Ventilation System Verification Issues for Select Agent BSL3 Laboratories




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Regulatory Basis for Verification Process

- 42 CFR Part 73.12 Biosafety
  - *"(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.*
  - *(b) The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).*
  - *(c) In developing a biosafety plan, an individual or entity should consider:*

    (1) The CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories" (BMBL)

"Biosafety and containment procedures sufficient to contain the select agent …"

- The BMBL is a nationally recognized "code of practice and an authoritative reference" for biosafety and containment practices*
- The BMBL is a performance based description of biosafety practices.
- Ventilation system design and practices** include:
  - *1) A ducted air ventilation system is required.*
  - *2) This system must provide sustained directional airflow by drawing air into the laboratory …*
  - *3) The laboratory shall be designed such that under failure conditions the airflow will not be reversed.*
  - *4) Laboratory personnel must be able to verify directional airflow .*

BMBL 5th edition, page 6*, and page 43**

Positive Pressure vs Airflow Reversal

- Conditions are related but not identical.
- Differential pressure is often monitored using a Building Automation System (BAS).
- Positive pressure is a 'red flag' for potential airflow reversal, but it is not an absolute indicator.

- The use of proper reference points for pressure differential readings is important.
- There is no 'zero tolerance 'requirement against positive pressure differentials in labs found in the select agent regulations or the BMBL.

Which failure conditions of BSL3 laboratory ventilation systems are the most important?

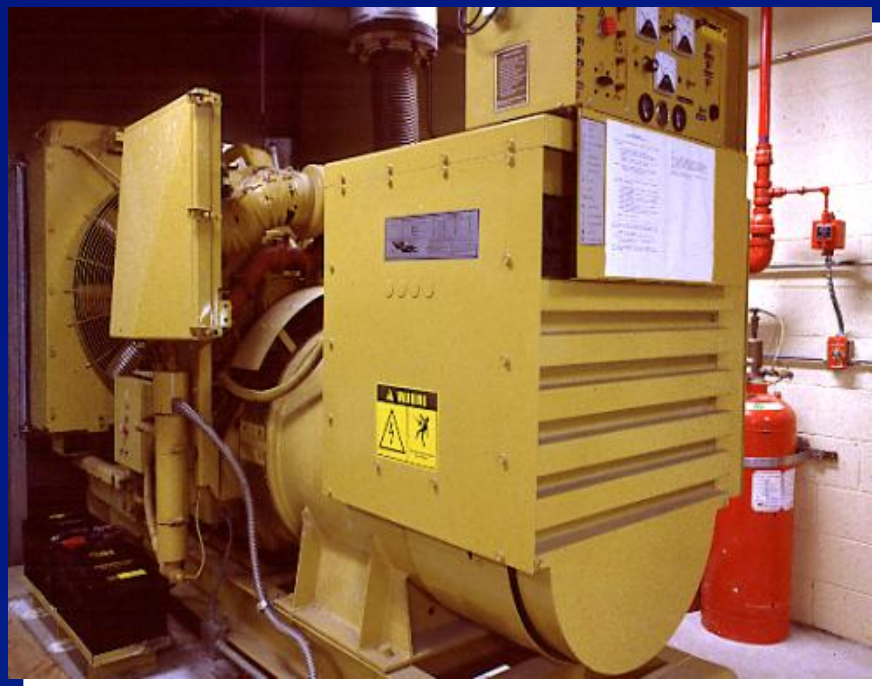
- Mechanical failure of exhaust fan or fan component
- Simultaneous power failure for supply and exhaust fan components
- Return from power failure to "normal" operating conditions (re-start)

Mechanical failure of exhaust fan or fan component

- 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 exhaust system, the capacity to transition from sustained inward air flow to a "static" condition, i.e., no air flow in or out of the laboratory, must be verified.

Simultaneous power failure for supply and exhaust fan components

- If emergency power supplies are available for the laboratory Heating, Ventilation, and Air Conditioning (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.



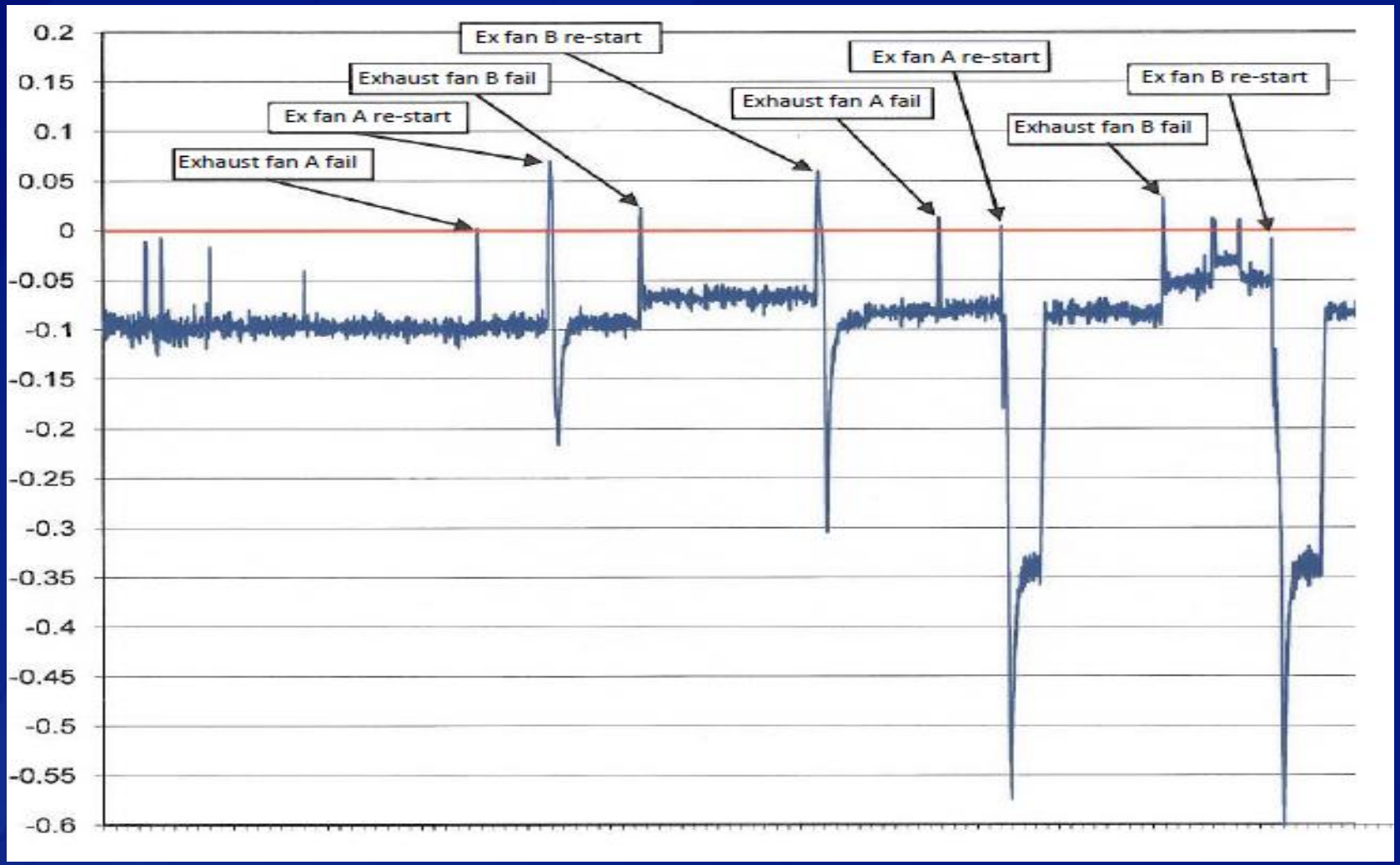
- If no backup power supply is available, the ability of the HVAC system to transition to a static condition, i.e., no inward or outward air flow, should be verified.

Return from power failure to "normal" operating conditions

- If emergency power supplies are 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.

What happens when the HVAC system fails?



When does an entity verify that "under failure conditions the airflow will not be reversed"?

- *"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."**

BMBL 5th edition, page 45

How does an entity verify that "under failure conditions the airflow will not be reversed"?

- Initial verification considerations
  - failure scenario testing
  - procedures for equipment maintenance and inspection must be developed
  - maintenance personnel training

- Annual verification considerations
  - failure scenario testing ?
  - review and documentation of maintenance
  - assessment of equipment and procedural changes, history of any airflow problems

Initial Facility Verification
circa 1988

The Atlanta Journal AND CONSTITUTION THURSDAY, NOVEMBER 10, 1988

Metro & State

SECTION B THE ATLANTA CONSTITUTION

Faulty Air-Flow System Delays Opening of CDC Laboratory

Discussion




For more information, please contact Select Agent Program

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