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## Biological Safety Cabinet Filter Testing – Lessons from Overseas

One of the primary mechanisms of Class II biological safety cabinet (BSC) performance is filtration, and we all know properly testing HEPA filters is more difficult than it appears. There are two major challenges in HEPA filter leak testing: the uniformity and distribution of the aerosol challenge and the scan rate.

Recently, I had the opportunity to review some international standards.

The method commonly used in North America, and the one with which most of us are familiar, is described in NSF/ANSI 49. It allows the calculation of aerosol concentration using the volumetric flow in cfm or cubic meters per second and one of these formulas:

English units	Metric units
$\frac{\text{_____ } \mu\text{g}}{\text{_____ liter}} = \frac{13,500 \times \text{_____ nozzles}}{\text{_____ ft}^3/\text{minute}}$	$\frac{\text{_____ } \mu\text{g}}{\text{_____ liter}} = \frac{6.37 \times \text{_____ nozzles}}{\text{_____ m}^3/\text{second}}$

Since 2002 NSF/ANSI 49 has required the manufacturer to determine the introduction points to provide uniform distribution of the aerosol within the cabinet. As it turns out, if you introduce the aerosol into one side of a centrifugal (squirrel cage) blower, the aerosol tends to stay on that side of the output. In the traditional Class II BSC with the blower underneath the work surface, if you introduced the aerosol on the right side of the work area, the left side of the downflow blower received very little aerosol. Leaks in that portion of the filter could go undetected.

The NSF/ANSI 49 procedure places the responsibility of ensuring uniform mixing on the certifier and suggests the use of a T-connection on the aerosol generator's output hose. The purpose of the T-connection is to more uniformly distribute the aerosol in the air drawn into the BSC. Ideally, we would like to spread the aerosol over the entire width of both the front and rear grilles. But usually we assume sufficient mixing as the air is drawn or pushed up inside the rear wall of the BSC, so the mixing across the width of the work area is the important factor.

EN 12469:2000 is the European standard specifying the basic requirements for biological safety cabinets. Its filter leak test methods differ from NSF/ANSI 49 in some interesting ways. First, it states to measure the average upstream concentration and does not present the formulas so commonly used in North America. Second, it allows the scanning of filters with a particle counter. Third, it states to determine the scan rate rather than defining the rate as does NSF/ANSI 49.

EN 12469 does not detail how to determine the scan rate but does cite ISO 14644-3 as a reference. ISO 14644-3 is the ISO international standard for cleanroom and controlled environment test methods. The

section on filter leak testing with an aerosol photometer is quite interesting. For our discussion, I would like to list two elements:

- It states to match the probe size and sample velocity to within 20% of the filter velocity
- It states the scan rate in centimeters per second is equal to  $15 \div$  probe width in centimeters.

#### **Scannable filter velocities per ISO 14644-3**

If we assume the 1 cfm ( $4.72 \times 10^{-4} \text{ m}^3/\text{s}$ ) photometer sample rate and 1.7 sq. inch ( $11 \text{ cm}^2$ ) probe opening described by NSF, we calculate a probe sample velocity of 85 fpm (0.43 m/s). The requirement to match within 20% of the probe sample velocity, we can handle the scan of filter velocities from 68 to 102 fpm (0.34 to 0.52 m/s) per ISO 14644-3. Unfortunately, some BSCs have filter exhaust velocities well in excess of the maximum. Some photometers provide different probes for these situations. For example, the black probe tip provided by ATI would allow scanning of filter velocities from 162 to 244 fpm (0.83 to 1.24 m/s).

#### **Scan rate calculation per ISO 14644-3**

The ISO 14644-3 formula assumes the proper aerosol photometer scan rate is approximately 1 square foot per minute. If the probe tip is very wide, the scan rate is slower. If it is narrow, the rate is faster. But regardless of the probe dimensions, the scanning time for a filter will take about 1 minute for every square foot of filter area ( $0.93 \text{ m}^2$ ). The formula provided where you divide 15 by the probe width in centimeters is just their way to get to that.

If we take the 1.7 sq. inch ( $11 \text{ cm}^2$ ) probe opening described by NSF and the minimum dimension of 0.50 inch (1.3 cm), we get a probe width of 3.4 inches (8.6 cm) and a scan rate of 0.68 inches per second (1.7 cm/second). In fact, to get the 2 inches per second scan rate using the ISO 14644-3 formula, we need a probe width of 1.16 inches (4.1 cm).

#### **Are there any good ideas we should apply to NSF methodology?**

It is no surprise that different standards state different things and it is clear the EN 12469/ISO 14644-3 aerosol photometer scan rate is different than that specified by NSF/ANSI 49. Most BSC certifications in North America are on NSF listed cabinets and in some cases are being certified by NSF accredited BSC field certifiers. The expectation and requirement placed on the certifier is to follow the NSF procedures. We should acknowledge that the NSF method is less rigorous.

The issue of matching the probe and filter velocities is less clear. While NSF/ANSI 49 does not specifically address it, the importance of matching the probe intake velocity to the filter velocity is well known. Many photometers provide alternative probe tips with different intake velocities. Properly matching the probe tip to the filter velocity is just using our equipment properly.

#### **What do you think?**

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Best Regards,

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