

# Annual Performance Verification for ABSL3 and BLS3 Facilities



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# Agenda

- ▶ Performance Verification Methods
- ▶ Impact of Standards and Guidelines
- ▶ Best Practices



# ABSL3 and BSL3 Facilities Differ

- ▶ Each BSL3 facility is unique
- ▶ Each BSL3 program is unique
  - ▶ SOPs differ
  - ▶ Staffing differs
  - ▶ Local requirements differ
- ▶ Therefore...Facility Performance Verification processes should differ

Cookie cutter  
approach  
doesn't work

# Tailoring the Verification Process

## Important considerations

- ▶ Risk assessments – initial & periodic
  - ▶ Select Agent usage
  - ▶ Aerosolizing of agents
  - ▶ PPE variations
- ▶ Building control system capabilities



# Performance Verification Methods

Basic: Verify functionality of most critical facility systems

- ▶ *Primary containment*: Biosafety cabinets and HEPA filters
- ▶ *Secondary containment*: Visual verification of room tightness
- ▶ Alarm verifications

# Performance Verification Methods

Comprehensive: Verify all critical facility systems

- ▶ Room integrity tests
- ▶ Efficacy of gaseous decontamination
- ▶ Complete failure tests

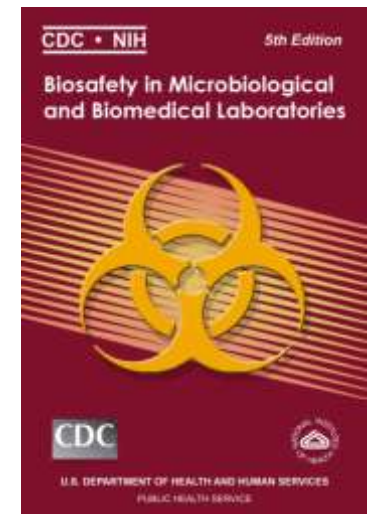
# Impact of Standards & Guidelines

- ▶ BMBL – 5<sup>th</sup> Edition
- ▶ DSAT Memo on BMBL content
- ▶ ANSI/ASSE Z9.14
- ▶ Other government requirements

# BMBL – 5<sup>th</sup> Edition

## BSL-3 D15:

*“The BSL-3 facility design, operational parameters and procedures **must** be verified and documented prior to operation. Facilities must be re-verified and documented at least annually.”*

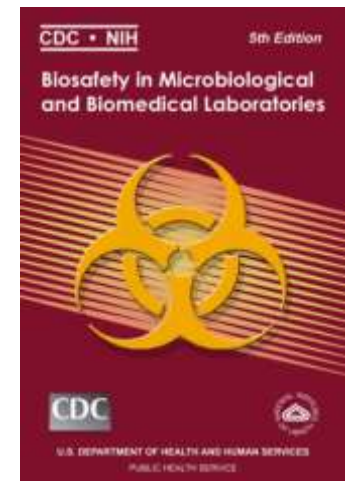




# BMBL – 5<sup>th</sup> Edition

## ABSL-3 D14:

*“The ABSL-3 facility...**must** be tested to verify that the design and operational parameters have been met prior to use... (and) re-verified at least annually against these procedures as modified by operational experience.”*



# DSAT Clarification for Select Agent Labs

*“Once verification has been approved by CDC/DSAT or APHIS/ASAP... failure conditions testing **need not be repeated**... if no major changes or problems affecting HVAC performance.”*

This addresses the mandate in the BMBL, but prudence and experience lead to the conclusion that periodic facility tests are necessary.

# ANSI / ASSE Z9.14 – 2014

*Testing and Performance Verification Methodologies  
for Ventilation Systems for BSL3 and ABSL3 Facilities*

*This standard provides testing standardization, uniformity, and consistency through the use of minimal performance-based testing and verification methodologies for BSL-3/ABSL-3 ventilation systems in facilities.*



# ANSI / ASSE Z9.14 – 2014

*Testing and Performance Verification Methodologies  
for Ventilation Systems for BSL3 and ABSL3 Facilities*

- ▶ Uses a risk-based approach.
- ▶ It is a voluntary standard. Conformance is determined by each institution that uses it.
- ▶ Provides testing scripts and recommended documentation.

# Other Government Requirements

- ▶ National Institutes of Health
  - ▶ Design Requirements Manual
  - ▶ BSL3 Certification Checklists
    - ▶ Apply to certification of NIH Facilities
- ▶ Health Canada CL3 Facility Certification Requirements
- ▶ Singapore Ministry of Health

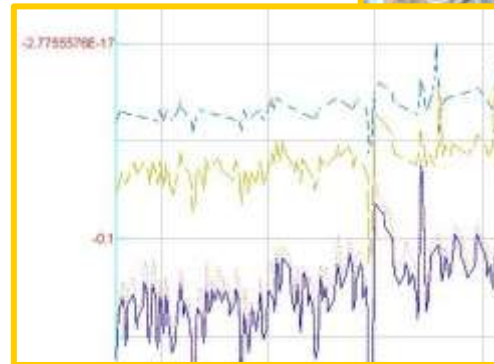
# Best Practices

- ▶ Use existing proven testing procedures
- ▶ Schedule a shut-down if you can
- ▶ Establish good pass/fail criteria



# Best Practices

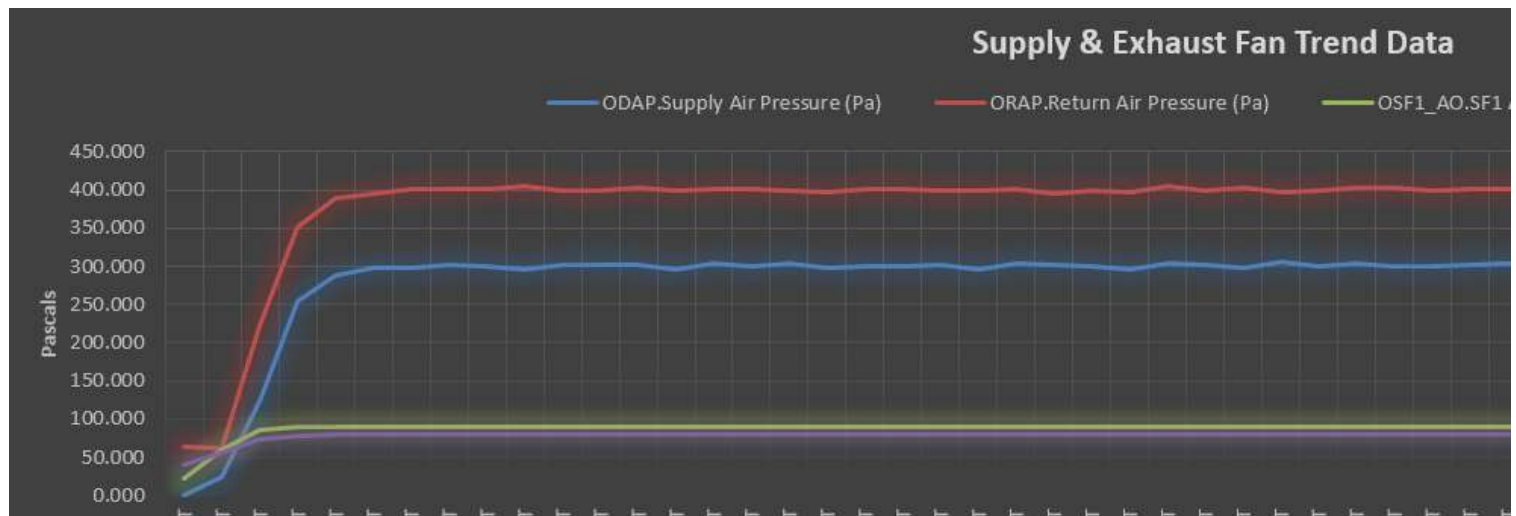
- ▶ Start with room integrity testing
- ▶ Use instrumentation and procedures that provide conclusive results
  - ▶ Airflow direction data
  - ▶ Normal and failure conditions



# Best Practices

## Important low-cost facility features

- ▶ Add gravity (non-actuated) backdraft dampers on each redundant exhaust fan





# Best Practices

## Important low-cost facility features

- ▶ Accurate and properly located control sensors
  - ▶ Duct pressure sensors
  - ▶ Reliable fan status sensing



# Best Practices



Ensure transfer of knowledge

- ▶ Use test procedures and performance results to train and inform facility users
- ▶ Improve operational and maintenance performance

# Conclusion

- ▶ Performance Verification Methods
- ▶ Impact of Standards and Guidelines
- ▶ Best Practices



# Thank you



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