The National Institutes of Health | Division of Technical Resources | Office of Research Facilities

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The formulae $\frac{\partial \rho \bar{U}_i}{\partial t}+\frac{\partial}{\partial x_j}(\rho \bar{U}_i \bar{U}_j)=-\frac{\partial \bar{P}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu \frac{\partial \bar{U}_i}{\partial x_j}\right)+g_i(\rho-\rho_0)$ for building $\frac{\partial}{\partial x_j}(\rho \bar{U}_i \bar{U}_j)=-\frac{\partial \bar{P}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu \frac{\partial \bar{U}_i}{\partial x_j}-\rho \overline{u_i' u_j'}\right)+g_i(\rho-\rho_0)$ state of the art $\frac{\partial}{\partial x_i}(\rho \bar{U}_i \bar{H})=\frac{\partial}{\partial x_i}\left(\lambda \frac{\partial \bar{T}}{\partial x_i}-\rho \overline{u_i' h'}\right)$ biomedical research facilities.

ANSI/ASSP Z9.14-2020

On March 31st, 2020, ANSI published the revised standard 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.

ANSI/ASSP Z9.14 has been used extensively both nationally and internationally since its original release in January 2014. The test methodologies provide a standardized, uniform, and consistent approach to ensure that all reasonable facility engineering controls and prudent practices are in place to minimize the risks associated with BSL-3/ABSL-3 laboratory operations. ANSI/ASSP Z9.14-2020 continues to be the only guidance available that provides a methodology to verify ventilation systems in high biocontainment facilities.

Background

The ventilation systems in BSL-3/ABSL-3 facilities must conform to current biocontainment guidelines and regulations, including those of the NIH, the CDC, and AAALAC. Verification that these systems are working as intended should be performed regularly, as defined by the institution. However, in 2012, the American Society of Safety Professionals (ASSP) and the American National Standards Institute (ANSI) conducted a "gap and needs analysis" and concluded that there was no single comprehensive testing methodology to verify that the ventilation systems in such facilities are performing appropriately. ANSI/ASSP Z9.14 was therefore developed to provide an extensive, graduated, risk-based approach to reaching containment goals appropriate to the risk of the agent and the laboratory.

Scope of ANSI/ASSP Z9.14 Revision

The scope of ANSI/ASSP Z9.14 – 2020 has not changed from the previous version, but the existing content has been updated, and new sections, appendices, and checklists were added. New content includes:

- Verification of Conformance to Regulations
- Corrective Action Plan Guidance
- Updated Definitions
- Methodologies to Perform Risk Assessment
- Risk Assessment and Corrective Action Checklists

ANSI/ASSP Z9.14 – 2020 provides guidance on the use of risk assessment and a performance-based approach, which are adaptable to any size or type of BSL-3/ABSL-3 facility. It is designed to be fully compatible with national and international health and safety management systems without duplicating or contradicting their requirements. ANSI/ASSP Z9.14 – 2020 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 with test administration. It may be used in whole or in part as an adjunct standard operating procedure, or along with other methodologies that may be available to minimize the risks associated with BSL-3/ABSL-3 facility operations.

Application and Use of ANSI/ASSP Z9.14

ANSI/ASSP Z9.14 – 2020 applies specifically to new or existing laboratories as well as research, pharmaceutical, and insectary facilities. The standard should also be applied if there has been a change of agents, procedures, or key personnel; a renovation; or a decommissioning. It provides users with guidance on inspecting ventilation system components, including visual verification procedures to ensure that system components support 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, and federal requirements, industry standards, and best practices. The revision gives stepwise guidance to conduct an effective risk assessment, and a comprehensive checklist has been added for users to confirm that the appropriate steps have been taken to ensure that the ventilation system operates as intended.

The standard's basic guidance for collecting, preparing, and retaining documentation; performing visual inspection; testing; and verification methodologies for the performance of ventilation system components remain unchanged. The 2020 revision contains more detailed procedures and risk matrices than its predecessor for use when deficiencies are identified through a risk assessment or in the course of testing and verification. It also provides details to conduct iterative corrective actions until the deficiencies are resolved to management's satisfaction.

'Design Requirements Manual (DRM) News to Use' is a monthly ORF publication featuring salient technical information that should be applied to the design of NIH biomedical research laboratories and animal facilities. NIH Project Officers, A/E's and other consultants to the NIH, who develop intramural, extramural and American Recovery and Reinvestment Act (ARRA) projects will benefit from 'News to Use'. **Please address questions or comments to:** shawm@nih.gov

Further details on this month's topic are available on the DRM website Section 6.6: BSL-3 & ABSL-3 Biocontainment
www.orf.od.nih.gov/TechnicalResources/Pages/DesignRequirementsManual2016.aspxPages/DesignRequirementsManual2016