

How to comply with CDC Guidelines

OVERVIEW

Sections of text are extracted directly from the Federal Register Vol. 59, No. 208, 10/28194, to compile this pamphlet.

This is not meant to be a substitute for the Guidelines, but a general overview of specific sections relevant to Biological Controls and its products.

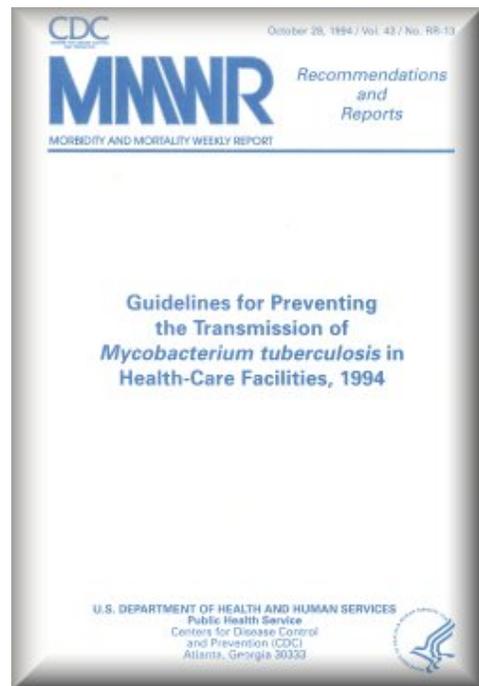
To purchase a complete copy of the CDC Guidelines, call the Superintendent of Documents, GPO, (202) 783-3238.

OUR MISSION

We believe, once you understand the new CDC guidelines, you'll understand why our products offer you the best means of compliance. This is based upon a design philosophy that each piece of equipment is designed to satisfy a particular problem, and each problem can be satisfied by an individual or combination of products that complement each other.

CDC ON NEGATIVE PRESSURE

"To control the direction of airflow between the room and adjacent areas, thereby preventing contaminated air from escaping from the room into other areas of the facility. The direction of air flow is controlled by creating a lower (negative) pressure in the area into which the flow of air is desired. For air to flow from one area to another, the air pressure in the two areas must be different. Air will flow from a higher pressure area to a lower pressure area. "



HOW BIOLOGICAL CONTROLS CREATES NEGATIVE PRESSURE

Our **MICROCON**® **EX** series, consisting of the **EX-BB**, **EX-BUV**, **ExC-BB**, and **ExC-BUV**, utilize HEPA filtration UV (option) for various room exhaust options. Wall, window or ceiling mounted, they direct air to either outside, back to return air system or corridor. Installation is quick, operation is economical, and maintenance is easy and safe. Monitor each room with the **ACCUSTAT** pressure monitor by adjusting some models to automatically maintain exhaust requirements. The **EX** series is better suited than costly engineering controls.

CDC ON MONITORING NEGATIVE PRESSURE ROOMS

"Differential pressure-sensing devices can be used to monitor negative pressure; they can provide either periodic (non-continuous) pressure measurements or continuous pressure monitoring. The continuous monitoring component may simply be a visible and/or audible warning signal that air pressure is low. In addition, it may also provide a pressure readout signal, which can be recorded for later verification or used to automatically adjust the facility's ventilation control system."

"Pressure-sensing devices should incorporate an audible warning with a time delay to indicate that a door is open. When the door to the room is opened, the negative pressure will decrease. The time delayed signal should allow sufficient time for persons to enter or leave the room without activating the audible warning."

HOW BIOLOGICAL CONTROLS MONITORS NEGATIVE PRESSURE ROOMS

The **ACCUSTAT** was designed as a room pressure differential monitor that measures both positive and negative pressure. It will compare the room pressure to that of the corridor and maintain an accuracy of .001 inches WG (water gauge) as identified on a large digital readout. User set alarm function warns visually and/or audibly of a room not in compliance after a one minute "false alarm" cycle has been triggered. Has locking key switch controls for on/off and negative/positive selections. Remote monitoring capabilities are available, as well as interfacing with building management systems. Two models are available, a stationary mount and a rechargeable battery operated portable.

ACCUSTAT

- accuracy to 0.001 "WG
- user set alarm points
- audible and visual alarms
- one minute delay alarm signal large digital readout
- remote monitoring capabilities on/off locking key switch stationary and portable
- measures positive negative pressure interfaces with Building Management Systems

Rooms not maintaining proper pressure differentials can be equipped with **MICROCON EX** series units which enhance room exhaust between 100 and 450 CFM, thereby providing adequate pressure differentials. Some units can also be tied to the **ACCUSTAT**. If the room pressurization reaches the pre-set alarm setting, a signal from the **ACCUSTAT** will increase the exhaust capacity of the exhaust unit. A five minute cycle repeats until the pressure condition is corrected. This is of critical importance since room pressure can vary throughout the day based upon HVAC and other operational factors.

CDC ON HEPA FILTRATION

HEPA filtration can be used as a method of air cleaning that supplements other recommended ventilation measures. HEPA filters are defined as air-cleaning devices that have a demonstrated and documented minimum removal efficiency of 99.97% of particles greater than or equal to 0.3 um in diameter. HEPA filters have shown to be effective in reducing the concentration of Aspergillus spores (which range in size from 1.5 um to 6 um) to below measurable levels (100- 02). The ability of HEPA filters to remove bacilli from the air has not been studied, however, M tuberculosis droplet nuclei probably range from 1 um to 5 um in diameter (i.e. approximately the same size as Aspergillus spores). Therefore, HEPA filters can be expected to remove infectious droplet nuclei from contaminated air. HEPA filters can be used to clean air before exhausting outside recirculated to other areas of the facility, or recirculated within a room.

HEPA Filter Cube

- minimum efficiency 99.97% on .03 microns
- certified HEPA filter
- bag-out filter change
- fool-proof, leak-free filter change
- unexposed primary filter

WHAT BIOLOGICAL CONTROLS' HEPA SYSTEMS DELIVER

CDC recognizes that HEPA filtration can play an important part in airborne TB controls. Our entire line of products utilizes HEPA filters as a primary means of airborne infectious bacteria capture. We provide certification and documentation on all our filter units. Our patented design of breathing zone filtration (BZF) and **CIRCUMFLOW®** airflow pattern provides a system unavailable elsewhere. Our BZF design is based upon the source or control capture concept. *CDC says, "Source control techniques can prevent or reduce the spread of infectious droplet nuclei into the general air circulation by entrapping infectious droplet nuclei as they are being emitted by the patient (i.e. source)."*

CDC ON IN-ROOM (PORTABLE) SYSTEMS

"Portable HEPA filtration units may be considered for recirculating air within rooms in which there is not general ventilation system, where the system is incapable of providing adequate airflow, or where an increase in ventilation is desired without affecting the fresh air supply or negative pressure system already in place. Effectiveness depends on circulating as much of the air in the room as possible through the HEPA filter, which may be difficult to achieve and evaluate. "

“As an alternate is the use of HEPA filtration units that are mounted on the wall or ceiling of the room if portable units are used; caution should be exercised to ensure they can recirculate all or nearly all the room air through the HEPA filter. Some commercially available units may not be able to meet this requirement because of design limitations or insufficient airflow capacity. In addition, units should be designed and operated to ensure that persons in the room cannot interfere with or otherwise compromise the functioning of the unit. ”

“Portable HEPA filtration units should be designed to achieve the equivalent of ~12 ACH. They should also be designed to ensure adequate air mixing in all areas of the hospital rooms in which they are used, and they should not interfere with the current ventilation system. ”

WHAT BIOLOGICAL CONTROLS' PORTABLE UNITS DELIVER

We have portable, stand alone, wall or ceiling mounted units all using the same basic filtration concept and air delivery system. The key CDC provision in this section is when there is the need for portable units. *“Care should be exercised to ensure they can recirculate all or nearly all of the room air through the HEPA filter.”* Depending on size of area to be cleaned, we can provide appropriate equipment to meet or exceed the 12 ACH (air changes per hour) required. Each product has proven its ability to clean all areas of a room rapidly, because each product has been carefully designed specifically for each individual application.

CDC ON INSTALLATION, MAINTENANCE AND MONITORING OF HEPA SYSTEMS

“Proper installation and testing and meticulous maintenance are critical if a HEPA filtration system is used, especially if the system used recirculates air to other parts of the facility. Improper design, installation, or maintenance could allow infectious particles to circumvent filtration, and escape into the general ventilation system. HEPA filters should be installed to prevent leakage between filter segments and between the filter bed and the frame.”

WHAT KIND OF HEPA FILTERS BIOLOGICAL CONTROLS USES

Any system is only as good as the HEPA filter and the seals around the filter. Since this is such a critical area, CDC recognizes that, unless these filters are properly constructed, installed, maintained and tested, you compromise the entire system by running the risk of reintroduction of infectious particulate into the environment or ventilation air system. We provide only individually tested and certified HEPA filters that meet or exceed all current Federal, military, pharmaceutical and industry standards. A filter is only as efficient as its seal. Our design is based upon a fool proof draw-latching mechanism that assures proper filter seating and sealing. Our HEPA filter is permanently sealed in a patented modular HEPA "filter-cube" design that provides an absolute seal, preventing air by-pass. This system provides superior performance during operation over conventional sealing and locking procedures.

CDC ON PRESSURE SENSING DEVICES TO DETERMINE FILTER REPLACEMENT

“A manometer or other pressure-sensing device should be installed in the filter system to provide an accurate and objective means of determining the need for filter replacement. Pressure drop characteristics of the filter are supplied by the manufacturer of the filter. Installation of the filter should allow for maintenance that will not contaminate the delivery system or the area served. For general infection control purposes, special care should be taken not to jar or drop the filter element during or after removal. ”

WHAT BIOLOGICAL CONTROLS PROVIDES TO DETERMINE FILTER REPLACEMENT

The **MICROCON** series of air purification products utilize a built-in minihelic gauge to measure air filter resistance, thereby monitoring filter replacement. Some competitive units use no gauge whatsoever; while others utilize a non-objective "idiot" light to determine filter performance. Our systems lend themselves to "bag out" filter removal procedures which eliminate personnel exposure to contaminated filters. Most competitive systems allow for direct exposure to contaminated filters because their system design requires the proper compression of rubber gaskets to assure their filter sealing integrity.

CDC ON AIR MIXING

“General ventilation systems should be designed to provide optimal patterns of airflow within rooms and prevent air stagnation or short circuiting of air from the supply to the exhaust (i.e., passage of air directly from the air supply to the air exhaust) ”

“Adequate air mixing, which requires that an adequate number of ACH be provided to a room, must be ensured to prevent air stagnation within the room. However, the air will not usually be changed the calculated number of times per hour because the airflow patterns in the room may not permit complete mixing of the supply and the room air in all parts of the room. This results in an “effective” airflow rate in which the supplied airflow may be less than required for proper ventilation. To account for this variation, a mixing factor (which ranges from 1 for perfect mixing to 10 for poor mixing) is applied as a multiplier to determine the actual supply airflow (i.e., the recommended ACH multiplied by the mixing factor equal the actual required ACH).”

“Smoke tubes can be used to visualize airflow patterns in a manner similar to that described for estimating room air mixing.”

WHAT BIOLOGICAL CONTROLS DELIVERS ON AIR MIXING

The **MICROCON 800 AND 400** series create a **CIRCUMFLOW** air pattern within the room that draws in air 360 degrees from the breathing zone. By exhausting air 360 degrees at the bottom, we create air currents and establish airflow patterns within the room to provide for propel air mixing and dilution. Our **CIRCUMFLOW** airflow pattern helps prevent air stagnation, dead air layers and pockets that can exist with uni-directional (one sided exhaust) air re-circulation systems. Based upon the room size and volume setting, we are able to provide the required air mixing and air change per hour (ACH) requirements as outlined by the CDC Guidelines.

CDC ON EXHAUSTING AIR FROM ISOLATION

“Air from TB isolation rooms and treatment rooms used to treat patients who have confirmed or suspected infectious TB, should be exhausted to the outside in accordance with applicable Federal, state, and local regulations. The air should not be re-circulated in the general ventilation. In some instances, re-circulation of air into the general ventilation system from such rooms is unavoidable (i.e., in existing facilities in which the ventilation system or facility configuration makes venting the exhaust outside impossible). In such cases, HEPA filters should be installed in the exhaust duct leading from the room to the general ventilation system to remove infectious organisms and particulate the size of droplet nuclei from the air before it is returned to the general ventilation system. ”

HOW BIOLOGICAL CONTROLS EXHAUSTS AIR FROM ISOLATION

Both the **MICROCON EX-BB** and the **ExC-BB** were developed specifically for this application. Both are variable HEPA filtered units that can exhaust or supply room air to negatively or positively pressurize an area. Each unit has great versatility allowing exhausted air to be directed outside or ducted directly into the ventilation system. This means of providing negative pressure has tremendous benefits over conventional engineering control in costs, time and performance. By recycling the air (once filtered) as opposed to direct outside exhaust, energy make-up costs are greatly reduced.

CDC ON DISCHARGE EXHAUST FROM BOOTHS, TENTS, AND HOODS

"Air from booths, tents and hoods may be discharged into the room in which the device is located or it may be exhausted to the outside. If the air is discharged into the room, a HEPA filter should be incorporated at the discharge duct or vent of the device. The exhaust fan should be located on the discharge side of the HEPA filter to ensure that the air pressure in the filter housing and booth is negative with respect to adjacent areas. Uncontaminated air from the room will flow into the booth through all openings, thus preventing infectious droplet nuclei in the booth from escaping into the room."

HOW BIOLOGICAL CONTROLS' ISOLATION BOOTH DISCHARGES

The **ISOPORT**® is a HEPA filtered enclosure that creates negative pressure within the booth by exhausting filtered air back into the room. The booth is comprised of tubular aluminum channels with mechanical interlocking latches that form a virtually airtight enclosure. Heavy gauge clear vinyl panels are permanently sealed to the aluminum channels. The door section is made up of two vinyl panels that seal in the middle with a full length magnetic closure strip. Plastic handles are attached to each door opening to allow ease of entry and exit.

Room air is drawn from an opening at the base of the door and flows through the booth to a rear exhaust port. A **MICROCON**, positioned outside the booth with a special intake HEPA filter, is drawing exhausted HEPA filtered air back into the room thereby creating negative pressurization. By using a ceiling mounted **ExC** unit, negative pressure can also be created while exhausted air can be discharged to the outside.

CDC ON LOCAL EXHAUST VENTILATION

"The exterior type of local exhaust ventilation device is usually a hood very near, but not enclosing, the infectious patient. The air flow, produced by these devices, should be sufficient to prevent cross-currents of air near the patients' face from causing escape of droplet nuclei. Whenever possible, the patient should face directly into the hood opening so that any coughing or sneezing is directed into the hood, where the droplet nuclei are captured. The device should maintain an air velocity of ~200 fpm at the patient's breathing zone to ensure capture of droplet nuclei."

HOW BIOLOGICAL CONTROLS CREATES LOCAL EXHAUST VENTILATION

The **MICROCON WallMAP PC** is a HEPA filtered air purifier mounted on a tubular frame. It is portable and provides for elimination of infectious airborne bacteria during cough-inducing procedures. The cart is mounted on four casters (two lockable), making transport easy and convenient. An all encompassing Plexiglas shield, mounted to a stainless top, provides an intake recess area allowing for contaminated air to be pulled directly into the HEPA filter and not circulated around the room. By positioning a patient directly in front of the intake, access to the patient from three sides is possible allowing for seated or individuals in wheel chairs to be properly treated. By exhausting through a HEPA filter, air does not need to be ducted out but can remain within the room.

SUMMARY

Biological Controls has provided filtration and contamination control products to the pharmaceutical, electronics, medical and health-care industries since its founding in 1973. Our new generation of systems and products developed for airborne infection control are unique to this application and many are protected under various US patents. Our products have been installed in over 2600 hospitals, medical, and health-care facilities worldwide. Reference lists and independent test studies guarantee the efficacy of their performance.