



Strategies in Commissioning for Biosafety

Presented by

G. Trevor Powers

tpowers@workingbuildings.com

WorkingBuildings, LLC

Agenda

- Identify requirements of a BSL-3 laboratory
- Understand how commissioning can be used as a tool to document these requirements
- Learn how to apply the commissioning process to the biological safety laboratory

Laboratory Systems

- Architectural
- Mechanical
- Electrical
- Specialty Equipment

All systems are integral to a functioning biosafety laboratory

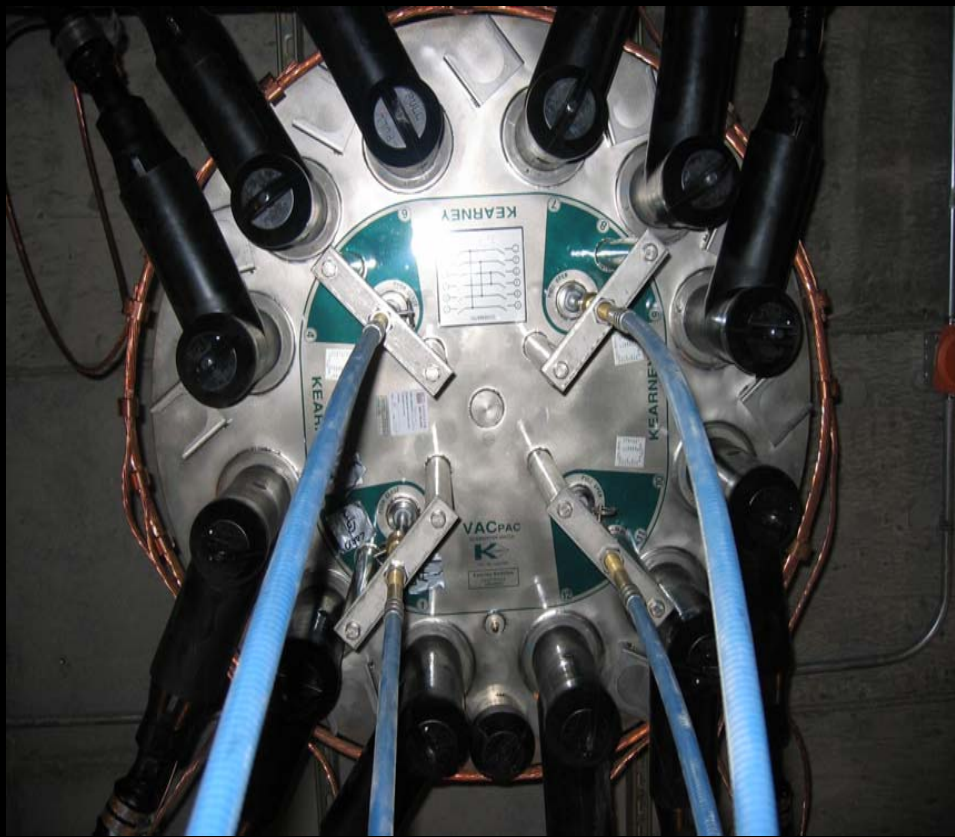
Laboratory Systems - Architectural



Laboratory Systems - Mechanical



Laboratory Systems - Electrical



Laboratory Systems - Specialty Equipment

QuickTime™ and a
TIFF (Uncompressed) decompressor
are needed to see this picture.



Biosafety Laboratory Requirements

- Biosafety in Microbiological and Biomedical Laboratories (BMBL)
 - Specifies procedural, equipment and facility requirements
 - Groups biosafety laboratories into 8 levels
 - BSL-1, BSL-2, BSL-3 & BSL-4
 - ABSL-1, ABSL-2, ABSL-3 & ABSL-4
 - Level dependent on type of agent used

Containment Barriers

- Primary - Biosafety cabinets & PPE
- Secondary - Laboratory Facilities
 - Designed for easy cleaning & decontamination
 - Method of decontaminating material leaving the space
 - Non-recirculating exhaust system
 - Vacuum lines protected
 - Containment penetration points must be sealed

Biosafety Level 3

- Agents with a potential for respiratory transmission
- Agents may cause serious and potentially lethal infection
- More emphasis on primary and secondary containment barriers than BSL-1 or BSL-2

Biosafety Level 3 - BMBL Requirements

- Annual verification & documentation of operational parameters & procedures
- Documentation of user training program
- Laboratory specific bio-safety manual
 - Requires knowledge of lab operation during all operating modes

Traditional Steps of Commissioning

- Develop Owner's Performance Requirements (OPR)
- Review Basis of Design
- Drawing Reviews
- Contractor Submittal Reviews

Traditional Steps of Commissioning

- Pre-functional Checklists
- Site Observation Visits During Construction
- Functional Testing
- Training Verification
- Warranty Review
- Final Report

All of these steps can be applied to the bio-safety laboratory

Owner's Performance Requirements

- Developed through workshops, interviews, questionnaires, ect.
- Defines success criteria for project
- Participants:
 - Owner, O&M staff, Biosafety officer, Researchers

Basis of Design

- Traditional commissioning reviews the MEP basis of design
- Verify that BOD meets OPR
- Should be coordinated with type of research being performed and method of decontamination

Design Reviews

- Focused review of laboratory systems
 - Containment systems
 - Maintenance access to components
 - Redundant systems
 - Operational sequences and alarms
 - Owner furnished equipment requirements

Submittal Reviews

- Review product data
- Review shop drawings
- Compare to OPR and BOD
- Should occur in parallel with designer review
- Owner furnished equipment

Pre-functional Checklists

- Goal is to do work right the first time
- Checklists supplement the design, they do NOT replace the design
- Not intended to replace manufacturer's instructions

Pre-functional Checklists

- Use the design drawings, specs, OPR, and BOD to create
- Get information to the contractor in simple, easy to understand language
- Convey quality expectations to contractor
- Helps the Owner track construction progress

Pre-functional Checklists

- Format:

- Yes or No questions
- Yes is always the correct answer
- No indicates a deficiency
- Keep it simple

Site Observation Visits

- Periodic site visit to verify installation
- Document deficiencies
- Be specific, take photos
- Meet with contractor to discuss findings
- Generate report quickly to minimize schedule impact

Functional Testing

- Verify installation meets OPR
- Should not be used strictly as a “punch-list” generating exercise
- Consider challenge testing of laboratory systems

Functional Testing

- Progress from equipment to system level
- Perform a BSL validation test
 - Tests & documents all aspects of lab with respect to OPR & BMBL
 - Tests & documents operation of the lab as a whole system during normal & emergency modes of operation

Functional Testing - Modes of Operation

- Normal mode
- Loss of utility power
- Fire alarm
- Supply fan failure
- Exhaust fan failure
- Maintenance modes

Training Verification

- Verify & document training program meets owner's needs
- Provides later documentation for lab audits

Warranty Review

- Responsibilities during first year of warranty include:
 - Review warranty requests
 - Perform seasonal and/or deferred testing
 - Conduct lessons learned workshop
 - Review warranty items with facility operations staff

Lessons Learned - Containment Envelope

- Negatively pressured lab on exterior wall
- No moisture barrier
- Water intrusion through gaps in pre-cast



Lessons Learned - HEPA Sizing

- Redundant exhaust fans on VSDs
- Both fans normally operating
- Redundant HEPAs
- HEPAs sized for parallel operation



Lessons Learned - HEPA Sizing (2)

- HEPAs selected
- Test section added
- Unexpected increase in pressure drop due to test section add
- Exhaust fans fell short



Lessons Learned - Access Panels

- Partitions not to structure
- Access panels in ceiling
- Direct path for air travel



Lessons Learned - Air Leakage

- Penetration points at above ceiling areas not sealed
- Increased air leakage through containment zone penetrations



Lessons Learned - Air Leakage

- Duct penetrating the ceiling - not sealed
- Most often observed in difficult to reach areas



Lessons Learned - Air Leakage

- Electrical receptacles & data ports
- Common failure points
- Review design details
- Require a mock up



Lessons Learned - Emergency Power Ops.

- System operated per OPR during emergency ops
- Room pressurization issues during generator cooldown



Lessons Learned - Water Usage

- Lab water system not sized to meet owners needs
- Unable to operate multiple washers and/or sterilizers



Conclusion

- Identified BSL-3 requirements
- Cx can help
- Application of the Cx process
- Observed failures

Contact Information

Trevor Powers
Commissioning Authority
Workingbuildings, LLC

678-990-8001

tpowers@workingbuildings.com

www.workingbuildings.com

