Procedure: Equipment Maintenance

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This procedure is sufficient for a smaller company with a few machines maintained mostly by operators. Larger companies may be more complex and will require significant modification to this procedure to encompass such things as maintenance management software, spare parts stocks, periodic or preventative maintenance, product change-over, etc.

# Purpose

This procedure describes the system, provides instructions and identifies responsibilities for maintenance of key process equipment and the support systems needed to meet production requirements at [Company].

# Scope

The scope of this procedure includes key process machines, equipment and tooling.

Where relevant, include clean rooms and associated equipment, HVAC (air filtration and air conditioning), storage freezers, etc.

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Production Engineer |  |
| Quality Manager |  |

Amend roles and responsibilities as applicable for your company processes and structure.

# Procedure

## Key process equipment and systems

Production Engineering is responsible for identifying key process equipment, machines and systems to be included in a formal, planned preventive maintenance program.

Key equipment is selected on the basis of the following criteria:

Identify the specific equipment used in the company’s facility and which are to be included in a formal maintenance plan, e.g. clean rooms, production equipment, HVAC, filters, etc.

* production equipment that must be periodically cleaned, adjusted and/or serviced to maintain proper operation and ensure process conformity
* equipment which, in the event of a breakdown, could damage or degrade product in a way not obviously visible
* equipment and machines that are critical for maintaining continuing process capability
* equipment and systems necessary for maintaining critical environmental conditions in production or storage areas

## Maintenance plan and schedule

Production Engineering must prepare maintenance plans for key machines and systems. Plans define the scope and frequency of maintenance activities and inspections. Those activities include, as appropriate, adjustments, cleaning, inspection and testing, fluid analysis, replacement of fluids, lubricants, filters, seals, gaskets, drive belts, etc.

Edit for relevance to the types of maintenance activities.

Maintenance plans should be based on the equipment manufacturer's recommendations and on previous experience with the equipment. Where appropriate information is provided, equipment manuals may be used directly.

## Adjustments

CFR 820, clause 820.70(g)(3) requires instructions for adjustments of equipment. This is not a requirement of ISO 13485 or ISO 9001 and may be omitted if appropriate.

Readily available, written instructions must be provided for production equipment requiring periodic adjustments by operators. This must include any limitations or allowable tolerances.

If SPC (Statistical Process Control) is used on a process, adjustment of equipment must be recorded on any control charts.

If SPC is not used, the above clause may be deleted. However, it is good practice to maintain records of adjustments critical to process conformity. (Such records are not a requirement of the standards.)

## Equipment performance monitoring

To identify equipment problems at an early stage and prevent breakdowns, operators are instructed to monitor tool wear, process performance, vibrations, etc. and report abnormal events to the supervisor.

## Maintenance records

Inspection, maintenance and repair activities are recorded in maintenance logs. Maintenance logs should include the following:

* date and time the maintenance activity was performed
* name of the person performing the maintenance/repair

The name of the individual performing the maintenance is required in CFR 820.70(g)(1) but not in ISO 13485 or ISO 9001.

* classification of the activity (inspection, maintenance, repair, etc.)
* description of the work performed
* record of replaced parts and/or supplies used
* reports (checklists, etc.) of equipment inspection/testing after the maintenance or repair (if appropriate)

If SPC is used, all equipment maintenance, adjustments, tool changes, repairs, etc. are to be recorded on the control charts.

If SPC is not used, delete the above clause.

## Inspection of maintenance activities

This is specified in CFR 820.70(g)(2) but is not required by ISO 13485 or ISO 9001. Delete this section if it is not appropriate.

Maintenance activities and adherence to maintenance schedules may be inspected during internal audits of the quality system (refer to Procedure QP802: Internal Quality Audits). The QA Manager is responsible for planning and carrying out these audits.

To satisfy CFR 820 auditors, it may be necessary to create a separate activity for auditing maintenance activities (i.e. outside of routine internal audits).

The purpose of inspections is to ensure:

* adherence to appropriate equipment maintenance schedules
* conformity of maintenance activities with requirements and procedures
* correctness and completeness of maintenance records

Results of maintenance inspections and audits are recorded and should include the date and the name of the individual conducting the inspections.

Ensure adequate, detailed records are kept if this function is incorporated in internal audits. Keep a record of what was inspected (even if there are no formal audit findings in this area).

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP802 | Internal Quality Audits |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
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List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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