AMERICAN NATIONAL STANDARD

ANSI/ASSE Z9.14 – 2014
Testing and Performance-Verification Methodologies for Ventilation Systems for Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3) Facilities

ANSI/ASSE Z9.14 – 2014

AMERICAN SOCIETY OF SAFETY ENGINEERS

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ANSI/ASSE Z9.14 – 2014

American National Standard

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

Secretariat

American Society of Safety Engineers
1800 East Oakton Street
Des Plaines, Illinois 60018-2187

Approved January 24, 2014

American National Standards Institute, Inc.

American National Standard

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Published February 2014 by

American Society of Safety Engineers
1800 East Oakton Street
Des Plaines, Illinois 60018-2187
(847) 699-2929 • www.asse.org

Printed in the United States of America

FOREWORD (This Foreword is not part of the American National Standard ANSI/ASSE Z9.14–2014.)

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

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 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 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 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 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 Engineers, 1800 East Oakton Street, Des Plaines, IL 60018-2187.

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 Ventilation Systems for Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3) Facilities that developed this standard was comprised of the following members:

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

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 regular periods 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

the damage from such an event that may occur

- The collective knowledge of biosafety and design professionals and owners/operators who recognize the need to establish uniformity in the requirements and methodologies for the testing and performance verification of the ventilation system of BSL-3/ ABSL-3 laboratories

The criteria contained herein should be supplemented, expanded, or consolidated as required to adapt to the specific testing and verification effort, the organization, and the specific regulatory and policy requirements that may apply in each case. Suggested acceptance criteria, where available, are provided in the standard. Establishment of acceptance criteria is the responsibility of facility management.

Acceptance criteria should be based on site-specific risk assessment and performance objectives.

2 Purpose

The purpose of ANSI Z9.14 is to provide a "one-stop" resource for guidance to inspect and test the performance of a BSL-3/ABSL-3 laboratory ventilation system.

3 Scope

Methodologies are provided to perform visual inspection and evaluation of:

1. Directional airflow
2. Anterooms
3. Primary containment systems
4. Building ventilation system
5. Heating, ventilation, and air-conditioning (HVAC) testing
6. Filtration
7. ABSL-3 and integration of individually ventilated caging, static caging systems, other elements; and downdraft tables
8. Document validation
9. Pressure reversal
10. Failure testing
11. Leakage issues related to HVAC
12. Qualifications of testers

ANSI Z9.14 focuses on performance verification of ventilation system-engineering controls and related systems within a BSL-3/ABSL-3 laboratory.

Testing and verification of ventilation systems in BSL-3/ABSL-3 labs include:

- Supply
- Exhaust
- Directional airflow
- Biosafety cabinets
- Air filtration
- Exhaust stacks
- Fan failure scenarios
- Redundancy
- Canopy hoods (autoclaves)
- Specific ABSL-3 requirements

Testing and verification of related systems within BSL-3/ABSL-3 labs include:

- Optimizing maintenance of pressure gradients and maintaining temperature and humidity
- Physical integrity

    - Sealing and leakage factors
    - Interlocking systems
    - Airlocks
    - Doors/windows
- Emergency and backup power systems
    - Alarms
    - Operating sequences

4 Definitions

Acceptance criteria – The indicators and agreed-upon requirements established by project stakeholders (standard-setting authorities, the institution, occupants, etc.) to determine when a space or component of a facility, e.g., a laboratory ventilation system, is adequate or meets design criteria and intent.

Animal biosafety level 3 (ABSL-3) – A level of laboratory containment that is suitable for work with laboratory animals infected with indigenous or exotic agents, agents that present a potential for aerosol transmission, and agents causing serious or potentially lethal disease. ABSL-3 containment builds on the standard practices, procedures, containment equipment, and facility requirements of ABSL-2.[1]

Anteroom – For the purpose of this standard, "anteroom" refers to the zone between the two self-closing doors in a facility designed to minimize air escaping from the containment space (e.g., laboratory, animal room, or central containment corridor) into non-containment spaces.

Authority having jurisdiction (AHJ) – An organization, office, or individual responsible for enforcing the requirements of a code or standard, or for approving equipment, materials, an installation, or a procedure.[6]

Automatic transfer switch (ATS) – An automatic device for transferring one or more load conductor connections from one power source to another.

Biocontainment – The practices, techniques, equipment, and facilities needed to contain biohazardous materials such as pathogenic microorganisms or toxins and preventing their release into the environment, thus minimizing worker exposure. Biocontainment includes the physical containment barriers in a facility, such as contained dressing and shower rooms, sealed service penetrations, specialized doors, entry and exit avenues to prevent cross-contamination, specialized air-handling systems for contamination control, personal protective equipment, biosafety cabinets and other primary containment devices, etc.

Biohazard (biological hazard, hazardous biological agent) – 1) An infectious or otherwise harmful biological agent or part thereof presenting a real or potential risk to humans, animals, plants, or the

environment[7]; 2) A potential source of harm caused by biological agents or toxins.[8]

Biological safety cabinet (BSC)[7] – An enclosed cabinet designed to serve as the primary means of containment for working safely with infectious microorganisms. A biosafety cabinet provides personnel, environmental, and product protection when appropriate practices and procedures are followed. Three kinds of biological safety cabinets, designated as Class I, II, and III, have been developed to meet varying research and clinical needs. Most biosafety cabinets use high-efficiency particulate air (HEPA) filters in the exhaust and supply systems. The exception is a Class I biosafety cabinet, which does not have HEPA-filtered supply air. Different kinds of Class II biosafety cabinets are used for different containment needs. They include Class II Type A1 cabinets (formerly designated Type A), Class II Type A2 cabinets (when exhausted to the environment, were formerly designated Type B3), and Class II Type B1 and B2 cabinets.[1]

Biological safety manual – A collection of standard operating procedures (SOPs), training documents, responsibilities, etc., that is specific to a facility.

Biorisk (biological risk) – A combination of the probability of occurrence of harm and the severity of that harm where the source of harm is a biological agent or toxin. The source of harm may be accidental or deliberate.[8]

Biorisk assessment [See also "Risk assessment"] – The process of evaluating the biological risk(s) arising from a biohazard(s), taking into account the adequacy of any existing controls, and deciding whether or not the biorisk(s) is acceptable.[8]

Biorisk-management (biological risk-management) – The systematic analysis of strategies and methods that is performed in order to minimize the likelihood of a biosecurity or biosafety incident. The process places responsibility on the facility and its manager to demonstrate that appropriate and valid biorisk reduction procedures have been established and implemented.[9]

Biosafety (biological safety) – The application of combinations of laboratory practices and procedures, laboratory function and design, safety equipment, and appropriate occupational health programs when working with potentially infectious microorganisms and other biohazards. Biosafety practices and procedures are designed to reduce the exposure of laboratory personnel, the public, agriculture, and the environment to potentially infectious agents and other biological hazards. The key principles of biosafety are risk assessment and containment. Biosafety also refers to the development and implementation of administrative policies to prevent the transmission of potentially harmful biologic

agents to workers, other persons, and the environment.

Biosafety level (BSL) – The combination of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed and the hazards posed by the infectious agents and the laboratory function or activity. Biosafety levels are described in the *BMBL*.[1]

Biosafety level 3 (BSL-3) – A level of laboratory containment applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and associated procedures.[1]

Biosafety professional/Biological safety officer (BSO) – An individual who identifies, assesses, and controls occupational health risks, adverse effects on the environment (including agriculture), risks to the community and public health associated with exposure to biohazardous agents and materials and develops programs to manage these risks. This professional is a key resource in the design and construction of containment facilities.[10]

BSL-3/ABSL-3 facility – A laboratory designed and operated at biosafety level 3 (BSL-3) or animal biosafety level 3 (ABSL-3).

Building automation system (BAS) – Automated systems used to alarm, monitor, and control building functions, such as smoke management; heating, ventilating, and air-conditioning (HVAC); and lighting.

Certification – A systematic, documented process to ensure systems perform in accordance with available certification standards or applicable verification guidance.[8]

Class III biological safety cabinet (Class III BSC)[7] – A gas-tight biological safety cabinet with a non-opening, completely sealed, viewing window that is accessed using long, heavy-duty rubber gloves attached to ports in the cabinet. Both supply and exhaust air are HEPA filtered, allowing for maximum protection of the environment and the worker. Operations in the cabinet are conducted through attached rubber gloves. The cabinet is maintained under negative air pressure of at least 0.50 in water gauge (w.g.) (120 Pascal [Pa]). Down-flow air is drawn into the cabinet through HEPA and ultra-low penetration air (ULPA) filters. The exhaust air is treated by double HEPA/ULPA filtration or by HEPA/ULPA filtration and incineration.

Commissioning – 1) A systematic process, through documented verification, that all building systems perform interactively

according to the documented design intent and owner's operational needs. 2) The process of ensuring that systems are capable of being operated and maintained according to design intent.[11]

Containment perimeter – The boundary between the laboratory, animal facility, or post mortem room, and the area outside of containment. An anteroom, if present, is considered to be within the containment perimeter.

Corrective action plan (CAP) – A step-by-step plan of action and schedule to remedy a deficiency or non-performance. A CAP assigns responsibility and a timeline, and specifications for documenting the corrective actions taken. The essential elements of a CAP include:

1. Assigning responsibilities (to ensure that a responsible individual is assigned for the identified deficiency or action item),
2. Creating an implementation schedule with set milestones,
3. Ensuring that corrective actions are taken for identified deficiencies,
4. Identifying a completion date and providing periodic updates against that completion date, and
5. Documentation indicating that all actions have been taken to correct the deficiencies (includes sign-off when corrective actions are completed).

Critical control air – The complete system that provides a required compressed air supply deemed necessary for the operation or fail-safe condition of critical BSL-3/ ABSL-3 HVAC, controls, or containment equipment (e.g., pneumatic dampers, air-powered sterilizer door gaskets, HVAC controls).

Decontamination – A procedure or set of procedures that eliminates or reduces biological agents and toxins to a safe level with respect to the transmission of infection or other adverse effects.[8]

Directional airflow – Air flow that moves from a low-hazard to a higher-hazard area.

Downdraft table – Specially-constructed autopsy/necropsy tables that are ventilated to partially control particulates, odors, and volatile chemicals. This type of engineering control typically requires a connection to building mechanical systems (plumbing, exhaust ventilation). There are available self-contained, portable downdraft tables that provide particulate protection through a HEPA filtration system which returns filtered air. These pieces of equipment must be tested and must comply with the design of the building and the manufacturers' recommendations.

Empirical testing – Testing based on observation and experiment; derived solely from experience.[12]

Environmental health and safety plan – An institution's/organization's policy document containing information and methods of working as part of the process for

minimizing risks to employees, visitors, and the environment.

Exhaust to supply interlock – A means of control (BAS, electrical) to shut off supply airflow to a BSL-3 suite in the event of exhaust system failure that could cause a reversal of pressurization in the containment zone.

Facility – An operational unit and associated buildings and equipment used to manage biological agents and toxins. A "facility" includes the laboratory, together with the supporting infrastructure, equipment, and services including ancillary rooms such as anteroom, changing rooms, sterilizing rooms, and storage rooms. In the context of this standard, additional kinds of facilities include vivaria, aquaria, and greenhouses.[8]

Facility manager – An individual who is responsible for the overall operation and maintenance of a facility.

Failure testing – A method of simulating a failure event to determine whether backup systems function as designed.

Filters – See HEPA, ULPA, SULPA

Fume hood – An engineering control with one open side for personnel access that is intended to contain and exhaust hazardous gases and vapors. The open side is equipped with at least one sash moving vertically or horizontally to modulate the size of the opening. Various baffles and airfoils are incorporated to provide linear airflow across the face of the opening in accordance with ANSI Z9.5.[13]

High-efficiency particulate air (HEPA) filter – An air filter consisting of ultra-fine fibers that is effective for trapping microscopic particles and infectious agents in the air. A throw-away, extended or pleated medium, dry-type filter with the following components: 1) rigid casing enclosing the full depth of the pleats; 2) minimum particulate removal of 99.97% of a 0.3-micron nominal particle size for HEPA or Type A filters.

Insectary – A specially designed facility for keeping, breeding, or observing living insects. In a BSL-3 insectary, the insects are the vectors for infectious diseases (assuming the insects have been infected with the specific agent under study). Special precautions must be taken to prevent escape into the environment as the insects may not be indigenous to the locale.

Inspection/audit – Conformity evaluation by observation and judgment.[8]

Laboratory – Room within a facility, designated for work with biological agents and/or toxins.[8]

Mitigation – The steps taken to alleviate current risk or prevent or reduce future risk.[14]

Material Safety Data Sheet (MSDS) – A document designed to provide both workers and emergency personnel with the proper procedures for handling or working with a particular substance. An MSDS includes information such as physical data (melting point, boiling point, flash point, etc.), toxicity, health effects, first aid, reactivity, storage, disposal, personal protective equipment, and spill/leak procedures. An MSDS is of particular use if a spill or other accident occurs.

Particle leakage estimation – A calculation of the quantity of air particles leaked under failure conditions that must be provided by the laboratory being verified if "zero-tolerance reverse airflow" cannot be achieved.

Personal protective equipment (PPE) – Material, including clothing (e.g., gown, gloves, respirators, safety glasses), used to prevent exposure to or contamination of a person by chemical or biological matter.[8]

Primary containment – The primary safety barrier for control of biohazardous materials to protect personnel and the environment from exposure to those materials. Primary containment requires using proper storage containers, good microbiological technique, and the use of appropriate primary containment devices.

— **Secondary containment –** The laboratory room or enclosure where the procedures are performed or the animals are housed. Secondary barriers include controlled access to the space and ventilation systems that minimize the release of infectious aerosols from the laboratory.

— **Tertiary containment –** The building envelope and physical operation with items such as shower, locker room, etc.

Primary containment device – Device providing primary containment of biohazardous material. Primary containment devices can include biological safety cabinets, centrifuges with sealed rotors or safety cups, equipment isolators, animal-caging or other equipment that protects personnel and environment from exposure to biohazards.

Risk – Combination of the probability of occurrence of harm and the severity of that harm.[8]

Risk assessment – The qualitative and quantitative evaluation of risk posed to human health, animal health, and/or the environment by the actual or potential presence and/or use of specific hazardous biological agents or other materials. Risk assessment is the exercise of identifying, analyzing, evaluating (probability versus consequence) and finally mitigating any potential hazard.[1,8] Risk assessment is a common first step in an overall risk-management process.[1] (See section 7, Risk Assessment)

Room air balance – A general term relating to mass air balance that describes the proper relationship of air within a laboratory with respect to the total exhaust airflow from the lab and the supply makeup airflow into the lab. The relationship of these airflows also establishes the pressure differential between the laboratory room and adjacent rooms and spaces.[13]

Room pressure differential monitor – Any device used to measure differences in pressure between two physically separated areas or rooms.

Select agents – Select agents and toxins are a subset of biological agents and toxins that the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) have determined to have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products. The current list of select agents and toxins can be found within 7 CFR § 331.3[15]; 9 CFR §§ 121.3, 121.4[16]; and 42 CFR §§ 73.3, 73.4.[17]

Sequence of operations – A fully descriptive, detailed account of system operation that is developed during the design process, and finalized upon commissioning, when the operational details are initialized and verified. The final record of system operation.[18]

Site-specific risks – Specific risks that are associated with the facility due to its unique geographic location, use of specific hazardous agents, and the proposed work processes and equipment involving hazardous agents used at that facility.

Standard – A document established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines, or characteristics for activities or their results aimed at achievement of the optimum degree of order in a given context. [19]

Standard operating procedure (SOP) – A set of written instructions that document a routine or repetitive activity followed by an organization.[8]

SULPA – Super-ULPA filters have an efficiency of 99.9999% on the same basis as ULPA filters. The low penetration expected from ULPA and SULPA filters is such that they must be totally free of even the smallest leak. The standardization of testing methods in both the United States and Europe for ULPA and SULPA filters is now in the process of being finalized. Until it is, the individual user requiring filters at this efficiency level must be certain that the tests performed on filters demonstrate their ability to meet the user-defined needs.[20]

Supply air – The total amount of air delivered to a space used for ventilation, heating, cooling, humidification, and dehumidification.[11, 21]

Testing and performance- verification – The systematic review of all features and processes associated with the laboratory ventilation system to ensure that the entire system and all its individual components are operating as designed.

Transducer – a device that converts an electrical signal into a pneumatic signal (i.e., I/P transducer means current-to-pressure).

Transport velocity – The air velocity required to prevent dry air contaminants from settling out in the duct.[22]

ULPA – Ultra-low penetration air filters have a minimum efficiency of 99.999% for particles in the most penetrating particle size at the specified media velocity. The most penetrating particle size is defined as that particle diameter for which penetration through the medium is a maximum.[20]

Ventilation system – 1) A system consisting of a supply system and associated devices and ductwork for delivering conditioned air to a space, point-source exhaust, and building exhaust systems and associated devices and ductwork for removing potentially contaminated air from a space; 2) the dilution ventilation system, HVAC system, building ventilation system, and their components; 3) a system for removing contaminated air from a space consisting typically of the following elements: (a) exhaust hood, (b) ductwork, (c) air-cleaning equipment, (d) exhauster, and (e) discharge stack.[23]

Verification – Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.[8]

Veterinary staff (at ABSL-3 facilities) – Individuals, who are appropriately trained and licensed to protect the health and safety of laboratory animals by performing animal husbandry and veterinary care.

Vivarium – (Latin, literally for "place of life"; plural: *vivaria* or *vivariums*) 1) Usually, an enclosed area for keeping and raising animals or plants for observation or research; 2) often, a portion of the ecosystem for a particular species is simulated on a smaller scale, with controls for monitoring and maintaining environmental conditions.

Volumetric air flow rate – The rate of airflow expressed in terms of volume (cubic feet or liters) per unit of time. Airflow is commonly expressed as cubic feet per minute (cfm) in U.S. customary system units (USCS) units or liters per second (L/s) in International System of Units (SI) units.[1]

5 Applicability and Conformance

5.1 Applicability

This standard applies specifically to new or existing Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3) laboratories and insectaries. This standard also applies to the aforementioned facilities if there has been a renovation, change of use, or decommissioning.

This standard applies to verification and testing of ventilation system components of any laboratory that is designed for working with agents at the BSL-3/ABSL-3 level as defined by the *Biosafety in Microbiological and Biomedical Laboratories* (*BMBL*).[1]

ANSI Z9.14 is a voluntary standard. This standard could apply to any BSL-3/ABSL-3 laboratory including small animal and insectary facilities.

The standard should be incorporated into the design of any BSL-3/ABSL-3 laboratory facility that is designed for working with agents at the BSL-3/ABSL-3 level as defined by the *BMBL*.[1]

It is designed to provide guidance for collecting, preparing and retaining documentation, performing visual inspection, and testing and verification methodologies for the performance of ventilation system components that have been previously identified in other manuals and documents that address high-containment laboratories or animal facilities.

ANSI Z9.14 may be used as an adjunct standard operating procedure (SOP), or along with other methodologies that may be available to ensure that the ventilation system in a high-containment facility can provide a safe environment for building occupants and the external environment.

ANSI Z9.14 may be useful for:

1. Facilities that have similar functions and risks, but do NOT follow the same testing methods for ventilation;
2. Users who require assistance to perform the tests.

5.2 Conformance

Conformance with this standard, in whole or in part, shall be determined by the individual institution. The date of conformance shall be determined by the institution choosing to use it. The institution should establish a transitional period to meet the expectations of the standard.

Minimal acceptable conditions for ventilation system performance in BSL-3/ABSL-3 facilities include: 1) During normal facility operations, the maintenance of air movement from areas that are not contaminated by any biological hazards towards areas that may be progressively more contaminated inside the laboratory. Depending on the specific risk assessment, biological hazards that may exist inside the containment barriers of BSL-3/ ABSL-3 must be controlled through the use of engineering controls, adequate administrative controls, practices and procedures, and proper use of personal protective equipment. The directional movement of air inside the laboratory between spaces with similar hazard profiles should be determined by operational needs. 2) Ventilation systems in BSL-3/ABSL-3 should be designed to minimize any outward flow of potentially contaminated air from inside to outside the containment zone during failures and recovery from failures of the ventilation systems. This is a fundamental requirement necessary to protect persons, animals, and the environment in areas outside of the containment zone.

Findings that individual test results do not meet the ideal conditions such as transient airflow reversal within containment spaces during some failure mode testing will not necessarily mean that a facility is deemed non-conformant. Rather, such findings documented and incorporated into the risk assessment process will enable the entity's administration to determine if corrective action is required. Corrective actions may be in the form of physical and/or administrative controls. Proper documentation of this process can be considered demonstration of conformance.

5.3 Verification of Conformance to Regulations

Identify the relevant regulations and standards through which the conformance verification process is made. Experts in the field shall be consulted.

This systematic review against previously identified relevant standards may result in the identification of deviations from these standards. The verification process shall not end until disposition for these deviations are identified and the results are verified to be as expected.

Perhaps the most essential comparison is that of the current status to local, state, and federal laws. In some cases, legal requirements may not have been promulgated. In which case, the final status comparison should be made to industry standards or best practices.

In addition to a comparison to regulations, industry standards and best practices, the heating, ventilating, and air-conditioning (HVAC) testing and performance results must be viewed in light of organizational requirements. These may be more restrictive to protect future liability.

As with all process steps, the verification of conformance to standards is not complete without retention of appropriate records as required by the original plan and relevant standards.

6 Overview

6.1 Ventilation-Testing Performance Categories

Testing and verification of ventilation systems in BSL-3/ABSL-3 labs shall include:

- Supply
- Exhaust
- Directional airflow
- Engineering controls such as biological safety cabinets (BSCs), micro-isolators, downdraft tables, fume hoods and other primary containment devices* connected to

Also, testing and verification of related systems within a BSL-3/ABSL-3 lab should include:

- Optimized maintenance of pressure gradients and maintenance of temperature and humidity
- Physical integrity
    - Sealing and leakage factors
    - Interlocking systems
    - Anterooms
    - Doors/windows

the ventilation system**
- Building automation system (BAS) set-point where supply and exhaust track each other
- Air filtration
- Exhaust stacks
- Redundancy
- Canopy hoods (autoclaves)
- Specific ABSL-3 requirements

*Those aspects of primary containment devices that directly affect the ventilation system performance (e.g., for a Class II B2 biosafety cabinet, the interlock between the biosafety cabinet and the heating, ventilating, and air- conditioning (HVAC) controls, but not the performance of the internal supply filter; micro-isolators, aerosolization chambers, glovebox).

**All other equipment that impacts the HVAC system, such as freezers, incubators, centrifuges.

Although this is not intended to be a test standard for primary containment devices, devices connected to the ventilation system must be confirmed to be properly operational and/or maintained and/or certified in accordance with their requirements.

- Emergency and backup power systems
  - Alarms
  - Operating sequences
  - Ventilation system integration with BAS, normal and backup power, and related critical systems (e.g., fire control systems)

6.2 Generic Typical Sequence of Testing and Performance-Verification

The following testing sequence is generic and needs to be adapted specifically to the facility being tested. A standard operating procedure

The following list includes typical elements of SOPs for performing performance-verifications of BSL-3 ventilation systems.

(SOP) shall be developed by qualified individuals for testing a facility to verify high-containment facilities. The verification shall only proceed when there is consensus with the SOP by all parties involved.

A risk assessment shall be included when developing the SOP for testing a facility to identify cases where the testing cannot be performed due to site-specific conditions.

Inclusion of individual elements for a given facility should be made based on site-specific conditions and risk assessment.

1. Identify the personnel needed to test the facility.
2. Provide a written test procedure for each test to be conducted.
3. State the acceptance criteria for each test to be conducted and the basis for those criteria.
4. Provide a drawing of the laboratory, showing where directional airflow/ pressure differential meters are to be located.
5. Provide a simplified schematic of directional airflows across doors into and within the containment zone.
6. Provide a simplified schematic of the ventilation system.
7. Provide a simplified schematic of the normal and emergency power systems.
8. State safety precautions to be taken pertaining to the testing to include a safety briefing requirement.
9. Address security issues and notifications.
10. Address verifications of alarms generated by the failures scenarios.
11. Provide a list of test equipment.
12. Provide documentation of the most recent calibration certificates of the test equipment used.
13. Address building occupant notifications.
14. Provide a testing script to be used with the requirement that the testing be conducted from start to finish, without interruption.
15. Provide a sign-in sheet requiring all testing participants to sign as witnesses

to the tests.

The testing regimen should include the verification of the ventilation system's normal operation prior to testing failure of ventilation system components. System set-points should be recorded for the exhaust and supply systems from the BAS, if applicable. These set-points are necessary to determine when the ventilation system has returned to its normal operation after a failure test. Calibrated differential pressure meters can be used and placed across each pressure differential test location as per the SOP drawing of the laboratory.

Each of these locations should be smoke-tested to verify the meter is measuring directional airflow as confirmed by the direction of the smoke.

A baseline of data should be logged for a minimum period (e.g., 4 minutes, with data of pressure recordings logged at a minimum of 5-second intervals). Likely failure scenarios that should be tested at a minimum are:

1. Failure of a single exhaust fan
2. If the laboratory has redundant exhaust fan(s), then each redundant exhaust fan is failed as a single exhaust-fan failure
3. Failure of multiple exhaust fans, as expected in worst-case scenarios
4. Normal start-up of ventilation system
5. Failure of a single air-handling unit (AHU)
6. If the laboratory has redundant AHUs or supply fans, then each redundant AHU or supply fan is failed as a single-fan failure

7. Failure of multiple AHUs or supply fans, as expected in worst-case scenarios
8. Normal power failure and transfer to emergency source power (uninterruptible power supply [UPS] or emergency generator)
9. Transfer from emergency power to normal power
10. Failure of BAS and controls system failure

Circumstances may be such that because of the normal and emergency power distribution, testing may not be easily accomplished. In which case, a simulated power test is sometimes possible where just the automatic transfer switch (ATS) can be manipulated. If not, then the suggested procedure is to verify that there is a maintenance program that annually tests the emergency generator under load conditions and there is annual maintenance of the ATS. If a test is simulated for the BSL-3 zone under test, test procedures should assess impact of adjacent areas that may be still running and may influence pressures; tests could also simulate concurrent failures in adjacent zones.

6.3 Roles, Responsibilities, and Qualifications

The ultimate responsibility for the safe operation of a BSL-3/ABSL-3 laboratory facility rests with the institution; specifically this falls to top management.

Two groups of individuals should perform the activities described in this standard:

1. **Entity Management** — Those individuals with facility-specific roles and responsibilities such as upper management/owner's representative, senior management, biological safety officer/biorisk- management advisor

2. **Testing and Verification Team** — Those individuals who will be actually performing the testing and performance-verification methodologies. The testing and verification team may be completely made up of individuals who are not associated with the entity (i.e., outside contractors) or they may be made up in whole or part by entity staff

Team experience should include:

- Working knowledge of current codes and standards applicable to the facility type and geographic location; aspects of design, construction, and commissioning; risk management; developing and implementing an integrated program of conformance; specific knowledge of facility operations' history including preventative maintenance performed, prior equipment failure, and detailed nature of work performed inside the operational facility
- Team and team leader should be designated by the BSL-3/ABSL-3 facility owner and consist of personnel deemed qualified to perform testing and performance-verification procedures

The following are some typical team members:

- Biosafety professional (BSO)
- Facility manager
- HVAC specialist
- Testing engineer

- Occupational health and safety specialist
- Operations and maintenance personnel
- Owners
- Principal investigator or lab director
- Controls specialist(s)

6.3.1 Role/Responsibility as It Relates to a BSL-3/ABSL-3 Facility

Entity Responsibilities:

Entities must establish management plans to maintain biosafety, biocontainment, and biosecurity.

Management plans should include:

1. Ensuring the formation of a ventilation and verification team with appropriate authority to implement a facility testing and verification program
2. Identifying a clear reporting structure to an entity or institutional official
3. Ensuring that the team is appropriately constituted and staffed with adequate resources
4. Ensuring that an appropriate risk assessment is conducted and documented to form the basis of the testing and verification program for the laboratory BSL-3/ABSL-3 facility
5. Ensuring testing and verification are done at an appropriate frequency
6. Ensuring that entity assignments are made and documented
7. Ensuring safe operation of the BSL-3/ABSL-3 laboratory. This is typically performed by top management such as the president/CEO. Providing resources for implementing this standard. This is typically performed by top or senior management
8. Collecting pre-inspection documentation

	9. Ensuring that the facility is safe to perform verification. This is typically performed by BSO or facility management 10. Ensuring that BSL-3/ABSL-3 lab entry requirements have been met. This is typically performed by a BSO or facility management, and includes safety and security training and occupational health requirements 11. Ensuring that required corrective actions to address identified deficiencies have been developed and completed 12. Ensuring that appropriate re-verification is completed to address deficiencies such as ascertaining intended results for the item of concern; issues that may have been impacted by the concern or elements of the corrective action plan (CAP) once completed
Member Responsibilities:	Each role/responsibility should be assigned to an individual; the individual may have more than one role/responsibility.
Testing and Verification Team Responsibilities:	
Team leader shall have ultimate responsibility for team activities including assignment of team roles and responsibilities and interactions with entity's leadership.	Team leader should ensure that team assignments are made and documented.
• Development of site-specific testing and performance-verification SOP • Testing and performance-verification documentation	See section 8, Guidelines for Implementing Testing and Performance-Verification

7 RISK ASSESSMENT

7.1 Risk Assessment Overview for Work with Hazardous Agents/Materials

A comprehensive risk assessment is an integral part of planning, design, construction, maintenance, and safe operation of any biocontainment facility and shall be done prior to opening a new, or after modifications, to an existing facility and whenever agents, procedures, and personnel change.

The risk assessment and subsequent corrective action plan (CAP) (see Appendix A) will ensure that testing and verification procedures can be performed in a safe and secure manner for all personnel involved.

Since each facility is unique, the risk assessment should be designed to factor in the specific features of each facility. Examples include but are not limited to the containment boundaries, hazardous materials / biological agents used including specific related SOPs, current decontamination SOPs, existing building engineering systems, existing system redundancies (if any), and the facility's current maintenance program. It should also include review of anticipated manipulations of the agents, as that might affect the mechanical needs of the laboratory.

The results of the risk assessment should be documented and maintained as part of the permanent record of the facility. The deficiencies that are identified in the risk assessment should be captured in the CAP (see Appendix A) that should be used in tracking remedial actions. Successive risk assessments should be performed until remedial actions are resolved.
During a risk assessment, hazards are evaluated in terms of the likelihood that a problem may occur and the damage and/or consequences it would cause if such an event did occur.

There are numerous factors to consider in performing a risk assessment (see Appendix B).

Risk assessment as it relates to testing and performance-verification methodologies for ventilation systems shall be performed by a team of qualified individuals.

A "Hazard Risk Matrix" can be used to record a risk rating for each hazard (see Appendix C).

The facility organization and/or management shall be responsible for coordinating the selection and involvement of appropriate personnel for the risk assessment and performance-verification of HVAC systems.

The team could include the BSO as defined in this document, responsible facility manager or director, veterinary staff (ABSL-3), building engineer, HVAC engineer or other subject specialists as appropriate, and maintenance staff and security personnel as required.

8 GUIDELINES FOR IMPLEMENTING TESTING AND PERFORMANCE VERIFICATION

8.1 Verification

Verification shall be done according to a pre-approved written plan that follows an acceptable model, and it shall be fully documented.

The major elements of verification are:

- Verification of documentation
- Verification of visual inspection
- Verification of conformance to relevant standards
- Verification of presence (that systems are maintained) and proper operation of systems and associated critical components
- Verification of testing

The steps in verification are:

- Visual inspection, document review
- Testing of assumptions
- Comparison to relevant standards
- Identification of deviations from

	standards and pre-defined acceptance criteria • Identifying further need for conformance with relevant standards Testing and verification may be done with internal or external resources. The resources must exhibit the requisite skills and knowledge to verify the work being evaluated.

8.2 Documentation

Documentation shall be maintained throughout the testing and verification process.	Documentation for testing and performance-verification of ventilation systems is a multi-level endeavor. Documentation occurs to some degree at all points in the process.
Regulatory and legal documentation shall be kept as a minimum requirement.	Decisions should be made about when documentation will begin, the sources of the documentation, specific documentation that is needed, the responsible parties for collecting and maintaining the documentation, and identification of a documentation coordinator.
The institution will determine the documentation confidentiality, security, and retention duration requirements for all records and findings.	

8.2.1 Required and Recommended Documentation

A plan shall be developed for the testing and performance-verification methodologies for the ventilation system of the facility.	The plan for the testing and performance-verification methodologies for the ventilation system of the facility should include: 1. Summary statement regarding the facility, location, ownership, nature of operations, extent of testing and

verification, and cessation of operations, if required
2. Project scope
3. Roles, responsibilities, and qualifications (see section 6.3) of individuals performing the tests
4. Test protocols and acceptance criteria for testing and performance- verification
5. When documentation will be collected
6. Document retention requirements
7. Location and contact information for record repository
8. Relevant SOPs
9. Documentation of risk assessments
10. Final report that should include:
    - Documentation of test results
    - Mitigation requirements and timeline for remediation
    - Certificates of calibration of test equipment
    - Recommendations

8.2.2 Evidence of Documentation

Basic background supporting information of the containment facility shall be provided for development of the Testing Plan.

Supporting documentation and relevant information are important to ensure an accurate testing and performance-verification of the ventilation system. Documentation should be maintained current to reflect architectural and/or engineering system changes.

Documentation should be verified as current, complete, and representative of the intended operating arrangements of each system as approved by the facility management, design engineers,

requirements of reviewing/approval authorities, and in accordance with the current risk assessment.

Examples of documents that should be maintained include (If applicable and available to BSL-3/ABSL-3 ventilation):

1. Architectural drawings
2. Containment boundaries
3. BSL-3 room air leakage report (if applicable)
4. Mechanical, plumbing, fire safety, and electrical drawings
5. Air-balance drawings
6. Airflow diagrams
7. Control diagrams and sequences of operation
8. Program of requirements (POR), basis of design (BOD), and HVAC-relevant project specifications
    - Facilities may not always have current or comprehensive BOD documents. In some cases, documents may not have been updated to reflect final requirements. Project BOD and construction documents should not solely be relied upon as complete or current, but must be tempered with the knowledge and experience of the facility biosafety officer, facility SOPs, and the verification team. Questions or concerns should be discussed with facility management to the extent such items impact completion of verification activities.
9. Commissioning documentation and performance-verifications for HVAC

systems and related components
- If commissioning and other testing documentation are not available, the facility should provide any documentation available to facilitate the testing and performance-verification of the ventilation systems.

10. Testing, adjusting, and balance (TAB) reports
11. Description of operational changes, modifications, or adjustments in practice that may differ from those published in record design documents
12. Maintenance schedules and records, including HVAC systems, control systems and instrumentation, electrical and stand-by power systems
13. Documentation of abnormal conditions and recorded system faults
14. Performance-verification reports, if available
15. Facility SOPs

Commissioning and other testing documentation should be provided for the verification process. If these documents are not available, the facility should provide any documentation available to facilitate the testing and performance-verification of the ventilation systems.
In addition to the previously noted commissioning and testing documentation, the following documentation (if available) should be provided for systems including (if applicable and available to BSL-3/ABSL-3 ventilation):

1. Supply air systems
2. Exhaust air systems
3. HEPA filter systems
4. Fume hood (if applicable)
5. Biosafety cabinets and other primary containment devices
6. Humidifiers
7. Chilled water/heating hot water systems
8. Steam and condensate systems
9. Supply and exhaust air valves
10. Lab/vivarium room temperature/ pressure control system
11. Animal cage racks
12. Building automation systems (BAS) (control sequences, graphics, and alarm reporting)
13. Ductwork and isolation dampers
14. Fumigant injection systems and ports (if available)
15. Heat recovery systems
16. Control air compressors for ventilation control
17. Variable frequency drives (VFDs)
18. Emergency power systems
19. Evidence that component testing, functional performance testing and integrated system testing have been completed after construction and after each time systems are modified

8.2.3 Ventilation-Testing Documentation Verification

Confirm that documentation resulting from the testing and performance-verification of the ventilation system has provided the appropriate information.

To ensure that the ventilation system for the laboratory facility is properly documented and available for verification by authorities and to serve as a baseline for future test comparisons, the following

documents should be verified (if applicable and available):

1. Normal and reduced air-change rates to emergency or energy- saving per containment room or zone as confirmed from TAB reports and building automation airflow reports
2. Directional airflows produced on design documents across all doorways supporting containment zones
3. Pressure differential values for normal and failure modes across each containment perimeter door
4. Test results of smoke testing for normal operation of all containment perimeter doors and large containment transfer devices such as autoclaves and pass-through cabinets
5. Test results of pressure differential trending logs (if available) of normal and failure mode testing, including electrical systems failure tests
6. Test results of BAS control alarms during testing of ventilation system; verifying that in-room containment perimeter access points and remote alarms are working
7. High-efficiency particulate air (HEPA) filter / housing test reports of efficiency, tightness, and structural integrity
8. Ductwork that is considered part of the secondary barrier tightness test reports
9. BSL-3/ABSL-3 room air leakage report (if applicable)

10. Biosafety cabinets and other primary containment devices that directly interact with the ventilation systems such as test results and certificates
11. Capture velocities for bench sweeps, canopies, and snorkels inside containment
12. Test results of devices such as downdraft tables and ventilation pass-through devices
13. Test results of room decontamination systems that integrate with the ventilation systems (if applicable)
14. Technical support area ventilation tests for directional airflow and HEPA filtration efficiency (if applicable)
15. Control instrumentation calibration records

8.3 Visual Inspection of Ventilation and Related Systems

The visual inspection methods and results shall be performed and documented as part of the performance-verification process for the ventilation system.

Visual inspection is conducted to confirm annual testing requirements and to prepare the facility for formal inspections by regulatory authorities or the authorities having jurisdiction (AHJ).

Visual inspection is conducted as part of the performance-verification process.

The inspection process, and the frequency and method of inspection are determined by local risk assessments or regulatory (e.g., Federal Select Agent Program requirements).

8.3.1 Visual Inspection and Evaluation of Engineering Controls

The verification process shall include review and visual inspection of ventilation system installation, including conformance with the requirements of applicable standards, the risk assessment, and any additional requirements necessary for proper operation and maintenance of the ventilation system.

In general, verification can be completed by:

- Inspection in field
- Review of as-built drawings and BOD
- Review of documentation of most recent tests
- Review of equipment certifications
- Review of daily charts/graphs or review of BAS

Review of documents only should not be considered as a substitute for visual inspection of apparent conformance in the field.

At a minimum, verify the following:

1. Verify no recirculation of room or equipment air to areas outside the containment area
   - Verification may be accomplished via review of current as-built drawings
2. Air change rates: Measure and calculate
   - Verification may be accomplished via review of current certified TAB report
3. Directional airflow: Inspect and compare to design
   - Verification may be accomplished by inspection of pressure-indicating devices at doors or via smoke tests at doors and comparing to as-built

drawings

4. Pressurization controls
   - Verification may be accomplished by review of as-built drawings
5. Filtration: Verify and compare to requirements
   - Verification may be accomplished by visual inspection in field and review of testing verification
6. Equipment redundancy (where applicable)
   - Verification may be accomplished by inspection in field and review of recent testing and commissioning documentation noting available system capacity and redundancy
7. Standby power: Verify and compare to design
   - Verification may be accomplished by inspection in field and review of recent generator testing and commissioning documents noting performance of mechanical systems with standby power
8. Power failure results from unplanned outages and impact on BSL-3/ABSL-3 ventilation
   - Verify BAS trend logs, alarms, and controls for the outage period and power restoration on pressure and directional airflow measurements
9. Instrumentation accuracy and calibration for critical devices
10. Interlocks

	• Verify appropriate operation of sequences and software interlocks and hardware interlocks for critical functions

8.3.2 Visual Inspection and Evaluation of Architectural Features

The verification process shall include an inspection of space configuration and adjacencies as they relate to ventilation strategies for containment and directional airflow and compare to design specifications.	The verification process should verify zones of containment risk levels and basic ventilation strategies. Assess location of BSL-3/ABSL-3 labs in relation to other zones such as BSL-2 support labs, offices and break rooms, elevators, loading docks, etc. for effects on laboratory pressurization and airflow. Access to the laboratory should be through a series of two self-closing interlocked doors. Assess the location of biosafety cabinets (BSCs), fume hoods and doors in relation to air flow and capture velocities from supply diffusers and exhaust grilles. Assess personnel traffic patterns to minimize influence of face velocity disturbance in relation to fume hoods and BSCs.
Visually inspect the location of accessible critical ventilation components to confirm no apparent condition which would likely pose risk of damage or malfunction, (e.g., chemical storage hazards, probability of mechanical damage, security concern, or improperly protected fire, environmental, or water damage risk).	

The integrity of all surfaces, penetrations and seals on the containment perimeter shall be visually inspected.

Penetration seals shall be readily visible (when applicable) for inspection, cleaning, and maintenance.

Penetrating components shall be sufficiently rigid in construction to maintain the integrity of the penetration seal.

Properly sealed laboratory surfaces (walls, floors, and ceilings) are essential to maintain controlled directional airflow and ventilation system performance. Room leakage or tightness is also critical when gaseous fumigants are used for decontamination. Examples of elements to inspect include:

1. Operational condition of doors, door gaskets, and thresholds
2. Windows on containment perimeter wall are non-operable and sealed-in-place type construction
3. Pass-through equipment for leak tightness, bio-seal, etc.
4. Double-door autoclave flange bio-seal
5. Piping and electrical wall or ceiling penetrations including fire sprinklers
6. Seals around light fixtures, receptacles, diffusers, and grilles
7. Sealing of electrical and communication/data wires within conduit
8. Components mounted to walls and ceilings

8.3.3 Visual Inspection of Directional Airflow

In the event that multiple containment zones exist in series within a laboratory or laboratory suite, the air shall flow from one space to the next, towards the space with the highest potential for contamination. This will create sequentially more negative room pressures.

Inward directional airflow is established by drawing air into the containment space from clean areas toward potentially contaminated areas (except as determined by specific site conditions such as clean room/containment spaces).

Directional airflow is dependent on the

	operational integrity of the laboratory's HVAC system and associated controls. HVAC systems should be carefully monitored and have periodic maintenance performed to sustain operational integrity. Loss of directional airflow compromises safe laboratory operation.
Devices used to verify airflow direction shall be inspected for function, visibility, and clarity of communication for the BSL-3/ ABSL-3 users. Where the devices are integrated into the HVAC control system, communication of alarm information to the control system shall be demonstrated. Time delays associated with containment space alarms shall be verified.	A means for users to verify airflow direction should be present. Monitors should be provided, both at the outer entry of the BSL-3/ABSL-3 suite (e.g., before entering the anteroom) and at interior doors, based on the facility risk assessment (e.g., at interior lab doors or major containment boundaries). The monitors should be mounted so they are visible when entering the rooms. These are typically installed on the cleaner side prior to entering the containment space.
In the event of loss of directional airflow, personnel in the containment space shall be notified of such condition via audible and/or visual alarms.	Alarm indication should be located inside the laboratory space(s), at the entrance of the laboratory suite, and at the remote notification location.
Directional airflow for the entire laboratory suite as a system must be evaluated for both normal operations and system failures, taking into account the presence of anterooms or other double-door configurations. Door operations shall be inspected for ability to maintain directional airflow.	The presence of at least two self-closing doors in series is a fundamental mechanism to achieve overall directional airflow in a BSL-3/ABSL-3 lab or suite. The operation of the doors should be verified to confirm that both (or all) the doors in series are not opened simultaneously. If mechanical interlocks are not present, facility SOPs should require that multiple doors are not opened simultaneously.

Inspection should include:

1. Ensuring that doors automatically close and latch
2. Checking function of door interlock systems or facility SOPs as appropriate
3. Checking the distance between entrance doors from the anteroom, making sure the distance is adequate for door operation. Additionally, the space between interlocked doors should be verified for the ability to move large pieces of equipment
4. Checking the emergency over-rides (release) of door interlock in emergency egress situations

If mechanical interlocks are present, open and close doors in all possible sequences. Ensure that delay set-points are tight enough to preclude inadvertent over-ride of interlock systems.

8.3.4 Visual Inspection of Exhaust Air System

Visual inspection of the exhaust air system shall include an assessment of the major features of the exhaust air system arrangement and installation.

Suggested verification and visual inspection methods are provided here. Alternately, for each piece of equipment in the system, manufacturer's preventive maintenance checklist may be used to complete the visual inspection requirements.

Inspection should include the following:

1. Exhaust air discharge stack location and velocities should be such that exhaust air is dispersed away from occupied areas and building air intakes, or verified by risk assessment and wind-

wake analysis. Velocity should be equal to or greater than that noted in the most recent version of project documentation listed in section 8.2.

- Verification of stack discharge velocity may be performed by review of stack airflow from current TAB report and diameter of stack outlet, stack velocity sensors, or fan airflow sensors in combination with stack discharge outlet diameter

2. Code mandated minimum distance between exhaust air discharge and outside air intake, operable windows, doors, and other building openings or occupied areas, for re-entrainment or airstream exposure potential.
   - Verification may be conducted in field and assisted by review of as-built drawings
3. Laboratory exhaust stack termination height should be verified to conform to applicable standards.
   - Verification may be conducted in field and assisted by review of as-built drawings
4. Verify presence and operation (if possible) of interlock between supply and exhaust air systems.
   - Verification may be conducted by review of control sequences in BAS and review of commissioning report
5. Verify that rainwater cannot accumulate in exhaust fan housing.
   - Verification may be conducted in field or by review of as-built drawings indicating fans offset from stack or via fan housings are provided with drains

	6. Terminal exhaust filters, if present. • Verify integrity of filters and seals
Primary exhaust air equipment condition and operation shall be assessed by visual inspection.	Visual inspection should include: 1. Exhaust discharge stack • Verify in field for stack condition, stability, supports, etc. 2. Exhaust fan and fan housing • Verify in field fan condition, corrosion, supports, abnormal vibrations, condition of flexible duct connections, etc. 3. Motor • Verify in field for condition, corrosion, supports, abnormal vibrations, etc. 4. Belts • Check for proper quantities, alignment, and tension; check maintenance records and logs 5. Belt guard • Check for presence of belt guard 6. Bearings • Check for abnormal noise; check maintenance records and logs for lubrication 7. Motor operating temperatures within equipment specifications • Check maintenance records and logs 8. Dampers and control • Check for condition of dampers, corrosion of damper components, condition of actuators, linkages, wiring and/or pneumatic tubing to actuators, etc. 9. Heat recovery coils, filters, and controls • Check condition of coils for

corrosion, leaks and cleanliness
- Check filters for cleanliness and pressure drop and review maintenance logs
- Check for condition of dampers; corrosion of damper components; condition of actuators, linkages, wiring, and/or pneumatic tubing to actuators, etc.

10. VFDs and motor controls
    - Check for proper installation in appropriate National Electrical Manufacturers Association (NEMA) enclosure
    - Check for operation within range of nameplate full-load current
    - Check for power and control wiring installed in raceways and protected from physical damage
11. Duct supports and connections
    - Verify that ductwork is supported at proper intervals to prevent failure or damage to ductwork
12. Dilution air dampers (if applicable)
    - Check for condition of dampers; corrosion of damper components; condition of actuators, linkages, wiring, and/or pneumatic tubing to actuators, etc.
13. Exhaust HEPA filter housings and filters (where provided) (refer to section 8.3.8, Visual Inspection of High-Efficiency Particulate Air (HEPA) Filters)
14. Exhaust bio-seal dampers
    - Check for condition of dampers (including integrity of seals); corrosion of damper components, flanges, and connections; gaskets

	for visible damage; condition of actuators, linkages, wiring, and/or pneumatic tubing to actuators, etc. 15. Proper access for equipment and system maintenance • Verify in field • Verify that the areas that house the HVAC and electrical equipment are ventilated for proper operation of the equipment
Accessible portions of exhaust air ductwork, distribution components, and room connections shall be assessed for integrity by visual inspection.	Visual inspection should include: 1. Exhaust ductwork construction materials, joining methods, gaskets, seals, etc. • Verify that the installation meets the project BOD and specification requirements. Inspect accessible elements of ductwork for evidence of corrosion, damage, or impending leakage 2. Segments of exhaust ductwork intended for gaseous decontamination should be of gas-tight construction. If an air valve is installed in these duct segments, SOPs should require bagging and taping or other appropriate procedures to avoid leakage of decontamination gases to surrounding spaces. Typically, gas-tight duct construction is provided by fully welded construction. All un-welded components such as air valves in these duct sections should be fully accessible for bagging prior to decontamination. 3. Exhaust air valves, actuators, and control wiring/tubing • Check for condition of air-valve

assembly; corrosion of housing; condition of actuators, linkages, wiring, and/or pneumatic tubing to actuators, etc.

4. Exhaust bio-seal dampers (where provided)
   - Check for condition of dampers; corrosion of damper components, flanges, and connections; gaskets for visible damage; condition of actuators, linkages, wiring, and/or pneumatic tubing to actuators, etc.
5. Continuous seal between ductwork and the room exhaust grille
   - Verify during initial installation and maintain written/photo-documentation for records
6. Insulation requirements for ductwork that is exposed to inclement weather where thermal differences can cause condensation
   - Verification should be conducted in field and should include inspection of wetted surfaces and insulation
7. Make sure any section of pressurized exhaust ductwork is not installed in enclosed areas near air-handling unit (AHU) intakes
8. Periodically inspect flexible duct connections in positive-pressure exhaust ducts located in enclosed spaces

8.3.5 Visual Inspection of Supply Air System

Major features of the supply air system arrangement and installation shall be

Suggested verification and visual inspection methods are provided here. Alternately, for

assessed by visual inspection.

each piece of equipment in the system, the manufacturer's preventive maintenance checklist may be used to complete the visual inspection requirements.

Visual inspection should include observation that the following components are present and in good operating condition:

1. Outside air intake louver
    - Verify for re-entrainment, cleanliness and security as noted above
2. Filters
    - Check filters for cleanliness and pressure drop and review maintenance logs
3. Coils and controls
    - Check condition of coils for corrosion, leaks, and cleanliness
    - Check condition of control valve actuators, linkages, wiring, and/or pneumatic tubing to actuators, etc.
4. Humidifiers and controls
    - Check condition of humidifiers for corrosion, leaks, and cleanliness
    - Check for visible condensation on surfaces (lack of absorption)
    - Check condition of control valve actuators, linkages, wiring, and/or pneumatic tubing to actuators, etc.
5. Supply fans
    - Verify in field fan condition, corrosion, supports, abnormal vibrations, condition of flexible duct connections, etc.
6. Motor
    - Verify in field for condition,

corrosion, supports, abnormal vibrations, etc.

7. Belts
   - Check for proper quantities alignment and tension
   - Check maintenance records and logs
8. Belt guards
   - Check for presence of belt guard
9. Bearings
   - Check for abnormal noise
   - Check maintenance records and logs for lubrication
10. Motor-operating temperatures within equipment specifications
    - Check maintenance records and logs
11. VFDs and motor controls
    - Check for proper installation in appropriate NEMA enclosure
    - Check for operation within range of nameplate full load current
    - Check for power and control wiring installed in raceways and protected from physical damage
12. Dampers and Controls
    - Check for condition of dampers, corrosion of damper components, condition of actuators, linkages, wiring, and/or pneumatic tubing to actuators, etc.
13. Duct supports and connections
    - Verify that ductwork is supported at proper intervals to prevent failure or damage to ductwork
14. Supply HEPA filter housings and filters, where provided (refer to section 8.3.8, Visual Inspection of High-Efficiency

Particulate Air (HEPA) Filters)

15. Supply bio-seal dampers, where provided
    - Check for condition of dampers; corrosion of damper components, flanges, and connections; gaskets for visible damage; condition of actuators, linkages, wiring, and/or pneumatic tubing to actuators, etc.
16. Proper access for equipment and system maintenance
    - Verify in field
17. Verify that the areas that house the HVAC and electrical equipment are ventilated for proper operation of the equipment
18. Outside air intakes for re-entrainment potential
    - Verify in field that required minimum distances are provided between outside air intake and lab exhaust, boiler exhaust, cooling towers, generators, loading docks, plumbing vents, vacuum pump discharge, etc.
19. Outside air intake
    - Verify in field for cleanliness, snow build-up, standing water in vicinity, blockage of screens and louvers, etc.
20. Outside air-intake security measures
    - Verify that security measures based on risk assessment are in place where the air-intake louvers are protected from potential incursions of unauthorized personnel (e.g., secured grilles)
21. Verify presence and operation (if

possible) of interlock between supply and exhaust air system
- Verification may be conducted by review of control sequences in BAS and review of commissioning report

22. Verify insulation requirements for ductwork including ductwork externally located that is exposed to inclement weather where thermal differences can cause condensation
    - Verification should be conducted in field and should include inspection of wetted surfaces and insulation and surfaces

Primary supply air equipment condition and operation shall be assessed by visual inspection.

Accessible portions of supply air ductwork, distribution components, and room connections shall be assessed and verified to be in good operating condition by visual inspection.

Visual inspection should include:

1. Supply ductwork construction materials and general condition, joining methods, gaskets, seals, etc.
    - Verify that the installation meets the project BOD and specification requirements
2. Segments of supply ductwork intended for gaseous decontamination (where provided, between supply bio-seal damper and room diffuser) should be of gas-tight construction, or SOPs should require appropriate procedures to avoid leakage of decontamination gases to surrounding spaces. Typically, gas-tight duct construction is provided by fully welded construction. All un-welded components in these duct sections should be fully accessible for bagging prior to decontamination.
3. Supply air valves, actuators, and control wiring/tubing

- Check for condition of air-valve assembly; corrosion of housing; condition of actuators, linkages, wiring, and/or pneumatic tubing to actuators, etc.
- Check re-heat coils for cleanliness and leaks. Where terminal humidifiers are provided, check for leaks and cleanliness
- Check condition of reheat coil and humidifier control valve actuators, linkages, wiring, and/or pneumatic tubing to actuators

4. Supply bio-seal dampers (where provided)
    - Check for condition of dampers; corrosion of damper components, flanges, and connections; gaskets for visible damage; condition of actuators, linkages, wiring, and/or pneumatic tubing to actuators, etc.
5. Continuous seal between ductwork and the room supply diffuser
    - Verify during initial installation and maintain written/photo-documentation for records
6. Supply diffusers should be located and installed so they do not interfere with BSC operation and provide best location for achieving effective room air-change rate/h
    - Verify in field for proper air distribution

8.3.6 Visual Inspection of Critical Control System Air and Power

Pneumatic control air system and control power system shall be assessed and verified to be in good operating condition by visual inspection so as to maintain any required critical control or secondary containment features during normal operation and in the event of loss of power, failure of a generator, or failure of primary compressors and equipment.

Visual inspection of pneumatic control equipment should include:

1. Primary and redundant equipment is adequately arranged and in proper operation.
   - Verify in field
2. Compressed air system should be served by standby power system.
   - Verify in field
3. Where a separate receiver and distribution piping is the selected means of system backup, a check valve or other fail-safe valve should be provided in the piping system to prevent loss/diversion of air from the critical system to the non-critical system. Alternative arrangements (such as uninterruptable power supply [UPS] systems) and backup air sources should be confirmed operational.
   - Verify in field
4. A check-valve or other fail-safe arrangement should be present in the compressor discharge piping or inlet connection to each air receiver to prevent loss of system air when the supply source is disabled.
5. Control air piping to sensing and control devices should be protected to avoid damage to piping and accidental failures at joints and device

terminations.

- Verify in field that control air piping and tubing is appropriately supported and adequately protected or not susceptible to damage

6. Verify in field pressure levels of control air reservoirs to ensure available pressure is provided in event of compressor failure.
7. Alarms should be provided at monitored BAS to indicate failure of compressed air source equipment or system pressure loss.
   - Verify in field at BAS
8. Air dew point should be low enough to prevent freezing or condensation of control air lines.
   - Verify in field that desiccant dryers (or equivalent to achieve required dryness) are used in the air-supply system and properly adjusted to at least 5°F (2.8°C) below the lowest temperature to which any portion of the system could be exposed
9. Verify air quality and visual inspect for adequate pressure. Critical air should be of not less than instrument air quality in conformance with ANSI/ISA S7.0.01.[24] Alarms should be verified operational at the BAS to indicate failure of compressed air source or system pressure loss.

	Visual inspection of control power system should include: 1. Control power for all heating, ventilating, and air-conditioning (HVAC) controls should be served by standby power system. • Verify in field or by review of as-built control drawings • Control power for controllers and critical control components should be provided with battery backup or UPS and appropriate memory • Verify in field 2. Control wiring to sensing and control devices should be protected to avoid damage and accidental failures at terminations. • Verify in field that control wiring is routed in conduits and conduits are appropriately supported and routed away from maintenance traffic areas

8.3.7 Primary Containment Equipment

Biosafety cabinets and other primary containment equipment connected to the ventilation system shall be assessed by visual inspection. All biosafety cabinets shall be certified before use, at least annually, and whenever relocated in accordance with National Science Foundation (NSF) Standard 49[7] or an equivalent method.	Inspection for BSCs and other primary containment equipment, when present, should include the following: 1. Review primary containment equipment (BSC or other) performance-verification document including serial number verification. 2. Verify that the testing agent/verifier has been supervised by an NSF-

approved testing agent/verifier and that their equipment meets current performance-verification requirements.

3. Verify that installation of BSC is correct for cabinet type.
4. Verify correct placement of primary containment equipment (BSC, fume hood, etc.) with respect to air devices, doors, and traffic patterns.
5. Class II Type A BSCs can recirculate HEPA-filtered cabinet air into the room. All thimble capture devices should be verified for operation and integration with the room exhaust.
6. Class II Type B1 biosafety cabinets are required by NSF 49[7] to be hard-ducted to ventilation system.
    - Verify appropriate duct connection and integrity
7. Class II Type B2 BSCs are required by NSF 49[7] to be hard-ducted to ventilation system.
    - Verify appropriate duct connection and integrity
8. Verify Class III BSCs are provided with HEPA-filtered supply air and double-HEPA-filtered exhaust air connections.
9. Verify that the exhaust of a Class III BSC is connected up through the second exhaust HEPA filter of the cabinet and that the supply air is provided in such a manner that it prevents positive pressurization of the cabinet.

10. Fume hoods that are placed inside BSL-3/ABSL-3 facilities should be inspected for airflow alarms (if present), filtration needs (carbon and HEPA), and recirculating options. An SOP should be in place for use of a fume hood, which is not the same as a BSC, including its integration to the rooms' negative pressure. If fume hoods are used inside BSL-3/ABSL-3 spaces, filtration requirements (HEPA and/or carbon), use of chemicals, chemical compatibility, decontamination, and efficiency testing need to be documented in SOPs and reviewed by verifying testing agents.
11. Other primary containment devices should be inspected per a SOP.

8.3.8 Visual Inspection of High-Efficiency Particulate Air (HEPA) Filters

HEPA filter installations shall be assessed by visual inspection. HEPA filters shall be tested at least annually.

Note: When the visual inspection of the HEPA filter housing requires accessing the potentially contaminated section of the housing, proper decontamination procedures should be taken following local risk assessments and SOPs.

Inspection should include the following:

1. Integrity of filter housing
    - Verify in field for general condition of filter housing, specified construction material, and pressure class. This can be reviewed together with filter shop drawings and factory testing.

	• Check for dents or damage to housing to note if welds are damaged or performance is compromised during further verification. • Check access doors, latches, and gaskets for proper operation. • Check for proper support of filter housing. Check for seismic bracing where required by local codes and project BOD.
Filter media shall be inspected before and after installation.	2. Visual inspection of filter media • Verify performance filter function/integrity will be verified through the methodology in section 8.4.7 at initial filter installation or replacement. • Verify in field the integrity of the filter media, filter frame, filter gasket (elastomeric or gel), and the seal between the media and frame. • Look for filter damages, percentage of patching of the filter media, damages to the gasket (tears or sagging), etc. 3. Ductwork in and out of housings • Verify in field that ductwork in and out of filter housings is of the specified material and construction type. • Verify ductwork is properly supported. 4. Bubble-tight isolation dampers

- Check for condition of dampers; corrosion of damper components, flanges, and connections; gaskets for visible damage; condition of actuators, linkages, wiring, and/or pneumatic tubing to actuators, etc.

5. Filter decontamination provisions
    - Verify in field that filter housing is equipped with decontamination provisions, if in place. Decontamination is required by a SOP prior to removal.
6. Bag-in/bag-out provisions (if applicable)
    - Procedures for use of bags, cinching straps, rubber bands, etc., should be strictly enforced when new and replacement filters are installed. During the annual efficiency test of the HEPA filters, straps and bag seals to the rings should be verified to be properly installed and that records exist of the proper installation before opening the access door of a potentially contaminated housing. Otherwise, decontamination procedures should be taken following local risk assessments and SOPs.
7. Testing in place
    - Verify in field that test sections are provided as a means for testing HEPA filters in-place prior

	to being placed into service. 8. Pressure gauges and connecting tubing • Verify in field that pressure-gauge tubing, joints, and connections are tight and leak-free. Verify pressure gauges for operation of filters within specified range. 9. HEPA-filter performance-verification reports • Review prior performance-verification and maintenance reports to evaluate the initial conditions of the filters when they were placed into service and any repairs performed since then.

8.3.9 Control Systems/Fail-Safe Operation

The verification process shall include review of documentation for each failure test performed.	Refer to section 8.3 for failure scenarios and related documentation.

8.3.10 Visual Inspection: Special Considerations for ABSL-3 Facilities

Visual inspection of ABSL-3 facilities shall include all applicable BSL-3 criteria. Ventilation system shall meet the requirements of *Guide for the Care and Use of Laboratory Animals* (*The Guide*).[25]	Inspection should include: 1. Based on a risk assessment, animal-caging systems should comply with primary containment requirements for BSL-3 operation and the facility SOPs. 2. Review connections between rack blowers and HVAC system (if provided) and ensure room balance and directional airflow is maintained. 3. Review fan blowers assigned to cage racks for operability, noise effects,

and connectivity.

4. Verify cages and their connecting ports are properly mounted to the internal-rack HVAC connections.
5. Review whether individually ventilated caging HEPA filter (if provided) testing tags are up-to-date and provided.
6. Verify if static loading on filter exceeds manufacturer recommendations or local set-points based on risk analysis.
7. Verify operability of local adjustable air valves attached to individually ventilated caging.
8. Verify that positive/negative (P/N) control valves (if provided) are properly set.
9. Review recirculating racks influence on room's air distribution and odor control devices.

8.4 Testing Ventilation and Associated Systems General Requirements

HVAC systems shall be tested and documented before initial operation, periodically thereafter (annually or as determined by facility-specific risk assessment) and after any significant alterations of the ventilation system or other alterations that can affect it.

Except where specifically indicated in the following subsections, test acceptance criteria shall be established by the facility risk assessment.

Given the high degree of variability in BSL-3/ABSL-3 facility layout and system configurations, this standard cannot define precise periodic testing frequencies or acceptance criteria for all conditions. Therefore, to accommodate this variability and to ensure that the testing reflects the actual work performed at each location, testing frequencies and acceptance criteria should be determined by facility-specific risk assessments.

	When performing a risk assessment to determine the frequency of periodic testing of HVAC systems, as well as acceptance criteria, facility owners should address factors including, but not limited to: • The relative risk of the BSL-3/ ABSL-3 work performed in the facility, other activities in the facility, and the facility's surroundings • Accessibility of HVAC components (e.g., ductwork installed in chases) • Relative risk (i.e., both probability and consequence) of a component's failure Examples of major changes to the HVAC system could include: 1. Replacement of exhaust or supply fans that serve the BSL-3/ABSL-3 containment areas 2. Replacement of ductwork valves or dampers that serve these areas 3. BAS logic programming changes 4. Structural changes to the BSL-3/ ABSL-3 rooms 5. Addition or removal of hard-ducted BSCs or fume hoods that cause changes in the air balance of the room with respect to the entire laboratory
All external instruments (i.e., portable or not a component of the building) used for testing	Instruments and testing devices should have cyclical calibration for validating

shall have been calibrated and/or certified using standards traceable to the National Institute of Standards and Technology (NIST; or equivalent standards). If devices that are components of the building (e.g., pressure sensors and airflow indicators) are used for testing purposes, they shall be calibrated annually using a calibrated external device.

performance and verifying that they have sufficient accuracy and range required for testing.

1. Obtain and include all recent certificates of calibration in test documentation.
2. Calibrations of instruments should be done at least annually.

8.4.1 Testing for Directional Airflow during Normal Operation

HVAC systems shall be tested for directional airflow to demonstrate that air in the BSL-3/ ABSL-3 flows from areas of lower risk to areas of higher risk during normal operation.

Generally, the directional airflow criterion for BSL-3/ABSL-3 facilities can be interpreted to mean that air should flow from “outside” the BSL-3/ABSL-3 space to the space(s) “inside” the BSL-3/ ABSL-3 facility where there is the highest probability of airborne contamination. This flow mitigates the risk of airborne-contaminants escaping the BSL-3/ABSL-3 facility. A BSL-3/ABSL-3 facility should be evaluated as a whole (i.e., an integrated system of HVAC elements, as well as doors and other architectural features) and in the context of the facility-specific risk assessment, when being evaluated with respect to this criterion.

The foundation for directional airflow testing should be to demonstrate that air originating from spaces that have the highest probability of airborne contamination will not escape the BSL-3/ ABSL-3 facility’s containment barrier. If that cannot be demonstrated, then the facility’s risk assessment should address the relative risk associated with such escape and include a determination of

specific measures taken to mitigate that risk.

Although this standard only applies to the escape of air at the containment barrier, testing of directional airflow should be performed at the transitions (i.e., doorways) and boundaries between areas of higher and lower risk between all spaces within the BSL-3/ABSL-3 facility as determined by the facility risk assessment. If directional airflow cannot be demonstrated under normal operating conditions at a transition point, then other mitigating factors such as the presence of two doors in series, personal protective equipment use, and the relative risk of the agents in use should be considered in determining the acceptance criteria for the test for that point.

Test Purpose and Methodology

HVAC systems shall be tested and documented for directional airflow during normal operations before initial operation, periodically thereafter (annually or as determined by facility-specific risk assessment) and after any significant alterations of the ventilation system or other alterations that can affect it.

Other systems/equipment that impact directional airflow under normal operating conditions shall be tested so that directional airflow can be demonstrated.

Purpose of Test: To verify that under normal operating conditions, the HVAC system provides directional airflow by drawing air into the containment space from clean areas toward potentially contaminated areas (except as determined by specific site conditions such as clean room/containment spaces). The testing should evaluate directional airflow both at individual doorways and for the entire laboratory suite.

Note: The testing should account for normal operating conditions such as door

opening/closing, which may affect the sustained directional airflow requirement at an individual doorway. Directional airflow should be evaluated for the entire laboratory suite as a system, taking into account the presence of anterooms or other double-door configurations, and operating conditions.

Recommended Methodology:
Directional airflow testing can be achieved by one of several methods such as:

1. Smoke testing
2. Validating pressure or airflow monitors
3. Verifying tell-tale visual signs such as thin lightweight materials
4. Audible testing devices
5. Tracer gases (such as sulfur hexafluoride, helium, or carbon dioxide), fragrances (e.g., peppermint), and theatrical fogs

Although one method is not preferred over others, the laboratories should be tested and verified for proper performance.

The above tests are suitable for verifying instantaneous performance of the ventilation system.

To verify steady-state performance over a period of time, the following methods (or equivalent) should be considered:

1. Historical trend log records from BAS
2. Other forms of historical logs maintained in accordance with the facility SOP
3. Log of differential pressure across doors for a minimum of time that reflects the test period, and any influence that disturbs the stabilization of the pressures with data logged at less than 5-second intervals, using calibrated portable differential pressure meters
4. Visual observation of airflow direction at doorways using a visual indicator (e.g., tell-tale, smoke, etc.)

Steady-state pressure differentials should remain between the minimum level needed for detection by the pressure sensor and the level at which door operation is adversely affected. The differential pressure must not exceed the level that causes the force required to operate the door to exceed applicable codes (e.g., fire code or Americans With Disabilities Act [ADA][26] requirements).

Smoke testing of the full door perimeter (360°) should be performed with the door in a closed and open position using a smoke-generating device that is moved slowly around the perimeter of the door. The test method should be based on a site-specific risk assessment, including factors such as the presence of two doors in series, gaskets or other seals, and transfer grills or other air-bypass devices.

When determining the extent of the door opening for the test, facility personnel should take into consideration the airflow offset at the doorway, the presence of other doors in series, and the relative risk of activities in the adjacent spaces.

Smoke testing of air-transfer devices should be done at different points along the face of the air-transfer grille.

Documentation: Test documentation should include specific doors, devices, and locations where test was conducted, chosen test method for each location and results of test for each location. The performance of the entire laboratory suite as a system should also be documented.

8.4.2 Testing for Directional Airflow during System Failures

HVAC systems shall be tested for directional airflow during system failures. During system failures, momentary changes in airflow patterns can be acceptable based on the facility risk assessment.

In general, air in the BSL-3/ABSL-3 should flow from areas of lower risk to areas of higher risk during normal operating conditions, but during system failures momentary static conditions or transient flow reversals can happen. Although the testing and acceptance criteria for directional airflow during normal operations (see section 8.4.1) should be applied to the evaluation of performance during system failures, the momentary static conditions or transient flow reversals that could happen during system failures should be evaluated in the context of the facility risk assessment.

To ensure that the HVAC systems in BSL-3/ ABSL-3 laboratories meet the basic functional containment requirement during failure events, the HVAC systems shall be tested and documented for directional airflow during system failures before initial operation, periodically thereafter (annually or as determined by facility-specific risk assessment) and after any significant alterations of the ventilation system or other alterations that can affect it.

When performing the risk assessment consider factors such as:

- The magnitude and duration of the event
- The relative risk of activities in the adjacent spaces
- Engineering and administrative controls in place during the event
- Use of primary containment devices and personal protective equipment

Test Purpose and Methodology

Purpose of Test: To verify that reversal of airflow from BSL-3/ABSL-3 laboratories during HVAC system failure conditions is minimized and in accordance with the acceptance criteria established in the risk assessment.

This standard addresses escape of potentially contaminated air from the containment barrier of a BSL-3/ABSL-3 facility. Site-specific criteria related to reversals within the containment barrier should be stipulated in the facility risk assessment. For reversals within the containment barrier, criteria for sequences and events that occur more frequently (e.g., a total power outage that might typically happen a few times a year) should be more stringent than for events that are likely to happen much less frequently (e.g., the tripping of a breaker that serves multiple exhaust fans). Site-specific acceptance criteria for higher risk

laboratories should be more stringent than for lower risk laboratories.

In addition to empirical testing (e.g., using smoke or tracer gases) of representative failure conditions, numerical simulation (e.g., computational fluid dynamics or other numerical methodologies) can be used to supplement the risk assessment.

Refer to the following sections for more specific information on the related systems and components that may be failed:

8.4.5 Testing of Heating, Ventilating, and Air-Conditioning (HVAC) System and Controls
8.4.6 Testing Electrical Systems Related to Heating, Ventilating, and Air-Conditioning (HVAC)

Recommended Methodology: HVAC verification should be performed and documented by personnel having experience with the HVAC system in the facility and/or expertise with HVAC systems in BSL-3/ABSL-3 laboratories. Test-failure scenarios, as applicable and determined plausible, should be based upon the complexity of the facility.

The types of tests described below and their frequency are provided as a comprehensive resource of methodologies that should be considered in developing a site-specific HVAC performance-verification plan.

Directional airflow testing during system failures can be performed using:

1. The measurement of differential pressures across a containment barrier, and all doors between the laboratory or vivarium and the containment barrier
2. Visualization or measurement of smoke/tracer gases at doors between the laboratory or vivarium and the containment barrier
3. Visual observation of airflow indicators at doors between the laboratory or vivarium and the containment barrier
4. A numerical testing methodology based on a risk assessment

Use of Differential Pressure Monitors:
Calibrated differential pressure monitors along with data loggers (portable units or instruments associated with BASs) may be utilized to measure and record steady-state and transient differential pressures during system failures.

Use of Smoke or Tracer Gases:
Visualization with smoke or tracer gas is a direct method of assessing whether air originating in the laboratory or vivarium escapes outside of the containment barrier. Methods could include the use of a smoke generator in the laboratory and photometer outside of the containment barrier, or a tracer gas and associated sensor outside the barrier to assess the

changes in airflow patterns. The detectors should be placed at locations determined by risks assessment.

Examples of acceptance criteria to be established in the risk assessment:

1. The differential pressure at any one of the barriers between any contaminated space and the clean space outside the containment barrier never reverses direction.
2. The differential pressure at any barrier between any contaminated space and the clean space outside the containment barrier remains in the proper direction while or at any time after the differential pressure of the next barrier towards containment reverses.
3. Smoke or tracer gases generated inside the laboratory or vivarium are not observed or detected outside the containment barrier.

Note: The program requirements and site-specific facility risk assessment may dictate more stringent or different acceptance criteria for areas inside the containment envelope. However, internal requirements are not addressed by this standard.

Failure tests: Failure conditions with recommended frequencies (*in italics*) that should be tested when applicable:

1. Mechanical or electrical failure of a single BSL-3/ABSL-3 exhaust fan or fan

component(s) (*initially and every 12–18 months*)

2. Failure of the normal/preferred source power supporting supply and exhaust fan components and transition to the emergency or alternate source. If a backup system (emergency or alternate source of power supply) is available for the laboratory HVAC system, the ability to transition from normal power to the backup system should be verified. If no backup system is available, the ability of the HVAC system to transition to a "static" condition, i.e., no outward airflow, should be verified (*initially and every 12–18 months*).
3. Return from power outage or emergency or alternate power source to normal or preferred power source (*initially and every 12–18 months*)
4. Electrical failure of multiple (including redundant) BSL-3/ABSL-3 supply fans or fan component(s). Plausible multiple fan failures are those fans fed from a common distribution element such as a single breaker (*initially*).
5. Supply fan failure of system serving adjacent areas (*initially*)
6. Exhaust fan failure of system serving adjacent areas (*initially*)
7. Single supply or exhaust system controller failure serving the BSL-3/ABSL-3 (*initially*)
8. Loss of communications on the BAS control local area network (LAN) (*initially*)

9. Controller power circuit trip (*initially*)
10. Failure of UPS output breaker or batteries for power to BAS (*initially*)
11. Duct static pressure sensor failure (*initially*)
12. Failure of automated bio-seal damper (loss of signal or power source to it (*initially*)
13. Failure of air terminal unit controlling airflow to the BSL-3/ABSL-3 zone (*initially*)
14. Closure of local fire/smoke dampers (*initially*)

If “no reversal”/desired airflow is accomplished in empirical testing, a numerical testing methodology may be used to evaluate the potential risk. By using a numerical testing methodology, the amount of air displacement and contaminant leakage that might occur during a power outage, which may result in a momentary positive pressure reversal in a BSL-3 facility, can be calculated. The ultimate goal in design and operation of a BSL-3 facility is to achieve sustained directional airflow such that under failure conditions the airflow will not be reversed. A numerical methodology should be applied when and only when all other measures to achieve zero tolerance have been ruled out. Only after determining that zero tolerance cannot be achieved for the BSL-3 facility in question should a numerical model be employed to perform a health and safety risk assessment to determine the reverse airflow tolerance.

Documentation: Results of the failure tests should be documented and filed appropriately.

Test documentation should be retained based on the document retention policy specific for each facility.

8.4.3 Testing of Anterooms

Anterooms shall be tested for directional airflow in conjunction with associated HVAC and door controls (refer to section 8.4.1 for specific information on testing for directional airflow).

The containment function provided by anterooms shall be tested and documented before initial operation, periodically thereafter (annually or as determined by facility-specific risk assessment) and after any significant alterations of the anterooms or associated ventilation system elements or other alterations that can affect that function.

Test Purpose and Methodology

Purpose of Test: To verify performance of ventilation systems serving the anteroom during routine entry and exit from the containment space.

Recommended Methodology:
Anterooms should be tested to verify functionality. The following tests should be done when applicable.

1. Test of self-closing devices on each door to latch the door in closed position
    - Door closers should be of sufficient strength to overcome pressures between adjacent spaces.
2. Verification of door interlock
    - If provided with electrically controlled door interlocks, test whether each door remains locked while the other is opened. Verify operation of emergency over-rides of locks.
    - If electrically controlled door

interlocks are not provided, verify the presence of other controls (e.g., signage, SOPs, the presence of more than two doors in series including windows in doors) that will sufficiently mitigate the risk of an overall loss of directional airflow when two doors are opened simultaneously.

3. Verification of alarms associated with non-closed doors, if provided
    - Test each door for duration of door opening and associated alarm function.
4. Verification of door switches linked to air valves or bubble-tight dampers, if provided
    - Test function of switches by monitoring the valve/damper operation with respective door switch position.
5. Testing for directional airflow should allow visible verification of smoke whether the door is closed or partially opened. Refer to section 8.4.1 for more information.

Documentation: Results of the tests should be documented and filed appropriately.

Test documentation should be retained based on the document-retention policy specific for each facility.

8.4.4 Testing of Primary Containment Equipment

Primary containment equipment that is connected to or affected by air currents from the HVAC system shall be tested and documented before initial operation, periodically thereafter (annually or as determined by facility-specific risk assessment) and after any significant alterations of the equipment or associated HVAC system elements or other alterations that can affect the equipment performance.

Test Purpose and Methodology

Purpose of Test: To verify that the ventilation system operations do not negatively affect the performance of the primary containment equipment that is connected to or can be affected by the ventilation system.

Examples of primary containment equipment that should be tested include, but are not limited to:

- Class I and II BSCs that discharge to the room (placement in the room with respect to air currents)
- Canopy (thimble) connected Class II BSCs
- Hard ducted Class II or III BSCs
- Hard-ducted Class I BSCs and chemical fume hoods
- Ventilated animal-caging equipment connected to the building exhaust system (see section 8.4.9)
- Equipment isolators connected to the building exhaust system

Recommended Methodology:
Class I and II biosafety cabinets that discharge to the room:

- Verify that air currents from door swings and the ventilation system do not interfere with air capture at the sash opening by testing with smoke or other visual indicator.

Canopy- (thimble-) connected Class II biosafety cabinets:

- Verify that air currents from door swings and the ventilation system do not interfere with air capture at the sash opening by testing with smoke or other visual indicator.
- Verify inward flow at the gap of the canopy (thimble) connection with smoke or other visual indicator. No smoke should return to the room once it enters through the gap under normal operation of the ventilation system.
- Verify that loss of inflow air at the canopy connection generates a local audible and visual alarm as required by NSF 49[7] section 5.23.4.

Hard-ducted Class II or III biosafety cabinets:

- Test and verify that the exhaust flow is within the acceptable airflow range provided by the manufacturer of the Class II and Class III BSCs.
- For Class II BSCs, verify that the supply fan interlock generates audible and visual alarms at a reduced exhaust volume of 20% within 15 seconds, and that the internal cabinet fan is interlocked to shut off at the same time the alarm is activated.
- For Class III BSCs, if the cabinet is

exhausted by a dedicated system that is separate from the room's general exhaust, ensure that when the cabinet exhaust is shut off, a visual and audible alarm is activated and the room ventilation system adjusts for the reduction of flow from the Class III BSC (i.e., the room's ventilation system prevents positive pressurization and/or an airflow direction reversal).

Hard-ducted Class I biosafety cabinets and chemical fume hoods:

- Test and verify that the exhaust flow and face velocity is within the acceptable ranges provided by the manufacturer of the BSC or fume hood or as required by applicable standards (e.g., ANSI/ASHRAE 110).[27]
- Verify that air currents from door swings and the ventilation system do not interfere with air capture at the sash opening by testing with smoke or other visual indicator.

Ventilated animal-caging equipment connected to the building exhaust system:

- The ventilated animal-caging equipment should meet the requirements for air-change rates and thermal or humidity requirements from *The Guide*.[25]

- Ventilated animal-caging equipment that is connected to in situ ventilation systems should be tested for proper operation to ensure directional airflow, negative pressure, and controls alarming.
- Ventilated animal-caging equipment that is integrated using single airflow-control valves from several cage racks should be tested with multiple racks connected and disconnected; valve performance needs to be validated whether it is installed with a 1 to 1 ratio or 1 to greater than 1 ratio.
- Ventilated animal-caging equipment that is connected to in situ ventilation systems should include tests to validate room pressurization with the individually ventilated cages disconnected.
- Test impact of in situ and facility system failures on ventilated animal-caging equipment performance; ventilated animal-caging equipment should maintain negative pressure.
- Verify procedures for total fan failure, including power failure and include electrical, normal, and standby power and UPS-failure tests if equipped.
- Test for fan interlocks between ventilated animal-caging equipment and exhaust fans if

supplied (if main exhaust fails, hard-connected ventilated animal-caging blowers should also fail.

- Where ventilated animal-caging equipment is used and the local risk assessment determines that reduced airflow rates are allowable, these rates should be tested to ensure containment pressure relationships and directional airflows are maintained.

Equipment isolators connected to the building exhaust system:

Due to the wide variety of equipment isolators in use (e.g., rigid vs. flexible walls, open vs. glove access, and self-exhausted vs. exhausted by the facility's ventilation system), the test methodologies described for other primary containment equipment should be applied as appropriate on a case-specific basis. For example, self-exhausted isolators with open access that discharge to the room should be tested using the same methodologies as Class I and II BSCs that discharge to the room.

Documentation: Test documentation should be retained based on the document retention policy specific for each facility.

8.4.5 Testing of Heating, Ventilating, and Air-Conditioning (HVAC) System and Controls

	Test Purpose and Methodology
HVAC systems shall be tested to verify the necessary air changes and directional airflow during normal operation and directional airflow during system failures.	HVAC systems for BSL-3/ABSL-3 laboratories should be designed to provide directional airflow without airflow reversals unless airflow reversal(s) are documented to be acceptable by a written risk assessment. These HVAC systems should also minimize any reversal of airflow out of the containment spaces during system failures.
Tests shall be performed before initial operation, and periodically thereafter as determined by the facility risk assessment and the SOP and after any significant alterations that can adversely impact the ventilation system.	**Purpose of Test:** To verify the capability of BSL-3/ABSL-3 HVAC systems to provide a safe and reliable containment airflow during normal operating conditions and system failure conditions. **General Methods:** A structured plan should be prepared for testing HVAC systems and controls that defines all performance-verification activities to be performed during this process. This plan should also identify all deviations that occur from the original design and subsequent modifications made thereafter. **Pre-testing Preparations:** Testing should be coordinated with relevant stakeholders (such as contractors, BSO, facility manager, third-party testing agents, laboratory technicians, etc.), following established SOPs as applicable. • Verify readiness of HVAC systems to be tested. Ensure sealing and

pressure integrity of the lab is per operational intent
- Confirm penetrations are sealed and not degraded (refer to section 8.4.8)
- Confirm doors are aligned as required and latch properly
- Confirm all door seals and sweeps are maintained and in proper order
- Confirm all traps are sealed or full including floor drains, sink drains, ice-machine drains, etc.

Example tests may include:
- Airflow rates and air change rates
- Airflow offsets
- Room differential pressure range
- Directional airflow
- Temperature and humidity requirements
- Exhaust air-stack discharge velocity
- Fire alarm and HVAC integration
- BAS and related control/alarm functions
- Peak HEPA filter loads
- Redundancy/capacity requirements

Frequency of Testing: Baseline performance-verification testing is necessary prior to initiation of laboratory operations and periodically thereafter. All operational parameters should be verified thoroughly for proper functionality during baseline testing.

Planning for subsequent tests of the HVAC system should be made based on the facility risk assessments and periodically re-examined to ensure adequacy of the plan.

The types of tests described below are provided as a comprehensive resource of methodologies for consideration in development of a site-specific HVAC performance-verification plan that should be developed for every high-containment laboratory.

Refer to section 8.4.2 for recommended intervals between re-testings.

8.4.5.1 A test to establish the baseline parameters of the HVAC system shall be performed for all containment spaces. These tests shall include actual measurements of supply, exhaust/return, and transfer airflow rates, calibration of airflow monitoring devices, and air change rates (changes per hour). Review airflow parameters currently indicated on control and monitoring systems and compare them to current requirements during each re-test. Tests shall be performed before initial operation, and periodically thereafter as determined by the facility risk assessment and SOP and after any significant alterations that can adversely impact the ventilation system.

Purpose of Test: Design airflows are established to maintain space temperature, relative humidity and minimum ventilation requirements. Airflow offsets are established to maintain directional airflows for containment. This test, normally entitled TAB, should confirm that the actual flow rates meet the performance expectations for meeting environmental conditions and directional airflow.

Refer to facility operating and maintenance records. Historical data on airflow available from control or monitoring systems should be reviewed during periodic testing. It is the responsibility of the facility's staff to calibrate airflow sensors in accordance with manufacturer's recommendations. Re-testing will typically not involve

checking airflow sensor calibration.

Recommended Methodology:
Determine and document laboratory ventilation performance requirements. Test methods utilized by TAB agents vary. However, the basic principles and methods should follow National Environmental Balancing Bureau (NEBB)[28] or Associated Air Balance Council (AABC)[29] test methods.

1. Measure actual airflows at all outlets and inlets.
2. Measure face velocity at primary containment, fume hoods, capture hoods, etc.
3. Confirm calibration of the airflow-measuring devices.
4. Ensure air distribution patterns within the room do not compromise primary containment or cause localized airflow reversals at barrier.
5. Calculate air-change rates and compare to design and current requirements.
6. Determine/calculate transfer airflows.
7. Assess indicated or measured airflow rates relative to design/current requirements.

During this testing, consider the effects of filter loading. During initial testing, airflows should be confirmed at the extremes of filter loading.

Documentation: Test documentation should include TAB documents listing

	airflow rates and, as applicable, comparison to the airflow rates indicated by monitoring and control systems, calculated air-change rates, and airflow offsets for each space. Test documents should also include trend logs of the airflow performance over time.
8.4.5.2 Test each room for directional airflow prior to initial operation and periodically thereafter, as determined by the facility risk assessment and SOP, and after any significant alterations that can adversely impact the ventilation system.	Refer to sections 8.4.1 Directional Airflow during Normal Operation and 8.4.2 Directional Airflow during System Failures.
This requirement is to physically test the differential pressure and directional airflow.	Refer to facility operating and maintenance records for review of historical documentation.
8.4.5.3 Measurement of temperature and relative humidity for all rooms inside the containment barrier and in rooms that support operations that are critical for the maintenance of the containment barrier shall be performed as indicated by facility risk assessments.	**Purpose of Test:** Design space temperatures and relative humidity are established to maintain occupant comfort, scientific equipment and process requirements, animal-holding requirements, etc. This test should confirm that the HVAC system meets the performance expectations to meet the required environmental conditions.
Baseline testing shall include calibration of sensors and confirmation of system's ability to maintain required conditions. Tests shall be performed before initial operation, and periodically thereafter as determined by the facility risk assessment and SOP and after any significant alterations that can adversely impact the ventilation system.	The risk assessment should identify critical rooms in which temperature and humidity maintenance are critical to containment. Refer to facility operating and maintenance records. Historical records should be reviewed to confirm the ability of the system to maintain conditions

over any applicable assessment period.

Recommended Methodology: To verify steady-state performance of space temperature and relative humidity the following methods (or equivalent) should be considered:

1. Confirm calibration of the temperature and humidity sensors or stats.
2. Confirm sensors are representative of required conditions.
3. Initiate set-point and load changes to confirm response of control systems.
4. Operate spaces across ranges of set-points, load conditions, and modes of operation and confirm system's ability to meet requirements.
5. Log conditions over at least one week and analyze data to confirm requirements are met (such as via historical trend logs, via calibrated BAS sensors or independent temperature and humidity loggers placed at representative locations in the space).
6. Log conditions over 2 hours to confirm requirements are met.

Documentation: Test documentation should include records of all sensor calibrations and tests and logs of space temperature and relative humidity for each space.

8.4.5.4 Measurement of BSL-3/ABSL-3 exhaust stack velocity to atmosphere shall be performed as indicated by facility risk assessments.	**Purpose of Test:** To verify that the exhaust discharge velocity is per the design requirement. The velocity should be equal to or greater than that noted in the most recent version of project documentation listed in section 8.2. This velocity may be modified based on a combination of risk assessment, facility use, and SOPs. BSL-3/ABSL-3 exhaust air system may or may not have HEPA filtration. The need to ensure that the exhaust plume is directed into the atmosphere and does not re-entrain into air intakes is important. Normally, survival of infectious material is limited outside of the natural hosts. Ensuring that exhaust plumes are high enough into the atmosphere allows for temperature fluctuations, dilution, and ultraviolet to avoid risks of infection and cross-contaminations. **Recommended Methodology:** Test airflow and velocity at all exhaust stacks for normal minimum airflow conditions. Test velocity under reduced airflow modes for failure scenarios or for reduced ventilation scenarios. **Documentation:** Test documentation should include velocity measurements for each test condition for each stack.
8.4.5.5 Each laboratory ventilation system shall be tested for response to fire/smoke alarms in accordance with requirements as	**Purpose of Test:** To verify containment directional airflow and system operations when building fire-protection systems

established in project documents, including the facility risk assessment and requirements of the AHJ. Tests shall be performed before initial operation and periodically thereafter as determined by the facility risk assessment and AHJ, including after any significant alterations that can adversely impact the ventilation or associated control systems.

are activated. Fire-protection and associated life-safety requirements for containment spaces are sometimes opposing regarding the required responses of the ventilation systems. The design intent and risk assessment should have specifically defined the responses to a fire or smoke condition. These parameters must be verified to ensure no sustained reversal of airflow occurs when fire protection systems are activated.

Recommended Methodology: Solutions will vary for individual facilities based upon a number of variables such as facility design, system zoning and fire separations, smoke-control approaches, pressurized fire shafts, etc. Each facility must therefore have a dedicated fire testing plan to ensure that the function and response of ventilation systems during fire alarm conditions are known to management and incorporated into the SOP and risk assessment.

Testing entity should, in collaboration with the responsible authorities, test fire-alarm procedures and potential impact on containment operations. List all adverse fire protection and containment implications and ensure SOPs address the containment implications.

Testing entity should review project design documents, and in particular the control sequence of operations, and if necessary, consult with facility

management and the local AHJ to determine what pertinent guidelines and standards have been adopted as code or waivers.

For example, National Fire Protection (NFPA) standards 45®,[30] NFPA® 90A,[31] and NFPA® 105[32] have implications that can directly affect required ventilation operation and fire-protection response. Inspect and test to ensure fire-protection approaches will not pose unacceptable risks to containment (e.g., ensure no smoke dampers have been installed in the exhaust system).

The following testing should be considered:

1. Initiate fire alarm outside of containment (*initially and as otherwise required*).
    - Confirm that in case of a fire alarm initiated outside the containment area, the fire-alarm system does not shut down or adversely affect the laboratory ventilation systems.
    - Confirm any smoke-control reactions do not cause sustained reversal of airflow from the containment area.
2. Initiate a fire alarm inside of containment (*initially and as otherwise required*).
    - Confirm that in case of a fire alarm initiated inside the containment area, the ventilation system reacts according to

requirements established by the design and risk assessment.
- Confirm the reaction does not cause a sustained positive pressure compared to the adjacent non-containment areas.

3. Initiate a smoke-/duct-detector activation (*initially and as otherwise required*).
   - Confirm that in case of a smoke-/duct-detector activation, the ventilation system reacts according to requirements established by the design and risk assessment.
   - Confirm that smoke control reaction does not cause a sustained positive pressure compared to the adjacent non-containment areas.

Acceptance criteria should be defined in the risk assessment.

Documentation: Test documentation should include containment performance (directional airflow) for various fire-alarm conditions tested.

8.4.5.6 The BAS/control systems shall be tested during abnormal operation and to verify performance as indicated by facility risk assessments. Tests shall be performed before initial operation and periodically thereafter as determined by the facility risk assessment and SOP and after any significant alterations that can adversely impact the ventilation system.

The following tests will ensure that the BAS and/or control systems properly control the HVAC systems within a containment laboratory and protect related primary, secondary, and tertiary containments. These tests should confirm the design and operating performances to maintain containment. The extent of building automation and

BAS systems shall be continuously monitored to facilitate an immediate notification and response by qualified personnel as appropriate to the alarm condition. In the event that the facility does not have an automated system, there must be a means for and verification of appropriate alarming and reporting.	control systems vary greatly among BSL-3/ABSL-3 laboratories. The intent of this section is to address typical HVAC and associated control elements in a BSL-3/ABSL-3 laboratory. Not all of these elements will apply to all laboratories. Apply the requirements below to applicable elements serving the facility. Structures and ductwork should be capable of withstanding both normal and abnormal pressures caused by fan failures, wind pressures, and other environmental influences. Excessive high pressures (positive or negative) caused by testing should be evaluated first and considered in the design and testing plan prior to testing. Pressure relief devices are available to mitigate this problem with excessive pressures. Performance testing should include tests conducted initially to establish baseline parameters and after any alterations of the BAS or other system component that may adversely impact the BAS function and periodically thereafter as indicated by facility risk assessments.
Verify alarms are functioning properly.	**Purpose of Test:** Alarms are necessary to provide notice to occupants and first responders in an emergency situation, out-of-range operating conditions, and failed operating conditions. Typical conditions include: 1. Laboratory or containment barrier pressure reversal 2. Door standing open

3. Simultaneous interlocked door opening
4. Failure of fans
5. Low exhaust duct static
6. Failure of HVAC control devices (e.g., variable air volumes)

Recommended Methodology: The following tests are recommended:

1. Verify that visual and audible notification devices annunciate upon abnormal operating conditions inside the containment zone by causing each alarm condition. For instance, cause pressure alarm by over-riding controls to change flows to the point they will result in an alarm condition.
2. Verify that visual and audible notification devices annunciate upon abnormal operating conditions inside the containment zone by over-riding alarm-mode trigger. For instance, over-ride the pressure alarm point on the BAS.

Confirm all occurrences of alarms are annunciated in the alarm module and tracked in the event log. Note that alarm annunciation can typically be done in concert with failure-mode testing.

Documentation: Document by listing all alarm devices verified and the conditions in which they were annunciated.

BAS input and output (I/O) device and/or control device shall be verified.	**Purpose of Test:** To verify I/O devices (sensors, safeties, valves, dampers, etc.) are calibrated and operating properly. The responsibility for configuring, calibrating, adjusting, etc. BAS devices will lie with entities other than the testing entity, such as the installing contractor or maintenance staff. The testing entity should perform quality assurance checks based on a sampling strategy to assess confidence in the BAS devices. **Recommended Methodology:** Review documentation of input calibration and output verification. Maintenance frequency recommended by manufacturer should be clearly indicated on documentation and documents should show adherence to recommended intervals. 1. Confirm I/O calibration and verification via spot check. • Select a mix of the I/O and confirm calibration, stroke and range, actuation, etc., as applicable • Check calibration of all differential pressure indicators monitoring containment barriers (*initially*) • Check calibration of minimum of a percentage of the differential pressure indicators monitoring the containment barriers 2. Confirm status indication on all exhaust fans under a belt loss

	scenario. Belts should be removed and motor should be run at full speed. Confirm control system identifies the loss of status in this scenario (*initially*). Refer to section 8.4.2.
	Documentation: Document by listing all devices that were tested and verified and their respective results.
	Confirm volatile programming of controllers is backed up and can be uploaded to the controller. The facility manager should identify the control program backup location and demonstrate that it is current.
BAS/control system functionality during normal operation shall be verified.	**Purpose of Test:** To confirm the BAS or control system operates properly over time during normal use. Refer to section 8.4.1 Testing for Directional Airflow during Normal Operation above, as well as for testing of HVAC and controls systems, as any applicable control system will be tested in the course of that testing. The following is specific to the BAS/ control systems.
	Recommended Methodology: Establish real-time monitoring of space pressure differentials either via the BAS or local instrumentation. Observe normal airflow control and static pressure and ensure airflows stay above minimum airflow rate (as indicated by design intent), and pressures remain with the acceptable range in accordance with the risk

assessment (typical acceptable range is above 0.03 and below 0.15 water gauge (w.g.) across the barrier with directional airflow from clean to dirty areas). The following tests should be considered:

1. Impose a minor set-point change to the airflow and static pressure loops and observe response and return to normal operational set-point.
   - Confirm containment barrier pressures remain within tolerance
2. Enter and exit the space in accordance with SOPs
   - Confirm the control system reacts in a stable fashion so as to maintain airflow and differential pressures within acceptable ranges
3. Operate sashes of primary containment across ranges applicable during normal use.
4. Configure the rooms and systems into all modes of operation per the design intent.
   - Confirm proper operation during those modes
5. Confirm airflow and pressure control on normal use of scientific equipment. Monitor the barrier differential pressure and airflow control during normal use of laboratory equipment. Examples include:
   - Partial blockage of downdraft and necropsy tables; percentage of blockage should be as stipulated in SOPs

	• Sash movement on biosafety cabinets and fume hoods • Repositioning of snorkel exhausts 6. Isolate primary containment devices as would be required for decontamination per the SOP. **Documentation:** Test documentation should indicate results of tests and data showing the responses of the control and HVAC systems. Characterize the response to the events tested. Document by listing all devices that were tested and verified and their respective results.
The BAS/control systems shall be tested during abnormal operation.	**Purpose of Test:** To confirm the BAS or control system reacts properly to plausible failures of HVAC and control system components. Refer to section 8.4.2 Testing for Directional Airflow during System Failures as the verification of the HVAC system under control system failures is covered in that section. The following tests elaborate more specifically on the testing of the control systems themselves. Tests should be performed to confirm the proper response of the BAS/control systems~~,~~ to ensure the containment barrier can withstand the forces imposed, and to ensure safe egress. **Recommended Methodology:** Establish real-time monitoring of space pressure differentials either via the BAS or local instrumentation. Observe performance of the BAS and control system through the failure events or abnormal operation.

Confirm the systems react effectively to minimize any directional airflow reversals, while not causing extreme forces on the doors and the containment envelope. Generally, initial reactions may result in more negative pressures than considered acceptable during normal operation; however, differential pressures should come back into the normally acceptable ranges within 30 seconds. Door forces caused by the ventilation system should not exceed manufacturer's recommendation for the application used and may vary per facility use and the SOP.

Consider testing the following failures:

1. Single supply or exhaust system controller failure serving the BSL-3/ABSL-3
   - Remove power from the controller and confirm the I/O positions per design intent and that the reaction of the systems does not violate the directional airflow criteria or cause extreme forces on the building envelope and/or extreme door forces.
2. Loss of communications on the BAS controls LAN
   - Defeat communications with individual controllers (for instance by removing the LAN cable from the controller), as well as power down switches or routers on the control LAN. Confirm the stand alone control of the controllers and the ability to re-establish

	communications when restored. 3. Controller power circuit trip • Fail power supplies to controllers 4. Failure of UPS output breaker or batteries for power to BAS 5. Duct static pressure sensor failure • Remove signal wire to the controller. Confirm the controller response to the failed sensor. 6. Failure of automated bio-seal damper • Remove the control signal to the actuator such as the voltage on an electropneumatic transducer; also remove the motive power to the actuator. 7. Failure of air terminal unit controlling airflow to the BSL-3/ABSL-3 zone • Remove the control signal to the actuator such as the voltage on an I/P transducer. Also, remove the motive power to the actuator. **Documentation:** Test documentation should indicate results of tests and data showing the responses of the control and HVAC systems. Characterize the responses to the events tested. Document by listing all devices that were tested and verified and their respective results.
Analyze historical trends and data available from BAS.	**Purpose of Test:** To confirm the facility has been performing per requirements over time. **Recommended Methodology:** The following tests are recommended: 1. Perform trend and event log analysis.

	Analyze the trends of the relevant biocontainment parameters and review the alarm and activity log for those parameters. • Containment zone differential pressure • Zone air changes (or component airflows) • Zone temperature • Zone humidity where it is controlled **Documentation:** Testing entity should produce summary report of findings to the owner. At a minimum, trends and alarm history should be reviewed.

8.4.6 Testing of Electrical Systems Related to Heating, Ventilating, and Air-Conditioning (HVAC)

	Test Purpose and Methodology
Record and document electrical power dip occurrence.	**Purpose of Test:** To ensure that ventilation systems are properly serviced with normal power, emergency/standby power, and UPS power (where installed), as determined by local risk assessment, and that they all work in accordance with design-performance objectives. Electrical systems provide the power (normal, emergency/standby, and UPS (where installed) for the operation of systems and equipment that support primary containment devices, secondary barriers, HVAC systems, treatment systems, and security. The electrical design engineer should verify the

desired performance expectations of the systems and operations during normal and emergency power conditions and verify which systems require additional protection with UPS (where installed). The electrical systems that control HVAC systems should be thoroughly tested verifying:

1. Adequacy of power supply to serve fans, pumps, valves, etc.
2. Power to fans and variable frequency drives (VFDs)
3. Power to airflow control devices
4. Power to BAS and other control systems for monitoring, controlling, and alarming HVAC normal and failure modes
5. Power to security and door systems that interface with HVAC such as door switches and magnetic locks that control airflow valves
6. Power to hydronic pumps that serve air-handling systems, and energy recovery systems inside HVAC systems
7. Appropriate monitoring and operation of critical electrical equipment to BAS
8. Monitoring of critical UPS (where installed) and standby power by BAS

Recommended Methodology:
Containment systems should respond in such ways as to avoid operating conditions that present risks to workers and the environment. Electrical systems including backup generators for normal power outages provide effective

strategies to maintain containment including minimization of flow reversals. Emergency generators can normally respond within 10–15 seconds to restore power, whereas UPS systems (where installed) provide continuity of power between transitions of normal to emergency power systems. Based on the risk assessment for the facility, each supporting system should have a documented sequence of operation/ strategy for power failure and restoration.

This will include the criteria for time limitations for power restoration. This section covers only the electrical power to the main electrical systems. As appropriate to address the risk assessment, similar testing scenarios should be considered for multiple levels of electrical failure, down to the individual systems.

As electrical power will be critical to all the containment systems, testing should be performed when all the containment systems are tested. If the facility primary electrical system includes load/shedding, multiple generating/standby units, or other electrical demand strategies, the failure scenarios should include testing to confirm that switching/operating the units does not impact the electrical failure-test scenarios.

Refer to section 8.4.2 Testing for Directional Airflow during System

Failures as the verification of the HVAC system under electrical failures is covered in that section. The following tests elaborate more specifically on the testing of the electrical systems themselves.

Test various power-failure scenarios. Electrical power failures and restorations should perform in accordance with the documented sequence of operations.

1. Test normal to/from emergency power (closed transition). This test should not interrupt power to critical systems serving the containment area for facilities where emergency power can be operated concurrently with normal power.
   - Switch to emergency power under a closed transition sequence
   - Record and document no electrical power dips, surges, or outages that impact the critical systems and subsystems
   - After determining all systems are stably operating, switch to normal power from emergency power and document no impacts to critical systems and/or subsystems
2. Test normal to/from emergency power (source interruption) interruption:
   - Systems and equipment should transition to/from emergency mode in a controlled manner. For

facilities where emergency power operates only when normal power is out, disconnect the normal power source
- Record and document that emergency power is supplied to all critical and subsystems intended
- After all systems have stabilized, restore normal power and document that there are no impacts to critical systems and/or subsystems

3. Test that operation of general UPS, where installed (into and out of source interruption), and equipment, should transition to/from UPS mode in a controlled manner. Based on the facility risk assessment, there should be documentation on the sequence of operations for the UPS and the minimum time the UPS will maintain service.
   - Disconnect power to UPS and determine that UPS operates to provide power to all connected loads for the intended time
4. Test operation of BAS UPS, where installed (into and out of service interruption). BAS controls should remain powered and active. The BAS/controls should be locally backed up and controls programming maintained during a power outage. There should be written documentation for the minimum time the UPS/batteries will maintain operation.

- Disconnect power to BAS (system/subsystems) and determine that UPS operates to provide power to the BAS for the intended time

If emergency generators exist, they should be tested on a weekly/monthly basis and have results recorded and retained.

Documentation: Test documentation should include results of each test conducted and results of weekly/monthly generator tests.

8.4.7 Testing of High-Efficiency Particulate Air (HEPA) Filters

Test Purpose and Methodology

8.4.7.1

HEPA filters shall be tested upon installation, 12-18 months from the last test or at a frequency to be determined by the site-specific risk assessment. Each HEPA filter or bank of HEPA filters shall be tested in situ by particle or aerosol challenge testing.

Purpose of Test: To verify HEPA filter leakage in situ.

Recommended Methodology:

1. Provide a list of all the HEPA filters associated with each lab and their factory-tested efficiencies plus the test certificate for each. This includes all necessary calibration documentation associated with test instrumentation.
2. All HEPA filters should be factory tested.
3. Ultra-low particulate air/super-ULPA (ULPA/SULPA) filters should be tested following manufacturing

recommendations and the local SOP.

4. Each HEPA/ULPA/SULPA filter test should be tested upon installation, annually, or more often based on the owner's SOP.
5. Filters should be decontaminated prior to testing based on a risk assessment. Follow the site-specific SOP for decontamination and test procedures.
6. If the HEPA filter is placed inside a filter housing that could not be isolated for decontamination and testing, all potentially contaminated duct work should be decontaminated based on a risk assessment, if aerosol sampling is required for determining the upstream concentration.
7. Each HEPA filter should be tested in situ by particle- or aerosol-challenge testing. If it is not possible to do a surface-scan test, then gross probe testing should be performed.
8. Test HEPA filters by using the scanning method according to the Institutes of Environmental Sciences and Testing, IEST RP-034.1[33] and NSF 49[7] standards.
9. Test HEPA filters using airflow rates at rated operational designs and/or 20% rated flow.
10. Upstream challenge concentration should be verified by actual measurement. If using a Laskin nozzle generator, it is allowable to

calculate the upstream challenge. There are several materials available for creating aerosol challenge. When utilizing an oil aerosol, PAO (poly-alpha-olefin) is the most widely used in the United States. PAO replaced DOP (diocytl-phthalate) because DOP is considered a carcinogen. There are other oils available for use, the testing entity owner should agree on the material to be used. When scan-testing using a particle counter, PSL (polystyrene-latex) spheres should be used.

11. For surface-scan testing, a 0.01% leak or higher is considered significant and the filter/gasket should be repaired or replaced.
12. For gross-probe testing, a 0.005% leak or higher is considered significant and the filter(s)/ gasket(s) should be repaired or replaced.
13. If the HEPA-filter housing is not equipped with the aerosol challenge injection/distribution ports, injection ports should be provided in the ductwork upstream of the HEPA filter(s) so that the aerosol challenge can be introduced. Adequate distance (approximately 8 duct diameters) should be given to provide a more even distribution of challenge to the filter(s).
14. If the HEPA-filter housing is not equipped with an upstream

challenge sampling port, an upstream challenge sampling port should be installed for measuring the upstream challenge. This should be just upstream of the HEPA filter(s).

15. If the HEPA-filter housing is not equipped with a scanning section, a downstream sampling port should be installed for gross probing the duct. This port should be placed where adequate air mixing can occur (approximately 8 duct diameters).
16. Filter leaks or gasket leaks can be repaired using room temperature vulcanizing sealant (RTV), 100% silicone, or by making a patch using filter media.
17. Filter leaks or gasket leaks can be repaired using RTV, 100% silicone, or by making a patch using filter media. Per IEST 0.34,[33] no patch should exceed 5% of the filter's face area. Suitable cure time should be allowed before re-testing.
18. HEPA filters should be changed when the filter fails the leak testing or when filter loading causes elevated static pressures resulting in the inability to maintain proper airflow. In some cases, filters may be changed based on a facility requirement or practice.
19. HEPA filters installed in series should be tested individually.
20. In-line HEPA filters may require the use of a portable fan to introduce

airflow for HEPA testing.

21. Where parallel redundant HEPA filters are installed, ensure that facility operations are not interrupted while testing filters and housings, except as determined by the facility risk assessment.

Documentation: Test documentation should include test results for each filter.

8.4.7.2 HEPA filter housings that are exposed to elevated pressures or incur gas decontaminations shall be tested for structural integrity and leakage at the factory, after initial installation, and at a frequency to be determined by the site-specific risk assessment.

Purpose of Test: To ensure that the integrity of the housing can be sealed for gaseous testing and withstand normal and maximum operating pressures experienced during fan failures.

Recommended Methodology:

1. Filter housings should be decontaminated prior to testing based on a risk assessment. Follow the site-specific SOP for decontamination.
2. The design engineer should provide the test pressure to be used (which is the system's maximum operating pressure) in accordance with the American Society of Mechanical Engineers (ASME) standard N509-2002, Nuclear Power Plant Air-Cleaning Units and Components (2002)[34]: a minimum test pressure of 1000 Pa (4" w.g.).
3. Where parallel redundant HEPA filters are installed, ensure that

facility operations are not interrupted while testing filters and housings, except as determined by the facility risk assessment. Follow decontamination procedures when using bypass filters or ducts.

4. Housing leakage rate should be tested in situ by pressure decay using devices such as dampers or shut-off plates. Acceptance criteria rate of leakage should not exceed 0.1% of volume/min at a minimum test pressure of 1000 Pa (4" w.g.).
5. Structural integrity should be tested to verify housing stability during normal and maximum operating pressures. Using a minimum of 1000 Pa (4" w.g.) minimum test pressure or whatever maximum pressure can be induced from associated fans (under failure conditions), i.e., sometimes this test pressure can exceed 2500 Pa (10" w.g.) or greater.
6. During the structural integrity test, visually verify that:
   - The housing shape is retained.
   - No deformations are visible.
   - Dampers remain in position and are sealable to bubble-tight/gas tight standards.
   - Structural supports are per design and approved construction.
7. The equipment used for the verification should have a valid calibration certificate on the date of test, if the equipment requires it.

8. Small in-line filters (e.g., installed in magnehelic/photohelic gauge lines) should be factory leak tested. Installation of the small in-line filters protecting magnehelic/photohelic gauges in the filter housing should be tested as part of the leak testing of the housing.

Documentation: Test documentation should include test results for each filter housing.

8.4.8 Testing of Ductwork and Room-Air Leakage

8.4.8.1 Ductwork that is (a) considered contaminated, (b) transports air containing hazardous substances, or (c) if used for gaseous decontamination shall be tested for its degree of structural resistance, tightness, and leakage.

Such ductwork shall be tested upon installation before initial operation (as determined by the facility risk assessment) and after any alterations of the ventilation system or other alterations that can affect the ductwork.

Test Purpose and Methodology

Purpose of Test: To ensure that ductwork serving containment spaces and transporting potentially contaminated air are sufficiently tight and structurally stable under normal and maximum operating pressures.

Prior to testing, the testing entity/individual should assess the performance requirements of the ducts such as maximum operating pressure, design pressure, duct pressure, and classification, etc.

Recommended Methodology:

1. Supply and exhaust ducts associated with containment zones should be tested to procedures defined by the Sheet Metal and Air Conditioning Contractors' National Association

(SMACNA) standard, Leakage Class A.[35] This test should be conducted only if the ductwork is not protected by HEPA filters. Tightness tests for leakage should be based on a risk assessment and whether the air systems are potentially contaminated or subjected to decontamination gases. The risk of ductwork contamination on the supply air side is minimized by the pressure of air and normal operations.

2. Ductwork systems on the exhaust side between the containment zone and HEPA filter should be tested in accordance with ASME N510, Testing of Nuclear Air Treatment Systems.[36] Acceptance criteria should be in accordance with design intent with a leakage rate not exceeding 0.1% of volume at 1000 Pa (4" w.g.).
3. Ductwork should also be structurally tested to endure normal and maximum operating pressures, especially during fan-failure testing. Tests could exceed 2500 Pa (10” w.g.) under certain failures. The testing entity/individual should assess ductwork design prior to fan-failure testing and verify structural capacity. When fan-failure tests occur, the ductwork should be observed for structural deformation and displacement from hangers and support.

Documentation: Test documentation should include specific sections of ductwork where the test was conducted and results of the test for each duct section. Provide the calibration certificates for the equipment used for the verification (should be valid on the date of test).

8.4.8.2 When required by the facility risk assessment, room tightness (room air-leakage test) shall be performed before initial operation, periodically thereafter (as determined by the facility risk assessment and the SOP), and after any alterations of the ventilation system or other alterations that can affect the room containment.

Purpose of Test: To verify and minimize unplanned/uncontrolled room air leakage to ensure proper HVAC control for directional airflow and to ensure HVAC systems react to room decontamination systems to avoid leakage of hazardous gases. When BSL-3/ABSL-3 laboratories are to be decontaminated by fumigation, penetrations in the barrier envelope should be sealed or capable of being sealed to prevent excessive migration of fumigants out of the space.

Recommended Methodology:

1. All room sealing should be done prior to performing final TAB and final setup of airflow control devices.
2. Visually verify that all architectural finishes are sealed, smooth, and void of chips and abnormal wear.
3. Visually verify all penetrations are sealed, smooth, and are capable of withstanding fumigation. The verification should include all service (electrical, gas, fire detection/ suppression water supply, and waste pipe) penetrations, sleeving/seals, window/door frames, light framing

seals to wall/ceiling systems, HVAC air devices, and other penetrations. Confirm components are secure to maintain integrity of penetrations.

4. Use small inspection mirrors to aid visualization of hard-to-reach areas.
5. Confirm visual inspections using smoke or soap bubbles as appropriate. Leaks can be visualized by smoke movement or bubble formation at the failure point. Room pressures (negative) during leak-finding tests can range from normal operating pressures to higher values (e.g., twice the normal value) as appropriate based on factors such as room construction, HVAC controls, and the ability to shut down BSL-3/ ABSL-3 operations for testing.
6. Additional test methods may be appropriate for initial commissioning of new construction and/or renovations, such as:
    - Operating the room at higher differential pressure values for the smoke/bubble tests (e.g., up to 2" w.g. (500 Pa): Testing at this pressure may be useful in conjunction with HVAC controls testing
    - “Room porosity” tests using airflow/pressure testing equipment similar to that used for duct-leak testing
    - Verify when the BSL-3/ABSL-3 space is in decontamination / fumigation mode (e.g., with the ventilation system off) that

	decontamination agent (or an odorous surrogate) is not drawn into the adjacent or nearby non-containment spaces by relatively negative pressures in those spaces Verify structural capability of wall and ceiling systems prior to determining leak test pressures. 1. Undesirable leaks should be recorded and repaired. Additional testing may be used to verify efficacy of repairs. There are various testing methods and criteria that have been used by other countries to verify leak rates of containment facilities. A study[37] that verified and tested 18 facilities in Australia proved that leak rates can be varied and greater than what is necessary to contain a gas, and that additional measures may be necessary during a gas-decontamination process. **Documentation:** Test documentation should include specific rooms where the test was conducted and results of the test for each room.

8.4.9 Testing of Specialized Heating, Ventilating, and Air-Conditioning (HVAC) Components of ABSL-3 Facilities

	Test Purpose and Methodology
Ventilation systems serving ABSL-3 rooms shall	**Purpose of Test:** To ensure that

be tested. Individually ventilated cage (IVC) rack systems connected to house exhaust shall also be tested in normal and failure-mode conditions.

ventilation requirements meet design performance requirements and serve to maintain containment. ABSL-3 facilities can present increased biosafety risks associated with the housing, care, and manipulation of animals with BSL-3 agents. Caging systems used in ABSL-3 can have a direct impact on the in situ ventilation-system performance.

IVC racks used in an ABSL-3 vary in design and function by manufacturer. Sealed IVC systems operated under negative pressure are considered to be primary containment equipment. Such systems exhaust cage air through the cage and/or rack to external or internal HEPA filters. Some IVC rack systems used in an ABSL-3 use cages that are operated under negative pressure, but are not sealed and may afford less protection under failure conditions. Specific risk assessment for each facility should include considerations of animals, agents, equipment, caging type, and conditions under both normal and failure-mode scenarios.

ABSL-3 rooms that use IVC systems should integrate the ventilation requirements of the IVC manufacturer with the in situ ventilations systems. The ABSL-3 room should consider the following testing criteria (in addition to BSL-3 requirements):

Recommended Methodology:

1. Animal room-ventilation design and test criteria should meet

containment directional airflow and pressurization needs and meet Institute of Laboratory Animal Research (ILAR) requirements for air-change rates and thermal/ humidity requirements.

2. IVC systems that are connected to in situ ventilation systems should be tested for proper operation to ensure directional airflow, negative pressure, and controls alarming.
3. IVC systems that are integrated using single airflow control valves from several cage racks should be tested with multiple racks connected and disconnected; valve performance needs to be verified whether it is installed with a 1 to 1 ratio or 1 to several ratio.
4. IVC systems that are connected to in situ ventilation systems should include tests to verify room pressurization with the IVCs disconnected.
5. IVC systems that have internal HEPA filtration should confirm HEPA filter-verification procedures. Ongoing verification should be determined based on local risk assessment.
6. Confirm proper airflow of IVC connections to in-house systems.
7. Test individually ventilated cage, cage change station, and BSC HEPA filters for efficiency, and confirm primary containment devices have been certified annually.
8. Test influence of increased heating

impact of wash-downs and cleaning
- Ensure that temperature gains are offset with cooling requirements and air change rates
- Ensure that additional temperature gains do not influence room-pressure differentials
- Confirm required pressure differentials are not contravened as a result of operating procedures
- Verify and test ventilation systems used for decontaminating the IVC rack, including the rack internal manifold and components

9. If units include automatic door operation, confirm proper operation and sealing.
10. Test the impact of in situ and facility system failures on IVC performance; IVC racks used in ABSL-3 rooms should maintain negative pressure.

    - Verify procedures for total fan failure, including power failure and include electrical, normal, and standby power and UPS failure tests, if equipped
    - Test for fan interlocks between IVC and exhaust fans if supplied (if main exhaust fails, hard connected IVC blowers should also fail
    - Where IVC are thimble connected to in situ exhaust,

test that the IVC can maintain performance by discharging exhaust air through a thimble connection when the main exhaust fails

- Where IVC are used and the local risk assessment determines that reduced airflow rates are allowable, these rates should be tested to ensure containment pressure relationships and directional airflows are maintained

Documentation: Test documentation should include specific rooms where the test was conducted and the results of the test for each room.

8.4.10 Testing of Heating, Ventilating, and Air-Conditioning (HVAC) Systems of Containment Support Areas

Appropriate directional airflow between containment support spaces and adjacent areas shall be maintained and verified in accordance with the risk assessment.

Test Purpose and Methodology

Purpose of Test: To verify appropriate pressure relationships for containment support areas (such as rooms housing liquid waste and carcass treatments or containment exhaust ductwork) are in conformance with the risk assessment. *The goal is to minimize potential for cross-contamination in the event of a failure*.

Recommended Methodology:

1. Identify applicable support spaces.
2. Perform directional airflow testing as outlined in sections 8.4.1 and 8.4.2.

Assess the risk of potential migration of contaminants from support spaces under failure conditions and implement physical and/or operational measures to mitigate the risk.

Documentation: Test documentation should include specific support areas where the test was conducted and the results of the test for each space.

APPENDICES

Appendix A – Corrective Action Plan (CAP) and Template

(The International Organization for Standardization (ISO) has templates for purchase. They include templates for CAPS, risk assessment, SOPs, etc. Go to: http://www.iso.org/iso/home/standards.htm; search for "Templates" then by template type, i.e., "risk assessment."

Corrective Action Plan

Institution Name	
Address	
Facility/Area Audited	
Auditor Name	**Audit Date**
Audit Agency	**Follow-up Action**
Performance-Verification Date/Seal	**Signature of Testing Agent/Verifier**

PURPOSE: This plan describes audit findings, documents, and responsibility for addressing the findings. It also describes progress towards addressing the findings.

INSTRUCTIONS: Provide enough information to enable the reader to understand the nature of the finding, the impacts, and the planned remedy.

DIRECTIONS: Create plan by area or by audit. Allow for the plan to be separate for the area or the auditor.

No. of Finding	Date of Audit by Item #	Facility Agree/ Disagree	Finding Description	Action Required	Risk-Level Priority Red Yellow Green	Owner/ Responsible Person(s)	Current Status	Planned Completion Date	Action Adequate to Proceed with Performance Verification (Yes / No)	Comments

Appendix B – Factors to Consider in Performing a Risk Assessment

1. Facility layout

2. Containment boundaries
   - Primary containment biosafety cabinet (BSC), caging systems, etc.
   - Secondary containment (rooms, hoods, etc.)
   - Tertiary containment (anteroom, shower, locker room, etc.)

3. Site-specific risks, (e.g., natural hazards such as seismic, high winds, floods, etc., proximity to public, proximity to other facilities or hazards that can introduce risk to the facility or its operational response)

4. Specialized laboratory equipment and use (particularly aerosol generating)

5. Access control

6. Waste management

7. Current security threat/risk – local, national, and international threats that could compromise the safety of the general public, the environment, the security of the personnel, the research, and the facility

8. Building utilities

9. Work flow/routing (internal and external)

10. Dependency upon outside sources for utilities, i.e., steam, electricity, gas, etc.

11. Building systems
    - Ventilation systems including HEPA filtration, isolation valves, exhaust versus supply duct locations
    - Building automation system
    - Existing system redundancies
    - Non-containment building systems that could adversely impact containment including fire suppression systems

12. Agents used including
    - Quantity / infectious dose
    - Concentration

- Route of transmission
- Availability of treatment

13. History of spills or accidental releases

14. Area and surface decontamination methodology
    1. Vaporized hydrogen peroxide
    2. Paraformaldehyde
    3. Chlorine dioxide
    4. Other

15. Regulations/standards/guidelines

16. New or existing equipment related to ventilation systems including but not limited to BSCs, Class III cabinet, fume hoods, HEPA filters, etc.

17. Systems replacement / part availability

18. Facilities current maintenance and preventative maintenance program

19. Catastrophic event

Appendix C – Hazard Risk Matrix

During a risk assessment, hazards are evaluated in terms of the likelihood that a problem may occur and the damage and/or consequences it would cause if such an event did occur.

The Hazard Risk Matrix can be used to record a risk rating for each hazard in the terms high, medium, and low. To use the assessment, several concepts must be understood.

- Hazard – Any situation that has potential to cause damage or exposure to people, animals, or the environment.
- Probability – Likelihood that the particular hazard will result in a possible release, damage, or exposure at this location.
- Severity – An estimation of how serious the potential problem might be in terms of harm to people, animals, the environment, or damage to property.

Sample Risk Matrix (Example 1)

This risk matrix has been designed and adapted from the Australia/New Zealand Standard for Risk Management, AS/NZS 4360:2004.[38] The risk priority rating on this matrix is represented by an alphabetical code as the key below outlines.

	Consequences				
Likelihood	**Severe (1)**	**Major (2)**	**Medium (3)**	**Minor (4)**	**Negligible (5)**
Almost certain (A)	E	H	H	M	M
Likely (B)	H	H	M	M	L
Possible (C)	H	M	M	L	L
Unlikely (D)	M	M	L	L	T
Rare (E)	M	L	L	T	T

Key to the risk rating

E Extreme risk — Immediate action required; this level of risk needs detailed research and planning by senior management.

H High risk — Action plan is required as soon as practicable by senior management.
M Moderate risk — Action plan is required by Area/Department Manager.
L Low risk — Managed by routine procedures and employees under supervision.
T Trivial risk — Unlikely to need specific application of resources.

The numbers and letters associated with the criteria for "likelihood" and "consequences" reflect accuracy in the rating. For example, a risk rating may be "H," but does that represent "possible and severe" or "likely and severe" or "likely or major," etc.? It is a way of explaining the reasoning behind the risk priority rating. It also recognizes that there are a few versions of the same rating, just with different criteria being assessed.

Sample Risk Matrix (Example 2)

This risk matrix has a risk priority rating represented by a numerical code as the key below outlines.

	How likely is it to be that bad?			
How severely could it hurt someone *or* how ill could it make someone?	**++ Very likely** could happen anytime	**+ Likely** could happen at some time	**= Unlikely** could happen, but very rarely	**– Very unlikely** may happen, but probably won't
Kill or cause permanent disability or ill health	1	1	2	3
Long-term illness or serious injury	1	2	3	4
Medical attention and several days off work	2	3	4	5
First aid needed	3	4	5	6

Key to the risk rating

1 and 2 The hazard has a high risk of creating an incident. It requires immediate executive management attention to rectify the hazard. Control action must be immediately implemented before working in the area or carrying out the work process.

3 and 4 The hazard has a moderate risk of creating an incident. It requires management attention in a reasonable timeframe to prevent or reduce the likelihood and

severity of an incident. Control action of a short-term nature would need to be taken immediately so that work could still be carried out with further long-term action taken to ensure that the hazard was fully controlled.

5 and 6 The hazard has a low risk of creating an incident. It requires supervisor and employee attention in a reasonable timeframe to prevent or reduce the likelihood and severity of an incident.

Sample Risk Matrix (Example 3)

This matrix is used by the U.S. Department of Defense and Department of Homeland Security for risk assessments.

Risk Assessment Matrix					
Probability of the Event Occurring					
Severity of the Outcome	**Frequent**	**Likely**	**Occasional**	**Seldom**	**Unlikely**
Catastrophic	Extremely High	Extremely High	High	High	Moderate
Critical	Extremely High	High	High	Moderate	Low
Marginal	High	Moderate	Moderate	Low	Low
Negligible	Moderate	Low	Low	Low	Low

Definition of Terms

Severity

- Catastrophic – Exposure or event results in death or permanent disability.
- Critical – Exposure or event results in severe injury or illness.
- Marginal – Exposure or event results in mild injury or illness.
- Negligible – Exposure or event results in need for first aid or minor medical treatment.

Probability

- Frequent – Occurs very often; expected to occur continuously.
- Likely – Expected to occur several times during an employee's tenure.
- Occasional – Expected to occur over a period of time; will occur at some point.
- Seldom – Occurs as an isolated incident; not expected to occur.
- Unlikely – Occurs rarely; cannot be considered impossible.

Appendix D – How to Compile a Standard Operating Procedure (SOP)

Every SOP should contain the following information using a comprehensive format such as that used by International Organization for Standardization (ISO; the ISO has templates for purchase. They include templates for CAPS, risk assessment, SOPs, etc. Go to: http://www.iso.org/iso/home/standards.htm; search for "Templates" then by template type, i.e., "risk assessment").

- Summary of SOP content
- Issue date
- Date of approval
- Title and authors (author may be the organization or lab)
- ID number, version number, page numbers
- Introduction
- Purpose/objective
- Applicability
- Responsibility
- Materials
- Step by step procedure
- Review, revision, and distribution process
- Approvals
- Relevant documents/references/regulations
- Management controls
- Training requirement

Appendix E – Index of Acronyms

AABC	Associated Air Balance Council
ABSL-3	Animal Biosafety Level 3
ADA	Americans with Disabilities Act
AHJ	authority having jurisdiction
AHU	air-handling unit
ASSE	American Society of Safety Engineers
ANSI	American National Standards Institute
ARS	Animal Research Service
ASHRAE	American Society of Heating, Refrigerating and Air-Conditioning Engineers
ATS	automatic transfer switch
BAS	building automation system
BMBL	*Biosafety in Microbiological and Biomedical Laboratories*
BSC	biological safety cabinet
BSL-3	Biosafety Level 3
BSO	biological safety officer
CAP	corrective action plan
DOP	diocytl-phthalate
HEPA	high-efficiency particulate air
HVAC	heating, ventilating, and air-conditioning
I/O	input/output

I/P	current to pressure
ISO	International Organization for Standardization
IVC	individually ventilated cage
LAN	local area network
NEBB	National Environmental Balancing Bureau
NEMA	National Electrical Manufacturers Association
NFPA	National Fire Protection Association
NIST	National Institute of Standards and Technology
NSF	National Science Foundation
Pa	Pascal
PAO	poly-alpha-olefin
P/N	positive/negative
RTV	room temperature vulcanizing
SMACNA	Sheet Metal and Air Conditioning Contractors' National Association
SOP	standard operating procedure
SULPA	super-ULPA
TAB	testing, adjusting, and balance
ULPA	ultra-low penetration aerosol
UPS	uninterruptable power supply
w.g.	water gauge
WHO	World Health Organization

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