



Standard Operating Procedure Preventative Maintenance

Page 1 of 5
ECN #
Effective:

SOP 7-016

Revision: 1

1.0 Purpose

- 1.1 To document the preventative maintenance process for manufacturing and test equipment.

2.0 Scope

- 2.1 Preventative maintenance applies to all manufacturing, testing and ancillary equipment that requires routine maintenance, repair, inspection, or adjustment.

3.0 Applicable Documents

- 3.1 FORM 0015 Preventative Maintenance Request Form
- 3.2 SOP 7-009 Calibration Procedure
- 3.3 SOP 7-014 Installation Qualification Procedure
- 3.4 QMSM Quality Management System Manual

4.0 Definitions

- 4.1 Equipment: Tooling or machinery used to manufacture or test products including controlled environment systems.
- 4.2 Preventative Maintenance System: A system that schedules and documents the preventative maintenance activity required and performed on process equipment.
- 4.3 Preventative Maintenance Procedure: A description of required actions to be performed on equipment.
- 4.4 Preventative Maintenance (PM): Scheduled equipment review, adjustment or repair to maintain equipment at optimum operating condition.
- 4.5 Preventative Maintenance Coordinator: An employee with responsibility to ensure the preventative maintenance activities are performed at the appropriate times.

5.0 Responsibilities / Authority

- 5.1 Originator: Responsible for ensuring equipment is entered into PM systems and for development of preventative maintenance procedures.
- 5.2 Quality Assurance: Reviews preventative maintenance requests, unscheduled maintenance and repairs, and related form approvals.
- 5.3 PM Coordinator: Responsible for issuing equipment identification numbers, ensuring all applicable equipment is on the preventative maintenance system. Reviews and approves all preventative maintenance documentation. Executes required maintenance at the scheduled times.

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