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Design Requirements Manual **News to Use**

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

Acoustical Door Design

Speech privacy and sound control are important factors when designing for healthcare environments and research laboratories. Ramifications linked to poor acoustical design include sleep deprivation, patient privacy, and doctor-patient confidentiality breaches, all of which are addressed in the Health Insurance Portability and Accountability Act (HIPAA). Sound can also impact research animals adversely as animal sensitivity to noise has been linked to changes in breeding and behavior as well as physiological effects.[1]

Basis of Design

The criteria for sound control should be clearly identified in the program requirements and scope of work. The Sound Transmission Class (STC) rating specifies how well a door or wall assembly prevents sound from passing through. Demising partitions separating occupied areas from public corridors and construction separating enclosed rooms and non-public corridors must be designed to achieve minimum STC and Noise Isolation Class (NIC) ratings, per the DRM. Components that will improve the STC rating of a wall assembly include slab-to-slab staggered or double metal studs, resilient channels, acoustical insulation, layered gypsum board, and the use of acoustical sealants at gaps and penetrations. Since sound transmission increases at wall openings, greater consideration should be given at door locations. Successful acoustical door integration is dependent on a complete wall assembly design and proper installation of its components.

Acoustical Door Assemblies

Sound control door assemblies include the door frame, leaf, threshold, perimeter seals, gasketing, astragal, door sweeps or automatic door bottoms, and hinges and may also include vision panels for increased visibility. Door seals and gaskets create a continuous airtight seal and are compressed against the leaf and frame. Door sweeps seal the gap between the bottom of the door and the threshold. The sweep can be made of neoprene, silicone, or a nylon brush. Automatic door bottoms are adjustable and are used when a higher degree of sound control is required. When the door is closed, the seal automatically drops and closes the gap at the bottom of the door. Cam lift hinges are specially designed for sound control doors. The door is lifted and lowered during travel, improving the seal along the door perimeter and creating a positive seal at the closed position.

Acoustical Door Design Considerations

High STC ratings can impact the design by requiring heavier steel doors, wider door frames, and specific framing requirements at the door jamb that cannot be easily addressed mid- or post-construction. Heavier doors may not only require additional detailing at the door jamb, such as double metal studs, specialty hinges, or added bracing, but can also trigger ABA/ADA requirements for automatic doors due to the force required to operate the door leaf. Design features such as view windows and material finishes can be aesthetically limited due to the STC rating as well as the cost and lead time associated with acoustical metal and wood doors. Additionally, glazing should be specified to match the STC rating of the door in order to maintain the acoustical characteristics of the door assembly.

Warranty & Testing

A variety of warranty and testing factors must be considered prior to construction. For instance, in order to meet manufacturer warranty requirements, field conditions may need to incorporate certain elements present in lab testing conditions, such as door frames that are infilled with grout or insulation. When specifying sound control requirements, it is important to set an acceptable STC range for field testing between two adjoining areas to account for the fact that ratings can differ when door assemblies are tested in the field. Acoustical assembly components such as seals, gaskets, and bottoms may also be required to be single sourced and installed by a certified installer. Hospital stops modify the door frame such that the stop terminates above the floor to prevent corners from collecting debris and obstructing wheeled equipment and are therefore not recommended where a desired STC assembly is to be tested or warranted.

Additional Resources & References

1. Role of Noise & Music as Anxiety Modulators, Applied Animal Behavior Science Volume 152, March 2014.

News to Use article *Laboratory Door Design Considerations* dated November 2020 and *Sound Design Metrics* dated September 2019 and *Vision Panels in Laboratory Doors* dated December 2017 for additional lab door design considerations.

FGI Guidelines for Design and Construction of Hospitals, 2018 for additional acoustical hospital design requirements.

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Further details on this month's topic are available on the DRM website DRM Section 4.2, Doors
https://www.orf.od.nih.gov/TechnicalResources/Pages/DesignRequirementsManual2016.aspx

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Laboratory Door Design Considerations

One of the documents the Design Requirements Manual (DRM) references is the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition. The BMBL outlines many requirements for BSL-2 and BSL-3 labs, including the requirement for self-closing doors. This is reflected in Section 4.2.2 of the DRM, which requires that laboratory doors have closers. Although open doors are preferred by some lab users and may have operational advantages, the benefits are frequently outweighed by safety, biocontainment, and other design considerations.

Differential Pressurization

Typical biomedical laboratory design relies on differential pressurization and the associated directional airflow to promote biocontainment. Directional airflow is achieved by the proper balance of the supply air against the exhaust and return air in the laboratory and is generally configured to uniformly move air from the cleanest/lowest hazard zones towards the dirtiest/highest hazard zones.

Differential pressure is controlled by HVAC settings and components such as sweeps and seals which adjust air leakage across the door. When the doors are cycled open and closed, differential pressure is momentarily lost until the HVAC system can build up the pressures across the door, a process called “recovery.” If doors are held open, differential pressures cannot develop, and the resulting airflow is ineffective for maintaining differential pressurization.

Laboratory Door Requirements

Fire Ratings. Lab doors may be required to be fire-rated, based on NFPA 45 and the approved life safety documentation. Rated door assemblies are required to be UL listed and must be self-closing. The DRM prohibits hold-open devices on laboratory doors which inhibit their closing and latching in the event of a fire. This prohibition is one reason the DRM disallows pocket doors, accordion doors, and most sliding doors in laboratory applications (other concerns include durability, maintainability, cleanability, poor ability to develop differential pressures across them, and poor egress performance).

Access Control. Physical access control restricts access to approved personnel as required by both the BMBL and DRM. The intent of access control is to promote safety and deter human-induced hazards such as accidents, contamination, sabotage, and real or intellectual property theft. Coordinate door security devices and hardware with the NIH Division of Physical Security Management (DPSM) per DRM Section 4.2.2.4.
DPSM can be reached at DPSM-ServiceRequest@mail.nih.gov.

Size. The DRM requires that at least one door into every laboratory be at least 3’6” wide, which can be achieved with a single door or an active/inactive unequal leaf pair. Larger doors may be required to accommodate oversized equipment and to provide future flexibility, regardless of the requirements of the initial lab occupant.

Swing and Latching. DRM 4.2.2.3 requires doors to swing in the direction of exit travel. DRM 4.2.2.7.F requires constant-latching flush bolts on the inactive leaf of double door sets.

Vision Panels. DRM 4.2.2.8 requires vision panels in all lab doors. Vision panels are the topic of a News to Use article *Vision Panels in Laboratory Doors* dated December 2017, which can be accessed for additional information.

Protection Plates. DRM 4.2.1.6 requires stainless steel protection plates to protect the finish of doors in high traffic areas. Protection plates on fire-rated doors, however, must conform to the rating of the door assembly.

Material and Finish. Like other laboratory finishes, doors, frames, and hardware shall be durable, cleanable, nonporous, and resistant to chemicals.

Depending on the function and use of the lab, additional requirements may apply. Refer to specific DRM sections for animal facilities, aseptic production facilities, and other specialty applications.

Additional Information

Biosafety in Microbiological and Biomedical Laboratories
https://www.cdc.gov/labs/BMBL.html
Vision Panels in Laboratory Doors
https://www.orf.od.nih.gov/TechnicalResources/Pages/DRM_News_to_Use.aspx

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Further details on this month’s topic are available on the DRM website DRM Section 4.2, Doors
https://www.orf.od.nih.gov/TechnicalResources/Pages/DesignRequirementsManual2016.aspx

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Design Requirements Manual **News to Use**

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

Standard Operating Procedures and Lab Design

Standard Operating Procedures (SOPs) are required for the operation of all laboratories. An SOP is a set of written instructions that describes in detail how to perform a laboratory process or procedure safely and efficiently. SOPs are especially important when work involves the use of hazardous materials, aseptic or highly regulated conditions, hazardous conditions, or other situations where an error in procedures can have serious consequences.

In many sections of the DRM, it is a requirement to use SOPs in the process of laboratory design, meaning they must be available for reference during the design process. This does not require that the full operational SOP of the laboratory be complete, but that the function of the lab is defined in sufficient detail so that the designer can optimize the lab's configuration and features for its processes and procedures.

SOPs

Labs are very expensive to build and operate and often involve hazardous conditions, so failure to follow procedure can have serious consequences. For these reasons, labs should be designed rationally relative to the lab's SOPs so that procedures are as efficient, safe, and intuitive as possible.

A well-written SOP will provide the designer with a wealth of information that will enable them to properly address features that are essential for lab operations, including:

- **Decontamination**. The details of decontamination, including methods, chemicals used, and frequency, will provide information relative to finishes, sealants, penetrations, and HVAC design.
- **Personal Protective Equipment (PPE).** The definition of PPE requirements will ensure that adequate space is provided, including space for shelving, bins, benches and other features.
- **Sequence of Procedures.** Procedures in a laboratory often proceed in a specific sequence, so locating equipment and workstations in a rational order and adequately adjacent to each other will increase efficiency while limiting conflicts and potential errors.
- **Management of Hazardous Materials.** The identification of hazardous materials in a lab will ensure that provisions are made for their safe handling, storage, and disposal.
- **Services and Utilities.** The determination of the optimal sequence of procedures will determine where services and utilities are located so that equipment can be optimally placed for use.

An SOP should be developed early in the design process. If the lab functions currently exist, the SOP can be derived from the current SOP and modified to incorporate new functions. If the lab does not exist, the intended users should develop a preliminary SOP based on planned procedures or processes.

The lab designer should read the SOP with the goal of understanding the required spaces, features, equipment, and adjacencies necessary to optimize lab for its function and for safe, efficient, and effective operations. Bottlenecks, conflicts, and crossed paths should be eliminated to the extent possible; equipment and other items should be located where needed and most convenient; and hazards should be located to minimize risk and in appropriate proximity to required safety devices.

If a lab is designed without referring to an SOP, the configuration and features will not be optimized for the lab's procedures and processes. In this case, the lab SOP will have to be modified to fit the lab configuration, which may require additional steps and introduce compromises to efficiency and safety.

Conclusion

Using SOPs in lab design enables a laboratory's configuration and features to be optimized for a its procedures and processes, resulting in a safer, more efficient lab and simpler, more intuitive SOPs. If an SOP is not used as a design tool, the lab's procedures and processes must be modified to fit the lab configuration, which can result in compromised safety and efficiency and a more complex SOP.

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Further details on this month's topic are available on the DRM website DRM Chapter 2, Planning and Programming
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The formulae $\frac{\partial \rho U_i}{\partial t}+\frac{\partial}{\partial x_j}(\rho U_i U_j)=-\frac{\partial P}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu\frac{\partial U_i}{\partial x_j}\right)+g_i(\rho-\rho_0)$ *for building* $\frac{\partial}{\partial x_j}(\rho\overline{U}_i\overline{U}_j)=-\frac{\partial P}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu\frac{\partial \overline{U}_i}{\partial x_j}-\rho\overline{u_i'u_j'}\right)+g_i(\rho-\rho_0)$ *state of the art* $\frac{\partial}{\partial x_i}(\rho\overline{U}_i\overline{H})=\frac{\partial}{\partial x_i}\left(\lambda\frac{\partial \overline{T}}{\partial x_i}-\rho\overline{u_i'h'}\right)$ *biomedical research facilities.*

Laboratory Floor Drains, Floor Sinks, and Traps

NIH laboratory buildings contain numerous plumbing and piping systems necessary for basic laboratory operations, including animal functions. Floor drains and traps are two of the many elements that make up these systems. All floor drains and floor sinks shall conform with requirements of the International Plumbing Code (IPC) or Uniform Plumbing Code (UPC) and Chapters 8 and 13 of NIH Design Requirement Manual (DRM).

Design Requirements

Floor drains/sinks are required wherever water is likely to accumulate and create a hazard, where intensive wet cleaning and water spray operations are required as described in Section 8.2.26 of the DRM, and where there is risk of flooding. Wet laboratories can be prone to flooding and susceptible to damage, especially in areas where autoclaves, glass washing, and water-intensive equipment is located as well as areas below a lab with a poorly installed floor drain above. Floor drainage specifically provides three basic functions for these areas:

- Interception – Effectiveness of surface fluid removal
- Conveyance of fluids – Ability of fluid movement or transport
- Ability to act as a barrier – Interface between the waste fluids and the sewer

However, there are risks inherent to laboratory floor drains. As drain components have ample water supply and by nature receive organic matter, they build up nutrients and provide an environment to harbor microorganisms. Many studies highlight the drain as the most significant area for microorganism activity. Floor drains in laboratories may also result in inappropriate disposal of biologicals or chemical materials and spills that must be otherwise handled by a spill-response protocol. Inadvertent chemical disposal and the presence of pathogens in the drainage system, as well as risks associated with drainage backups and sewer gas, are some of the reasons to properly maintain floor drain systems. The use of electric trap primers, as stated in section 8.2.24 of the DRM, can assist with the maintenance.

Floor drain location should consider the various risks while complying with code requirements. In laboratory buildings, there are many non-laboratory areas that require floor drains, such as interstitial/mechanical rooms, kitchen areas, cage wash areas, service corridors and non-human primate (NHP) and large animal areas. However, NIH does not allow the use of floor drains in laboratory areas, as stated in section 8.2.26.2 of the DRM, or in highly controlled environments such as Tissue Culture labs and Aseptic Processing rooms (ISO 7 and ISO 8), as stated in section 13.4.2 of the DRM.

Floor drains are designed to perform as receptors of fluids from various processes; as a result, their installation requires the use of a trap seal and vent piping as shown in the Figure 1, Floor Drain-Trap Diagram.

When floor drains are subject to cleaning or accidental spills, it is not surprising that drainage components can harbor bacteria; they are prone to biofilm formation, and cleaning and disinfection of floor drains and traps does not remove all surface-borne microorganisms. Furthermore, because trap seals are normally filled with water, there is the potential for infiltration of sewer gas into the laboratory if the seals are not properly maintained. Even during cleaning, the removal of the foul air trap, which can clog if particulates are not removed, may promote circulation of the fouled air between a contaminated sewer system and the production area. These factors and their associated potential for contamination all contribute to the need for careful location of floor drains and sinks.

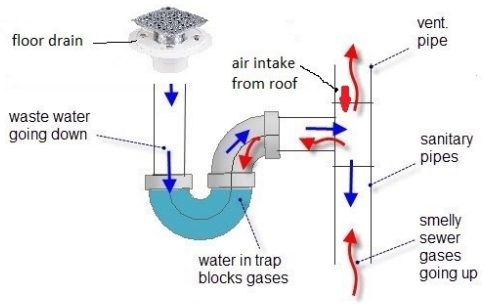

Figure 1 Floor Drain-Trap Diagram

Additional Design Requirements and Considerations

During laboratory renovation work, existing floor drains or floor sink locations must be coordinated with the laboratory design to ensure proper application of the drainage system per DRM Section 8.2.26.3 and 8.2.26.4. These sections and those referenced in the Design Requirements above will assist architects and engineers in properly designing details and specifying the types of floor drains or floor sinks appropriate for various areas of a laboratory building at NIH, per section 8.2.26.1 of the DRM.

Conclusion

Proper selection, design, and installation of suitable floor drains or floor sink assemblies, including traps, are crucial to avoid unintended flooding and ensure safe fluid waste removal while maintaining an effective barrier from sewer waste contamination. A risk assessment should be considered when locating or reusing floor drains to evaluate all possible scenarios for laboratory contamination and flooding.

Resources

1. NIH Design Requirements Manual (DRM) Revision 1.5: 03/26/2020
2. International Plumbing Code (2018)
3. Journal of Hygienic Engineering and Design, Hygienic Design and Operation of Floor Drainage Components

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Further details on this month's topic are available on the DRM website DRM Section 8.2 Plumbing Fixtures and Equipment
https://www.orf.od.nih.gov/PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines/Pages/DesignRequirementsManual2016

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Backflow Prevention in Water Supply Systems (Part 2)

In NIH laboratories and Animal Research Facilities (ARF), an independent laboratory water distribution system is required to maintain separation between a facility's laboratory water supply and potable water supply. The rationale for this is to minimize the requirements for testable backflow devices within the labs and ARFs (see DRM 8.3.6). This significantly reduces the need for floor drains in lab areas (which can pose additional hazards) as well as flood risks associated with certain required backflow protection devices and ongoing maintenance costs. The dedicated lab water supply system is segregated at the building water service entrance (prior to any building connections) and provided with (N+1) high-hazard type Back Flow Preventer (BFP) devices.

Dedicated Laboratory Water Systems

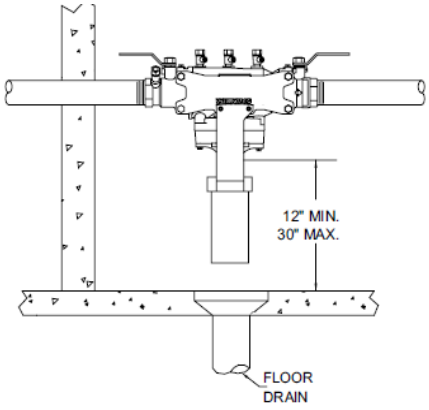
This segregated lab water system approach allows many lab water supply connections to be adequately protected with approved point of use, non-testable BFPs where high hazard devices would otherwise be required if the connections were served from a facility potable supply system. The benefits of this system also include reductions in annual operations and maintenance costs and research disruptions. Although the lab water system is segregated from the potable supply, risks to system water quality must still be controlled and minimized. High hazard BFPs may still be required to address certain higher risk connections. DRM Table 8.3.6 "Backflow Protection" lists connection points/equipment that would be connected to the dedicated laboratory water system and the method of protection required for each application and use point.

Potable Water Laboratory Applications

There are certain laboratory applications that require potable supplies arranged and protected from backflow in accordance with plumbing code and the DRM and which cannot be served by the lab water supply system. Where potable water is required, the BFP application shall be in accordance with the IPC, including Table 608.1. A few examples include supply to animal drinking water systems, high-purity water systems, emergency fixture supply systems, clinical instrument sterilizers, animal feed prep, surgical handwash, and make-up water to aquatics facilities. Proper physical separation from other water supplies (e.g. lab water supply) and plentiful labeling of potable and lab water piping within the lab or ARF are essential to help protect against improper connections during future renovations.

BFP Requirements

The installation of BFPs shall be justified by risk. The designer shall consider annual maintenance and service requirements for testable devices including ancillary devices, such as properly sized drain receptors and trap primers. Where required, BFPs must be located in unconcealed, readily accessible locations with proper service clearances and shall not be located above ceilings or where water discharge would not be fully controlled. Testable BFPs shall be located in proximity to properly sized drain receptors that can accommodate the full flow of the device in the event of discharge. Improperly sized and/or located drain receptors have resulted in significant facility damage from flooding due to uncontrolled draining of BFPs under failure conditions. There are additional requirements and restrictions for BFP installation in specific applications such as High Containment labs (see DRM 8.6.2).



ASSE 1013 Typical Installation

The engineer of record (EOR) must specify post-installation testing of each testable device following ASSE or ABPA procedures by a certified cross connection control device tester. Further, the EOR shall specify the contractor must provide a BFP log at the conclusion of the project to list all device locations, types, model and serial numbers, testing/replacement requirements, and testing reports at project turnover in the Operation and Maintenance documentation. Testing must occur prior to occupancy with results turned over within 60 days of completion. All testable devices require a dated test tag be attached to the BFP to indicate test results.

Resources

1. NIH Design Requirements Manual (DRM) Revision 1.5: 03/26/2020

2. International Plumbing Code (IPC - 2018)

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Further details on this month's topic are available on the DRM website Section 8.3 Water Systems
www.orf.od.nih.gov/TechnicalResources/Pages/DesignRequirementsManual2016.aspxPages/DesignRequirementsManual2016

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Backflow Prevention in Water Supply Systems (Part 1)

Water systems serving Laboratory and Animal Research Facilities (ARF) must be reliably safe and uncontaminated. Water supplies for domestic applications (e.g. clinical, administrative, food service, emergency fixtures, etc.) must be reliably potable. Yet complex piping systems in large biomedical research and clinical facilities can have hundreds of potential risks (cross connections) that must be anticipated and mitigated to ensure safe and reliable water supply. One of the greatest risks to maintaining safe and uncontaminated water supplies is "backflow"; when applying backflow protection, it is also crucial to consider facility flood prevention and protection. The NIH Design Requirements Manual (DRM) comprehensively addresses these issues.

What is Backflow?

Water piping systems can be subject to various forms of flow-reversals which may potentially result in chemical, pathogenic, or aesthetic contamination that renders the water supply non-potable and unfit for intended uses. The process that causes flow reversals is known as "backflow" and the physical condition that can facilitate backflow at a specific point in a piping system is known as a cross connection.

Backflow primarily occurs in two ways: back-siphonage and back-pressure. Back-pressure is a forced flow reversal, typically associated with a direct connection between a contaminated source and a lower pressure water system. There are many instances where this can occur, including make-up water supplies to pumped piping systems, cage wash equipment, and boilers. Water supply pressure does not need to be lost for a back-pressure backflow incident to occur; it only needs to be overcome at a given point in the system.

Back-siphonage is one of the most common causes of backflow and is caused by a negative (below atmospheric) pressure condition in a supply system. An unplanned service disruption, pipe break, or fire-fighting event is often implicated in back-siphonage by pressure losses and flow reversals. One hazardous example of backflow can occur in laboratories where aspirating devices or hoses are connected to faucets (or through emergency drench hoses) that do not include appropriate backflow protection. Static head in tall buildings can also result in flow reversals, and if there is a cross connection present, the contamination can siphon into the piping system. Process operations involving chemicals can therefore pose special risks. Lab vacuum systems, chemical cleaning, water treatment of piping systems, and even traditional faucets and drench hose eyewash fixtures can all result in cross connections that must be protected.

Impact of Backflow and Preventative Measures

The results of backflow events have ranged from aesthetic inconveniences (tastes and smells) and illnesses to far more serious problems where water supply systems were contaminated with pesticides, toxic chemicals, and pathogens. There are many documented cases of potable water contamination that occurred due to uncontrolled cross connections. From 1981 to 1998, the Centers for Disease Control (CDC) documented 57 waterborne disease outbreaks related to cross connections, resulting in 9,734 reported illnesses.[2] These included both microbiological and chemical contamination incidents; although well documented, these cases likely represent only a fraction of actual occurrences.

The DRM and major plumbing codes such as the International and Uniform Plumbing Codes (IPC and UPC, respectively) address minimum standards and protections to ensure clean and safe water supplies. In NIH facilities, the planning, tracking, and control of these issues requires careful attention, from initial facility design through operations and maintenance, due to the sheer quantity of potential risks. Strict control of the materials of construction and plumbing system design arrangements is necessary to ensure adequate water supply pressure and to avoid or mitigate contamination risks and cross connections. This includes proper selection and application of Back Flow Preventer (BFP) devices. Systems that are not constructed of approved materials suitable for potable water must not be interconnected with potable water supplies without appropriate backflow protection.

Part 2 of this article will discuss DRM requirements, examples of how and where they are to be applied, and the associated rationale.

Resources

1 NIH Design Requirements Manual (DRM) Revision 1.5: 03/26/2020

2 EPA white paper: Potential Contamination Due to Cross-Connections and Backflow and the Associated Health Risks (2001)

3 International Plumbing Code (2018)

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Further details on this month's topic are available on the DRM website Section 8.3 Water Systems
www.orf.od.nih.gov/TechnicalResources/Pages/DesignRequirementsManual2016.aspxPages/DesignRequirementsManual2016

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Design Requirements Manual **News to Use**

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

Accessibility Law: ABA and ADA Differences

Accessibility is a universal requirement for all Federal facilities for which the Division of Technical Resources (DTR) cannot grant a waiver. As a federal entity, the National Institutes of Health must follow the requirements in the Architectural Barriers Act (ABA) standard (Design Requirements Manual, Section 1.9). While they are very similar, there are also some differences between what the ABA standard requires for accessibility and what the American with Disabilities Act (ADA) standard requires.

Accessibility Laws

The ABA of 1968 was the first federal law to address accessibility. The ABA standard applies to facilities built or altered with federal funds (grant or loan) or leased by the federal government. The standard also applies to structures built on "behalf" of the federal government (i.e. built on federal land with private sector funding). The U.S. Access Board enforces the ABA standard; complaints alleging federal facility noncompliance can be filed with the Access Board.

The Access Board develops the minimum accessibility guidelines for both the ABA and ADA standards. Note that the "F" in front of the scoping requirements in the ABA standards stands for federal. The "F" denotation is only shown in the ABA Standards.

The ADA of 1990 is a civil rights law enforced by the U.S. Department of Justice. It provides access for people with disabilities by establishing standards for design and construction. The Access Board develops the minimum design guidelines, standards, and construction requirements set forth in the ADA standards as adopted by the Department of Justice. New construction and alteration requirements apply to both private and public entities. Public entities such as stale and local governments are covered by Title II. Private entities such as commercial facilities and places of public accommodation are covered by Title III.

Key ABA and ADA Differences

- **Employee Work Areas:** Specific to the ADA standard is 203.9 Employee Work Areas. Many of the access requirements no longer apply in an area if it is used only by employees to do their work. The minimum requirements for work areas are that employees are entitled to "reasonable accommodations" (ADA standard Advisory 226.1 General). ABA standards do not include this exception; all work areas must be accessible as if open to the public unless otherwise stated.
    - **ABA Standard Advisory F226.1 General:** In facilities covered by the ABA standard, this requirement applies to work surfaces used by employees. Five percent, but not less than one, of permanently installed work surfaces in each work area must be accessible.
- **Modifications and Waivers**: The ABA standard authorizes modifications or waives the accessibility standards for buildings and facilities covered by the ABA standard on a case-by-case basis. This is not an option in the ADA standard.
- **Leasing Requirements:** The ABA standard has leasing requirements, but the ADA standard does not. These requirements only apply where the federal government leases in whole or in part, and do not apply where money is given to a non-federal entity which then leases a facility. The ABA standard can apply to non-federal entities where a grant or loan is provided for design, construction, or alteration.
- **Barrier Removal Obligation Requirements:** The ABA standard has no barrier removal obligation requirements, unlike the ADA standard. Under the ABA, access requirements are triggered when alterations are done. Also, the scope of the alteration triggers the size of the improvement. There is no cost ceiling for renovations (meaning no 20% provision) under the ABA standard, unless it is technically infeasible.
- **Vehicles:** The ABA standard does not apply to vehicles such as buses and trains, unlike the ADA standard. The ABA standard is limited to buildings and facilities.
- **Privately-Owned Residential:** Privately-owned residential structures not leased by the federal government are not subject to the ABA. Even if the structure received federal funding, the design work is not subject to ABA requirements. ADA requirements still apply to these structures.
- **Vertical Access Exceptions:** Under the ADA standard, accessible routes between stories are not required in private sector facilities under three stories tall or having less than 3000 square feet per story. There is no similar exemption in the ABA standard. Most new construction two-story buildings covered by the ABA must provide vertical access. The only exception is for two-story facilities where one floor does not have public space and the second floor has a maximum occupancy of 5 persons or fewer. This last exception is part of both the ABA and the ADA standards.

Summary

Designers of federal facilities must be familiar with the differences between the ABA and ADA. When appropriate, the ABA must be applied in its entirety, and requests for exceptions, waivers, and interpretations should be directed to the US Access Board.

Resources

US Access Board: https://www.access-board.gov/

Guide to the ABA Standards: https://www.access-board.gov/guidelines-and-standards/buildings-and-sites/about-the-aba-standards/guide-to-the-aba-standards

US Department of Justice - Americans with Disabilities Act: https://www.ada.gov/

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Further details on this month's topic are available on the DRM website Section 4.6 Furnishings and Equipment
www.orf.od.nih.gov/TechnicalResources/Pages/DesignRequirementsManual2016.aspxPages/DesignRequirementsManual2016

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ANSI/ASSP Z9.14-2020

On March 31st, 2020, ANSI published the revised standard ANSI/ASSP Z9.14-2020 Testing and Performance-Verification Methodologies for Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3) Ventilation Systems.

ANSI/ASSP Z9.14 has been used extensively both nationally and internationally since its original release in January 2014. The test methodologies provide a standardized, uniform, and consistent approach to ensure that all reasonable facility engineering controls and prudent practices are in place to minimize the risks associated with BSL-3/ABSL-3 laboratory operations. ANSI/ASSP Z9.14-2020 continues to be the only guidance available that provides a methodology to verify ventilation systems in high biocontainment facilities.

Background

The ventilation systems in BSL-3/ABSL-3 facilities must conform to current biocontainment guidelines and regulations, including those of the NIH, the CDC, and AAALAC. Verification that these systems are working as intended should be performed regularly, as defined by the institution. However, in 2012, the American Society of Safety Professionals (ASSP) and the American National Standards Institute (ANSI) conducted a "gap and needs analysis" and concluded that there was no single comprehensive testing methodology to verify that the ventilation systems in such facilities are performing appropriately. ANSI/ASSP Z9.14 was therefore developed to provide an extensive, graduated, risk-based approach to reaching containment goals appropriate to the risk of the agent and the laboratory.

Scope of ANSI/ASSP Z9.14 Revision

The scope of ANSI/ASSP Z9.14 – 2020 has not changed from the previous version, but the existing content has been updated, and new sections, appendices, and checklists were added. New content includes:

- Verification of Conformance to Regulations
- Corrective Action Plan Guidance
- Updated Definitions
- Methodologies to Perform Risk Assessment
- Risk Assessment and Corrective Action Checklists

ANSI/ASSP Z9.14 – 2020 provides guidance on the use of risk assessment and a performance-based approach, which are adaptable to any size or type of BSL-3/ABSL-3 facility. It is designed to be fully compatible with national and international health and safety management systems without duplicating or contradicting their requirements. ANSI/ASSP Z9.14 – 2020 may be useful for (a) facilities that have similar functions and risks, but do not follow the same testing methods for ventilation; (b) facilities that cannot meet the ventilation recommendations of the most current *BMBL* when renovating or retesting; and (c) users who require help with test administration. It may be used in whole or in part as an adjunct standard operating procedure, or along with other methodologies that may be available to minimize the risks associated with BSL-3/ABSL-3 facility operations.

Application and Use of ANSI/ASSP Z9.14

ANSI/ASSP Z9.14 – 2020 applies specifically to new or existing laboratories as well as research, pharmaceutical, and insectary facilities. The standard should also be applied if there has been a change of agents, procedures, or key personnel; a renovation; or a decommissioning. It provides users with guidance on inspecting ventilation system components, including visual verification procedures to ensure that system components support the safe operation of the facility's ventilation system (i.e., directional inward airflow, response to failures, minimizing leakage, etc.) and methodologies to help comply with current local, state, and federal requirements, industry standards, and best practices. The revision gives stepwise guidance to conduct an effective risk assessment, and a comprehensive checklist has been added for users to confirm that the appropriate steps have been taken to ensure that the ventilation system operates as intended.

The standard's basic guidance for collecting, preparing, and retaining documentation; performing visual inspection; testing; and verification methodologies for the performance of ventilation system components remain unchanged. The 2020 revision contains more detailed procedures and risk matrices than its predecessor for use when deficiencies are identified through a risk assessment or in the course of testing and verification. It also provides details to conduct iterative corrective actions until the deficiencies are resolved to management's satisfaction.

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Further details on this month's topic are available on the DRM website Section 6.6: BSL-3 & ABSL-3 Biocontainment
www.orf.od.nih.gov/TechnicalResources/Pages/DesignRequirementsManual2016.aspxPages/DesignRequirementsManual2016

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

Preparing for FDA Pre-Operational Review of APF Projects (Part Two)

NIH operates a growing portfolio of Aseptic Processing Facilities (APF). These designated APFs support patient care and research programs by enabling the effective use of aseptic techniques for the safe processing, manipulating, compounding, or admixture of therapeutic, prophylactic, and diagnostic drugs and medical devices for human use. The stated purpose of the FDA's Pre-Operational Reviews of Manufacturing Facilities is to provide an opinion as to whether the work described (facility, process, or both) in the documents would comply with current Good Manufacturing Practices (cGMP), per FMD-135. For a full description of the APF program and the FDA's Pre-Operational Review Program, please see Part One of this article.

The various types of post-design review may occur at any or all the following stages, depending on the project:

Pre-Construction Review

At this stage, the review involves studying and commenting on the complete design package, including drawings; specifications; URS (updated); Basis of Design (BOD), which includes updated and expanded facility diagrams; RA (updated); System Level Impact Assessment (SLIA), which establishes system and facility boundaries as well as robustness, resiliency, and redundancy requirements; and Project Validation Master Plan (PVMP). The comments at this phase tend to delve into materials of construction and construction detailing; drainage and water systems; product systems; compressed air systems; heating ventilation and air-conditioning (HVAC) systems; and process equipment configurations, along with their associated piping systems and controls.

Construction/Equipment Installation and Qualification Review

The FDA will respond to requests for an on-site review of specific portions of the construction while it is in progress. Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), and validation and control data are collected and stored under document control during and after this phase. They will be available for FDA review upon request.

Pre-Production Review

At the pre-production phase, the FDA generally follows the guidance of the applicable Compliance Program and their Investigations Operations Manual (IOM). At this point, the NIH will have produced a large volume of facility documents that are validated per Good Documentation Practice (GDP). Many of these documents are currently in, or are in the process of migrating to, the Document Management System (DMS), where they will be maintained as current throughout the life of the facility. The users will complete the development of the facility's other establishment files and preoperational memo in coordination with the Office of Research Support and Compliance (ORSC) prior to beginning production at the facility.

The facility documents described above are generally developed by outside subject matter experts (SMEs) and contracted directly by the users, or under the umbrella of the design and construction project contracts. These documents are prepared in coordination with the end user, ORSC, and Facility Compliance and Inspection Section (FCIS). In a highly collaborative and integrative process, the user and ORSC tend to focus on process and regulatory compliance associated with the products to be produced, while the user and FCIS tend to focus on assuring that the facility being designed meets or exceeds the acceptance criteria as described in the User Requirement Specification (URS), which can be traced back to regulation and risk analysis.

The intent of the NIH's layers of internal oversight and the FDA's external oversight is to ensure the Safety, Integrity, Strength, Purity, and Quality (SISPQ) of the products being produced in order to minimize the risk to our patients as part of an overall quality system. The NIH Quality Management System (QMS) is a formalized system of interacting documents, processes, procedures, resources, and responsibilities for achieving quality policies and objectives that promote patient and worker safety, in accordance with all applicable guidelines and regulations. The QMS requires appropriate quality management personnel to oversee the use of the facility, as well as the development and maintenance of documents.

The FDA's review on cGMP compliance can reveal defects or vulnerabilities, especially early in the facility development process. These faults could lead to costly corrective action or risk of contamination, increasing the risk to patient safety – the avoidance of which is the shared goal of both the FDA and the NIH.

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Preparing for FDA Pre-Operational Review of APF Projects (Part One of Two)

NIH operates a growing portfolio of Aseptic Processing Facilities (APFs). These designated APFs support patient care and research programs by enabling the effective use of aseptic techniques for the safe processing, manipulating, compounding, or admixture of therapeutic, prophylactic, and diagnostic drugs and medical devices for human use. These facilities include those where the materials handled are bioburden-controlled, aseptically processed, or terminally sterilized, as well as supporting laboratories which provide testing of the environment within these facilities, their processes, and/or products. APFs process materials intended for direct injection (e.g. parenterals), mucus membrane administration (e.g. ocular, inhaled, nasal treatments), or tissue contact administration (e.g. implants). APFs shall be operated in a state of control, as defined by the facility's Quality Management System (QMS).

For new APFs and significant renovation projects, it is the typical practice of the NIH, under the guidance of the Clinical Center's Office of Research Support and Compliance and The Office Of Research Facilities, Division of Technical Resources, in collaboration with the end user and outside subject matter experts, to request a Pre-Operational Review of Manufacturing Facilities by the FDA. The stated purpose of the FDA's Pre-Operational Review is to provide an opinion on whether the work described (facility, process, or both) in the document would comply with current Good Manufacturing Practices (cGMP), per FMD-135. The NIH is not engaged in commercial production, but it shares many of the same concerns as a commercial manufacturer regarding the prioritization of patient safety. NIH retains the responsibility to design, construct, commission, qualify, validate, and operate APFs in a state of control.

There are multiple types of review which may be requested under a Pre-Operational Review. This article covers Design Review; the second article in this series will cover Pre-Construction Review, Construction/Equipment Installation and Qualification Review, and Pre-Production Review.

Design Review

The Design Review meeting generally occurs at or after the end of the design-development phase, 30 days after the submission of a document package to the FDA. This package consists of the User Requirements Specification (URS); flow diagrams, which may include but are not limited to room classifications and pressurization, gowning-level zones, raw material, finished material, personnel, waste, and other diagrams which illustrate the implementation of the contamination/cross-contamination prevention strategies, including segregation, separation, and unidirectional flows; and Risk Assessment (RA) and mitigations. Other technical and illustrative documents may also be included, which describe how the completed facility will meet cGMPs and other regulatory requirements. The FDA has shown keen interest in how construction and maintenance activities may impact ongoing operations nearby, something which should be clearly described in the documents.

The documents must be advanced enough to permit meaningful review and comment and must be provided well in advance of the meeting. The meeting is intended to address NIH's questions to the FDA, but also any questions or concerns the FDA may have about patient risk. These meetings are held at the FDA's offices, and are attended by the end user chief (who submits the documents to the FDA) and representatives of key departments within the user group, ORSC, and FCIS. This small contingent will present and respond as representatives of the NIH's intent during the meeting, then will interface with the larger project team afterwards to develop written responses to any questions or requests for additional information from the FDA.

The intent of the NIH's careful, layered approach to these projects, the engagement of multiple levels of Subject Matter Experts, the FDA's external oversight, and the ongoing NIH-internal oversight of operations and maintenance of each APF in the NIH portfolio is to ensure the Safety, Integrity, Strength, Purity and Quality (SISPQ) of the products being produced. This helps prioritize both patient and worker safety.

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Design Requirements Manual **News to Use**

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Designing for Leak and Flood Resistance

NIH buildings contain a myriad of plumbing and piping systems necessary for basic building operations as well as laboratory, clinical, and animal care functions. With so many systems, it is inevitable that leaks and floods occur, so it is incumbent for the design process to include appropriate risk assessment and for the design to incorporate appropriate flood-resistant measures. Leaks and floods can severely hinder the safety, efficiency, and operations of critical facilities and have detrimental effects on research. The consequences of water damage can include compromised infection control and aseptic conditions, loss of containment, damaged finishes and equipment, mold growth, and abeyance of services.

Flood-resistant detailing is addressed in many sections of the DRM. Section 2.2.1.3H, Leak and Flood Prevention, requires that mechanical rooms and interstitial levels be designed to prevent leaks and that floor assemblies be waterproofed. Section 4.3.1.1C, Flood Resistant Detailing, requires that a water-impervious material be installed at the base of gypsum board walls in all areas prone to flooding or water damage. These requirements are intended to limit the propagation of water from leak-prone areas to other areas of the building, and to protect walls from water damage when a flood occurs.

The DRM requirements listed above are minimums, and all projects must undergo a risk assessment to identify additional flood mitigation measures based on the criticality of the facility, age of the infrastructure, history of failures, and other pertinent factors. Risk Assessment is defined in Section 1.3, Definitions, and further clarified in Sections 1.14.1, Critical Facility Risk Assessment and Certification and section 1.15.6, Risk Assessment, Systems Failure and Disaster Mitigation.

Design Requirements

General Building Requirements. The DRM contains requirements for overall building design to minimize both the chance of flooding and any damage if flooding does occur. Section 1.15.6E12 prohibits the location of major infrastructure equipment in areas susceptible to flooding. Section 1.15.6E19 prohibits the installation of wet equipment rooms above critical facilities, and Section 1.15.3L requires a flood-monitoring system in areas where this cannot be avoided. Section 8.1.5.1A prohibits the location of piping above surgical areas, clean rooms, high containment areas, or other critical and sensitive spaces unless directly serving those spaces. In addition to these general requirements, specific requirements are provided by area type.

Mechanical rooms and interstitial levels. Section 2.2.1.3H denotes mechanical rooms and interstitial levels as particular concerns for leaks and floods due to the concentration of piping, plumbing systems, and mechanical equipment. The floors in these areas must be waterproof and designed to contain water and direct water to drains. Concrete floors must be finished with a durable, abrasion-resistant waterproof system which will bridge cracks. Penetrations, shafts, slab edges, and other paths for water propagation must be detailed with curbs, sleeves, upturns, or other protective elements. Sloped floors, berms, or other methods must be provided at doors and corridors to contain water. Section 6.3.8 requires freeze protection measures for 100% Outside Air Handlers to prevent coil ruptures.

Vivariums. Vivariums are water-intensive facilities by necessity and are therefore susceptible to flooding. All floors within a vivarium must be seamless with integral bases per section 2.4.3F. Drains serving cage wash equipment must be designed to accommodate surge flow. If walls are constructed of gypsum board, the base must be backed by water-impervious board to protect the gypsum board from water per section 4.3.1.1C.

Laboratories. Laboratories can be a source of flooding and highly susceptible to flood damage. Areas that use a lot of water (autoclaves, glassware washers, equipment rooms, areas at emergency showers) are prone to flooding and should have seamless, waterproof flooring with integral bases to contain water. Aseptic production facilities, clinical laboratories, and other sensitive and critical areas should be detailed to protect them from water and to limit damage if flooding occurs. This can be done by detailing adjacent mechanical rooms and wet rooms appropriately and only using materials in their construction that are nonabsorbent and which will not support mold growth.

Conclusion

Leaks and floods cannot be eliminated entirely from laboratory, clinical, and animal care facilities. However, their impact can be minimized and the disruption to operations limited through risk assessment, thoughtful planning, and good design and detailing.

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Ice Machines

Section 4.5.1.13 of the DRM requires an ice machine on each floor of a lab building. This addresses the fact that ice is commonly used by laboratories to keep samples and reagents cold during procedures, which means obtaining ice should not require traveling long distances or between floors.

Laboratories are unique, so the requirements of laboratory users should be assessed early in the Programming Phase of a project. A large building may need more than one ice machine on a floor, and ice machines may not be required on a largely dry or analytical lab floor (in which case a Request for Variance must be submitted and approved).

Design Considerations

Ice machines are available in a wide range of types and sizes, and the requirements for a project should be documented in the Basis of Design and on the Room Data Sheets and Equipment Schedules (see DRM Appendices F and G). Important factors to consider when selecting a unit include the type of ice produced (cubes, nuggets, or flakes), daily capacity, and bin size.

Ice machines are common resources and therefore should be centrally and conveniently located along the main corridor. Due to the potential for spilled ice and water, they should not be located in the corridor itself, but in an adjacent room or alcove. This area should have a waterproof floor (epoxy or sheet material) sloped to a drain, with an integral base detailed for flood resistance, per DRM 4.3.1C.

Dry ice may also be required depending on facility needs, and a dry ice machine can be co-located with a traditional ice machine. Dry ice machines use liquid carbon dioxide piped from central bulk storage tanks. Dry ice is produced in blocks, pellets, or flakes in a variety of capacities. It is a hazardous material because it is extremely cold, so a dry ice machine should be in a locked room unless it is in a controlled-access corridor. Due to sublimation, dry ice machines should be located in well-ventilated spaces with oxygen monitors and alarms.

Engineering Considerations

Water serving an ice machine may be sourced from the domestic (potable) or laboratory (non-potable and isolated) water service depending on the function. Machines that produce ice for human consumption must be from a domestic water system per DRM Section 8.3 and the International Plumbing Code (IPC). When an ice machine serves a dedicated laboratory function, both the ice machine and the water service to the machine must be clearly marked as non-potable and not for human consumption.

Ice machines making ice for human consumption must be provided with some form of backflow protection. Backflow preventers are required by the American Society of Inspectors of Plumbing and Sanitary Engineers (ASSE); in most cases, modern ice making equipment uses integral backflow prevention. Integral backflow preventers are preferred because they eliminate the need for an external backflow preventer, which would require routine maintenance and yearly certification. Ice machines for dedicated laboratory ice production do not require backflow protection, per DRM Table 8.3.6.

Filtration of water service to an ice machine should be installed per the manufacturer's recommendation to prevent scaling and buildup of particulates and sediments. Analysis of the incoming water quality may be necessary to determine the required filtration in order to maximize the quality of the ice output and reduce cleaning requirements.

Whether serving potable or non-potable applications, ice machines should be drained to sanitary waste due to machine flushing and cleaning agents, following the latest edition of the Federal Food Code for ice machines. A laboratory ice machine may drain to the sink tail piece in situations where it is local to a laboratory sink. All other applications should be drained to a funnel floor drain with an approved air gap. See DRM Section 8.4.10 for specific drain configuration requirements.

Air-cooled ice machines can release large amounts of heat into the environment, so a mechanical engineer needs to review the HVAC system capacity to confirm it is sufficient to handle the heat load of the ice machine. If the ice maker is being added as part of a renovation project, the heat load will need to be identified in the Room Data Sheet (DRM Appendix F) and should be included in the facility heat load calculations in the Basis of Design. Water-cooled ice machines may be connected to building chilled water or condenser water systems. Per DRM Section 6.3.6.2, water-cooled ice machines may not draw their cooling water from a domestic or laboratory water source, nor may cooling water be sent to a drain in a one pass cooling configuration.

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