Exhaust Options Available for a Class II Biological Safety Cabinet (EN 12469)

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Key Words
Biological Safety Cabinet, BSC, Class II, EN 12469, exhaust, Thermo Scientific

Introduction

Biological Safety Cabinets (BSCs) or microbiological safety cabinets are available in various classes dependent on application.

The Class II BSC (also known as the Class II, Type A2 BSC under NSF49 terminology), is globally the most common type of BSC in use. It is estimated that around 95% of all BSCs installed in the world today are Class II BSCs.[1] A Class II BSC is the most versatile and economical cabinet available. It is designed to protect from biological hazards and offer a sterile work area while also protecting the environment.

The Class II BSC is available in three options of exhaust. It can be either recirculating, thimble ducted, or direct ducted. The purpose of this application note is to provide information on how these exhaust options work and suggestions on selecting an exhaust type. This will assist lab planners, construction companies, architects and engineers on choosing which type of BSC will suit their application.

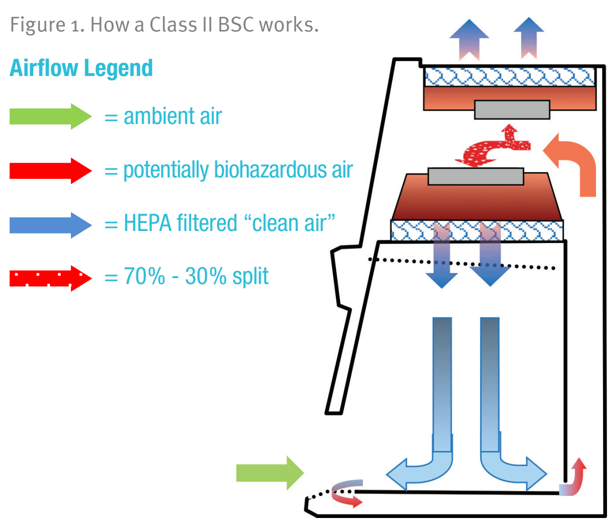
Class II Biological Safety Cabinets How it works

EN12469 certification definition: Safety Cabinet with a front aperture through which the operator can carry out manipulations inside the cabinet and which is constructed so that the worker is protected, the risk of sample and cross contamination is low and the escape of airborne particulate contamination generated within the cabinet is controlled by means of an appropriate filtered internal airflow of the exhaust air.[2]

Note: A typical way of achieving this is by means of a uni-directional downward (laminar) airflow inside the cabinet and an air-curtain at the front aperture.

A biological safety cabinet will take air from the room, at the front aperture. The air being drawn in at the front aperture must be ≥0.40m/s as per EN12469 standard. This is the basis of containment, and this "inflow" air is what creates the air barrier, or curtain, at the aperture. Downflow air is pushed through a HEPA filter by a fan/motor. This is known as unidirectional airflow. According to EN12469, the average downflow velocity must be between 0.25m/s and 0.50m/s. This sterile air is what protects the product inside of the cabinet. Once the downflow air hits the work surface it will split, with 50% going to the back grill of the work area, and the other 50% going to the front grill in the work area. The air that goes to the front grill then hits the inflow air and is pushed downwards into the front grill, creating the air barrier, or curtain, that protects the user. All of this air will then pass up into the downflow plenum and split. Approximately 70% of the air will be "recycled" via the downflow fan, and will be pushed back through the downflow HEPA filter. The remaining 30% will be pushed out through the exhaust HEPA filter. This filtered exhaust air is then expelled back into the laboratory. Alternatively, it can be pushed into a ducted exhaust system to outside air. All the exhausted air is clean, filtered air.

Figure 1. How a Class II BSC works.



BSC Class	Protection Offered	Biological Safety Level
II	Personnel, sample, environment	1-3 Suitable for working with moderate to severe potential hazards

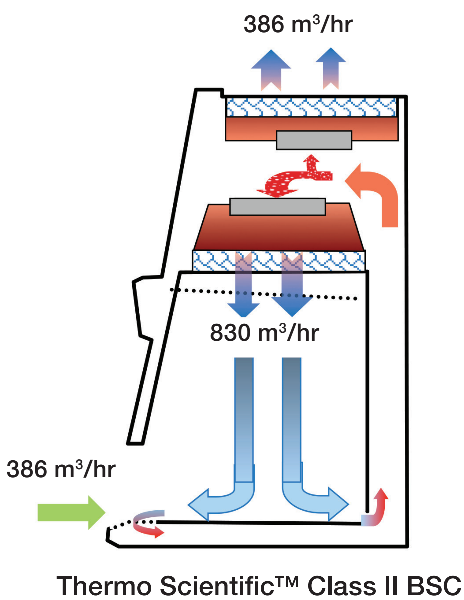
Types of Exhaust

Recirculating

The most common way to exhaust air is by recirculating. The BSC takes air from the room via the front aperture and then exhausts the same volume of HEPA filtered clean air back into the room. The principle is simple: what goes in, must come out.

Figure 2. Recirculating 1.2m Class II BSC with air volumes.

NOTE: Under United Kingdom guidelines, when installing a BSC into a Containment Level 3 laboratory, it is recommended that the BSCs are ducted out to atmosphere. If this proves difficult, then a recirculating BSC can be used but with double exhaust HEPA filtration.



Because recirculating BSCs move the air back into the room, this makes them more energy efficient than a thimble or a direct ducted system.

HEPA filters are fundamental to the safe and efficient working of any BSC. They capture and trap particulate matter very effectively, most importantly contaminated airborne biological agents. The HEPA traps and "filters" the contaminated particles, exhausting clean air. Class II BSCs use H14 HEPA filters. A H14 HEPA filter will capture 99.995% of the Most Penetrating Particle Size (MPPS), which is the size that it is least effective at capturing (for example, 0.3 μm). This will give a work area clean zone classification of at least ISO Class 5. HEPA filters actually get more efficient as they load over time.

However, HEPA filters have a weakness. They are unable to handle volatile, toxic or nuisance gases. Therefore any use of toxic gas or chemicals in a recirculating BSC is strictly prohibited. Whatever gas or chemical is in the work area will be exhausted straight back in to the laboratory, exposing lab personnel to potentially hazardous vapors. Exhaust HEPA filtration only removes airborne aerosols and particulates including biohazards, but not chemical fumes. If small amounts of chemicals are to be used in a recirculating BSC and if approved by safety personnel, then a carbon filter can be installed via the exhaust HEPA filter.

As per EN12469, a recirculating BSC is now permitted to be used with a single exhaust HEPA filter. This is different than the now obsolete BS5726 (parts 1 and 3 which EN12469 replaced). The British Standard stated that recirculating BSCs must have double exhaust HEPA filtration. The EN12469 has superseded this; however in some institutes, particularly in the United Kingdom and other parts of Northern Europe, it is still common practice to specify double exhaust HEPA on recirculating BSCs. At this point, there are arguments for and against the use of double exhaust HEPA filtration. One of the main points against the use of an additional or double exhaust HEPA filter is that a Class II BSC is an open fronted device. While microbiological and KI Discus[3] containment testing demonstrate high degrees of containment at the front opening, there is the potential for particulates to escape from the workspace opening. The exhaust HEPA filter will be H14 (99.995% efficient at MPPS), so adding another exhaust filter may not make a difference since there is potential for leakage at the front aperture anyway.

Total cost of ownership is important, and sometimes overlooked, when selecting the correct exhaust configuration for a BSC. An extra exhaust HEPA filter on the BSC will increase total cost of ownership because: the BSC will use more electricity, the fan(s) will have to work harder, the BSC will take longer to test, and the cost for the extra filter. The correct choice for your lab should be based on your application together with a risk assessment.

Siting of a recirculating BSC also requires good planning. It is important to note that you will be exhausting air back into the room. Exhaust air can create turbulence. If you have other BSCs in the room, this may potentially cause airflow problems for them. A simple smoke pattern test can help you get an accurate picture of how the air is moving in the room. Different BSC models and design will exhaust air at different velocities. Exhaust air and velocity are dependent on various parameters. For example, HEPA filter size and airflow velocity design will determine exhaust velocity rate. Additionally, the standard practice of locating a BSC away from doorways, air conditioning, human traffic and other laboratory equipment must also be considered. BS 5726 parts 2 and 4 (which were recommendations and are not superseded by EN12469) can be useful in helping you with location decisions.

A recirculating BSC should not be used:

- If volatile or toxic chemicals are to be used in the BSC, unless there is an approved carbon filter added.
- When cytotoxic material is being used in the BSC.
- If there is a need for regular fumigation and there is no means in which to purge the fumes into atmosphere.
- When prohibited by local guidelines, regulations or risk assessment, for example in a Containment Level 3 laboratory in the United Kingdom. Though in that situation, recirculating with a double exhaust HEPA filtration system is acceptable.

Thimble

Thimble extract exhaust systems are becoming very common around the globe; they are the most common form of ducted BSCs. There are many advantages to this type of system when compared to a direct duct system; these will be highlighted a little later in this document.

All thimble BSC exhaust systems essentially work to the same principles. Based on internal testing, they typically have a 15%-30% higher extract rate than the BSC extract air volume. This ensures full capture of all exhaust air from the BSC. Thimble exhaust systems will normally run on a 24/7 basis. Therefore, air is being extracted from the laboratory all of the time. Because of this, thimble exhaust is popular when negative pressure in the laboratory is required. Thimble systems achieve this irrespective of whether the BSC is switched on or off.

For example, (based on a Thermo Scientific™ 1.2m BSC), when the BSC is switched on and is in operation, it has an inflow/exhaust volume of 386m³/hr. The thimble exhaust system is extracting or "pulling" 15% more than the BSC. Because of this, full capture of all HEPA filtered air from the BSC is achieved. With the added 15%, the full amount of air leaving the laboratory is 444m³/hr.

When the BSC is switched off, the full amount of air (444m³/hr) is extracted via the thimble. None is extracted via the front aperture of the BSC. So whether the BSC is on or off, the same amount of air is extracted: in this case, 444m³/hr. However, it should be noted that laboratory air extracted via the thimble is not HEPA filtered.

Finally, if the building exhaust system (external fan) should fail while the BSC is in operation, all air would be extracted back into the room via the exhaust HEPA filter of the BSC. This extracted air would be safe since it passed through a HEPA filter ensuring personnel protection has not been compromised.

Figure 3 shows a typical thimble setup for a Thermo Scientific™ Safe 2020 1.2m biological safety cabinet.

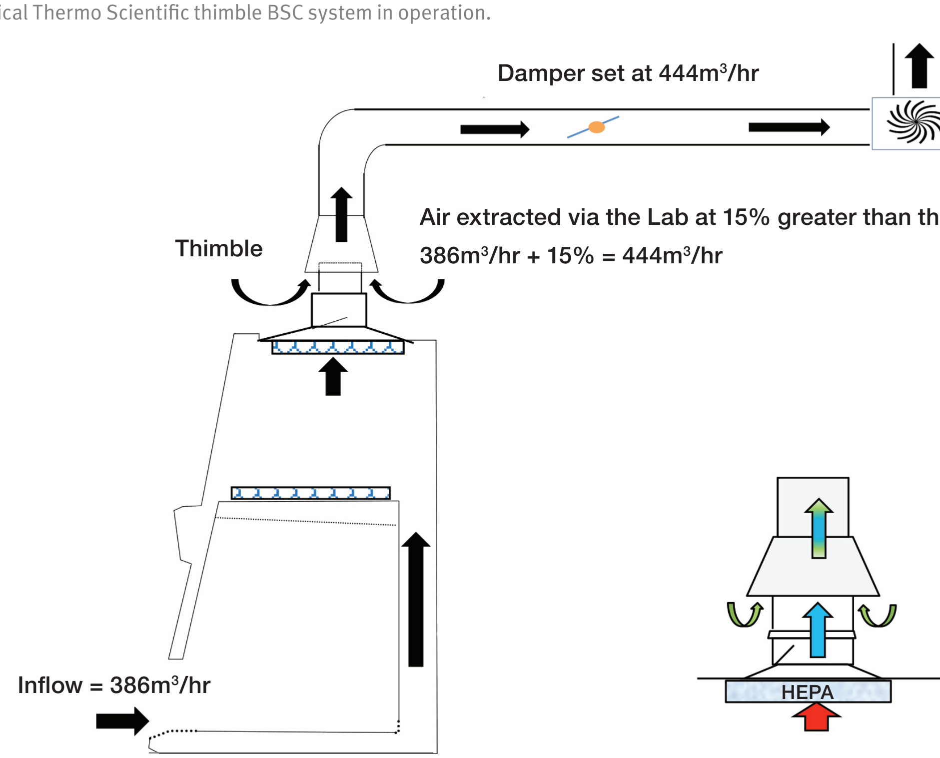
Applications and advantages

Because all inflow air is exhausted into the atmosphere, unlike a recirculating BSC, volatile toxic chemicals may be used within the thimble extract exhausted BSC. Of course this is subject to the chemicals used and also to local and country specific regulations. In addition, a full risk assessment should be performed by the responsible safety officer on site.

Another advantage of using this type of exhaust system is that room pressure is constantly maintained, whether the cabinet is in operation or switched off. This is advantageous where there is a requirement for the room or laboratory to be under constant negative pressure. There is no need for bypass systems or dampers to be installed. However, considerations must be made to the supply or make up air for the room. This can be achieved either by a passive system, whereby the air supply for the room is taken from a supply grill within the door, such that the air is then scavenged from surrounding areas, and fed to the cabinet and thimble extract. More commonly, an active system is used, whereby ventilation is incorporated into the laboratory via an air conditioning unit or supply air grill. Active systems, on the whole, are more expensive and ultimately the conditioned air will be expelled to atmosphere.

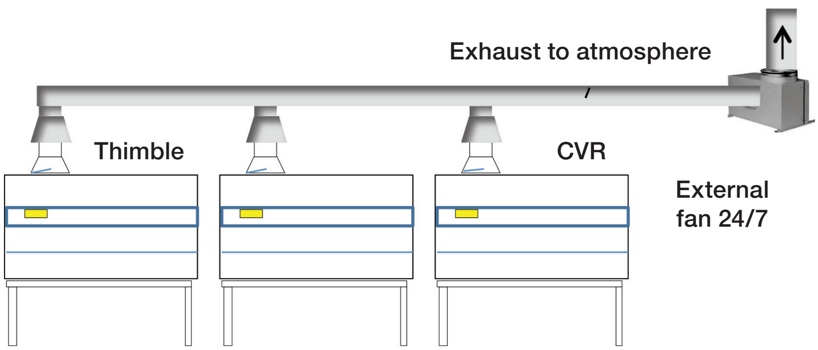
Connecting multiple biological safety cabinets to one thimble system is also possible. It is common to see up to four BSCs on one common extract with a single exhaust fan. This is an attractive design feature that can simplify building HVAC systems, and ultimately can result in significant cost savings in relation to energy, materials and installation costs. See Figure 4.

Figure 3. A typical Thermo Scientific thimble BSC system in operation.



Although a thimble exhaust is commonly referred to as a ducted installation, its behavior is somewhat different to a traditional hard ducted install. Because there is an "air gap" otherwise known as an "air break" at the exhaust point, this virtually eliminates issues with static pressure fluctuations within the plant extract system. These fluctuations typically happen on hard ducted design systems when multiple BSCs are sharing the same exhaust fan. Weather conditions can also affect static pressure within the duct. Pressure fluctuations can also stem from the laboratory. An example of this is when the laboratory door is opened and closed. A correctly installed thimble system with a constant volume damper (CVR), together with a correctly commissioned BSC, will comfortably handle fluctuations in pressure and not compromise safety to samples or personnel.

Figure 4. Multiple BSCs on a thimble system.



A Thimble exhaust BSC should not be used:

- If large amounts of volatile or toxic chemicals are to be used in the BSC.
- If not permitted by local guidelines and regulations or the risk assessment.
- If makeup air or passive air systems are not in place and made available to supply the cabinet and system with air.

Direct Duct

This method of exhaust is becoming less frequently used, due to the popularity of the thimble system.[4] However, it still certainly has a place in the BSC industry, mainly in Europe, and particularly in Northern European countries such as Norway, Sweden and the United Kingdom.

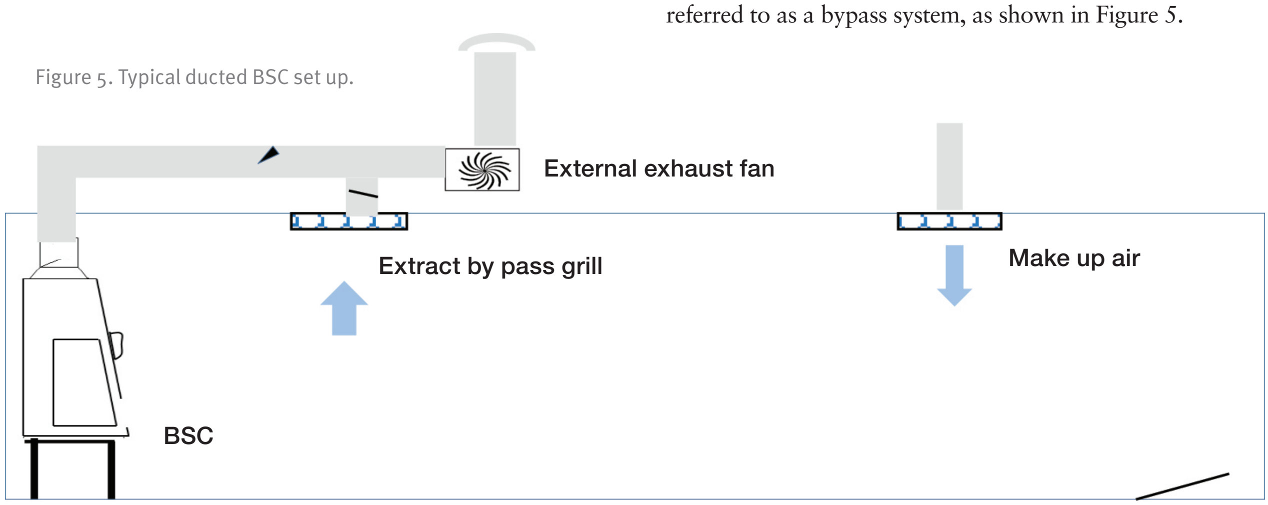
An important point to note is that NSF/ANSI 49, the United States standard for BSCs, has outlawed direct duct exhaust connection.[5] Any Class II, Type A2 BSC that has this system in place is non-compliant to NSF/ANSI 49. The European standard EN 12469 does allow the use of direct ducted exhaust for BSC and is not affected by the change with NSF/ANSI 49.

Different considerations must be taken into account when comparing recirculating and thimble extracts. This is because direct ducted cabinets behave differently, and are influenced by other factors. The main principles for a BSC ducted exhaust system is that it must be treated as a complete air handling system, together with other forms of air handling mechanisms for each facility.

A direct ducted BSC works by taking air from the room or laboratory, via the front aperture, then expelling it direct to atmosphere. All air exhausted to the atmosphere is clean air, as it would have passed through the BSC's HEPA filter system. Because this type of exhaust is a "closed system" and there are no "air breaks" like there are with a thimble, fluctuations within the ducting can take place. These fluctuations within the duct can have an adverse effect on the performance and safety of the BSC. Because of pressure differentials within the duct and the room where the BSC is located, the BSC behaves relative to the room conditions. If the room pressure is increased, then the cabinet pressure will also increase and vice versa. These different states of conditions must be controlled with extract grills and possibly with bypass or variable air volume (VAV) dampers.

For example, if the BSC is exhausting 386m^3/hr of air from a lab when in operation, when the BSC is switched off there will be reduced air leaving the room, as the building extract system is no longer being "helped" by the BSC's fan. In some configurations, switching the BSC off closes an exhaust damper above the BSC so no air will be drawn from the room. If the lab needs to be kept at a stable and constant pressure and also has a required pressure regime to maintain, then an extraction grill would need to be in place to keep the pressure constant and stable in the lab when the BSC is off. When the BSC is switched on again, the airflow drawn through the extract grill would be reduced, or not extract, via a shut-off damper linked to the BSC. This can be all incorporated into the duct install and is commonly referred to as a bypass system, as shown in Figure 5.

Figure 5. Typical ducted BSC set up.



Make up air to supply the ducted BSC is also of paramount importance. Just like the thimble system, this can be incorporated via a passive or active system. The active system is more common and a HEPA filtered supply grill within the lab is normal.

Connecting a ducted BSC on to a multiple exhaust installation can be difficult. As described earlier, pressure fluctuations within the ducting system can cause issues with airflow and containment of the BSC. In particular, when a BSC is switched off, it will affect other BSCs on that system. This can be controlled and managed with VAV dampers, but where use of a direct ducted Class II BSC is permitted and is selected by the user, Thermo Fisher Scientific recommends having a single BSC on a dedicated duct with its own exhaust fan with regular testing and maintenance by qualified service engineers.

Applications and advantages

This type of extract is preferred for some regions and applications when pressures are critical to the laboratory, for example in a Category Level 3 laboratory (as per ACDP).[6] The BSC and extract can be incorporated into the HVAC design,and assist in keeping a negative pressure within the laboratory.

Also, the use of a small amount of trace chemicals inside this ducted BSC is allowed, depending on which chemicals are used. A full risk assessment of chemical use should be standard practice.

If fumigation is performed on a regular basis, a direct ducted BSC should be considered. Purging formaldehyde or aeration of H_2O_2 can be easily achieved and exhausted directly to the atmosphere with a direct ducted BSC. Use of dampers, shut off valves and other isolation methods should also be considered. Any extraction to atmosphere is subject to country and local regulations.

As with any type of ducted containment device, there are caveats to a ducted Class II BSC, including:

- High start up cost
- Ductwork, external fan, damper installation
- Susceptiblity to change in room pressure
- Susceptiblity to weather conditions
- High running cost
- Extraction of air from the lab that needs to be replaced
- High energy consumption
- Higher carbon footprint than a recirculating or thimble exhaust

Is a ducted BSC safer than a recirculating BSC?

Sometimes a ducted Class II BSC is perceived to be safer than a non-ducted device, but this is not correct.

Application and materials used within the BSC will determine whether you need a ducted or recirculating BSC. But both offer the same level of biological safety to the operator, and it is important to remember both are prone to the same potential issues of breach of containment. Human traffic, air conditioning, air supply diffusers, doors opening and closing and potentially poor operator techniques will have a detrimental effect on aperture efficiency on Class II BSCs.

One of the most common myths is the assumption that because a ducted BSC expels air into atmosphere, it compensates for the risk of any leakage on the exhaust HEPA filter. Thus, a more costly ducted cabinet would be specified rather than a recirculating type. It is important to recognize that a Class II BSC is an open fronted device. Therefore, we accept that there can and will be leakage from the front aperture. This is seen, proven and measured by performing either a KI Discus test or microbiological test. These tests are known as front aperture retention efficiency tests. In many instances, it is overlooked that there can be leakage from the front aperture. This potential leakage is comparable to any leakage that may happen with an exhaust HEPA filter. This logic can also be applied to the use of adding an additional HEPA filter to the exhaust. Does it make sense to do this - dual exhaust HEPA filters, when there is potential for leaks at the front aperture? Risk assessments, country specific standards, and local regulation should be adhered to.

What type of BSC exhaust do you require?

In most instances a recirculating Class II BSC will be sufficient. If you are not working with chemicals, and rarely need to fumigate or decontaminate, then recirculating is a sufficient option. One application for this would be tissue culture. If there is a need for fumigation, either the service engineer will have appropriate equipment or if the operator fumigates regularly as a part of their own practices, most manufactures will offer a variety of accessories and options to deal with this on a recirculating BSC. As mentioned previously, in some regions there is also the ability to introduce carbon filtration in addition to HEPA filtration to handle minute quantities of chemicals if required.

If a BSC is required to help maintain room pressures, volatile toxic chemicals are to be used within the BSC, or fumigation is completed on a regular basis, you should consider direct or thimble ducted BSCs. Additionally, careful planning should be given to factors including: ducting installation, space contingencies, atmosphere extraction, exhaust ventilation regulations and compliance, and the effect of the lab and the surrounding areas.

Standards

Understanding the standard specific to your country is important.

NSF/ANSI 49 is a very robust standard. It does not recognise the use of direct ducted Class II, Type A2 BSC. This is because it deems the use of thimble (also referred to as a “canopy”) to be far superior in handling exhaust fluctuations in the duct. Another recent change to NSF/ANSI 49 concerns the use of BSCs on thimble systems. It now states that an alarm must be present to determine any air exhaust failure from the external fan. This alarm must be activated within 15 seconds of external fan failure. In addition the BSC fans must continuously operate.

EN12469 is arguably less robust than the NSF/ANSI 49 when it comes to exhaust options for BSC. It briefly mentions the use of external exhaust and states it is mandatory to use a visible anti-blowback damper when exhausting to atmosphere, but what it fails to do is define direct duct or thimble. The standard moves slightly away from the hard and fast mandatory regulations of old, and puts more of an emphasis on risk assessment and input from manufacturers and specialists in the industry.

DIN12980 Cytotoxic manipulations within a Class II BSC are permissible. This is in accordance to DIN12980, which is the standard associated with cytotoxic handling within a Class II BSC[7]. These Class II BSCs are used for cytotoxic manipulations and have an added set of "safe change" HEPA filters directly under the work surface. DIN 12980 recommends that BSC used for this application must be of the ducted type.

Summary

A Class II BSC is a complex device. There are many parameters and different factors and variables that can affect its performance, efficiency and ultimately safety. This application note has focused on one specific factor, exhaust air. There are many other factors that make a Class II BSC safe. HEPA filtration, airflow control including downflow and inflow, compliance to standards, alarms, testing and validation all contribute to its safety. Compromising any one of these factors can compromise the safety of the BSC.

Since the days of BS5726 , NF X 44-201, and DIN 12950 and the other country specific BSC standards, technology in BSCs has dramatically changed over the last 10 years. Manufacturers of BSCs have significantly benefitted from DC motor technology, HEPA filter technology, ergonomics, design, and construction. These together with the harmonized European standard EN12469 and U.S. standard NSF/ANSI 49, make a fully compliant BSC safer now than ever.

With constant awareness, education and assessment, risk that is associated with these devices can be controlled and calculated. But in the end, safety is the most important factor to the millions of daily users of BSCs.

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