ANSI/ASSP Z9.14-2020

Testing and Performance-Verification Methodologies for Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3) Ventilation Systems

AMERICAN SOCIETY OF SAFETY PROFESSIONALS

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American National Standard

Testing and Performance-Verification Methodologies for Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3) Ventilation Systems

Secretariat

American Society of Safety Professionals
520 N. Northwest Highway
Park Ridge, Illinois 60068

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American National Standard

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FOREWORD (This Foreword is not part of the American National Standard ANSI/ASSP Z9.14–2020.)

The Z9.14 Subcommittee was chartered to develop the American National Standard, Testing and Performance-Verification Methodologies for Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3) Ventilation Systems.

Over 1,000 BSL-3/ABSL-3 laboratories and animal facilities have been constructed in the United States. The design for their ventilation systems has been largely guided by the criteria defined in successive versions of *Biosafety in Microbiological and Biomedical Laboratories* (*BMBL*) from the Department of Health and Human Services (DHHS), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH) (Biosafety in Microbiological and Biomedical Laboratories (BMBL) n.d.)[1]; the American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) standards[2]; *U.S. Department of Agriculture Animal Research Service (USDA ARS) 242.1 Manual*[3]; *World Health Organization (WHO) Biosafety Guidelines: Biosafety Manual*[4]; and the *National Institutes of Health Design Requirements Manual* (*DRM*).[5] Many of these guidelines offer design requirements, but lack the testing and performance-verification methodology to ensure the safe operation of the ventilation system for these laboratories.

Using a risk assessment and performance-based approach, this standard provides the technical specifications and background information needed to address the technical, engineering, and associated systems for ventilation within a BSL-3/ABSL-3 laboratory. As such, it is fully compatible with biorisk-management systems and national and international health and safety management systems without duplicating or contradicting their requirements.

The purpose of the ventilation system is to provide the necessary environment for biocontainment, occupational health, and animal health in accordance with standards and containment guidelines. It specifically is designed to prevent unintended release of aerosolized infectious biological agents.

The ANSI/ASSP Z9.14 standard provides the combined knowledge acquired over the years by biosafety professionals, design professionals, and owners/operators of BSL-3/ABSL-3 laboratories, which establishes the requirements and methodologies for the testing and performance verification of the ventilation system.

The ANSI/ASSP Z9.14 standard focuses specifically on the ventilation system features of BSL-3/ ABSL-3 facilities. Because the ventilation system is affected by and has an effect on other systems and equipment in a laboratory, those systems and equipment may be included in the standard, to some extent, as an associated system.

ANSI/ASSP Z9.14 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.

How to Read This Standard

ANSI/ASSP Z9.14 is presented in a two-column format. Beginning with section 5.0, Applicability and Conformance, the left column presents the requirements of the standard; the right column provides clarification and explanation of the requirements and information on "how to comply" to the standard. The standard contains appendices that are informative and are not considered a mandatory part of the standard. The standard is not meant to be all-encompassing. Rather, it establishes minimum acceptable criteria for completing the verification process and documenting the necessary information for regulatory and historical purposes. It is somewhat general in nature so that it can be applied to any BSL-3/ABSL-3 laboratory. We hope, however, that future versions will continue to expand and amplify these concepts as additional experience is gained. Suggestions for improvement of this standard are welcome, they should be sent to: American Society of Safety Professionals, 520 N. Northwest Highway, Park Ridge, IL 60068.

This standard was processed and approved for submittal to ANSI by the American National Standards Committee on Ventilation Systems. Approval of the standard does not necessarily imply (nor is it required) that all Committee members voted for its approval. At the time ANSI approved this standard, the Z9 Committee had the following members:

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The Z9.14 Subcommittee

The Z9.14 Subcommittee on Testing and Performance-Verification Methodologies for Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3) Ventilation Systems that developed this standard was comprised of the following members:

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Director, Division of Technical Resources

Louis DiBerardinis, CIH, CSP, Vice Chair, Massachusetts Institute of Technology (MIT)
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1 Executive Summary

Testing and verification of the ventilation system of laboratories that operate at Biosafety Level 3 (BSL-3)/Animal Biosafety Level 3 (ABSL-3) are necessary processes for ensuring that the performance and operation of the systems consistently maintain a safe environment for human occupants, research animals, and the internal and external environment. Because each facility is unique, testing and verification acceptance criteria will differ among facilities. Therefore, a risk-based approach to testing and verification of the ventilation system is recommended. It is highly encouraged that each facility develops and maintains standard operating procedures (SOPs) that address testing and verification of the ventilation system and associated components. Additionally, there should be SOPs for performing a risk assessment and for the sequence of testing and performance verification. Risk assessments should be performed initially and at least annually throughout the life cycle of the facility.

ANSI Z9.14 provides recommendations for testing methodologies, guidance on the ventilation system components that should be inspected visually, and what is needed to verify that the system components operate such that the overall system's performance (i.e., directional inward airflow, response to failures, minimizing leakage, etc.) can be verified to ensure safe operation of the facility's ventilation system. A verification program needs to consider and compare federal, state, and local regulations for future use, best practices, and organizational requirements.

This standard provides the user with:

- Testing standardization, uniformity, and consistency through the use of minimal performance-based testing and verification methodologies for BSL-3/ABSL-3 ventilation systems
- Technical background and information that addresses the engineering and associated systems for ventilation within a BSL-3/ABSL-3 laboratory using the many tenants of a risk assessment and performance-based approach that is fully compatible with biorisk-management systems and national and international health and safety-management systems without duplicating or contradicting their requirements
- Risk assessment guidance and methodologies to identify hazards that can be evaluated in terms of the likelihood that a problem may occur and