

Auditing a Calibration, Preventative Maintenance & Housekeeping System

Title: Auditing a Calibration, Preventative Maintenance & Housekeeping System					
Auditor Manual: 09					
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Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

Audit Training Manual: 09

**Auditing a Calibration, Preventative
Maintenance & Housekeeping System**

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Maintenance: The combination of all technical, administrative and managerial actions during the lifecycle of an item intended to retain it in or restore it to a state in which it can reliably perform a required function. Maintenance can be planned or unplanned.

Normal Operating Range: The normal operating limits of the instrument, equipment or system as required for operation within a process.

Preventive Maintenance System (PMS): This system brings together people, equipment and procedures (including scheduled maintenance plans) to ensure that an asset is available for operation in accordance with its functional specification.

Process Tolerance: The limits within which a process parameter should be maintained to ensure adequate product quality.

Standards: measurement systems or artifacts, traceable to National or International Reference Standards, which are used to calibrate test equipment.

Test Equipment: Measurement systems used to calibrate critical instrumentation.

Traceability (General): The ability to trace the history, application or location of that which is under consideration (ISO 9000:2000).

Traceability (with respect to calibration): The ability to relate individual measurement results through a continuous sequence of measurement accuracy verifications, to nationally (or internationally) accepted measurement systems.

Explanation of Topic

Introduction

Calibration of critical items, preventive maintenance and housekeeping, while not appearing to be the most important parts of GMP, are vital to keep a site in compliance and producing quality product.

If an audit is being performed on calibration, preventive maintenance or housekeeping, the two GMP systems that should be reviewed during the audit are:

- Ø Quality System
- Ø Facilities and Equipment System

The site audited should have SOP(s) in place describing the overall calibration and maintenance program including:

- Ø How critical items requiring calibration and maintenance are identified (a risk/GMP assessment should be in place for defining what is critical and not)

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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.
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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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- Ø A statement of the trace ability to national or international standards
- Ø The date, signature, and identification of the laboratory performing the calibration
- Ø The as-found status reported by the laboratory performing the calibration
- Ø The as left status of the instrument and whether this meets the acceptance criteria
- Ø Reference to the procedures used
- Ø Signature of the person who performed the calibration
- Ø Test equipment certificates as appropriate

Raw data supporting calibration jobs should be retained in accordance with the site retention period schedule.

Preventive Maintenance

Preventive maintenance is considered planned maintenance. This maintenance is performed on equipment, instruments or systems to:

- Ø Ensure equipment is able to operate normally within its specifications before an unplanned repair is needed
- Ø Extend the operating life of the equipment or instrument
- Ø Replace worn parts before they affect equipment or instrument performance which will affect drug quality
- Ø Provide routine or recommended maintenance such as lubrication.

All preventive maintenance should be scheduled at sufficient frequency to ensure that equipment, instrumentation and systems, are within their operating limits under normal operating conditions. Frequency may be established through consideration and review of the following criteria:

- Ø Work performed during qualification
- Ø Frequency of use
- Ø Experience and application
- Ø Process requirements
- Ø Criticality of device with respect to GMP impact
- Ø Duty and environment of instruments
- Ø Historical trend data
- Ø Required accuracy of process
- Ø Regulatory aspects
- Ø Maintenance recommendations from the manufacturer

The rationale for the frequency of the preventive maintenance must be documented. The frequency should be on the conservative side by ensuring that no product is at risk because of infrequent maintenance.

The site should have an approved preventive maintenance schedule. A written approved procedure to manage calibration and maintenance according to the schedule should be in

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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.

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- Ensure that personnel have received adequate training.
 - Ø Verify that there is a documented training and qualification program for any person responsible for conducting calibration, preventive maintenance or housekeeping.
 - Ø Verify that detailed job-specific training is conducted and documented for each employee.
 - Ø If external personnel are used to perform the calibration, preventive maintenance or housekeeping function, ensure that they have been qualified and are competent.
 - Ø Verify that the training program incorporates requirements for temporary employees and consultants.

- Ensure that there is a calibration program in place at the site.
 - Ø For calibration of equipment, instrumentation and systems, ensure that there is a written and approved program for managing calibration. This program should contain the following information:
 - An inventory of critical equipment, instruments and systems (including computer systems) requiring calibration should be available and include appropriate acceptance criteria.
 - Specific calibration requirements including limits and parameters for each piece of equipment, instrument or system.
 - The accuracy, precision and linearity of the calibration need to be relevant to the critical instrument and scale of measurements.
 - Frequency of calibration for each piece of critical equipment, instrumentation, or system.
 - Review system for issuing calibration schedule.
 - Determine timeframe within which calibration must be performed.
 - Determine what will happen if calibration does not take place as scheduled
 - Standards and testing equipment to be used in each calibration, which can be traced, back to a primary standard.
 - Methods to be used in each calibration.
 - Documentation for recording calibration results.
 - Calibration schedules.
 - Procedures detailing what to do in the case of an out of tolerance result.
 - Procedures for performing trends on calibration data.
 - A system for retention and retrieval of calibration history and data.
 - Requirements for using contractors.
 - Documentation that computer systems for calibration program management are validated

- Ensure that there is a preventive maintenance program in place at the site.
 - Ø For maintenance of equipment, instrumentation and systems, ensure that there is a written and approved program for managing maintenance.