

ISO 9001 Documentation

Maintenance Plans for Tools

1. Purpose

The purpose of this document is to define the requirements for establishing, implementing, and maintaining Maintenance Plans for Tools used in the organization's operational processes, in alignment with ISO 9001:2015. This ensures that all tools — including production tools, inspection and measuring equipment (IME), jigs, fixtures, molds, dies, cutting tools, and other process-specific tools — are regularly maintained to sustain their functionality, accuracy, reliability, and compliance, thereby supporting consistent product quality, process control, and operational efficiency.

2. Scope

This procedure applies to all tools and tooling equipment that are utilized in:

- ❖ Manufacturing or assembly processes
- ❖ Inspection, testing, or measurement activities
- ❖ Product or process development
- ❖ Quality control or validation
- ❖ Any other operation that may impact product conformity or process performance

It includes but is not limited to:

- ❖ Hand tools and power tools
- ❖ Gauges, measuring instruments, and test equipment
- ❖ Jigs, fixtures, molds, dies, and templates
- ❖ Cutting tools, blades, and forming equipment
- ❖ Specialized or custom tools for specific operations
- ❖ Automated or semi-automated tooling systems

3. References

- ❖ ISO 9001:2015 – Quality management systems – Requirements
(Clauses: 7.1.3, 7.1.5, 8.5.1, 10.2)
- ❖ Organization's Quality Manual
- ❖ Control of Monitoring and Measuring Equipment Procedure
- ❖ Preventive and Predictive Maintenance Procedure
- ❖ Equipment and Tool Calibration Procedure
- ❖ Document Control Procedure
- ❖ Risk Management Procedure
- ❖ Maintenance / Facility Management Policy

4. Definitions

Term	Definition
Tool	Any device, implement, or equipment used to perform a specific operation in a process, including production, inspection, assembly, or testing.
Maintenance Plan	A documented schedule and set of activities for inspecting, servicing, cleaning, calibrating, repairing, or replacing tools to ensure their proper functioning and longevity.
Preventive Maintenance	Scheduled maintenance performed to prevent unexpected tool failure or degradation.
Predictive Maintenance	Maintenance based on the condition or performance data of the tool, often using sensors or usage monitoring.
Corrective Maintenance	Maintenance performed in response to tool failure or identified defect.
Calibration	The process of verifying and adjusting the accuracy of measuring tools or equipment.
Tooling Lifecycle	The full span from tool acquisition, installation, use, maintenance, and eventual decommissioning or replacement.

5. Responsibilities

Role	Responsibility
Tool Owners / Department Supervisors	Identify tools requiring maintenance, ensure maintenance plans are in place, and ensure adherence to scheduled activities.
Maintenance Team / Technicians	Perform scheduled and corrective maintenance tasks, document activities, and report issues.
Quality Assurance	Ensure that maintenance activities for inspection and measuring tools support measurement traceability and accuracy.
Engineering / Technical Support	Assist in developing maintenance specifications, tool care guidelines, and specialized maintenance procedures.
Management Representative	Ensures that tool maintenance supports the effectiveness of the QMS and compliance with ISO 9001 requirements.

6. Maintenance Planning Requirements (ISO 9001:2015 Clauses 7.1.3, 7.1.5, 8.5.1)

6.1 General Requirements

- ❖ The organization shall establish maintenance plans for all tools that:
- ❖ Have an impact on product quality, process performance, or measurement accuracy
- ❖ Are subject to wear, degradation, misalignment, or drift over time
- ❖ Are critical to operational safety, regulatory compliance, or customer requirements

Maintenance plans shall define:

- ❖ What tools require maintenance
- ❖ Type and frequency of maintenance (preventive, predictive, corrective)
- ❖ Specific maintenance activities (cleaning, lubrication, inspection, adjustment, calibration, replacement)
- ❖ Responsible persons or teams
- ❖ Required tools, spare parts, or materials
- ❖ Documentation and recordkeeping requirements

7. Types of Maintenance Activities

7.1 Preventive Maintenance

- ❖ Performed at scheduled intervals (daily, weekly, monthly, quarterly, annually)

- ❖ Includes cleaning, lubrication, inspection, alignment, and minor adjustments
- ❖ Helps prevent unplanned downtime and tool failure
- ❖ Based on manufacturer recommendations, historical data, or risk assessment

7.2 Predictive Maintenance

- ❖ Uses condition monitoring tools (e.g., vibration analysis, thermal imaging, usage tracking)
- ❖ Identifies early signs of wear or failure
- ❖ Optimizes maintenance timing based on actual tool condition

7.3 Corrective Maintenance

- ❖ Performed when a tool fails, malfunctions, or is found out of specification
- ❖ Includes troubleshooting, repair, or replacement of damaged components
- ❖ Root cause analysis may be required for recurring issues

7.4 Calibration (for measuring tools)

- ❖ Performed in line with the Control of Monitoring and Measuring Equipment Procedure
- ❖ Ensures that gauges, meters, and inspection tools remain accurate and traceable
- ❖ Includes adjustment, verification, and documentation of calibration results

8. Maintenance Plan Development

Maintenance plans are developed based on:

- ❖ Tool criticality (impact on quality, safety, or compliance)
- ❖ Manufacturer guidelines or technical specifications
- ❖ Usage intensity or operating conditions
- ❖ Historical failure data or maintenance logs
- ❖ Regulatory or customer requirements
- ❖ Risk assessments related to tool failure

The maintenance plan for each tool or group of tools includes:

Element	Description
Tool ID / Description	Name, type, model, serial number
Location	Where the tool is stored or used
Maintenance Type	Preventive, predictive, corrective, or calibration
Frequency	How often maintenance is to be performed (e.g., every 30 days, quarterly)
Maintenance Tasks	Detailed steps or activities (e.g., clean, inspect, calibrate, replace part)
Responsible Person / Team	Who will perform or oversee the task
Tools / Spare Parts Needed	Items required to complete the maintenance
Documentation Required	Log sheets, checklists, calibration certificates, etc.
Review / Update Frequency	How often the plan is reviewed for continued suitability

9. Implementation and Control

- ❖ Maintenance tasks are performed on schedule and documented accordingly
- ❖ Maintenance logs or checklists are maintained for each tool or group
- ❖ Out-of-service tools are tagged, quarantined, or removed from use until maintenance is completed
- ❖ Maintenance personnel are trained and competent to perform required tasks
- ❖ Critical tools may have preventive maintenance as a precondition for use

10. Documentation and Recordkeeping

The following records are maintained as part of the tool maintenance process:

- ❖ Maintenance plans (master list or schedule)
- ❖ Maintenance logs or checklists (showing completed tasks, dates, personnel)
- ❖ Calibration certificates (for measuring tools)
- ❖ Repair or replacement records
- ❖ Root cause analysis reports (for repeated failures)
- ❖ Tool status reports (active, under maintenance, out of service)

Records are:

- ❖ Retained per the Controlled Record Retention Policy
- ❖ Available for internal audits, management review, and customer inquiries
- ❖ Stored in a controlled format (paper or digital)

11. Monitoring and Review

- ❖ Maintenance plans are reviewed periodically (e.g., annually or upon process/tool change) to ensure they remain effective and relevant
- ❖ Trends in tool failures or maintenance needs are analyzed to support continuous improvement

Effectiveness is evaluated through:

- ❖ Reduction in tool-related downtime or defects
- ❖ Compliance with maintenance schedules
- ❖ Feedback from users and maintenance staff

12. Compliance with ISO 9001:2015

This procedure supports compliance with the following ISO 9001:2015 clauses:

- ❖ Clause 7.1.3 – Infrastructure (tools as part of operational infrastructure)
- ❖ Clause 7.1.5 – Monitoring and measuring resources (for calibrated tools)
- ❖ Clause 8.5.1 – Control of production and service provision (ensuring tools are maintained for consistent output)
- ❖ Clause 10.2 – Nonconformity and corrective action (addressing tool failures or maintenance lapses)

13. Conclusion

Establishing and maintaining effective Maintenance Plans for Tools is essential to ensuring the reliability, accuracy, and safety of operational processes. Proper maintenance prevents tool-related quality issues, reduces downtime, extends tool life, and supports compliance with ISO 9001:2015 and customer expectations.

A structured and proactive approach to tool maintenance contributes to operational excellence, product quality, and continual improvement, while safeguarding the integrity of the Quality Management System.

14. Revision History of This Document

Rev No.	Date	Revised By	Approved By	Description
v1.0	2025-10-29	John Wang	Janice Lee	Initial release of ISO 9001 Documentation - Maintenance Plans for Tools

Note: All controlled documents must be accessed through authenticated and approved channels. Employees must notify QA/Document Control in case they identify outdated or conflicting versions.

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