

Guidance 085 Preventive Maintenance

- Management of overdue PM; and
 - Documentation requirements for individual PM instructions (i.e., PM Work Orders).
2. Documented Instructions for PM Requirements and Activities (e.g., PM Job Plan) should include, as applicable, the following:
- Identification of systems and associated components;
 - Instructions for performing PM, including:
 - Disassembly and reassembly;
 - Measurement taking;
 - Adjustments and/or replacements; and
 - Functional testing;
 - Identification of specialized tools and/or standards to be used;
 - Types of inspections for wear, damage, or failure;
 - Identification of documentation required; and
 - Special consideration (e.g., safety precautions, permits, environment).
3. Criteria to Consider When Classifying a PM Task(s) include, but are not limited to:
- Potential for the PM Task to:
 - Result in contamination of the product or materials;
 - Affect the safety, identity, strength, quality, or purity of the product or materials;
 - Affect the control, performance, or verification of functions that have a direct impact on product quality; and
 - Affect the production, monitoring, evaluation, storage, or reporting of data used to accept or reject product or materials, or data used to support Regulatory Compliance – Practices; or
 - The PM Task is a Non-Intrusive Condition Based Monitoring or Predictive Maintenance Activity.
4. PM Frequency and Rationale for the Frequency shall be based on consideration of, at least the following:
- Manufacturers' recommendations;
 - Intended use and criticality;
 - Frequency of use;
 - 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