Commissioning: A Critical Strategy for Risk Management in the BSL-3 Environment

October 5, 2016

ENVIRONMENTAL HEALTH & ENGINEERING, INC.

Agenda

- Biosafety Laboratory Principles
- Containment
  - Primary
  - Secondary
- Commissioning Definition
- Containment Strategies
- Case Studies
- Summary

Biosafety Laboratory

- Biosafety Principles
  - Containment
    - Microbiological Practices
    - Safety Equipment
    - Facility Safeguards
  - Risk Assessment
    - Process that enables the appropriate selection of containment requirements that can prevent Laboratory Associated Infections (LAI)

Biosafety Laboratory Containment

BSL-3 Key Elements to Ensure Containment

- Primary containment
  - Equipment (biological safety cabinets – BSCs)
  - Work practices
- Secondary containment
  - Physical lab construction (architectural)
  - Exhaust redundancy and supply interlock
  - Control schemes
  - Room pressurization
  - Backup power

Risk Assessment

Risk Assessment– Process that enables the appropriate selection of containment requirements that can prevent LAIs.

- Primary factors fall into two broad categories:
  - Agent hazards
  - Lab procedure hazards
- Facility Safeguards
  - Space integrity is crucial
  - Direction airflow (pressurization) requires operational integrity of the HVAC system. HVAC systems require careful monitoring and periodic maintenance to sustain operational integrity.

“The laboratory shall be designed such that under failure conditions the airflow will not be reversed.”

– BMBL 5th Edition

Commissioning (Cx)

- Laboratory
  - A systematic review and documentation process signifying that specified laboratory components and *systems* have been installed, inspected, functionally tested and verified to meet the project design and applicable standards.
- Biosafety Laboratory
  - Verification of the *physical construction* and *performance* of *critical containment components.*

Biosafety Laboratory Cx

BSL-3 System *Performance* = *Containment*

- Performance Criteria
  - Redundant Capacity
    - Response time
  - Controls
    - Failure alarms
  - Pressurization
    - Local and remote measurement devices

Design Phase – Focused Review

Ensure

Capacity	Control	Failure Alarm
	• Sequence • Pressurization Scheme	

Design Phase – Focused Review

To achieve		
Containment	Schedule Adherence	Reduced Cost Increases

Biosafety Lab Construction

CDC BSL 3 Lab Facility Requirements

Yes	No	
☑	☐	Laboratory is separate from public traffic
☑	☐	Access to laboratory is restricted
☑	☐	Entry is through two self-closing doors
☑	☐	Doors are lockable
☑	☐	Automatic or hands-free sink located close to an exit and is designated for hand-washing
☑	☐	Walls, floors and ceilings are constructed for easy cleaning and decontamination
☑	☐	Seams are sealed
☑	☐	Walls, ceilings and floors are smooth, impermeable to liquids and resist chemicals used in the room
☑	☐	Floors are monolithic and slip-resistant
☑	☐	Penetrations in the room are sealed or are capable of being sealed
☑	☐	Spaces around ducts, between doors and frames are capable of being sealed for decontamination
☑	☐	Bench tops impervious to water
☑	☐	Bench tops resistant to moderate heat

Partial list……….

NIH BSL 3 Requirements in addition to CDC

Yes	No	
☑	☐	Ventilated airlock designed to separate common corridors from BSL III containment laboratory
☑	☐	Ceiling has a smooth, sealed finish
☑	☐	Ventilation is single pass air
☑	☐	Laboratory must be kept negative with respect to outside corridors and laboratories
☑	☐	Supply and exhaust ducts must be supplied with gas-tight dampers
☑	☐	Ductwork between the laboratory and the damper is gas-tight
☑	☐	Access panel supplied that allows access to critical mechanical equipment
☑	☐	Panel is piano-hinged and gasketed with gas-tight gaskets
☑	☐	All penetrations in laboratory must be sealed with a smooth finish
☑	☐	All joints between fixed cabinetry and the floor or wall must be smooth coved and sealed
☑	☐	Light fixtures are gasketed or sealed at the point of penetration into the laboratory

Partial list……….

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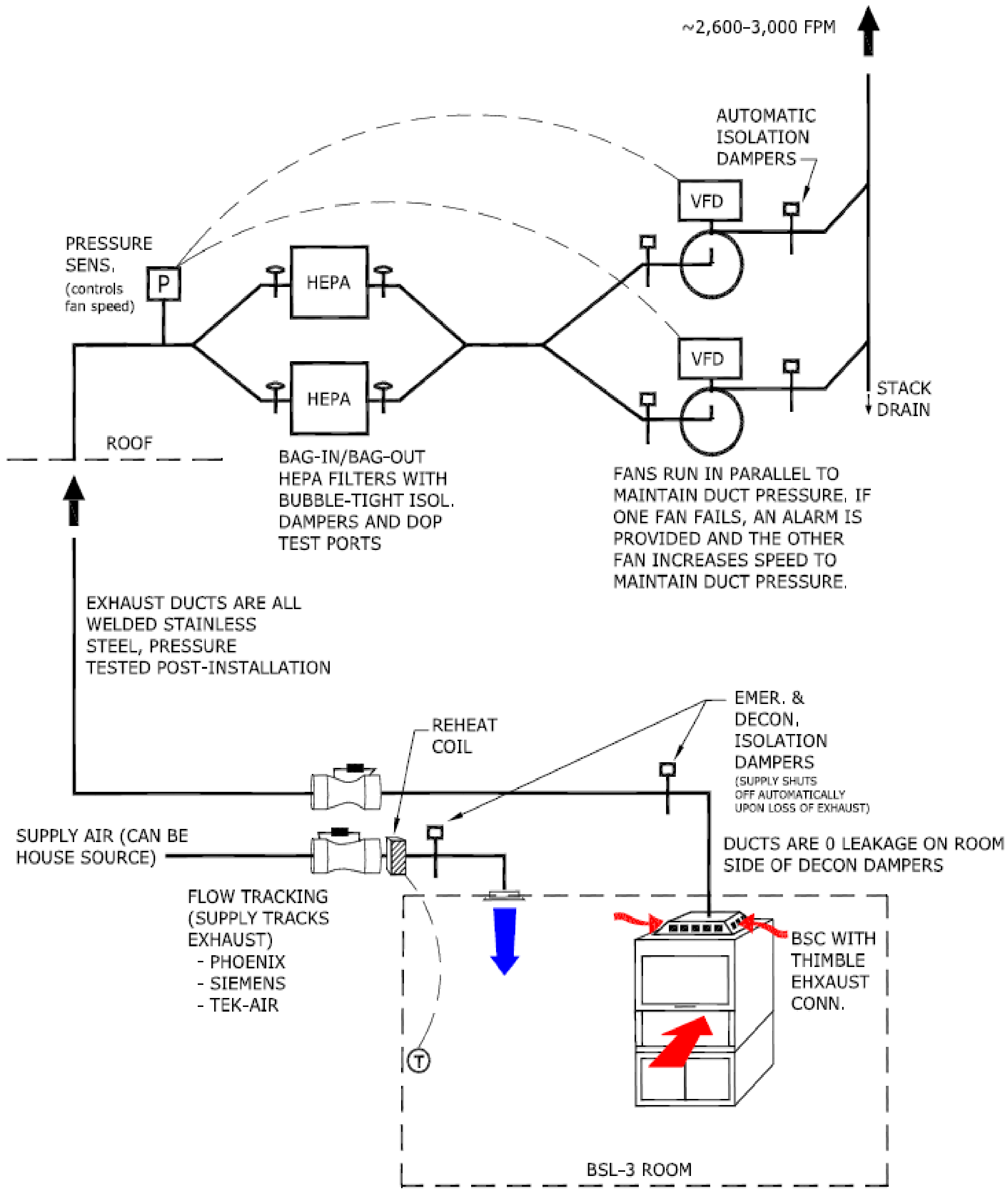
Partial list……….

Engineering Control Elements

- Facility Design and Construction (secondary barriers)
  - Specialized ventilation systems to ensure:
    - Direction airflow and pressurization
    - Lab isolation
    - Filtration
    - Air conditioning and heating
    - Air lock at lab entrances

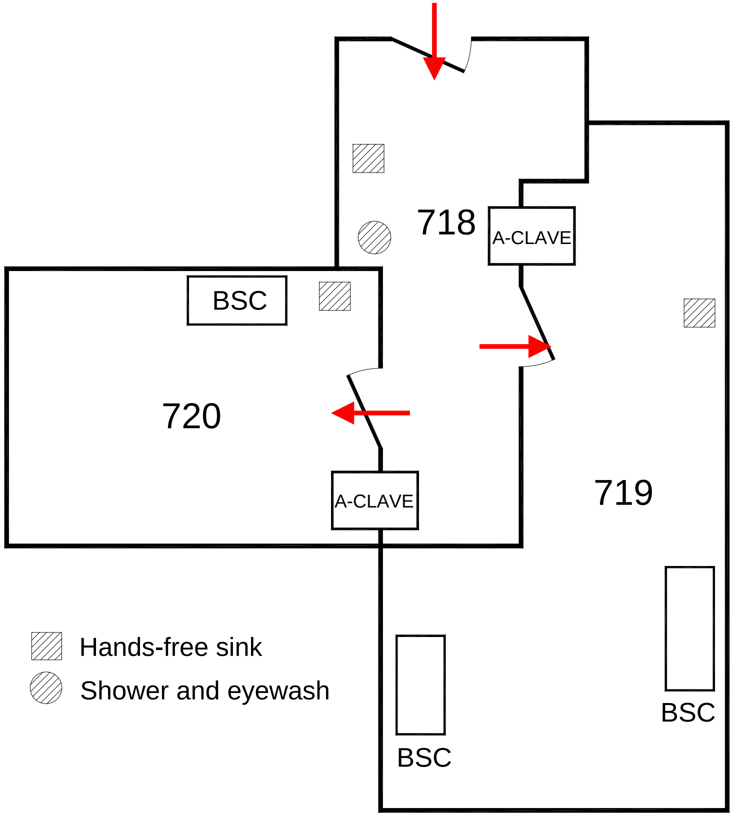
Key Engineering Control Components

- Exhaust fan redundancy
  - Timing goals
- Supply air isolation dampers
- Ducted ventilation system
  - Welded exhaust ductwork
- HEPA Filtration
  - Gas-tight isolation dampers
  - Bag-in/Bag-out capabilities or decontamination ports
  - Filter leak testing capability
  - Annual filter and housing certification
- Pressure monitoring (local and remote)
- Control alarms


~2,600-3,000 FPM
AUTOMATIC ISOLATION DAMPERS
VFD
VFD
PRESSURE SENS. (controls fan speed)
P
HEPA
HEPA
STACK DRAIN
ROOF
BAG-IN/BAG-OUT HEPA FILTERS WITH BUBBLE-TIGHT ISOL. DAMPERS AND DOP TEST PORTS
FANS RUN IN PARALLEL TO MAINTAIN DUCT PRESSURE. IF ONE FAN FAILS, AN ALARM IS PROVIDED AND THE OTHER FAN INCREASES SPEED TO MAINTAIN DUCT PRESSURE.
EXHAUST DUCTS ARE ALL WELDED STAINLESS STEEL, PRESSURE TESTED POST-INSTALLATION
REHEAT COIL
EMER. & DECON. ISOLATION DAMPERS
(SUPPLY SHUTS OFF AUTOMATICALLY UPON LOSS OF EXHAUST)
SUPPLY AIR (CAN BE HOUSE SOURCE)
DUCTS ARE 0 LEAKAGE ON ROOM SIDE OF DECON DAMPERS
FLOW TRACKING (SUPPLY TRACKS EXHAUST)
- PHOENIX
- SIEMENS
- TEK-AIR
BSC WITH THIMBLE EHXAUST CONN.
T
BSL-3 ROOM

Performance (Containment) Testing

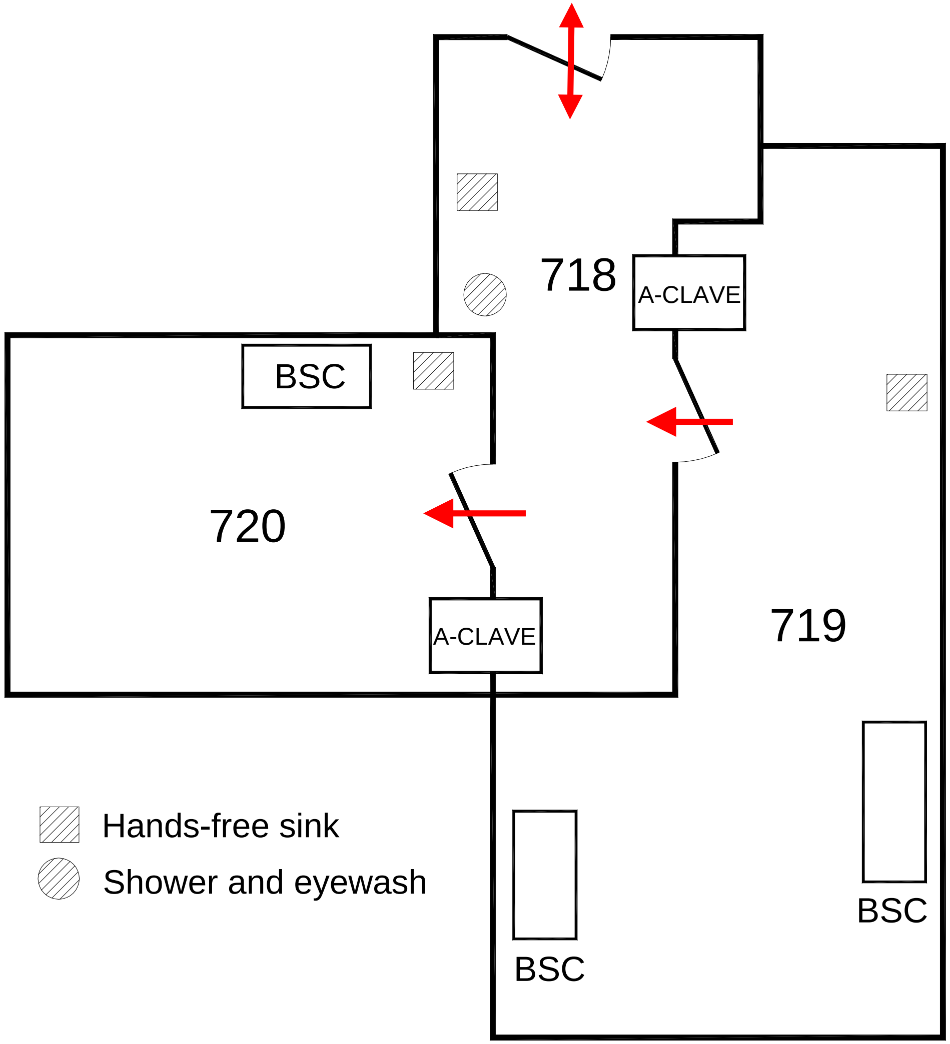
1. **As-Found Conditions**	Criteria Pass	Criteria Fail	Note:
Space pressurization (record in inches water column using calibrated EH&E digital manometer)	☑	☐	



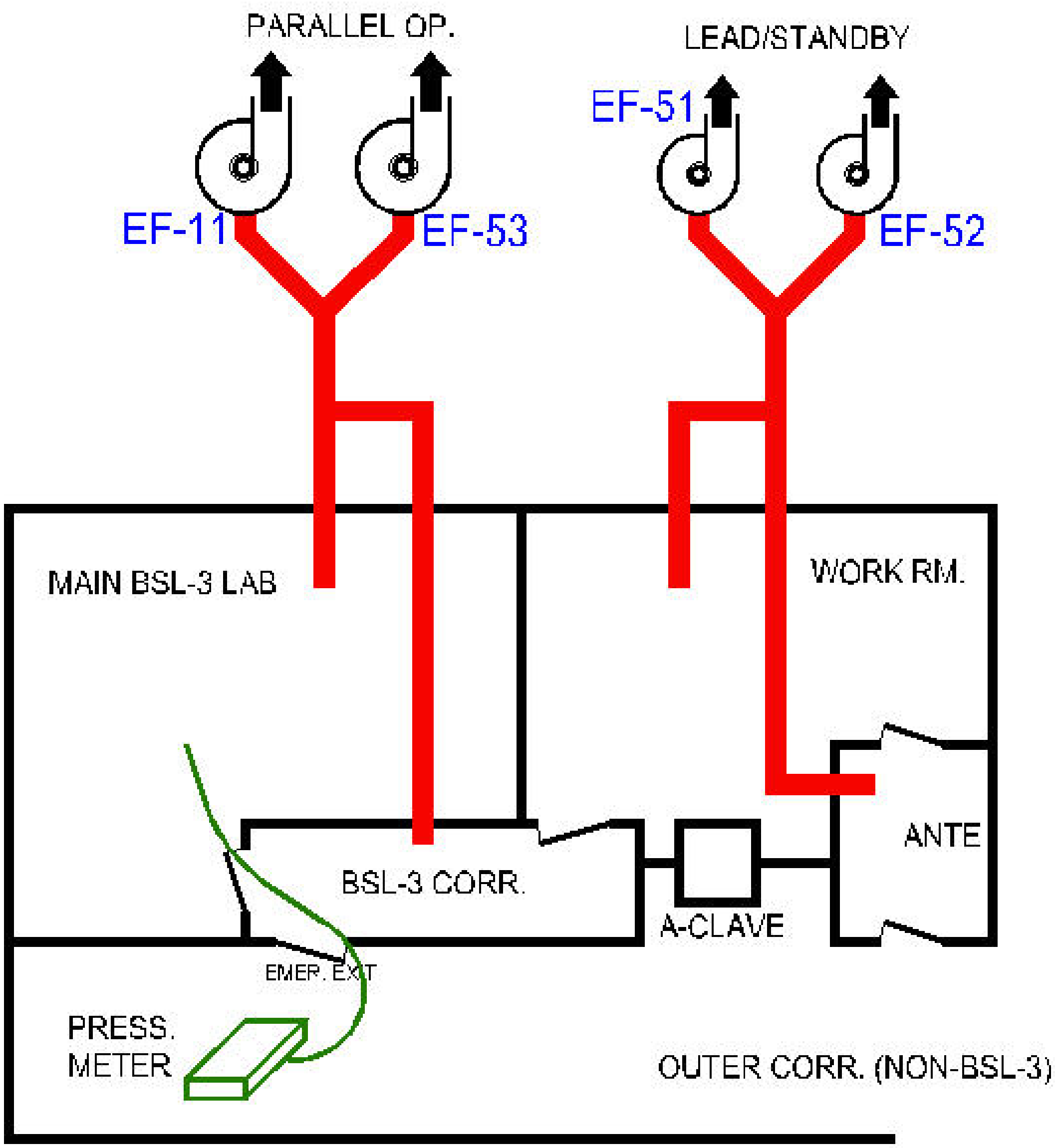
Performance (Containment) Testing

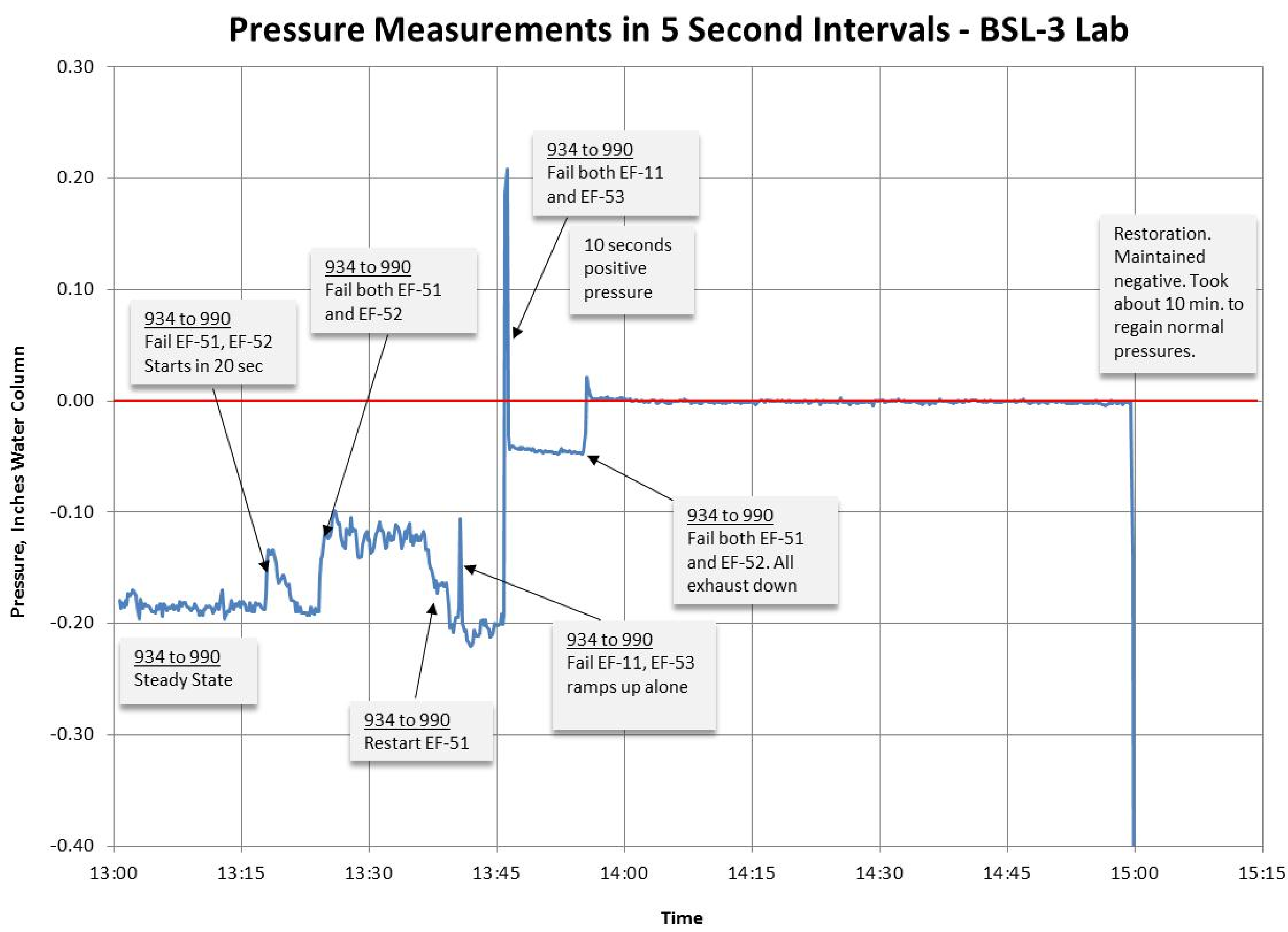
3. Failure Scenarios and Alarming	Date	Criteria Pass / Fail	Note:
A Fail operating fan (EF-51 or EF-52) at VFD			
Note time for backup fan to start: _~20__ sec	10/22/12	Pass ☑ Fail ☐	
Observe pressure at 934A, B, and C. Document transient results in detail, e.g., net changes, if wrong way pressure observed, for how long, etc.	10/22/12	Pass ☑ Fail ☐	
BSL-3 rooms became very slightly more negative (e.g., from -0.08” to -0.10”) briefly, then returned to their original values.			
Verify BAS alarm for failed fan	10/22/12	Pass ☑ Fail ☐	
B Fail remaining fan (EF-51 or EF-52) at VFD—both units down			
Observe pressure at 934A, B, and C. Document transient results in detail, e.g., net changes, if wrong way pressure observed, for how long, etc.	10/22/12	Pass ☑ Fail ☐	
Insignificant change. Magnitude of whole suite negative pressure diminished -0.18” to -0.12”.			
Document resulting pressures across main room boundaries below.	10/22/12	Pass ☑ Fail ☐	
Verify BAS alarm for failed fan	10/22/12	Pass ☑ Fail ☐	

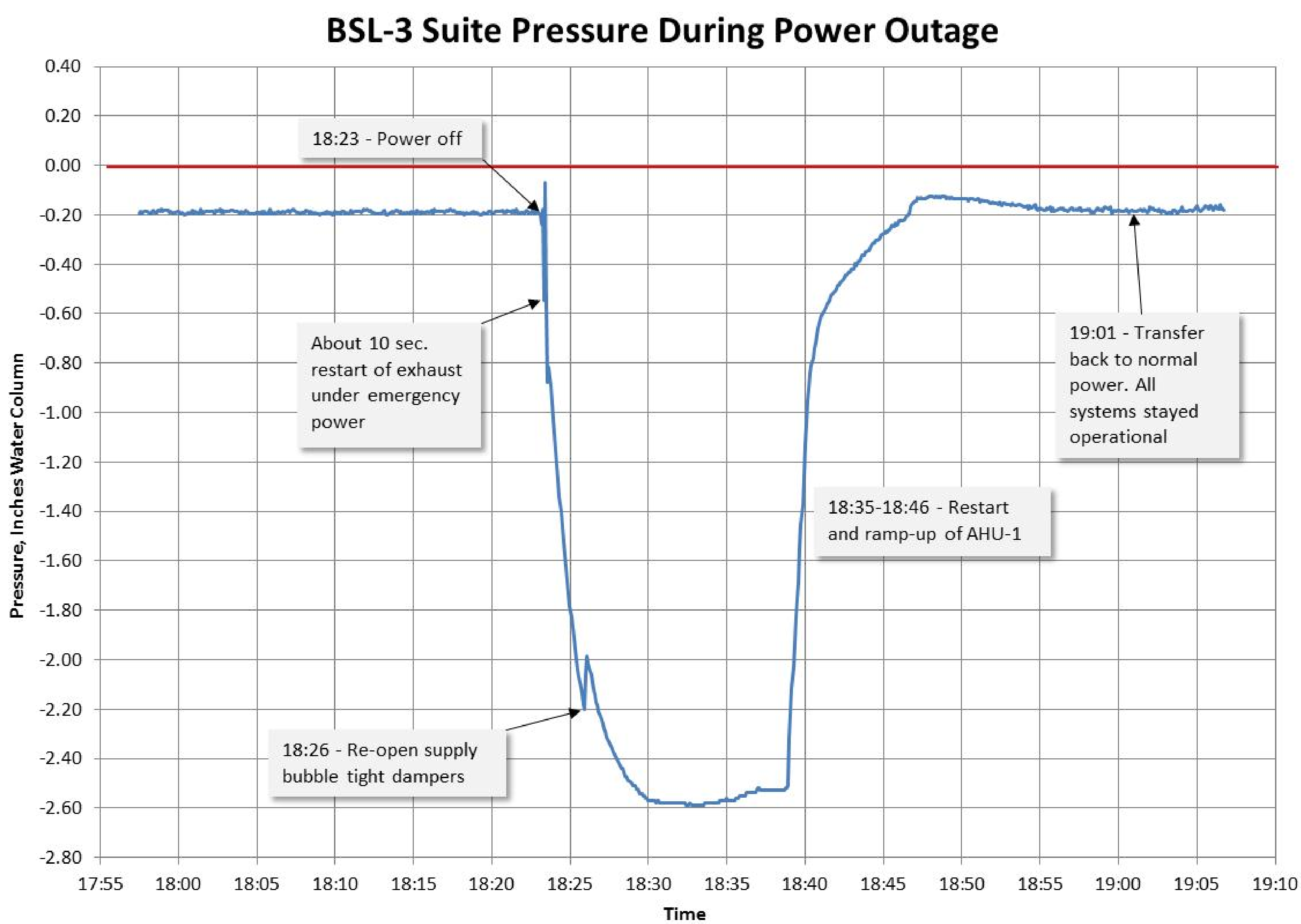
Record Pressure, Full Exhaust Failure



Failure Testing Example

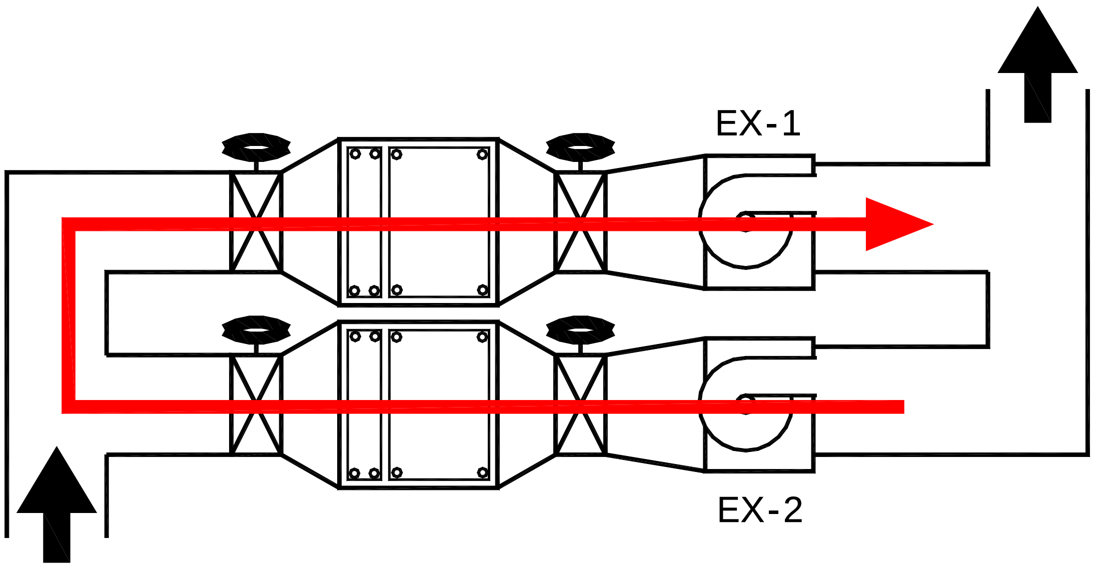



Pressure Measurements in 5 Second Intervals - BSL-3 Lab
0.30
0.20
0.10
0.00
-0.10
-0.20
-0.30
-0.40
Pressure, Inches Water Column
13:00
13:15
13:30
13:45
14:00
14:15
14:30
14:45
15:00
15:15
Time
934 to 990 Steady State
934 to 990 Fail EF-51, EF-52 Starts in 20 sec
934 to 990 Fail both EF-51 and EF-52
934 to 990 Restart EF-51
934 to 990 Fail EF-11, EF-53 ramps up alone
934 to 990 Fail both EF-11 and EF-53
10 seconds positive pressure
934 to 990 Fail both EF-51 and EF-52. All exhaust down
Restoration. Maintained negative. Took about 10 min. to regain normal pressures.


BSL-3 Suite Pressure During Power Outage
0.40
0.20
0.00
-0.20
-0.40
-0.60
-0.80
-1.00
-1.20
-1.40
-1.60
-1.80
-2.00
-2.20
-2.40
-2.60
-2.80
Pressure, Inches Water Column
17:55
18:00
18:05
18:10
18:15
18:20
18:25
18:30
18:35
18:40
18:45
18:50
18:55
19:00
19:05
19:10
Time
18:23 - Power off
About 10 sec. restart of exhaust under emergency power
18:26 - Re-open supply bubble tight dampers
18:35-18:46 - Restart and ramp-up of AHU-1
19:01 - Transfer back to normal power. All systems stayed operational

Case Study: Redundancy Failure

- Exhaust failure test at the exhaust fan disconnect
  - Failure not registered (no BAS run indication)
  - Failed fan dampers stayed open

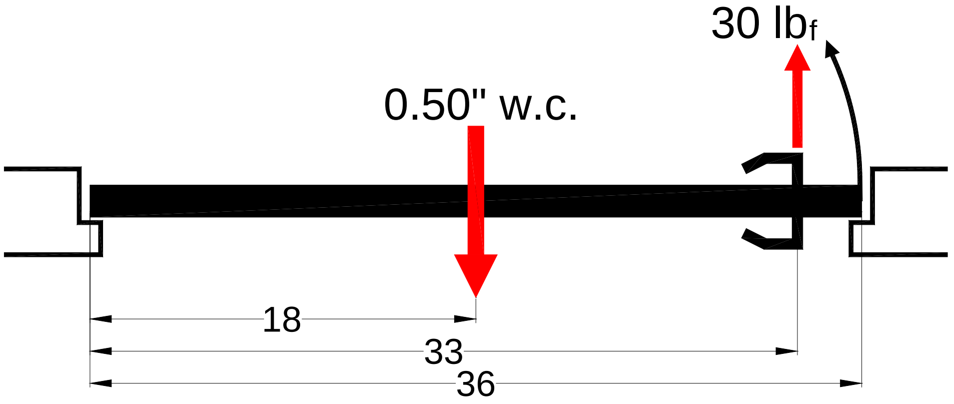


Case Study: Erratic Pressure Control

- Space too tight for selected HVAC control systems
  - Standard office type VAV controls installed for cost savings rather than higher end systems
    - A low end system with ±120 cfm yields ±0.034” fluctuations
    - A better system with ±40 cfm yields ±0.004” fluctuations

Case Study: Door Force Difficulties

- Emergency purge sequence caused excessive door force
  - Exhaust forced to 100% speed
  - Egress door force limit typ. <30 lb_f
  - Adjust speed during Cx



Summary

Successful BSL-3 Laboratories:

1. Primary containment, SOPs, risk assessment and containment plan
2. Establish sensible acceptance criteria in keeping with BMBL 5 and established criteria based on risk
3. Commissioning as a risk management function provides a methodical path to BSL-3 containment and overall performance

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