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Introduction to Stability in Aseptic Processing Facilities – Part 1

Introduction

NIH Aseptic Processing Facilities (APFs) are cleanrooms which process or support the processing of drugs and/or biologic products in accordance with current good manufacturing practices (cGMP) for human use. These facilities require control of critical environmental parameters, including room differential pressure (dP), temperature (TEMP), relative humidity (RH), and air changes per hour (ACH). They are also designed and operated to limit the spread of particulates to protect the product from contamination, and to promote patient safety by preventing personnel from sweating and shedding both viable and non-viable particles (e.g., mold, spores, fungi, yeast, etc.). Operating a cleanroom facility in a state of control is required by Title 21 Code of Federal Regulations Part 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs, General, Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals. These parameters must remain stable (i.e., exhibit minimal oscillation, noise, and drift) within a specific range during normal operations and recover fully after an upset event (such as failure of a primary air handling unit, exhaust fan, generator testing, or other electrical power disruption, etc.). Room dP is the most critical parameter for assessing the stability of the facility and is the key indicator for ensuring that airflows are maintained as designed.

Importance of Stability with APFs

Environmental monitoring and control systems for APFs utilize high performance and high precision equipment/devices and control methods to maximize the stability of critical environmental parameters (e.g., room dP, TEMP, and RH) and maintain them within specified limits. High performance equipment/devices used in APFs include fast-acting air terminal actuators, which allow for rapid airflow changes to counter any room-side changes. High precision devices used in APFs include sensors with a high degree of accuracy and tight calibration criteria to ensure the data being recorded are reliable and accurate. Airflow tracking and airflow cross limiting are two control methods NIH uses to maintain differential pressures between adjacent spaces. For positive pressure rooms, the exhaust terminals will track the supply terminals. For negative pressure rooms, the reverse will occur. These devices and control methods minimize oscillating conditions (which is the most general stability issue) that can stress processing equipment, cause the overall environmental conditions to become less predictable, and increase recovery time after an upset event. Oscillating conditions can also cause stress to materials of construction and increase worker discomfort, which collectively can adversely impact product quality and patient's safety.

Critical Environmental Parameters Stability Criteria

NIH has established the following acceptance criteria that are evaluated as part of the stability trend review during the commissioning process to assess if the APF is stable for all critical parameters. Typical acceptance criteria for dP stability are established in static (at rest) modes. The following criteria apply to NIH APFs:

- **dP:** The mean average for dP shall be no less than 0.02" w.c. from the alarm limits. If the alarm limits are 0.02" w.c. and 0.1" w.c., the mean average is between 0.04" w.c. and 0.08" w.c. For negative dP rooms, dP values are preceded by the minus sign. The shift in mean dP should not be more than 0.06" w.c. (max-min) in amplitude of oscillation using 1-min trend data. The max-min amplitude should not cross alarm limits; this is referred to as noise. The shift of mean dP over a 24-hour period shall not be more than 0.01" w.c. using 1-min trend data; this is referred to as drift.
- **TEMP:** Shall be within +/- 0.5°F of setpoint and 1°F top to bottom oscillation.
- **RH:** Shall be within 5% of setpoint and no more than 10% top to bottom oscillation.

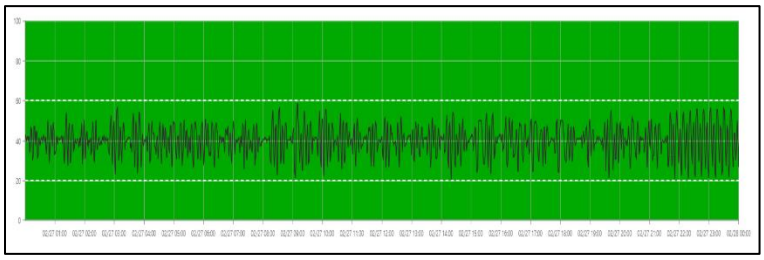

Figure 1: Oscillation (solid black line) of Relative Humidity in an APF illustrating lack of stability.

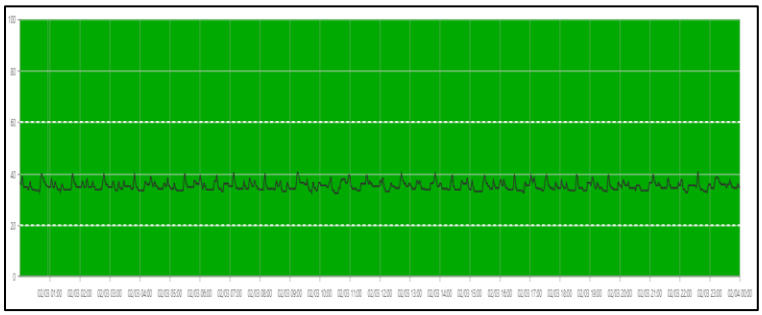

Figure 2: Stable Relative Humidity in an APF

Conclusion

Establishing and maintaining stability for all criterial parameters will ensure all APFs at NIH meet quality and safety standards for all products and processes, as well as provide optimal levels of comfort for workers inside the APFs.

Part 2 of this series will cover the stability trend review process and how it is utilized to ensure that all critical parameters have successfully met the stability acceptance criteria.

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Introduction to Stability in Aseptic Processing Facilities – Part 2

Introduction

Part 1 of this article series discussed the importance of achieving and maintaining stability for NIH's Aseptic Processing Facilities (APFs) and briefly introduced the acceptance criteria for stability. This article will cover the stability trend review process and how it is utilized to ensure that the critical environmental parameters (i.e., differential pressure [dP], air changes per hour, temperature, and relative humidity) meet their stability acceptance criteria.

Stability Trend Review

Precursors to Stability Trending: Complete all construction that impacts room leakage prior to stability trend review. This includes HVAC system Testing, Adjusting, and Balancing (TAB); Building Automation System (BAS) sensor calibration; and BAS loop tuning.

Stability Trending: The commissioning, qualification, and validation (CQV) team executes BAS pre-functional commissioning, a process which includes collecting 72-hour (minimum) initial and final trends, though shorter trend periods may be utilized to assess corrective actions and adjustments. Trends are typically taken based on one-minute intervals for both static (at rest) and dynamic modes. During trend collection, access to APFs is controlled and activities are logged. Trending the following is also recommended concurrent with static and dynamic trending: outdoor air conditions; control valve and air damper positions; and air handler unit (AHU) supply air temperature, relative humidity, and supply and exhaust system duct static pressure and fan speed.

Trends must show the cleanroom is operating within the acceptance limits for both static and dynamic modes. Trends shall also show the ability to recover quickly from an upset condition such as power loss, power blip/voltage sag, emergency generator test. For major disruptions such as those requiring restart of the AHUs, the proportional integral derivative (PID) loops shall be set to allow for all room critical parameters (temperature, relative humidity, differential pressure, and air changes per hour) to recover and achieve stability within 30 minutes.

Stability Trend Review: Room stability is evaluated by reviewing the collected trend graphs for each of the critical parameters. For static mode trends, the cleanroom must have all services functioning and production equipment installed and capable of being operated or operating, but without operating personnel within the facility. For dynamic mode trends, the cleanroom must be configured as in a static mode, but with normal production activities or simulated production activities during testing.

During the critical parameter trend stability review, the review team identifies and evaluates areas that do not meet stability acceptance criteria, then identifies the root cause of these failures. This evaluation generally includes, but is not limited to, door sweeps; door operations; BAS controls (such as valve hunting or drastic change in damper position, sensor/device issues, control loop tuning, infrastructure/utility support, different modes of operation, schedule of lead/lag equipment switchover, setpoint change); personnel log; and activity log. Corrective actions are then identified and executed prior to the next trend review. Any activities performed between the static and dynamic trend reviews should be documented so that the action can be reverted if it improves one trend but worsens the other. This process is repeated until all parameters have met the stability acceptance criteria defined in Part 1 of this article series. Once stability is achieved, it is expected that this stability will be maintained until the facility turned over to the Division of Facilities, Operation, and Maintenance (DFOM) for Operations and Maintenance phase activities.

It should be noted that large and complex APFs typically require more time for the balancing, tuning, and adjustments required to achieve stability than smaller, less complex facilities, specifically for room dP. The project team should consider these influences when establishing the acceptance criteria.

Conclusion

Stability trend review is an iterative process that is utilized to ensure that all critical parameters successfully meet the stability acceptance criteria. At NIH, stability is monitored throughout the life of the cleanroom facility, and any changes made to the facility during Operations and Maintenance phase are subject to an Engineering Change Management Standard Operating Procedure to minimize any unintended consequences of changes.

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Effective Pass-Through Chamber Design – Part 1

Introduction

Biomedical research facilities, cleanrooms, and similar facilities commonly have workflows which require efficient and reliable means for transferring materials between areas of varying levels of control. This article will explore some of the essential planning, design, and specification considerations for effective pass-through chamber (PTC) design. Next month, the second part of this series will address considerations for effective PTC commissioning, qualification, and validation.

Design Considerations

Before beginning to specify, design, or select a system, an integrated project team (IPT) should explore PTC planning and design options and address several considerations, including:

Context: While all PTCs facilitate the transfer of material between differing zones of control, it is essential to understand the implications of whether the material is transiting between differing levels of security (maintaining chain of custody, etc.), ISO classification, safety, risk, etc. This article series focuses on the higher criticality/risk end of this spectrum.

Regulatory Requirements: Critical PTCs are often used in pharmacy, radiopharmacy, and biologics processing facilities and their support spaces. These spaces are governed by various application-specific United States Pharmacopeia General Chapters, though many reference back to USP General Chapter <797> Pharmaceutical Processing – Sterile Preparations. In cleanrooms, ISO 14644 will apply. Other regulations specific to the PTC instance may also apply.

Capacities: The IPT must understand the throughput/cycle rate demanded by the workflow, whether the PTC will be operated with a cart/shelf retained inside, the size and weight of carts and/or other equipment or supplies to be passed through the PTC, etc. The orientation, net clear opening, clear door operation area, and types of doors selected must be considered in the context of the workflow and space constraints.

Administrative vs. Engineering Controls: Administrative controls are work practices which reduce the frequency, severity, or impact of risks and may include means for enhancing the detection of a risk occurrence. Examples of administrative controls include cleaning of the PTC, wipe down of materials entering/leaving the chamber, etc. Engineering controls remove or reduce a risk and may include door gasketing to ensure the chamber reliably prevents lower classified air from leaking through the chamber to the better classified air on the opposite side of the PTC; using HEPA- or ULPA-filtered supply air to dilute any particles in the air within the chamber; providing exhaust air to remove suspended particles from the chamber; etc. The need for and types of controls should be identified individually for each PTC until the net risk is reduced to below the risk tolerance of the authority having jurisdiction (AHJ) or designated responsible individual (this could be the end user, an infection control or safety officer, etc.).

Material Selection: The material selection is crucial for ensuring cleanability, maintainability, resistance to degradation when exposed to the cleaning chemicals identified in the administrative controls, and performance when exposed to any of the biological agents that the PTC can be expected to be exposed to during its service life. Type 304 stainless steel with a D-finish is a typical selection for the PTC carcass and doors because of its corrosion-resistance, hardness, non-porosity, and limited reactivity, but certain applications may require better grades of stainless steel or other materials.

Airflow and Recovery: A PTC should be considered part of both the architectural and HVAC environments. The chamber sits between differing classifications, which may include different environmental parameters, particularly absolute pressures, and ISO classifications. As such, like with an airlock or anteroom, it is critical to understand the differential pressures to each of the connected spaces (non-pressurized, bubble, cascade, or sink) to ensure directional airflow and to minimize turbulent flow, thereby minimizing the ingress of contaminants into better classified areas. Note that the time it takes to equilibrate pressures and purge the chamber volume with new, filtered supply air may significantly impact the throughput of the PTC. For chambers provided with supply and/or exhaust air (i.e., active PTCs), the small chamber volume often means that the airside controls will be operated at inefficiently low volumes. Where multiple PTCs are on the same air valve, the ability to individually trim each chamber becomes essential.

Design Features: After considering the various design features and acceptance criteria described above, the architects and engineers on the ITP can now focus on the specifications. All PTCs should be designed for cleanability, meaning they should be crack/crevice free with smooth, rounded corners and similar features. Generally, all critical PTCs should feature an interlocking system to prevent the simultaneous opening of both doors – this system may be manual or electronic (the latter may facilitate timed recovery periods to signal to the user that it is safe to open the chamber door). If using HEPA- or ULPA-filtered air, it is useful to provide challenge ports for filter certification, which would typically be installed on the dirty side of the PTC. Maintainability is also a key consideration, including ensuring door gaskets are readily replaceable and specifying reliable hinges and latching hardware. Ensure that any potentially hazardous PTC exhausts are managed appropriately to protect personnel. In critical applications, ensure that PTC electronics, fans, etc., are connected to emergency power.

Conclusion

The design and specification of PTCs requires the risk-based consideration of various administrative and engineering controls to deliver an appropriate set of requirements to the construction contractor, manufacturer, and the commissioning, qualification, and validation contractors. The IPT is responsible for bringing these elements together to provide an appropriate PTC system that promotes patient safety while meeting the user's needs for throughput safe working conditions and reliable research outcomes.

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Effective Pass-Through Chamber Commissioning, Qualification, and Validation – Part 2

Introduction

The first article in this series explored essential planning, design, and specification considerations for effective pass-through chamber (PTC) design for biomedical facilities. During the design phase, the Integrated Project Team (IPT) should develop the acceptance criteria for the PTC and the test protocols which will be executed. This article address considerations for effective PTC commissioning (Cx), qualification (Qx), and validation (Vx), collectively referred to as CQV, which are essential for ensuring the PTCs are fit for their intended service at facility turnover.

Commissioning (Cx)

Commissioning refers to the systematic process of ensuring the PTC, as constructed and adjusted, functions according to design specifications. Cx begins during the design phase (i.e., Design Qualification, or DQ) and includes review of the design documents against the user's requirements to ensure that the information to be conveyed to the contractor, manufacturer, and CQV agent is consistent with the user's design intent. The contractor will furnish a manufacturer's submittal, including drawings, and product literature which must be reviewed to ensure conformance with the approved construction design documents.

For critical PTCs, the owner may include a Factory Acceptance Test (FAT) where the CQV agent travels to the factory to execute the FAT protocol. This demonstrates general conformance with the project requirements, though some testing, such as that which involving pressurization and airflows, may be limited at the factory. Typical FAT testing includes a visual inspection for assessing construction quality, a checklist of features and dimensions, a wipe test over all exposed surfaces to ensure there are no defects which might snag a glove or cleaning cloth, and possibly a soap bubble test to identify issues with door and glazing seals. The FAT results in a deficiency list for resolution before the units are shipped to the site. The Cx agent documents the installation process and any adjustments that need to be made to ensure the units are functioning properly, including troubleshooting as necessary.

Upon installation, a Site Acceptance Test (SAT) protocol may be executed to ensure the FAT-identified defects have been resolved and that the units have not been damaged during transit and installation. The Cx agent also documents the completion of all required facility operations and maintenance training. Cx of PTCs with supply air (SA), exhaust air (EA), or both can be a complex undertaking. Multiple active PTCs can be tied to the same air valve, which also provides airflow with the associated clean room. Each PTC is also provided with its own trimming damper to balance the airflow. Balancing the airflow to the active PTC can only be done with both PTC doors closed. The addition of active PTCs can extend the time and effort it takes to achieve airflow and pressure stability and successfully commission the space.

Qualification (Qx)

Qualification involves the systematic evaluation of Cx data to establish a documented record that the chamber consistently performs as intended. For PTCs used in pharmaceutical applications, qualification is broken into discrete sections, including:

- Installation Qualification (IQ): verifies that the PTC has been manufactured, installed, and configured according to the approved-for-construction design documents and any manufacturer's specifications or installation checklists.
- Operational Qualification (OQ): verifies that the PTC is functioning correctly and that the cleaning protocol can maintain the user's required cleanliness level. OQ also verifies airflow and ensures particles from the lower-classified side are prohibited from traversing the PTC to the better-classified side.
- Performance Qualification (PQ): verifies that the PTC is functioning consistently over time, at rest, and under simulated routine operations.

Validation (Vx)

Validation involves the evaluation of the data generated in Cx and IQ/OQ/PQ, ensuring the documentation is complete and conforms with Good Documentation Practice (GDP). Vx should also confirm the traceability of the features of the PTC as it was designed, manufactured, installed, commissioned, and qualified to fulfill the applicable regulatory, risk assessment, and user requirements. Please note that Qx and Vx are typical only in Aseptic Processing Facilities and are not typical of all active PTC installations.

Conclusion

Cx is indispensable for establishing the reliable function of PTCs in biomedical applications, while Qx and Vx are necessary in certain critical environments. Meticulous documentation and adherence to regulatory standards are key factors in ensuring that PTCs meet the rigorous demands that are put on them, contributing to the success and integrity of scientific endeavors.

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Networked Lighting Control

Introduction

Electrical engineers must consider important design features when designing networked lightening controls. These include its key topologies, components, configurations, and operational protocols. In addition to the distribution layout/configuration, a designer must evaluate the lighting control sensors, types of controllers, computer programs specific to lighting controls, and continuous dimming features.

Types of Layouts

Networked lighting is comprised of permanently connected electrical equipment supplied from a generating source. Distribution mediums can include power cables, low-voltage wiring, or Ethernet cables. Networked distribution layouts depend on a variety of factors such as hardware, devices, levels and types of communications, database, facility (occupancy types), and location of the service. The most common types of networked lighting layouts are radial, star, ring, and interconnected layouts:

1. Radial layout includes bus and branching (tree) layouts:
   a. Bus refers to nodes connected linearly, with communication following a direct pathway between nodes.
   b. Branching (tree) refers to multiple nodes that aren't connected linearly, requiring reconfiguration of the distribution.
2. Star layout refers to all nodes linked directly to a central hub, enabling communication between any two nodes through the hub. While a central hub is necessary for this layout, the addition of a new node to a star network usually has minimal impact on existing communication, as each node connects directly to the hub.
3. Ring layout refers to a closed loop of nodes that communicate in a circular fashion. Data is passed from one node to the next until it reaches its intended destination. The addition of nodes to a ring network can disrupt communication flow, potentially necessitating reconfiguration to ensure continued efficiency and reliability.
4. Interconnected (mesh) layout involves nodes which are interconnected through multiple redundant connections, creating robust communication pathways. This redundancy ensures that if one connection fails, alternative routes are available, enhancing reliability and fault tolerance. The addition of a new node to a mesh network expands its coverage and potentially enhances its resilience. However, the impact of adding nodes varies depending on the network's architecture and scalability.

Network Components and Protocols

The most common types of networked lighting components include:

1. Sensor technologies:
   a. Motion sensors enable lights to adjust brightness or switch on/off in response to detected motion. Sensors can either be integrated within the luminaire or installed separately.
   b. Lighting intensity sensors enable lights to adjust brightness or switch on/off based on the presence of artificial light or daylight. Sensors may be integrated into fixtures or mounted on walls/ceilings.
2. Wall controllers offer autonomous lighting control within the space, integrating occupancy sensors, timeclocks, and photocells.
3. Scene-controllers integrate lighting devices to enable the operation of multiple lights across various spaces based on pre-set schedules.
4. Individual controllers allow personal lighting control, giving users the ability to individually set lighting levels.
5. Continuous dimming refers to the ability to adjust the lighting intensity seamlessly and smoothly using 0-10V control to scale its output. For example, at 10 V, the controlled light should be at 100% of its potential output, and at 0 V it should at 0% output.

Wireless lighting control systems consist of relay modules or power packs, typically installed on a luminaire or a junction box within the space. They also include input devices such as sensors and switches as well as management devices such as gateways, which function similarly to wireless routers. These input devices interact with a power controller. Wall-mounted switches typically send signals directly to the luminaire controller and can be integrated with an occupancy sensor. These wireless lighting control fixtures are typically designed with PC software which communicates with the lighting control panel for user-defined settings and adjustments.

Protocols entail a set of rules governing device design to ensure interoperability. Lighting control protocols can be open, allowing devices from different manufacturers to communicate, or proprietary, restricting communication to devices from a single manufacturer.

Conclusion

Networked lighting control requires the correct hardware design, software and operating system to allow a range of user-adjustable lighting functions and controls. Designers must consider the most appropriate layout and the necessary fixtures and components in order for a lighting system to meet the needs of a facility and its users.

Further Reading

1. IES, Illuminating Engineering Society

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Multiple Level Parking Garage Design Considerations and Maintenance

Introduction

Designing and maintaining a multiple level parking garage involves many considerations to ensure its functionality, safety, aesthetics, and longevity. These considerations include structural integrity, vehicular circulation, environmental impact, user experience, and ongoing maintenance.

Design Considerations

Structural Integrity:

The garage must support vehicle weight, impact loads from vehicle movement, and additional loads such as snow, wind, and seismic. Most parking garages on the NIH Bethesda campus have a design live load of 50 psf, which is 25% greater than the minimum design live load required by the International Building Code (IBC). Engineers evaluate these loads to ensure safety and durability. Common materials used in parking garage construction include reinforced concrete, pre-stressed concrete, and structural steel. Material choice depends on site conditions, time, and budget constraints. Proper traffic coating is essential to prevent salt and other chemicals from penetrating the surface of the concrete, which can cause significant structural damage to the reinforcing and concrete surface over time.

Vehicular Circulation:

An efficient ramp design is critical for smooth traffic flow. Options include straight, helical, or sloped floors, each of which affects the speed and ease of navigation. Strategic placement of entrances and exits minimizes congestion on surrounding streets. The layout of a multiple level parking garage must maximize space utilization while ensuring easy access. Angled parking spaces facilitate easier parking and retrieval but are less space-efficient than straight-in parking stall designs. Adequate overhead clearance height for different types of vehicles, including emergency vehicles and ADA vans, is essential. The design should consider potential future expansion or conversion to different uses.

Safety and Security:

Adequate illumination is essential for safety and security, including accident reduction and deterrence of criminal activity. LED fixtures are energy efficient, especially when combined with vacancy sensors (see table 10.7.3 of the NIH *Design Requirements Manual* for parking garage lamp types). Conveniently located and easily accessible distress call stations placed at every level of the parking garage greatly enhance security. CCTV cameras may be provided to enhance safety in areas with inadequate sightlines. Strategically placed mirrors and signs can help to mitigate blind spots and improve safety in high traffic areas. Sprinkler systems, fire alarms, smoke ventilation, mass notification systems, and emergency egress routes are mandatory. Sprinkler systems must be designed and constructed to protect from freezing.

User Experience:

It is crucial to ensure compliance with ADA standards by providing accessible parking spaces, ramps, and elevators. Beyond ADA requirements, clear wayfinding helps drivers navigate efficiently. Color-coded floors and various technology, such as integrating real-time occupancy tracking with digital displays, enhance efficiency and user experience, as does a well-lit, clean, and aesthetically pleasing garage. Landscaping around the garage and attractive facades help it blend into the urban environment and can provide easily identifiable and safe entry and exit points to the garage for vehicles and pedestrians.

Environmental Considerations:

Incorporating sustainable building practices such as using recycled content materials, installing solar panels, and implementing adequate stormwater management reduces environmental impact (see section 8.4.20.7 of the NIH *Design Requirements Manual* for parking garage drainage). It is increasingly important to provide electric vehicle charging stations as the number of electric vehicles grows. Proper ventilation for garages reduces exhaust fume buildup for personnel safety.

Maintenance Considerations

Regular structural inspections to identify cracks, spalling, and other structural issues are a must. Early detection can prevent minor issues from becoming major problems. Lighting, ventilation, fire safety systems, and elevators require regular checks to ensure they are functioning correctly. Regular cleaning of surfaces, especially in high-traffic areas, prevents the buildup of dirt, oil, deicing salts, and debris that can cause surface degradation. A well-maintained drainage system will prevent water accumulation or flooding that can lead to structural damage, premature corrosion of structural steel, and safety hazards.

Conclusion

Designing and maintaining a multi-level parking garage requires a holistic approach that balances numerous factors. From structural integrity and vehicular circulation to safety, user experience, environmental impact, and maintenance, each aspect plays a critical role in creating a functional, safe, and efficient parking design. By carefully addressing these design considerations, engineers and operators can ensure the parking garages meet current needs and adapt to future changes while remaining safe and cost-effective.

References

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2. International Building Code

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Review vs Approval: Construction Submittals

Introduction

Construction submittal documents (which may include shop drawings, material samples, engineering calculations, product cutsheets, mockups, vendor information, material data sheets, warranties, guarantees, diagrams, etc.) are a means of communicating how the contractor intends to achieve the design intent as conveyed by the approved-for-construction documents. Reviewing construction submittals can often be a meticulous and time-consuming process, but it is critical to ensure conformance to the relevant specifications, design drawings, and other approved-for-construction documents. The construction contractor performs the initial review and is generally responsible for ensuring count, dimensional coordination, sequence with other work, existing conditions, compatibility with other work, and other factors that are reviewed as part of the contractor's independent quality control process. This is followed by subsequent review by the Architect/Engineer (A/E) of Record and other NIH reviewers (including professional staff, users, and contracted independent consultants). Per contract language and liability, the A/E is responsible for technical conformance review of construction submittals. Other NIH parties provide review focused on conformance with design intent, including functionality, maintainability, operability, reliability, etc.

Review Practices

The contractor must provide the initial review and approvals of all submittals, followed by the A/E of record, who is responsible for compliance with the construction documents. It is preferable to wait until the A/E of record has reviewed the submittals before beginning NIH review, though project timelines often demand parallel review by the NIH. In all cases, NIH reviewers must exercise care to not give direction to the contractor, unless delegated with such authority by the Contracting Officer (CO). Reviewers must also be cautious to avoid unintentionally transferring risk from the A/E and construction contractor to the Government. To mitigate this risk, the Federal Acquisition Regulation includes a clause that states that "approval by the CO shall not relieve the contractor from responsibility for errors or omissions"[6]; regardless, avoid creating approval language which confuses the distribution of risk as defined by the contract or which may be used in a manner that appears to alter the contract. The proper tool for resolving this type of condition is the change order process, managed by the CO.

NIH reviewers should compare the submittal to the approved-for-construction specifications and other documents, identifying and commenting on any deviations (e.g., discrepancies, inconsistencies, etc.) from the specifications, applicable regulations, quality, fitness for use, function, compatibility, reliability, maintainability, etc. Reviewers should also consider ensuring the provision of all operational and maintenance clearances. Overall, look for whether the submittal appears fit for the intended purpose. Catching potential problems early in the submittal process can save time, money, and potential maintenance headaches.

Submittal Review vs Approval

Although NIH reviewer comments should generally seek to avoid transferring risk to the Government, there are instances where selection and/or approval by NIH representatives is required, such as:

Submittals Requiring A/E Approval: The most typical submittal type, where the A/E of Record or their designee is responsible for a Quality Control (QC) level of review of the proposed product and selected options (e.g., material of construction, finishes, functions, etc.) against the approved-for-construction documents (i.e., specifications having determinative authority, supplemented by the calculations, drawings, basis of design, etc.). In this case, NIH reviewers are responsible for a Quality Assurance (QA) review, ensuring adequate QC by the Contractor and the A/E and conformance with applicable codes, regulations, standards, and the contract.

Submittals Requiring Government Selection: These submittals are subject to QC review by the contractor and A/E, but additionally require limited approval of selections (e.g., color, style, etc.) from a range of products of types which meet predetermined acceptance criteria. Though the contract language typically identifies such selections as requiring CO approval, this is generally delegated to the Contracting Officer's Representative (COR) or to a Project Officer (PO), and these selections are often deferred to the end user of the project. These selections should be of a nature that conveys little to no risk to the government.

Submittals Requiring Government Approval: Some projects involve specialized equipment or systems in which neither the A/E or contractor has expertise or are of a level of criticality which demands government acceptance. In such cases, the contract will generally specify the need for that government approval. In these cases, the NIH user is often a subject matter expert (SME) or is advised by a contracted, external SME. The government should be identified in the contract language as narrowly responsible for approval of submissions related to this item. To defray the risk the government assumes in this case, QC reviews by the contractor and A/E are required. These reviews are often supplemented by factory and site acceptance testing, commissioning, testing, and in some cases qualification to ensure compliance with predetermined acceptance criteria, including fitness for purpose and reliability requirements.

Conclusion

Reviewing submittals is a complex task, but one which is essential for ensuring NIH receives the quality of work it needs from our contractors. However, it is critical to ensure that risk is not unintentionally transferred to the NIH in this process.

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UPS Battery Failures

Introduction

UPS battery power-related downtime incidents are proven to be the costliest failures in commercial and industrial facilities due to their impact on all connected systems and equipment. This article covers likely causes of failures and UPS selection and design choices to avoid failures and minimize their impact.

Causes of UPS Failure

Like any other battery, UPS batteries have a lifespan and require replacement when they no longer supply 80% of rated amp-hour. However, UPS battery life may be impacted by factors other than time. For instance, extreme temperatures can also affect the capacity of the batteries. High ambient temperature will degrade the batteries, or if temperature drops below a certain degree, they may underperform. Another degrading factor is over-cycling – constant over-cycling causes premature battery end-of-life. If a battery is charged and discharged too frequently, the battery contacts deteriorate, which in turn reduces the battery's capacity.

Failures in UPS batteries can also occur due to poor equipment design or inadequate planning. For example, if a UPS is replaced with a larger capacity UPS and the air conditioning is not upgraded and doesn't produce a sufficient volume of chilled air, the battery will subsequently overheat. To avoid this, air conditioning units must run efficiently during hot summer days and must be serviced regularly to ensure proper and adequate cooling of the UPS system.

Dust build-up on the battery can also cause overheating. The accumulation of statically-charged dust particles coupled with condensation can pass through the UPS's ventilation and deteriorate the battery contacts.

Overheating is one of main culprits of UPS failures. An overloaded UPS continuously operating at 100% or greater output will overheat. Fans are integrated throughout the UPS in specific places to maintain effective component cooling, and a single fan failure can cause overheating. Other causes of failure include overcharging, incorrect float voltage, and being left in storage too long without recharging.

UPS Selection and Design Choices

A single-phase UPS is usually used for smaller loads such as security system control, voiceover IP, distributed services, or any other rack-mounted application. Smaller remote IT stations may rely entirely on a single-phase UPS to keep the infrastructure operational. It is critical to choose the correct battery type for a single-phase UPS, given a failure due to poor equipment design will affect the entire facility or system served. A good option is valve-regulated lead-acid technology. In contrast, inferior or second-rate batteries may shut the whole system down if one cell exceeds a high temperature unless the system employs a strict battery management system (BMS). In data center applications, a large three-phase floor-mounted UPS system is preferable to multiple single-phase UPS units. In addition, three-phase UPS systems shall include a maintenance bypass switch to ensure uninterrupted power during maintenance.

When installing a single-phase UPS, the designer must consider the "form factor." Form factor is a hardware design aspect that defines and prescribes the size, shape, and other physical specifications of electrical and electronic components; different form factors may be appropriate for different contexts. The best practice to install a small UPS is on a DIN rail, a standard metal rail used for mounting electrical control equipment inside an equipment rack, which facilitates equipment cooling. The UPS also needs to comply with *DRM* 7.4.14.2 – Central Uninterruptible Power Supply Systems, which mandates BAS monitoring of UPS for basic status, common alarms, and battery voltage.

Conclusion

Given the criticality of good UPS system design and the potential impact of a failure, it is necessary to ensure that UPS batteries are appropriately managed for reliability and sustainability. This includes evaluating the optimal UPS location, reviewing the mechanical environmental systems (i.e., ventilation, humidity, temperature), developing a comprehensive UPS maintenance program with standardized UPS preventive maintenance services (i.e., routine UPS checks and shakedown), and implementing a Battery Monitoring System through the building's SCADA system. Engineers need to pay special attention to the UPS's degrading factors and work closely with the maintenance team to ensure optimal UPS functionality.

References

1. NIH *Design Requirements Manual*, Section 7.4.14.2 – Central Uninterruptible Power Supply Systems

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BAS Control for Variable Flow Hydronic Systems in Laboratory Facilities

Introduction

This article covers the foundational aspects of Building Automation System (BAS) control for variable flow hydronic systems serving preheat, reheat, and cooling water for HVAC in laboratory buildings, including process cooling water systems serving chilled beams and MRI equipment.

Pump Redundancy and Staging

Hydronic system distribution pumps are required to be redundant (N+1) in NIH laboratory facilities. This means a minimum of two pumps are required; however, NIH preference is to have at least two primary pumps and one standby pump per system. Pump sequencing shall provide for automatic start of the backup pump upon primary pump failure, stopping the backup pump when it is no longer needed, rotation of the lead device, and maintenance lock out.

Flow and Capacity Control

Where a variable frequency drive (VFD) modulates pump capacity, the BAS controls the drive to maintain the differential pressure (dP) at the set point based on differential pressure sensors located in supply and return lines at selected locations. Pump speed modulation shall be based on a low signal selection of multiple differential pressure sensors. The dP set point may be reset based on terminal requirements when practical. Programming should be in place to avoid one terminal device driving the entire system unless it is critical. The BAS shall monitor flow on most systems; however, exceptions may be granted where there is no value to diagnostic monitoring or measurement and verification.

Bypass Valve Operation

The variable flow system must always have a means to operate under low-flow conditions (i.e., when the load is low enough for a single pump to be operating). The minimum continuous stable pump flow will be provided by the pump manufacturer and should be clearly indicated on equipment submittals and coordinated with controls sequences. The minimum flow bypass should be equipped with a 2-way control valve and a nearby dP sensor. If the pump speed begins to drop below the pump minimum flow, the 2-way control valve modulates open to maintain flow and the dP setpoint. The valve begins to modulate closed once the load on the system increases and the flow demand rises above its minimum setpoint for a specified duration. The BAS should be capable of monitoring control valve position and dP setpoint.

Temperature Control

The temperature control for hydronic loops depends on the application. For tertiary pumps supplying chilled water to air handlers and supplemental cooling units, the discharge temperature is controlled by modulating the 2-way control valve in the secondary water return in sequence based on reset schedule and bridge bypass flow. In summer, discharge temperature is the same as the incoming campus supply temperature. In the case of preheat and reheat systems with steam to water converters, the 1/3rd and 2/3rd steam control valves will be modulated in sequence to maintain leaving water temperature for each converter. In the case of process cooling water systems, the chilled water control valve for each heat exchanger shall be modulated to maintain leaving water temperature for each heat exchanger. The temperature set point may be reset. The supply and return temperatures on all systems shall be monitored by the BAS.

Pump Status

Status shall be monitored via current switch and the BAS shall prove pump status matches the command. Status must be valid whether the drive is normal or in bypass. The BAS shall enunciate a “pump failure” alarm whenever the pump is commanded to run and status is not proved within an adjustable debounce time. The BAS shall enunciate a “hand operation” alarm when the pump is commanded off and on status is indicated. In no case shall a loss of status coincident with a loss in power be alarmed as a failure. Drives shall have an automatic restart programmed. A Hand-Off-Auto (HOA) switch should be provided with the pump VFD or starter.

Fill Pressure Control

Fill pressure control on hydronic systems can be accomplished by a system connection to a makeup water source equipped with an automatic makeup control valve set to maintain a specified fill pressure. If it is a glycol system, a glycol pump and its associated pressure control sensor should be used to maintain the fill pressure from a water/glycol mixture source such as a tank or reservoir. In both water and glycol systems, the operation should be automatic, and the BAS should be capable of monitoring the fill pressure and flow.

High or Low Limit Control

Where a convertor (heat exchanger) is used in the system, there should be a high or low limit temperature switch located in the discharge piping of each convertor which shall close its respective control valve when leaving water/glycol temperature rises above or falls below a certain temperature. High limit switches are needed on steam to water/glycol converters serving preheat, reheat, or heat recovery systems as a system safety. A low limit switch may be needed on process cooling or chilled beam converters that may not be able to handle colder chilled water temperatures.

Conclusion

Reliable BAS monitoring and instrumentation is key to an effectively managed hydronic system for a safe and efficient operation strategy. Equipment staging, monitoring, and control instrument calibration should be routinely analyzed to ensure the system is operating as intended and at its most efficient ranges.

References

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Lighting Design Considerations for Animal Research Facilities

Introduction

Proper lighting is critical in animal research facilities (ARFs) to ensure animal health and the reliability of the research test results. Lighting levels and controls depend on the usage of the space and on the type of species occupying the space. As with all aspects of ARF design, veterinarians and animal care staff must be consulted. This article reviews recognized good design practices.

Key Points

In ARFs, lighting must be carefully controlled to maintain consistent light cycles (photoperiods). Artificial light can significantly disrupt the natural circadian rhythms of animals, leading to hormonal imbalances and disrupt their feeding, mating, nourishment, and sleep patterns.[1] Tailored lighting strategies based on animals' natural habitats and behaviors are therefore necessary for optimal welfare. In addition, the intensity and color spectrum of light can significantly impact animal behavior; for instance, using warm-toned lights during the resting phase can promote relaxation, while cooler tones may be used during active periods. Improper nighttime lighting also contributes to cancer in animals: exposure to artificial light at night has been linked to increased tumor formation.[2] See "Further Reading" at the end of this article for more on the effects of light on animals.

Important Factors: Design for Artificial Lighting & Controls

1. **Light cycle:** Maintain a consistent light/dark cycle based on the animal's natural photoperiod.
2. **Light intensity:** Adjust light intensity depending on the activity level required (e.g., lower intensity during resting periods).
3. **Light color:** Select an appropriate color temperature based on the animal's visual needs and desired behavioral response. Choose lighting with warm colors and minimize the percentage of blue light (which has been linked to negative effects on animals[3]) emitted. Using warm-colored bulbs and reducing blue light emission will help mitigate negative impacts and preserve natural behavioral responses.
4. **Lighting uniformity:** Lighting for vertically stacked cages or aquatics tanks in racks should be uniform for all enclosures.
5. **Light source selection:** Light is an environmental factor that is extrinsic to animals and exerts a profound influence on the regulation of neurohormonal and neurobehavioral systems of animals.[3] LED lighting is a popular choice due to its energy efficiency and the ability to adjust the intensity as needed.
6. **Control coordination:** An LED driver must be coordinated with specified controls to avoid lamp flickers in an ARF. LED drivers in fixtures and controls such as occupancy sensors should be calibrated to avoid lamp flickering.
7. **Using amber or red lights:** Long-wavelength lights such as amber and red lamps may be used as they provide sufficient lighting for human visibility but are less noticeable to most animals.
8. **Environmentally friendly certification:** Lighting equipment for animal research labs shall comply with the animal design requirements. The "Underwriters Laboratories (UL) Listed" certification for lighting fixtures identifies environmentally friendly lighting solutions that have low color temperature and help reduce light pollution.
9. **Smart control technology:** The advancements in smart control technology simplify the management of light intensity, while adaptive controls ensure the preservation of natural darkness during nighttime. Investing in smart controls and LED technology allows a user to conveniently regulate lights, establish timers or dimmers, activate motion sensor lighting, and even adjust the emitted light's color.
10. **Lighting control system:** APFs should have a programmable lighting control system in facilities using either a BAS (Building Automation System) or a standalone system. This system should allow for the control and adjustment of lighting capabilities.
11. **Occupancy sensors:** Occupancy sensors in facilities shall have no ultrasonic sound emissions, as these may cause inadvertent distress in animals.
12. **Power levels:** In an animal research/surgery lab, 50% of lighting fixtures should be set to normal power while the remaining fixtures should be set to emergency power using a single toggle switch.

Schedules

Maintaining proper written and tracked lighting schedules in ARFs helps ensure that the lighting is following the predetermined schedule in each of the lab's animal research rooms. Best practices typically include using light sensors to ensure that the lights are turned 'on' or 'off' according to lighting schedules and providing 24/7 monitoring of the lights inside an ARF. Issue real-time alerts as necessary so that personnel can identify whether any experiments are at risk and take corrective action. Light sensors can also be remotely calibrated to conform to different lighting systems and intensities and offer various customization options to meet the lab's research needs.

Conclusion

Lighting is important design aspect in animal labs and can impact the quality of scientific research. Understanding the impacts of light intensity, measurements, and calibrations allows designers to take corrective actions to minimize light intensity and variability, thereby improving animal welfare and the accuracy of research experiments.

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