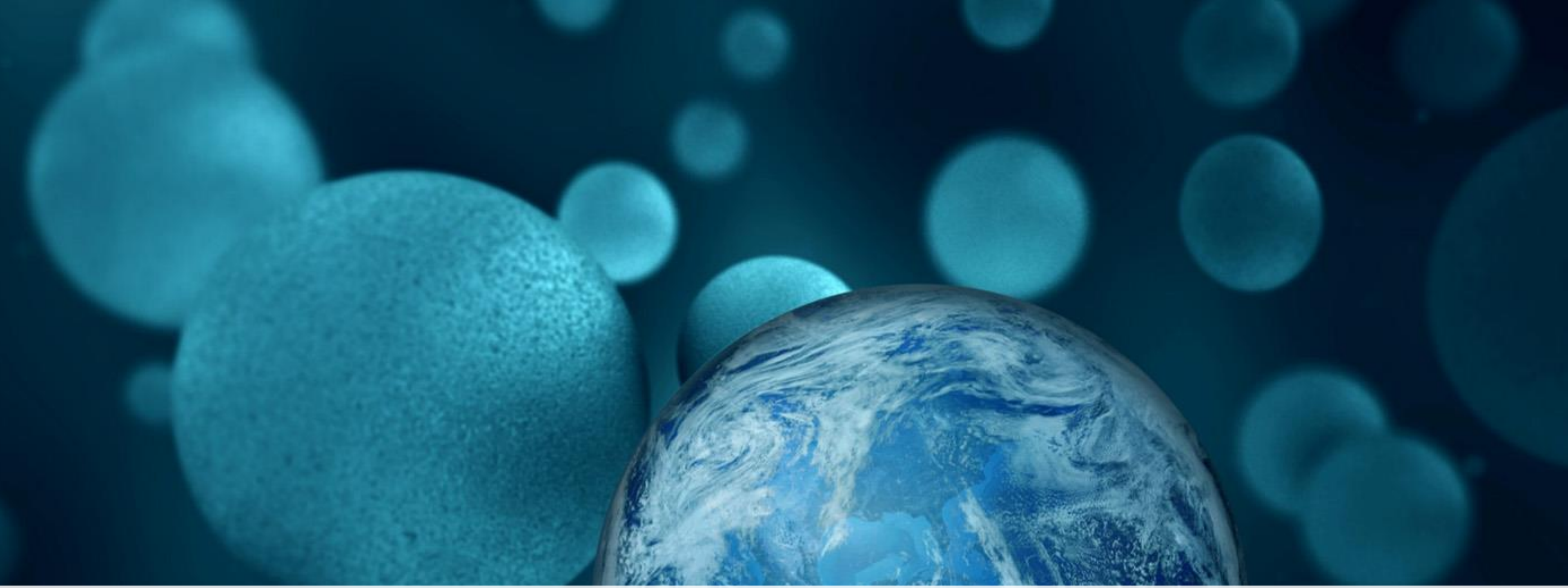

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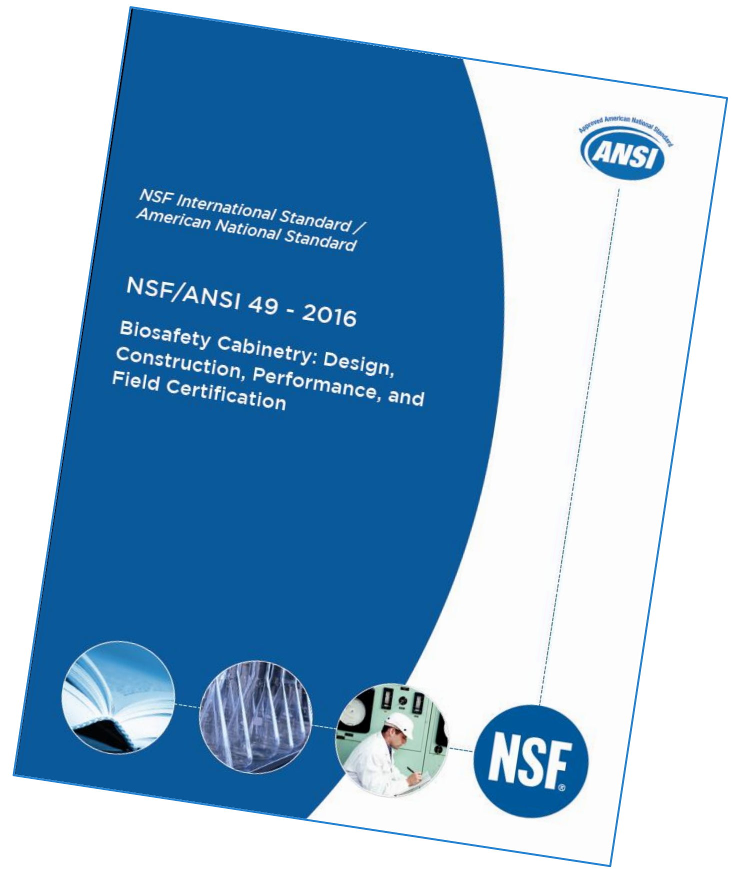
Future Directions and Historical Development of NSF/ANSI 49 – Biosafety Cabinetry: Design, Construction, Performance and Field Certification

David S. Phillips, DM

1974 1989 Current

- NSF/ANSI 49 – 2016 “Biosafety Cabinetry: Design, Construction, Performance, and Field Certification”
- First published in 1976 and revised 15 times up through 2016
- An American National Standard since 2002
- 15 manufacturers listed as of August 2018 with over 240 models. 34% of models manufactured outside North America



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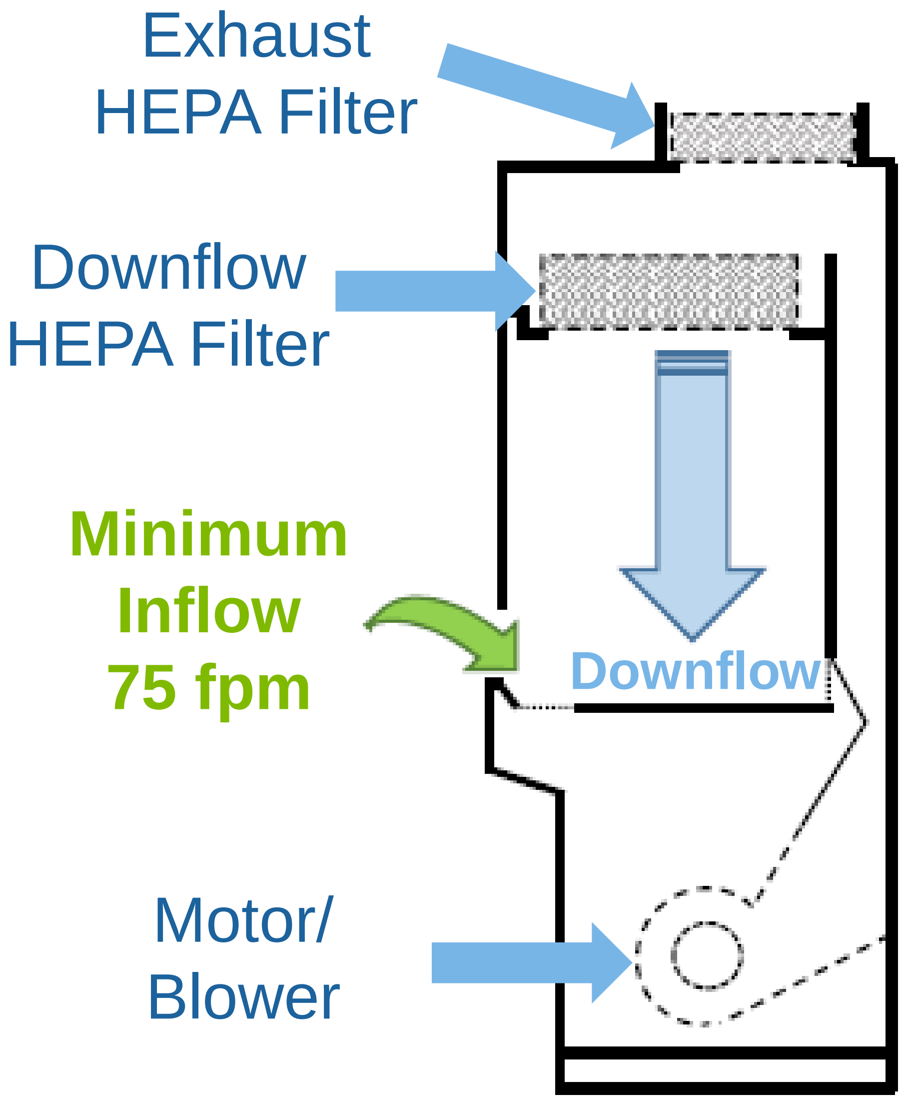
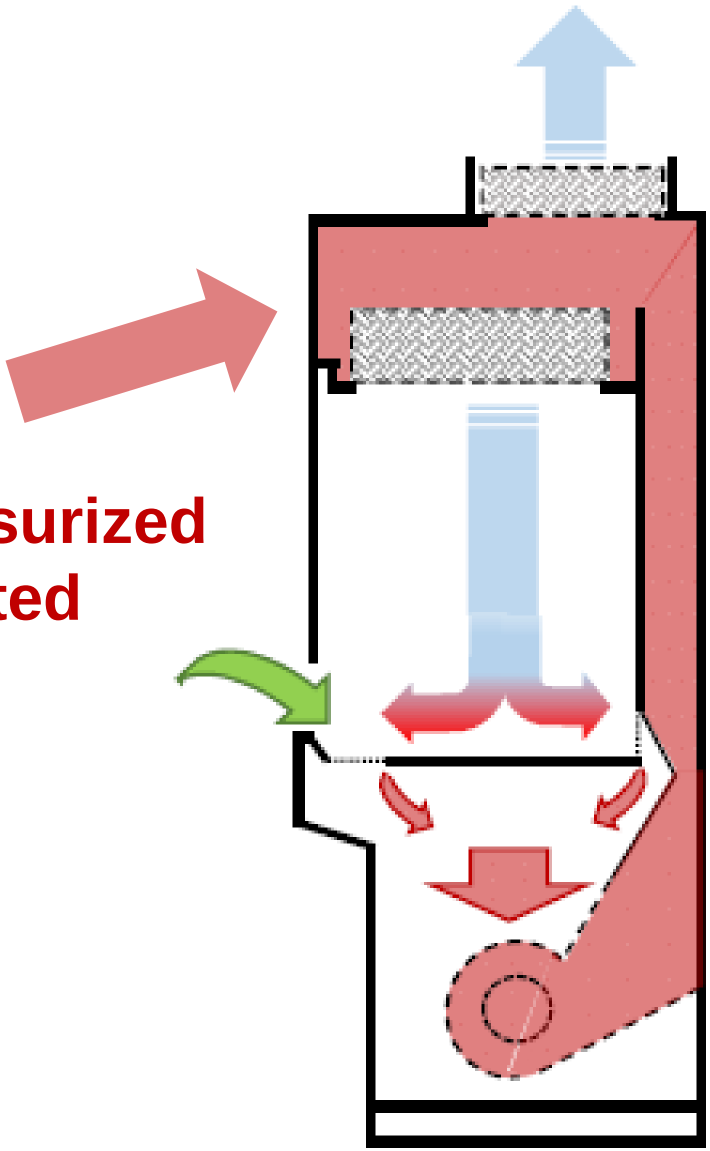
NSF Standard 49 - 1976

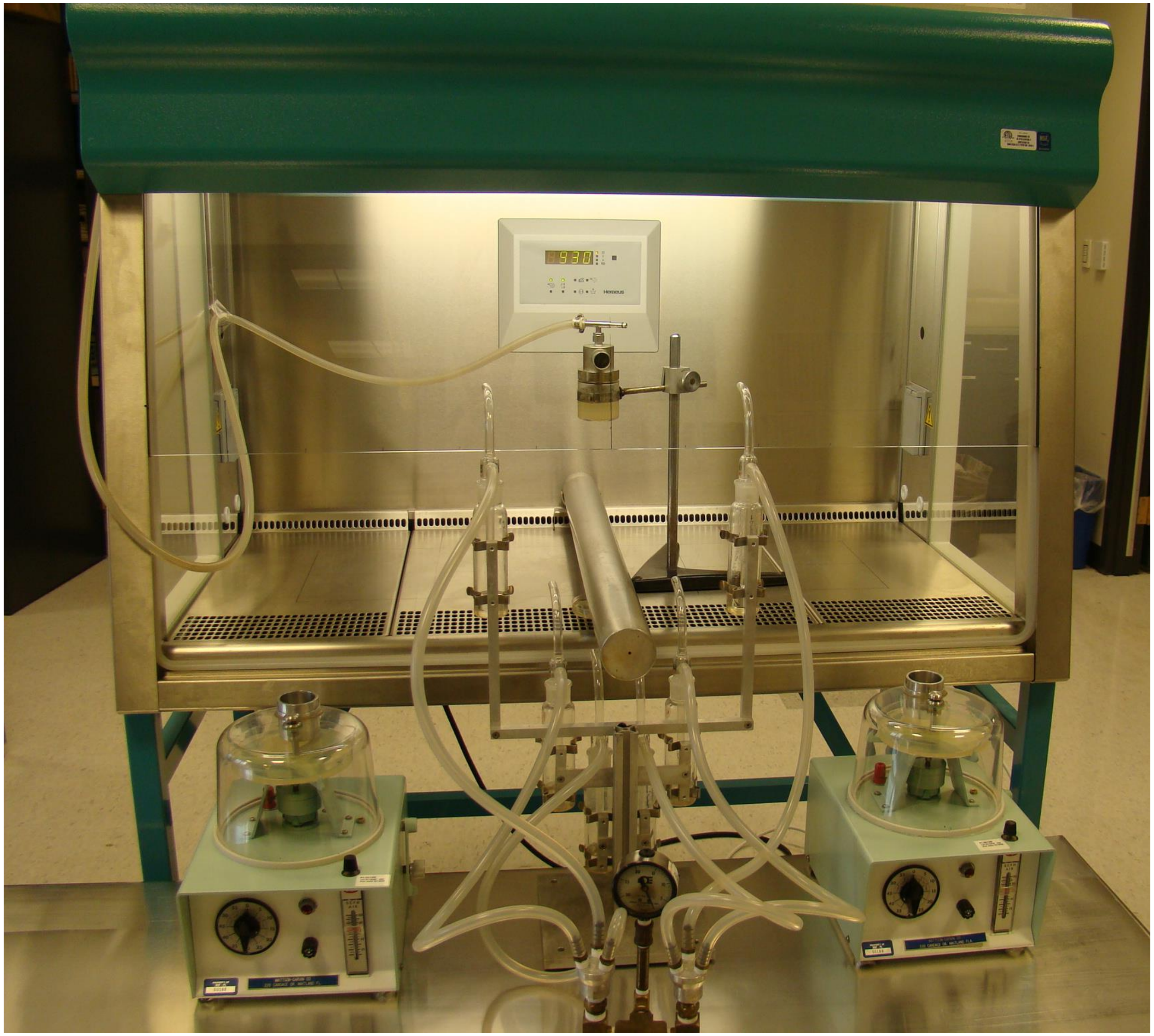


NSF Standard 49 - 1976

Exposed
Positively Pressurized
Contaminated
Plenum



NSF Standard 49 – Personnel Protection Test

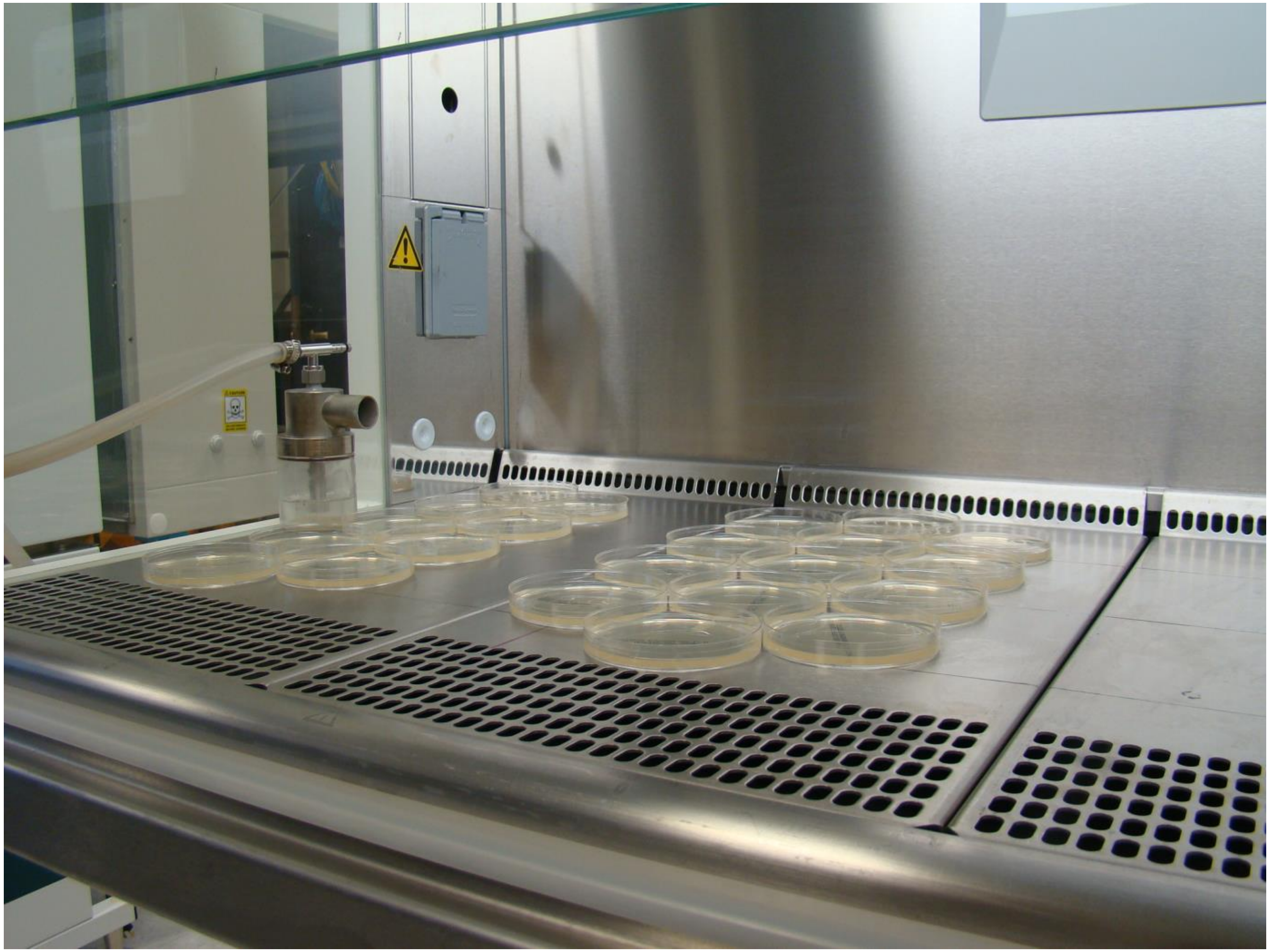


- 1 to 8 x 10^8 *B. subtilis* spores challenge
- 8 samplers
- ≤ 15 cfus allowed
- Minimum efficiency 99.999985%

NSF Standard 49 – Product Protection Test

- 1 to 8 x 10^6 *B. subtilis* spores challenge
- Media plate coverage
- ≤ 5 cfus allowed
- Minimum efficiency 99.9995%

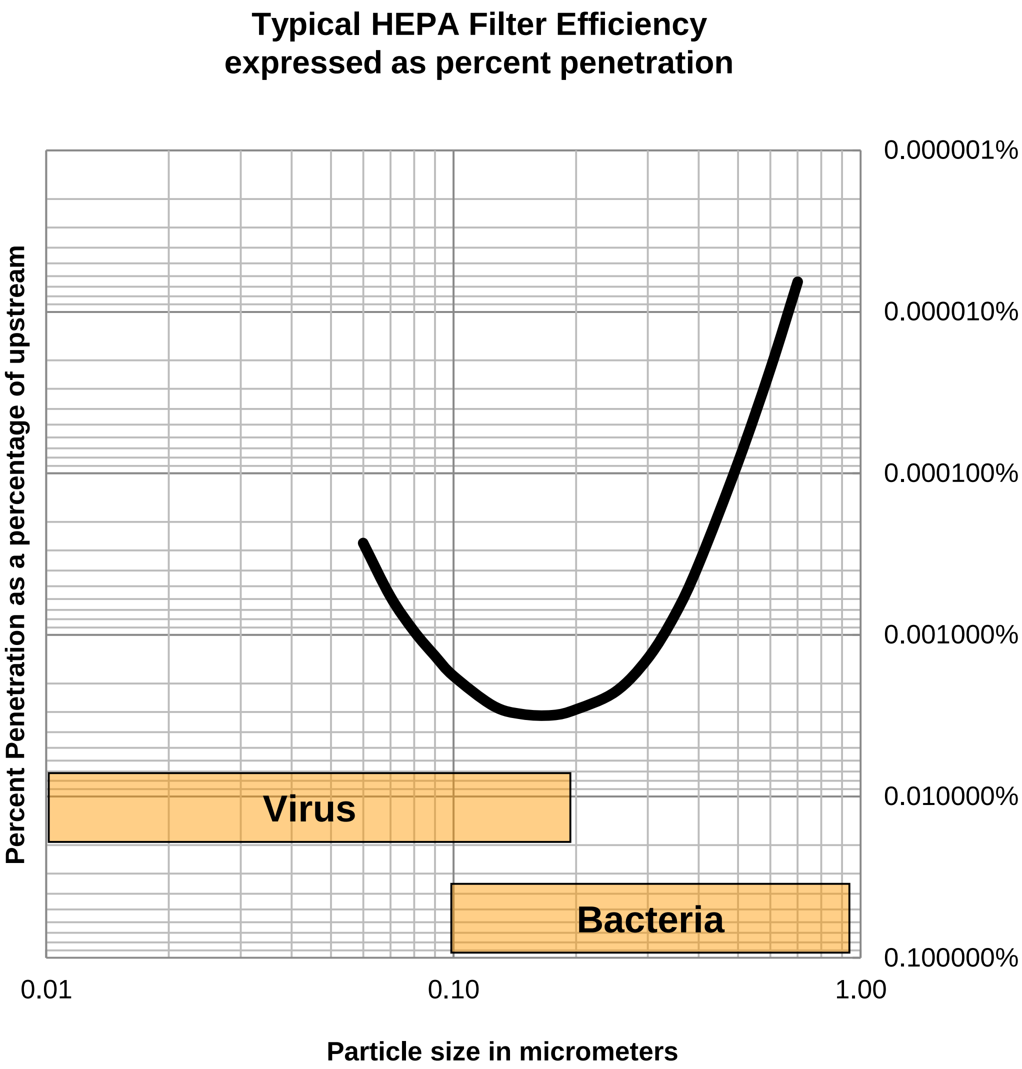
NSF Standard 49 – Cross Contamination Test



- 1 to 8 x 10^4 *B. subtilis* spores challenge
- Media plates > 14” from side
- ≤ 2 cfus allowed
- Minimum efficiency 99.98%

HEPA Filters

- Cumulative Filtration – The different mechanisms of filtration combine to produce an overall filtration efficiency with a Most Penetrating Particle Size (MPPS).
- HEPA Filters do not affect gas.

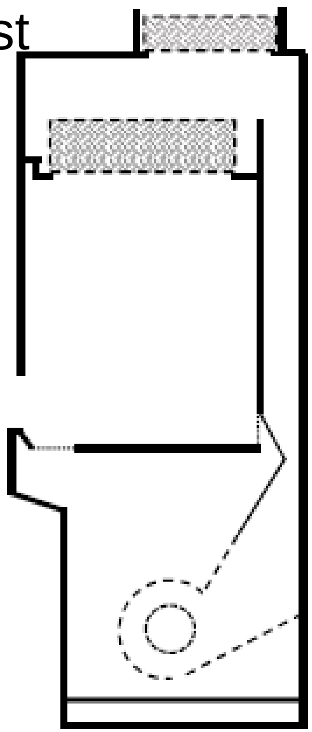


NSF Standard 49 – 1983 The Types

Minimum Inflow:
75 fpm

Filtered exhaust vented to laboratory

Exposed positively pressurized contaminated plenums: Allowed



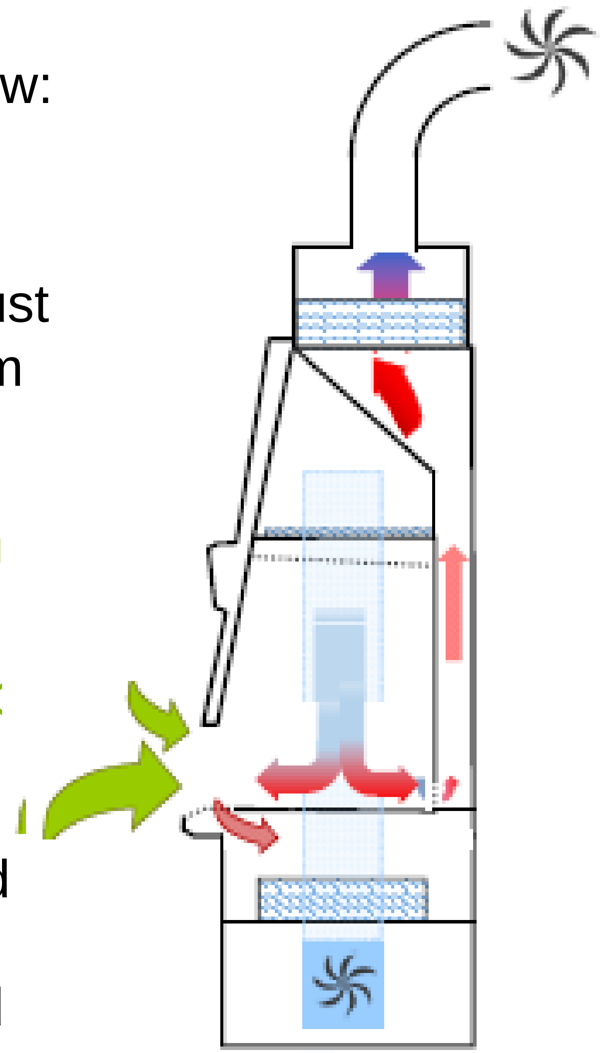
A

Minimum Inflow:
100 fpm

Filtered exhaust removed from laboratory (externally exhausted)

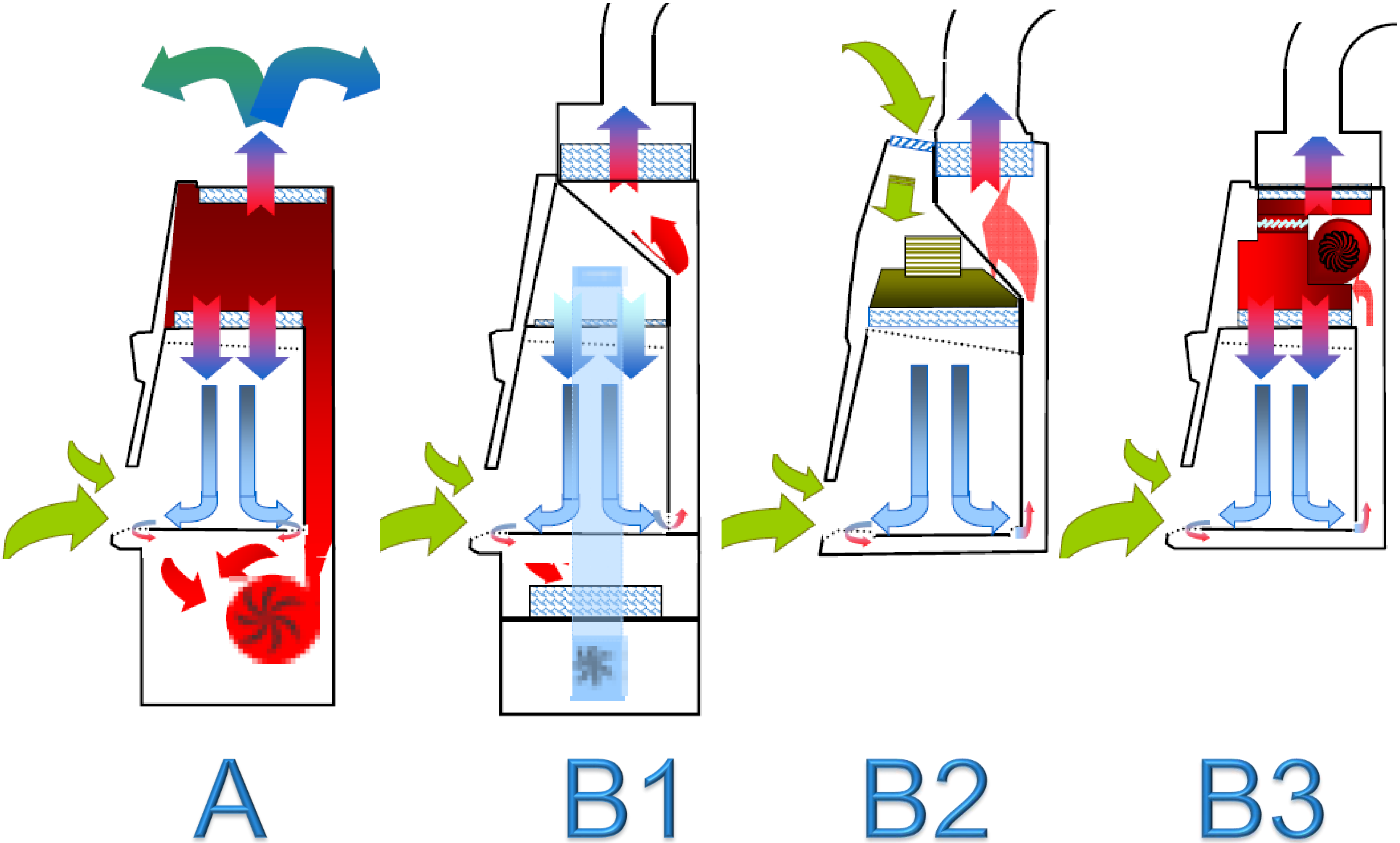
Minim
Inflo
100 f

Exposed positively pressurized contaminated plenums: **<u>NOT</u>** allowed



B

NSF Standard 49 – 1983 Types A, B1, B2 and B3



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Usage recommendation for Types A, B1, B2 and B3 - 1983

	Toxic Chemicals	
A	No	
B1	Yes, as adjunct, if	MINUTE amounts, in direct exhaust portion OR recirculation okay
B2	Yes, as adjunct	
B3	Yes, as adjunct, if	(exhausted) MINUTE amounts if recirculation okay

Usage recommendation for Types A, B1, B2 and B3 - 2016

	Volatile Toxic Chemicals	
A1	If volatile chemicals, must be connected to external exhaust system	Cabinets may be used for work with volatile chemicals if permitted by a chemical risk assessment (Refer to Section E.3.1.3).
A2		
C1		
B1	(By definition, connected to exhaust)	
B2		

- BSCs are typically not designed to handle chemicals in flammable or explosive quantities.
- Consider the potential affect of some chemicals on the filter media, frames, and gaskets.

E.3.1.3 Question three: What types and quantities of chemical vapors will be generated in the BSC?

As important as the preceding question, the user must also foresee the types and quantities of chemical vapors that will be generated in the cabinet. Because chemical vapors can freely pass through HEPA or ULPA filters, both Class I and Class II BSCs must be exhausted out of the laboratory when used with these types of chemicals. For the Class II BSCs, Types B1 and B2 must be direct connected to an external exhaust system in order to operate properly; Types A1, A2 and C1 can be converted to operate in either a canopy ducted or recirculating mode, depending on the users' requirements. The airflow patterns of Types A1, A2, B1, B2 and C1 Biosafety Cabinets are shown in figures E2, E4, E5 and E7, respectively.

Class II BSCs typically do not feature explosion-proof electrical components in their work area or internally. Therefore, use of flammable or explosive materials in quantities above their explosive limit are not recommended.

Types of chemicals used in cabinet should be considered as some can destroy the filter medium, housings and gaskets causing loss of containment.

The percentage of air in the work area that is recirculated within the BSC versus exhausted varies, based on the BSC type, subtype, and in some cases, where the chemicals are released in the work area.[43 44 45]

When flammable or explosive chemicals are to be used in a BSC, it is the users' responsibility to:

- be fully cognizant with the properties of chemical(s) and the hazards associated with them;
- calculate the highest percent of recirculation that may occur in the BSC being used;
- ensure the concentration of chemical(s) released in the work area do not exceed their explosive limit;
- utilize the lowest quantities of the chemical(s) required for the procedure being performed, and;
- have appropriate spill/splash cleanup procedures in place before using the chemical(s).

User responsibilities in using BSC with volatile chemicals - 2016

When flammable or explosive chemicals are to be used in a BSC, it is the users' responsibility to:

- be fully cognizant with the properties of chemical(s) and the hazards associated with them;
- calculate the highest percent of recirculation that may occur in the BSC being used;
- ensure the concentration of chemical(s) released in the work area do not exceed their explosive limit;
- utilize the lowest quantities of the chemical(s) required for the procedure being performed, and;
- have appropriate spill/splash cleanup procedures in place before using the chemical(s).

How to calculate the max % of chemical recirculation in a BSC

$$C_d = \frac{X}{Q_i}$$

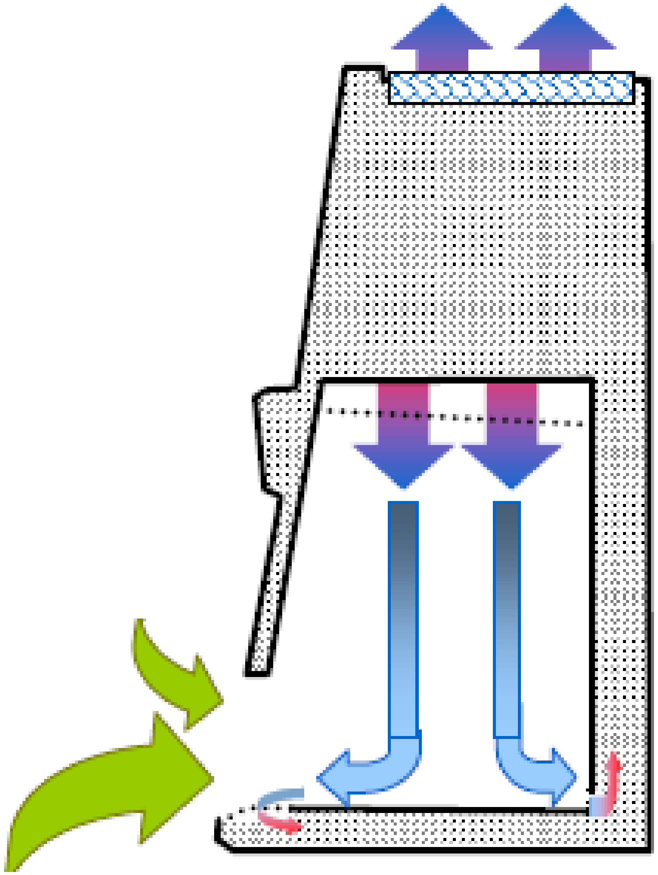
C_d • maximum concentration

X • amount of volatile material entering BSC

Q_i • amount of air drawn into the cabinet.

"Comparison of Chemical Vapor Handling by Three Types of Class II Biological Safety Cabinets" by D. G. Stuart, M. W. First, R. L. Jones, Jr., and J. M. Eagleson Jr. (reprinted from Particulate & Microbial Control, March/April 1983)

Type A1 or A2



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How to calculate the max % of chemical recirculation in a BSC

$$C_d = \frac{0.800\,liters/minute \times 0.03}{275\,cfm \times 28.32\,lpm/cfm} = 3.08 \times 10^{-6} = 0.000308\% = 3.08\,ppm$$

- C_d • maximum concentration
- X • amount of volatile material entering BSC
- Q_i • amount of air drawn into the cabinet.

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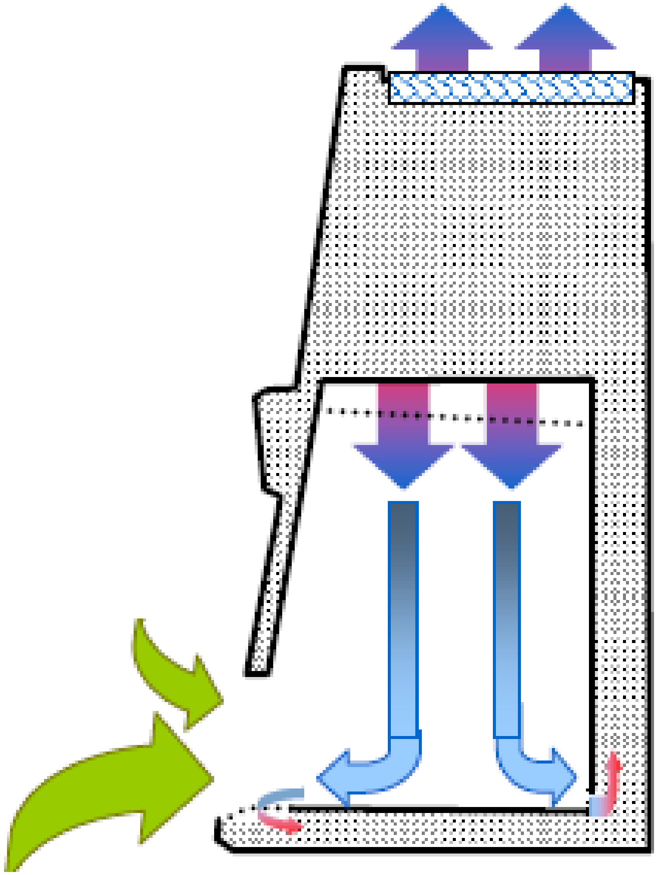

How to calculate the max % of chemical recirculation in a BSC

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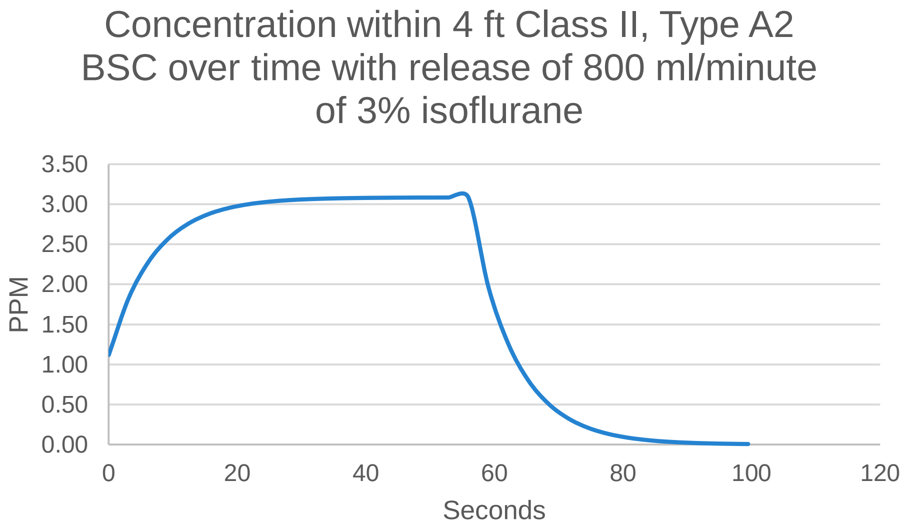

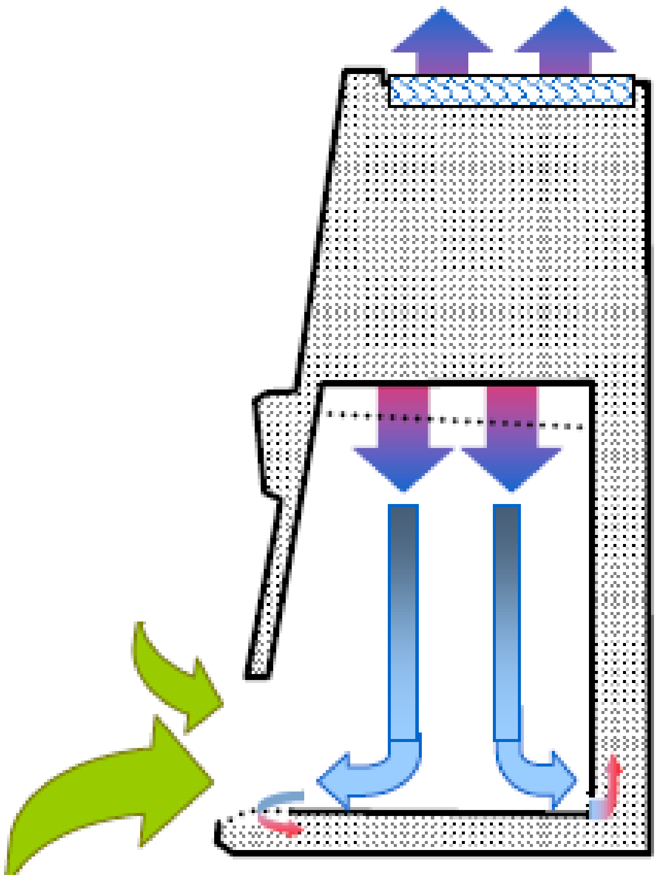

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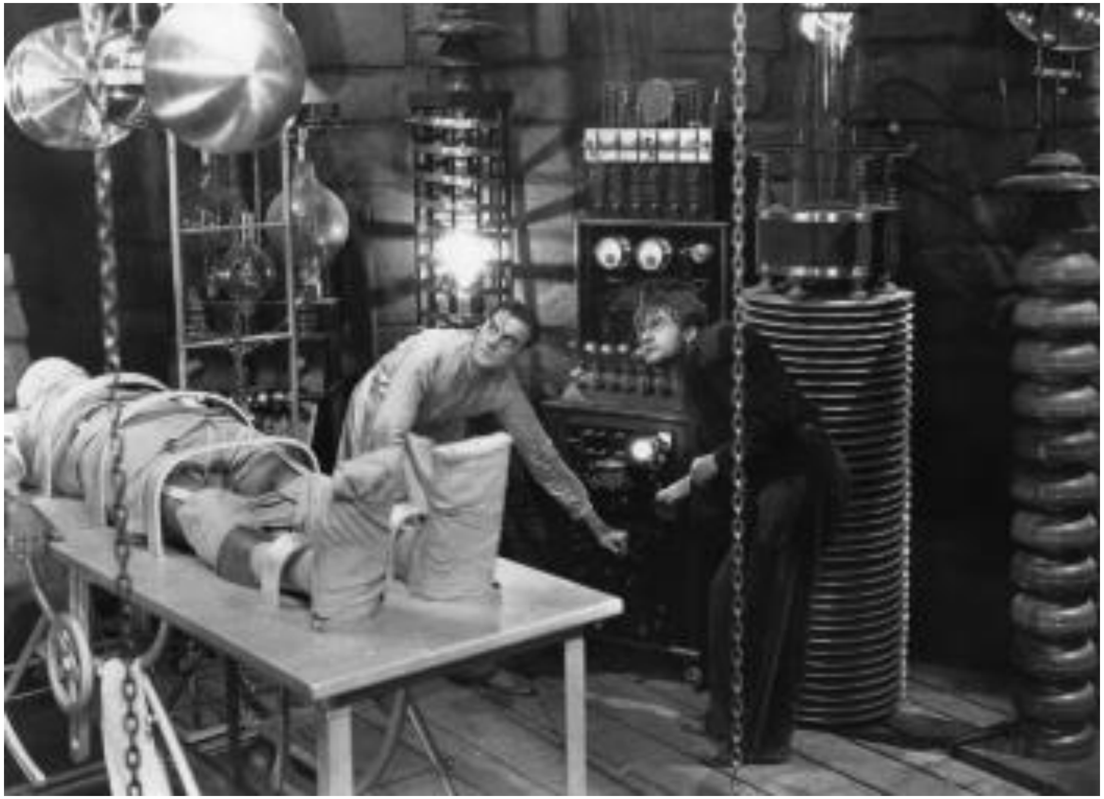
Don’t fight the future

From Section 1.3 Variations in design and construction

Major modifications require appropriate tests for conformance. Major modifications include, but are not limited to, changes in the following: location or capacity or quantity or all three of blower/motor(s); size or design or both of air plenums; position of High Efficiency Particulate Air/Ultra Low Penetrating Air (HEPA/ULPA) filters; position or redesign of work surface; work area intake and exhaust air grilles; window placement or design; access opening size; location and size of exhaust port; and built-in accessory equipment (centrifuges, ultraviolet lighting, supports for intravenous drug container, arm rests, etc.). Relocation of utility service equipment (electrical outlets, petcocks, etc.) is not considered a major modification if other provisions of this Standard are not compromised.

Connectivity



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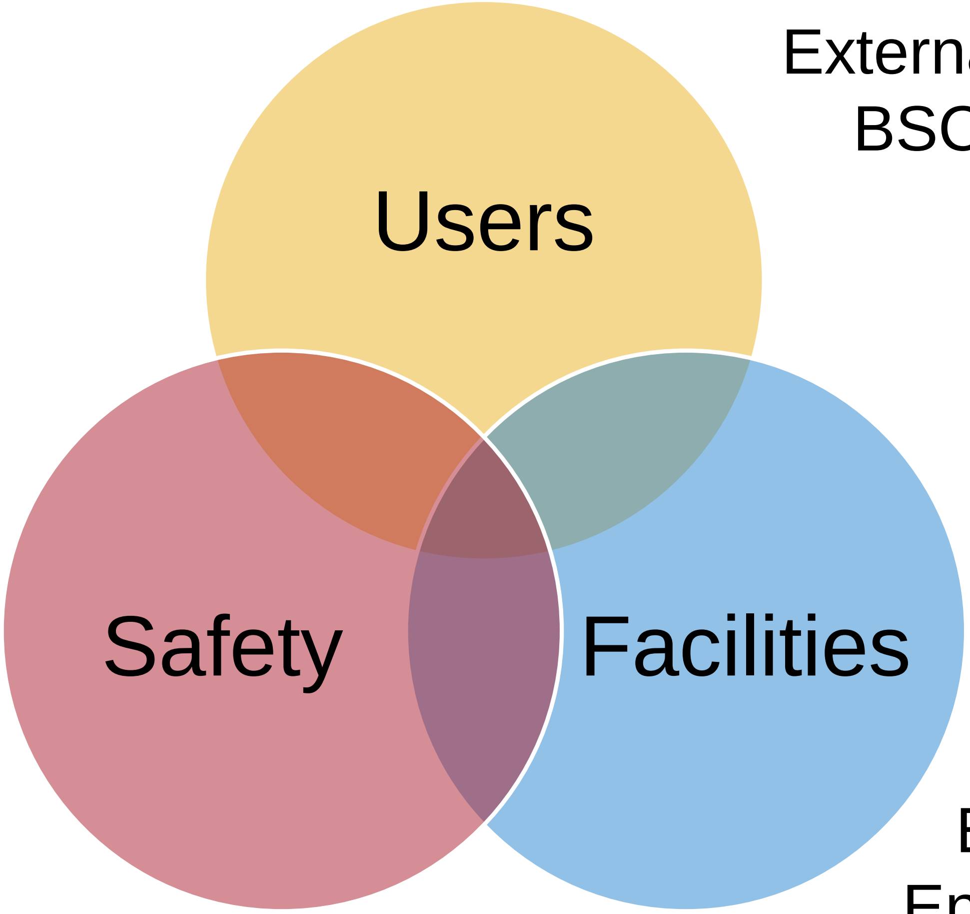
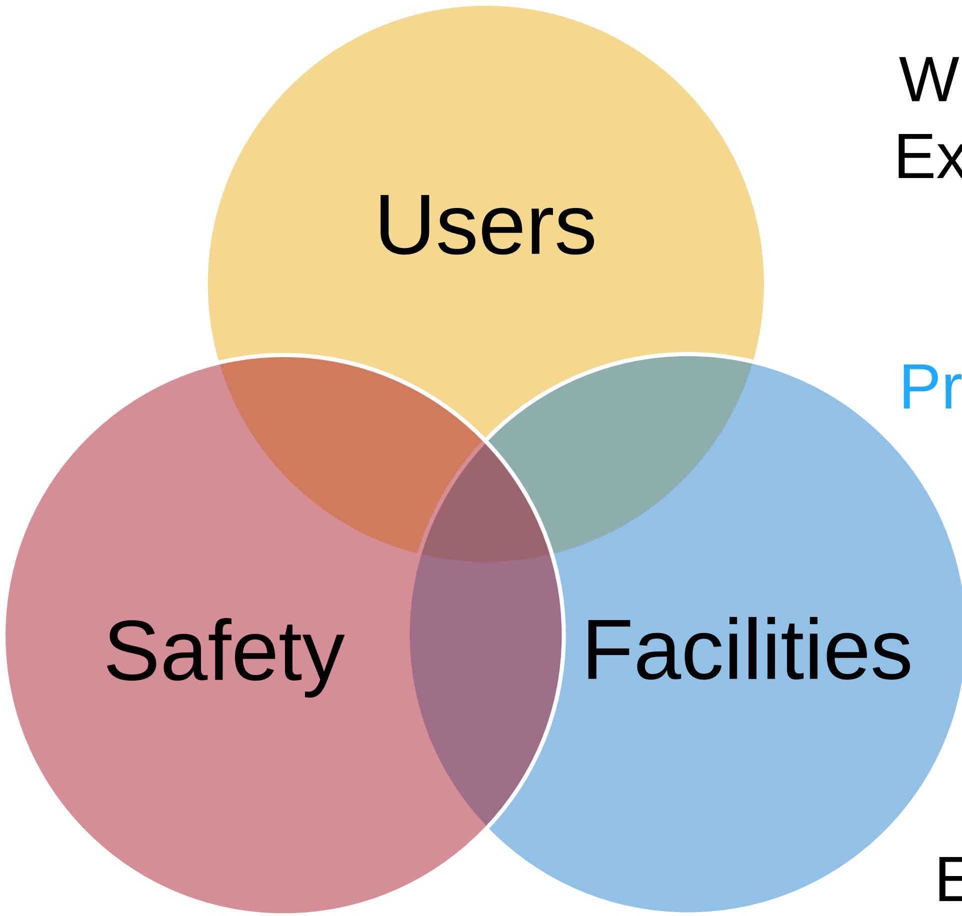
Connectivity



Window position
External exhaust
BSC airflow

External exhaust
Energy consumption
BSC airflow?

Connectivity



Window position
External exhaust
BSC airflow
Scheduling
Protocol support

Certification due
Biosecurity monitoring
Compliance documentation

External exhaust
Energy consumption
BSC airflow

Class II BSCs are great!

"Why don't I get a respirator?"

Dave Phillips

david.phillips@thermofisher.com

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