

Preventative Maintenance Program for Instrumentations, Equipments and Utilities

In the event of a preventative maintenance work order being returned, with some operations not completed, an evaluation must be made as to whether the preventative maintenance is acceptable as complete with these operations not executed.

If the preventative maintenance order is considered incomplete, a new execution date for those steps to be executed must be agreed, written on the order, and signed by the Engineering Head or designee. The work order should then be rescheduled to allow the completion of the outstanding operations.

6.1.3 Non performed Preventative Maintenance

If the work order has been returned to the Engineering Head or designee as not executed according to the schedule it must be assessed for either re-execution at a new agreed date, or assessed to be skipped.

If the work order contains instructions to work on equipment with a GMP impact, or the work order is marked as GMP relevant, the action must be approved by the Quality, Engineering and Production Leader of the operational area.

If the work order is to be skipped, the hard copy must be annotated with this detail. The skipped work order must be filed and archived.

6.1.4 Preventive Maintenance Frequency

The frequency of preventative maintenance work once established will be re-evaluated using the trending reports and any other historical data of the concerned instrumentation, equipment or utility as the primary criteria before changing the maintenance frequency.

Maintenances frequencies may be adjusted based on the results of previous maintenance, e.g. broken bearings etc. A decision to change the maintenance interval must be related to responsible management and be approved by the Quality Assurance department.

6.2 Trending

The Engineering Head or designee is responsible to perform a periodic trending analysis on the results of all maintenance activities for each instrumentation, equipment and utility. Out of trend results must trigger a Corrective and Preventive Action (CAPA) activity to improve the performance of the preventive maintenance program.

6.3 Archiving of PM Documentation

The Engineering Head or designee is responsible to assure that all PM related documentation is completed, accurate and traceable before archiving. The PM documentation must be filed and archived in water and fireproof archives.

7 ATTACHMENTS

7.1 Attachment 1: Management of preventative maintenance (1 page)

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SOP	XX_WWW_ZZZ_YYYY	1.0	Approved	8/11