



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

9.0 References

- 9.1 None