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

Design Requirements Manual **News to Use**

September 2018

Vol. 02, No. 21

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.

APF Doors, Frames & Hardware

Doors are a critical component to any laboratory, but in critical environments, such as Aseptic Production Facilities (APFs), they take on an even more important role. An APF is a facility which produces 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. APF doors serve as an access control barrier; preventing unauthorized entry, but more critically, they function as an extension of the HVAC system for the protection of the product being produced, to ensure patient safety, and to prevent exposure of the public to potentially hazardous materials. Doors are a critical component of the systemic design for the segregation of varying levels of ISO classification; for control of airflow direction; developing differential pressures; and regulating the frequency of extent disruption of the ingress and persistence of airborne contamination within classified areas through insuring unidirectional airflow and adequate room recovery time between door cycles.

Door and Frame Types: Swing doors, Sliding doors, and Roll-Up doors are the typical cleanroom door types, as other door types tend to have difficult to clean pockets, crevices, and other details which do not lend themselves to a well-maintained APF environment. Although unequal pair doors are common, due to space constraints, large single slab doors are often preferable, due to reduced crack length. For frequent use doors, swing doors are generally preferable because of their ease of maintenance. Sliding and roll-up doors tend to pose challenges for precise control and adjustment of air leakage, which is important for ease of TAB. Cleanroom grade doors are fully flush on all sides, without voids, crevices, or cracks which would require caulking.

Where installed as part of a rated assembly, clean room doors rated to meet or exceed those stipulated for the wall in which they are installed (ratings require similarly resistant frames, hardware, and installation details). APF doors and frames are generally high-grade stainless steel, aluminum, and smooth finished GRP or FRP. Powder coated, and anodized aluminum finish is permissible. The doors and frames should generally present the smoothest and most flush condition practicable on the cleaner side of each door, and be configured to open to the higher-pressure side, deferring to the latter condition when these are in conflict.

Lites: Full lite doors are preferable in APFs, for observation, but half-lite doors are the most common. Lite kits and glazing must be of clean-room grade, meaning creating few/no gaps, crevices, seams, and be fabricated from robust materials that are resistant to degradation from frequent exposure to the aggressive cleaning chemicals and methods used in these environments.

Opening and Closing Devices: Many APF doors are configured with automatic openers, and those which are not are generally provided with automatic closers with sufficient closing force compress the door seals and latch the door against the design air pressure. Automatic operators are prevalent because the required opening/closing forces tend to get high due to the air pressures required to adequately segregate areas within the facility to mitigate the risk of contamination of products being produced. Operators and closers which fit within the door head are the most typical. Where operators must extend beyond the face of the frame, the top surface should be pitched to prevent the formation of a horizontal ledge, which could accumulate dust.

Door Hardware: Door systems shall be fully integrated with automatic openers, emergency egress overrides, door interlock systems, door status indicator lamps, door position switches, electrified mortices/mag-locks, etc. The following are brief comments on a variety of APF door hardware types. All APF door hardware should be stainless steel, with smooth, polished finish.

- **Hinges:** High load lift-off (pivot) hinges are preferred over ball bearing knuckle high load hinges, due to cleanliness, but both are allowable.
- **Handles, Handsets, Locks, and Push/Pulls:** Should be stainless, or other appropriate material, smooth, and non-snagging.
- **Kick, Mop, Armor Plating, and Crash Bars:** While kick and mop plating can protect and prolong the service life of doors, the tendency to treat, especially interior facility doors as subject to the impact demands of a typical laboratory door should be carefully considered. Crash bars should be minimized or eliminated from APF doors for the same reason.
- **Sweeps, Astragals, and Thresholds:** APF outer facility doors may generally receive typical, pest-resistant bristle sweeps, but these are not permissible elsewhere in classified spaces within the APFs. Bristle astragals are prohibited in APFs. Mechanically operated drop-down sweeps should be avoided in favor of solid, adjustable height sweeps. Thresholds should be avoided throughout APFs. Where dissimilar floor material transitions occur, they should be accomplished via flush transitions.

Jamb Space: The "real estate" around the strike side jamb of APF doors is often congested with operator wave-sensors, emergency door overrides, door status indicator lamps, room number signage, duplicative BAS/EMS sensors and status displays, fire alarm strobes, telephones/intercoms, and other wall-mounted elements. The designer should carefully and fully model these elevations to ensure commonality of position of these elements between doors, and to ensure constructability of the intended configuration, due to the large number of conduits and back boxes involved, competing for stud space.

Conclusion: APF Doors, Frames, and Hardware is a challenging sub-specialty. Improper specification and detailing can lead to increased level of effort to maintain, and heightened patient risk.

'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 Section 6.3 Doors & Hardware
https://www.orf.od.nih.gov/PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines/Pages/default.aspx