The National Institutes of Health | Division of Technical Resources | Office of Research Facilities

Design Requirements Manual **News to Use**

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The formulae $\frac{\partial \rho \bar{U}_i}{\partial t}+\frac{\partial}{\partial x_j}(\rho \bar{U}\bar{U}_j)=-\frac{\partial \bar{P}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu\frac{\partial \bar{U}_i}{\partial x_j}\right)+g_i(\rho-\rho_0)$ for building $\frac{\partial}{\partial x_j}(\rho\bar{U}\bar{U}_j)=-\frac{\partial \bar{P}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu\frac{\partial \bar{U}_i}{\partial x_j}-\rho\overline{u_i'u_j'}\right)+g_i(\rho-\rho_0)$ state of the art $\frac{\partial}{\partial x_i}(\rho\bar{U}\bar{H})=\frac{\partial}{\partial x_i}\left(\lambda\frac{\partial \bar{T}}{\partial x_i}-\rho\overline{u_i'h'}\right)$ biomedical research facilities.

# BAS & EMS Systems

Aseptic Production Facilities (APF) are facilities which produce drug and/or biologic products for human injection, implantation, ingestion, inhalation, or absorption. This includes facilities where non-aseptic products are produced using aseptic practices. Characteristic of all APFs is tight environmental control and monitoring.

The Building Automation and control System (BAS) is the automatic control system which manages the APF's heating, ventilation and air conditioning systems. The core function of the BAS is to maintain a stable environment, between stipulated ranges for temperature, relative humidity, airflow and airflow direction. The secondary function of the BAS is via robust protocols to control the startup, shutdown, and changeover of mechanical systems in an organized, systematic, and automated manner to minimize risk to the products being produced and to the facility itself. Often the data for the BAS is transmitted over a robust and resilient protocol, such as BACnet. The BAS is commissioned and regularly recalibrated to ensure it is operating within specified parameters. The BAS controls all aspects of the HVAC system, including air handlers, exhaust valves, chilled water system, hot water system, and other components. The BAS is often designed and maintained as a "validatable" system, but is generally not validated, particularly for systems which are not predominantly APF facilities.

The Environmental Monitoring System (EMS) exists for regulatory compliance. Certain environmental parameters, are stipulated in the User Requirement Specification document, and substantiated by a formal risk analysis of the facility, processes, and products. Like the BAS, the facility EMS collects data on temperature, relative humidity, differential pressure, airflow, and in some cases other factors, such as particle counts, access control, and specific parameters of scientific and production equipment. The EMS monitors and records this data, and alarms notifies the users of deviations from the specified parameters. The EMS is a validated system, and follows Good Documentation Practice (GDP). The EMS is often a proprietary 3rd party system.

**Selection of Sensors:** The BAS and EMS must be selected for compatibility, calibration strategy, and resistance to damage from cleaning chemicals and procedures.

**Location of Sensors:** Sensors must be located where they can give representative data, free from localized distortion due to equipment discharges, door cycling, and similar interference. BAS and EMS sensors surveilling the same factor (i.e. humidity, temperature, etc.), must be collocated to the extent practicable. Generally this can be interpreted to be within 914 mm (3'-0") horizontally, on the same wall or ceiling plane, and of particular importance for temperature sensors, installed at the same elevation. The location of the sensors shall promote replacement and recalibration.

Sensors can be placed in the exhaust duct. This location makes the BAS and EMS field devices much more resistant to damage from cleaning, however, accessibility for service and calibration can be a space and convenience issue.

**Installation of Sensors:** All devices which penetrate the APF envelope must be sealed and/or gasketed to the adjacent architectural finish material. These penetrations must be firmly anchored to resist differential movement. Back-boxes shall be cast metal, sealed to the adjacent architectural finish material. Conduits which penetrate these boxes shall be sealed to prevent the movement of air and vermin.

**System Architectures:** There are various system architectures which have been deployed at APFs, each with specific strengths and weaknesses:

- Fully independent BAS and EMS Sensor systems:
  - \+ Highest level of redundancy for data continuity in case of the loss of an EMS sensor
  - \+ Sensitive to identification of sensor drift
  - \- High number of sensors which demand significant wall area
  - \- Most challenging to keep control over recalibration activities (schedule, NIST Traceability to a common standard, etc.)
  - \- Care must be exercised during procurement

- Shared sensors with splitter: There is a single or dual sensor of each type deployed to each location for facility monitoring.
  - \+ Fewer sensors means it is easier to keep the facility clean
  - \+ Strong control over recalibration
  - \- Splitter failure is a single point of failure, which is undesirable in a critical system
  - \- With single sensors of type, sensor drift may go unnoticed
  - \- Must be supported by risk analysis

**Calibration:** There must be a clear protocol for calibration and testing of HVAC Systems, and BAS/EMS sensors, in particular.

**Alarm Requirements:** It is considered good practices to set the action alarm at the extreme acceptance conditions and have an engineering "alert" at conditions just outside the normal operating range to alert engineering personnel of a potential unusual condition. Differential pressure (dP) can change very quickly, and therefore, has potential to create nuisance alarm whenever a door is opened. DP alarms should have time delays.

**Conclusion:** In short, the BAS and EMS monitor the facility, but the BAS also controls the facility.

'Design Requirements Manual (DRM) News to Use' is a monthly ORF publication featuring salient technical information that should be applied to the design of NIH biomedical research laboratories and animal facilities. NIH Project Officers, A/E's and other consultants to the NIH, who develop intramural, extramural and American Recovery and Reinvestment Act (ARRA) projects will benefit from 'News to Use'. **Please address questions or comments to:** Shawm@nih.gov

Further details on this month's topic are available on the DRM website Chapter 13 Aseptic Production Facilities
https://www.orf.od.nih.gov/PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines/Pages/DesignRequirementsManual2016