LAMINAR FLOW EQUIPMENT

- Overview and Guide for a safe employment -

Davide Simone
Area Export Manager

Faster S.r.l. – a DGroup company
Via Merendi 22, Cornaredo (MI) – Italy -
davide.simone@faster.dgroup.it
+39 02 93991606
+39 340 7641035

BASIC ELEMENTS

- Air Cleanliness Classification
  - Class 100 – Class ISO 5 – Class A
  - Filters Classification
  - Hepa filters – Classification – Efficiency – References

LAMINAR FLOW EQUIPMENT

- How it works – Positive and Negative pressure
- Groups and Applications
- LAF cabinets, biohazard and cytotoxic safety cabinets

BIOLOGICAL RISK

- Preamble
- Pathogens Classification
- EU and US Classificiation
- A Guide for a safe and correct employment

Air Cleanliness Classification for clean room environment

References framework

- **Federal Standard 209E** (version. E of 1992) (obsolet since 2001)
- **ISO 14644-1** Air Cleanliness Classification (06/99)
- **ISO 14644-2** Test and surveillance procedures to accomplish 14644-1 requirements (09/2000)
- **ISO 14644-3** Test execution procedures (11/2004)
- **ISO 14644-4** Design,construction and start-up (2004)
- **ISO 14644-5** Operations (2004)

Air Cleanliness Classification for clean room environment

References framework

- **ISO 14644-6** Glossary (2004)
- **ISO 14644-7** Separative devices (hoods, glovebox, isolators, mini-clean room) (2004)
- **ISO 14644-8** Airborn molecular classification (2005)
- **EC** Guide to Good Manufacturing Procedure (in force since 09/2003)
- **NBP FU XI Ed.**

CLASS 100

(US/UK – Anglosaxons System)

Max. 100 particles with diameter in a range between 0,5 e 5 µm in 1cubic feet of air (28 litres about)

CLASS M 3.5

(SI – International Unit System)

As above,but in 1 cubic meter of air (1000 l)
Max. 3530 particles admitted (0,5 µm)
Max. 10600 particles admitted (0,3 µm)

Federal Standard 209E

Classe di contaminazione		LIMITI DI CLASSE									
		0.1 micron		0.2 micron		0.3 micron		0.5 micron		5 micron	
		Unita' di vol.		Unita' di vol.		Unita' di vol.		Unita' di vol.		Unita' di vol.	
		(m^3)	(ft^3)	(m^3)	(ft^3)	(m^3)	(ft^3)	(m^3)	(ft^3)	(m^3)	(ft^3)
M1		*350*	*9.91*	*75.7*	*2.14*	*30.9*	*0.975*	*10.0*	*0.283*		
M1.5	1	*1240*	*35.0*	*265*	*7.50*	*106*	*3.00*	*35.3*	*1.00*		
M2		*3500*	*99.1*	*757*	*21.4*	*309*	*8.75*	*100*	*2.83*		
M2.5	10	*12400*	*350*	*2650*	*75*	*1060*	*30.0*	*353*	*10*		
M3		*35000*	*991*	*7570*	*214*	*3090*	*87.5*	*1000*	*28.,3*		
M3.5	100			***26500***	***750***	***10600***	***300***	***3530***	***100***		
M4				*75700*	*2140*	*30900*	*875*	*10000*	*283*		
M4.5	1000							*35300*	*1000*	*247*	*7.0*
M5								*100000*	*2830*	*618*	*17.5*
M5.5	10000							*353000*	*10000*	*2470*	*70.0*
M6								*1000000*	*28300*	*6180*	*175*
M6.5	100000							*3530000*	*100000*	*24700*	*700*
M7								*10000000*	*283000*	*61800*	*1750*

ISO EN 14644-1

CLEANLINESS CLASS	CLASS LIMIT											
	0.1 µm		0.2 µm		0.3 µm		0.5 µm		1.0 µm		5.0 µm	
	Volume unit		Volume unit		Volume unit		Volume unit		Volume unit		Volume unit	
	m^3	ft^3	m^3	ft^3	m^3	ft^3	m^3	ft^3	m^3	ft^3	m^3	ft^3
ISO Class 1	10	0	2	0								
ISO Class 2	100	2	24	0	10	0	4	0				
ISO Class 3	1000	28	237	6	102	2	35	0	8	0		
ISO Class 4	10000	284	2370	67	1020	28	352	9	83	2		
ISO Class 5	100000	2840	23700	637	10200	289	3520	99	832	23	29	0
ISO Class 6	1000000	28409	237000	6732	102000	2897	35200	999	8320	236	293	8
ISO Class 7							352000	9999	83200	2363	2930	83
ISO Class 8							3520000	99999	832000	23636	29300	832
ISO Class 9							35200000	999999	8320000	236362	293000	8320

EC-GMP Annex 1 2003

EUROPEAN COMMISSION

- Vol. 4 Pharmaceutical legislation
  Drugs regulation for Human and Animal

EC-GMP Annex 1 2003

	AT REST		IN OPERATION	
Grado	NUMERO MASSIMO DI PARTICELLE AMMESSE PER m^3 UGUALI O SUPERIORI A:			
	0.5 µm	5µm	0.5µm	5µm
A	3.500	0	3.500	0
B	3.500	0	350.000	2.000
C	350.000	2.000	3.500.000	20.000
D	3.500.000	20.000	Non definito	Non definito

SUMMING UP…

✓ **Class 100** *according to Fed.209 (obsolete since 2001)*

=

✓ **Class ISO 5** *according to ISO 14644-1 (in force)*

=

✓ **Class A** *according to GMP (in force)*

WHAT IS AN HEPA FILTER ?

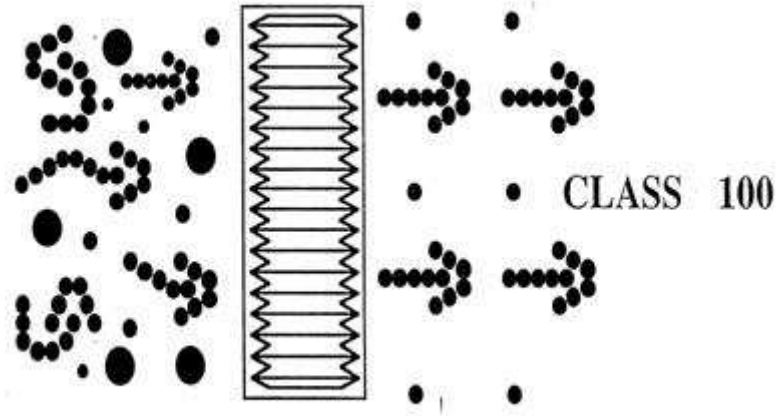
H.E.P.A. is the acronimous for High Efficiency Particulate Air.

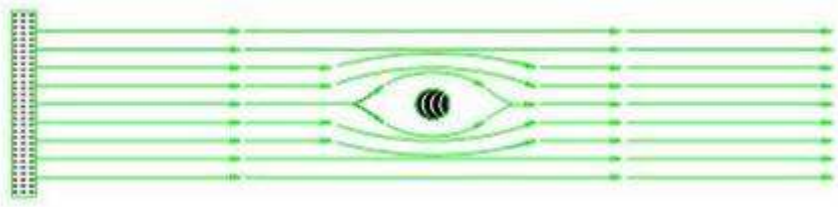
This is a media made of crinckled glass micro-fibers welded with epoxy glue in an aluminium frame. The filter face is covered with a cloth diffusor grid which helps air diffusion downwards. HEPA filters are also called “absolute filters”

WHAT IS AN HEPA FILTER ?

The filter is usefull for:

- remove particulate
- generate laminar flow





HEPA FILTER – Classification and Efficiency -

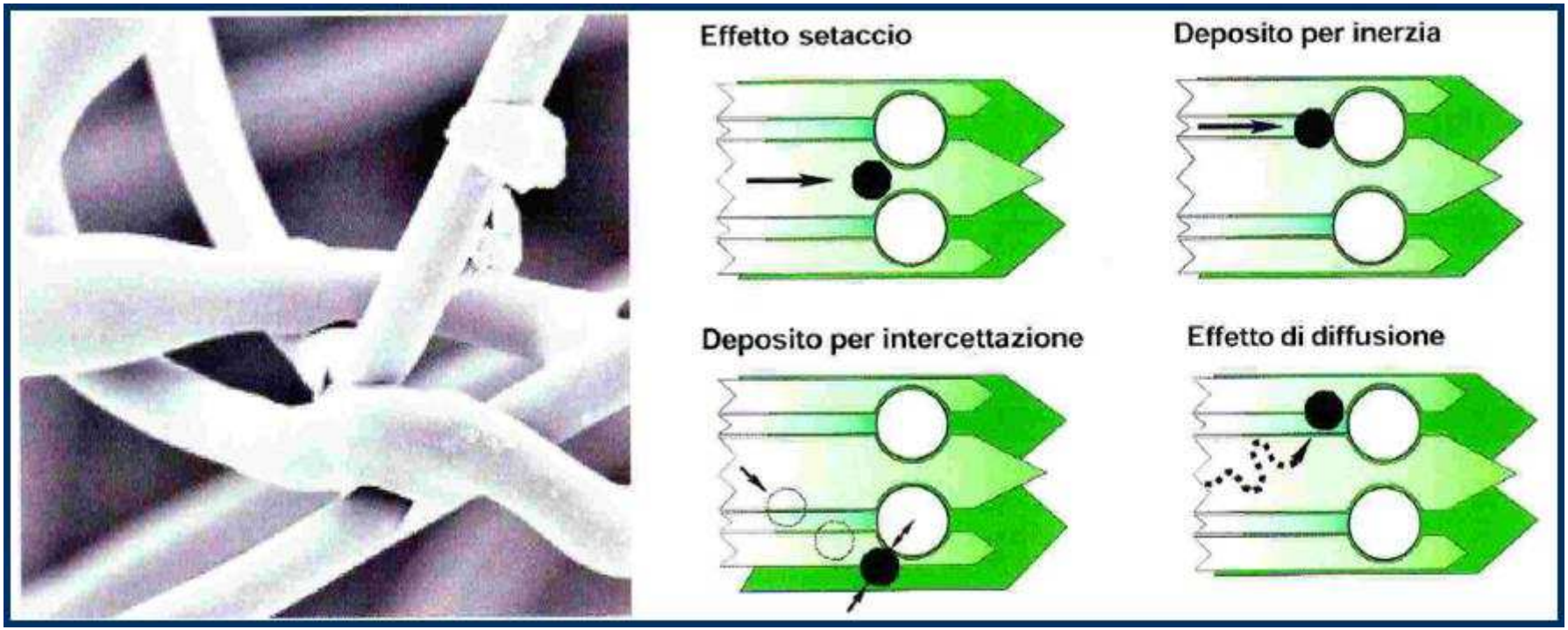
Grado di separazione integrale per MPPS	Classe di filtrazione secondo				
	EN 1822	DIN 24183	DIN 24184	BS3928	Mil. Std. 292
≥ 85%	H 10	EU 10	Q	EU 10	-
≥ 95%	H11	EU 11	R	EU 11	≥ 95%
≥ 99,5%	H 12	EU 12	-	EU 12	≥ 99,97%
≥ 99,95%	H 13	EU 13	S	EU 13	≥ 99,99%
≥ 99,995%	H 14	EU 14	-	EU 14	≥ 99,999%
≥ 99,9995%	U 15	EU 15	-	-	-
≥ 99,99995%	U 16	EU 16	-	-	-
≥ 99,999995%	U 17	EU 17	-	-	-

The European norm regulating the classification and filters efficiency is the norm ***EN 1822***.

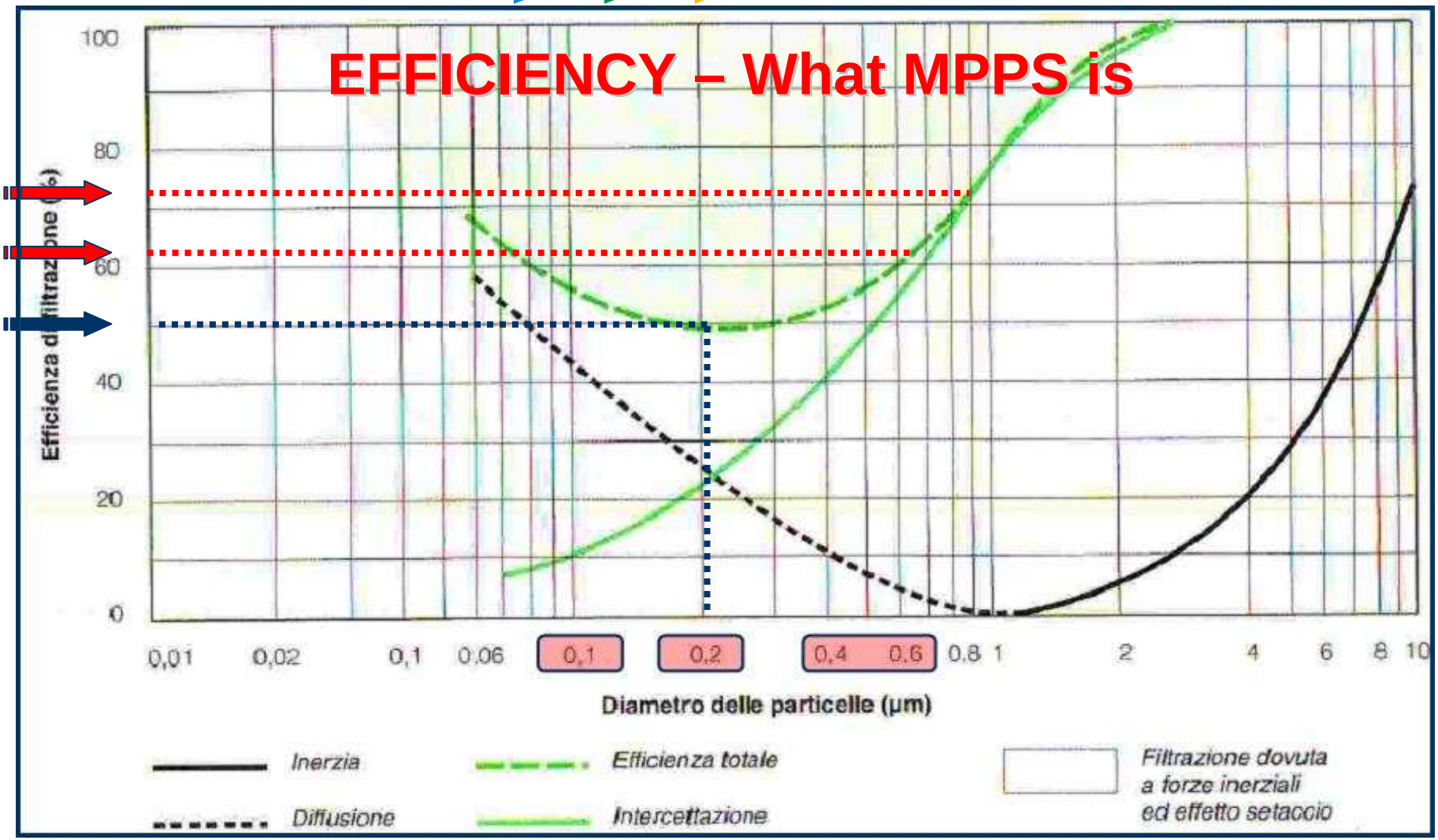
This norm requires to declare the efficiency of the filter tested on the most penetrating particle size ***(MPPS)***

FILTER'S EFFICIENCY – What MPPS is

Preamble



EFFICIENCY – What MPPS is



HEPA FILTER – Efficiency according to EN 1822 -

The efficiency of HEPA H14 according to EU standard is as follows:

- 99,999% on the particles sizes of 0,12 and 0,30 micron
- 99,995% MPPS on the particles of 0,18 micron

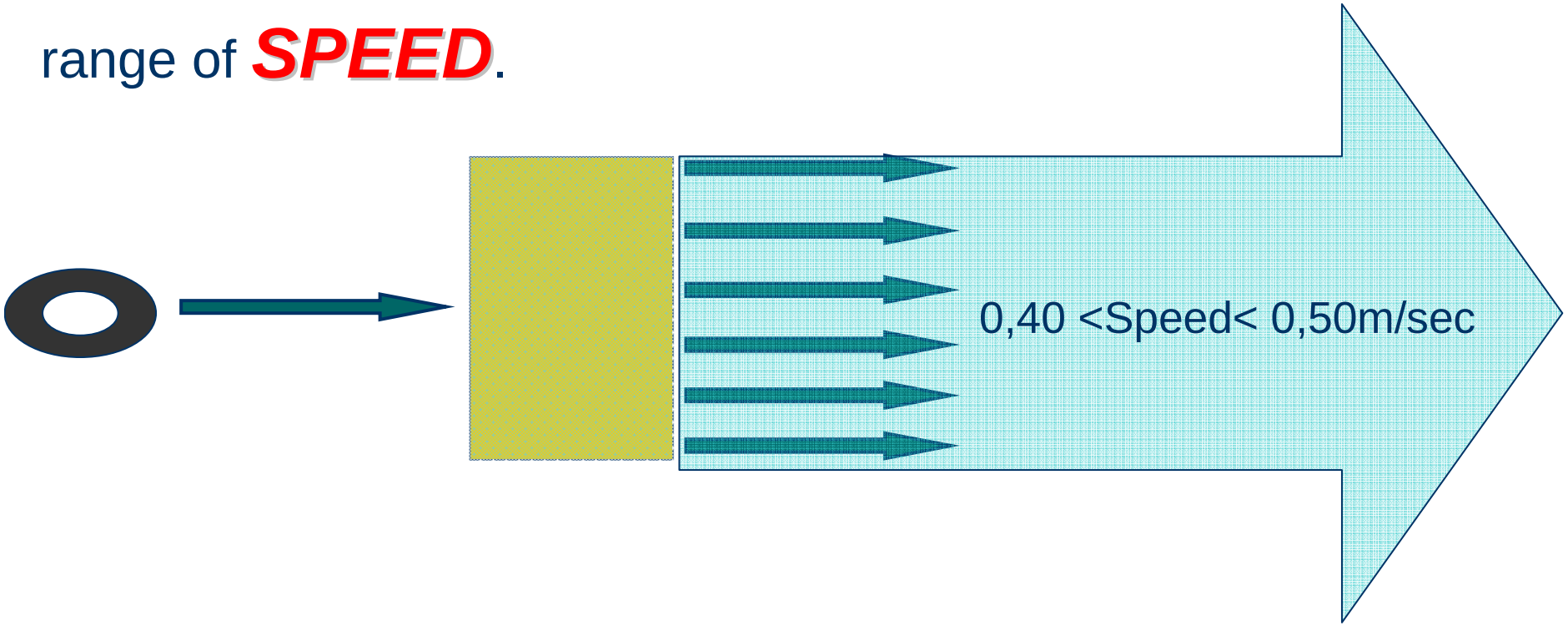
This means that 0,005 particles out of 100 are able to pass throught the filter

H14 in Europe = U15 in USA

the efficiency is the same

a. What laminar flow is and how it works

Laminar flow is ***AIR*** forced through a ***FILTER*** in a given range of ***SPEED***.



a. What laminar flow is and how it works

H14 HEPA FILTER

Speed
0,45m/sec

Class ISO 5 according to ISO:EN 14644-1

Air blew at ***0,45m/sec*** through an ***HEPA filter*** generates a ***sterile environment*** in ***laminar flow*** conditions. Laminar flow is made of parallel stremlines full filling the given volume, preventing from anything from the external environment to reach the volume and anything from the inside to exit from the given volume

c. Positive and Negative pressure, working principals

Overpressure and Negative pressure in few words:

NOT IN

Blowing → Positive Pressure → Air flow Barrier from external Environment

= STERILITY

NOT OUT

Breathing → Negative Pressure → Air flow barrier from internal Environment

= CONTAINMENT

LAMINAR FLOW CABINETS CLASSIFICATION

- **Horizontal laf cabinets** ***(positive pressure)***
- **Vertical laf cabinets** ***(positive pressure)***
- **Microbiological safety cabinets** ***(negative pressure)***
- **Cytostatic safety cabinets** ***(negative pressure)***

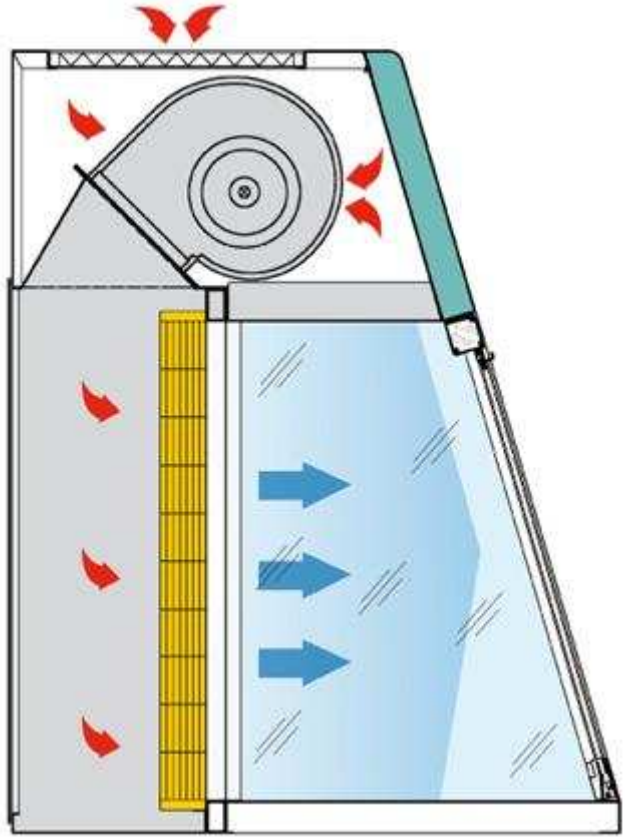
HORIZONTAL LAMINAR FLOW

- to protect the product handled
- to create a sterile working volume

Applications

- Microbiological-sterility test
- Petri dish preparation for microbiology
- IVF (In Vitro Fertilization)
- PNT (Parental Nutritional Preparation)
- Sterile Handling

HORIZONTAL LAMINAR FLOW



VERTICAL LAMINAR FLOW

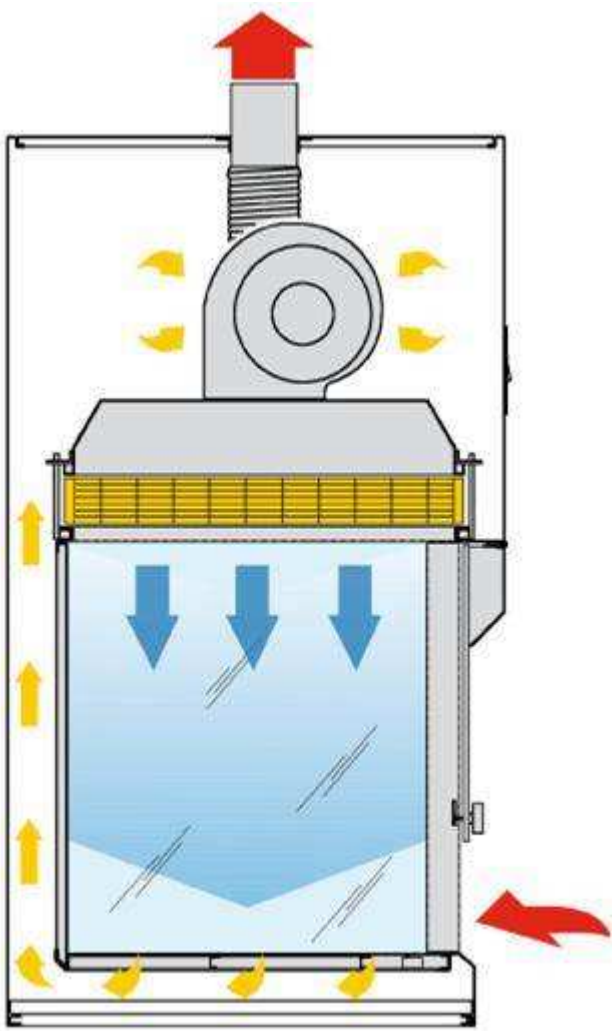
- to protect the product handled
- to create a sterile working volume

Applications

- Microbiological-sterility test
- Petri dish preparation for microbiology
- IVF (In Vitro Fertilization)
- PNT (Parental Nutritional Preparation)
- Sterile Handling

LAF EQUIPMENT

VERTICAL LAMINAR FLOW



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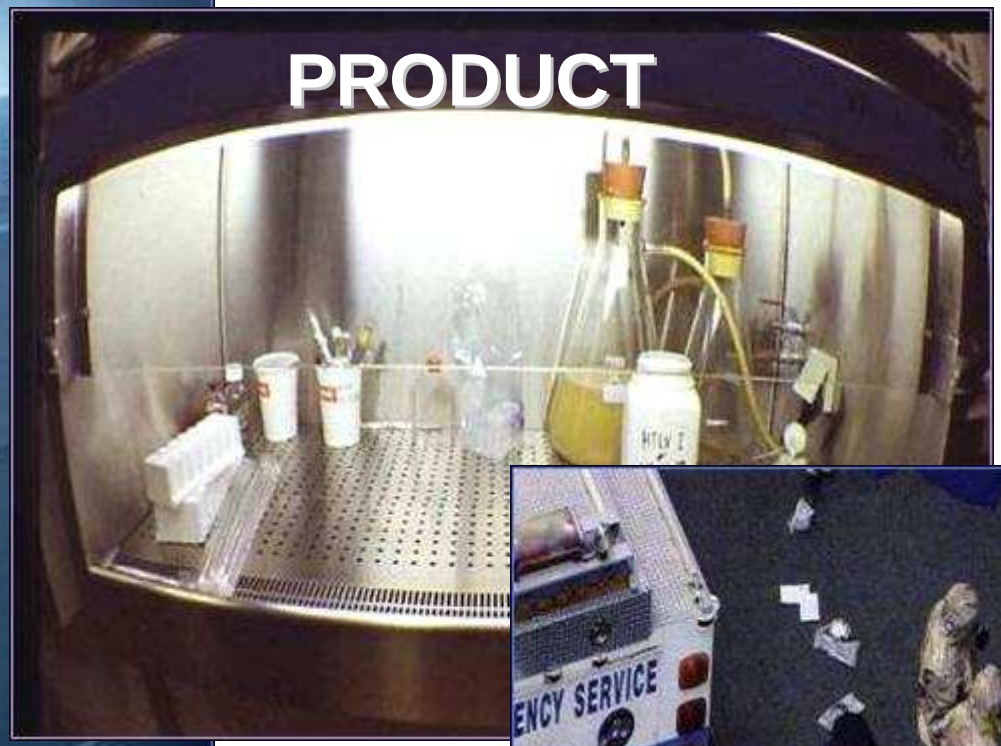
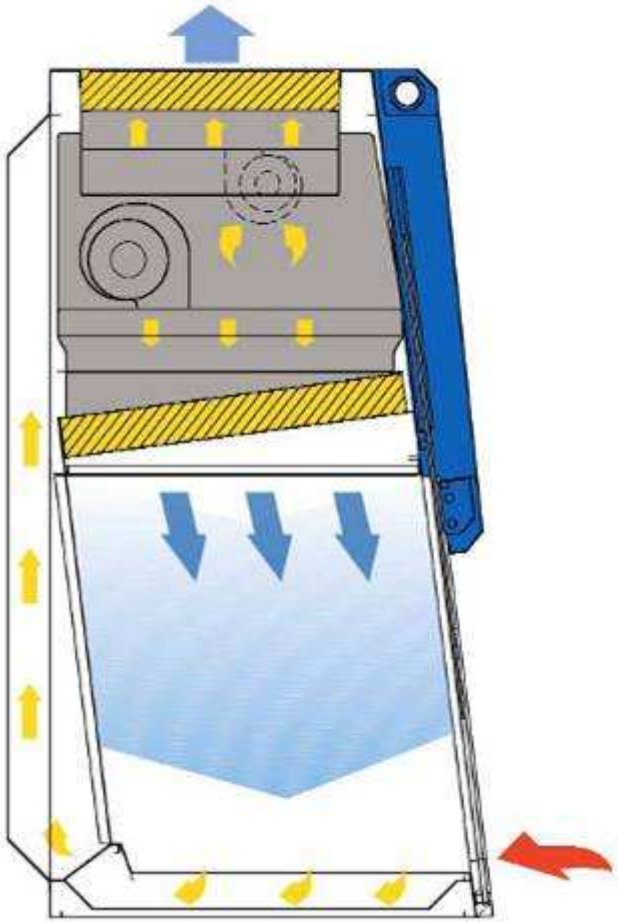
MICROBIOLOGICAL SAFETY CABINETS

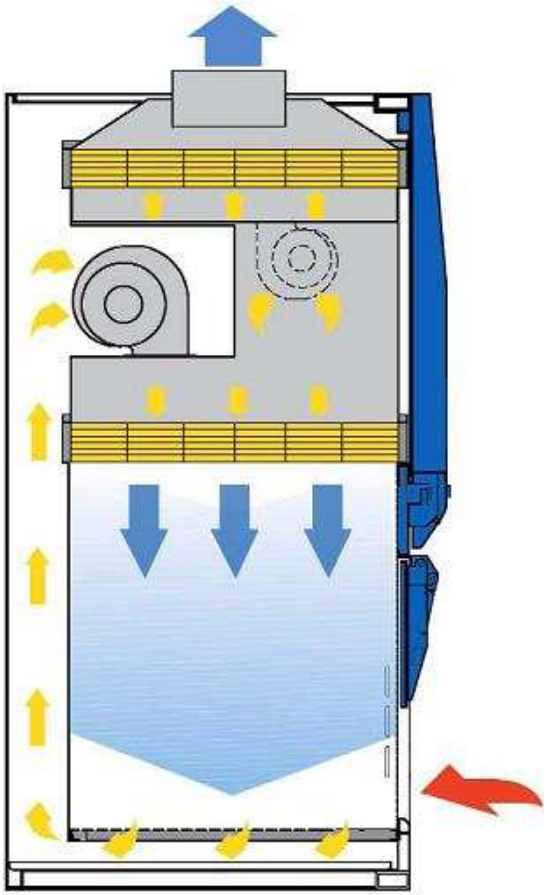
LAF EQUIPMENT



MICROBIOLOGICAL SAFETY CABINETS



MICROBIOLOGICAL SAFETY CABINETS



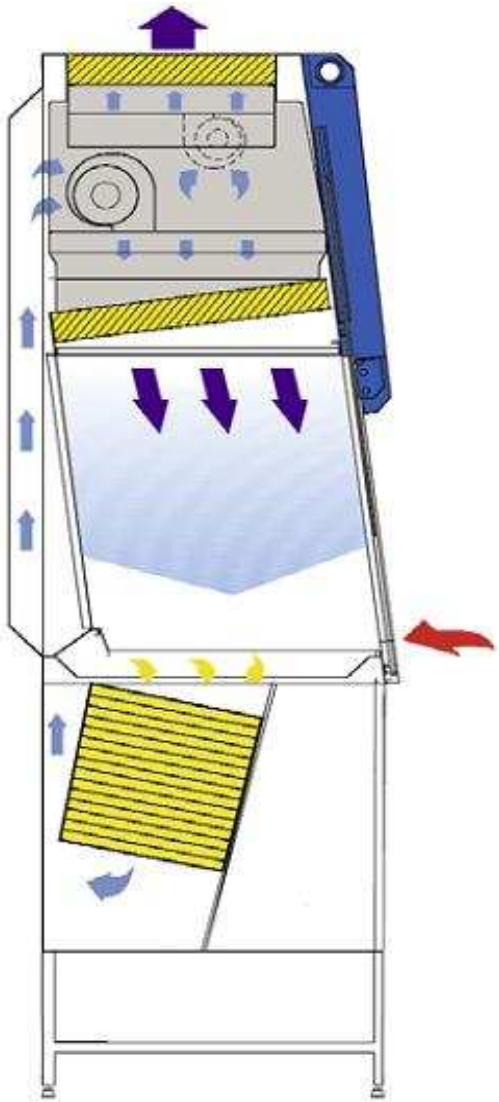
CYTOTOXIC SAFETY CABINETS

- to deliver triple protection
- to guarantee change of the filters in safe conditions

Applications

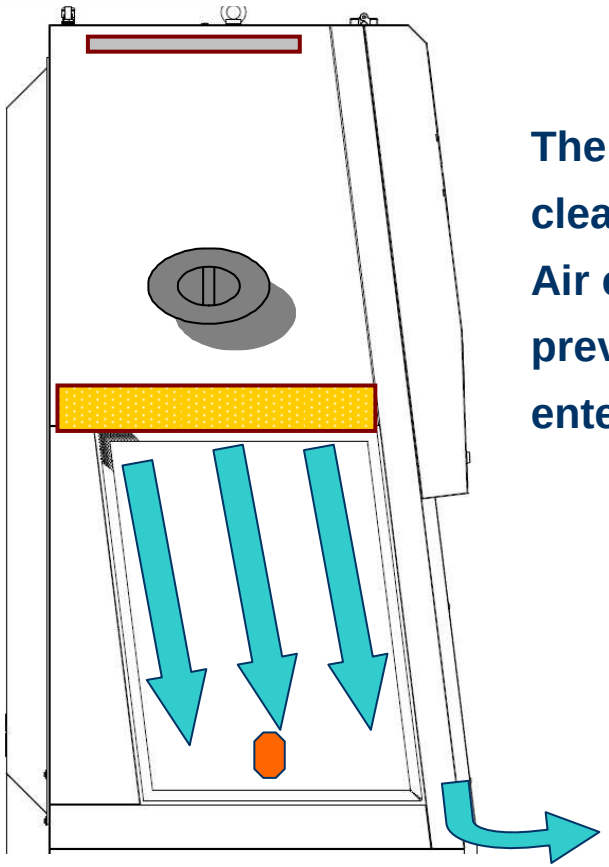
- Preparation of cytotoxic drugs
- Preparation of chemo-therapeutics
- Pathogens handling
- CMR products handling

LAF EQUIPMENT



CYTOTOXIC SAFETY CABINETS

POSITIVE AND NEGATIVE PRESSURE: Working principles



Product Protection

The unit works in *overpressure* bathing the sample with clean air (ISO 5 according to ISO:EN 14644-1).

Air exhausted from the front generates the air flow barrier preventing from contaminated particles from the outside to enter into the working area.

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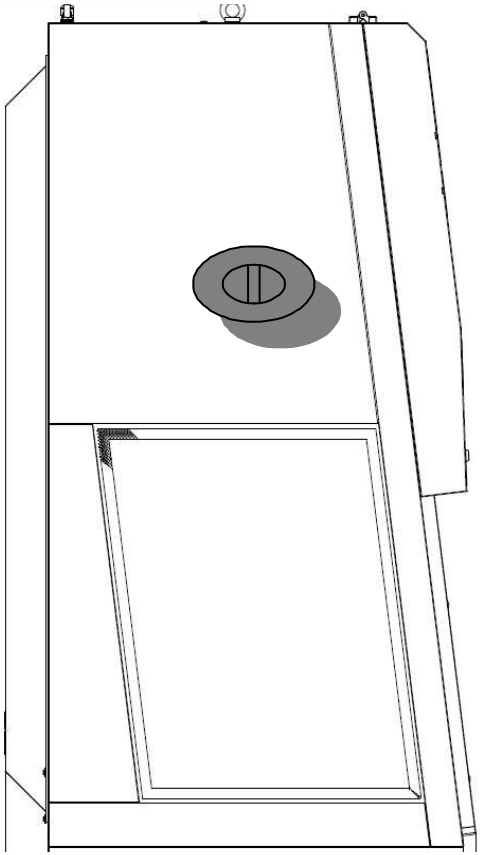
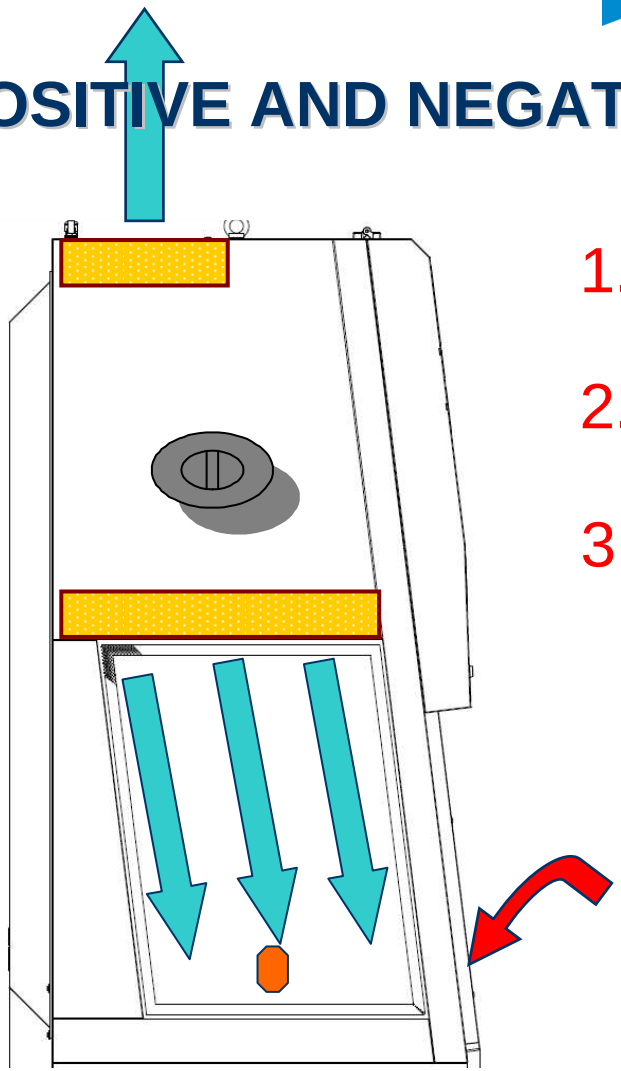
POSITIVE AND NEGATIVE PRESSURE: Working principles



Product, Operator and Environment Protection

The unit is a Microbiological Safety Cabinet according to EN 12469:2000, working in *negative pressure*. The unit delivers *Product Protections* by means of the downflow in laminar flow conditions, *Operator Protections* by means of the frontal air flow barrier, *Environment Protection* by means of the hepa filtered ehxausted air.

POSITIVE AND NEGATIVE PRESSURE: Working principles



1. Product Protection
2. Operator and Environment Protection
3. Environment Protection

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Preamble…

Safety is NOT for sale

Working in safe conditions is the result of a whole of behaviours and processes which include:

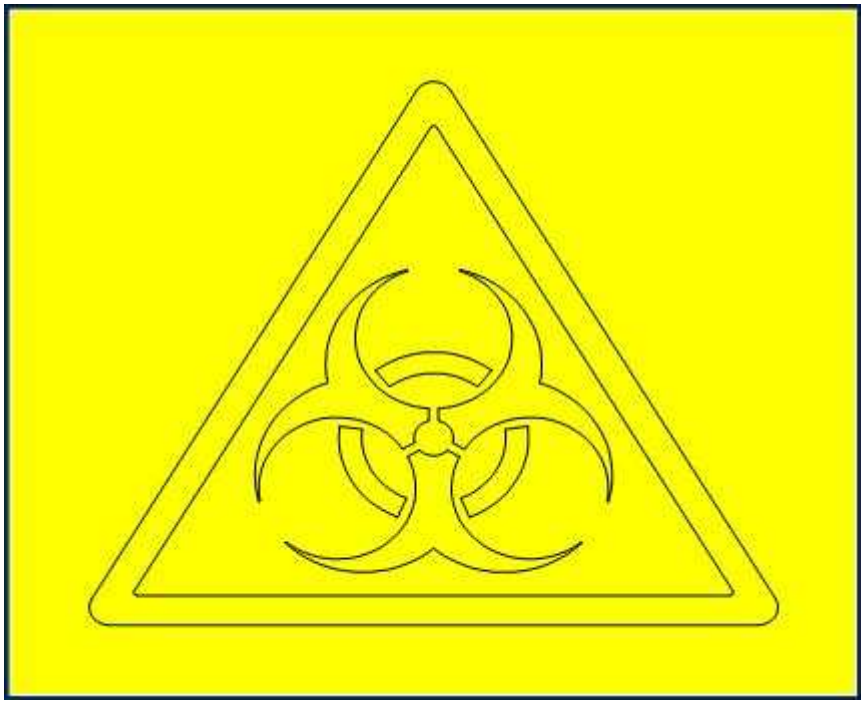
- Continuous risk analysis
- Operator's training
- Operational protocols
- Correct working behaviours
- Appropriate PPE (Protective Personal Equipment)
- Appropriate protective devices

Safety is NOT for sale

MSC and PPE cannot guarantee any protection if are not followed the correct and appropriate *procedures*. Safety is granted by the *professionalism*, *knowledge*, carefullness and *awareness* of each single act. Correct procedures combined with the use of MSC and PPE can drastically reduce **the risk of pathogens contamination** towards the operators and the environment

PATHOGENS CLASSIFICATION

BIOHAZARD



How many types of biological hazardous organisms exist ?

CDC – Center for desease control

DPAG – Dangerous Pathogens Advisory Group

4 Groups of Biological Hazardous Organisms

BIOLOGICAL RISK

Group 1 CDC → Organism does not create human desease

Group 2 CDC → Organism creates human desease but there is an effective treatment

Group 3 CDC → Organism creates severe human desease and can spread into the community but an effective treatment is available

Group 4 CDC → Organism creates severe human desease and can spread into the community and effective treatment is still unknown

PATHOGENS CLASSIFICATION

Two standard classifications are set worldwide:

1) European Standards
2) American Standards

PATHOGENS CLASSIFICATION

EU ➔ *BSI 5726 (GB)*
NF 44-201 (F)
DIN 12950 (D)
EN 12469:2000 (Europe)
MSC - Microbiological Safety Cabinet "Biohazard":
Class I Total exhaust cabinets
Class II Recirculating cabinets
Class III Glove boxes

USA ➔ **NSF 49** *(USA)*
Class I
Class II: II Type A1, II Type A2, II Type B1, II Type B2
Class III

BIOSAFETY CABINETS CLASSIFICATION

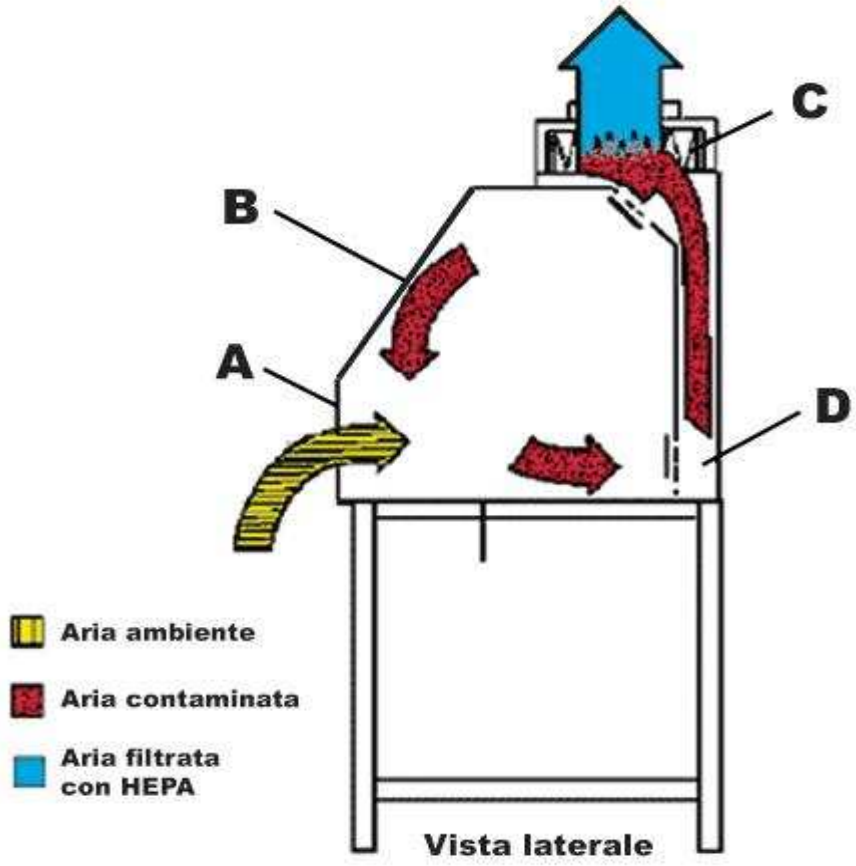
EN 12469:2000	NSF/ANSI 49
Class I	Class I **(same as EN)**
Class II	Class II A2 ***70% recirculated / 30% exhausted / not ducted***
70% recirculated / 30% exhausted / not ducted	Class II B1 ***30% recirculated / 70% exhausted / ducted***
	Class II B2 ***total exhaust / ducted***
	Class II B3 ***70% recirculated / 30% exhausted / ducted***
Class III	Class III **(same as EN)**

CLASS I

Class I – Application

- to handle low and moderate pathogen agents belonging to Group 1

CLASS I


C
B
A
D
Aria ambiente
Aria contaminata
Aria filtrata con HEPA
Vista laterale

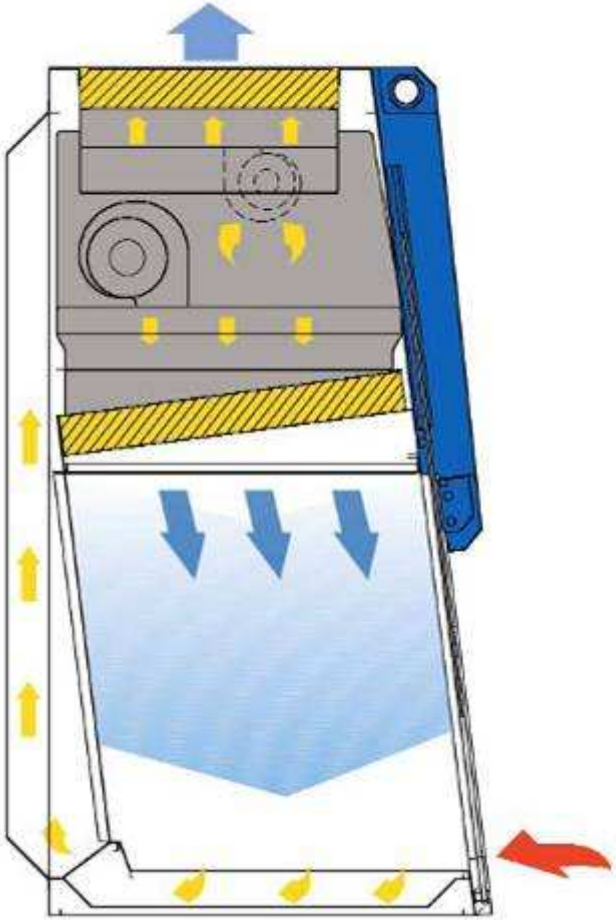
BIOHAZARD
SafeFAST Top

CLASS II

Class II – Application

- to handle pathogen agents Group 2

CLASS II

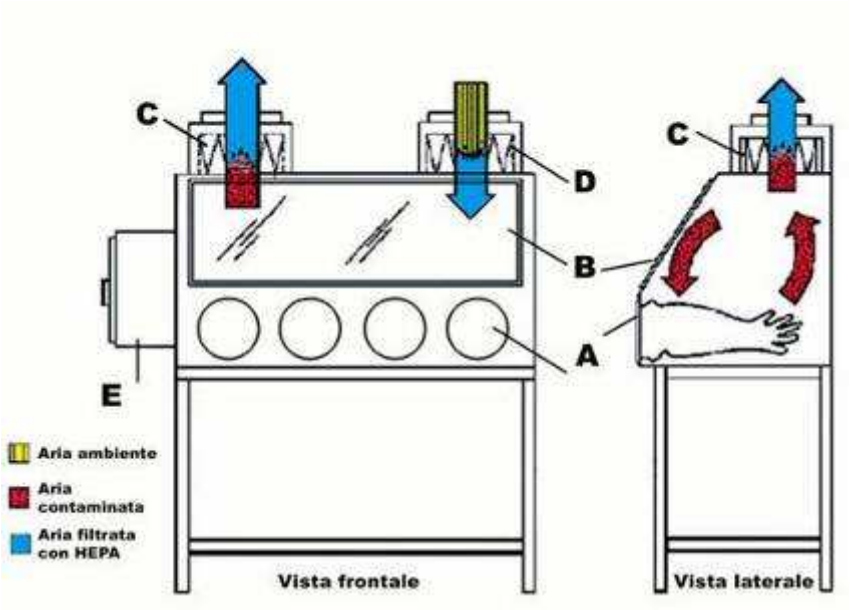


CLASS II

Class III – Application

- Glove box cabinets to handle pathogen agents belonging to Group 3 and 4 in appropriate laboratory classified BL3 and BL4

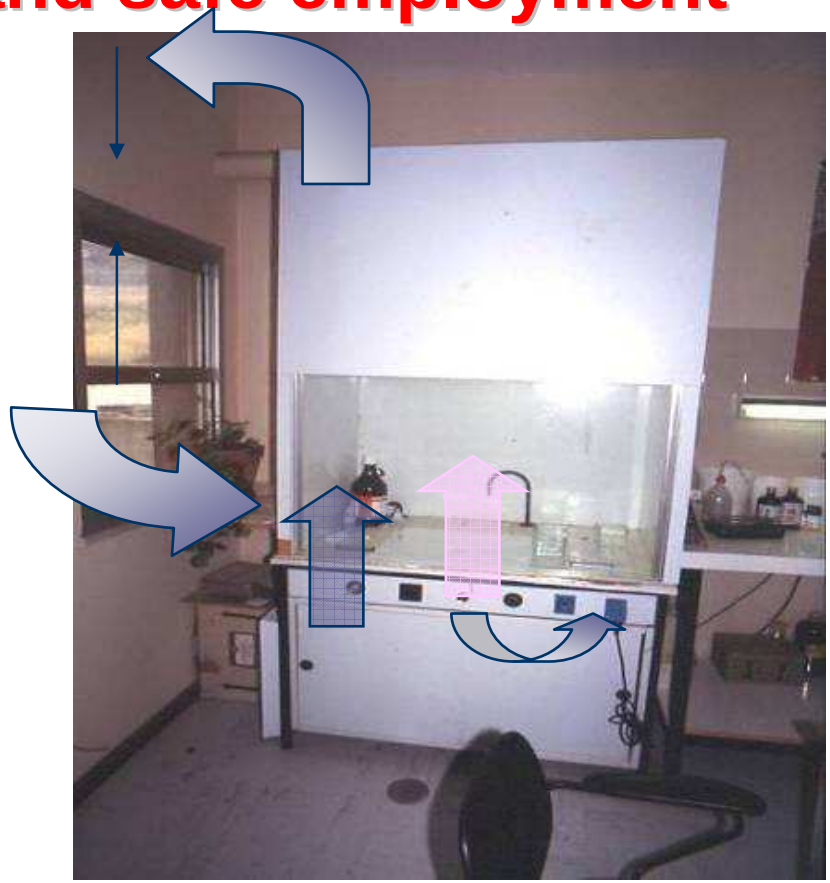
CLASS II


C
D
B
A
E
C
Aria ambiente
Aria contaminata
Aria filtrata con HEPA
Vista frontale
Vista laterale

BIOHAZARD CABINETS

A guide for a correct and safe employment

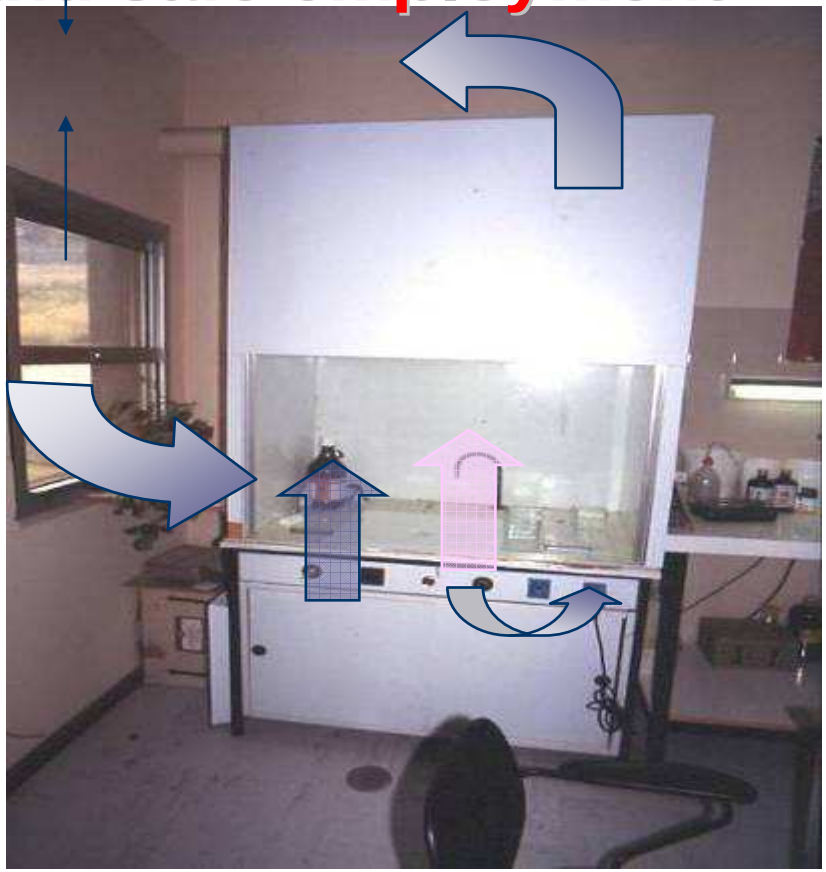
POSITIONING



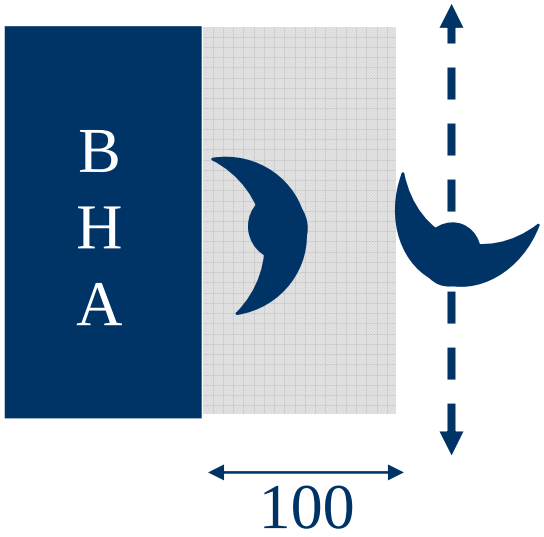
BIOHAZARD CABINETS

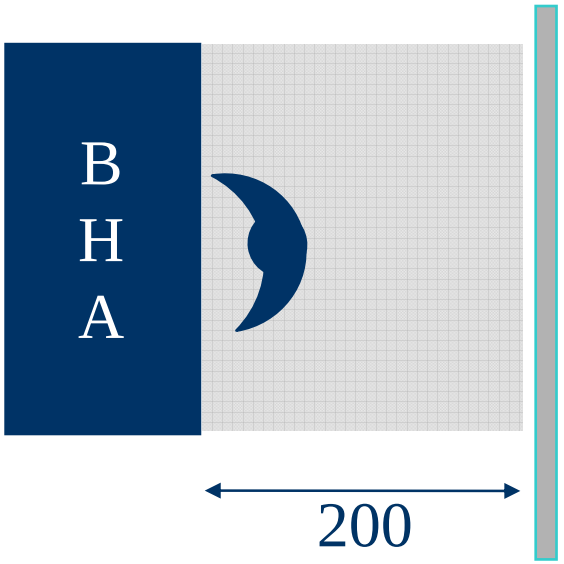
A guide for a correct and safe employment

- The correct position of the cabinet inside the lab is far from turbolences considering doors, windows and air conditioning inlet distance

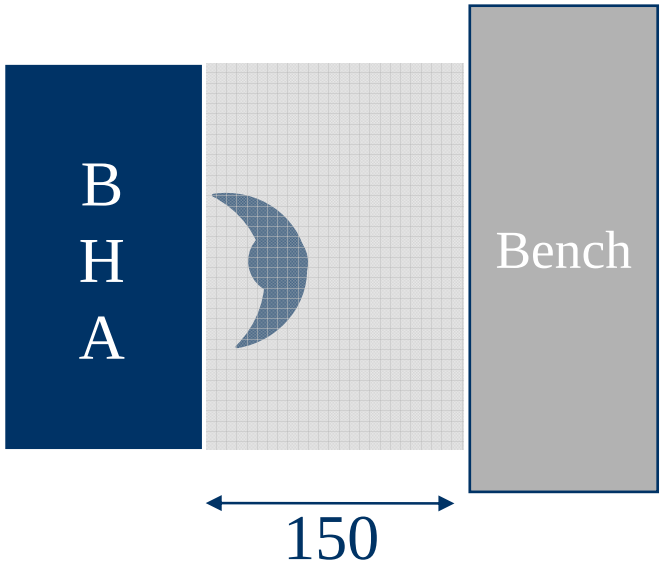


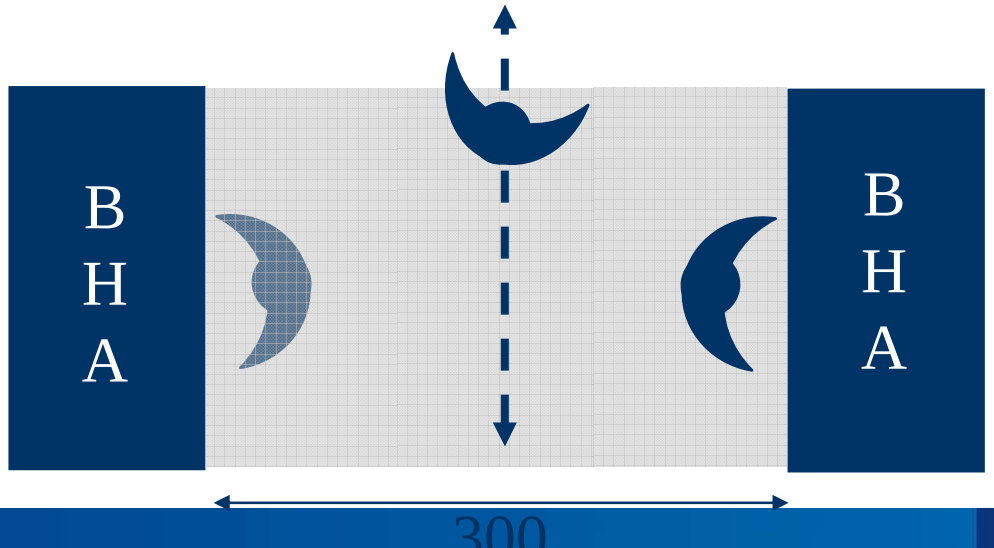
POSITIONING… consider the intermediate distances between the hoods, benches, walls and routine operations





BIOLOGICAL RISK





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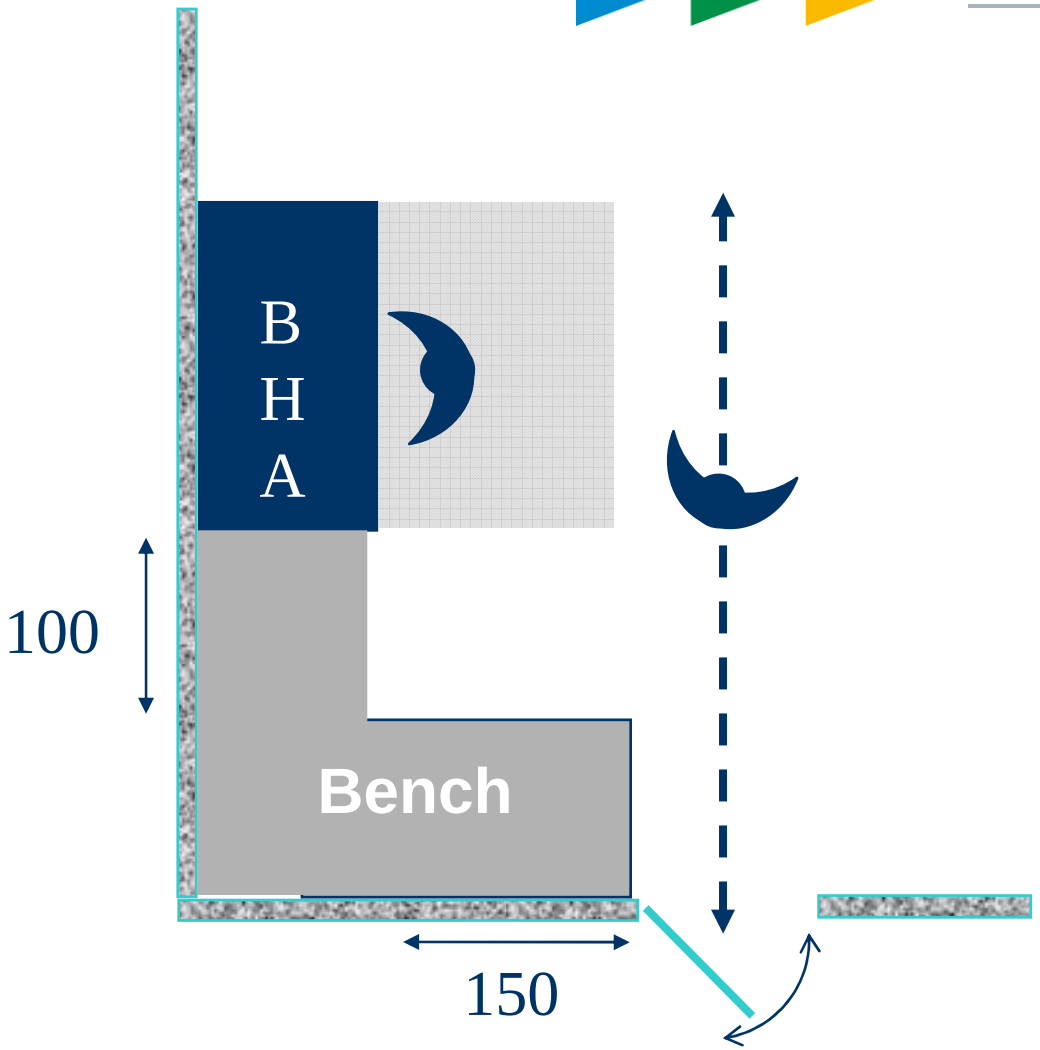
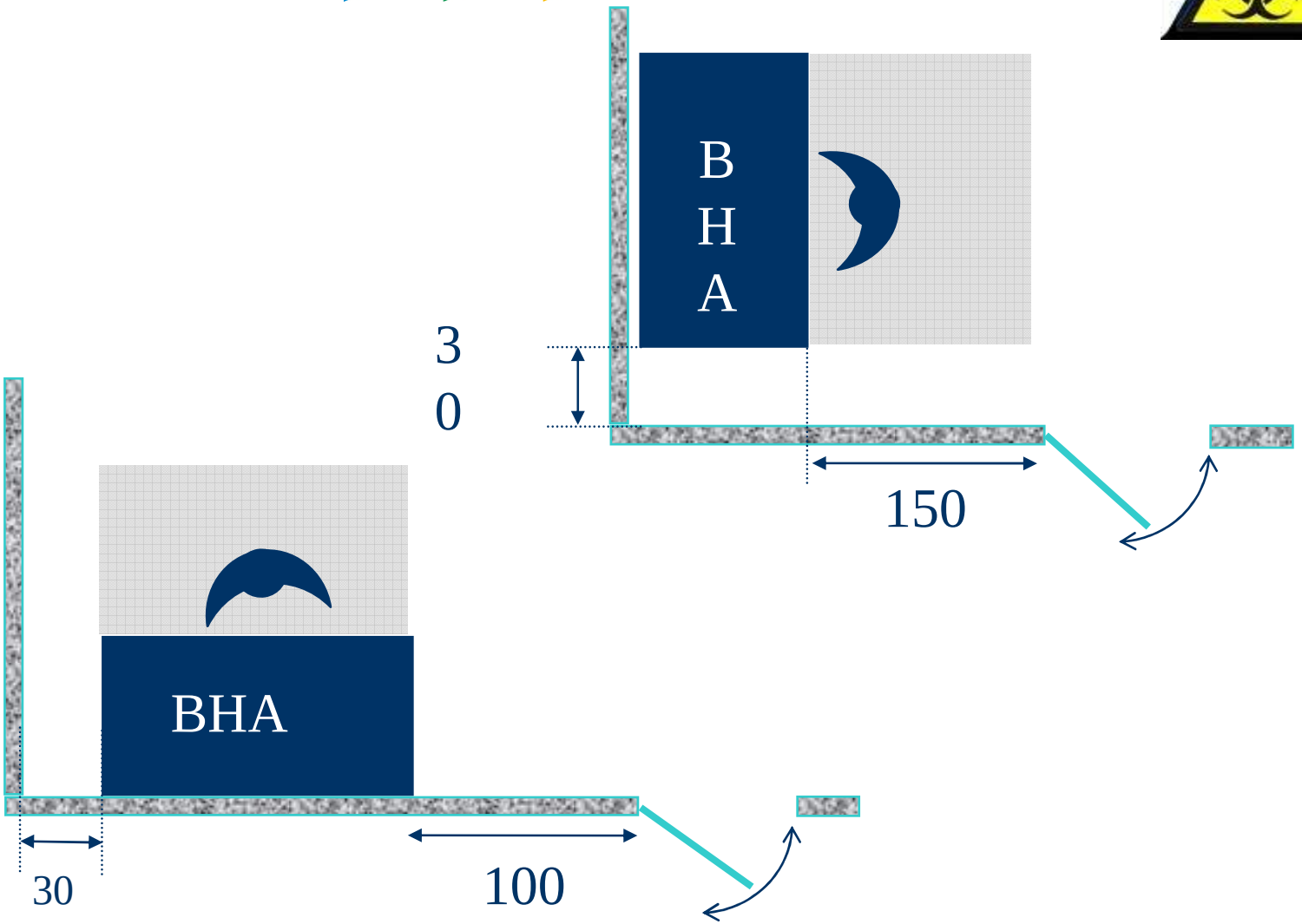
BIOLOGICAL RISK



BIOLOGICAL RISK



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BIOHAZARD CABINETS

A guide for a correct and safe employment

WORKING

BIOHAZARD CABINETS

A guide for a correct and safe employment

1) Arrange a check list of:

- **Operations to do**
- **Main and essential items to be used**

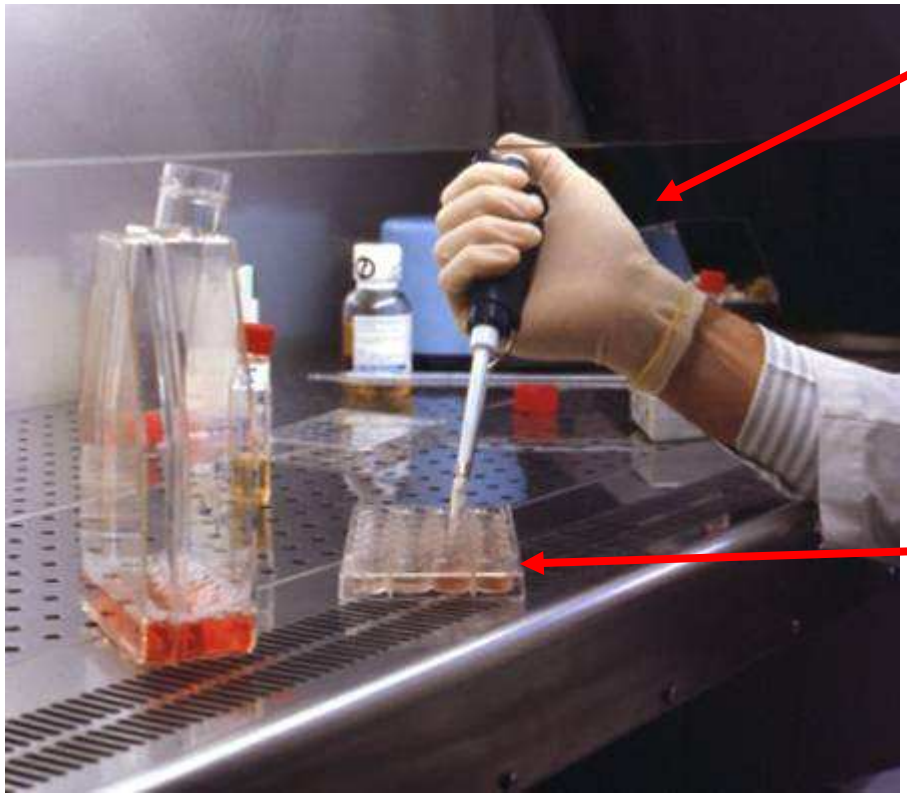
2) Switch ON the cabinet at least 10-15 minutes before starting to work with the cabinet

3) Wear appropriate PPE garments

Disinfect the working surfaces carefully, top-down movements starting from periphery to the centre

Introduce just the essential items inside the chamber

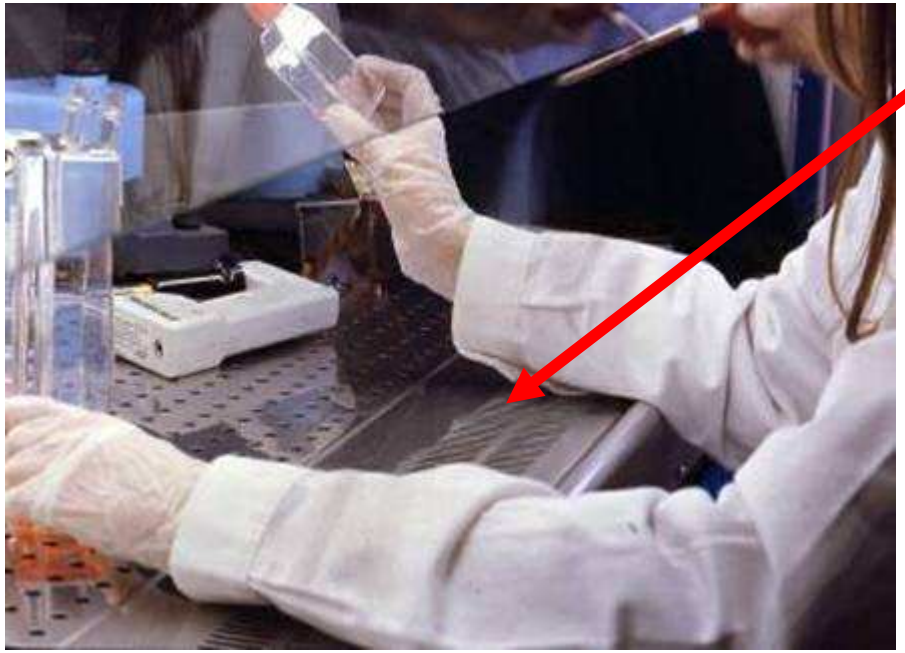
WHILE HANDLING THE PRODUCT



The components which are not essential, must be placed on the back side of the chamber

Working with sterile material positioned on the inlet grid, expose the product to contamination coming from the environment

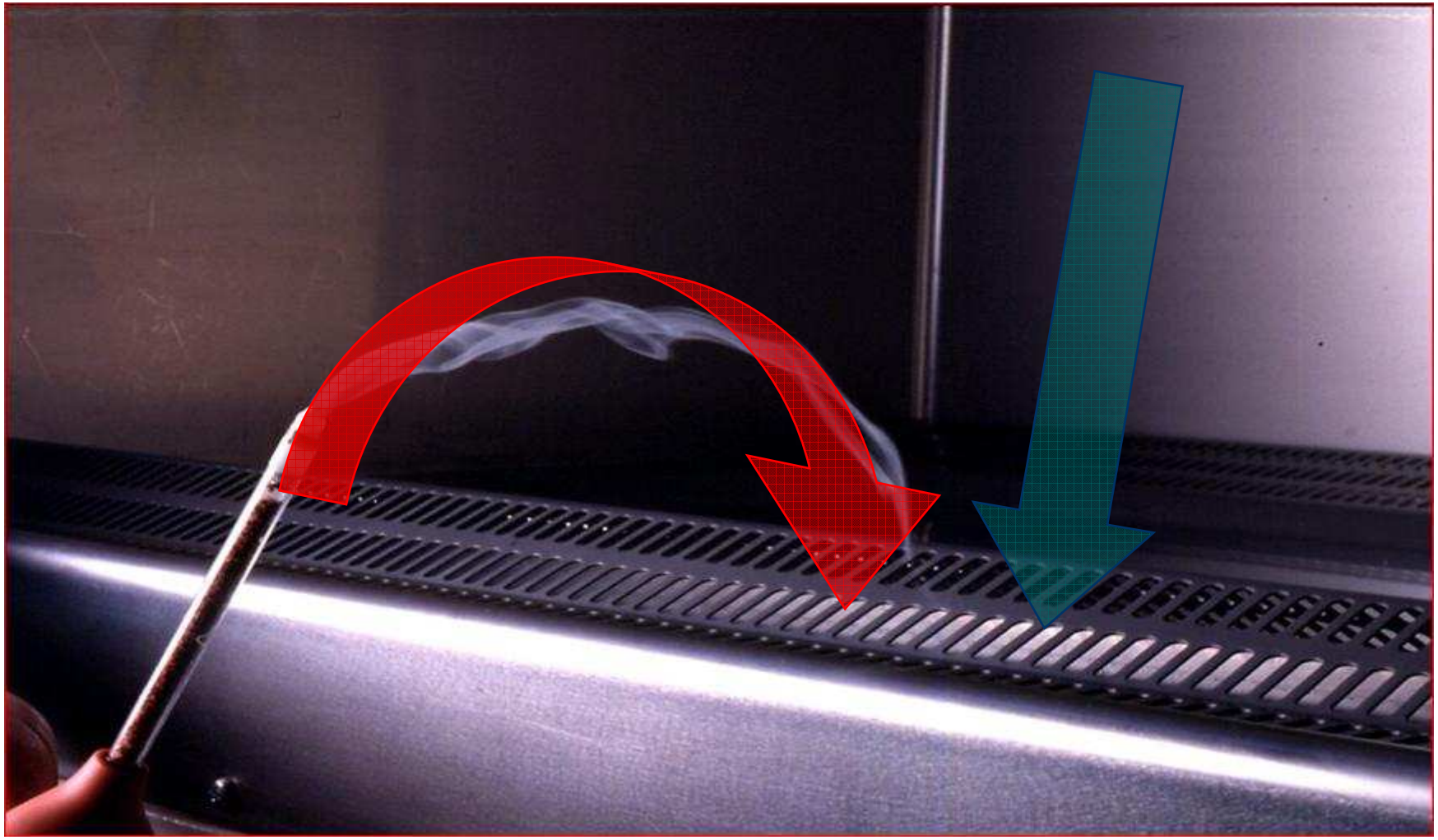
Keep the arms in correct position

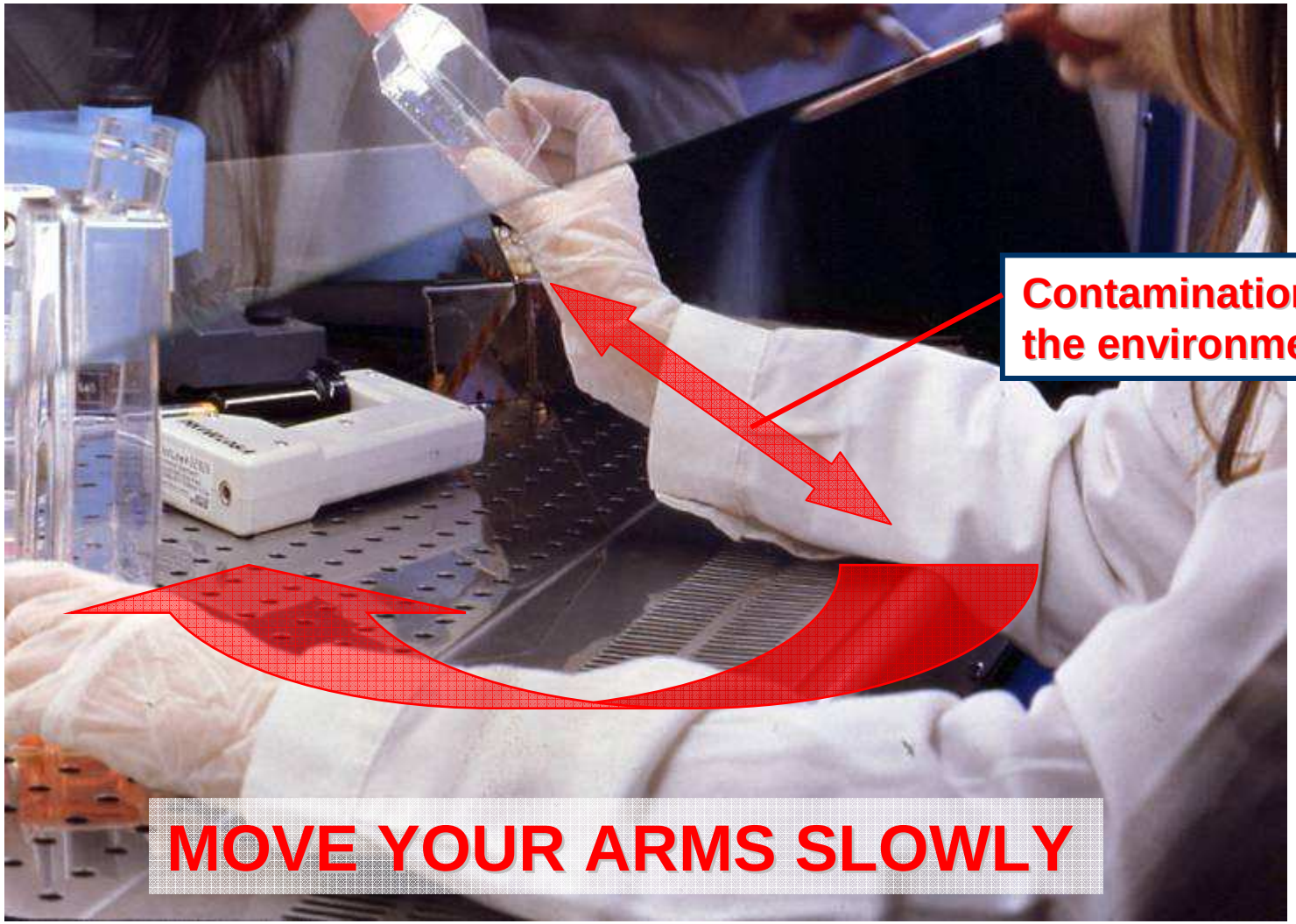


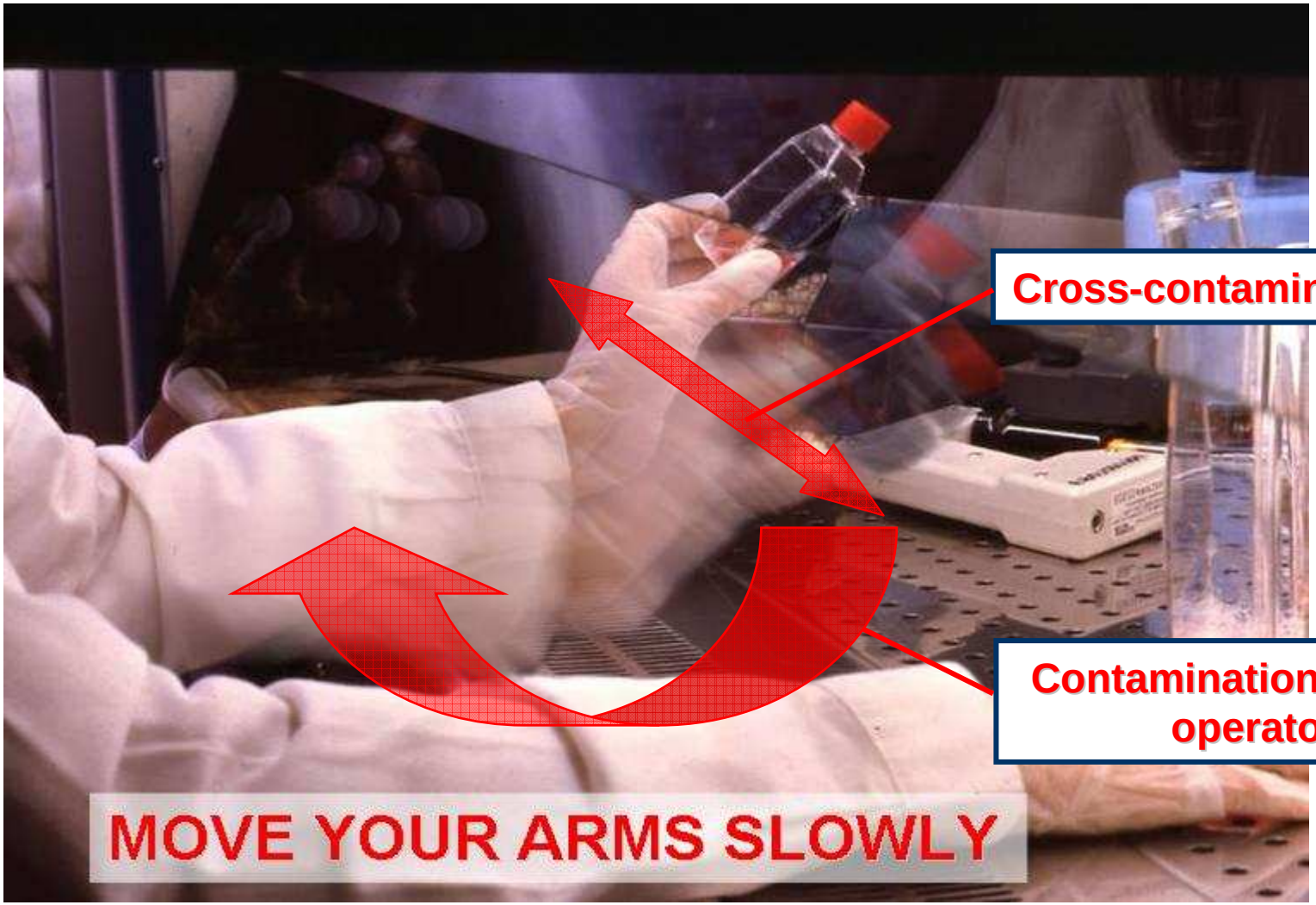
Keep the inlet grid free from any obstacle

Keep the arms in correct position

Operator is the first source of contamination for the product and contamination for himself




Contamination from the environment
MOVE YOUR ARMS SLOWLY



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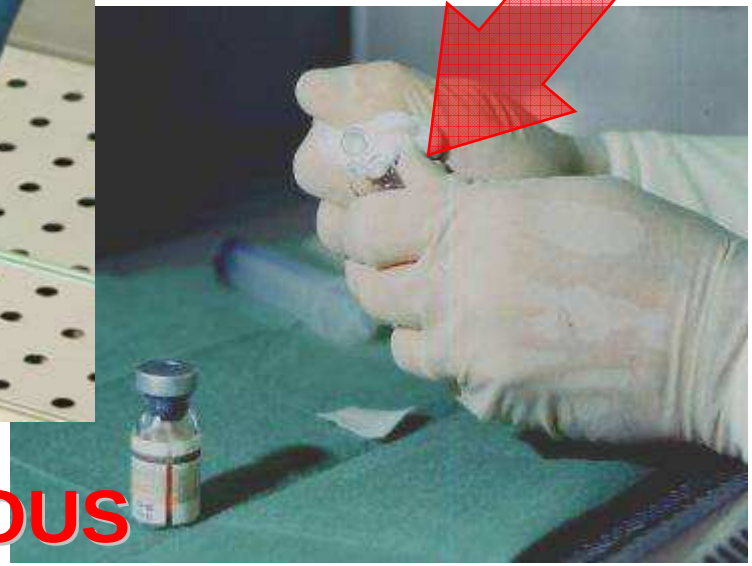
Use appropriate tools to transfer liquids



POTENTIALLY DANGEROUS

*Summing up…*to work in safe conditions means :

- To move the arms parallel to the working surface
- To work from the center to the back side of the working surface
- Before handling the products, wash your arms with the LAF bath for 1 minute about to remove the particles from your garments

*Summing up…*to work in safe conditions means :

- Introduce just the essential components
- Don’t close the inlet grid with arms or tools
- Avoid rapid movements of your arms, in particular side movements
- Don’t work too close to the inlet grid area
- Avoid to put your arms on top of sterile materials
- Don’t open the frontal window while working

How to avoid BIOLOGICAL CONTAMINATION RISK

Correct cabinet's employment

Correct working behaviour

Handle small volumes

Correct cabinets maintenance

Correct contaminated waste management

Correct cleaning and decontamination procedures

FASTER RANGE OF PRODUCTS

Biological safety cabinets:

SafeFAST Elite

SafeFAST Top

SafeFAST Classic

FASTER RANGE OF PRODUCTS

Cytotoxic safety cabinets:

CytoFAST Elite

CGB – Cytotoxic glove box

FASTER RANGE OF PRODUCTS

LAF cabinets :

Vertical LAF cabinets:

- FlowFAST V
- SmartFAST
- SmartFAST mini

Horizontal LAF cabinet:

- FlowFAST H

THANK YOU FOR YOUR ATTENTION

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