U.S. Army Public Health Command (Provisional)

formerly U.S. Army Center for Health Promotion and Preventive Medicine

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Just the Facts...

Biological Safety Cabinets: Certification

Biological Safety Cabinets (BSCs) are the primary containment device used to protect the worker, environment and product from exposure to infectious agents within the laboratory. A properly functioning BSC is essential for working with infectious agents. The Department of the Army's DA-PAM 385-69, Biological Defense Safety Program requires all Class II BSCs to be National Sanitation Foundation (NSF) certified. For an explanation of BSC classes please refer to Fact Sheet, Biological Safety Cabinets: Types. NSF/ANSI Standard 49 defines the tests that all Class II BSCs must comply with to be certified. The standard includes requirements for design, construction and performance in order to provide personnel, product and environmental protection, reliable operation, and durability as well as being easy to clean.

An exhaustive set of tests are performed on each cabinet prior to leaving the factory. In addition, field tests must be performed on each cabinet at the time of installation and at least annually thereafter, whenever the HEPA filters are changed, maintenance repairs made to internal parts or when the cabinets have been moved. Field testing/ certification must be performed by National Sanitation Foundation (NSF) accredited certifiers. Qualifications for the NSF certifiers include; (1) a high school diploma and (2) either 1 year of experience performing field certifications and completion of a training course on bio-safety cabinets or 3 years experience performing field certification tests. The certification examination consists of a 3.5 hour written test followed by an 8 hour practical exam. Students are required to use their own equipment, with appropriate calibration documentation. Students are monitored during the

exam to ensure they are very familiar with their equipment. After passing the exam and obtaining NSF certification individuals must maintain their Certification status by completing a certain minimum number of BSC Field Tests each year.

The following tests are performed by on-site field certifiers. These tests are designed to ensure cabinet integrity as well as proper air inflow, exhaust and distribution within the work space. They are the minimum required tests which must be performed on the BSC for it to be "NSF/ANSI 49 Field Certified". Additional tests are performed at the factory prior to shipment. They include; Electrical leakage, Light intensity, Vibration, Noise level and UV Light check (if UV lighting is used).

- 1. <u>Down-flow velocity test</u>: measures the velocity of air moving through the cabinet.
- 2. <u>Inflow velocity test:</u> measures the velocity through the work access opening.
- 3. <u>Airflow Smoke Patterns test:</u> designed to ensure proper airflow into and within the workspace. The smoke will quickly show any dead spots or air coming out the front workspace rather then the exhaust.
- 4. <u>HEPA filter test</u>: will determine the integrity of the HEPA filters used within the cabinet.
- 5. <u>Cabinet integrity test (A1 cabinets only)</u>: a pressure test to ensure seams, gaskets, seals, etc., are free of leaks.
- 6. <u>Site installation integrity tests</u>: performed to verify that the cabinet is properly integrated into the facility.

More information on the certification testing requirements or the certifier accreditation process, including a list of current NSF certified testers may be found at http://www.nsf.org/business.

The importance of ensuring BSCs are functioning properly cannot be overemphasized. The consequences of using faulty equipment can range from contaminated product and wasted research time to serious illness and/or death of laboratory personnel. Although the NSF/ANSI Standard 49 only applies to Class II BSCs, all cabinets, Class I, II, and III cabinets must be tested and certified at the time of installation, and at least annually thereafter, whenever HEPA filters are changed, maintenance repairs are made or when changes to the surrounding environment are made, such as moving the cabinets or making changes to the rooms exhaust system are made that could effect changes in the cabinet's performance. Some guidelines/requirements may stipulate testing every 6 months (i.e., pharmaceuticals, hazardous drug preparations), check with you local installation/program.

A note on mobile laboratories: Mobile Laboratories present a unique challenge in many ways. Equipment used in today's laboratories is highly sophisticated, sensitive to vibration, temperature and humidity extremes. These labs are often deployed to remote regions with little or no access to equipment manufacturer technical support staff. In cases where NSF certified testers are not available, those chosen to perform the testing should have as many of the certification requirements as possible, (i.e., training, testing, equipment). See NSF website listed above for specific requirements.