

Strategies in Commissioning for Bio-Safety

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Synopsis

The bio-safety suite is an interdependent system of components that influence the performance of each other and the suite as a whole. These subsystems include: building envelope, supply air system, exhaust air system, space temperature and humidity control systems, plumbing systems, decontamination systems, security, fire alarm, building automation system, monitoring system, lighting and lighting controls, containment boundaries, emergency power systems and laboratory equipment such as washers, glove boxes, sterilizers, fume hoods, and bio-safety cabinets.

Each of these systems must be verified to operate correctly prior to turnover. In addition to verifying the functionality of each individual system, special consideration must be taken during the design, construction, acceptance and occupancy phases of the laboratory regarding how the operation of each of these systems affects the operation of other systems within the lab. Many times a failure of one system can be a failure of the laboratory as a whole. The effects of a failure of a single lab system on the laboratory as a whole should be documented. This documentation will allow bio-safety officers to create standard operating procedures (SOPs) and emergency protocols that will limit the chance of spreading contamination and protect research during an unplanned event.

About the Author

Trevor Powers began his engineering career in the US Navy as a submarine nuclear plant operator and quality assurance inspector. It was there that he gained his extensive knowledge of containment systems and learned the benefits of procedural compliance. Trevor has taken this knowledge gained in the military and applied it toward the commissioning process for many high performance buildings and laboratories. His extensive laboratory commissioning experience includes state-of-the-art cancer research facilities, BSL-3 laboratories, Vivariums, bio-informatics, sterilizers, decontamination systems, glove boxes, safety cabinets, and fume hoods. Trevor has a B.S. in Mechanical Engineering from the Georgia Institute of Technology and is a LEED™ Accredited Professional. He is currently employed by WorkingBuildings, LLC in Atlanta, GA as a commissioning authority.

Introduction

The world is now more aware of the threat posed by bio-terrorism and emerging and reemerging infectious diseases. In order to fight these threats, they must be studied. It is no wonder that so many new bio-safety laboratories are being designed and constructed. Some of these facilities are being built on campuses employing researchers and staff who are intimately familiar with the nuances of working in a BSL-3 and higher environment. However, many of these facilities are being built for owners who have never before built, operated or maintained a bio-safety laboratory.

The commissioning process can serve as a useful tool to all of these owners to verify and document that the building design, construction, and operation meets their performance requirements and the standards set forth in publications such as Biosafety in Microbiological and Biomedical Laboratories (BMBL).

Elements of the BSL-3 Laboratory Suite

The BMBL defines a BSL-3 area as a clinical, diagnostic, teaching, research, or production facility in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by inhalation. All procedures involving manipulations of infectious materials within a BSL-3 laboratory must be performed by personnel in personal protective clothing, a biological safety cabinet or some other containment device. All personnel working within the laboratory must have specific training in the handling of pathogenic and potentially lethal agents.

The BSL-3 laboratory has special equipment and design features that must function properly to protect the researchers and the public. The laboratory must also have a set of protocols and procedures to direct researchers on proper lab practices, to govern emergency actions and to provide guidelines on maintenance, decontamination and cleaning procedures. These procedures should not be generic, but be based upon actual laboratory system and equipment operation as documented during the commissioning process.

Microbiological Practices

All researchers working with toxic chemicals or agents within the laboratory setting are familiar with standard laboratory practices. These practices include hand washing after handling chemicals or specimens, the use of mechanical pipetting devices versus mouth pipetting, control of the use of sharps within the lab and restrictions on eating, drinking and the handling of contact lenses and cosmetics within the laboratory. Other practices are considered standard within a bio-safety laboratory of any level. These practices include the following:

- All manipulations of infectious material are performed in a manner to reduce the creation of aerosols

- Work surfaces within the laboratory are decontaminated daily and whenever a spill occurs
- All regulated wastes must be decontaminated prior to off site removal and disposal
- An effective insect and rodent control program is in place

In addition to the controls practiced for standard biological safety laboratories, the BMBL requires the following special practices be implemented for BSL-3 labs:

- Keeping laboratory doors closed during active experiments
- Restricting lab access to persons required for program or support purposes
- Specialized training for all persons entering the laboratory
- Providing bio-hazard signage at lab entrance
- Lab personnel receive immunizations for agents to be handled and are periodically tested for infection
- Laboratory specific bio-safety manual is prepared and its protocols are followed
- All manipulations involving infectious materials are conducted within a biological safety cabinet
- Routinely decontaminate work surfaces and equipment
- All potentially contaminated waste materials must be decontaminated prior to disposal
- Animals and plants not required for the experiments shall not be present within the laboratory
- All spills and accidents that result in a potential exposure to an infectious agent are immediately reported and evaluated.

Primary Barriers

The primary containment boundary between the infectious agent and the laboratory staff is key to protecting against infection. This boundary is made up of personal protective clothing, respiratory and face protection, biological safety cabinets and other containment equipment. Protective clothing consists of solid front gowns, scrub suits or coveralls. This clothing should be worn while in the laboratory, but removed prior to exiting. All reusable clothing must be decontaminated prior to cleaning. Use of gloves in conjunction with frequent hand washing is imperative when handling infectious material or infected animals. Also, respirators and face protection must be utilized when in a laboratory containing an infected animal. All manipulations involving infectious materials should be performed within the confines of a biological safety cabinet. When a safety cabinet is not available or cannot be used due to procedural requirements then appropriate personnel protective equipment and other measures of physical containment must be enacted.

Secondary Barriers

The secondary containment boundary protects against the spread of contamination outside of the biological safety laboratory. The secondary containment boundary of a biological safety laboratory is the laboratory itself. Special considerations must be taken during the design and

construction of a bio-safety lab to minimize the spread of contamination outside of the lab and potential infection of staff outside of the containment area and/or the public. For a BSL-3 laboratory, the BMBL requires that the lab be provided with the following features:

- In general the lab space should be separated from other areas of the building that are open to unrestricted personnel
- The lab must contain a hands free sink near its exit
- The lab must contain an eye wash station
- The surfaces of the walls, ceilings and floors must be constructed in such a manner as to provide for easy wipe down and cleaning
- Bench tops must be waterproof and resistant to chemicals
- Spaces between equipment and casework must be cleanable
- Windows must be sealed and non-operable
- Bio-safety cabinets are located away from doors and air diffusers
- Air systems must be designed for 0% recirculation and provide for directional airflow from clean to dirty areas
- Exhaust air must be directed away from air intakes and occupied areas
- Decontamination method such as an autoclave is available for laboratory wastes
- Air recirculation within the lab is acceptable if the air is filtered using HEPA filtration
- Vacuum lines must have HEPA filtration and liquid disinfectant traps
- Adequate lighting must be provided

In addition to the above requirements, the BMBL requires that the design, operational parameters and procedures be verified and documented prior to operation. The operation of the lab must be re-verified on a yearly basis. The commissioning process is well suited to help owners meet this verification and documentation requirement.

Commissioning as a Tool for Bio-safety

Many owners are looking to their commissioning authorities to provide the BMBL required verification and documentation for their biological safety laboratories. However, the commissioning process can help the owner do much more than simply document and verify the laboratory's operation. The process can help ensure that the laboratory's design, construction and operational parameters meet the owner's specific requirements.

Other tools provided by the commissioning authority have been proven to be beneficial to laboratory owners. For instance, the biological safety officer and other staff are provided with necessary information regarding the design and operational parameters of the lab in the commissioning report. This information allows laboratory staff to write appropriate laboratory protocols and procedures. Without information regarding how the lab actually functions in all operational and emergency modes, comprehensive procedures cannot be developed.

The commissioning process is generally considered to be made up of five phases. The phases are: planning, design, construction, acceptance and warranty. Since BSL-3 laboratories require

an annual verification of laboratory operation, the warranty phase can be thought of as “warranty and beyond”. Each phase of the commissioning process presents tools and opportunities to provide the owner with a successful final product.

Planning Phase

Every building requires a strong foundation to carry it through its life cycle. The commissioning process also requires a strong foundation in order for its full potential to be realized. This foundation is made up of the owner’s performance requirements (OPR), also known as the design intent, and the commissioning plan.

The OPR is defined by ASHRAE Guideline 0 as a written document detailing the functional requirements of the project and the expectations of how the project will be used and operated. In order for this document to be most effective, representatives from all groups of people that will occupy, operate, maintain and otherwise be affected by the building must be involved in the creation of the OPR. The OPR defines the project goals as well as the performance and success criteria. Bio-safety laboratories present unique requirements in the creation of the OPR since the facility must comply with the containment and safety protocols related to the agents that will be present in the laboratory. If the intended use of the labs is not defined and documented early in the process, much time and money can be lost in the form of project changes late in the construction and validation process. The OPR is a valuable tool for the commissioning team during all phases of the project.

The commissioning plan is defined by ASHRAE Guideline 0 as a document that outlines the organization, schedule, and allocation of resources and documentation requirements of the commissioning process. Communication protocols should be clearly defined within the commissioning plan. The commissioning plan is a living document that will evolve as the project evolves. It helps to provide clarity and understanding to other members of the project team regarding the commissioning process and the commissioning authorities role in the project.

The OPR and commissioning plan can be developed at any stage of the project. However, in order for them to be most useful they should be developed early in the planning phase so that the designers have a documented record of the owner’s requirements for the project and can design the building or space to meet these requirements.

Design Phase

During the design phase, the role of the commissioning authority is to verify that the requirements of the OPR are being met within the design. Commissioning focused reviews of the basis of design documentation, schematic design documents and final design documents are performed by the commissioning authority. The OPR can be used as a tool by the design team when preparing the basis of design document (BOD) and other design documents. In its most basic form, the BOD is a document that defines the assumptions made in the development of the project design that achieves the requirements of the OPR. For a biological safety laboratory, it is important the laboratory design parameters meet the requirements of regulating agencies such as

the Centers for Disease Control (CDC) and the National Institute of Health (NIH). These requirements should be outlined in the BOD and listed as requirements in the OPR. A complete BOD has the following components:

- Narrative descriptions of systems and components
- Descriptions of how systems and equipment are intended to be maintained
- Descriptions of applicable codes and standards
- Description of fire/life safety systems
- Listing of design assumptions
- Manufacturer's equipment information

When designing a biological safety laboratory, the design team must address all issues. If a sealed containment space is required by the OPR, the design team must provide details on how containment boundary penetrations are to be sealed. It is not enough to simply say "seal all containment zone penetration points" and leave it up to the installing contractors to take care of the rest. System and equipment control sequences must be clearly defined. Sensor performance requirements must be specified. An off the shelf sensor may not be appropriate for a BSL application. The design team must also keep maintenance accessibility at the forefront of their design considerations. Equipment requiring maintenance should not be installed above BSL-3 ceilings. The number of equipment access panels in the containment zone is to be minimized. These access panels will likely become points of failure in the containment boundary. If an appropriate OPR was created during the project-planning phase these types of requirements will have already been documented. In the design phase the commissioning authority will simply verify that the OPR requirements have been met.

The commissioning team performs other tasks during the design phase that add value to subsequent phases of the building. Examples of these tasks are as follows:

- Update commissioning plan based on design phase input
- Develop commissioning specifications to be included in the design documents
- Develop draft construction checklists and functional performance test procedures
- Assist in the development of training and O&M manual requirements

Construction Phase

The owner's performance requirements have been documented. The design is complete and meets the requirements of the OPR. Now it is the contractor's job to take the design documents and build the laboratory. The following is a list of commissioning activities performed during the construction phase:

- Update the commissioning plan
- Commissioning focused review of manufacturer's equipment submittals
- Commissioning focused review of contractor's shop drawings
- Finalize construction checklists and provide to appropriate contractors

- Track progress of construction checklist completion
- Verify construction is in accordance with OPR requirements
- Develop finalized functional performance test procedures
- Verify that O&M documentation meets the requirements of the OPR

The OPR document can serve as a useful tool to the contractors during the construction phase. By having access to the OPR, the contractor will have an understanding of what the owner expects of the project. The commissioning authority will document the building construction and verify that it meets the OPR. This task is often performed through the use of construction checklists and/or construction site observations by the commissioning authority.

Construction checklists provide the contractor with a consolidated list of requirements for the proper installation or construction of a piece of equipment, system or design feature. These checklists are not intended to take the place of manufacturer's start up procedures. Their purpose is to document that the building construction and equipment installation meets the requirements of the OPR. The construction checklists should be created and approved by all members of the commissioning team. These checklists are completed by the contractor and provided to the commissioning authority for review and verification. The completed checklists are provided as part of the commissioning report. The checklists also inform the commissioning authority that the equipment and systems are ready for functional testing.

Acceptance Phase

Training and functional testing activities are considered part of the construction phase by ASHRAE Guideline 0. These activities are most effective when they are performed after construction is complete. Therefore, many commissioning services providers make these tasks part of a separate phase called the building acceptance phase.

The observation and documentation of equipment and system functional performance testing is an important acceptance phase commissioning activity for any project. However, for a BSL-3 laboratory this activity is vital. The BMBL requires that the laboratories design and operational parameters be verified and documented prior to making the laboratory fully operational. If this requirement is not met, the lab cannot be certified as a BSL-3. Operation of laboratory systems and the lab as a whole should be documented for normal and emergency modes of operation. A thorough commissioning authority will challenge the lab systems by writing test procedures for "what if" scenarios. Operation of the laboratory during all conceivable equipment line-ups should be documented. With documentation of how the lab operates during every imaginable operational scenario, the bio-safety staff can write specific protocols of action to minimize the spread of contamination and exposure to personnel in other areas of the building.

Other activities performed by the commissioning authority during the acceptance phase include the following:

- Review of training plans including agendas, schedules and handouts
- Verify training meets OPR requirements

- Update commissioning plan
- Review final O&M manuals
- Test & balance verification spot checks
- Provide draft final commissioning report

Warranty Phase & Beyond

The warranty phase of a building begins when the contract specifies that equipment warranties are to start (often at substantial completion) and continues throughout the contractual warranty period. During the warranty phase the commissioning objectives are as follows:

- Complete seasonal testing of systems and equipment
- Document and track warranty callbacks and investigate any systemic issues
- Document lessons learned for application on the next project
- Document and verify the accomplishment of continuing owner training
- Interview the end users, operators and maintenance staff to identify issues prior to the end of warranty
- Complete the final commissioning report

For a biological safety laboratory, the warranty phase activities are performed exactly like any other commissioned project. The major difference is that for bio-safety laboratories of BSL-3 and above, the laboratories must be validated on an annual basis. This validation can be performed by the laboratory operations staff under the supervision of the bio-safety officer or by a third party testing agency. Often, the commissioning authority that wrote the initial functional and validation testing is a prime candidate to supervise and observe the annual validation test.

Conclusion

The biological safety laboratory presents its own unique obstacles and challenges. Laboratories must meet not only the requirements of guidelines such as the BMBL, but also the specific requirements of the type of research that will be performed within its walls. A laboratory that is not functional is of little use to anyone. The commissioning process provides an ideal delivery method for a laboratory of this nature. Proper use of the commissioning process will ensure that the documentation is in place for bio-safety personnel to write lab specific procedures and protocols. The commissioning process also provides for the development of baseline documentation of how the building is operating and turnover. For an owner with little or no experience operating and maintaining a BSL-3 laboratory, the BSL savvy commissioning authority can be an invaluable tool. An owner with experience operating and maintaining a BSL laboratory most likely already understands the benefits of the commissioning process.

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