NIH DESIGN REQUIREMENTS

DESK GUIDE

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The National Institutes of Health

Division of Technical Resources

Office of Research Facilities

The formulae $\frac{\partial \rho \bar{U}_i}{\partial t}+\frac{\partial}{\partial x_j}(\rho \bar{U}_i \bar{U}_j)=-\frac{\partial \bar{P}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu \frac{\partial \bar{U}_i}{\partial x_j}\right)+g_i(\rho-\rho_0)$ *state of the art* $\frac{\partial \rho \bar{U}_i \bar{U}_j}{\partial x_i}=\frac{\partial}{\partial x_i}\left[\left(\mu+\frac{\mu_t}{\sigma_\kappa}\right)\frac{\partial \kappa}{\partial x_i}\right]+(C_1-C_{1RNG})\frac{\varepsilon}{k}(P+C_3G)-C_2\rho\frac{\varepsilon^2}{k}$ $\frac{\partial \rho \bar{U}_i \varepsilon}{\partial x_i}=\frac{\partial}{\partial x_i}\left[\left(\mu+\frac{\mu_t}{\sigma_\varepsilon}\right)\frac{\partial \varepsilon}{\partial x_i}\right]+C_1\frac{\varepsilon}{k}(P+C_3G)-C_2\rho\frac{\varepsilon^2}{k}$ $\frac{\partial \rho \bar{U}_i \bar{T}}{\partial x_i}=\frac{\partial}{\partial x_i}\left(\lambda\frac{\partial \bar{T}}{\partial x_i}-\rho\overline{u_i t}\right)$ $\frac{\partial \rho \bar{U}_i k}{\partial x_i}=\frac{\partial}{\partial x_i}\left[\left(\mu+\frac{\mu_t}{\sigma_k}\right)\frac{\partial k}{\partial x_i}\right]+P+G-\rho\varepsilon$ $\frac{\partial}{\partial x_j}(\rho \bar{U}_i \bar{U}_j)=-\frac{\partial \bar{P}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu\frac{\partial \bar{U}_i}{\partial x_j}-\rho\overline{u_i u_j}\right)+g_i(\rho-\rho_0)$ $-\rho\overline{u_i u_j}=\mu_t\left(\frac{\partial \bar{U}_i}{\partial x_j}+\frac{\partial \bar{U}_j}{\partial x_i}\right)-\frac{2}{3}\rho k\delta_{ij}$ *for building biomedical research facilities.*

USE & PURPOSE

The Design Requirements Manual (DRM) Desk Guide has been developed to assist designers, researchers, Project Officers, Contract Officers, and other stakeholders involved in the development and operation of National Institutes of Health (NIH) facilities to assist with navigating the requirements and guidance established within the NIH, Division of Technical Resources (DTR) DRM 2016. The Desk Guide is not meant to replace the full, unabridged DRM nor should it be used as a standalone document for design of NIH facilities.

The DRM has been developed by the Division of Technical Resources over many years; its development has involved professionals from industry, academia, and government. This diverse group includes designers, architects, engineers, researchers, veterinarians, maintenance staff, biosafety specialists, and others, all with expertise in a variety of disciplines and unique insights into the complicated design, construction, and functional issues involved in building NIH facilities. The DRM represents cutting edge design guidance and standards which support the NIH mission.

Any questions, comments, or suggestions about the DRM or DRM Desk Guide can be submitted to the Division of Technical Resources by contacting the Chief of Standards and Policy at drm@mail.nih.gov.

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Chapter 1

Chapter 1, Administration, covers many fundamental aspects of facility design at NIH. Research facilities are unique among building types and require significant planning and expertise to build and operate. Safety of the facility's occupants and the general public is paramount; therefore, it is crucial for designers and stakeholders to understand the risks as well as mitigation measures necessary. Many important decisions must be evaluated by a project's stakeholders to determine the best design for both the researchers as well as the research itself.

Section 1.1: General Administration

- DRM Application
- DRM Organization
- All technical requirements, drawings, and standards shall be coordinated amongst disciplines.
- Feedback on DRM to be submitted to drm@mail.nih.gov.
- The A/E shall use latest editions of referenced codes and standards.
- Guiding Principles from HHS:
  - Environmental and Functional Needs
  - Safety Health and Security
  - Economy
  - Conservation and Resources
  - Preservation of Historic and Cultural Resources
  - Sustainable Design
- In cases of conflict between codes and standards the most stringent shall apply.
- Permits / Inspections
- Geographic / Local Issues

Section 1.2: Required Codes and Standards

- The listed codes and standards and referenced throughout the DRM shall be considered part of the requirements of the DRM.
- Where it is unclear which set of requirements is applicable, consult the Authority Having Jurisdiction (AHJ) for direction.
- Projects in Maryland must comply with the Code of Maryland Regulations (COMAR) unless otherwise noted.
- Section 1.2.1 Required Codes and Standards
- Section 1.2.2 Additional Guidance
- Contact information for Office of Research Facilities Development and Operations / Office of Research Services

Section 1.3: Definitions

- The definitions in the DRM must be read in association with relevant definitions given in any other appropriate and applicable laws and regulations, and similar Government-wide requirements.
- Section 1.3.1 List of Definitions

Section 1.4: Measurement of Space

- Measurement Details & Calculations:
  - New Construction
  - Renovations & Additions
  - Leases
- Net Assignable Area Definition
- Rentable Area Definition

Section 1.5: Project Design Review

- General Guidance for Reviewing Projects
- Variance Request Procedures
  - Alternates equivalent or superior to requirements
  - All requested variances within a discipline to be submitted as a single package
  - Technical supporting data must be submitted
  - Variance submission does not guarantee acceptance
  - 10 working day review period after submittal
  - All variance to be submitted by completion of design

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development phase
- Design submission requirements
- Roles and Responsibilities:
  - Architectural / Engineering Services
  - Project Officer
  - NIH Technical Review Staff

Section 1.6: Project Cost Monitoring and Control

- Programmatic Requirements
- Cost Monitoring Procedures
- Estimate Requirements

Section 1.7: Value Engineering

- Design Contract Value Engineering (VE)Procedures
  - Sustainable Design
  - Schedule
  - Value Engineering Proposal (VEP) Requirements
- Construction Contract VE Procedures
  - Contract Thresholds
  - Sustainable Design
  - Documentation
  - Evaluation of Proposal
- VE Regulations
- VE in Research Facilities

Section 1.8: Sustainable Design

- The policy for sustainable and high performance buildings applies to all buildings under the control of the NIH.
- Projects of all sizes should pursue sustainability goals to the maximum extent feasible and document within the Basis of Design.
- Comprehensive Approach
- Sustainability Policy & Compliance
- HHS Guiding Principles for New Construction, Major Renovations, and Leases

Section 1.9: Accessibility

- Federal facilities must comply with standards under the Architectural Barriers Act Accessibility Standards (ABAAS)
- Guidance and Information

Section 1.10: Commissioning

- The level or scope of Cx for any single project shall be determined by the complexity of the project.
- The NIH requires Commissioning (Cx) for all projects including new buildings, renovations, and expansions.
- NIH Cx Requirements
- Cx Process During Different Phases:
  - Programming, Conceptual Design, Schematic, Construction Documents, Bidding, Construction, Acceptance, Endurance Test, and Warranty Phases
- If the facility is a BSL-3 and/or ABSL-3, the facility shall be validated by DOHS. Commissioning of the laboratory systems will be observed by the DOHS/ Safety Engineering Activity (SEA) group.

Section 1.11: Environmental Management and Radiation Safety

- General requirements and specific goals for managing environmental issues
- Applicable Federal Laws:
  - Clean Air Act
  - Clean Water Act
  - Hazardous Materials Transportation Act
  - National Environmental Policy Act
  - Resource Conservation and Recovery Act
  - Safe Drinking Water Act
  - Toxic Substances Control Act
  - Worker Safety Requirements
- Common Safety Issues
- General Hazardous Substances Receiving, Storage, Staging, and Handling Criteria
- Bulk Storage Facilities / Above-Ground Storage Tanks
- Decommissioning
- Radiation Safety

Section 1.12: Integrated Pest Management

- General requirements and goals for managing pest

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issues on NIH campuses
- Integrated Pest Management
  - Facility Design
  - Structural Repairs
  - Sanitation
  - Monitoring
  - Communication
  - Record-Keeping
  - Pest Control
  - Program Evaluation
  - Safety
  - Quality Assurance
  - Early Involvement
- Facility Design Elements
- Pest Management Consultation, Design Review, and Program Support

Section 1.13: Security Requirements and Procedures

- Division of Physical Security Management (DPSM) Roles and Responsibilities
- Security Requirements and Application
- Security Document References
- Procedures (Planning through Construction)
- Miscellaneous Security Requirements
- Disclosure of Sensitive Data

Section 1.14: Inspection, Acceptance, Activation, and Occupancy

- Covers transition from construction phase to beneficial use and occupancy
- Critical Facility Risk Assessment and Certification
- Inspections and Acceptance
  - Quality Control, Responsibility for Conformance, Inspections and Testing, Work Adjustments/Acceptance, Contract Requirements, Basic Warranties, Adjustments of Basic Warranty, Manufacturers', Subcontractors', and Suppliers' Warranties
- Occupancy
- Operations & Maintenance Manuals

Section 1.15: Common Engineering Systems' Requirements

- Covers issues generally applicable to engineering systems and may be specialized within research facilities
- Common Engineering Requirements / Issues
  - Minimizing Disruptions, Redundant Arrangements, Protection from Catastrophic Failure, Planning for Future, Extra Capacity, Biosecurity, Service Access, Coordination of Plans, Penetrations, Abandoned Infrastructure
- Preservation of Service
- Technical Requirements of Systems Planning
- Supplemental Requirements for Animal Research Facilities
  - Coordination with Program, Humane Care, Controlled Access, Exposed and Out of Reach Utilities, Barrier Facilities, Pipe Routing
- Supplemental Requirements for High Containment Facilities
  - Coordination with Program, Maintenance Access, Access Control, Material Selection & Edges, Penetrations, Sealants, Envelope, Waste, Communicatio n & Operation Issues, Exposed Piping, Access Panels
- Section 1.15.6 Risk Assessment, Systems Failure & Disaster Mitigation
- Failure Corrections and Root Cause Analysis
- Contractor Qualifications

ADMINISTRATION

The National Institutes of Health

Division of Technical Resources

Office of Research Facilities

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Chapter 2

The purpose of planning and programming is to identify and document factors to ensure that the design will be efficient, responsive to scientific objectives, suited for investigative staff and a long-term asset for NIH. The goal is to gather information and define project objectives, space requirements, and other critical functional criteria. Development of a detailed, comprehensive program document in the early stages of a project provides a solid, rational basis on which subsequent decisions and developments are based.

Section 2.1: Research Laboratory Predesign

- Integrated Planning & Design Stakeholders:
  - Executive Oversight
  - Users
  - Architects/Engineers
  - Safety
  - Commissioning Agent (CA)
  - NIH groups: DTR, DFP, DEP, DOHS, DRS, DFM, DFS, UEB, DFOM, DPSM, CIT, ADRB, OHPE, CCOFM, TMB, etc.
- All projects must conform the applicable NIH master plan.
- Project Program & Parameter Considerations:
  - Boundaries, Utilities, Current Program, Safety, Hazardous Materials, Building Integrity Guidelines, Sustainability, Budget, Schedule and Phasing
- Programming Data Collection Tools
  - Exhibit 2.1, Research Facilities Program Questionnaire
- Documentation of Predesign
- Laboratory Planning
  - Considerations for Staffing, Space Requirements, Functional Relationships, Circulation, Workplace Enhancement, Flexibility, Occupational Health and Safety, and the Laboratory Type
- Figure 2.1.3.3 shows an example of relationship diagrams within and Animal Research Facility
- Predesign Deliverable Requirements

Section 2.2: Research Laboratory Design

- Organizational Issues
  - Functional Zoning
  - Interrelationships
  - Blocking & Stacking of Program Elements
  - Efficiency Assessment
- Operational Issues
  - Circulation
  - Workflow
  - Logistical Support
  - Security
  - Occupational Safety
- Infrastructure Issues
  - Capacities, Location, and Size of Primary Utility Systems
  - Utility Distribution Methodology
  - Maintenance Access Methodology
  - Redundancy/Emergency Utilities
  - Future Load Capacity
  - Security
  - IT and Communications
  - Leak and Flood Prevention
- The laboratory module is the fundamental organizational basis of a laboratory building
- Laboratory services shall also be distributed on a modular basis
- Primary Laboratories, Open and Closed Labs, and Support Laboratories
- Personnel Support Area
  - Considerations for Offices, Lobbies, Locker and Shower Areas, Conference Rooms, Storage Areas, Break Areas, Interaction Areas

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- Considerations for Circulation
  - Security, Logistics, Ghost Corridors
- Building Operation Areas
  - Housekeeping, Material Handling Areas, Shipping and Receiving Areas, Hazardous Material Waste Rooms

Section 2.3: Animal Research Facility Predesign

- Applies to Animal Biosafety Level 2 Research Facilities
- All Animal Research Facilities (ARFs) shall comply with the latest edition of *The Guide for the Care and Use of Laboratory Animals*.
- Consider Infrastructure and Schedule and Phasing Issues
- Data Collection Tools:
  - User Questionnaire (Exhibit 2.2)
  - Animal Census
  - Animal Health Status
  - Equipment
  - Standard Operating Procedures (SOP)
- Documentation Requirements
- Animal Research Facility Planning Considerations
  - Location, Space Requirements, Contamination Control, Functional Relationships, Circulation, Workplace Enhancements, Flexibility, Utility Systems
- Risk Assessment and Biosafety Level Criteria
- Animal Holding Room Considerations
  - Population, Caging Types, Species Separation, Barrier Suites, Noise, Vibration, Floor Drains
- For a typical cage wash relational diagram see Figure 2.3.4.2
- Required Storage Areas:
  - Feed Storage, Bedding Storage, Cage Storage, Soiled Cage Marshaling, Supply Storage, Bulk Detergent Storage
- Requirements for specialized spaces and ARF areas:
  - Animal Intake and Quarantine, Necropsy, Surgical Suites, Insectaries, Aquatics, Animal Imaging, Behavioral Suites
- Plan and Program Deliverables

Section 2.4: Animal Research Facility Design

- Organizational, Operational, and Infrastructure Issues:
  - Functional Zoning, Interrelationship of Functional Components, Relationship of ARF to other Building Functions, Blocking & Stacking, Circulation, Worflow, SOPs, Equipment Throughput, Logistical Support, Security, Occupational Safety, Utility Capacity, Utility Distribution, Maintenance Access, Vibration and Acoustic Control
- Modular Design Considerations
- Material and Finish Considerations
  - Smooth, impervious, easily sanitized details
  - Sealed penetrations
  - Partitions with suitable substrates
  - Wall protection
  - Water resistant, seamless ceilings
  - Floors capable of withstanding heavy abuse
  - Finishes resistant to degradation
  - Door sizes capable of accommodating racks
  - Easily sanitized and durable casework
- ARF Security Requirements
- Animal Holding Room Requirements
  - Caging & Equipment Coordination, Lighting, Environmental Monitoring and Control, Plumbing, Animal Drinking Water
- Receiving / Quarantine Rooms Requirements
- Storage Requirements
- Janitor's Closet Requirements
- Cage Wash Area Requirements
  - Cage Processing, Clean and Dirty Rooms, Construction, Plumbing, Cage Wash Equipment, Chemical Storage, Cage Repair Shop
- Corridor Requirements
- Vertical Transportation Requirements
- Loading Dock Requirements
- Surgical Suite Requirements
- Insectaries Requirements
- Aquatic Holding Room Requirements
- Animal Imaging Requirements
- Necropsy Requirements

PROGRAMMING & PLANNING

The National Institutes of Health

Division of Technical Resources

Office of Research Facilities

The formulae for building state of the art biomedical research facilities.

- Behavioral Suite Requirements
- Administrative Area Requirements
- Utility Systems Requirements

Section 2.5: Biocontainment Facility Predesign

- Applies to BSL-3 and ABSL-3 Research Facilities
- Principles of Biosafety
  - › Primary Barrier
  - › Secondary Barrier
- Experienced Design Team
- Predesign Guided by Risk Assessment
- Consider Master Planning Issues
- Project Parameters
  - › Risk Assessments, Special Studies, Community Relations, Infrastructure, SOPs, Regulatory Requirements, Budget
- Data Collection
  - › Containment Entry & Exit Procedures, Security and Biosecurity Requirements, Waste Management, In Situ Decontamination, Facility Shutdown Requirements, Maintenance Requirements, Cage Processing, Animal Use, Animal Procedures, Carcass Disposal, Agent Transport and Storage Requirements, Facility Maintenance, General Operational Issues, Emergency Procedures, Commissioning and Certification Requirements
- Documentation Requirements
- Biocontainment Facility Planning
  - › Location Considerations
  - › Space Requirements
  - › Functional Relationships (See Figure 2.5.3.3 (A) and 2.5.3.3 (B))
  - › Containment Zone
  - › Circulation
  - › Flexibility
  - › Utility Systems
- Select Agent Program Actions
- Decontamination Considerations
- Security Requirements
- Specialty Areas
  - › Aerobiology, Imaging, Large Animal Facilities, Insectaries
- Planning and Programming Deliverables

Section 2.6: Biocontainment Facility Design

- Conceptual Design Considerations
  - › Organizational Issues
  - › Operational Issues
  - › Infrastructure Issues
- Modular Design Considerations
- Facility Design Requirements
  - › Exterior Envelope
  - › Partitions
  - › Floors
  - › Ceilings
  - › Penetrations and Sealants
  - › Doors, Frames, and Hardware
  - › Windows
  - › Access Panels
  - › Casework
  - › Equipment
  - › Signage
- Security Requirements
- Design Documentation

The formulae for building biomedical research facilities. The state of the art

Chapter 3

NIH facilities are developed to provide environments conducive to the pursuit of research. Important aspects of this environment are site utilities, site improvements, and landscaping. Site utilities, including steam, chilled water, storm, sanitary sewer, and other underground services, are vital for the safe, efficient, and reliable operation of NIH facilities. Site improvements, including roads and parking lots, sidewalks, and other constructed site elements, are important to the smooth flow of people and vehicles on NIH campuses. Landscaping is an important aspect of NIH facilities because of its impact on both the visual appeal of the campuses and the support of native species and ecosystems.

Section 3.1: Site Civil Design

- Comply with Codes and Standards listed in Section 1.2
- Master Planning & Design Principles
- Local Requirements and Standards:
  - Maryland Department of Transportation State Highway Administration (MDOT SHA)
  - Washington Suburban Sanitary Commission (WSSC)
  - Montgomery County Department of Transportation
  - Maryland Department of Environment (MDE)
  - The Federal Emergency Management Agency (FEMA)
- Design Documentation
  - Proposed Site Plan
  - Existing Conditions Site Plan
  - Site Development Plan
  - Sediment Control Plan
  - Site Utility Plans
  - Storm Water Plans
  - Site Improvement Plans
  - Landscape Plans
  - Specifications
  - Estimates

Section 3.2: Site Development

- Site Development Design
  - Grading Plans
  - Stockpiling Requirements
  - Sediment and Erosion Control
  - Storm Water Management
- Local Requirements
  - MDE Thresholds and Review

Section 3.3: Site Utilities

- Utility Piping Standards
- Site Utilities Design Requirements:
  - Service Life, Reliability, Setbacks, Location, Protection, and Damage Mitigation, Utility Disruption & Restoration, Field Confirmation, Inspection & Testing, Profiles, Manholes, Corrosion Resistance, Corrosion Resistance, Geotechnical Investigation, Excavation, Shoring Systems, Utility Connections, Benchmark, Sizing, Quality Control & Assurance, Pipeline Stress / Flexibility, Direct Buried Insulated Systems, Materials, Computer Modeling
- Identification of Underground Utilities
- Local Requirements
- Additional Water Systems Requirements
- Additional Gravity Sewer Requirements

Section 3.4: Site Improvements

- Site Improvement Requirements
- Pavement Composition (Table 3.4.1)
- Parking & Paving Requirements
- Sidewalks, Curbs, and Gutters
- Loading Docks and Delivery and Service Areas
- Parking
- Snow Removal
- Screening
- Fences
- Site Furnishings

Section 3.5: Landscaping

- Landscape Design
  - Planting
  - Landscape Lighting Design
  - Landscape Maintenance and Pest Management
  - USDA Plant Hardiness Zones
- Tree Requirements & Considerations

The formulae $\frac{\partial \rho U_i}{\partial t} + \frac{\partial}{\partial x_j}(\rho U U_j) = -\frac{\partial P}{\partial x_i} + \frac{\partial}{\partial x_j}\left(\mu \frac{\partial U_i}{\partial x_j}\right) - \frac{2}{3}\rho k \frac{\partial}{\partial x_i}$ *state of the art* $\frac{\partial \rho U_i U_j}{\partial t} = \frac{\partial}{\partial x_i}\left(\left(\mu + \frac{\mu_t}{\sigma_k}\right)\frac{\partial k}{\partial x_i}\right) + P + G - \rho\varepsilon$ *for building* $\frac{\partial \rho U_i \varepsilon}{\partial t} = \frac{\partial}{\partial x_i}\left(\left(\mu + \frac{\mu_t}{\sigma_\varepsilon}\right)\frac{\partial \varepsilon}{\partial x_i}\right) + C_1\frac{\varepsilon}{k}(P + C_3 G) - C_2\rho\frac{\varepsilon^2}{k}$ *biomedical research facilities.*

Chapter 4

Architecture provides the safe, efficient, and pleasant environment necessary for a facility's operations. This includes comfortable and attractive workspaces, flexible and efficient laboratories, and all required common, support, and ancillary spaces. NIH architectural requirements include high-performance exterior envelopes, rational and efficient arrangements of spaces, use-appropriate finishes and furnishings, and all of the supporting services and infrastructure needed for highly complex scientific programs.

Section 4.1: Exterior Envelope

- Design of Exterior Envelope:
  - Site Conditions
  - Building Use
  - Energy Performance Goals
  - Environmental Issues
  - Other Factors (Maintenance, Aesthetics, etc.)
- General Requirements
  - Moisture Migration, Air Infiltration, Thermal Resistance, Joint Sealants
- Exterior Walls
  - Compatibility of materials & aesthetics
  - Design based on standards, specifications, and publications for system selected
  - Design to control exterior & interior elements
  - Vapor retarders
  - Dewpoint analysis
  - Detailing for water
  - Air barriers & vapor drive determined
- Considerations for Exterior Cladding
- Consideration for Mechanical, Electrical, and Other Equipment on Exterior
- Masonry Considerations
  - CMU Backing Wall
  - Structural Metal Studs Flexure Requirements
  - Anchorage Requirements
- Curtain Wall Requirements
- Wall Thickness Considerations
- Roofing Considerations
  - Compatibility / Durability, Warranties, Standards, Wind Resistance, Roof Penetrations, Roof-Mounted Equipment, Slope, Overflow Protection, Future Vertical Expansion, Accessibility, Fall Protection, Lightning Protection
- Window Considerations
  - Operable Windows, Appearance / Function, Standards, Flashings / Sealants, Sill Slope, Blast Protection
  - Glazing Considerations
  - Provisions for Window Cleaning
  - Windows for Historic Buildings
- Window Covering Considerations
- External Shading Considerations
- Mock-Ups
  - Testing, Protocols, Seismic & Environmental Considerations

Section 4.2: Doors

- General Requirements (All Doors)
  - Minimum Door Sizes
  - Consider Unusual Heights or Widths
  - Durability Requirements
  - Exposure to Harsh Environment
  - Differential Pressures
  - Access Control
  - Visual Access
  - Hardware Requirements
- Life Safety Requirements
- Physical and Electronic Security Requirements
- Requirements for Exterior Doors
  - Aluminum Storefront Doors & Frames

- Steel Doors & Frames
- Requirements for General Interior Doors & Frames
- General Hardware Requirements
- General Glazing Requirements
- Laboratory Door Requirement
  - Minimum Door Sizes
  - Direction of Swing
  - Signage Requirements
  - Frame & Construction Requirements
  - Hardware Requirements
  - Glazing Requirements
- Animal Research Facility Door Requirements
  - Construction Requirements
  - Minimum Door Sizes
  - Door Swing
  - Security Requirements
  - Hardware Requirements
  - Glazing Requirements
- Specialty Doors, Frames, and Hardware Requirements

Section 4.3: Partitions

- General Partition Requirements
  - Minimum wall board thickness and stud gauge
  - Mold & Flood Resistance
  - Furring, Bracing, & Blocking Requirements
  - Finish Levels
  - Wall Protection
  - Life Safety
  - Structural Requirements
  - Physical Security
  - Acoustic Requirements
- Laboratory Partition Requirements
  - Minimum Stud Gauge
  - Strapping Heights (Figure 4.3.2.1)
  - Acoustic Considerations
- ARF Partition Requirements
  - Construction Considerations
    - Durability
    - Chemical Resistance
    - Wet Area Conditions
  - CMU Partitions
    - Block Texture, Surface, & Sealing
  - Concrete Substrate Surface Requirements
  - Wall Protection & Corner Guards
  - Sanitary & Pest Considerations
  - Acoustics

Section 4.4: Interior Finishes

- General Requirements for Finishes
  - GSA P100
  - Building Integrity Guidelines
  - Life Safety, Durability, and Sustainability Considerations
- Minimum Requirements
  - Floors:
    - Floor Flatness & Slip Resistance
    - Floor Moisture Protection
    - Sheet Flooring Installation
    - Carpeting Minimum Requirements
    - Wall Base
  - Walls:
    - Painting Requirements
    - Decorative Wall Finishes
  - Ceilings:
    - Acoustic Tile Requirements
    - Gypsum Board Requirments
    - Open Ceilings
    - Moisture Considerations
    - Access Panels
- Laboratory Finishes
  - General Requirements
    - Smooth
    - Sanitizable
    - Resistant

- Floor and Base Requirements
- Wall Finish Requirements
- Ceiling Requirements
  - Height
  - Acoustic Tile Requirements
  - Open Ceilings
  - Moisture Considerations
  - Gypsum Board
- Chair & Furnishing Finishes

- ARF Finishes
  - General Requirements
    - Abuse Resistance
    - Mock-Up Requirements
    - Installer Qualifications
  - Floor & Base Requirements
    - Monolithic & Nonporous
    - Seamless
    - Integral Cove Base (Figure 4.4.4.2.2)
    - High-Performance Resinous Floors
  - Wall Finish Requirements
    - Coating Systems
    - Panelized and Sheet Wall Systems
  - Ceiling Requirements
    - Coating Systems
    - Suspended Panel Systems
  - Access Panels
- Aseptic, BSL-3, ABSL-3, and Similar Facilities
  - Compatible with Agents
  - Record of Performance
  - Life-Cycle Considerations
  - Panelized Composite Systems
  - High-Performance, Reinforced, Multi-coat Resinous Paint Finishes
  - Testing Requirements

Section 4.5: Casework and Millwork

- General Requirements
  - Shelving Height Restrictions
  - Structural Requirements
  - Pest Control
- General Use Casework and Millwork
  - Construction
  - Hardware
  - Plastic Laminate Requirements
- Laboratory Casework
  - Material, Finish, Modularity, Countertop Dimension and Materials, Knee Space, Electrical Receptacles, Panels, and Shelving Requirements
  - Flammable Storage Cabinets
  - Task Lighting
  - Sink Requirements
  - Detailing
  - Safety Devices
    - Eyewashes
    - Emergency Showers
    - Fire Extinguisher Cabinets
- ARF Casework
  - Minimize Fixed Casework
  - Cleanable
  - No Concealed Spaces
  - Coutertop Material Considerations

Section 4.6: Furnishings and Equipment

- General Requirements
  - Coordination
  - Ergonomic
  - Comply with Accessibility
  - Sustainable
  - Structural Considerations
  - Documentation Requirements
    - Design Phase
    - Construction Phase

- Transportation Routes
- Sanitation Considerations
- Mail Distribution
- Fire Extinguishers
- Systems Furniture
  - Flame Spread Requirements
  - Responsibility
  - Wiring
- Chemical Fume Hoods
  - Specifications
  - Placement
  - Construction
  - Testing Requirements
- Biological Safety Cabinets
  - Selection
  - Placement
  - General MEP Requirements
- Autoclaves
  - Location
  - Finish & Lighting
  - Exhaust
  - Pressure
  - Seal
- Ice Machine & Dry Ice Bin Considerations
- Specialized Equipment Considerations
- Flammable Storage Refrigerators / Freezers
- Explosion Proof Refrigerators / Freezers
- ARF Furnishings
  - Cage Wash Equipment Considerations
  - Fume Hoods & BSCs
  - Downdraft Tables
  - Lockers
  - Benches
  - Gowning Storage

Section 4.7: Vertical Transportation

- Elevator General Requirements
  - Elevator Speed and Type (Table 4.7.1.4)
  - Elevator Lobbies and Groupings (Table 4.7.1.5)
- Escalators
- Wheelchair Lifts

Section 4.8: Loading Docks

- General Requirements & Considerations (Section 4.8.1)
- Waste-Handling Considerations (Section 4.8.2)
- Animal Research Facility Loading Dock Requirements (Section 4.8.3)

Section 4.9: BSL-3 and ABSL-3 Biocontainment

- Barrier Considerations
- Exterior Envelope
  - Security Considerations (Access, Blast / Intrusion Resistance, Protection)
- Doors
  - Exterior Door Considerations
  - Interior Door Considerations
- Partition Construction Requirements
- Interior Finish Requirements
  - Floor, Wall, and Ceiling Finishes
- Penetrations and Sealants
- Access Panel Requirements
- Casework Requirements
- Decontamination
- Autoclaves
- Equipment
  - Service
  - Bioseals
  - BSCs
  - Liquid Decontamination
  - Pass Through Cabinets
  - Dunk Tanks
- Signage
- Mock-Up Requirements
- Commissioning Requirements
- Certification Requirements

Chapter 5

Structural design is crucial to a building's performance, and key to its utility as a research facility. Critical assessment of proposed structural framing should reflect future needs. The structural design of a facility influences all other components and therefore should be well planned and coordinated with all design disciplines.

Section 5.1: Structural Design

- Codes and Standards
  - "Control of Cracking in Concrete Structure" ACI 224R. American Concrete Institute
  - Specifications for Structural Concrete, ACI 301. American Concrete Institute
  - "Code Requirements for Environmental Engineering Concrete Structure" ACI 350 for American Concrete Institute
  - "Concrete Structures for Containment of Hazardous Materials" ACI 350.2R American Concrete Institute
  - "Minimum Design Loads for Buildings and Other Structure" ASCE 7
  - "Building Code Requirements for Structural Concrete" ACI 318. "American Concrete Institute
  - Unified Facilities Criteria – UFC 4 – 023-03 "Design of Buildings To Resist Progressive Collapse"
  - Unified Facilities Criteria – UFC 4 – 010-01 (Department of Defense) DoD Minimum Anti-terrorism Standards for Buildings
  - "International Building Code" International Code Council, Inc.
  - PTI TAB 1-06: Post-Tensioning Manua
  - AISC Steel Design Guide Series II – Floor Vibrations Due to Human Activity
  - AISC Steel Construction Manual American Institute of Steel Construction. American Institute of Steel Construction
- Prevention of Progressive Collapse
  - Guidance from UFC 4-023-03
- Below Grade Extension Requirements
- Equipment Access
- Geotechnical Reports
- Concrete Finished Floor Level
- Post-Tensioned Concrete Requirements
- Primary Structural Support
- Dynamic Framing Systems
- Formwork Requirements
- Recycled Materials in Concrete
- Additional Requirements
  - Shoring
  - Benchmark
  - Roof Live Load
  - Column Lines & Scales
- Design Documentation Requirements

Section 5.2: Structural Loads

- Load Requirements
  - Minimum Live Loads (Table 5.2.1(A))
  - Live Load Reduction
  - Dead Loads
  - Superimposed Dead Loads (Table 5.2.1(B))
  - Hanging Loads
  - Wind Loads
  - Seismic Loads
  - Snow Loads
- Vibration Limits (Table 5.2.2)
- Thrust Block Requirements

Section 5.3: Animal Research Facilities

- Structural Bay Sizing
- ARF Locations
- Vibration Control
- Floor Slab Depressions
  - Floor Depressions / Topping Slab Requirements
  - Floor Areas Subject to Salt Water
- Progressive Collapse
- Security

Section 5.4: BSL-3 and ABSL-3 Biocontainment

- Codes and Standards
- Standards of Quality
- Prevention of Progressive Collapse
- Serviceability Considerations
- Load Requirements
- Deflection Limits (Table 5.4.6)
- Drift Requirements
- Importance Factors
- Shielding

Chapter 6

HVAC Systems for all NIH facilities shall be designed to meet the following minimum criteria: Maintain space temperature and humidity at the required set points and filtration at prescribed levels, be reliable, maintainable, redundant, while operating without interruption and with a proper control system, meet federal sustainable design and energy conservation standards and mandates, maintain prescribed space background noise and vibration criteria generated by HVAC systems and provide ventilation to remove fumes, odors and airborne contaminants.

Section 6.1: Heating, Ventilation, and Air Conditioning Design

- Guidance is provided for various references to different types of facilities throughout NIH.
- Heating and cooling load calculations shall be performed for all NIH projects to right-size all HVAC equipment.
- Minimum equipment loads shall be used in design load calculations, see Section 6.1.3.1 for specific requirements.
- See Table 6.1.4 for Animal Population Densities
- For Outdoor Design Conditions at the NIH Bethesda Campus see Table 6.1.7.
- HVAC Systems for laboratories and ARFs:
  - Working Environment
  - Dedicated Air
- Central HVAC systems shall be provided with multiple AHUs and EFs to provide N+1 redundancy.
- HVAC for Animal research facilities (ARF):
  - Independent
  - Redundant N+1
  - Polymerase Chain Reaction Rooms
  - TEM and SEM Microscope Rooms
- ARF surgical areas:
  - Independent HVAC
  - N+1 Redundancy
  - Cage wash areas
  - Surgical Facilities
    - Operating/Surgical Rooms
    - Sterile Supply Room
    - Animal Preparation Room
    - Post Recovery Room
  - Animal Procedure Room
  - Animal Neurobehavioral Laboratory
  - Imaging Rooms
  - Animal Isolation
  - Feed Storage Rooms
- For laboratory indoor design conditions see Table 6.1.9.1.
- For indoor design conditions for animal holding areas see Table 6.1.9.2.
- Minimum outdoor air ventilation rates for laboratory spaces are defined in Section 6.1.11. Higher rates will be used as required to meet loads.
- See Table 6.1.11.3 for ventilation rates in animal facilities. Good conditions within the animal environment tend to minimize unintended stress on animals.
- Relative room pressures shall be designed to control directional air flow.
  - Once Through Airflow Principle
  - Negative Vs. Positive Air Pressure
  - Amount of Supply Air Flow
  - Special Laboratories
- Animal facilities shall be designed for: air quality; room acoustics supply air temperature; supply air humidity; airflow quantities; air velocity; air diffusion within the space.
  - Adaptation/Protection
  - Infectious Populations
  - Conventional Facilities
  - Barrier Facilities

- Anterooms
- Dirty Elevator Shafts
- Special Pressurization Requirements

- All supply, exhaust and return air must be ducted.
  - See Section 6.1.14 for specific requirements for various space uses.
- Anterooms must have:
  - Controllable supply and return.
  - Differential pressure sensors: anteroom to lab; anteroom to corridor.
- Program equipment must be identified early in design phase
  - Comply with all standards
  - Equipment requirements must be maintained
  - Mechanical systems must be design to meet equipment requirements
- DRM provides multiple sections of requirements for location of supplies and returns associated with BSCs.
  - Requirements for Class II type A and B Cabinets
  - Dedicated Exhaust Terminals
  - Exhaust Air Grille Requirements
  - HEPA Filtration
  - The use of BSCs
- DRM provides multiple sections of requirements for location of supplies and returns associated with Fume Hoods.
  - Testing requirements
  - Performance ratings
- See Section 6.1.18 for design for mechanical and electrical rooms.
- HVAC, electrical and plumbing systems shall be zoned.
- All systems must be designed for maintainability.
- Heating at the Bethesda campus shall be provided from the central plant steam.
- Cooling at the Bethesda campus shall be provided from the central chilled water plant.
- Every exhaust air system is unique and must be specifically designed.
  - Flex Connections at fans
  - Fume hood exhaust ductwork/fans
  - Exhaust air discharge stack
  - Dampers
  - Controls
  - Snorkel Exhaust systems
  - VAV Fume Hoods
  - Exhaust Redundancy
  - Animal Exhaust Air systems
  - Necropsy and pathology exhaust systems
  - Isolation room exhaust systems
  - Exhaust filtration
  - Canopies used for wet exhausts.
- HVAC systems shall be designed and equipment selected using best practices to achieve optimal energy-efficiency and water conservation, without compromising the research program, safety, reliability, or the requirements within the DRM, code, and referenced standards.
- Systems shall be designed and materials selected to minimize potential for loss of service and to limit impact on laboratory research and ARF operations in the event of disaster or malfunction.

Section 6.2: Supply Air Handling Systems

- Labs/ARFs AHUs and EF sized to provide future requirements per Section 6.2.1, requirements for administrative areas are also given.
- All ductwork to be designed, fabricated and installed in accordance with Table 6.2.2 (A) and Table 6.2.2 (B).
- Duct lining is not permitted in air handling equipment and ductwork
- Flexible ductwork may be used for branch duct connections in low-pressure supply and air transfers systems
- Requirements for locations of outdoor air intakes are defined in Section 6.2.3. Included in the requirements are:
  - Clearances from exhaust/contaminant sources of all types.
  - Distances above ground level and away from any site

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elements. Specific distance clearances are provided.

- Exhaust discharge requirements are defined in Section 6.2.3, including clearances from roof elements, minimum velocities, and manifold requirements and allowances.
- Air Dispersion Modeling used to calculate the minimum separation between intake and exhaust.
- Administrative and general use AHUs designed to meet ASHRAE Standards 62 and 90.1 or International Mechanical Code (IMC).
- Large conference rooms or assembly areas, not be connected to routine office space on the same air handling system
- Air handling units for laboratory and animal research facilities to meet Section 6.2.4.2.
- Air filtration requirements are defined in Section 6.2.5. Included in this section are:
  - Minimum final filters on laboratory supply air.
  - Requirements for ARFs final filters
    - Including ARF surgical rooms.
  - Clinical facility filters:
    - Including prefilters and final filters.
    - Surgical facility filters.
- Fan filter units not recommended unless duct system not capable of overcoming HEPA filter pressure drop.
- Humidification systems to be used to maintain space relative humidity.
- Steam Injection Humidifiers may be located in AHU or within the supply duct.
- Humidifiers must have a high limit humidistat downstream of manifold.
- Adiabatic humidifiers may not be used in laboratories, ARFs, administrative facilities or clinical facilities.
- Clean steam humidification shall only be used where specifically required by user.
- Variable and constant air volume centrifugal and plenum fans serving multiple zones shall be equipped with VFDs.
- All fans in a manifold
  - To be identical
  - Have isolation dampers.
- No motors in the airstream of fans serving laboratories and ARFs.
- All motors
  - Premium high efficiency
  - Selected to optimize system efficiency.
- Motors power factor ratings when equipment is operating at the design duty based on motor sizes are called out in Section 6.2.8.
  - All motors to be variable speed shall be rated for such use.
- See Table 6.2.8.1 for Minimum Full-Load Nominal Efficiency of Electric Motors
- Each prime motor and standby motor in a system shall have independent VFDs.
- Equipment must be matched to the VFD
- VFDs must have a manual bypass independent of the drive.
- VFDs must be as close as practical to the motor served
- All VFDs must be tested at job site under full load conditions.
- Emergency generator exhaust
  - Do not create excessive back pressure
  - Shall not be connected to any other equipment.
- See Section 6.2.9 for design and construction requirements for emergency generator exhaust piping.
- Emergency generator room design:
  - Remove heat and fumes created by the generator and accessories.
  - Maximum space temperature and rises in the space temperature shall not be exceeded.
- A safe and continuous fuel oil piping and storage system. See Section 6.2.9.2.

Section 6.3: Piping Systems

- Hydronic heating and cooling systems shall be closed loop with forced recirculation.
  - Only cooling tower systems can be open loop systems.
- Hydronic heating and cooling systems shall be variable flow control with VFDs on the pumps
- Piping systems shall be designed to be parallel piping arrangements

The formulae $\frac{\partial \rho U_i}{\partial t} + \frac{\partial}{\partial x_j}(\rho U_i U_j) = -\frac{\partial P}{\partial x_i} + \frac{\partial}{\partial x_j}\left(\mu \frac{\partial U_i}{\partial x_j}\right) - \frac{2}{3}\rho k \delta_{ij}$ *state of the art* $\frac{\partial}{\partial x_j}(\rho \overline{U_i U_j}) = -\frac{\partial P}{\partial x_i} + \frac{\partial}{\partial x_j}\left(\mu \frac{\partial U_i}{\partial x_j} - \rho \overline{u_i u_j}\right) + g_i(\rho - \rho_0)$ *for building* $\frac{\partial \rho U_i \varepsilon}{\partial x_i} = \frac{\partial}{\partial x_i}\left(\left(\mu + \frac{\mu_t}{\sigma_\varepsilon}\right)\frac{\partial \varepsilon}{\partial x_i}\right) + (C_1 - C_{1RNG})\frac{\varepsilon}{k}(P + C_3 G) - C_2 \rho \frac{\varepsilon^2}{k}$ $\frac{\partial}{\partial x_i}(\rho \overline{U_i H}) = \frac{\partial}{\partial x_i}\left(\lambda \frac{\partial \overline{T}}{\partial x_i} - \rho c_p \overline{u_i T}\right)$ $\frac{\partial \rho U_i k}{\partial x_i} = \frac{\partial}{\partial x_i}\left(\left(\mu + \frac{\mu_t}{\sigma_k}\right)\frac{\partial k}{\partial x_i}\right) + P + G - \rho \varepsilon$ *biomedical research facilities.*

- Provide balance/flow metering at each floor and every main branch in a hydronic system.
- Every hydronic system shall have:
  - Drain isolation valve and each branch and riser.
  - Expansion compensation from expansion tanks or diaphragm tanks.
  - Air elimination
  - Positive pressure at the highest point of each system.
- Hydronic systems to be filled from domestic water direct connection with isolation valve, backflow preventer and pressure relief valve.
- See Section 6.3.2 for pipe sizing requirements.
- Pumping stations shall have:
  - Two primary pumps and one stand by pump
  - All pumps shall be sized the same
  - Pumping capacity of each pump increased by 20% for future capacity.
- The maximum speed of a centrifugal pump shall be per Section 6.3.3.
- Differential by pass control valves located at the pump are not permitted.
- Hydronic coils must have a method of water balance and control.
  - Larger coils must be equipped with pipe mounted flow meter fittings.
  - Large hydronic coils must have thermometers and pressure gauges on the supply and return of each coil.
- Terminal control valves on a VFD system
  - 2-way modulating control valves on return side of the coils
  - Balancing valve on return
- Run out piping to terminal coils shall be of minimum diameter, see Section 6.3.2.
- All heating water systems on the Bethesda Campus shall be generated from the central plant steam system.
- Primary equipment in the heating water systems provided as N+1.
- Heat exchangers on heating water systems shall be ASME rated shell and tube type with minimum future capacity.

- Preheat coils at the Bethesda Campus shall have a minimum of glycol solution per Section 6.3.5.
- NIH Bethesda Campus cooling is by connection to the campus central chilled water distribution system.
- Chilled water temperature based on entering water temperature per Section 6.3.6.
- Primary, secondary and tertiary chilled water distribution systems to be used at NIH Bethesda Campus.
  - See Section 6.3.6 for definitions and uses
  - See Figure 6.3.6 for a diagram of a building tertiary system.
- Special areas requiring precise temperature control or that must remain in constant operation due to their critical nature may be supplied with a dedicated water chiller.
- Chilled water for dedicated equipment such as MRI equipment, lasers and electron microscopes
  - Dedicated chiller
  - Dedicated water to water heat exchanger connected to the campus chilled water.
  - Once through potable water is prohibited except in emergency situations.
- Steam at the NIH Bethesda Campus is generated from the campus central plant at pressures per Section 6.3.7.
  - Domestic hot water
  - Heating hot water
  - Humidification
  - Miscellaneous equipment such as autoclave cage washers, etc.
- Steam pressure classifications at NIH: Low Pressure; Medium Pressure; High Pressure.
- Operational pressures of various equipment see Section 6.3.7.D.
- Steam connections to buildings at NIH Bethesda to be made by extension of existing steam tunnels into each building.
- Steam pressure reducing stations (PRV) shall be located as close to the building entrance as possible.
  - Separate reducing stations throughout the building to be avoided.

biomedical research facilities.

- Sizing and construction of PRV stations see Section 6.3.7.1.
- Steam condensate return units:
  - Shall not be used for steam pressure reduction
  - Designed for pump replacement without reduced operation of the unit.
- For steam trap applications see Table 6.3.7.3.
- All steam, steam return and condensate systems shall be designed for a minimum pipe and fitting rating specified in Section 6.3.7.4.C.
- See Table 6.3.7.4 for Steam and Steam Condensate Piping Criteria.
- Steam safety relief valves shall be piped separately and discharge at a minimum distance above the building roof per Section 6.3.7.4.L.
- Protection of 100% outdoor air coils:
  - Freeze protection thermostats to provide complete coil coverage
  - Leak detection required in and around air handling units
  - Coils must be properly sized
  - Preheat control valves must be properly sized.
- For all requirements for piping materials, fitting materials and joint types for all systems including specialty water systems and plumbing systems see Exhibit 6.3.
- Minimum pipe sizing for any equipment connection shall be per Section 6.3.9.2.A.
  - Piping reductions may only be taken at the connection point to the equipment.
- Horizontal piping hanger support spacing:
  - Shall meet minimum spacing requirements between hangers and changes in horizontal direction per Section 6.3.9.3 unless part of a designed system.
  - Unless part of a designed system.
- Vertical piping support:
  - Shall be supported at each floor and changes in vertical direction per Section 6.3.9.3.
- Mechanical and electrical equipment, and piping to be provided with labeling and identification
  - See Section 6.3.9.6.

Section 6.4: Thermal Insulation Systems

- Thermal insulation used: To limit heat transfer to and from surfaces, provides personal protection, prevent condensation, moderate freeze protection, noise control, fire safety
- Insulation requirements for piping and ductwork to meet or exceed ASHRAE Standards 90.1 and 90.2.
- Insulation for use at NIH
  - Shall meet minimum flame spread and smoke development ratings per Section 6.4.1.B.
  - Installed by skilled and certified mechanics per the Department of Labor, Bureau of Apprenticeship and Training.
- Insulation not to be applied until all testing and inspections have been completed.
- Insulation shall be provided on all piping, equipment and valves for personal protection.
- Insulation exposed to weather shall be covered in metal jackets made of aluminum or 304 stainless steel.
- See Section 6.4.1.1 for systems that do not require insulation.
- See Exhibit 6.4 for insulation materials and thicknesses on piping, equipment and ductwork.

Section 6.5: Noise and Vibration

- The objective of the acoustical design of HVAC systems: Ensure spaces are not adversely affected by the HVAC system related noise and vibration.
- Animal facilities:
  - Excessive noise can create distress in animals
  - Excessive or sudden noises during construction should be avoided.
- Effect of noise from exterior equipment on neighboring properties must be considered during designing.
- Noise transmitted through duct systems is a common sources of acoustical issues. Properly size ductwork, fans, equipment.
  - Sound attenuation must be considered in the acoustical design of a facility.
- Duct lining may not be used to address acoustical, or

any other issues, in NIH facilities.

- Maximum Requirements for Noise Levels are in Table 6.5.2.
- Laboratory equipment such as compressors and vacuum equipment with high noise levels must consider acoustical treatment.
- See Section 6.5.7 for specific requirements for ductwork and piping isolation.
- Maximum allowed noise levels from mechanical equipment are specified in Section 6.5.5.
- See Table 6.5.7 for Vibration Isolator Types and Minimum Static Deflection for Machinery.

Section 6.6: BSL-3 & ABSL-3 Biocontainment

- The ventilation system is central to the biocontainment facilities' performance and operation. This section includes additional requirements to be included in BSL-3 and ABSL-3 facilities, as defined in the HHS/CDC/NIH Biosafety for Microbiological and Biomedical Laboratories (BMBL).
- Ventilation system is designed:
  - To maintain directional air flow from areas of lesser to greater contamination.
  - System to be designed to prevent any air reversal from areas of contamination.
- All major equipment including air handlers, fans, HEPA filters, pumps, chillers and boilers will designed with an N+1 redundancy.
- Primary containment equipment must maintain negative pressurization even when it is out of service or during equipment failure.
- Any exposed piping or ductwork must be designed to with stand cleaning agents to be used within the facility.
- Any penetration of piping or ductwork through the BSL-3 containment barrier must meet the requirements in Appendix L, Sealant Table.
- BSL-3 and ABSL-3 supply air handling systems must be independent.
- Supply air ductwork downstream of isolation dampers must be welded stainless steel.
- Laboratory quality industrial grade air terminals shall be used for each room.
- BSL-3 laboratories air changes per hour shall be per Section 6.6.3.
- Ventilation of ABSL-3 shall be per Section 6.6.4
- Systems designed to maintain minimum differential pressure between pressure zones.
  - Visual indication of pressure differential must be provided
- Anterooms required between corridor and biocontainment space
  - Negative to the corridor
  - Positive to the containment room
- BSL-3 and ABSL-3 provided with dedicated independent exhaust air systems.
- Exhaust ductwork to be:
  - Welded, Gas tight, Stainless steel, Minimum 18 gauge, capable of decontamination
- HEPA filtration recommended for each exhaust system.
  - If not required by the user the system should be design to be expandable to handle HEPA filtration in the future.
  - Filters to be located as close as possible to the containment barrier penetration.
- Bubble tight isolation dampers to be located to isolate rooms or sections as needed for decontamination.
- Stainless steel exhaust canopy hoods, provided above autoclave doors.
- Valves and connection devices serving BSL-3 autoclaves, located outside the containment barrier.
- Design VFDs serving BSL-3 to restart into a coasting motor without damage.
- All HVAC equipment and controls required to maintain containment to be connected to emergency power.
- All design phases of BSL-3 and ABSL-3 shall be reviewed by NIH DTR and DOHS.
- See Section 6.6.18 for inspection and testing requirements of HVAC systems for BSL-3 and ABSL-3 facilities.

Chapter 7

The Building Automation System (BAS) plays an important role in control, operation, and energy efficiency of NIH facilities. The BAS design, including detailed sequences of operation, should be provided during the facility design. This chapter includes design elements for control system design/specification, control schematics, topology, and infrastructure. System level requirements such as air handling systems, supply and exhaust air systems, etc. as well as component level requirements (i.e. converters, heat exchangers, exhaust air stacks, etc.) are included. Component quality / accuracy / tolerance for various applications and software/software set up requirements are provided.

Section 7.1: Design Considerations

- BAS shall be a network configuration.
- BAS includes central servers, local building workstations, field panels, controllers, sensors and actuators.
- Provisions for additional controls points future growth.
- Existing BAS is evaluated by A/E early in the design phase to determine feasibility to implement current BAS design standards.
- Coordinate with operating organization and get approval on point naming convention.
- A/E shall develop a clear SOW for the control / information as part of their design.
- Develop the scope for the IT interface requirements for the BAS.
- Compatibility between new and existing systems must be coordinated by the A/E.
- Design documentation to include specifications, control system I/O points and sequences of operations.
- Design specifications and drawings: Delineate limits of responsibility / requirements for all listed items.
- System Architecture definition including single line diagram.
- Control system vendor calculations are provided during the submittal phase to ensure necessary speed of response for the controls.
- Detailed control schematics and written sequences of operation are required.

Section 7.2: Infrastructure

- BAS network topology, data communication protocols and control network components.
- Redundancy requirements are obtained using data storage at the local supervisory panel level and database servers.
- Any new BAS system(s) must be fully integrated with the existing BAS installations.
- The control vendor shall define all necessary gateways, switches and routers to efficiently segment/architect the LAN.
- Where multiple manufacturer control devices are used, they must be accessible and modifiable from the single supervisory system. A/E is encouraged to use as few manufacturers as practical.
- DRM requires client/server architecture, the BAS shall include a server computer to store all the information required by the BAS and manage client access to that server. See Section 7.2.5 for server requirements.
- Operator Workstations have additional monitoring and reporting requirements for Animal Research Facilities.
- Configuration of Control LAN's includes consideration of control panel locations and access for service.
- Operators workstations are only to facilitate human interaction with the BAS and do not execute automatic control.
- Intranet remote connections capability via Ethernet intranet is required and subject to NIH security conditions for access.

Section 7.3: Applications

- Building Level Requirements.
- Section defines the general physical I/O requirements and sequences for various applications.
- Building level Input / Output (I/O) points.
- Rooms with differing requirements are to be zoned separately.
- Common laboratory requirements - temperature and

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pressure independent volume control.

- Fail positions fail to last condition/position in most spaces. Animal holding rooms failure positions shall be coordinated with the veterinarian.
- Animal Holding Rooms – Monitored points are required to maintain AAALAC accreditation. See Section 7.3.4. for points list.
- Microscope rooms – Microscope manufacturer may require tight control of temperature necessitating PID control using RTD or thermistor type temperature sensors.
- NMR / MRI suites – inclusive of oxygen sensor(s) in event of cryogen venting to space.
- Freezer rooms shall be controlled by the BAS. Where LN_2 is utilized must include oxygen level monitoring and emergency exhaust activation.
- Environmental rooms controlled by packaged control systems and monitored by the laboratory environmental monitoring system.
- Controls must be closely coordinated with the space requirements for temperature, humidity, gas detection and oxygen sensors as needed to maintain conditions and coordinate with manufacturer requirements.

Section 7.4: Systems-Level Requirements

- This section describes the control loops that form the system and how those control loops operate.
- Supply and Exhaust Systems
  - Individual Air-Handling Units (AHU) shall be controlled by one single controller with stand-alone capability.
  - Interlock is required between supply and exhaust air systems where supply works in concert with exhaust.
  - BAS shall provide for smooth start-up and staging.
  - All AHU's shall have two-pole freeze stats with manual reset.
  - Supply air pressure controlled to maintain optimal control and minimum energy consumption.
  - Headered (multiple AHU and exhaust) systems have additional control requirements.
  - Airflow monitoring is required for all supply and exhaust systems per Section 7.4.2 and on critical environments required by program.
  - Exhaust systems shall be controlled by one single controller with stand-alone capability.
  - Interlock exhaust with the supply air system is required where exhaust works in concert with supply.
  - Exhaust system pressure is limited until supply system status is confirmed to prevent excessive negative pressure.
  - For VAV systems Laboratory Exhaust, system stack velocity must be monitored where bypass is not used to maintain stack at constant volume.
- Steam Systems
  - Modulating control valve are required and shall have equal percentage or liner characteristic.
  - Where steam modulation is used as the only means of capacity control, two valves shall be provided in a 1/3 to 2/3 arrangement to improve controllability.
  - Clean steam (where required) - BAS shall monitor and alarm high and low pressure from the boiler and steam generator, in addition to high / low water levels.
  - Where packaged controls are provided for clean steam generator BAS will monitor an overall alarm condition.
- Hydronic Systems
  - At least one key point of static pressure shall be monitored and alarmed for low system pressure.
  - Supply and return temperatures must be monitored
  - Flow monitoring is required on most systems
  - Provide reset control of source equipment where feasible. See Section 7.4.7.1 for reset strategies for heating systems.
  - Redundant / staged pumps are automatically started, staged and rotated and sequenced.
- Chilled Water Systems CHW (Central Plant)
  - Connection and control designed to maximize facility temperature differential and reliability, and avoid any adverse impacts (pressures / temperatures) on the distribution system.
  - Building CHW control valve(s) shall be selected for high turn-down ration and proper control over plant-pressure differentials.
  - Temperature and flow monitoring are required on the campus and building sides of the system.
  - Process CHW systems shall be controlled by a primary controller, which alarms and automatically switches to back-up source upon loss of primary source.
- Plumbing, Gas, Fuel and Electrical Systems

- Alarm sources shall provide an indication of fault criticality.
- Booster pumps / packages – BAS shall monitor and alarm on supply pressure and temperature.
- Sump pump and lift stations the BAS shall at minimum include level switches to monitor sump / basis level alarms.
- Packaged drainage neutralization systems shall provide a general alarm to the BAS system. Where BAS controls the system an analog pH sensor is required.
- The BAS shall monitor the level in any primary fuel oil storage tanks and alarm in case of transfer pump failure.
- Laboratory air systems - BAS shall monitor and alarm the supply air pressure and dew point.
- Vacuum Systems - The BAS shall monitor and alarm the main vacuum system and where HEPA filtration is installed shall monitor and alarm filter differential pressure.
- Emergency power transfer switch position shall be monitored and consideration for input to control / restart certain critical controllers
- Central UPS are monitored for basic status (i.e. common alarm, battery voltage).
- Automatic lighting control systems shall be interfaced with the BAS when required by the program.

Section 7.5: Component-Level Requirements

- The BAS shall confirm fan isolation dampers are open prior starting and monitor status through a current switch.
- For minimum fan / damper control points, see Section 7.5.2.1.
- Fans controlled by a VFD require hand-off-auto (HOA) switches on the VFD.
- Fans controlled by a VFD, see Section 7.5.2.2 for minimum fan control points.
- On VFD applications interface between the BAS and fan VFD shall be hard wired.
- A HOA (Hand off Auto) switch shall be provided on pump motor starter or VFD.
- BAS will annunciate pump failure and hand operation.
- Pump status shall be monitored through appropriate current switch.

- See Section 7.5.4 for minimum required control points on pumps.
- AHU coil control shall be via modulating valve(s) and include a temperature sensor immediately downstream of the coil before other heat transfer elements.
- See Section 7.5.5 for minimum required control points for coils.
- Sensors within an AHU shall be averaging unless they are after a well-mixed condition.
- Preheat Coil Set point shall be dynamically adjusted.
- Preheat Coil control valve shall be modulating normally open when used for general heating and normally closed when used for animal facility.
- Glycol preheat Coil: supply temperature to the coil shall be reset based on outside air temperature.
- Steam Preheat Coils: shall be controlled by 1/3 to 2/3 valve arrangement.
- Chilled water control valve shall fail open for 100% outdoor air units, coils serving computer rooms or other spaces that preliminary need cooling.
- Chilled water control valve shall fail close for recirculating systems (standard occupied zones).
- General space reheat valves shall fail in the last position or open, animal holding rooms fail in the last position or closed, computer room fail closed.
- See Section 7.5.5.3 for applications that floating type actuators for reheat coils shall not be used.
- Converters require properly sized valves in a 1/3 to 2/3 arrangement.
- Where redundant Converters are required, provide automatic ability to isolate units independently
- See Section 7.5.6 for minimum required control points for converter.
- All humidifiers shall be provided with high humidity limit sensor(s) and automatic high limit cutout.
- Jacketed humidifiers require BAS control of the two position isolation valve on the steam supply.
- Packaged humidification systems shall have BAS monitor of common alarm(s).
- BAS shall monitor differential pressure status of each filter bank and provide indication of loaded filter condition.
- For all HEPA filter banks a pressure sensor (AI) shall be used in lieu of a pressure switch.
- Air Terminals

- VAV / CV terminals shall be pressure independent and fully DDC on secondary controllers (except critical applications, which are on primary controllers).
- Terminals damper fail position shall apply to the space/ component it is serving.
- VAV terminals serving fume hood shall be fast acting (full stroke < 2 second) electronic actuators.
- Fume hood controls shall meet control requirement mandated by NIH/ASHRAE 110 modified fume hood testing.
- VAV terminal boxes serving laboratories shall use devices to allow re-zeroing of the pressure sensor without stroking the dampers.

- Fume Hoods
  - Fume Hood (FH) shall have flow monitors either provide by control manufacturer (VA) or by FH manufacturer (CAV)
  - Flow monitors shall include indication of safe air flow with audible and visual alarms that activate when face velocity is out of range and an emergency ventilation switch or button.
  - BAS shall monitor fume hood alarm condition, except that devices provided by the institute shall not be connected to the BAS
- Ducted BSCs
  - Exhaust flow from ducted BSC (B1/B2) cabinet shall be constant volume controlled by a dedicated laboratory grade terminal unit and can be on secondary controller.
  - Ducted BSC in a critical zone shall be controlled by the primary controller controlling that zone.
  - Where ducted BSC isolation damper on exhaust to allow for decontamination, the damper shall be monitored by BAS.
  - For a ducted BSC (B1 / B2), with factory provided exhaust pressure sensor to shut down the cabinet fan if there is a loss of building exhaust.
- Miscellaneous Terminal Units
  - Fan coil units (FCUs), unit heaters, etc. shall be fully DDC controlled by application specific secondary controllers.
  - FCUs with secondary drain pan sensors shall be alarmed to BAS.
  - Active chilled beam: Provide an instrumentation and control strategy to avoid condensation using both dew point calculation for critical locations and locally with condensate detection.
  - Active chilled beam: Provide a instrumentation and control strategy to avoid condensation in two stages:
    - Water temperature control based upon air dew point calculation for critical locations.
    - Locally in the room, using condensate detection to close chilled water valve.
  - Chilled water supply for temperature CB's must be actively maintained.

Section 7.6: Installation

- Defines requirements for controllers, sensors, software and components that make up the system.
- Temperature Sensors
  - Provide matched sensor pairs: where control sequence requires controlling to a temperature rise (building loop) and pair is used for calculating difference for use in sequencing and load calculations.
  - Acceptable room temperature sensors: platinum resistance temperature device (RTD), thermistor or integrated circuit
  - Single point duct temperature set point: sensor shall be type 316 stainless steel, sensing element shall be a platinum RTD thermistor or integrated circuit.
  - Averaging duct temperature sensors: sensing element shall be a platinum RTD thermistor.
  - Liquid immersion pipe temperature sensor: Sensing element for chilled water shall be platinum RTD.
  - Outside Air temperature sensors: sensing element shall be platinum RTD, thermistor or integrated circuit.
- Humidity, Pressure and Flow Sensors
  - Pressure sensors (Air static pressure and velocity transmitters): provide the smallest range feasible for the application.
  - Fluid flow sensors (< 2:1 Turndown): use an inline venture flow with DP transmitter.
  - Fluid Flow sensors (> 2:1 Turndown): use turbine flow meter, vortex shedding meter, magnet meter or for water ultrasonic flow meter per Section 7.6.5.
  - Airflow sensors: use a Pitot tube averaging grid.
  - Flow sensors: use hot-wire anemometer grid or vortex shedding grid stations.

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- Current Switches
  - Current Switches shall be provided for status indication of constant speed motors.
  - Current Switches shall be provided for status Variable speed motors.
- Control Valves
  - Control valve close-off pressures shall be specified to close off against extreme anticipated conditions and selected so that they are not oversized.
  - Control valves: BAS output to modulating valve shall be analog with exceptions of terminal reheat valves, fan coils and unit heaters may be floating or PWM when not serving critical spaces.
  - Steam control valves: shall be cage guided globe or plug valve with linear or equal percentage characteristic, modulating valves shall be sized for in excess of 75% of rated steam supply temperature.
  - Water control valves: modulating valves may be globe, ball or butter fly valves with equal percentage or linear characteristic.
- Control Dampers / Actuators
  - Control damper structural rating shall exceed maximum anticipated conditions such as fan dead head. Dampers shall be opposed blade.
  - Outside air dampers shall be low leakage with damper seals.
  - Standard VAV terminal damper control maybe floating or PWM when not serving critical spaces.
  - Actuators: Shall be electronic unless there is a compelling case for pneumatic. High torque damper actuators used for containment applications shall be pneumatic.
  - Standard electronic actuators shall be UL-873 listed. Where fail positions required provide spring return with adequate close-off force.
  - Fast acting electronic actuators for VAV terminals on fume hood and the associated tracking zone dampers.
  - Pneumatic actuators: heavy duty with stroke indication and spring return.
- Compressed Air System
  - Compressed air systems shall be limited to special cases where very large torque is required.
  - Air compressor shall be oil free using duplex compressors sized for < one-third duty cycle.
  - Where central plant compressed air is utilized, filtration and air drying is required for instrumentation air.
  - Where compressed air serves controls in critical facilitates, a primary and back-up source shall be provided.

Section 7.7: BSL-3 and ABSL-3 Biocontainment

- Controls and control sequences shall not reverse the air flow under plausible failure conditions.
- Control components shall be selected so that in any plausible failure scenario, the supply air flow rate will decrease more quickly than exhaust for negative containment spaces.
- Provide hard-wired interlock between supply and exhaust controllers.
- Zone terminal units' controllers shall be on uninterruptible and emergency power.
- Supply and exhaust systems shall be controlled by one single controller with standalone capability, units serving BSL-3 areas shall be controlled by a primary controller.
- Isolation damper closing rates shall be tuned to isolate the lagging system quicker than the leading system.
- Differential pressure monitors with alarm capability on critical containment zones shall be provided.
- Controllers shall have the capability to automatically restore their volatile memory upon loss of current.
- Where fireman's override controls are used the A/E shall consult with the DFM to determine the damper positions when override is activated.
- Mechanical systems shall include isolation dampers for decontamination.
- Anterooms shall be passively pressure controlled (fixed air flow offset) to create a required pressure differential
- Cross limiting loop shall be provided to prohibit excessive negative pressures from occurring.
- In BSL-3 / ABSL3 provide visual strobe alarm whenever any given space pressure becomes the reverse of intended pressure for more than 20 seconds or whenever the HVAC fails.

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Chapter 8

The purpose of this chapter is to address common requirements for safe and efficient design for all plumbing, fixtures, process piping systems, and special process piping systems and to provide general guidance to be used for specialty systems that may be unique or specifically designed for use in laboratory, animal research facilities (ARF) and other specialized program areas that are addressed on a specific project.

Section 8.1: Plumbing General Requirements

- Equipment sizing and capacity per Section 8.1.3
  - All high or constant demand loads
  - Independent of diversities shall be applied
- Multiple local services provisions are not acceptable in lieu central services.
- Major new services requires DTR approval per Section 8.1.3.2
- Operational throughput (system's capacity) shall accommodate worst case operational conditions
- Piping, fittings, and joint materials and methods shall be compatible with system application and shall be specified in accordance with Exhibit 6.3, Piping Designation, Material, Fittings, and Joints.
- Systems shall be designed for variability/flexibility.
- Design systems for optimal energy-efficiency and water conservation. Consider future system growth.
- Redundancy with individual VFD, per Section 8.1.3.4
- In Animal Research Facilities
  - Hand washing sinks shall be provided with hands-free operation
  - Animal drinking water shall be addressed as required in Section 12.2, Animal Drinking Water Systems
- Avoid bellows type expansion joints for any fluid deemed hazardous, use loops, guides and anchors, per Section 8.1.5.4.
- Pressure Reducing Valves (PRVs) can be staged to maintain capacity for essential building functions, per Section 8.1.7.
- In cleanrooms, a suitable quality control plan shall be developed and followed to ensure proper design and installation of any validated, sterile or cGMP type spaces in specs, per Section 8.1.8 for additional information.
- In shared Lab/Clinical crossover, spaces shall be designed for most-restrictive clinical function
- Control valves:
  - Shall be sized based upon engineering calculations
  - Sizing based on pipe line size is not acceptable
  - Instrumentation and controls shall be hard-wired
  - Wireless controls are not acceptable. See Section 8.1.9.
- Plumbing systems shall be fully commissioned including failure/recovery scenarios, per Section 8.1.13.
- Utility metering
  - For primary services at each building, from central plant or campus underground infrastructure
  - For makeup water Central cage wash area, see Section 8.1.14.

Section 8.2: Plumbing Fixtures and Equipment

- Stainless steel products shall be evaluated on weld quality, post-weld passivation, smooth surface profile, cleaning and re-passivation per Section 8.2.2.
- The Fixture Power Supply
  - Hydropower or lithium-type battery (only for conventional public toilet rooms or non-critical application)
  - Hard wired are preferred at all locations, per Section 8.2.8.
- Water closets shall be wall-mounted, flushometer-valve type, with an electronic hands-free flushometer, hard wired, and on standby power with manual flush override and shall designed for heavy commercial/industrial use, per Section 8.2.3.
- Urinals
  - Wall-mount or flush in-floor type with non-hold open mechanical manual flush override are acceptable when standby-power is not available
  - Waterless urinals are not permitted, per Section 8.2.4.
- Lavatory Sinks
  - Self-rimming/drop-in type are not acceptable
  - Materials including Stainless steel
- Food Service Sinks
  - NSF certified or approved equivalent
  - Sinks for sanitary applications shall be provided without overflows

- Dump Sink
  - Utility
  - Food Service
  - Autoclave
  - Other dumping of liquids, per Section 8.2.5.
- Faucets and spouts in lab and hand wash sinks:
  - Provide proper water flow rate ranges
  - Laminar flow or aerated streams
  - Continuous run-time or cycle time interval.
  - Floor mounted pedals are not accepted in ABSL-2, discouraged in BSL-2 areas or higher
- Water supply to sensor-activated faucets shall be tempered at the point of use, with a thermostatic valve provided at the fixture-supply connection and individual to the fixture being served, per Sections 8.2.6 and Section 8.2.7.
- Showers
  - Control valves shall be controlled by thermostatic or combination thermostatic and pressure-balance type where the upstream hot water supply includes duplex
  - Master thermostatic mixing-valve assemblies
  - Maximum outlet temperature and water flow at showers shall be limited
  - Provide with a floor (base) that includes a positive slope toward the drain, constructed of durable, impervious materials, per Section 8.2.9.
- Emergency Shower and Eyewash
  - Shall be available to serve each laboratory space/area where hazardous materials are handled, corrosives and other areas in accordance with 29 CFR 1910.151 and ANSI Z358.1
  - Flow alarm (emergency shower) shall be provided. The alarm shall provide local audible and remote alert
  - Floor drains shall not be provided for emergency showers that must be located within conventional labs per Section 8.2.10.
- Floor Drains are not required in janitor mop sink closets
- Drinking fountains and bottle fillers shall not be located in lab areas, per Section 8.2.12.
- Hose bibb/hydrants shall be provided
  - Within mechanical equipment rooms, kitchens, loading dock areas, accessible/flat roof tops, within or adjacent to planters for watering, and where necessary for maintenance and cleaning
  - In compliance with ASSE is required for exterior units and interior units per Section 8.2.13.

- Waste Disposers in any lab area shall be subject to review and approval of the Office of Research Facilities (ORF) and DOHS, per Section 8.2.14.
- Lab Sink
  - Materials
  - Wall-hung lab sinks are used in wet ABSL areas per Section 8.2.17.
- Labware washers shall be in full conformance with ASSE 1006 per Section 8.2.18 and Section 12.1.
- Fume Hoods
  - Water connections shall include atmospheric vacuum breaker mounted high, exposed on the exterior of the hood.
  - Internal vacuum breakers are not acceptable. Refer to Section 8.2.20.
- Hose Station
  - In-wall recessed outlet box to serve utilities for lab equipment such as indirect waste drain, water or other utilities
  - The box size, material and waste dimensions per Section 8.2.24.
- Floor drains are required where water may likely accumulate and create a hazard, and also where intensive wet cleaning and water spray operations are required, including but not limited to the following areas:
  - Kitchen areas, including serving lines
  - Mechanical equipment rooms
  - Toilet rooms with two or more flushometer operated fixtures or water closets
  - Shower or tub room including just outside of showers
  - Service corridors subject to wash-down, wet materials, or heavy traffic from exterior, such as loading dock areas and major ARF corridors
  - Non-human primate (NHP) and large animal areas
  - Cage wash areas
  - Where stainless steel drains/floor sinks are required, the entire drain body and grate shall be stainless per Section 8.2.26.

Section 8.3: Water Systems

- Cold Water Systems
  - Provide insulation as necessary to maintain water temperatures.
  - Where cold water systems exceeds maximum temperatures, a risk assessment is required for additional microbial control

- Water Distribution
  - A separate and distinct central laboratory/non-potable water subsystem shall be provided and distributed throughout the building
  - Source and isolated from the domestic water system with parallel backflow preventers, which have been sized and arranged to provide redundancy. See Table 8.3.4, Water Distribution.
- Piping shall be identified in a clear and unambiguous manner. Labeling of piping and systems shall follow NIH standards to provide consistent and uniform identification. See Exhibit 6.3.
- Each distribution system and all equipment and materials specified shall be to potable water standards. See Table 8.3.5, Water Distribution System Pipe Sizing.
- Piping systems shall be properly insulated. Refer to Section 6.4, Thermal Insulation Systems.
- Water Quality
  - Backflow Protection specific restrictions shall be as defined by the DRM. See Table 8.3.6, Backflow Protection.
  - Water quality to be maintained at very high levels. See Table 8.3.6, Backflow Protection.
- Emergency Shower and Eyewash
  - Fixtures shall be served from potable water systems per ANSI Z358.1 with backflow protection and proper identification
  - Water tempering is required in compliance with ANSI Z358.1
    - Tempered water systems cannot serve multiple floors or multiple buildings.
    - Tempered systems must be insulated to prevent heat gain in lines.
    - Tempered system must be looped to prevent dead legs
    - Tempering valves must be lockable
  - All emergency fixture water should be clearly marked per Section 8.3.7.
- Hot Water
  - Microbial control approach shall be approved by ORF and DOHS and may require a risk assessment
  - Temperature control shall be accurate over entire flow range
  - Hot water shall be heated, per Table 8.3.8, Minimum and Maximum Hot Water-Outlet Temperatures.
  - Hot water system temperature maintenance shall be provided for all systems through the use of continuous pumped circulation
  - Recirculation pumps shall be in parallel with redundancy per Section 8.3.9, Hot Water Circulation and Temperature Maintenance for additional information.
  - Requires BAS monitoring to alert deviation accepted range of the operating set point for multiple temperature zones
  - A maximum temperature set point may be provided per Section 8.3.10, Hot Water System Temperature Control and Over-Temperature Protection.
- Animal Research Facilities
  - Cage wash, and similar areas may be supplied from common laboratory water systems serving areas of equivalent biosafety level, except that extension directly from the potable water system shall be provided to all areas and functions for which potable water is specifically required
  - Appropriate backflow protection is required for hose stations per Section 8.3.11.
- Provisions to control scale shall be provided wherever the on-site water analysis demonstrates water supply conditions may be detrimental to long-term operation or impose excessive maintenance per Section 8.3.12.
- Quality Control
  - Systems shall be hydrostatically pressure tested with potable water maximum working pressure
  - System shall be flushed, adjusted, commissioned, and disinfected with approved materials and delivered water quality tested by qualified labs
  - All cross-connection control devices shall be tested, verified and recorded per Section 8.3.16.

Section 8.4: Drainage Systems

- For connections to the various systems for discharge compliance, refer to Table 8.4.1, Waste Discharge Classifications/Required System Connection.
- Waste that require any form of special treatment prior to discharge to public sewer systems shall be treated individually at each building.
- Waste Piping
  - Piping size shall comply with Table 8.4.5, Minimum Waste Piping Diameters.
  - Piping, materials, and joint methods shall comply with Exhibit 6.3.
  - Drains receiving wastes sufficiently cold shall refer to Exhibit 6.4.

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- Animal research facility (ARF) waste systems with proper slope and velocity
- Avoid locating cleanouts above or within sensitive spaces, fixed sensitive or hazardous equipment areas or risk associated with cleanout opening and subsequent waste clean-up issues would be hazardous per Section 8.4.6.
- Regardless of the provision of after-cooling arrangements, pipe materials for drainage systems receiving routine potentially high temperature waste shall be of materials and joint methods approved for high temperature waste systems per Section 8.4.7.
- Appropriate waste water cooling arrangements shall be provided. See Section 8.4.8 for additional information.
- Drainage systems including all connected lines shall be designed to flow by gravity wherever possible and the use of pumping systems shall be avoided
- Backwater valves shall be automatic and shall be provided for any drainage main that serves fixtures or equipment with a flood level rim per Section 8.4.9.
- Indirect waste and direct waste connections shall be provided per Section 8.4.10, Indirect Waste, Direct Waste, and Equipment Connections.
- Reliable electric time-clock actuated primers per Section 8.4.11, Trap Seal Maintenance.
- Waste System
  - Laboratory and other corrosion-resistant waste and vent systems shall be separate from the general sanitary waste and vent system and shall be provided in accordance with Section 8.4.13.
  - Waste from ARF areas shall be segregated from other non-ARF building areas to the extent possible
  - Waste with high solids may discharge as sanitary waste independent of other building areas and may bypass the pH treatment system after regulation compliance.
  - Waste from cage washers, tunnel washers, and cage wash areas shall discharge as lab waste through pH treatment systems per Section 8.4.14.
- Central pH Treatment Systems
  - Not automatically required in all laboratories; however, automatic monitoring systems are required in all lab and ARF buildings
  - pH system shall be on standby power
  - pH Systems to be sized without significant oversizing
  - Grinders to be provided in ARF waste streams
  - Shall be alarm to the BAS
  - Any omission of central pH treatment in a laboratory building shall be subject to approval of ORF and DEP. Refer to Section 8.4.15, pH Monitoring and Neutralization: General Requirements.
  - Waste streams with significant solid-matter load or significant pH challenges are better suited to the batch-type process, and for such applications continuous type systems are not acceptable. Refer to Section 8.4.15.2.
  - Continuous-flow active-type systems and batch-type systems duration shall be per Section 8.4.15.3.
- Fats, Oil, and Grease (FOG)
  - Waste pretreatment to effectively capture FOG is required for all food service
  - Health concerns dictate that grease traps and their maintenance requirements
  - An exterior gravity grease interceptor of not less than two compartments shall be designed and sized per Section 8.4.17.
- Oil–Water Separators/Interceptors
  - Separators/interceptors shall be provided to serve potential sources of non-food service based oil discharge.
  - Interior installation is not permitted except as approved by the DFM. Refer to Section 8.4.18.
- Condensate Line
  - Indirect waste pipe sizing and discharge requirements, see Table 8.4.19.
- Storm Drain
  - Storm systems shall be conventional atmospheric pressure gravity type.
  - Neither primary nor secondary roof drainage may spill from one roof area onto a lower roof. Refer to Section 8.4.20.
- Sump Pump
  - Sewage sump pumps
  - Lab waste sump pumps
  - Sanitary sump pump
  - Resistant to hydrogen sulfide gas and routine chemicals and cleaners.
  - Sewage and lab waste basins location
  - Redundancy
  - Storm pump
  - Refer to Section 8.4.21.
- Systems shall be fully inspected tested and commissioned. Refer to Section 8.4.22.

Section 8.5: Natural Gas/Fuel Gas Systems

- Natural gas shall be utilized as the primary fuel gas

source in NIH facilities.

- LPG may be used for remote buildings subject to approval of ORF and DFM for the application, and installation. Refer to Section 8.5.1.
- Interior Building Storage
  - › Distribution
    - » Fuel gas-piping distribution systems that serve laboratories shall be low-pressure systems
    - » Fuel gas piping systems shall be electrically bonded to a grounding electrode
    - » Each laboratory floor shall have an isolation valve that is quickly accessible for emergency shut-off
    - » Gas pressure control, regulation and venting
    - » Biological Safety Cabinets (BSC) fuel gas shall not be piped to biological safety cabinets
    - » Fuel gas piping systems shall be electrically bonded to a grounding electrode. Refer to Section 8.5.2.
  - › Testing
    - » Gas piping systems shall be blown clean free of debris and residual oil
    - » Testing shall be performed to ensure no cross-connections are present
    - » Fuel gas piping shall be tested in accordance with NFPA-54 (or NFPA-58 as applicable)
    - » Fuel gas systems shall be tested after all gas turrets have been installed. Refer to Section 8.5.3.

Section 8.6: BSL-3 and ABSL-3 Biocontainment

- General Requirements
  - › Plumbing services shall not be piped directly to any primary containment device without approval of the NIH, in accordance with the risk assessment, and provision of an approved, redundant backflow protection arrangement to isolate the connection from any other system
  - › Each pressurized piping penetration from outside the barrier into containment shall be provided with an isolation (shut-off) valve located outside the containment barrier serving only the BSL-3 area(s). Refer to Section 8.6.1.
- Potable Water System
  - › Water supply to BSL-3 spaces shall be isolated from other functions.
  - › Where the water supply is from the building general laboratory water system, a manufactured double-check valve assembly shall be utilized for containment barrier isolation
  - › Outlets requiring potable supply direct from the domestic potable water system (e.g., emergency eyewash, showers, and toilet room/shower fixtures located in containment) shall be isolated from other functions with backflow preventer
  - › An ASSE 1015 backflow preventer is adequate for serving only toilet room/shower-out room fixtures without hose-supplied outlets
  - › Backflow preventers are required for connections to high hazard equipment.
  - › Connections to tissue digesters
  - › Where softeners or other water conditioning devices are required, they shall be located upstream of backflow preventers, outside containment. Refer to Section 8.6.2.
- High Purity Water
  - › Purified water systems serving BSL-3 areas shall be completely independent of any clinical systems or other applications
  - › Point of use purified water production units, fed directly from the BSL-3 lab water and selected for the on-site water chemistry to deliver required water quality(s) is the preferred method of providing high purity water within BSL-3 spaces, and shall be utilized unless approved by NIH
  - › Central vs. point of use systems life cycle cost analysis
  - › Purified water systems shall not circulate between outlets
  - › Recirculation of fluids downstream of any backflow preventers back into the supply side is prohibited. Refer to Section 8.6.3.
- Animal Drinking Water
  - › Animal drinking water serving BSL-3 shall be completely independent of other containment levels
  - › Water supply serving animal drinking water treatment and distribution systems shall be taken directly from building potable water and the supply to the BSL-3 area system and shall be isolated from all other systems with a backflow preventer located outside the containment barrier per DRM
  - › Double-check valve assemblies may be provided downstream of BFP devices
  - › Production systems (RO, acidification, chlorination, etc.)
  - › Controls are located inside containment. Refer to Section 8.6.4.
  - › The use of disinfectant traps and hydrophobic filters in vacuum systems

- Filters utilized shall be at least HEPA efficiency for liquid and gas streams

- Vacuum Systems
  - Materials for vacuum system equipment, piping, seals, and components
  - Risk assessment
  - Point of use vacuum
  - Decontamination ports and manual drains shall be isolation valves and capped
  - Vacuum pump exhaust and vent lines approved per the facility risk assessment
  - For vacuum pumps requirements refer to Section 8.6.5.
- Compressed Gases
  - Gas cylinders location
  - Provision of fuel gas service within containment shall be avoided. Refer to Section 8.6.6.
- Veterinary Medical Gas Systems (VMGS)
  - Veterinary Medical Gas Systems (VMGS) for BSL-3 (ABSL-3) areas shall be completely independent of systems from areas outside BSL-3 containment and protected.
  - Portable VMGS cylinders dedicated for this purpose on an as-needed basis.
  - Filters
  - VMGSs alarm and alarm panels
  - Where all required procedures necessitating scavenging cannot be conducted within an approved ducted capture device, active scavenging shall be provided. Refer to Section 8.6.7.
- Critical Compressed Air/Controls
  - Redundancy
  - Standby power
  - Monitoring through BAS
  - Biohazardous contamination avoidance
  - Piping/tubing, joint connections materials. Refer to Section 8.6.8.
- Waste Systems
  - Venting, deep seal traps
  - Waste and venting systems for BSL-3 areas shall be zoned separately from other waste or vent streams
  - Effluent and decontamination. Refer to Section 8.6.9.
  - Piping Materials, fittings, shower drains, per Exhibit 6.3.
- Liquid Nitrogen and Cryogenic Fluids
  - Vacuum jacketing insulation
  - Oxygen monitors/sensors requirements. Refer to Section 8.6.10.
- Plumbing Fixtures
  - Sink faucets
  - Sink faucets shall be hands-free type that are either electric sensor operated and hard-wired to AC power
  - Water closet and trap
  - Hand-held showers shall not be utilized. Refer to Section 8.6.11.2, Showers.
  - Service sinks and faucet outlet
  - Floor drain/sinks within containment shall be avoided. Refer to Section 8.6.11.7.
  - Emergency fixtures. See Section 8.6.11.8.
- Filters
  - HEPA filters for gaseous piping systems
  - Filter selection for vacuum systems shall ensure total pressure drop
  - Valves for backflow protection of gases in lieu of sterilizing grade filters. Refer to Section 8.6.12.2.
- BSL-3 vacuum valves shall be Type 316 stainless type. Refer to DRM Section 8.2.12.3 Section 8.6.12.3.
- For additional plumbing requirements for special applications refer to Section 8.6.13.
- Pressure Relief Discharge Devices
  - Autoclave chambers
  - For BSL-3 applications, refer to Section 8.6.14.
- Testing and Inspections
  - All piping systems
  - Plumbing Fixtures
  - HEPA, in-line filters
  - Compressed air
  - For special testing and inspection requirements of plumbing systems serving the BSL3 containment refer to Section 8.6.15.

Chapter 9

The NIH Division of the Fire Marshal (DFM) is the designated Authority Having Jurisdiction (AHJ) on all NIH owned property. DFM provides consultative services upon request for leased facilities.

Section 9.1: Fire Protection Systems

- Use latest edition of codes and standards; NFPA annexes mandatory
- Occupancy Classification for laboratories and animal holding areas
- Laboratory Fire Hazard Classification – minimum Class C per NFPA 45
- Fire Resistance-Rated Construction – laboratory corridors a minimum one hour fire rating
- Flammable liquid storage cabinets requirements including size and quantity, location, integrity of installation, venting, etc. (see also chapters 2, 4, and 6)
- Glazing-comply with IBC
- Listed Equipment – fire protection equipment shall be listed for appropriate use
- Design Documentation – Information required at appropriate stages of a project
  - Fire protection submission guidelines
  - Fire rated assembly locations
  - Sprinkler system submittals
  - Fire Hydrant locations and details
  - Fire Alarm system submittals including fire alarm riser diagram

Section 9.2: Fire Suppression Systems

- Automatic Sprinkler systems
  - Only facilities < 2,000 sf exempt with written DFM approval.
  - Laboratory and non-laboratory sprinkler classifications
- System design
  - Sprinkler locations shall not be shown on design drawings with exceptions
  - Final sprinkler drawings and hydraulic calculations shall be sealed by a registered fire protection engineer or NICET level III or IV
- Design criteria
  - Sprinkler calculation requirements
  - Safety margin – a minimum of 10% or 10psi, whichever is greater
  - Water supply - water flow test data is supplied for Bethesda and Poolesville campuses
- Backflow preventer – required on all new systems
- Drainage - required for all systems
- Materials and Equipment required for the sprinkler systems
  - Quick response sprinklers shall be used throughout
  - Special sprinklers – certain areas require quick response gasketed concealed sprinklers
  - Temperature rating – sprinklers shall be ordinary temperature except as specified in this section
  - Guards – required for sprinklers within 7 ft of the floor and areas in animal holding areas
  - Pipe material – sprinkler pipe shall be schedule 40 black steel
  - Joining method – with galvanized pipe, threaded or cut grooved only. Welding is not permitted
- Installation
  - Freeze and mechanical protection – Required for all exterior sprinkler mains
  - Painting - Sprinkler piping shall be painted red, with exceptions
  - Control valve location
  - Service valve type
  - Sprinkler clearance - specific NIH requirements near shelving
- Standpipe systems
  - General standpipe requirements
    - Facilities with two or more stories above grade require an interior Class I standpipe system
    - Standpipe system design – design to pressures given for manual and automatic systems
  - Standpipe System Installation
    - Freeze and Mechanical Protection – Required for all

exterior standpipe systems
    - » Painting - standpipe piping shall be painted red
    - » Control valve location requirements
- Fire Hydrants – requirements for new hydrants including location, type installation, roadway valves, and painting,
- Fire Department Connections –requirements including location, specifications and placard
- Fire pumps –requirements including installation, test header and flow meters
- Other Suppression systems
    - › Antifreeze systems – not permitted
    - › Preaction systems – limited use as approved by DFM

Section 9.3: Fire Alarm and Mass Notification Systems

- Fire alarm systems
    - › General - Required for all facilities, existing campus reporting system shall be functional, fire alarm systems must be programed to designated network control centers
    - › Initiating Devices
        - » Pull stations – NIH specific requirements
        - » Smoke detection – NIH specific requirements
        - » Duct smoke detectors – in Bethesda, only allowed in ambulatory healthcare and healthcare occupancies
    - › Notification Signals
        - » Use standard notification sequences for the appropriate campus
        - » Fire alarm signal – NIH specific requirements
    - › Notification Devices – NIH specific requirements
    - › Wiring
        - » Standards – NIH specific standards – meet existing except in building 10 on Bethesda campus
        - » Splicing – Not permitted except when utilizing terminal strips of an existing notification appliance or initiating device
        - » Multiconductor cable – The cable is custom made for the NIH Bethesda campus and no splicing allowed
- Fire Alarm System Installation
    - › Control panels – install in buildings main lobby/ entrance
    - › Circuit breakers – lockable listed circuit breakers not required
    - › Conduit – NIH specific requirements
    - › Electrical back boxes - NIH specific requirements
    - › Exposure – NIH specific requirements for areas with varying temperature/humidity/moisture
    - › Painting – NIH specific requirements for concealed and exposed fire alarm conduits
    - › Battery backup – required on all fire alarm systems
- NIH Bethesda Campus Mass Notification requirements
    - › Mass notification inputs will be retransmitted simultaneously over all fire alarm notification circuits
    - › Programming is required to all emergency communications centers on campus

Section 9.4: Life Safety Features

- Means of Egress
    - › Loading dock exit door is not a required egress path, clear aisle space must be maintained around lab furniture, fire alarm system can't unlock egress doors
- Self-Luminous Exit Signs
    - › Installation – self-luminous exit signs are not allowed
    - › Existing signs – notify Division of Radiation Safety if self-luminous exit sign is found
- Fire Department Access
    - › Fire Apparatus access – NFPA 1 with NIH specific requirements
    - › Roof access – flat roofs > 2 stories must have at least one stairway access
    - › Key box – Knox boxes shall be provided in all new construction for fire department entry
- Fire Extinguishers
    - › General – DFM must review all extinguisher and cabinet submittals
    - › Laboratories – fire extinguishers must be located in the corridor
- Smoke Control Systems
    - › Engineering analysis must be completed
    - › Acceptance testing must be completed
- Dampers – NIH specific requirements
- Emergency Power
    - › Generators must be connected to all emergency circuits

Chapter 10

The planning of the electric power distribution is important to support all facilities in the NIH. The purpose of this chapter is to provide design guidance for the development of the electrical systems, with the goal that can achieve future growth and create electrical infrastructure uniformity throughout NIH. This chapter is compiled with electrical services for normal and emergency power, site electrical distribution, motor control, power quality and grounding, testing and operational requirement, lighting and power distribution systems, and specific electrical design for animal research facilities and laboratories, including BSL-3 and ABSL-3.

Section 10.1: Electrical System Design

- Consider System Growth
- Use latest editions of Codes and Standards
- Design Documentation:
  - Items required on drawings.
  - Site design drawing requirements
  - Required information on Panel Schedules
  - Required calculations and analysis
  - Power system study
- Project specifications to include Testing & operational training requirements and Startup & checkout of building systems
- Minimum tests required for electrical equipment provided in Table 10.1.6

Section 10.2: Electrical Service and Normal Power

- Electrical Power Distribution:
  - System Architecture
  - Service Voltage
  - Spare capacity
  - Electrical Schematics
  - Medium and Secondary Voltage Service Equipment
  - Selective coordination requirements
  - Power quality requirements
  - Load segregation
  - Utilization voltages for lighting, heating and motors
- Coordination of medium voltage feeder connection to existing system
- Medium voltage equipment requirements
  - Primary Switch, network transformer and secondary network protector
  - Remote monitoring and control
  - Single warranty for substation assemblies, transformers and components
  - Applicable standards for design, assembly, testing and installation
- Secondary voltage service equipment requirements
  - Network protector and relays – applicable standards and required components
- Secondary Switchgear – Main and tie breakers, Main Bus, Circuit Breaker type, Number of mains, Bus stubs, Cubicles, Spare cubicles, Spaces with full bus including draw-out assemblies, bussed connections and hardware, Bussed extension, Transient Voltage Surge Suppression, Grounding, Spot network grounding, Overcurrent device requirements, metering, Control power, Test switches, Hoist for lifting circuit breakers, internal heaters and tools for maintenance
- Distribution transformers minimum performance specifications - coil material, energy star compliance
- Energy start rated Dry-type transformer
- Switchboard and panelboard requirements – Bus material, Interrupting capacity, Main circuit breaker, branch circuit breaker type, Spare breakers, Panel Directory, Phase balance Heat shrink insulation sleeves for certain size switchboards, Minimum interrupting capacity, Minimum size for branch panel boards, Ganged single pole circuit breakers, Neutral and ground

The formulae for building state of the art biomedical research facilities.

bus size, Panelboard trim, lock and Key
- Animal Operating room panels
- Busway requirements – Maximum current rating, Bus material, type of busway, concrete curbs for vertical penetrations
- Motor Control – Types of starters, Starter requirements
  - Motor control center requirements – Bus material, Starter, Short circuit protection, control wiring, metering and heaters
  - High efficiency motors overcurrent protection
  - Ladder diagrams and sequence of operations
  - Enclosures to meet environmental requirements
- Electrical Work Space – Location for Transformers, secondary substations, distribution switchgear, generators, transfer switches and other electrical distribution equipment.
- Working clearances for secondary switchgear
- Electrical room requirements
  - No piping, ducts or other equipment not serving the electrical rooms in the electrical room
  - Ventilation requirements
  - Electrical closets – Stacked, Sleeves from the floor, Location requirements
  - Equipment removal route
  - Equipment pad
  - Outdoor installation of cables
  - Arc Flash Warning

Section 10.3: Emergency Power

- Emergency power load demand table
- Life safety loads
- Legally required standby loads
- Optional standby loads
- Emergency Generator
  - Emergency Generator location
  - Considerations for Generators located indoors and outdoors
  - Load banks for Generators testing
  - Fuel storage
  - Monitoring of day tank
  - Automatic Transfer Switches
  - Receptacles for portable generators
  - Fire department receptacles in Montgomery county, Maryland
  - Acceptance testing requirements

Section 10.4: Site Electrical Distribution

- Distribution Duct Systems General requirements
  - Redundancy, coordination, Type, Spare capacity, bending radius, Cable pulling, Sealing, Ground conductor, Duct type, Direct buried conduits for selected applications
  - Concrete encasement
  - Elevation considerations
- Manhole and Handhole Installation – Size, Cover, Location, Grading, Cable mounting, Pulling irons, Sumo, Manhole Grounding

Section 10.5: Wiring Methods and Other Requirements

- Conductors and Cables
  - Medium Voltage cable requirements, cable termination requirements, Splices, Existing cable type, cable identification and cable testing
  - Requirements for cables rated 600V or less – Conductor material, Insulation type, Voltage drop, Minimum wire sizes, dedicated neutrals for 120V receptacle circuits, Minimum size for shared neutral in multi-wired furniture
  - Number of current carrying conductors in a conduit
  - Cable identification – Power conductor, Control wiring
  - Temporary wiring requirements
  - Branch circuit loading
  - Wiring terminations, Common disconnect for multi wire branch circuit, Isolated Ground circuits
- Raceway
  - Conduit applications, sizes and types including minimum conduit size, fittings type
  - Allowed instances for direct buried cable

- Requirements for conduit installation within buildings – Routing, Support, Transition and Identification
- Underground conduit installation requirements – Medium voltage cables, Direct buried conduit applications, minimum cover, marking, empty conduits.
- Considerations for pulling cables in existing conduits
- Cable pulling tensions and sidewall pressures shall not exceed manufacturer's recommendations
- Cable tray applications
- Surface Metal raceway applications – Type, dividers, circuit breakers, circuit taps, receptacles and circuits for specialty equipment

- Wiring Devices
  - Requirements for Switches and receptacles – Types, Bracket and terminal, Receptacle orientation, cover plates, design load, computer and printer outlets, minimum outlet requirements for certain spaces
  - Plug load control considerations
  - Light switches and receptacles installed near safety showers
  - Circuits for automatic flush valves, faucet sensors and paper towel dispensers
  - Disconnect switch requirements
  - Nameplates and circuit identifications
  - Existing electrical system demolition requirements
  - Laboratory and Animal research facility requirements – dedicated panelboards, dedicated circuits for specialized equipment, minimum wiring in animal operating rooms, Alarm and Monitoring for freezers, Specific conduit applications and installation requirements. Specific device boxes in ARFs, Requirements for Switches and receptacles in ARFs

Section 10.6: Power Quality and Grounding

- Harmonics - Perform a power system analysis to determine if mitigating measures are required when a large number of harmonic generators are anticipated
- Some mitigating measures - k-rated transformers, specifying harmonic filters, oversizing neutral conductors
- Consideration for sensitive equipment
- Uninterruptible Power Source requirements – Redundancy, Spare capacity, Maximum demand, Battery type, Alarm and Monitoring, loads recommended on standby generator
- Transient Voltage Surge Suppression – Instances when required at service entrance, branch circuit panel
- Grounding - Ground System Resistance requirements at service
  - Domestic water connection or water services is a conducting material.
  - Ground ring installation requirements - Transformer Pad, Main Electrical Room and Transformer Vault, Instances when Building ground ring is required, Ground ring spacing, Welding type, Test well and monitoring
  - Transformer grounding requirements
  - Ground bus type and locations where a ground bus is required
  - Main electrical room ground bus
  - Grounding requirements for Metal Structures and Objects
  - Substation fence bonding requirements
  - Grounding and bonding requirements for raised floors
  - High frequency signal reference grounding requirements
  - Grounding and bonding conductor requirements
  - Protection of ground conductors
  - Labeling of grounding electrode conductors
  - Ductbank and Load bank grounding requirements
- Lightning Protection System
  - Risk analysis per NFPA 780
  - Master C label requirements
  - Ground ring for building
  - Modification of existing lightning protection system
  - Lightning rod type

Section 10.7: Lighting

- Lighting Design Guidelines
  - Visual factors consideration

- Ambient lighting levels in Table 10.7.2
- Lighting calculations requirements

- Interior Lighting
  - Supports required for recessed lights and pendant light fixtures
  - Task lighting requirement
  - Light distribution consideration
  - Emergency Lighting requirements for various rooms
- Exterior Lighting
  - Exit lighting, Security lighting, Street Lighting, Walkways Lighting, Architectural Lighting and Loading dock lighting
  - Consideration for light pollution
  - Lighting pole requirements – Pole base, Pole identification, Pole Grounding, Surge Protection and other requirements
- Lamps
  - Color rendering index and average rated life for LED lamps, Fluorescent lamps, Compact Fluorescent lamps etc.
  - Fluorescent ballast and LED driver requirements
- Lighting Control
  - Automatic lighting control systems, Lighting Zones, Motion Sensor and Local Switches, Dimming, Digital Timers, daylight harvesting, tandem wiring and unswitched emergency light
  - Animal Research Facility Lighting – Fixture type, Control coordination, Occupancy sensors types,
  - Animal holding area lighting – Power source, Large animal and Non-human Primate Holding Rooms, Small Animal and Rodent Holding Rooms, Flexibility
  - Light levels for various areas in an ARF in Table 10.7.6
  - Animal Holding Area Lighting Control - Lighting Control Systems requirements, User Interface, Battery Backup, Monitoring, Reporting and Alarming, Programmable Diurnal Cycle, Diurnal "Off" Cycle, Caretaker Cycle, Dimming Control and Lighting operation
  - Lighting and Control for Other Areas in ARF - Autoclave and Cage Wash Service Areas, Quarantine Rooms, Cubicle Holding Rooms, Non-human Primate Holding Ante-rooms, ABSL-2 Procedure, Necropsy, and Treatment Rooms, Animal Surgery Rooms, Storage Room, Locker and Toilet Rooms, Offices and Administration Areas, Facility Supervisor's Office, Feed and Bedding area, Receiving/Decontamination Area, Corridors, Medical Pathological Waste Holding and Aquatic Feeding Area

Section 10.8: BSL-3 and ABSL-3 Biocontainment

- Normal Power systems
  - Electrical service redundancy
  - Switchgear, Location of distribution equipment, reliability
- Standby power requirements in addition to Section 10.3
- Requirement for a UPS
- Emergency Generator sizing
- General Requirements
  - Electrical Installation in Containment Areas - Containment Barrier Penetrations, Submission and Mock-up, Sealing Requirements per Appendix L
- Conduit, Conductors, Cables, and Boxes
  - Conduit type, Seal-off, Surface metal raceways
  - Power wiring types
  - Other system wiring sealing requirements
  - Boxes for all systems – Type and depth, Cast boxes, Sealing
- Lighting – Light fixture type, decontamination consideration, light fixture housing and lens types
  - Lighting layout in lab areas, Imaging lab light fixture types
- Emergency Lighting - Emergency Power Source, Emergency Battery Ballast, ABSL-3 Areas emergency ballast type
- Lighting control – Sealed enclosures for all lighting control including occupancy sensors

DESIGN GUIDELINES FOR ELECTRICAL

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

The formulae $\frac{\partial \rho U_i}{\partial t} + \frac{\partial}{\partial x_j}(\rho U_i U_j) = -\frac{\partial P}{\partial x_i} + \frac{\partial}{\partial x_j}\left(\mu \frac{\partial U_i}{\partial x_j}\right) + g_i(\rho - \rho_0)$ $\frac{\partial \rho U_i k}{\partial x_i} = \frac{\partial}{\partial x_i}\left(\left(\mu + \frac{\mu_t}{\sigma_k}\right)\frac{\partial k}{\partial x_i}\right) + P + G - \rho\varepsilon$ *for building* $\frac{\partial \rho U_i \varepsilon}{\partial x_i} = \frac{\partial}{\partial x_i}\left(\left(\mu + \frac{\mu_t}{\sigma_\varepsilon}\right)\frac{\partial \varepsilon}{\partial x_i}\right) + (C_1 - C_{1ENG})\frac{\varepsilon}{k}(P + C_3 G) - C_2\rho\frac{\varepsilon^2}{k}$ $\frac{\partial}{\partial x_i}(\rho \overline{U_i U_j}) = -\frac{\partial P}{\partial x_i} + \frac{\partial}{\partial x_i}\left(\mu \frac{\partial U_i}{\partial x_j} - \rho \overline{u_i u_j}\right) + g_i(\rho - \rho_0)$ $\frac{\partial \rho U_i \varepsilon}{\partial x_i} = \frac{\partial}{\partial x_i}\left(\left(\mu + \frac{\mu_t}{\sigma_\varepsilon}\right)\frac{\partial \varepsilon}{\partial x_i}\right) + C_1\frac{\varepsilon}{k}(P + C_3 G) - C_2\rho\frac{\varepsilon^2}{k}$ *biomedical research facilities.*

The formulae $\frac{\partial \rho U_i}{\partial t} + \frac{\partial}{\partial x_j}(\rho U_i U_j) = -\frac{\partial P}{\partial x_i} + \frac{\partial}{\partial x_j}\left(\mu \frac{\partial U_i}{\partial x_j}\right) + g_i(\rho - \rho_0)$ $\frac{\partial \rho U_i k}{\partial x_i} = \frac{\partial}{\partial x_i}\left(\left(\mu + \frac{\mu_t}{\sigma_k}\right)\frac{\partial k}{\partial x_i}\right) + P + G - \rho\varepsilon$ *for building* $\frac{\partial \rho U_i \varepsilon}{\partial x_i} = \frac{\partial}{\partial x_i}\left(\left(\mu + \frac{\mu_t}{\sigma_\varepsilon}\right)\frac{\partial \varepsilon}{\partial x_i}\right) + (C_1 - C_{1ENG})\frac{\varepsilon}{k}(P + C_3 G) - C_2\rho\frac{\varepsilon^2}{k}$ $\frac{\partial}{\partial x_i}(\rho \overline{U_i U_j}) = -\frac{\partial P}{\partial x_i} + \frac{\partial}{\partial x_i}\left(\mu \frac{\partial U_i}{\partial x_j} - \rho \overline{u_i u_j}\right) + g_i(\rho - \rho_0)$ $\frac{\partial \rho U_i \varepsilon}{\partial x_i} = \frac{\partial}{\partial x_i}\left(\left(\mu + \frac{\mu_t}{\sigma_\varepsilon}\right)\frac{\partial \varepsilon}{\partial x_i}\right) + C_1\frac{\varepsilon}{k}(P + C_3 G) - C_2\rho\frac{\varepsilon^2}{k}$ *state of the art* $\frac{\partial}{\partial x_i}(\rho \overline{U_i U_j}) = -\frac{\partial P}{\partial x_i} + \frac{\partial}{\partial x_i}\left(\mu \frac{\partial U_i}{\partial x_j} - \rho \overline{u_i u_j}\right) + g_i(\rho - \rho_0)$ $-\rho \overline{u_i u_j} = \mu_t\left(\frac{\partial U_i}{\partial x_j} + \frac{\partial U_j}{\partial x_i}\right) - \frac{2}{3}\rho k \delta_{ij}$

Chapter 11

The objectives of this chapter are to establish uniformity of telecommunication systems design, construct a telecommunications system that is compatible with other building systems, and provide provisions for future system growth. This chapter provides the design requirements for telecommunications construction criteria, including inside and outside plant design for telephone, local area network, audio visual, security, antenna, wireless network, and miscellaneous systems.

Section 11.1: Telecommunication Systems Design

- Consider System Growth
- Use latest editions of Codes and Standards
- Request CIT standard document at the beginning of all projects.
- Design Documentation:
  - See Appendix E, A/E Submission Requirements at each stage submission.

Section 11.2: Telecommunications/Local Area Network Closet/Room Construction Criteria

- Telecommunications Closet
  - Quantity based on distance limitation of the farthest work area outlet
  - Closet size and location - stack between multistory
    - Shall NOT share with building or custodial services, and any occupant-related servers and systems
  - Dedicated telecommunications closet, not shared with others
  - Consider minimum separation from electromagnetic sources
  - Room build-out requirements – fire-rated wall, A-C fire retardant plywood, white paint, fire-rated door and swing, card reader, open ceiling, antistatic flooring, emergency panelboard, HVAC system, grounding system, electrical outlets on each wall, and lighting layout against racks and overhead cable tray location
  - Network Equipment Electrical Requirements:
    - Verify with CIT for outlets required for UPS at the racks - minimum of three outlets per rack.
  - Fire Protection Requirements
    - Provide as required by applicable codes
    - Consider Sprinkler heads with wire guard, fire alarm notifications, fire extinguishers, and barrier penetrations
- Additional Requirements
  - Avoid other utility systems not serving this closet pass through the closet
  - Drip Pans under wet pipe
  - Require Cable trays for hallway and closet
  - Consider conduit connections – to Main Closet, to roof for antenna farm, and between multiple closets on the same floors.

Section 11.3: Cable Management

- Inter-Building Riser - sleeves or slots, and open shaft
- Cable Management System
  - "Basket" type cable tray and its bonding jumper
  - Non-ferrous or aluminum cable tray in high magnetic fields or radiofrequency interference
  - Consider cable tray access and maximum span distance installation
- Horizontal Pathways
  - Work Area Locations – outlet box, conduit with pull wire to cable tray (NO "daisy chain"), grounding and bushing
  - Barrier penetrations requirement per Appendix L, Sealant Table

Section 11.4: Site Utility

- Duct Bank Construction
  - Sizing duct bank depending on size of building – coordinate with CIT
  - Concrete encasement
  - Elevation considerations

- Concrete testing
- Manhole Installation – size, location, grading, frames and covers, sump frame and grate, pulling eyes in walls, pulling and lifting iron in floor, bolting inserts, expansion anchors, cable stanchions, cable arms, cable-support insulators, manhole grounding, and duct sealing compound
- Outside Plant (OSP) Pull Boxes/Handholes – select metal or non-metallic pull boxes with cover based on mounting location

Section 11.5: Audio Visual Systems

- Cables Termination Locations: AV equipment rack, Intermediate Distribution Frame (IDF), or Main Distribution Frame (MDF), unless otherwise determined by NIH/CT/OD/CTIVS.
- Dedicated power outlets for each rack
- Consideration for cable types, cable bandwidth, power balun, HD cable length, plenum rated cable, and conduit size
- Dedicated conduit run, not shared with CIT pathway
- Floor boxes, wall boxes and wall plates
- Display devices – video and audio connectivity
- Projection Systems – mounting requirement
- External Devices – cameras, microphone, speaker, and projection screen
- NIH/CT/OD/CTIVS – not responsible: carpentry, millwork, electrical work, painting, and replacing or cutting grid-work in ceiling.
- Consider ceiling tile replacement for installation

Section 11.6: Antenna and Miscellaneous Systems Requirements

- Distributed Antenna System (DAS)
  - Compatible and accommodate of new and existing board range of wireless services - two-way radio, first responder, paging, cellular, PCS, WiFi and others
  - System design - fully engineered for comprehensive coverage, site survey and mapping, installation and documentation, testing and acceptance
  - System architecture – single point connection, passive structure, repeater or extender, wireless LAN and access points, amplification and filtering, and third party equipment interface
  - Compatibility Partner Program - test and evaluate for compatibility with DAS
- Miscellaneous Systems
  - Building automation system, utility monitoring, security systems, elevator room support, and cable TV system
  - Cabling requirement, refer to Section 11.3, Cable Management

Section 11.7: Security Systems

- Coordinate with Division of Physical Security Management (DPSM)
- Additional requirements: Section 1.13, Security Requirements and Procedures and NIH Policy Manual Chapter 1381.
- Comply with manufacturer's requirement, codes and standards
- Consider security system wiring, conduit, cabling, grounding, back boxes, junction boxes, and labeling with color codes
- NIH DPSM Outside Plant (OSP) – right-of-way and route design, OSP space design, OSP cabling hardware, and OSP grounding, bonding, and electrical protection systems
- DPSM Security Building Systems
- Design in accordance with the Level of Protection (LOP) requirement of the Facility Security Level.
- Electronic physical access control system requirement in sensitive areas.
- DPSM CCTV Cameras Systems
  - Installation only with approval of DPSM

Chapter 12

The purpose of this chapter is to provide guidance for the design of critical NIH process production and piping systems including: High Purity Water (HPW); Animal Drinking Water (ADW); Compressed gases; and Cryogenic, Laboratory Vacuum and Veterinary Medical Gas Systems. The quality and purity of water delivered to the point of use can impact research results and introduce variables. Requirements for the production and distribution of High Purity Water are provided to ensure that a reliable and consistent water quality source is maintained at all use points for research facilities. Animal Drinking Water is a critical system that has direct impact on animals and associated research. Production, Distribution, and Microbial Control are some of the many impactful subjects that are addressed. Compressed gases and Cryogenic systems are used in a variety of applications and configurations. Design requirements, including control, alarming, distribution, primary supply and back-up supply sources are provided. Laboratory vacuums systems are utilized for numerous laboratory applications and are typically provided in most research facilities. The source system design (including method(s) to decontaminate), distribution system, and testing requirements are included.

Section 12.1: High Purity Water Systems

- Requirements for production and distribution of HPW systems
- HPW quality is defined in the project Basis of Design and design specifications see Table 12.1.1.
- Selection of suitable water contact materials / components is critical to maintain water quality in the system.
- P&ID documents and sequences of operation are required.
- Engineering calculations / hydraulic modeling are required
- HPW systems shall be designed to accommodate routine sanitization
- Central distributed HPS are used for most laboratory applications.
- Central HPW shall be configured as listed to include two-pass RO
- HPW distribution shall utilize continuous recirculation with avoidance of dead-legs to each use point.
- Point of Use Polishers: Typically furnished by the end users
- Water testing by an accredited laboratory
- Storage tanks: Shall provide 24-hours of operating capacity
- Pressurization / Distributions pumps shall be selected to provide N+1 redundancy
- Distribution system piping shall be sized for current load plus 20% future capacity.
- Distribution approach reverse return / direct horizontal distribution approach. Each lab module shall be able to be isolated by a single supply valve and return valve.
- Quality Control / Quality Assurance plans are required.
- Appendix N contains methods that are used to assure water quality in HPW and ADW systems. Subjects including sanitization, disinfection, testing requirements, mitigation for test failures and acceptance are included.

Section 12.2: Animal Drinking Water Systems

- Automated, piped ADW systems are preferred for larger facilities, NHP and larger animals
- Pre-packaged waters / purchased water may be preferred for small facilities and special applications
- Central fill and piped distribution systems are both subject to the same requirements for water source, production requirements and system design.
- On-site water quality testing is required to determine appropriate treatment and pre-treatment steps.
- ADW system shall be dedicated and independent from

all other systems

- ADW systems shall be fully engineered and documented.
- Make up water is from dedicated RO with GAC, with very limited exceptions.
- Ultraviolet radiation (UV) is not acceptable as the exclusive means of microbial control.
- ADW Production Components
- Microbial control - provisions to address microbial and biofilms
- System design shall ensure fresh water turn-over of each piping segment at least twice daily
- All wetted materials shall be selected must be suitable for food contact.
- Initial water quality testing shall be specified to occur during facility commissioning or system acceptance phases.

Section 12.3: Compressed Gas and Cryogenic Systems

- Supply System primary, back-up capacity must be determined
- Systems configured so that can be taken off-line without causing disruption or contamination of the facility supply.
- Alarm monitor is required and depended upon application see Table 12.3.1.A and Table 12.3.1.B.
- Compliance with ASME B31.9, B31.9, NFPA-55 and applicable recommendations of CGA is required
- Prior to operation gas systems shall be verified free of cross-connections, pressure tested and verified for required cleanliness / purity
- Cryogenic systems must be inspected by the cryogenic design professional or designated cryogenic inspector prior to start-up.
- Bulk Gas systems are provided with a connection for emergency backup bulk supply
- Oxygen level monitors and visual / audible alarms are required per NFPA-55
- Central compressed air is considered a critical service and shall be arranged to ensure continuous availability
- Compressed air systems must meet quality requirements for particulates, dew point, hydrocarbons and liquid / gaseous contaminants.
- Primary source of compressed air at Bethesda is the Central Utility Plant distributed to buildings. Back-up compressed air systems are installed within each building.
- Air intakes shall be taken from the exterior of the building away from contaminant sources.
- Provision of central distribution of CO_2 is typically required and where installed is considered a critical service.
- Liquid Nitrogen (LN_2) may be required in some facilities as a central system. Piping and system materials for laboratories and ARF shall be suitable for oxygen service.

Section 12.4: Laboratory Vacuum Systems

- A dedicated central laboratory vacuum system is required to serve each laboratory facility and shall be completely independent of other vacuum systems (i.e. medical, animal surgical, etc.).
- Secondary means are required at each central system to protect service personnel from potential exposed to biohazards (e.g. decon ports)
- Laboratory vacuum system equipment shall be single of multi-stage partial recovery, liquid ring type or vertical screw units.
- Liquid ring seal water conservation is an important consideration
- Systems shall be arranged to ensure reliability and continuous service (e.g. N+1, emergency power).
- Distribution sizing and arrangement are important factors and minimum requirements are provided.
- Standing pressure test is required to demonstrate a leak-tight system.

Section 12.5: Veterinary Medical Gas Systems for Animal Research Facilities

- Requirements for compressed gas and vacuum systems

required for animal medical applications.

- Systems are completely independent from other lab or human medical applications.
- In general, NFPA/ISO medical gas provisions with regard to cleanliness, minimum source supply, equipment design and reliably apply to these systems.
- VMGS shall be served by building stand-by power (NFPA-99 or ISO-7396 configuration). Electrical failures cannot interrupt VMGS supplies.
- Source supply: Automatic cylinder or bulk supply, each with appropriate redundant secondary supply source.
- A single combination type alarm panel may function to serve both as a master alarm and area alarm.
- Manifolds for VMGS gases shall be fully automatic switch-over type and provided with alarm monitoring.
- Systems valves shall be lock-open type and keyed to facility standards unless located in secure / restricted access area.
- System testing and installation must conform to NFPA-99 Category 1 or ISO 7396 except as modified in this section of the DRM.
- All work shall be performed by ASSE/ANSI 6010 and 6015 certified installers and shall be specified in the project specifications by the designer.
- Installations are required to be inspected during construction and prior to use by an independent medical gas system inspector.
- Veterinary surgical vacuum system shall be provided for veterinary medical applications only and cannot serve any other laboratory applications.
- Veterinary surgical vacuum equipment shall be protected with N+1 configuration of filters and liquid separators
- Typical requirements for various VMGS functional areas and considerations (outlets, terminal unit locations, quantity and placement) are listed in Table 12.5.6.

Section 12.6: Plumbing Requirements for Specialized Equipment

- Provision of piping systems for unique systems that do not fit within the scope of other DRM sections.
- General requirements including: Code compliance, system redundancy and process failure.
- Hazardous Process Fluid systems require a risk assessment and approval from ORF / ORS stakeholders.
- Hazardous chemical must be stored in minimum necessary quantities and safest manner.
- Maximum chemical quantities must comply with NFPA and IFC standards.
- All components of systems and distribution shall be visible for routine inspection.
- Diking shall be provided and sized for containment of complete system volumes.
- Comprehensive BOD documentation must be provided including O&M and sequences of operation.
- Remote Bedding Disposal Systems design / operation considerations including: redundant components evaluation, failure assessment, provisions for system service and piping access.
- Detergent Systems / Cage wash: Chemical location, design parameters, containment for and routing of pressurized chemical lines. Requirements for a fully detailed design.

Chapter 13

Chapter 13, Aseptic Production Facilities (APFs), describes the continuous and collaborative efforts required from project initiation to the end of the project facility life cycle for these types of facilities. NIH's APFs produce therapeutic and diagnostic products for human use, inclusive of those required to follow Current Good Manufacturing Practice (cGMP) regulations, and aseptic processing (for those manufacturing biological products), for the production of Phase-I and II clinical trial products.

Section 13.1: General Aseptic Production Facility Requirements

- The purpose of this section is to establish minimum criteria for NIH APFs which helps ensure that patients receive products of appropriate strength, identity, quality, purity, and other factors related to patient safety; this section focuses on those factors that can be directly or indirectly impacted by the facility.
- Failure to adequately design, build, and operate APFs under-control, can threaten patient and worker safety. Due to the level of risk inherent in APFs, there are significantly higher requirements for these facilities, compared with typical laboratories (e.g., BSL-2, 2/3, etc.).
- Aseptic Production Facilities are highly regulated environments, based upon the product being produced, and the locations the products are to be administered. See Table 13.1.1.

Section 13.2: Predesign Phase

- Define the product to be produced; from that follows the state of control requirements, including facility Critical Process Parameters (CPP), Critical Quality Attributes (CQA), Critical Safety Attributes (CSA), Business Essential Attributes (BEA), and Optional Attributes (OA).
- The GxP regulatory parameters which must be satisfied can be complex; there may be more than one regulation that applies, which will need to be harmonized via user-led risk analyses.
- Statement Of Requirements (SOR), developed per Section 13.2.3.B, is the initial facility document.
- User Requirement Specifications (URS), per Section 13.2.3.C is based on the SOR. The URS is the foundational document used in the development of the Basis Of Design (BOD), the Design itself, Design Qualification (DQ), and the Validation Master Plan (VMP).
- Highly qualified teams are required for work on/in the APF environment, per Section 13.2.4.

Section 13.3: Design Phase

- A formalized risk assessment shall be conducted to identify and mitigate risks to the product in accordance with ICH Q9, "Quality Risk Management," using appropriate procedures, facilitators, and structured tools.
- Develop a number of APF Facility-documents, including the Basis Of Design (BOD) per Section 13.3.2 and the URS.
- Common APF Design Elements and considerations are described in Section 13.3.3-4.
- Design-phase Commissioning, Qualification and Validation (CQV) activities are defined in Section 13.3.5, Section 13.3.7, and Section 13.3.12.
- Good Documentation Practice (GDP) and Document Change Control are defined in Section 13.3.8.
- Design Qualification is required of most APF projects.

Section 13.4: Biologics Facilities

- NIH Biologics facilities (including cell processing, tissue culture, viral vector, and other similar facilities) are typically designed for the manufacture of multiple products, either concurrently, or sequentially (campaigned).
- Known infectious biological material is processed in BSL-2 rooms, separate from biological material that has tested negative for infectious diseases.
- The design, engineering, and procedural controls can mitigate the risk of contamination of the product being produced.

Section 13.5: Compounding Pharmacy Facilities

- NIH Compounding Pharmacy facilities are part of the Aseptic Processing Facilities (APF) portfolio where medications used for NIH clinical trials are manufactured, stored and dispensed. The products dispensed shall be sterile (if so specified), of correct identity (ingredients), purity (free from contaminants), and strength. The products must be dispensed into sterile, accurately labeled containers, and stored in carefully monitored and controlled environments, appropriate for the products being stored.
- Appropriate engineering and administrative controls through facility design, construction, and operation shall ensure that the facility is operated in a state of control, and produces an appropriate environment for CSP preparation, storage and dispensing.
- The remainder of this section describes the progressively cleaner sequence from non-controlled and not classified areas to the Direct Compounding Area (DCA).

Section 13.6: APF Design Requirements: Architectural

- Architectural finishes and details must promote cleaning, maintenance and proper operations of the APF.
- Architectural finishes and components shall be cleanable, durable, and selected to be compatible with the anticipated chemicals and methods used for cleaning, disinfection or sterilization and protocols used by the program without degradation.
- Ceilings, walls, and floors shall be monolithic and seamless to the extent practicable. All joints, gaps, seams, penetrations and voids in and within the facility, shall be completely sealed, to enhance sanitation, facilitate gas and/or vapor decontamination, and maintain pressure differentials.
- Doors play a critical role in the overall design as they function to maintain pressurization and, prevent contamination.
- Modular wall and ceiling panelized systems provide significant performance advantages over stick-built and coated systems, including uniformity, high resistance to degradation, and incorporation of clean room detailing.

Section 13.7: APF Design Requirements Structural

- APF structural requirements shall be per Section 13.7.1.
- Floor flatness requirements are addressed, in particular, to address 5-sided cart pass through chambers, which utilize the floor as their sixth-side, as the door swings need a free traverse as well as a flat floor for the closed position to ensure the door can adequately seal.

Section 13.8: APF Design Requirements: HVAC

- Correlates between various classification schemes discussed in Table 13.8.1.
- APF outdoor design conditions per Section 6.1.7 and Table 6.1.7.
- APF indoor design conditions include where human comfort is the only requirement, and the other factors in determining a temperature and humidity range appropriate for the product being produced in a given room. See Section 13.8.3 for expanded description.
- Dedicated HVAC Systems are recommended for APFs. HVAC systems and components require a minimum n+1 redundancy, per Section 13.8.5, with capacities per Section 6.2.1.
- Through risk assessment and user requirements, the A/E shall determine if 100% OA or recirculating systems are appropriate for product (patient), and worker safety and energy conservation.
- Air change rates for achieving and maintaining required differential pressures and air cleanliness, in particular, are discussed in Section 13.8.7.
- Room pressurization for controlling the migration of contaminants are discussed in Section 13.8.8.
- Airlocks shall be designed to effectively control airborne contamination between rooms of different classifications and maintaining differential pressures between spaces of differing classifications and risks. See Section 13.8.9.
- In APF air distribution systems, numerous, uniformly distributed air outlets/inlets, shall be used to create an airflow pattern that generally moves uniformly downwards from ceiling to floor, washing the area with unidirectional airflow.
- APF-specific ductwork shall comply with Section 6.2.2, and Section 13.8.12, which are intended to decrease the likelihood for the ductwork to be the source of particle generation.
- AHUs serving APFs shall comply with Section 6.2.4.2 and Section 13.8.14, intended to address enhanced corrosion resistance, and the number of rows in cooling coils to address the higher than typical CFM requirements of these systems and the associated impact on humidity control.
- Air filtration, as the primary means for the reduction of

The formulae for building state of the art biomedical research facilities.

airborne contamination, is described in detail in Section 13.8.15.

- Exhaust air systems serving APFs are required to conform to the requirements of Section 6.1.22, Section 6.2.3, Section 6.2.7, and Section 13.8.16.
- Humidification systems are uncommon in APFs at the NIH, but requirements for these systems are include in Section 13.8.17.
- Chilled water, heating water, steam and emergency electrical systems serving APFs are required to meet or exceed the stringency of those systems serving other NIH laboratory spaces.
- Fluid piping above APFs shall be eliminated to the extent practicable. Mitigation of risk is incorporated into the construction where such piping cannot be rerouted/ eliminated.
- Supply air fans, exhaust fans, controls and BAS and all devices and equipment serving APFs shall be connected to an emergency power system, and capable of restarting without damage or intervention, per Section 13.8.23.
- Equipment, ductwork and piping systems serving APFs shall be accurately identified to designate function and direction to mitigate the risk of service disruptions and other potential sources of contamination/adulteration of the products being produced.

Section 13.9: APF Design Requirements: HVAC Controls

- This section addresses the APF-specific Building Automation Systems (BAS) design considerations, as well as the specific requirements for control sequence design. APFs shall meet all the requirements of Sections 7.1-6 and meet additional requirements as outlined in Section 13.9, to provide a greater level of safety and reliability of operation than is typical for an NIH Laboratory.
- HVAC system and APF environmental parameters shall be monitored and controlled, recorded and alarmed via a commissioned BAS control system, including temperature, humidity, airflow, and room differential pressure. For instrument certification
- Critical parameters, including temperature, humidity and room differential pressure, shall also be monitored, recorded, and alarmed on an independent, validated Environmental Monitoring System (EMS).
- Supply and exhaust systems shall be controlled by a single controller with stand-alone capability and with tracking relationships established between airflow terminals. See Section 13.9.2.
- Automatic dampers in the exhaust shall fail-open. Automatic dampers in the supply shall fail-closed if another means is not provided to prohibit reverse pressurization in the event of applicable failures.
- The BAS shall provide differential pressure monitors on classified spaces to indicate the room differential pressure and shall alarm when the pressure goes beyond established, room-specific, thresholds and time durations. See Section 13.9.4.
- Critical HVAC parameter sensors and controls are detailed in Section 13.9.5. This section establishes sensor sensitivity, range, location, reliability, robustness, co-location of BAS and EMS sensors, and other APF-specific parameters.
- To control the migration of contaminants, APF air distribution systems shall be designed as robust and resilient, to attain and maintain pressure levels and airflow direction relative to adjacent areas per Sections 13.9.6-10, including due to power interruption, generator testing, or controller, communications, or other reasonably foreseeable failure.
- Cross-limiting loops shall be designed and maintained to restrict the leading system from exceeding the lagging system by a specified value that shall be set to prohibit damage or unreasonable door opening force due to hyper/hypo-pressurization.
- System reaction to fan failure is described in Section 13.9.14.
- HVAC controllers shall have the capability to automatically restore their volatile memory upon loss of power.
- BAS programming code shall be reviewed and cleaned of unused and other "junk" code, during commissioning.

Section 13.10: APF Design Requirements: Plumbing

- Plumbing systems determined to be direct impact shall be subject to testing, commissioning and validation, per Section 13.10.1.
- Fluid piping over APF spaces shall be limited to that required specifically to serve such spaces.
- Where piping must be exposed within APF spaces, it shall be mounted to walls or ceilings with manufactured, stainless steel sanitary piping supports.
- Where insulated piping is required within APF areas, the insulation and joint system shall be specifically

manufactured to be non particle-generating, suitable for use in clean room applications, or fully encased in an approved durable and sanitary containment annulus of not less than Schedule 5 wall thickness, with approved sanitary termination fittings.

- Lab water may not be used as a source of water supply for any APF purpose.
- Domestic water should only be present at the early stages of gowning and late stages of de-gowning for hand washing and as a water source for non-sterile equipment processes, and avoided to the extent practicable in ISO-8 or better spaces. See Section 13.10.2.
- The types and usage of "Pharmaceutical Water" are described in Section 13.10.3.
- Drain-waste-vent (DWV) systems are a known source of contamination, so sinks should only be present in low or non classified areas within APFs.
- Domestic water systems are a known source of contamination, so plumbed emergency fixtures should only be present in non-classified areas within the APF. Where allowed by risk analysis and approved, the use of sealed, sterile eyewash stations s are preferred. See Section 13.10.6.
- Requirements for LN2 systems are detailed in Section 13.10.7
- Requirements for clean compressed gas systems are detailed in Section 13.10.8, except for vacuum, which is described in Section 13.10.10.
- Requirements for pharmaceutical compressed air systems are detailed in Section 13.10.9.

Section 13.11: APF Design Requirements: Fire Protection

- APF shall be designed in accordance with latest NFPA edition, building and local codes and the NIH Fire Marshall.
- The use of aspirating smoke detection should be considered for sensitive APF areas, subject to the NIH Fire Marshall's approval.
- The type of fire suppression system utilized for the APF shall be evaluated by project with DTR and the Fire Marshall's office.
- Single interlock cross-zoned, pre-action systems, utilizing nitrogen-charged piping and specialized detector s for cleanroom environments are recommended for consideration in APFs.
- Sprinkler heads shall be of the quick-response type except in areas designated for standard response per the DRM with rooms within cleanrooms requiring airtight devices.
- Sprinkler heads with "gasketed" ceiling cover plates and cleanroom rings over concealed, fast-acting pendant sprinkler head are the industry-preferred type for cleanroom areas but, require the approval of DTR and DFM.

Section 13.12: APF Design Requirements: Electrical

- APF facilities shall provide emergency power in accordance with those described in Section 10.3.1 and Section 13.12.3.
- APF wiring methods, shall be designed for corrosion resistance, and sealed against airflow as described in Section 13.12.4.
- Panelboards serving nonlinear equipment shall be provided with 200% neutral bus to account for harmonic heating.
- Lighting in APFs are challenging, due to the high percentage of ceiling area that is occupied by HVAC terminal devices. This is further complicated by the need for higher levels of uniform illumination to facilitate cleaning inspections. See Table 13.12.6 for a detailed description of these requirements.
- APF luminaries must be designed and maintained as sealed or flush, glare-free, and chemical resistant. Their impact on airflow must be considered during design.

Section 13.13: APF Design Requirements: Low-Voltage Systems

- Similar to line voltage systems, APF Low Voltage Systems shall be designed for corrosion resistance, and sealed against airflow.
- Cleanroom intercoms and telephones should be configured to minimize movement of personnel across ISO-classifications.
- All cleanrooms shall be provided with CCTV cameras or provisions for their future installation. Cameras shall be placed in wipe-down compatible covers to allow remote monitoring of all areas identified as high-risk by the user's QA.
- Provide n+1 panelboards and UPS in the LAN room for all of the communications systems.

Section 13.14: APF Design Requirements: Environmental Monitoring System (EMS)

- The end user is responsible for the Environmental Monitoring System (EMS), which shall monitor critical APF environmental parameters, and be fully commissioned, calibrated, qualified and validated. The AE and construction contractor shall design and install all back boxes, conduits, provide all necessary power and LAN connection points, but does not actually install the EMS, which is done under separate contract by the end user. The commissioning, qualification, validation, operation and maintenance of the EMS shall conform to be the responsibility of the EMS, per validated O&M protocols.
- The EMS and BAS are typically stand-alone systems, but with appropriate approval, may share common sensors, upstream of a signal splitter at the sensor and high speed bus. In such cases, the qualified portion of the EMS shall be firewalled off from the main BAS, with unique access control, security, change control, audit trail, calibration management, non-volatile record creation and report generation, and be fully 21 CFR Part 11 compliant with the ability to be qualified and validated by the end user and their consultants.
- When separate sensors are used, they shall be co-located to ensure data accuracy.
- Additional requirements for system architecture, and component minimum specifications can be found in Sections 13.14.1-8.

Section 13.15: Construction Phase

- Construction management of APF have additional requirements and responsibilities which are highlighted in this section. See Section 13.15.0 and Section 13.15.1 for additional requirements.
- A project-specific Construction Quality Plan (CQP), shall be provided by the construction contractor for review and comment; see Section 13.15.2.
- Construction contractor shall execute clean build specifications throughout all construction phase activities. See Section 13.15.3 and Section 13.15.4.
- APF review of construction submittals faces a higher degree of scrutiny than a typical laboratory project, particularly with respect to testing documentation.
- The CQP must correlate with the PVMP, which defines the testing, sequence of testing and documentation requirements and during construction.
- All APF projects will have commissioning (Cx), and most will have Qualification (Qx) and/or Validation (Vx), as described in the Project Validation Master Plan (PVMP).
- All Modular Unit Systems (MUS) and major factory build components, such as AHUs, shall be subject to Factory Acceptance Test (FAT) and Site Acceptance Test (SAT). See Section 13.15.8 for additional description of FAT/SAT requirements.

Section 13.16: Facility Commissioning, Qualification, and Validation Phase

- This section addresses the roles and responsibilities of Cx, Qx and Vx activities during the project lifecycle.
- The end user is responsible for developing and maintaining a Validation Master Plan (VMP). The VMP sets forth the acceptance criteria for the APF and the overall validation philosophy. See Section 13.16.1.
- All APF projects shall develop a PVMP during the design phase, which conforms to the VMP and URS, and is progressively updated and maintained through the course of the project. All project facility validation activities are planned, executed and documented in accordance with the PVMP. See Section 13.16.2-5 for additional description of the PVMP and its subsidiary documents.
- The Commissioning Master Plan (CMP) is a component of the PVMP; developed by CxA during design and executed concurrent with the construction of the project. See Section 13.16.3.
- The Qualification Mater Plan (QMP), and Validation Master Plan (VMP) may be combined with the CMP, if performed by the same team; the hybrid document is referred to as the CQV Plan. The QMP, VMP, and CQV Plan are components of the VMP, developed by the Cx, Qx, and Vx contractors and executed during design (Design Qualification), Construction, and Post-Construction phases of the project, prior to project handover. See Sections 13.16.3-5.

Section 13.17: APF Facility Certification Requirements

- The purpose of APF facility certification is to ensure protection of patients, products, and workers. The general guidelines for APF certification requirements are explained in this section.

- All instruments used in certification shall have valid calibration certificates based on frequency and method of calibration per ISO 21501-4.
- Testing requirements of an APF may include some or all of those described in Sections 13.17.1-11. The tests required to be performed shall be outlined in the VMP, and described in detail in the PVMP.
- APF cleanrooms (ISO classified areas) shall be validated to a required class of cleanliness defined in ISO 1464.1; acceptable methods for evaluation and measurement for Certification are specified in ISO 14644-3 which cites required and optional tests.
- Table 13.17.0 outlines ISO 14644 and NIH required and optional tests.

Section 13.18: Project Closeout and Facility Handover Phase

- This section describes a formalized project closeout process and the required documents, subsequent to the acceptance of the fully executed PVMP.
- Project closeout documents include those which end at the point of facility acceptance as well as documents that persist and are to be updated/maintained as current throughout the life cycle of the facility.
- A Certificate of Use is issued by the DTR/FCIS upon acceptance of all required documents. See Section 13.18.0 and Exhibit 13.3 for additional details.
- A dashboard is also created for (internal NIH use) for individual APFs, to provide a quick graphic display/ review of the BAS sensor data of the facility and an overall indication of the health of the facility.

Section 13.19: Cleaning and Sanitation

- One of the features which distinguish APFs from other laboratories and healthcare spaces is the development and maintenance of a robust and verified, effective cleaning program.
- All surface finishes and interface details shall be selected to be compatible with the chemicals and methods used for cleaning, disinfection or sterilization, without damage.
- Air systems shall be designed, constructed, located to facilitate cleaning, maintenance and proper operation. The design of the HVAC systems shall accommodate physical decontamination to the extent practicable and configuration for the air handling system shall accommodate appropriate isolation and compartmentalization to safely deploy gaseous decontamination agent on an as-needed basis.

Section 13.20: Operations & Maintenance

- Appropriate Operations and Maintenance (O&M) of APFs is essential for maintaining the facility in validated state.
- DFOM has the responsibility of establishing and executing an APF O&M program and associated SOPs under the QA and Oversight of DTR/FCIS.
- SOPs shall be established for the O&M of facility equipment & systems that support critical process parameters.
- APF Facility SOPs shall address routine, preventive and corrective maintenance and, any planned or unplanned facility, system or equipment upset or shutdown, and other SOPs as required to support the APF Facility O&M Program. Other SOPs shall include, but not be limited to Root Cause Analysis (RCA), Corrective and Preventive Action (CAPA), and Change Control. See Sections 13.20.1-5.
- Good documentation practice, training, education and auditing of these practices are all critical to ensuring that the cGMP facility is appropriately managed, operated and maintained in a validated state. See Sections 13.20.5-6.
- A list of critical APF spare parts and consumables shall be maintained and controlled by DFOM to ensure availability of correct (preferably like for like, but functional equivalents, where necessary), documented, replacement parts and consumables.
- ORF/DFOM shall develop and maintain a training program for APF O&M, under the QA oversight of ORF/DTR/FCIS. See Section 13.20.8.
- ORF/DTR/FCIS shall develop and maintain a facility audit program for APFs. Audits may be external, conducted by regulatory bodies, internal, conducted by NIH staff, or contract SMEs, to assure readiness for external audits. Audits may be routine, announced and planned, or they may be unplanned and unannounced. They may be for cause, or may be for other purposes, unrelated to a for-cause report or event. See Section 13.20.9.

Appendices

The Appendix covers a wide range of topics and provides additional information, forms, and templates which are referenced throughout the body of the DRM. All users of the DRM should become familiar with the contents of the Appendix. Summaries of each are found below.

Appendix A: Biological Safety Cabinet (BSC) Placement Requirements for New Buildings and Renovations

- Appendix A, The BSC Placement Requirements, dictates the safe placement and usage of Biological Safety Cabinets within NIH Facilities. The requirements are accompanied by illustrations which show some of the more common configurations.
- Refer to Appendix A for detailed information.

Appendix B: Downdraft Table Particle Capture Efficiency Calculation

- Appendix B, Downdraft Table Particle Capture Efficiency Calculation, provides a means to calculate the particle capture of downdraft tables and verify their safe usage.
- Refer to Appendix B for detailed information.

Appendix C: BAS for Bethesda Campus and Satellite Sites

- Appendix C, BAS for Bethesda Campus and Satellite Sites, provides additional information on Building Automation System requirements along with the necessary IT provisions.
- Refer to Appendix C for detailed information.

Appendix D: HVAC

- Appendix D, HVAC, covers many of the formulas and studies which drive requirements found within the DRM Mechanical Design chapter.
- Refer to Appendix D for detailed information.

Appendix E: A/E Submission Requirements

- Appendix E, A/E Submission Requirements, lists all the expected and necessary documents needed for NIH review of a project. Additionally, this appendix dictates the quality expected of the documents.
- Refer to Appendix E for detailed information.

Appendix F: Room Data Sheets

- Appendix F, Room Data Sheets, provides sample room data sheets of common spaces within laboratories. The data sheets are meant to be a guide for other designers and should be custom to each project.
- Refer to Appendix F for detailed information.

Appendix G: Sample Equipment Schedule

- Appendix G, Sample Equipment Schedule, provides a template which designers may use to determine equipment requirements within their own projects. This schedule should be tailored to each project as needed.
- Refer to Appendix G for detailed information.

Appendix H: DRM Links

- Appendix H, DRM Links, provides hyperlinks to many important standard, regulatory, or industry organizations.
- Refer to Appendix H for detailed information.

Appendix I: Abbreviations, Acronyms, and Units of Measure

- Appendix I, Abbreviations, Acronyms, and Units of Measure, provides the user with many of the common abbreviations and units of measure found within the DRM.
- Refer to Appendix I for detailed information.

Appendix J: Lease Facilities DRM Checklist

- Appendix J, Lease Facilities DRM Checklist, outlines the extent to which the DRM should be applied to facilities leased by NIH.

The formulae $\frac{\partial \rho U_i}{\partial t} + \frac{\partial}{\partial x_j}(\rho U U_j) = -\frac{\partial P}{\partial x_i} + \frac{\partial}{\partial x_j}\left(\mu \frac{\partial U_i}{\partial x_j}\right) + g_i(\rho - \rho_0)$ $\frac{\partial \rho U_i k}{\partial x_i} = \frac{\partial}{\partial x_i}\left(\left(\mu + \frac{\mu_t}{\sigma_k}\right)\frac{\partial k}{\partial x_i}\right) + P + G - \rho\varepsilon$ $\frac{\partial}{\partial x_j}(\rho \overline{U_i U_j}) = -\frac{\partial P}{\partial x_i} + \frac{\partial}{\partial x_j}\left(\mu \frac{\partial U_i}{\partial x_j} - \rho \overline{u_i u_j}\right) + g_i(\rho - \rho_0)$ $-\rho \overline{u_i u_j} = \mu_t\left(\frac{\partial U_i}{\partial x_j} + \frac{\partial U_j}{\partial x_i}\right) - \frac{2}{3}\rho k \delta$ $\frac{\partial \rho U_i \varepsilon}{\partial x_i} = \frac{\partial}{\partial x_i}\left(\left(\mu + \frac{\mu_t}{\sigma_\varepsilon}\right)\frac{\partial \varepsilon}{\partial x_i}\right) + C_1 \frac{\varepsilon}{k}(P + C_3 G) - C_2 \rho \frac{\varepsilon^2}{k}$ $\frac{\partial}{\partial t}(\rho \overline{U_i U_j}) = -\frac{\partial P}{\partial x_i} + \frac{\partial}{\partial x_j}\left(\mu \frac{\partial \overline{U_i U_j}}{\partial x_j} - \rho \overline{u_i u_j}\right) + g_i(\rho - \rho_0)$ *for building* $\frac{\partial \rho U_i \varepsilon}{\partial x_i} = \frac{\partial}{\partial x_i}\left(\left(\mu + \frac{\mu_t}{\sigma_\varepsilon}\right)\frac{\partial \varepsilon}{\partial x_i}\right) + (C_1 - C_{1RNG})\frac{\varepsilon}{k}(P + C_3 G) - C_2 \rho \frac{\varepsilon^2}{k}$ $\frac{\partial}{\partial x_i}(\rho \overline{U_i H}) = \frac{\partial}{\partial x_i}\left(\lambda \frac{\partial \overline{T}}{\partial x_i} - \rho c_p \overline{u_i T}\right)$ *biomedical research facilities.*

- Refer to Appendix J for detailed information.

Appendix K: DRM Variance Form

- Appendix K, DRM Variance Form, is referenced throughout the DRM and serves to allow exemptions from DRM requirements. Exemptions may be granted on grounds of burdensome existing conditions or other materials, systems, or products which meet the intent of the DRM through performance equivalence.
- Refer to Appendix K for detailed information.

Appendix L: Sealant Table

- Appendix L, Sealant Table, provides various sealant types and where they should be applied within NIH facilities.
- Refer to Appendix L for detailed information.

Appendix M: Interior Signage Manual

- Appendix M, Interior Signage Manual, provides a guideline for the expected signage and wayfinding within NIH facilities.
- Refer to Appendix M for detailed information.

Appendix N: High Purity and Animal Drinking Water System Sanitization, Lab Testing, and Acceptance

- Appendix N, High Purity and Animal Drinking Water System Sanitization, Lab Testing, and Acceptance, provides an outline to ensure that water quality meets the needs of specific programs within NIH.
- Refer to Appendix N for detailed information.

Appendix O: Specialty Labs

- Appendix O, Specialty Labs, provides design guidance on unique research spaces such as Insect Facilities and Electron Microscope Facilities. Additional sections will be added as future needs are identified.
- Refer to Appendix O for detailed information.

The formulae $\frac{\partial \rho U_i}{\partial t}+\frac{\partial}{\partial x_j}(\rho U U_j)=-\frac{\partial P}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu\frac{\partial U_i}{\partial x_j}\right)+g_i(\rho-\rho_0)$ $\frac{\partial \rho U_i \varepsilon}{\partial x_i}=\frac{\partial}{\partial x_i}\left(\left(\mu+\frac{\mu_t}{\sigma_\varepsilon}\right)\frac{\partial \varepsilon}{\partial x_i}\right)+(C_1-C_{1RNG})\frac{\varepsilon}{k}(P+C_3G)-C_2\rho\frac{\varepsilon^2}{k}$ $\frac{\partial \rho U_i k}{\partial x_i}=\frac{\partial}{\partial x_i}\left(\left(\mu+\frac{\mu_t}{\sigma_k}\right)\frac{\partial k}{\partial x_i}\right)+P+G-\rho\varepsilon$ $\frac{\partial}{\partial x_j}(\rho\overline{U_i}\overline{U_j})=-\frac{\partial \overline{P}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu\frac{\partial \overline{U_i}}{\partial x_j}-\rho\overline{u_i u_j}\right)+g_i(\rho-\rho_0)$ $\frac{\partial}{\partial x_j}(\rho\overline{U_j}\overline{T_j})=-\frac{\partial \overline{P}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu\frac{\partial \overline{U_i}}{\partial x_j}-\rho\overline{u_i u_j}\right)+g_i(\rho-\rho_0)$ $-\rho\overline{u_i u_j}=\mu_t\left(\frac{\partial \overline{U_i}}{\partial x_j}+\frac{\partial \overline{U_j}}{\partial x_i}\right)-\frac{2}{3}\rho k\delta$ *state of the art* $\frac{\partial}{\partial x_j}(\rho\overline{U_j}\overline{T_j})=-\frac{\partial \overline{P}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu\frac{\partial \overline{U_i}}{\partial x_j}-\rho\overline{u_i u_j}\right)+g_i(\rho-\rho_0)$ *for building biomedical research facilities.*