis have not been maintained during the work

### **Use of contractors for calibration and maintenance**

Site procedures should define the approach to management of calibration and maintenance performed by external contractors and calibration service suppliers, including requirements for contracts/service level agreements/shared SOPs. The roles and responsibilities of the contract acceptor and contract giver need to be defined in an appropriate written agreement. Delineation of responsibilities should be agreed.

SOPs should describe the provision of calibration and maintenance records or certificates by external contractors. This should include a review of work performed to verify that it has been completed to an acceptable standard, and approval by the site indicating that the appropriate acceptance criteria have been met.

### **Housekeeping of a facility**

Housekeeping within a facility is designed to provide a clean, sanitary and well-maintained environment. Specific activities of housekeeping include sanitization and cleaning, removal of waste and general maintenance of the facility.

Rest and refreshment premises should be separate from other areas. Facilities for changing clothes, and for washing and toilet purposes should be easily accessible and appropriate to the number of users. Toilets should not directly communicate with production areas.

### **Sanitization and cleaning**

The facility should be kept in a state of cleanliness commensurate with the activities and functions performed. To ensure this, there should be approved written procedures that include cleaning schedules, methods, equipment, sanitizing and cleaning agents, cleaning requirements, and materials. Cleaning and sanitization should be documented. Those personnel performing the cleaning should be trained and competent in the procedures appropriate to their function. If external contractors are used to perform cleaning, they should be trained to the same level and competency as internal personnel. Training must be documented.

The site should have a documented program for prevention of infestation from rodents, birds, insects and other vermin. This program should designate what rodenticide, insecticide fungicide and fumicide can be used at specific locations within the facility to ensure that equipment, components and drug products are not contaminated. The personnel administering the program, either internal or external, should be thoroughly trained. If an external contractor is used, they should be supervised by a member of the site.