



News for the Federal Biorisk Management Policy Community

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Feedback and Submissions Welcome

We want to hear from you! Please contact Janelle Hurwitz (janelle.hurwitz@hhs.gov) with any comments, suggestions or news ideas for future editions of S3 Newsletter. Feel free to submit general information for inclusion or drafted articles. If you have an idea, we are happy to work with you in drafting a piece. Articles should be in MS Word format, fewer than 1000 words, with author/contact name and email address. Pictures and diagrams in jpg format are encouraged and welcome. Thank you!

ANSI/ASSE Z9.14 "Testing and Performance Verification Methodologies for Ventilation Systems for Biological Safety Level 3 (BSL-3) and Animal Biological Safety Level 3 (ABSL-3) Laboratories" Leads Standard Development for High-Containment Laboratory Testing and Performance

By Farhad Memarzadeh, Chair ANSI Z9.14; Director, Farhad Memarzadeh, Chair ANSI Z9.14; Director, Division of Technical Resources, National Institutes of Health, Bethesda

On January 24, 2014, the American National Standards Institute approved the new standard, "Testing and Performance - Verification Methodologies for Ventilation Systems for BSL-3/ABSL-3 Facilities" (ANSI/ASSE Z9.14-2014).

ANSI/ASSE Z9.14 focuses on performance verification of engineering controls related specifically to ventilation system features of BSL-3/ABSL-3 facilities. Z9.14 is the only guidance that provides a methodology to verify ventilation systems in such facilities. The standard provides one component of a more extensive graduated and risk-based approach to reaching containment goals appropriate to the risk of the agent and the laboratory activity.

The new Z9.14 standard was published in March 2014. Visit www.asse.org/standards or call ASSE Customer Service at (847) 699-2929 for more information.

A new standard, Testing and Performance-Verification Methodologies for Ventilation Systems for Biological Safety Level 3 (BSL-3) and Animal Biological Safety Level 3 (ABSL-3) Laboratories (ANSI/ASSE Z9.14-2014), was released in January 2014. The standard provides a voluntary, systematic approach to evaluate safety design features, operations, and engineering processes and controls in BSL-3/ABSL-3 laboratories and animal facilities. The recommended test methodologies in ANSI/ASSE-Z9.14 provide standardized, uniform,

and consistent guidance to ensure that all reasonable facility engineering controls and prudent practices are in place to minimize, to the greatest extent possible, the risks associated with laboratory operations and the use of biohazardous materials.

The Government Accounting Office (GAO) established the need to "develop, in consultation with the scientific community, national standards for the design, construction, commissioning, and operation of high-containment laboratories, specifically including provi-

sions for long-term maintenance." A consequence of the establishment of more U.S.-based BSL-3/ABSL-3 laboratories is the unknown level of risk when laboratory accidents occur (GAO, 2009, 2013) and the extensive amount of time and expense needed to satisfy the "subjective" demands imposed during testing and verification. ANSI/ASSE Z9.14 is the first standard to address the concerns expressed in the GAO reports.

In response to the identified need, the American Society of Safety Engineers (ASSE) and the American National Standards Institute (ANSI) conducted an extensive "gap and needs analysis" (Memarzadeh & DeBerardinis, 2012); they found that there is no single resource for a comprehensive testing methodology that can be used uniformly from one facility to another to verify that the ventilation systems in such facilities are performing appropriately. ANSI/ASSE Z9.14 provides one component of a more extensive, graduated, risk-based approach to reaching containment goals appropriate to the risk of the agent

Performing a risk assessment is the critical first step in the planning, design, construction, maintenance, and safe operation of any BSL-3/ABSL-3 facility.

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and the laboratory activity for the 1,300+ BSL-3/ABSL-3 laboratories that exist in the United States (American Biological Safety Association, 2008).

The ventilation system of a BSL-3/ABSL-3 laboratory is central to

its performance and operation. It is specifically designed to prevent unintended release of infectious biological agents that may cause unintended human and animal exposures internally to the working environment or externally to the outside environment. It is critical that the ventilation system conform to current biocontainment guidelines and regulations (*Biosafety in Microbiological and Biomedical Laboratories; BMBL*; U.S. Department of Health and Human Services [HHS], Centers for Disease Control [CDC], National Institutes of Health [NIH], 2009; Association for Assessment and Accreditation of Laboratory Animal Care [AAALAC], 2010).

Typically, the design of U.S. BSL-3/ABSL-3 laboratories is guided by the criteria defined in the *BMBL*, the *NIH Design Requirements Manual* (if the facility is NIH funded), the U.S. Department of Agriculture (USDA) Agricultural Research Service (ARS) select agent regulations and local codes where applicable.

Scope and Use of ANSI/ASSE Z9.14

ANSI/ASSE Z9.14 covers:

- a. Directional airflow—a primary testable target
- b. Airlocks and anterooms—double-door interlocking
- c. Primary containment systems—focus on biosafety cabinets
- d. Building ventilation system (alarm/interface with decontamination systems and other systems that would influence the automation)
- e. HVAC testing—air-handling units, exhaust fans, redundancy in systems, dampers, related to plumbing
- f. Filtration
- g. ABSL-3 and integration of Individually Ventilated Cages (IVC) static caging systems, oth-

er elements, downdraft tables (ventilation implication)

- h. Document validation (systems based)
- i. Pressure reversal—provides methodologies that allow a facility to comply with *BMBL*
- j. Failure testing—addresses need, types, and frequency
- k. Leakage issues related to HVAC
- l. Qualifications of testers

The standard uses a risk assessment and performance-based approach and as such is adaptable to any size or type of BSL-3/ABSL-3 facility. The standard is designed to be fully compatible with biorisk management systems and national and international health and safety management systems without duplicating or contradicting their requirements. ANSI/ASSE Z9.14 may be useful for (a) facilities that have similar functions and risks, but do not follow the same testing methods for ventilation; (b) facilities that cannot meet the ventilation recommendations of the most current *BMBL* when renovating or retesting; and (c) users who require help in test performance. It may be used as an adjunct standard operating procedure or along with other methodologies that may be available to ensure that the ventilation system in a BSL-3/ABSL-3 facility provides a safe environment for building occupants and the external environment.

ANSI/ASSE Z9.14 applies specifically to new or existing laboratories; and research, pharmaceutical, and insectary facilities designed to perform at the BSL-3/ABSL-3 level if there has been a change of agents, procedures, key personnel, renovation, change of use, or decommissioning. ANSI/ASSE Z9.14 also covers the inspection of the ventilation system components of any laboratory designed to handle agents and infected animals that require BSL-3/ABSL-3 containment as defined by the latest edition of the *BMBL*. The standard provides users with guidance on what ventilation system components should be inspected visually; verification procedures to ensure that system components provide for the safe operation of the facility's ventilation system (i.e., directional inward airflow, response to failures, minimizing leakage, etc.); and methodologies to help comply with current local, state, federal requirements, and industry standards and best practices.

Performing a risk assessment is the critical first step in the planning, design, construction, main-

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tenance, and safe operation of any BSL-3/ABSL-3 facility. When deficiencies are identified through a risk assessment or in the course of testing and verification, an iterative corrective action plan (CAP) ensures that testing and verification procedures can be performed in a safe and secure manner for all personnel involved. ANSI/ASSE Z9.14 provides a sample CAP and several hazard risk matrices. In addition, the standard gives guidance for collecting, preparing, and retaining documentation; performing visual inspection; and testing and verification methodologies for the performance of ventilation system components.

The ANSI/ASSE Z9.14 Committee, chaired by Farhad Memarzadeh (NIH) and Vice Chair Louis DiBerardinis (MIT), is made up of experts from safety organizations and associations including:

- American Biological Safety Association (ABSA)
- American Society for Microbiology (ASM)
- Association of Public Health Laboratories (APHL)
- International Federation of Biosafety Association (IFBA)
- Controlled Environment Testing Association (CETA)
- National Energy Management Institute (NEMI)
- U.S. government agencies (Department of Health and Human Services [including the National Institutes of Health and Centers for Disease Control and Prevention,] Department of Agriculture—Agricultural Research Service, Department of Homeland Security)
- U.S. and Canadian academic institutions (e.g., University of Texas, Cornell University, Carleton University, Harvard University, Texas A&M University, University of Pittsburgh, University of Louisville, University of California—Irvine, Massachusetts Institute of Technology)

The Committee also includes commissioning engineers, biomedical facility ventilation systems engineers, biorisk management experts, as well as qualified users and facility managers.

In summary, the challenge for a standard of this scope is to be flexible enough for old and new facilities, to recognize that not all risks are equal, and to address normal and failure modes—particularly directional airflow and contaminants. ANSI/ASSE Z9.14 is a voluntary technical stan-

dard and methodology that provides detailed information on the testing and performance-verification of ventilation and related systems required within a BSL-3/ABSL-3 facility; it is the first standard of its kind. It will help to educate biosafety professionals and biocontainment engineers who must specify or perform tests regarding the performance of ventilation systems in BSL-3/ABSL-3 facilities.

The use of ANSI/ASSE Z9.14 as an approved testing methodology will provide consistency in the industry and serve as a first step in meeting the GAO recommendations on high-containment laboratories and other code and regulations. The criteria in the standard may be supplemented, expanded, or consolidated as required by the specific testing and verification effort, the organization, and the regulatory and policy requirements specific to each facility.

ANSI/ASSE Z9.14 (2014) may be purchased online at ABSA, ANSI, or ASSE websites.

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