Ask the Experts

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Do you have a biosafety question and you’re not sure whom to ask? Send your questions to the “Ask the Experts” column and I’ll get them answered for you. Drawing from my own experience or that of other experts in the field we’ll try to compile a thorough and comprehensive answer to your question. Please e-mail your questions to jkeene@biohaztec.com or to the Chief Editor, Barbara Johnson, at barbara_johnson@verizon.net.

Should a Biosafety Level 3 laboratory be pressure-tested prior to being occupied?

Lately there has been a push to have new BSL-3 containment laboratories meet certain pressure testing requirements. The public concern is that containment laboratories “must be contaminated” or there would be no need for containment. In fact, a containment laboratory, even a BSL-4 laboratory, is rarely if ever contaminated since all work with the biohazardous agents is performed in primary containment devices. The laboratory serves as the secondary containment device. The requirements for containment at various levels are based on the assumption that an accidental release of hazardous material might occur and be disseminated to the outside environment. This rarely happens, but the appropriate design and safe operation of the facility will assure that should it happen, the agents would not be released.

A number of documents have been used as references for the pressure-testing requirements. These documents generally are related to the design parameters for existing containment facilities. However, each containment facility is unique in its engineering design, and the design and operation of a new containment facility should not necessarily be inextricably linked to any existing laboratory. A particular document entitled “Annex 9—Recommendations on Air Tightness Standards for BSL-3 Laboratories,” authored by G. W. Pickering in 1982, has been presented by a number of persons as the basis for the requirement to “pressure test” new BSL-3 containment laboratories. This document is now over 20 years old and the pressure-testing conclusions found in it are based on the use of HVAC control strategies which have long since been outdated. However, in spite of its age, the document does correctly maintain that “many PC3 and PC4 research laboratories do not need to meet the same level of air tightness as they are not dealing with animals and all work is performed in biological safety cabinets that act as the primary containment device within the laboratory structure.” The reference document also states that “the leakage evaluation is more relevant to gaseous formaldehyde decontamination than to containment of disease aerosols....” Thus, the basic document upon which the requirements for “air tightness” of containment laboratories are based does not indicate that containment laboratories, even in the 1980s needed to be pressure-tested.

Pressure-testing of the containment laboratory is a difficult, time-consuming, and expensive task requiring a complete sealing of the laboratory space, including doors, ventilation ducts, drains, etc. The exercise results in data that are only valid for the period of time that it is being tested. Since doors, ventilation ducts, and drains must be unsealed for operation, the testing in no way provides any indication of safety under in-use conditions. Certainly, modern
BSL-3 laboratories do not need to be pressure-tested.

While the pressure-testing requirement may have been considered necessary at a time when supply and exhaust fans could not be interlocked and the failure of an exhaust fan could, conceivably, result in inadvertent and unnoticed pressurization of the laboratory, current HVAC control equipment and alarm systems allow for more accurate control of systems and better control of airflow and pressurization. Since the control of directional air flow in sealed spaces is extremely difficult, HVAC systems for BSL-3 containment laboratories should be designed and constructed to react automatically to prevent the facility from accidentally becoming positively pressurized during any type of failure of the system. This requirement can be accomplished in a number of ways using modern HVAC control systems. When building new, or renovating old, containment spaces, the design and operation parameters of containment HVAC systems should be reviewed, prior to finalization of construction documents, by qualified biosafety professionals as well as engineers who have a documented expertise in containment requirements. HVAC supply and exhaust systems must be appropriately designed to insure the integrity of the containment under any failure conditions, and the facility must be certified to have been constructed and to be operated in accordance with the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories* and other applicable guidelines.

At a time when there is an emphasis on the design and construction of biological containment laboratories, and a public perception that these labs can be dangerous to the environment and general public, it is imperative that containment design requirements be as flexible as possible while insuring the integrity of the containment facility. It is important to consider that governments will be asked to regulate the design and construction of these facilities to insure their safe operation. Any governmental regulation of the construction of biological containment laboratories should allow for the use of the most modern technological equipment and should not be so proscriptive as to discourage improvement in the HVAC control equipment and strategies. Any regulatory body required to develop regulations for insuring containment should request input not only from the architects and engineers, but also from trained and knowledgeable biosafety professionals before finalizing any regulations.

**Reference**