Feature: **Biosafety**

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A European view

More and more frequently European users of Microbiological Safety Cabinets (MSCs) are being offered "Total Exhaust" or B2 cabinets. These cabinets are described in the American standard, NSF/ANSI 49. This article provides information to the European MSC community, so this type of MSC can be properly understood

TWO commonly referenced standards addressing MSCs are the European standard: EN 12469:2000, and the US standard: NSF/ANSI 49-2007. While there are differences in nomenclature and scope, the standards are in general agreement. One difference is NSF/ANSI 49 sub-categorises the Class II MSC category into four types; A1, A2, B1 and B2. These types reflect differences in the containment and control of gases, not necessarily particulate matter or biological agents.

The Class II MSC as prescribed in EN 12469 is generally equivalent to the NSF/ANSI 49 Class II, Type A2 cabinet. Both cabinets can vent filtered exhaust air into the laboratory or to the outside through an exhaust connection. Class II, Type A2 MSCs have a minimum inflow velocity requirement of 0.51m/s while EN 12469 has a minimum of 0.4m/s. Neither EN 12469 nor NSF/ANSI 49 A2 cabinets are allowed to have potentially contaminated positively pressurised plenums on the outer wall of the cabinet. Plenums are spaces or compartments within the MSC. As air is pushed or pulled through the MSC, these plenums become either positively pressurised (with air tending to leak out) or negatively pressurised (with air tending to leak in). Plenums within the MSC are also considered either "potentially contaminated" or "not potentially contaminated". Both the EN and the NSF MSCs require that all potentially contaminated positively pressurised plenums are surrounded by a negatively pressurised plenum to ensure that no hazard leaks into the environment.

Both the EN 12469 Class II and the NSF/ANSI 49 Class II, Type A2 cabinets have recirculation of air within the cabinet. Using the Thermo Scientific MSC-Advantage as a depiction of this, Figure 1 shows a schematic of an MSC with an inflow of 494m^3/h and a downflow of 808m^3/h. Any contaminant released into the sample chamber will be diluted first into the 808m^3/h of air flowing from the downflow filters. As this air is captured by the front and rear intake grills and pulled out of the sample chamber, it mixes further with the 494m^3/h of air drawn into the front aperture of the cabinet. The resulting 1302m^3/h of air travels into the motor plenum above the sample chamber where 494m^3/h (40%) is expelled through the exhaust filter and the remaining 808m^3/h are pushed through the downflow filter back into the sample chamber. This process occurs once every 4 seconds, or a minimum of 15 times a minute.

There is no EN 12469 equivalent to the NSF/ANSI 49 Class II, Type B2 cabinet, which has no recirculation within the sample chamber whatsoever. As shown in Figure 2 - downflow air is drawn into the cabinet through a separate opening at the top of the cabinet and is pushed through the downflow filter into the sample chamber. Any contaminant released into the sample chamber is captured by the front and rear intake grills and is pulled out of the sample chamber. It mixes with the air drawn into the front aperture of the cabinet and captured by the front grill. All of the air pulled from the sample chamber (downflow) and all of the air pulled in the front aperture (inflow) is pulled through the exhaust filter and through the exhaust duct and expelled from the building.

The B2 MSC offers two unique attributes compared to the NSF/ANSI A2 and the EN 12469 Class II MSC. First, it has no recirculation within the sample chamber. While a Class II MSC connected to an external exhaust also expels all air from the cabinet from the building, it recirculates some air within the sample chamber. In the B2 cabinet, all of the gas is immediately exhausted while in the EN 12469 MSC it is diluted and exhausted over a small period of time. Using the airflows from the EN 12469 Class II MSC in Figure 3, if one litre of a gas is released into the sample chamber, it would be reduced to a concentration 1 part per million (ppm) in 1 minute, 1 part per billion (ppb) at 2 minutes and 0.5 parts per trillion at 3 minutes. This small amount of recirculation and rapid dilution makes the sample chamber recirculation in an EN 12469 Class II MSC acceptable for most applications.

Secondly, there may be guidelines requiring different types of cabinets for the amount of chemicals to be used. The recommendation within NSF/ANSI 49 for canopy or thimble connected A2 MSCs suggests minute quantities of volatile toxic chemicals and tracer amounts of radionuclides required as an adjunct to the microbiological work can be used. Figure 3 is a diagram of a Class II MSC with a thimble connection. The opening to the room in the connection between the MSC and the external exhaust allows the MSC to maintain proper flow and containment of cabinet exhaust even with some variation in the external exhaust. The NSF/ANSI 49 recommendation for the B2 MSCs does not restrict the amounts to "minute" or "tracer" but still limits the chemicals and radionuclides to only those "required as an adjunct to the microbiological work".

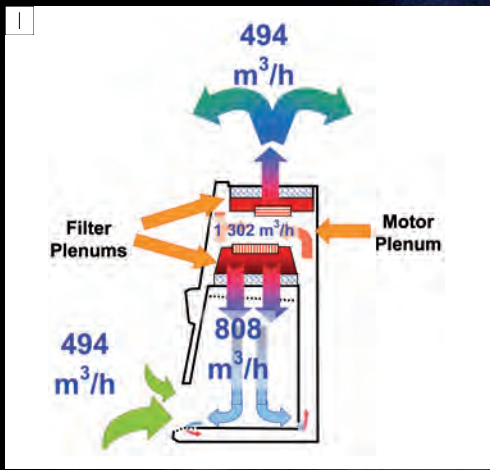

Figure 1: Class II MSC

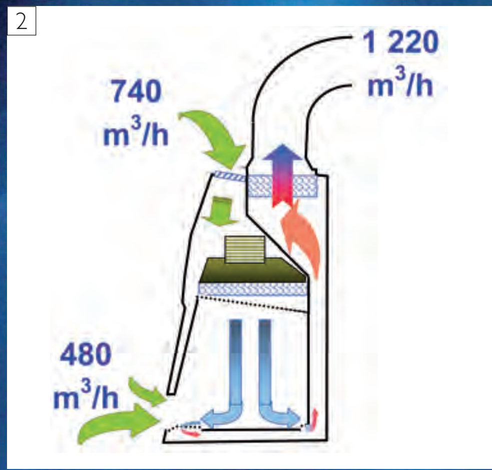

Figure 2: Class II, type B2 MSC

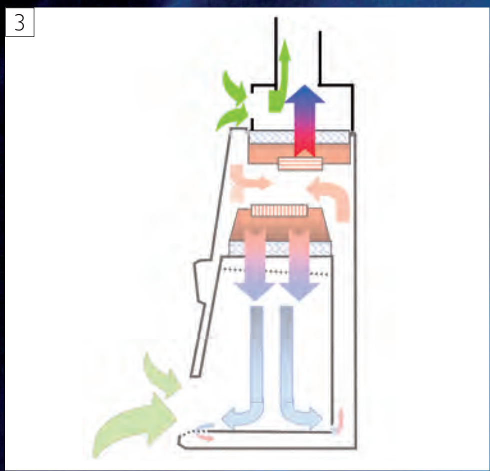

Figure 3: Thimble connection

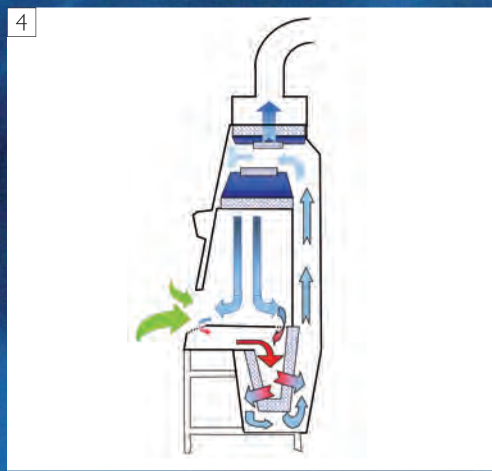

Figure 4: Triple filter Class II MSC

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The usage recommendations provided in NSF/ANSI 49 can be misleading as they are provided with no discussion of the costs and difficulties in operating a B2. Let us consider these costs and difficulties so we can more effectively match the class and type of MSC to the application.

Using the 1.2m Thermo Scientific 1300 Series B2 MSC shown in Figure 2 as an example of general B2 design, 740m^3/h is drawn from the room into the cabinet's downflow fan and pushed through the downflow filter into the sample chamber at an average velocity of 0.28m/s. This cabinet relies on its connection to an external exhaust to operate. This external exhaust fan pulls 1220m^3/h through the exhaust filter. 740m^3/h of this amount comes from the downflow air entering the sample chamber. The remaining 480m^3/h comes through the front aperture and establishes the inflow velocity of 0.53m/s necessary to protect the MSC user from potential contaminants escaping the sample chamber.

Note the inflow velocity is a by-product of the downflow and exhaust flow. If the exhaust varies, the inflow is affected, since the downflow remains stable. Changes in exhaust are magnified in the inflow – exhaust variation as little as 5% can cause a 13% change in inflow. Such variances are very common due to the cabinet's dependence on roof blowers. Exhaust filter loading and fan maintenance can allow variations. Drive belts of exhaust fans may wear and slip or require adjustment. The automatic valves controlling the distribution of flow through combined exhaust systems have maintenance requirements and imperfect precision. Unlike the stand alone Class II MSC venting the filtered exhaust into the laboratory, the B2 cabinet is a small part of a complex airflow system. The B2 inflow can vary as a result of almost everything impacting the building ventilation systems.

A comparable EN 12469 Class II MSC connected to an external exhaust with a canopy or thimble connection can maintain the proper inflow with variations in the external exhaust as great as 20 to 25% while continuing to capture any non-particulate hazards such as gas contained in the MSC exhaust.

By definition, the Class II MSC provides protection to the user, the product and the environment. Protection to the user is provided by sufficient and steady inward flow of air. Simply put, in a B2, exhaust variation can compromise user protection.

Exhausting air in a lab costs money. Every cubic metre of air expelled from a laboratory is replaced with air from the outside environment. This outside air may require filtration, heating or cooling and treatment for humidity. This consumes energy and resources. Mills and Sartor estimated the annual cost of approximately $4.50 USD per cubic foot of air per minute or about €2 per m^3/h of exhaust per year. The exhaust requirement of 1220m^3/h for the 1.2m wide Class II, Type B2 MSC could cost the user €2 440 per year in additional ventilation expense.

While providing the advantage of no recirculation within the work chamber and immediate exhaust of any gaseous materials from the sample chamber, the B2 MSC requires additional ventilation and expense and is more vulnerable to exhaust variation. In contrast, the European style Class II MSC canopy connected to external exhaust will provide biological containment while working with small amounts of volatile toxic chemicals and tracer amounts of radionuclides with a significantly lower ventilation requirement, lower overall cost and much greater tolerance of external exhaust variation. The NSF/ANSI 49 Class II, Type B2 MSC does offer benefits for some applications, but the costs and compromises are significant and must be considered when selecting a Class II MSC. **LN**

The German Standard DIN 12980 which addresses safety cabinets for handling Cytotoxic drugs includes the requirement that the MSC provide for the safe replacement of filters contaminated with cytotoxic drugs. The biological decontamination methods ordinarily used with MSCs prior to filter replacement have no effect on these hazardous chemicals. One of the major methods described in the standard to achieve safe replacement is the triple filter MSC shown in Figure 4. Note how hazardous particles are captured in the primary HEPA filter below the work surface, leaving the remaining filters, plenums and fans essentially free of contaminants.

In contrast, the US National Institute for Occupational Safety and Health does not address the difficulties in filter replacement and service but instead seeks to minimise even the slightest opportunity for any gases released in the preparation of hazardous drugs to linger in the sample chamber by preferring a B2 MSC or isolator unless assured the drugs cannot volatilise. So while Europe promotes safe preparation of hazardous drugs by connecting the MSCs to external exhaust and providing for the safe completion of the inevitable filter replacement, the US adds exhaust and recirculation requirements but does not address safe filter replacement.

REFERENCES

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