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Design Requirements Manual **News to Use**

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Planning for Oversized Equipment

When designing for oversized equipment, such as Magnetic Resonance Imaging machines (MRIs) and Nuclear Magnetic Resonance spectrometers (NMRs), designers often overlook factors such as the route equipment will travel, height of existing ceilings, width of doors, and size and type of elevators along the route. This can cause problems, because while facilities last decades, equipment does not, and must sometimes be replaced. The significant size and weight of MRIs and NMRs require planning for both immediate considerations and future accommodations.

Path of Travel

The design team should review travel paths for equipment and study how it is brought into and removed from the building.

Section 4.6.1.5 of the DRM, Transportation Route, states:

Delivery pathway through the building, both horizontal and vertical, must be verified during the design phase to ensure an adequate route is available for equipment components or pallets. Doors, elevators, corridors, areaways, parking areas, loading docks, entrances, and all other components of the route shall be of adequate size and load-bearing capacity to accommodate the installation or replacement of large equipment. Assessment shall include turning radii, clearance for rigging, and notation of any actions that will be required (i.e., removing doors from frames, removing light fixtures). Rationale: Costly, disruptive modifications to the building should not be necessary to deliver or remove large equipment in or out of the building.

Factors to consider along the route of travel include:

Ceiling Heights. Corridor heights, including bulkheads, may be insufficient for the movement of large equipment.

Door Widths. NMR and MRI magnets are often wider than typical doors and may therefore require larger openings.

Floors. The load-bearing capacity of floors along travel paths must be evaluated. Temporary floor protection may be necessary to prevent damage to existing finishes, and temporary shoring may be required to ensure against overloading.

Elevators. Large equipment may exceed the capacity of freight elevators, and cab height may be insufficient for the components.

Building Access. Section 5.1.5 of the DRM, Equipment Access, states that designers should "plan and provide access to service existing and replace obsolete equipment." The rationale for this is to provide "foresight into how instruments/equipment can be moved from and into the building horizontally and vertically, including set-up of equipment needed for the move, which will be critical to minimizing any building damage that may occur from equipment transport." To avoid expensive changes to buildings, spaces which house this type of equipment should be designed with the consideration for knock out panels or roof hatches for ease of installation and removal.

Rigging Planning

The path for moving equipment in and out of the building, as well as for repair or replacement, should be determined during the conceptual design phase.

Magnet weighing 38,000 pounds lifts off from South Drive

The number and size of cranes to be used must be evaluated based on the equipment, the location of the area receiving the equipment, and site and operating constraints. Road closures, site planning, and other pre-approvals associated with bringing in cranes are required in advance of these activities to provide adequate time for coordination.

Documentation Requirements

Section 4.6.1.4 of the DRM, Documentation Requirements, states that the "path of travel from point of delivery to final destination for oversized and overweight pieces of equipment …**shall be illustrated** and included as a drawing sheet" (emphasis added). Working with the manufacturers from the beginning of the project is key to successful equipment installation. This section of the DRM also specifies the following:

- Location of service areas and clearances shall be identified on the construction drawings.
- Equipment plan and schedules shall state if vendor/ trade support is needed upon delivery.
- Equipment clearances shall be illustrated on the equipment plans accommodating the worst-case requirements. All specified manufacturers should be accommodated in design clearances and utility accommodation, not just the basis of design manufacturer.
- Equipment performance specifications for contractor-furnished equipment should clearly indicate responsibilities of the contractor, owner, and the NIH.
- During the construction phase, the designer, equipment user, and the Project Officer shall review all movable equipment to ensure that models that have changed during the design process can be accommodated at time of delivery.

Summary

At NIH, our clinicians eagerly await the latest breakthroughs in technology for new and innovative healthcare, and equipment is part of their success. It is important to ensure that facilities are properly designed to accommodate specialty equipment, including its installation, removal, repair, and servicing.

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

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Quality Assurance and Quality Control

Appendix E of the DRM, A/E Submission Requirements, outlines the content and quality requirements for design document submissions. To meet these requirements it is necessary for the A/E to utilize Quality Assurance (QA) and Quality Control (QC) procedures. QA and QC are separate and distinct activities, both of which are necessary to ensure the quality of an end product, including design documents and construction.

QA is the conscious planning and implementation of systems and procedures to ensure that a process is carried out with a high probability of success. QA is typically proactive, and begins at the onset of a process. QA focuses on failure prevention.

QC is the systematic checking of an end product to identify failures and either correct or eliminate them. QC is typically reactive, and conducted at the end of a process. QC focuses on failure detection.

QA and QC During Design

It is required that a designer produce high quality construction documents, which the Construction Specification Institute defines as "clear, concise, correct and complete."[1] A QA process should address the specific complexity, scope, and requirements of a project. The process must include appropriately qualified and experienced staff, thorough understanding of requirements and regulations, progress and coordination meetings and 'lessons learned' from other projects, review comments, and QC feedback. QA may also include peer and constructability reviews, checklists, standards and templates, and other quality-driving tools.

The QA process ensures that the documents produced are of high quality. Some errors are inevitable, however, and the QC process is required to identify those errors so that they can be corrected. A designer's QC process must include a review of all documents (BOD, drawings, and specifications) by an experienced interdisciplinary QC team. The QC team should check documents for accuracy, coordination, completeness, constructability, and compliance with regulatory and contractual requirements. The QC team must have the authority to delay the issuance of documents until they have certified that quality standards have been met. The QC team should report deficiencies so that they can be addressed in an improve QA process.

QA and QC During Construction

The definition of 'quality' of construction can vary by project. Generally, it means meeting project parameters (such as cost, schedule, and contractual and regulatory requirements), avoiding disputes, meeting the design intent of the construction documents, and producing a facility that meets the owner's expectations and performs as intended.

Every project should have a written QA plan which outlines the required processes, standards and policies. The QA plan must define the efficient and organized management of all aspects of the construction process, including personnel, information and documentation, site, regulations and approvals, schedules and budgets. Personnel roles and responsibilities must also be defined, including responsibilities for safety, communication, coordination and quality. Processes for inspections and observations, and for reporting unacceptable work or activities, including remedial actions, must be defined

QC involves testing and inspecting the work being installed. A QC manager must be identified who is independent of the project superintendent, and who has the authority to accept or reject work. Inspections and testing by the contractor, subcontractors, and government should be performed at required times, and results should be provided to the QC manager without delay so that corrective actions can be taken if necessary. All actions should be communicated and documented.

Conclusion

A high level of quality is the objective of every design and construction project; if a design submission or element of the built work is rejected, the schedule and budget of the project will be negatively impacted. The effort that goes into QA and QC acts as insurance against the cost of delays, disputes and damaged reputations caused by quality failures.

References

[1]CSI Construction Product Representation Practice Guide

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DRM Update: Grooved Piping

The recent DRM update has made a significant change to piping requirements. NIH-DRM Exhibit 6.3 "Piping Designation, Material, Fittings and Joints"[1] previously stated that grooved piping was approved for use in various mechanical applications, including chilled water, condenser water, and process cooling water. The DRM revision, however, has removed grooved piping and the associated joints as an acceptable option for these mechanical and HVAC applications (see updated DRM Revision 1.1, dated 8/22/2018).

Previously, where such joints were permitted on these piping systems, it was required that joints "shall only be permitted where the joints are located to be accessible." The intent was to permit inspection of the joints to determine if they were subject to leakage over time. This precluded the use of such a pipe-joining method in enclosed chases, above critical spaces, or within non-accessible areas.

While the use of grooved piping is accepted by the industry for these applications, it's impossible to inspect the joints to ensure ongoing integrity once piping is installed and fully insulated without removing and later re-installing the piping insulation. Over the past several years, the NIH Campus has experienced several high-profile failures of grooved piping joints on chilled water and heating water applications. These failures resulted in flooding, loss of building use, impact to research, and significant costs associated with remediation. In order to reduce potential for future flooding, NIH has determined that joints on the affected systems will be welded, threaded, or joined as otherwise permitted by the newly revised DRM. This impacts installations at the Bethesda campus only; other off-campus NIH locations will be evaluated in consultation with the facility operations staff.

Designers will need to include provisions for pipe movement and expansion in designs with approved joining methods (e.g. welding, threading), which do not accommodate movement that grooved pipe couplings will tolerate (see DRM Section 6.3.9.4, "Thermal Expansion," for further provisions).

This update does not impact any approved fire protection piping systems or other approved systems (such as above ground domestic or lab cold water), fitting types, or joining methods as designated and approved by DRM Exhibit 6.3. The fire protection piping systems at the Bethesda campus are installed per applicable NFPA requirements and as approved by the NIH Division of the Fire Marshall, the campus's authority having jurisdiction (AHJ). Piping systems for fire protection in any location other than the Bethesda campus will be installed as determined by the AHJ. Other grooved joint applications (e.g. domestic water above ground) remain a potential option, provided that all requirements listed within Exhibit 6.3 and its associated notes are met.

Applications where the design engineer believes that a grooved piping system would provide advantage over the approved joining method for mechanical piping systems can submit a DRM variance form[2], which will be evaluated for the specific project application and facility risk analysis.

Resources

[1] DRM Exhibit 6.3 "Piping Designation, Materials, Fittings, and Joints," keyed note 13

[2] DRM Appendix K: *DRM* Variance Form

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Further details on this month's topic are available on the DRM website Chapter 6 Piping Systems Section 6.3
https://www.orf.od.nih.gov/PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines/Pages/default.aspx

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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.

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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

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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.

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Ceiling Heights in Laboratories

DRM section 4.4.3.4 includes a required minimum ceiling height of 9'-0"and an optimal ceiling height of 9'-6" in laboratories. Although laboratories by their nature are individually planned and must respond to the requirements of the research to be conducted, good practice and long experience has proven that these ceiling heights are necessary to provide the flexibility required by evolving research programs.

Laboratories are regularly updated to reflect changes in staffing, equipment and research protocols. A new lab or major renovation should be designed to accommodate the planned use for which programming and planning is conducted, but also to accommodate future equipment and functions that can reasonably be anticipated for the space. Although ultimate flexibility and universal adaptability is an unrealistic expectation, a laboratory design is not successful if it cannot accommodate a reasonable range of upgrades and changes.

Many DRM requirements and good practices are intended to provide the design with features to accommodate future programs, equipment and protocols, even if not required by the specific program that will occupy the space at the time it is being designed and constructed. This forethought is necessary so inevitable future program changes can be accommodated without major renovations. These include:

- A flammable storage cabinet is required in every lab to allow for chemical use. (4.5.3.2)
- 42" door widths are required to allow for the installation of large equipment. (4.2.2.2)
- Lab air exchange rates are not reduced during off-hours to allow for extended operations.
- Offices floor loading is required to be 100 PSF to allow for conversion to lab. (5.2.1)
- DRM 6.2.1 calls for a 20% increase in sizing for air handling and exhaust systems. This is not a safety factor, but a future factor for expansion in research technology and changes in space usage which happens often at NIH.

This same rationale supports the requirement that ceiling heights be adequate to allow lab users wide latitude when purchasing and/or reusing equipment. Equipment should be selected based on function, value and other program considerations and not be limited by the ceiling height of the lab.

Biological safety cabinets (BSCs) are one example of a common equipment type whose selection and function may be limited by ceiling height. Two widely-used recirculating BSC units by leading manufactures are 60.9" and 61.8" tall, resulting in units that are over 8'-0" tall when installed on standard 3'-0" bases. Most BSC manufactures require a minimum of 8" clearance above the BSC for air flow, and NIH Division of Occupational Health and Safety (DOHS) required a minimum of 1'-2" above BSCs for access to filters for inspection and maintenance. Both of these units function without limitation at 9'-6" ceiling height, but have operational or installation limitations in a space with a 9'-0" ceiling height. Limitations increase further as ceiling heights decrease.

Lower ceiling heights will force restrictions on the lab user regarding the equipment selection, installation or operation. For a BSC a researcher may be limited on which unit can be purchased or the unit may have to be installed on a lower or telescoping base. Additionally, existing units may not be able to be reused.

Additional reasons for the 9'-0" ceiling height include:

- 9'-0" allows for more efficient direct/indirect pendant lighting.
- 9'-0" allows for more diffuse distribution of air, resulting in lower air velocities and more efficient distribution.
- Aesthetics and spaciousness.
- Transmittance of daylight deeper into the lab.

Conclusion

When programming a new space, whether for new construction or a major renovation, designers must consider flexibility for both the current user as well as future occupants. This includes providing adequate ceiling height, as required by DRM section 4.4.3.4. This is challenging and no space can be fully adaptable to future changes but designers must reasonably anticipate the ever changing needs of research. It is the designers' responsibility to ensure laboratory programs are not unduly limited by facility restrictions including ceiling heights.

'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 DRM Section 4.4.3 Laboratory Finishes
https://www.orf.od.nih.gov/PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines/Pages/DesignRequirementsManual2016

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Design Requirements Manual **News to Use**

June 2018

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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 $\frac{\partial}{\partial x_j}(\rho\overline{U}_j\overline{U}_i)=-\frac{\partial\overline{P}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu\frac{\partial\overline{U}_i}{\partial x_j}-\rho\overline{u_i'u_j'}\right)+g_i(\rho-\rho_0)$ 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.

Demising Partition Acoustic Requirements

The 2016 Design Requirements Manual (DRM) requires that demising partitions between functionally separate areas achieve a Sound Transmission Class (STC) of 50 per ASTM E90. Additionally, construction separating enclosed rooms and non-public corridors shall achieve a minimum Noise Isolation Class (NIC) of 45 per ASTM E336.

As measured under ASTM E90, STC provides an estimate of the sound transmission loss through space-dividing elements of all kinds including operable partitions, floor-ceiling assemblies, doors, windows, roofs, and panels. The STC rating is an invaluable tool when designing a space; however, it represents sound transmission loss under ideal laboratory conditions and does not consider sound transmission along indirect paths or flanking paths. ASTM E336 determines the NIC and provides test methods and procedures to assess the sound isolation between two rooms separated by a common partition and includes both direct and flanking paths for sound.

Virtually all partitions contain a mix of construction, e.g. doors, convenience outlets, windows, etc. within a partition; so consideration for flanking paths of sound is immensely important. A hairline crack will decrease a partition's transmission loss by about 6 decibels (dB). A 1 in^2 opening in a 100 ft^2 gypsum board partition can transmit almost as much sound as if the entire partition did not exist.[1] The entire construction assembly should be appropriately detailed to ensure sound does not transmit across two acoustically isolated spaces. See Figure 1 for an example of high sound isolation construction.

Acoustic Design

Designers should recognize the acoustical needs of each space as well as communication needs within a space with the users and / or project stakeholders. Functionally separate spaces may be a conference room adjacent to a public corridor, an office adjacent to an auditorium, or a classroom adjacent to a noisy mechanical room. Acoustical design should consider the noise to signal ratio, which is the determination of whether a signal (speech, music, etc.) is audible or intelligible above the ordinary background noise of the environment. Unless required by programmatic needs, some level of noise is desirable to avoid an acoustically "dead" space. Additionally, a quiet environment with little to no background noise requires a higher degree of sound separation to achieve the same privacy versus an environment with more background sound. In order to help determine the type or use of a space to the acceptable level of background noise, maximum noise criteria levels are established within Table 6.5.2 of the DRM.

Certain areas within NIH facilities may require greater STC ratings and acoustic considerations, such as spaces within an Animal Research Facility due to some species' sensitivity to noise and vibration. Section 4.3.3.9 requires partitions separating cage wash areas, large animal areas, and other functions that generate undesirable noise to achieve a minimum STC of 60.

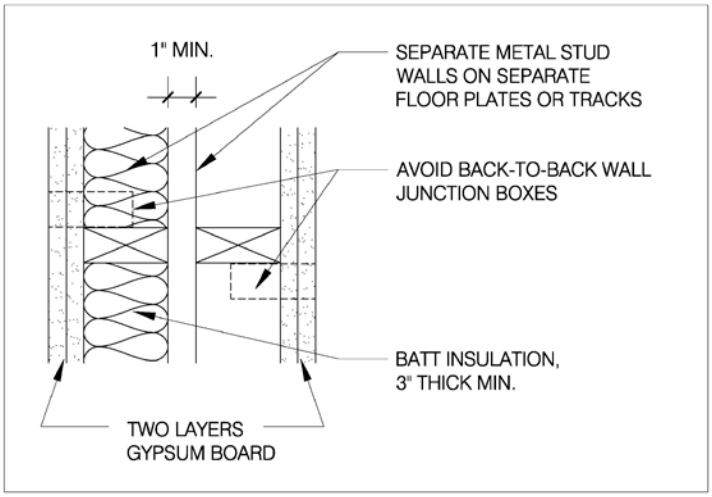

Figure 1: High Performance Acoustic Wall Construction

Design Considerations

No matter the size or scope of a project the following considerations must be evaluated by the design professionals to determine the appropriate acoustical treatment. Each room or space should be evaluated by:

- The type of space and its function within the facility.
- The level of communication needed or acceptable articulation index within each space.
- The level of privacy or isolation necessary from other spaces.
- All surrounding spaces and their potential for creating unwanted noise.

As with other aspects of design and construction there is no one size fits all solution to controlling and mitigating noise; however, through years of experience and testing with metrics such as STC and NIC, designers have many tools available to them. Good design must incorporate the acoustic requirements of a space into both its architecture and building systems.

References

1. Ballast, David Kent, and Steven E. O Hara. *ARE Manual.* PPI, 2016.

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Further details on this month's topic are available on the DRM website DRM Section 1.15 Common Engineering Systems' Requirements
https://www.orf.od.nih.gov/PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines/Pages/DesignRequirementsManual2016

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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* $\frac{\partial}{\partial x_j}(\rho\overline{U_j U_i})=-\frac{\partial \bar{P}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu\frac{\partial \overline{U_i}}{\partial x_j}-\rho\overline{u_i' u_j'}\right)+g_i(\rho-\rho_0)$ *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.*

Request for Variance

The overarching goals of the DRM are to ensure that NIH facilities are safe, efficient and in compliance with the Biosafety in Microbiological and Biomedical Laboratories (BMBL) and other applicable codes and standards. Although the DRM is a comprehensive document, it is recognized that there are methods of achieving these goals that differ from those prescribed, and which may be more appropriate for a particular situation. For this reason DRM Section 1.5.1, Variance Request Procedures, is provided.

Request for Variance form

DRM provisions are not intended to prohibit the use of alternative systems, methods, or devices that are not specifically outlined, provided that the proposed alternative is equivalent or superior with regards to value and performance.

Appendix K: DRM Variance Form

DIVISION OF TECHNICAL RESOURCES (DTR)
NIH DESIGN REQUIREMENTS PROJECT SPECIFIC
REQUEST FOR VARIANCE

Drawing Reference:
Detail Number:
Spec. Section Reference:
Paragraph # in Guidelines:
Campus ☐ On ☐ Off

To: Variance Review (301) 451-4954
Email: ORFDTRAmbulCenter@mail.nih.gov Phone
From:
Project Officer Email
A/E Name Phone Date
Work Request Number Proposed Variance Subject
☐ Yes ☐ No Type
New Construction e.g. lab, animal, office, HSL?

(Variances should be requested during pre-design or early in the design phase.)

Project Title
Building Number Estimated Construction Cost
Location Project Percent Completed %
Describe Variance. State specifically how it deviates from the guidelines, how it improves the existing condition and the advantage to implementing. Provide hard copy supporting documents as necessary to variance coordinator:

Provide recommendation of discipline or disciplines to review variance; i.e. mechanical, electrical, architect, civil, structural, fire protection or other:

PLEASE DO NOT FILL IN BELOW THIS LINE.

DTR Routing:

DTR Response:

☐ APPROVED ☐ NOT APPROVED ☐ REVISE & RESUBMIT

NIH Design Requirements Manual 1163

(Figure 1)

During the course of programming and design development the Architect / Engineer (A/E) should reference the DRM and identify all issues which may require variances. Variances may be necessary to accommodate existing building constraints or site conditions, required technology, or the standards of a building or institution. Cost, user preference and 'the way it was done before' are generally not bases for variances. DRM Appendix K (Figure 1) is the Request for Variance form, which requires the following information:

- Project identification, including Work Request number and the names and contact information for the Project Officer (PO) and A/E.
- Project title, building number and location, project percent complete.
- Variance description. This should state the proposed deviation, justification for the deviation and a demonstration of equivalency. Provide the advantage to implementing the proposed variance, and the rationale for exemption from the requirement.

In order for a variance to be properly assessed, the Request for Variance and supporting documentation should provide the reviewers with a complete understanding of the function and layout of the spaces and systems in question. The function is often conveyed with a narrative including pertinent facts regarding operation, use and special conditions. For a renovation the layout is often conveyed with demolition and new work plans. Supporting technical data may consist of cut sheets, specifications, manufacturer's instructions, calculations, etc. Not providing sufficient data for the variance review may result in a delay.

Variance Process

Completed forms shall be submitted by the A/E through the PO. All requested variances within a single discipline shall be submitted as a single package (i.e. all mechanical in one package). This ensures that all related variations are reviewed at one time to preclude conflicts in guidance.

The Request for Variance forms that meet the prescribed criteria will be reviewed by applicable NIH review offices. If the submittal is incomplete, or requires resubmission, additional time may be required for the review. Submissions are based on specific conditions, locations and circumstanced, and future variance approvals are at the A/E's risk. ***A variance submission request does not guarantee variance acceptance. Acceptance of a variance does not relieve A/E of any responsibilities as a design professional.***

Following the submittal of a complete package by the PO, 10 working days should be scheduled for a review. Additional time may be necessary depending on the complexity of the request, coordination with other requests, or resubmission due to incomplete documentation. This timeframe shall be considered when developing the overall project development schedule.

All known variances shall be submitted before the completion of the design development stage (35%) for a project. In some cases, the need for a variance may be the result of work done after the design development stage. Only in these cases will late variances be considered.

If a variance is granted the Request for Variance form and back-up material should be included in the project documentation.

Additional Considerations

DRM Section 1.2.1 lists codes and standards that must be used in conjunction with the DRM. The Request for Variance form is used for variances from DRM requirements only.

NIH cannot grant waivers or variances from federally-mandated sustainability or energy efficiency standards or requirements.

NIH cannot grant waivers for accessibility compliance. All requests must be submitted to the U.S. Access Board.

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Further details on this month's topic are available on the DRM website DRM Section 1.5.1, Variance Request Procedures
https://www.orf.od.nih.gov/PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines/Pages/DesignRequirementsManual2016

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Design Requirements Manual **News to Use**

April 2018

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

Risk Assessment and Disaster Planning

NIH facilities and the work contained therein are extremely valuable, and loss due to a facility failure are potentially incalculable. This is addressed in the NIH DRM Section 1.15.6 *Risk Assessment, Systems Failure & Disaster Mitigation.* The need and purpose for Section 1.15.6 is summarized in the Rationale:

Failures in systems can cause substantial impact to facility operations and loss of research. Many catastrophic utility failures can be prevented or controlled by provision of redundant equipment and appropriate standby power supplies, commissioning activities, automated monitoring and response plans. These specific additional precautions should be addressed in the architectural and engineering design of systems for research and vivaria along with an evaluation of additional risks in conjunction with the program to ensure appropriate plans are maintained and to mitigate risks. The rapid restoration of services and minimization of damage is critical in any emergency and is best accommodated through careful planning and installation quality control. The requirements of this section are not all-inclusive, and are not intended to address all provisions necessary for safety or to prevent and mitigate failures. System designers/engineers must appropriately consider each system and the inherent risks and features to ensure proper design, operation, and failure response on a project specific basis.

Risk Assessment

Risk assessments should be conducted early in project planning to identify potential hazards. A properly conducted risk assessment measures the criticality of each architectural and engineering system, its potential for failure, and the consequences of a failure. Once the risk assessment has been conducted appropriate mitigation plans should be developed.

The degree of formality of risk assessments will vary by application, however formal risk assessment is required for hazardous systems, high containment facilities, aseptic production facilities, patient safety and other critical systems and facilities. NIH risk assessments must be prepared by, or in consultation with, subject matter experts and then reviewed and approved by appropriate representatives of all organizations with applicable expertise and authority, which may include impacted institutes and centers, DOHS, DRS, ORF, DFM, DPSM and others.

Disaster Planning

Disaster planning is of utmost importance in research facilities as the unplanned loss of critical infrastructure and system failures can lead to the loss of research and risks to safety. The A/E should work with research personnel to determine the courses of action that should be taken if failure of one or more systems occurs and evaluate potential risks and preventative and mitigating actions.

Considerations

Every facility presents unique risk assessment and disaster planning challenges. Considerations should be tailored to the parameters of the project but should include:

Logistics: Plan for disruption in the delivery of critical supplies due to weather or other events. This directly influences how much area needs to be set aside to accommodate reasonable reserves.

System Design: Systems shall be designed and materials selected to minimize potential for loss of service, to avoid or minimize impact on research and facility operations in the event of disaster or malfunction. Mitigations may include appropriate redundancies, quality of system components, planning for access, maintenance and repair of downed equipment in a safe and minimally disruptive manner. Monitoring and alarming of critical systems should be included for the notification of personnel.

Site and Project-Specific Risks: The A/E should consider the site and project-specific risks associated with each system, both in terms of regular maintenance and operations activities and disaster response.

Disaster Response Plan Coordination: Provisions to address disaster response in regard to engineering systems shall be coordinated with facility disaster response plans.

Requirements: Disaster planning scenarios may include:

- Loss of power (failure of primary, or in critical applications failure of backup power)
- Loss of heating/cooling/supply air capacity
- Loss of exhaust air capacity
- Loss of HVAC (environmental) controls
- Delay/disruption of scheduled deliveries (minimum on hand stock of critical supplies)
- Loss of critical equipment (process or storage equipment)
- Loss of containment/isolation
- Other potential scenarios, including a list provided in DRM 1.15.6E.

Disaster After Action: After a failure or repetitive failures has occurred, the need for root cause analysis and mitigating action shall be considered and shall be reported to ORF.

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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 $\frac{\partial}{\partial x_j}(\rho\overline{U}_i\overline{U}_j)=-\frac{\partial\overline{P}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu\frac{\partial\overline{U}_i}{\partial x_j}-\rho\overline{u_i'u_j'}\right)+g_i(\rho-\rho_0)$ 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.

Postformed Plastic Laminate

A series of News to Use articles in 2015 provided a review of benchtop material options in laboratories[1]. They noted the drawbacks and limitations of plastic laminate benchtops, due to issues of delamination and durability. For this reason the DRM prohibits the use of plastic laminate tops in critical NIH facilities:

- Section 4.5.3.1, *Laboratory Casework,* prohibits the use of plastic laminate benchtops at sinks or other wet locations.
- Section 4.5.4, *ARF Casework,* prohibits the use of plastic laminate components of any kind in animal research facilities.
- Section 4.9.8, *Casework,* prohibits the use of plastic laminate components in BSL-3 biocontainment labs.

Plastic laminate is only allowed to be used in dry areas of standard BSL-2 labs and in non-lab areas such as administrative areas, conference rooms and break rooms. During value engineering exercises the value of alternate materials, including phenolic resin in lab areas and solid surfaces in non-lab areas, should be acknowledged for their aesthetics, longer life and reduced maintenance.

Figure 1: Standard Plastic Laminate

When plastic laminate must be used for budgetary or other reasons it is incumbent on the designer and specifier to provide materials and details that provide the greatest durability and the best aesthetics to increase the value of the project.

Standard Plastic Laminate

Standard plastic laminate installation has individually applied laminate surfaces and squared-off corners, resulting in exposed seams, open joints and raw laminate edges (figure 1). Exposed seams provide a pathway for moisture to the substrate which can result in delamination. Open joints accumulate dirt and water and must be sealed and maintained, which is a particular concern in clinical spaces and areas where cleanliness is important. Raw edges expose the unattractive dark craft paper core of the laminate, which is a particular concern in conference rooms and other public areas.

One option for eliminating many of these issues is to utilize postforming plastic laminate where possible.

Postformed Plastic Laminate

Postforming wraps an entire countertop assembly in a continuous surface of laminate (figure 2). The postforming process applies laminate to a substrate in both flat surfaces and concave or convex curves, usually to form a bullnose edge and backsplash. This results in a continuous surface which is both aesthetically appealing and functionally desirable, since it eliminates exposed seams, open joints and raw laminate edges.

Figure 2: Postformed Plastic Laminate

Postforming details with large radii can be done with most commercial laminates. Smaller radii requires the use of thinner postform-grade laminates produced by most major laminate manufacturers. The laminate is heated to a specific temperature, bent over and adhered to a radiused substrate. Postformed countertops are usually fabricated in long lengths in a shop and cut to length in the field.

Postforming is well suited for straight lengths of countertop, such as credenzas in conference rooms and countertops in break rooms and copy/print rooms. Most laminate is available in 30", 36" and 48" wide sheets, so single sheets can cover a 24" or 30" deep postformed countertop, including bullnose edge and backsplash, without a seam.

[1]January, February, March 2015, News to Use articles, https://www.orf.od.nih.gov/policiesandguidelines/pages/drm_news_to_use.aspx

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

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

DRM Chapter 13: Aseptic Production Facilities

A major DRM revision, Revision 1.0, was published on February 13. The major addition is Chapter 13, *Aseptic Production Facilities*. This new chapter addresses the complexities and unique processes needed in design, construction, operations and maintenance of an Aseptic Production Facility (APF).

Successful APF projects require continuous and collaborative effort from project initiation to the end of the facility life cycle. NIH's APFs produce therapeutic and diagnostic products for human use, inclusive of those required to follow current Good Manufacturing Practice (cGMP) regulations, aseptic processing (for those manufacturing biological products) and for the production of Phase-I and II clinical trial products (including pharmacy compounding of sterile products). Chapter 13 references sections of the DRM when the criteria are the same as other NIH facilities; however Chapter 13 contains requirements specific to APFs which do not directly fit within the scope of other DRM sections.

The purpose of Chapter 13 is to establish minimum criteria for NIH APFs to ensure that patients receive products of appropriate strength, identity, quality, purity, and other factors related to patient safety. Chapter 13 provides requirements to mitigate risks where the facility can have a direct or indirect impact.

Risks

Failure to adequately design, build, and operate APFs under-control can result in the contamination of products, threatening patient and worker health and safety. Due to the level of risk, there are significantly higher and more stringent requirements for APFs compared with typical research laboratories.

Statutes, Regulations, Standards and Guidelines

APFs are highly regulated facilities with specific statutes, codes, standards, regulations, and guidelines based upon the product being produced and the locations where the products are administered (e.g. extra-jurisdictional enforcement may be applicable).

Above and beyond these requirements are Good Engineering Practice (GEP) and cGMP which are, at their core, driven by risk analysis.

Process Changes

APFs are challenging to design, build, commission, validate (qualify and certify) and operate. Unlike much of the DRM, which focuses on basic design requirements, Chapter 13 includes the exhaustive and highly prescriptive documentation requirements that APFs demand. Extensive attention is given to the context-specific definitions of Statement of Requirement (SOR), User Requirement Specification (URS) and Basis of Design (BOD). Commissioning, qualification and validation requirements take on new dimensions in APF projects through the Validation Master Plan (VMP). Many of these documents are subject to change control, which is a formalized process for authorizing changes to specific documents.

Robustness, Resilience and Readiness

The purpose of the heightened scrutiny under which APFs are designed and operated is patient protection. APFs in which drugs and biologics are manufactured must achieve and maintain the requisite cleanliness and operating environments. APFs are subject to regular, thorough cleanings with a protocol of aggressive chemical agents which require all material used in construction be appropriately selected, detailed and installed to resist degradation. Typically a cleaning may involve a process called a triple cleaning, involving three successive applications, each with a different chemical agent.

Due to their critical nature and cost of operation, APFs are uniformly intolerant of downtime and disruption of operations. Risk assessments and Standard Operating Procedures (SOPs) must identify and address points of failure and scenarios which have an impact on operations. An example of failure is a pressure reversal, which allows less clean air to migrate towards areas which have more stringent ISO classifications or induces cross contamination. If this was to occur the APF would have to be taken off-line for triple cleaning and testing before being allowed to resume operations.

These facilities are regularly monitored by specially trained, dedicated staff to identify out of specification conditions, and then, in accordance with SOPs, develop and institute Corrective and Preventative Action Plans (CAPAs).

Contents of Chapter 13

Chapter 13 includes the following sections:

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Light Gauge Steel Wall Framing

Most non-loadbearing interior walls are framed with light gauge steel framing. DRM sections 4.3.1.1 and 4.3.2.1 provide minimum gauges for steel framing for office and laboratory walls at 22 and 18 gauge respectively. As noted in the commentary, these are minimums, and not to be used in all conditions. Due to the widely variable uses, configurations and performance requirements of laboratory facilities it is incumbent on the designer to determine the appropriate gauge and detailing for each application.

Performance Considerations

Interior framing serves many purposes besides holding up wall finishes, including:

Acoustics. Acoustic performance is essential for many functions, including offices and conference rooms, patient confidentiality, and vivariums. Related to acoustic performance is the transmission of vibration which is important with sensitive equipment and animals. The DRM sets minimum Sound Transmission Class (STC) ratings for wall assemblies of 50 for functionally separate areas and 60 for animal holding rooms. These values are minimums which should be assessed relative to the facility's function and may have to be exceeded to address specific program requirements. The gauge, spacing and detailing of the framing may have to be modified to meet the required STC rating.

Containment. For many types of labs the wall finish system constitutes the containment barrier. The integrity of the finish system, which can be a high performance coating or an applied panelized material like fiberglass reinforced plastic (FRP), is dependent on the integrity of the underlying wall system. A wall which moves or deflects can transmit that movement into the finish system, which can result in cracks or open seams and loss of containment. A maximum acceptable wall deflection should be determined and the wall framing designed accordingly.

Support of Shelving, cabinetry and equipment. The DRM specifies that laboratory shelving be designed for a capacity of 50 lb. per linear foot for a 12" deep shelf, and proportionally greater for deeper shelves. For a wall with tiers of deep shelving that could translate into hundreds of pounds of load per linear foot of wall. Wall framing must be detailed to support the maximum design wall loading, including asymmetrical lateral loading. In Addition to shelving, equipment which may be heavy, vibrating or sensitive may also have to be supported. Strapping must be provided as specified in DRM 4.3.1.2B.

Pressurization. All labs are required to be pressurized relative to the corridor, and some labs have cascading pressure between rooms that can result in substantial relative pressure differentials. Walls must be designed to withstand pressure without excessive deflection or cracking of finishes. During failure-scenario testing the pressure may increase substantially beyond the design steady-state conditions.

Shielding. Some laboratory walls incorporate electromagnetic, x-ray or other types of shielding. Shielding can be on the surface of the wall or incorporated into the structure of the wall. Shielding consultants will advise whether frame walls are appropriate and how they must be detailed.

Utilities. The designer needs to have a full awareness of the utilities located within a wall. Utilities such as piping and conduit may be less than 3 5/8" in size, but require a greater depth due to supports or connectors.

Fire Ratings. In addition to other requirements, walls required to be fire rated must be designed to the criteria of a UL design for the appropriate rating.

To perform as required the components and detailing of a steel frame wall must be carefully selected. One basic consideration is whether the studs can end above the finished ceiling or whether they must extend to the structure above. Fire ratings, STC rating, load capacity and deflection must all be considered.

Stud Design. A major factor in stud design is deflection. In most cases deflection should be limited to L/240, but less deflection may be required to maintain finish integrity. A number of gypsum board and steel framing manufacturers provide deflection tables for studs, but these do not account for the loading and performance requirements of laboratory buildings.

The performance of steel wall framing can be increased in a number of ways, including:

Increase stud depth. Although 3 5/8" is the minimum DRM-allowable depth for standard walls, studs are available in a range of depths of 6" and greater.

Decrease stud spacing. Although 16" is the minimum DRM-allowed spacing, studs can be spaced at 12".

Increase stud gauge. Stud gauge can be increased beyond the minimum 18 and 22 gauges.

Stiffener channels. Wall stiffness can be increased by installing stiffener channels through the steel stud knockouts or otherwise reinforcing the studs.

Summary

The performance needs of laboratory wall framing systems should be determined and documented as a project requirement. Framing should be designed to address these requirements, not solely based on DRM minimums or standard deflection tables.

'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

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