Issue 110
March 2021
Division of Technical Resources
Office of Research Facilities
National Institutes of Health
Technical News BULLETIN

Metrics and KPIs in Aseptic Processing Facility Operations

Introduction

A Key Performance Indicator (KPI) is a quantifiable measure that characterizes a metric, or group of metrics, over time to demonstrate health, stability, and control. KPIs support the regulatory requirement to operate facilities in a state of control; they are derived from critical parameter metrics (Temperature (TEMP), Relative Humidity (RH), Differential Pressure (dP), and Air Changes per Hour (ACH)) used for reporting the health of individual rooms, whole facilities, and the entire Aseptic Processing Facility (APF) Portfolio. Critical environmental parameters are the most important metrics to report, as they have defined regulatory requirements and can directly impact the product being produced in the APF.

Facility-level KPI acceptance criteria are often recorded in the User Requirement Specification (URS), which provides traceability to the performance required to conform to regulatory, equipment, process, or material-related limits. Other KPIs that are reported on specific systems and utilities, include the health of specific utilities, calibrations, and O&M Performance, with several others currently in development.

APF KPIs are established using SMART criteria, which involves asking: Is the objective **Specific**? Can you **Measure** progress towards that objective? Is the goal realistically **Attainable**? Is it **Relevant** to the operation of the APF and program objectives? Finally, does the KPI fulfill the **Timeframe** requirements of the objective?

Metrics

A metric is a quantifiable measure of the health of a component, system, or utility. Metrics use a variety of calibrated probes and sensors to measure characteristics of interest, which are reported to the Building Automation System (BAS) for monitoring and control or to a qualified Environmental Monitoring System (EMS) for monitoring only. For control systems, there is an established setpoint to which the BAS will control the environment. The BAS will not command the system to react to values within a dead band range above and below the setpoint, which prevents the system from "hunting" and experiencing accelerated wear. Beyond this range may be upper and lower alert limits, depending on the metric; however, there is no regulatory requirement for alert limits, and alerts may result in frequent notifications (nuisance alerts). Beyond the alerts are upper and lower alarm limits established by the URS. Delays filter transitory effects of minor/typical occurrences, such as door openings, so that systems only alarm at significant events.

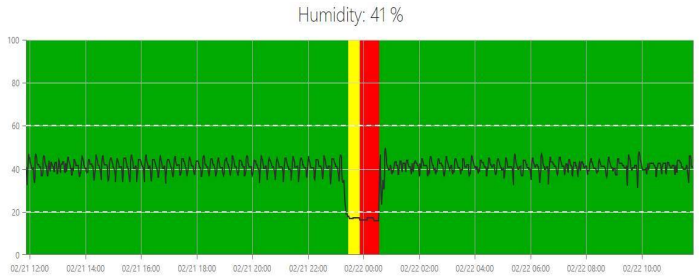
Sensors and probes must be calibrated on a regular schedule to assure reliability of the data. Trends are evaluated to assure values do not drift towards alert/alarm levels over time, which would indicate the system or component may need adjustment, maintenance, or recalibration. Trends of concern are reported in the FCIS APF Daily Report and investigative measures are initiated as a precursor to corrective actions. In the future, automated trend analyses may be featured in FCIS dashboards to track and communicate these issues more effectively.

Scales for Metrics

APF metrics are generally reported using the following scale:

GREEN	The measured value is between the upper and lower alert values, or has exceeded these alert values for less than the delay interval.
GRAY	There is data/communications loss.
YELLOW	The measured value is between the alert and alarm value for longer than the alert delay interval, or the measured value has exceeded the alarm values for less than the alarm delay interval.
RED	The measured value is at or beyond the lower or upper alarm value for a period longer than the alarm delay interval.

The metric in the example below includes dashed horizontal lines, which are the upper and lower alarm limits. There are no alert limits for this metric; note that the setpoint would generally be the midpoint between the dashed horizontal lines (alarm limits). The bold black sinusoidal line represents the data from the sensor probe, in this case tracking RH. Mid-time interval, the RH exceeded the lower alarm value for the duration of the delay interval, as depicted by the yellow band. Because the value continued to exceed the lower alarm value for longer than the delay, the sensor went into alarm, as depicted by the red band. When the probe detected that the humidity returned to within the normal operating range, the background returned to green.



Conclusion

Metrics measure the health of systems and environmental parameters. KPIs synthesize one or more metrics into more complex structures which provide insight into the health of groups of systems, entire facilities, or even the entire APF portfolio. Both metrics and KPIs are trended to analyze their performance over time and demonstrate operation in a state of control. Loss of control or trending towards a loss of control can indicate issues which need to be investigated and mitigated, including calibration, progressive failures of components, or defects in operating codes. Metrics and KPIs should be regularly reviewed against internal factors (such as changes in equipment, utilities, and operations) and externalities (such as technology, regulation, and program requirements) to provide assurance that the facility is operating within appropriate parameters and in a state of control, and that it is as ready as possible for unplanned disruptions.