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FMC Daily Reporting and Oversight of APF Critical Parameters

Introduction

The Division of Technical Resources (DTR) / Facility Compliance Inspection Section (FCIS) generates daily reports of Facility Monitoring of Critical parameters (FMC) in Aseptic Processing Facilities (APFs) and distributes them via email to user groups and select personnel. Critical parameters include room temperature (TEMP), relative humidity (HUM), differential pressure (dP), and Air Changes per Hour (ACH); the set points for these parameters and their associated alarms are derived from the User Requirement Specification (URS) and detailed in a Critical Environment Parameter Worksheet (CEPW). Reports generated by the APF Daily Report application include an overview of all critical parameter alarm conditions (Incident Reports) from the previous day and are meant to provide review and oversight of key facility parameters and ensure the APFs are operating in a "state of control" in accordance with current Good Manufacturing Practice (cGMP) regulations and established criteria.

Data Collection

Data associated with incidents is collected from the following sources for the coverage date (normally the previous day):

- Division of Facilities Operation & Maintenance (DFOM) Building Automation System (BAS) – such as System Activity Log (SAL – logged activities including alarm acknowledgement, object changes, and data uploads and downloads) and trending data derived from the BAS (raw data sets collected per pre-defined trend configuration). Trending data configuration is normally interval collection (at a defined interval period) or Change of Value (COV – when a data point deviates from the previous set of data more than a defined value).
- DTR/FCIS APF Dashboards – such as trending graphics and raw trending data (see Figure 1).

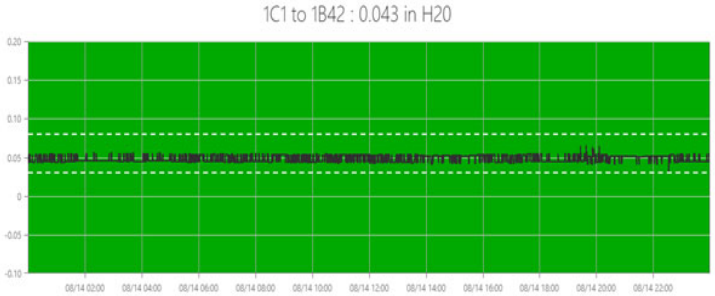

Figure 1: Example of APF Dashboard Trending Graphic

- DFOM Computerized Maintenance Management System (CMMS) – such as the cGMP LogBook Report and Work Plans/Work Orders.
- Environmental Monitoring System (EMS) data, if available (the EMS is generally a qualified user system which monitors critical environmental parameters of the facility without controlling them; it may monitor other user-specific parameters).
- Other planned activities – such as the End User's cleaning schedule, emergency generator testing, and BAS server maintenance activities.

Data Analysis/Findings

The reporter analyzes data for the following:

1. Out Of Specification (OOS) or Alarm Conditions – This is the main incident type related directly to Critical Parameters, indicating whether the space environment was out of the control range per the URS. The application creates an incident report with any related information, i.e., start/clear time, planned activities, and any LogBook notes such as findings/cause or immediate action taken.
2. Missing Trending Data – The reporter generates an Incident Report for any missing data (data gap).
3. Safety Incident – The reporter generates an Incident Report for safety device alarms such as oxygen sensor alarms.
4. Others – The reporter generates Incident Reports for any abnormal operating condition that is detected from trend analysis, such as out-of-trend values, shifting trends which are abnormal but not out of range (e.g., not in alarm), etc.

All incidents will be inputted into the application and reported. Open incidents that require further investigation will be sent via the application for feedback from DFOM and/or the End User.

Follow Up/Update on Previous Findings

Previous findings (open incidents) are tracked within the application, which documents all feedback, information, and communication between DTR/FCIS, DFOM, and the End User until the incident is resolved and closed. Some incidents may necessitate a Root Cause Analysis (RCA), Corrective Action and Preventive Action (CAPA), or System Discrepancy/Deviation (SD), which are also tracked within the application.

Conclusion

FMC daily reports help support communication among APF stakeholders and ensure that incidents are investigated, resolved, and documented in an appropriate and timely manner. These reports and associated oversight of APFs ensures compliance with regulatory requirements, including Good Manufacturing Practices (cGMPs), and supports continuous and collaborative efforts for the operation and maintenance of APFs.

Additional Reference

1. DTR-SOP-10007 Generation and Distribution of the DTR-FCIS Facility Monitoring Daily Report of APF Critical Parameters
2. DTR-SOP-1005 Corrective Action and Preventive Action (CAPA) Procedure for Maintenance of Aseptic Processing Facilities
3. DTR-SOP-1003 System Discrepancy / Deviation Management Procedure for Maintenance of Aseptic Processing Facilities
4. FCIS Facility Monitoring of Critical Parameters in APF Daily Report Application: https://dtrdata.orf.od.nih.gov/apfdaily/ (Access permission is required.)