

Preventive Maintenance

- Environmental conditions;
- Location;
- Performance history including failure rates of similar systems or components;
- Potential consequence of failing to complete PM;
- Identified failure modes [e.g., Failure Mode Effects Analysis (FMEA)];
- Overall lifecycle; and
- Condition Based Monitoring (e.g., vibration analysis, oil analysis, thermography).

If required, PM frequencies may be adjusted based on the criteria listed above. The justification for establishing and/or changing the PM frequency should be provided and reviewed by Engineering/Maintenance or the Business Unit responsible for PM, and approved by the System Owner and the Site Quality Team.

PM frequency may be scheduled using either calendar time (e.g., annual) or equipment usage [e.g., every one hundred (100) hours of use or every ten (10) batches produced].

5. The System Owner should be notified when PM activities are complete and should verify that the work is complete and the system and associated components are ready for use. The System Owner should document the verification and accept the system and associated components back into service.

6. The System Owner and the Site Quality Authority should be notified if PM is not performed within the scheduled frequency.

If Critical PM Tasks or PM work are not completed according to the PM frequency requirements and the system and associated components are subsequently used, a deviation report should be written and approved by the System Owner and the Site Quality Team. The deviation report should be included or referenced in the batch record(s) for any batches or lots produced using the system and associated components.

7. Replacement of Parts should be performed as a like-for-like change. If part replacement is not a Like-for-Like Change, the change should go through the Site change control process and be approved prior to implementation.

8. PM Requirements and Activities Instructions or PM Tasks that support both critical and non-critical components should be subject to the documentation requirements for critical components.

9. PM Work should be documented. The documentation should include:

- Maintenance performed, including reference to the PM Task performed or written instructions used;
- Identification and location of the system and associated components on which maintenance was performed;
- Identification of any parts replaced during maintenance;
- Identification of materials used (e.g., food grade versus non-food grade lubricants, coolants);
- Identification of any change control requests implemented;
- Measurements or observations made;
- PM completion date;
- Signature and date of the person performing maintenance; and
- Signature and date of Business Unit owner (e.g., Engineering/Maintenance) approving the completed activities.