The Efficiency of HEPA Filters in the Air-handling System of a Bio-containment Laboratory in India

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Abstract

The High Security Animal Disease Laboratory (HSADL) in Bhopal, India is a BSL-4 laboratory that was constructed following the Labystad (The Netherlands) model and was commissioned in 1997 as a bio-containment facility to undertake research and diagnostic work on exotic and emerging diseases of animals in the country. The laboratory's air-handling system is comprised of 23 air-handling units (AHUs) with 97 HEPA filters (Anfilco, India) fitted in 92 filter housings. Preventing environmental contamination is achieved by maintaining graded negative pressure ranging between -50 to -200 Pascals. This paper discusses the efficiency of the HEPA filters following the dioctylphthalate (DOP) testing carried out over a decade-long period. Out of the 81 (83.5%) filters replaced during this period, HEPA filters of 59 (72.83%) housings were replaced once; of 17 housings (20.98%) were replaced twice, and of 6 housings (7.4%) were replaced three times. Major reasons for the replacement of these filters include blockage (48.18%) and lowered efficiency (51.85%) of the filter medium. The majority of the filter changes at HSADL can be attributed to the routine ageing of the filters, resulting in the degraded mechanical strength of the filter medium or choking due to aerosols and dust. Some areas of the laboratory encountered a higher rate of filter change and the reasons thereof are discussed. These observations regarding HEPA filter efficiency in AHUs are probably the first in a tropical environment. The possible roles of factors such as the availability of a dense tree canopy in the direction of the air flow, the close location of the lab to a large water body, and the lab's distance from the dusty highways in the longevity of this laboratory's HEPA filters are also discussed. This study re-emphasizes the need for regular monitoring of the HEPA filter function in the AHUs and their prompt replacement when damaged to ensure effective bio-containment.

Introduction

High efficiency particulate air (HEPA) filters are widely used all over the world to prevent contamination of the environment from microbiological containment laboratories and experimental animal establishments. Since the time when HEPA filters were introduced in military establishments for protection against particulate chemical, biological, and radiological warfare agents (First, 1996), HEPA filters have become an integral part of air-handling systems in virtually all laboratory and pharmaceutical establishments where clean and safe air is of paramount importance. These filters have a minimum efficiency of 99.97% for particles $\geq$0.3 microns in diameter and are the principal components of any air-handling system (AHS) in bio-containment laboratories (Abraham et al., 1998). One of the major challenges and requirements faced by bio-containment laboratories has been to ensure full functional capacity of the HEPA filters. The HEPA filters are comprised of five major components: (1) extensively pleated filter medium; (2) corrugated separators, usually made of aluminum; (3) a frame that holds the filter medium and separators; (4) adhesive that cements the filter and separators to the frame; and (5) a gasket to make the filter airtight. In an extensive review on filter ageing, First (1996) has reported that in the due course of time HEPA filters undergo mechanical damage or ageing wherein one or more filter components are subjected to wear, embrittlement, corrosion, and other physical and chemical changes. These changes ultimately result in the failure of the integrity and efficiency of the HEPA filters. Since the AHS of the containment laboratories is required to be functional around the clock and throughout the year, the integrity and efficiency of HEPA filters must be checked at frequent intervals as an integral part of the biosafety protocol of the bio-containment facility (Abraham & McCabe, 2007).

Failure-proof functioning of HEPA filters in air-handling systems is a prerequisite for any bio-containment laboratory, and the assessment of these filters' reliability over a period of years plays an important role in ensuring higher bio-containment standards in a biological laboratory (Abraham et al., 1998). The importance of evaluating HEPA filter efficiency in containment laboratories handling exotic pathogens for a particular country or those with a higher risk of airborne transmission cannot be overemphasized. HSADL in Bhopal, India is a BSL-4 laboratory established to undertake research and diagnostic work on the exotic and emerging diseases of livestock in India. The air exchange to the entire containment area is carried out through a complex air-handling system through individual air-handling units (AHU). This paper analyzes the performance of HEPA filters used in the air-handling system for over a decade.

Materials and Methods

The containment area of the entire laboratory is divided into a laboratory (1,875 m^2), an animal wing (1,135 m^2) located at the ground level and an effluent treatment plant (ETP) (2,840 m^2) located at 3 m or 5.3 m below ground level. Preventing environmental contamination by aerosols is achieved by maintaining negative pressure in the containment area between -50 to -200 Pascals. To ensure the maintenance of this negative pressure inside the containment area, the electrical interlocking system controls the supply and exhaust air in such a way that the supply fan starts operating along with the initiation of the operation of the exhaust fan. The laboratory is supplied with a dedicated uninterrupted electrical supply; however, in the case of an accidental electric failure negative pressure is maintained with the help of zero leakage dampers and the flow control dampers that regulate the air supply and exhaust.

The air-handling system of the entire laboratory area is administered with the help of 23 air-handling units (AHUs). Depending on the size of the unit, and the air exchange requirement based on the functions of individual laboratory unit, these 23 AHUs (Caryaire Equipments India Pvt Ltd) are compartmentalized into 92 filter housings containing 97 HEPA filters (Anfilco, India). The air supply to the laboratory is carried out via a pre-filter with an efficiency of 99% down to 5 microns. The filtering media of this pre-filter is made up of a synthetic polymer and is supported by aluminum-anodized mesh. The filter pack is sealed to the frame by an epoxy-based adhesive. It has a rated flow of 2,000 CFM, having the initial pressure drop and final pressure drop of 6.5 mm WG and 19.0 mm WG, respectively. In addition to this pre-filter, the air supply system also consists of *micro vee* filters that have the same construction material as the pre-filter but with an efficiency of 95% down to 5 microns.

The exhaust air from the laboratory is carried through the pre-filter followed by HEPA filters. The filtering medium in the HEPA filters is a glass fiber. The medium is pleated into several folds and these folds are separated by spacers made of aluminum foil. The media pack and the aluminum spacers are bonded to the frames by an epoxy-based adhesive. The filters have a rated flow of 1,300 CFM, with an initial and final pressure drop of 25 mm WG and 75 mm WG, respectively. Certain high-biohazard zones of the laboratory, such as the individual rooms in the animal wing area, are fitted with double HEPA filters arranged in a series to counter the higher risk of microbial contamination in this area. The air in the laboratory area is re-circulated in the ratio of 70:30 (Recirculation:Exhaust), whereas the animal wing of the laboratory has a 100% exhaust system.

Since AHUs in the laboratory run continuously throughout the year, annual testing of the filters is carried out alternately through an in-house testing mechanism followed by an independent external agency to ensure the integrity and efficiency of the HEPA filters in the AHU. The efficiency of the filters is tested with the help of dioctylphthalate (DOP) tests, and the integrity of the filter medium and the efficacy of the filter seal in the housing are recorded following the test. A DOP penetration percentage above 0.01% is considered a failed test, and a filter change is recommended. In addition, each filter housing is fitted with a differential pressure meter (DPM) that measures the difference in the air pressure before the air enters the pre-filter and when the air exits the HEPA filter. An increase in the differential pressure above 50 mm WG indicates a blocking of the filters and requires immediate replacement.

For the sake of data analysis, the period from 1st April to 31st March is taken as 1 year. The installation of the air-handling unit for the laboratory and its commissioning were completed in November 1997; therefore, the data are analyzed for a period of 10 years (i.e., April 1998 to March 2008). Details regarding filter locations, negative pressure maintained in these areas, the air flow inside the laboratory areas etc. are given in Table 1.

Results and Discussion

The data analyzed for the period of April 1998 to March 2008 have indicated that a total of 81 filters were replaced during the 10 years after commissioning. The details are presented in Table 2. During installation of the HEPA filters, three filters were replaced immediately after their installation since leakage was observed during final testing after installation and prior to commissioning of the laboratory. These replacements were carried out due to damage to the filters during their installation and hence have not been accounted for in Table 2. After the commissioning of the laboratory, out of the total 81 HEPA filters replaced, 59 filters (60.82%) were replaced once. Seventeen filters among these previously replaced filters showed filter damage and had to be re-replaced, whereas five filters (of second change category) were again replaced following failed filter efficiency tests.

In the present study, the reasons for filter replacement are attributed to lowered efficiency of the filter medium and blockage of the filter medium.

Owing to the reduced efficiency of filter medium below the recommended level (less than 99.97%); a total of 33 filters (34.02%) had to be replaced. The filters' low efficiency could have occurred because the filters lost mechanical strength, as is known to happen

Table 1
Details of AHU Data at HSADL, Bhopal

Filter Location	Air Pressure (Pascals)	Air Flow (CFM)	Number of Filter Housings	Number of Filters
Lab Corridor	-100	7800	13	13
Inner Change Room	-50			
Central Laboratory	-120	12440	18	18
Dirty Dispatch	-120	810	2	2
Biochemistry & Cell Culture Lab	-120	4650	7	7
Workshop & BSO Office	-120	3790	6	6
Central Lab Fume Hood	-120	705	2	2
Radioisotope Lab	-200	3023	5	5
Glassware Washing Room & Autoclave Room	-120	2100	4	4
Effluent Treatment Plant (ETP) Basement (-3 m)	-150	4570	6	6
Animal Corridor	-100	4000	9	9
Combined Room	-150	660	3	3
Post Mortem Room	-200	1700	3	3
Isolator Room	-100	210	2	2
Large Animal Rooms	-150	660	4	8
Small Animal Rooms	-150	330	3	4
Animal Airlock	-50	210	1	1
Basement Airlock (-3 m)	-50	210	1	1
Laboratory Airlock	-50	210	1	1
Bio-Cooker Room (Rendering Plant) (-5.3 m)	-100	1700	2	2
Total			92	97

with ageing filters (Edwards, 2002), or because of the failure of the epoxy seal holding the filter medium to the filter frame (Abraham & McCabe, 2007). Abraham et al. (1998), due to their experience with HEPA filter replacement in a biological laboratory, have reported that the lower efficiency of the filter medium occurs because of leakages (usually "pinhole" leaks) or defects in the gasket seal securing the filter frame to its housing. Since no specific study was carried out in this regard, the possibility for either or both of these reasons for the efficiency failure cannot be ruled out. In summer, the ambient temperature of Bhopal city is in the range of $40^{o}C$ - $45^{o}C$ for at least 2 months. Since the AHUs are located on the top floor that lacks any cooling system, such high temperatures could also result in some damage to the filter's polymer or epoxy seal and could have resulted in reduced filter efficiency.

In any high-containment microbiological laboratory, HEPA filters perform the basic function of biocontainment through the air-handling systems associated with microbiologically secure areas to prevent the escape of infectious aerosols. A high differential pressure meter (DPM) value indicates the blocking of the filters. In the present case, 26 filters (26.8%) had to be changed due to blocking. In the majority of the housings (except the ones in laboratory animal rooms, which are fitted with double HEPA filters), the pre-filters preceded HEPA filters during air supply and prevented HEPA filter blocking due to larger particles (> 5μ); however, replacement of more than 26% of the filters due to blocking indicates the involvement of smaller particles (3μ - 5μ) in blocking the filters. The filter blockage could also be due to a reduction in the binding compound content in the filter medium (Edwards, 2002), consequently causing more frequent blocking of the filters present in the air exhaust system, or physical medium failure (First, 1996). Other laboratories similar to this one have also experienced these problems of filter leakages and filter blocking due to dust loading (Abraham et al., 1998; Edwards, 2002).

Analysis of filter changes based on location is presented in Table 3. It is commonly observed that HEPA filters from the areas with minimum movement have more longevity. The filters for fume hoods and all airlocks are still functioning after 10 years without any damage or blockage, whereas 16 filters (11+4*+1** of 18 filter housings) from Central Laboratory needed to be replaced.

One interesting finding in the study was the high

Table 2

Details of HEPA Filter Changes During a Decade of Their Commissioning

Year	Number Changed Due to DOP Test Failure			Number Changed Due to Filter Blockage			Total Filters Changed			
	1st change	2nd change	3rd change	1st change	2nd change	3rd change	1st change	2nd change	3rd change	Grand Total
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
1997-98	INSTALLATION									
1998-99	0	0	0	0	0	0	0	0	0	
1999-00	0	0	0	0	0	0	0	0	0	
2000-01	0	0	0	0	0	0	0	0	0	
2001-02	3/97 (3.09)	0	0	0	0	0	3/97 (3.09)	0	0	
2002-03	7/94 (7.45)	0	0	3/94 (3.19)	0	0	10/94 (10.64)	0	0	
2003-04	0	1/15 (6.67)	0	2/84 (2.38)	1/15 (6.67)	0	2/84 (2.38)	2/15 (13.33)	0	
2004-05	11/82 (13.41)	0	0	8/82 (9.76)	1/32 (3.13)	0	19/82 (23.17)	1/32 (3.13)	0	
2005-06	2/63 (3.17)	3/37 (8.11)	0	4/63 (6.35)	0	1/6 (16.67)	6/63 (9.52)	3/37 (8.11)	1/6 (16.67)	
2006-07	7/57 (12.28)	2/42 (4.76)	0	1/57 (1.75)	0	1/7 (14.29)	8/57 (14.04)	2/42 (4.76)	1/7 (14.29)	
2007-08	3/49 (6.12)	3/51 (5.88)	0	8/49 (16.33)	6/51 (11.76)	3/15 (20.00)	11/49 (22.45)	9/51 (17.65)	3/15 (20.00)	
Total	**33/97 (34.02)**	**9/59 (15.25)**	**0**	**26/97 (26.80)**	**8/59 (13.56)**	**5/17 (29.41)**	**59/97 (60.82)**	**17/59 (28.81)**	**5/17 (29.41)**	**81 Filters changed**

Explanation:

- Denominator in columns 2 and 5 indicates total number of unchanged filters, whereas numerator indicates number of filters changed out of the total available up to that year (cumulative data).
- For second change, denominator in columns 3 and 6 indicates number of filters available from only previously changed (first change from columns 2 and 5, respectively), whereas numerator indicates number of filters changed out of the total available up to that year (cumulative data).
- For third change, denominator in columns 4 and 7 indicates number of filters available from only previously changed (second change from columns 3 and 6), whereas numerator indicates number of filters changed out of the total available up to that year (cumulative data).
- Data in columns 8, 9, and 10 represent total number of filters changed due to DOP test failure and blockages.
- Figures in parentheses indicate percentage.

frequency of filter replacement in the effluent treatment plant (Table 3), where all six filters from six housings were replaced, five were replaced for a second time, and four for a third time. Five out of six failures were due to filter blockage. Of these, three filters were replaced three times and five were replaced twice, indicating a higher replacement rate for this AHU compared to the others in the laboratory. The effluent treatment plant has steam autoclaves and the excess steam released from the valves to maintain steam pressure during autoclaving results in an exceptionally high moisture content and higher aerosolization of the ETP environment. Abraham et al. (1998), in their study on HEPA filter replacement in a biological laboratory, have attributed higher deterioration of filters due to water, dust, and smoke and have reported higher filter replacement rates where condensation of water vapor in vent filters resulted in filter damage. The ETP is located in the basement with three-quarters of it at 3 m below ground level and carries the ducting and piping from every part of the lab. Accumulated dust on these parts is difficult to clean, so dusting of this area is carried out manually by sweeping and could result in greater filter blockage. A change in cleaning practices using motorized vacuum cleaners is being recommended for the laboratory, and the impact of this change in practice could be the subject of future studies.

Following commissioning of the laboratory in 1997, the first filter replacement was carried out in 2002, and

Table 3
Area Distribution of HEPA Filters and Their Replacements

Area of Laboratory	HEPA Filters Available	Changed due to DOP Test Failure	Changed due to Blockage	Total Number of Filters Replaced
Lab Corridor Inner Change Room	13	6	3	9
Central Laboratory	18	5+3*	6+1*+1**	11+4*+1**
Dirty Dispatch	2	0	1	1
Biochemistry Cell Culture	7	1	4	5
Workshop BSO Office	6	3+2*	2	5+2*
Central Lab Fumehood	2	0	0	0
Radioisotope Lab	5	3	1	4
Glassware Wash, Autoclave Room	4	4+1*	0	4+1*
Effluent Treatment Plant	6	1+1*	5+4*+4**	6+5*+4**
Animal Corridor	9	2	0	2
Lab Animal Room	3	1	1	2
Post Mortem Room	3	2+1*	0	2+1*
Isolator Room	2	1	0	1
Large Animal Rooms	8	1	3+3*	4+3*
Small Animal Rooms	4	0	3+1*	3+1*
Animal Airlock	1	0	0	0
Basement Airlock	1	0	0	0
Laboratory Airlock	1	0	0	0
Cooker Room	2	0	0	0
Total	97			59+17*+5**

* Second Change
** Third Change

the majority of the filters (i.e., 79%) were replaced 6 years after laboratory commissioning. The longevity of the HEPA filters depends on a number of factors, such as dust concentration, temperature, humidity, severe conditions like earthquake or violent explosion resulting in a long duration of pressure pulses or shock pulses (Osaki & Kanagawa, 1989), air supply and exhaust pressure, quality of the filter medium, or sealant system-induced pressure pulses (e.g., sudden starting of air blowers). In this period, HSADL has not experienced any adverse climatic changes, such as high-speed winds, dust storms, etc., that could result in large-scale filter damage. As suggested by Edwards (2002), the only significant pressure pulse that could be experienced by HEPA filters in a biological laboratory could happen when AHS fans start or fan swap occurs between an in-service fan and stand-by fan. Some filter damage due to such procedures might have occurred at HSADL too. Considering the dry and dusty tropical environment of the region for most of the year, one would expect a remarkably reduced shelf life for the HEPA filters in such laboratories. Longer filter shelf life in this study could be attributed to many probable reasons including the following: (1) The laboratory is located in very close proximity to a lake that brings northern winds with a relatively lower concentration of dust in the direction of the laboratory; (2) The laboratory is situated about 1 km from the highway; consequently, the dust concentration is relatively low as compared to many other places in the region; (3) The laboratory campus has a fairly thick tree canopy that might have trapped a good amount of the dust.

The majority of the filter changes currently at HSADL can be attributed to the routine ageing of the filters resulting in the degraded mechanical strength of the filter medium or choking due to aerosols and dust. Replacing all the filters of the same age when degradation of some of the filters is observed in a laboratory has been suggested (Edwards, 2002). However, this decision needs to be based on laboratory-specific requirements, logistics, the economics of filter-changing, and most importantly the availability of a foolproof monitoring mechanism to check the quality of the filters on a regular basis.

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Erratum: Cover Art in *Applied Biosafety* (Volume 14, Number 2, 2009)

An error in file reading has resulted in a misrepresentation of the geographical locations of biosafety organizations on the cover art published in Volume 14, Number 2, 2009. A corrected map is provided in this erratum. The information contained in the "About the Cover" description is accurate and serves to assist in locating the biosafety organizations on the map. The stars represent the locations of the following global biological safety associations and working groups: African Biosafety Association, American Biological Safety Association, ABSA-Canada, Asia-Pacific Biosafety Association, Biosafety Association of Central Asia and the Caucuses, Biosafety Association of Pakistan, European Biosafety Association, Israeli Biological Safety Association, Japanese Biosafety Association, National Biosafety Association of Brazil, Philippines Biosafety and Biosecurity Association, Taiwan Biological Safety Association, and the Thailand Biosafety Working Group.