

BSL-3/ABSL-3 Verification

- BSL-3 D9: “The laboratory shall be designed such that under failure conditions the airflow will not be reversed.”
- ABSL-3 D6: “The ABSL-3 animal facility shall be designed such that under failure conditions the airflow will not be reversed.”
- BSL-3 D15: “The BSL-3 facility design, operational parameters and procedures must be verified and documented prior to operation. Facilities must be re-verified and documented at least annually.”
- ABSL-3 D14: “The ABSL-3 facility design and operational procedures must be documented. The facility must be tested to verify that the design and operational parameters have been met prior to use. Facilities should be re-verified at least annually against these procedures as modified by operational experience.”

The Federal Select Agent Program Policy is based on the above BMBL Standards as currently published and is subject to change. Current policy:

I. BSL-3/ABSL-3 Initial HVAC Verification (BMBL: BSL-3 D9/ABSL-3 D6)

Initial HVAC design verification must be performed and documented by someone with experience and expertise with the HVAC system prior to operation. This initial HVAC design verification ensures that secondary containment is maintained under failure conditions to prevent possible exposure of personnel outside the containment boundary. After HVAC verification is initially documented, the testing need not be repeated, providing no major changes have been made to, or major problems noted with, the HVAC system. See Section II below for details on major changes and major problems which may require repeat HVAC verification.

Documentation must be provided of verification of HVAC design functionality under failure conditions. The failure conditions for verification include:

a. Mechanical failure of exhaust fan or fan component(s):

- If redundant fans are present, the ability to transition to the alternate fan without reversal of air flow from potentially contaminated laboratory space into “clean” areas surrounding the laboratory must be verified.

- If no redundancy is present in the laboratory HVAC system, the capacity to transition from sustained inward air flow into the laboratory to a “static” condition, i.e., no air flow out of the laboratory must be verified.
- b. **Simultaneous power failure supporting supply and exhaust fan components:**
- If emergency power supply is available for the laboratory HVAC system, the ability to transition from “normal” power to the backup system without a reversal of air flow from the laboratory should be verified.
 - If no backup power supply is available, the ability of the HVAC system to transition to a “static” condition, i.e., no outward air flow, should be verified.
- c. **Return from power failure to “normal” operating conditions:**
- If emergency power supply is available, it should be verified that the ability exists to transition from backup power to normal power without a reversal of air flow from the laboratory.
 - If no backup power supply is available, the ability of the HVAC system to return to normal operating conditions, without a reversal of air flow from laboratory spaces to clean areas surrounding the laboratory should be verified.

II. BSL-3/ABSL-3 Repeat HVAC Verification (BMBL: BSL-3 D9/ABSL-3 D6)

Once the BSL-3/ABSL-3 HVAC verification has been completed and approved by CDC/DSAT or APHIS/ASAP, HVAC failure conditions testing need not be repeated, providing there have been no major changes made to the HVAC system and no major problems noted with HVAC performance. Examples of major changes to the HVAC system which may require re-verification of HVAC design functionality under failure conditions by someone with experience and expertise with the system include: replacement of exhaust or supply fans that serve the BSL-3/ABSL-3 containment areas, replacement of ductwork valves or dampers that serve these areas, replacement or repair of HVAC system control wiring, building automation system logic programming changes, structural changes to the BSL-3/ABSL-3 rooms, or addition or removal of hard-ducted BSCs or fume hoods. Examples of major problems with HVAC performance that may require re-verification of HVAC design functionality under failure conditions include:

frequent failures of the HVAC system, supply-exhaust interlocking system failure, observation that directional air flow is reversed under normal conditions, observation that HVAC alarms are not working, or that any BSCs with an HVAC connection are not working properly.

III. Acceptance Criteria for HVAC Verification (BMBL: BSL-3 D9/ABSL-3 D6)

The documentation provided must demonstrate that under exhaust fan or normal power failure conditions, or during normal power start-up, there is no reversal of air which originates within the BSL-3/ABSL-3 laboratory or vivarium room that travels all of the way outside the containment boundary. A facility may be considered to pass the HVAC verification tests as long as laboratory air does not exit the containment barrier of the facility. The BSL-3 anteroom is considered to be within the containment envelope. A positive pressure excursion is not necessarily an airflow reversal; if a brief, weak positive pressure excursion is noted, a repeat test may be performed with airflow observation using an airflow indicator such as a smokestick, or dry ice in a container of water, at the base of the closed laboratory door to confirm whether airflow reversal is occurring.

IV. BSL-3/ABSL-3 Initial Facility Verification and Annual Re-verification (BMBL: BSL-3 D15/ABSL-3 D14)

In addition to initial HVAC verification and re-verification as described above, the following are the minimum facility verification requirements that an entity is expected to perform and document initially for a BSL-3 or ABSL-3 laboratory and again at least annually. Some entities may choose to perform additional facility verification beside what is listed below.

- a. The means of detecting air flow (tell tale, magnehelic or digital gauge, Baulin-Tube®, etc.) has been confirmed to accurately reflect observed air flow. It is recommended, but not required, that digital or magnehelic gauges be calibrated annually.
- b. Inward directional airflow has been confirmed by observation for the laboratory.

- c. Decontamination systems (autoclave, room decontamination systems, digesters, liquid effluent systems, etc.) have been confirmed to be operating correctly.
- d. If a Building Automation System has the capacity to monitor and record performance measurements, e.g., differential pressures, the entity is encouraged to capture and store data from potential failure events, drills, etc. This information may provide verification of system performance. In addition, any programmed BAS alarms should be verified for proper functioning.
- e. All alarms (fire, air flow, security, etc.) have been checked and are functioning according to established specifications.
- f. Laboratory HVAC HEPA filters, if present, have been certified annually.
- g. Exhaust fan motors have been checked and routine maintenance conducted.
- h. The laboratory has been checked for unsealed penetrations, cracks, breaks, etc. and these have been repaired if present.
- i. All biological safety cabinets have been certified annually.
- j. Seals on centrifuges, Class III cabinets, gloves on Class III cabinets, etc. have been checked and replaced if required.
- k. Drench showers, eye wash stations, and hands free sinks have been confirmed to be operating properly.

If there are any questions about this policy, please contact the CDC DSAT Facility Specialist Susan Loring at 404-718-2012 or gkj8@cdc.gov, or the APHIS/ASAP Facility Specialist Robert L. Rice at 301-734-5557 or robert.l.rice@aphis.usda.gov.