



4.1 General requirements

Your company has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 9001:2008 and TS 16949:2009. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement the QMS *Your Company* has:

- § Identified the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Manual
- § Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram
- § Determined criteria and methods needed to ensure that the operation and control of the processes are effective, *and documented them in quality plans, work instructions and the Measuring, Monitoring and Analysis Table*
- § Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes
- § Established systems to monitor, measure and analyze these processes, and
- § Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes

When *Your Company* out sources any process that affects product conformity, technical responsibility is maintained and the control of these processes are identified within the QMS.

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

- § A documented Quality Policy
- § This Quality Manual
- § Documented Procedures
- § Documents identified as needed for the effective planning, operation and control of our processes, and
- § Quality Records



1.0 Purpose

- 1.1 This procedure describes the process for determining, providing and maintaining the infrastructure needed to achieve conformity to product requirements.

2.0 Responsibilities

- 2.1 *Maintenance personnel are responsible for the preventive maintenance of facilities and equipment.*
- 2.2 *The Facilities Manager* is responsible for facilities and equipment planning using a multidisciplinary approach.
- 2.3 *Manufacturing Engineering* for developing and implementing the evaluation and monitoring of the effectiveness of existing operations.
- 2.4 *The Facilities Manager* is responsible for maintaining the contingency plans.

3.0 Definitions

- 3.1 Infrastructure: buildings, workspace and utilities, process equipment and supporting services.

4.0 Equipment/Software

- 4.1 Not Applicable.

5.0 Instructions

- 5.1 Infrastructure needs are identified during quality planning and planning of realization processes. Planning processes are documented in the Quality Manual and the Planning of Product Realization Processes Procedure. (MP-710).
- 5.2 Infrastructure is maintained by using a Preventive Maintenance Program.
- 5.2.1 Maintenance evaluates facilities, equipment and other infrastructure to determine areas where preventive maintenance work needs to be done.
- 5.2.2 The preventive maintenance database *or spreadsheet* lists each item that requires preventive maintenance, and the maintenance schedule.
- 5.2.3 The *maintenance manager* is responsible for generating a preventive maintenance schedule for each maintenance cycle and distributing them to the appropriate individual or function.
- 5.2.4 The maintenance staff will perform the maintenance according to work instructions or equipment manuals. The schedule lists the due date for the work to be completed.
- 5.2.5 Records of the maintenance performed are maintained on work orders or in maintenance logs.



- 5.2.6 Maintenance personnel sign and date the PML or work order when the work is completed, and return it to the maintenance manager.
- 5.2.7 The *maintenance manager* updates the spreadsheet or database to indicate that the maintenance has been completed.
- 5.3 Work orders are also issued for unscheduled maintenance (repairs). Data on unscheduled maintenance is collected by the maintenance manager, and summarized for management review.
 - 5.3.1 Preventive maintenance schedules may be changed based on the analysis of data at management review.
- 5.4 Facilities layout
 - 5.4.1 Under the direction on the *Facilities Manager* a multidisciplinary approach is used to optimize the facility space for material handling and product flow.
 - 5.4.2 *Manufacturing Engineering* has developed and implemented methods for monitoring and evaluating the effectiveness of the operations.
 - 5.4.3 In the event of an emergency that interrupts product realization processes such as power, labor or equipment failures, contingency plans maintained by the *Facilities Manager* will be implemented to satisfy customer requirements.

6.0 Forms and Records

- 6.1 *Preventive Maintenance Spreadsheet or database.*
- 6.2 *Preventive maintenance summaries*

7.0 Attachments

- 7.1 *None*

8.0 Related Documents

- 8.1 P-560 Management Review Procedure
- 8.2 P-710 Planning of Product Realization Processes Procedure
- 8.3 Quality Manual
- 8.4 Contingency plans

9.0 References

- 9.1 None



F-622-001
Action Plan for Training-Form

Name: _____

Date Prepared: _____

Training or Action Planned	Date Scheduled	Completed Initial/ Date	Effectiveness Evaluation
		Trainer: _____ Trainee: _____	Plan: _____ Effective: yes no Date: _____ Supervisor: _____
		Trainer: _____ Trainee: _____	Plan: _____ Effective: yes no Date: _____ Supervisor: _____
		Trainer: _____ Trainee: _____	Plan: _____ Effective: yes no Date: _____ Supervisor: _____
		Trainer: _____ Trainee: _____	Plan: _____ Effective: yes no Date: _____ Supervisor: _____