

Thermo Scientific Biological Safety Cabinets New Lab Construction Glossary of Terms

Access Opening (also called Front Access Opening or Sash Opening or Work Aperture): The front opening of the chemical fume hood or Class II biological safety cabinet (BSC), through which work is performed. (adapted from SEFA 1-2006, Section 9.0)

Activated Carbon Filter: A filter that can trap trace amounts of chemicals and toxic odors.

Aerosols: Colloids of liquid or solid particles, less than 10 µm in diameter, suspended in gas.

Aerosol Generator: Electronic instrument used to generate an aerosol that is used to challenge HEPA filters for integrity.

Aerosol Photometer: Electronic instrument used to detect leaks on HEPA filter integrity testing. Used in conjunction with a generator.

Air Changes per Hour (ACH or AC/H): The number of times the air in a space (typically a room) is theoretically replaced during an hour. This is used as a measure of ventilation in a room. (adapted from SEFA 1-2006, Section 9.0)

Airflow Velocity: Measured in metres per second (m/s) or feet per second (f/s).

Airflow Volume: Measured in cubic metres per second (m³/s) or cubic feet per minute (ft³/min or cfm).

Airflow Uniformity: The required airflow pattern where all readings are within 20% of the average air velocity.

Anemometer: A measuring device used to measure air velocity.

Aperture Protection Factor (APF): A measurement of the containment safety of a Class II cabinet. This is done by using the KI-DISCUS test.

Aseptic: A sterile environment, free from contaminating particles or organisms.

Bio-Hazard: A contraction of biological hazard meaning a biological agent that is a threat to humans. (adapted from NSF/ANSI 49-2008, Section 3.2)

Biological Safety Level (BSL): There are four biosafety levels, BSL 1, 2, 3, or 4, consisting of combinations of laboratory practices and techniques, safety equipment and laboratory facilities. Each combination is specifically appropriate for the operations performed on the documented or suspected routes of transmission of the infectious agents and for the laboratory function or activity. BSL1 is appropriate for work with the least hazardous agents. BSL2 is typical of many biological laboratories including most hospital microbiological laboratories. BSL3 is used when more hazardous agents are handled. BSL4 is for work with the most dangerous agents.

Biological Safety Cabinet (also called BSC or Biosafety Cabinet, formerly called Biohazard Cabinet): A Class I, II, or III biological safety cabinet that provides personal or personnel protection AND environmental protection by HEPA filtration of the exhaust flow from the cabinet, which captures any biological hazards. The Class II and Class III BSCs also provide product protection through the provision of HEPA filtered clean air to the work area. The Class II BSC also provides protection from cross-contamination within the work area through the provision of laminar flow clean air flowing through the work area, which is not provided by all models of Class III BSC.

Carcinogenic: A cancer-causing substance.

Certification (or Field Certification): Documented test results showing performance and safety of a cabinet.

Chemical Fume Hood (or Laboratory Hood): A device located in a laboratory, enclosed on five sides with a movable sash or fixed partial enclosed on the remaining side. It is constructed and maintained to draw air from the laboratory and to prevent or minimize the escape of air contaminants into the laboratory. It also allows chemical manipulations to be conducted in the enclosure without insertion of any portion of the employee's body other than hands and arms. (adapted from OSHA's Occupational exposure to hazardous chemicals in laboratories 1910.1450 (b))

Class I Biosafety Cabinet: A ventilated cabinet for personnel and environmental protection, having an unrecirculated inward airflow away from the operator that exhausts all air to the atmosphere after filtration through a HEPA filter. Class I cabinets are suitable for work where no product protection is required. (adapted from NSF/ANSI 49-2008, Section 3.4.1)

Class II Biosafety Cabinet: A ventilated cabinet for personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA filtered exhausted air for environmental protection. NOTE – When toxic chemicals or radionuclides are used as adjuncts to biological studies or pharmaceutical work, Class II cabinets designed and constructed for this purpose should be used. (adapted from NSF/ANSI 49-2008, Section 3.4.2)

Class II, Type A1 BSC: This is the first Class II BSC design. It only needs a minimum inflow of 75 fpm and until 2009 was allowed to have positive pressure contaminated plenums exposed to an outer wall.

Class II, Type A2 BSC (formally Class II, Type A/B3 BSC): The most common type of BSC. It is required to have a minimum inflow of 100 fpm and is not allowed to have positively pressurized contaminated plenums exposed to an outer wall of the cabinet. Most biological applications (like cell culture and biosafety) do not use volatile toxic chemicals or volatile radionuclides so an A2 vented to the laboratory is ideal. If volatile toxic chemicals or volatile radionuclides are used with the biological research, they can externally exhaust this cabinet through a thimble connection.

Class II, Type B1 BSC: The first externally exhausted or ducted Class II BSC design, which is not commonly used today. It has a minimum inflow of 100 fpm and no positively pressurized contaminated plenums. The recommended usage for volatile toxic chemicals is the same as for the thimble A2.

Class II, Type B2 BSC (also called a Total Exhaust Hood): The preferred type of Class II BSC by NIOSH (US) for work with anti-cancer (cytotoxic or hazardous) drugs. It has a minimum inflow of 100 fpm and no positively pressurized contaminated plenums. It has a large exhaust requirement as measured by flow (in cfm/cmh) and suction (in static pressure – inches w.g. or pascals). Its recommended usage for volatile toxic chemicals is the same as for the thimble A2.

Class III Biosafety Cabinet: A totally enclosed, ventilated cabinet of leak-tight construction. Operations in the cabinet are conducted through attached rubber gloves. The cabinet is maintained under negative air pressure of at least 0.50 in w. g. (120 Pa). Downflow air is drawn into the cabinet through HEPA filters. The exhaust air is treated by double HEPA filtration or by HEPA filtration and incineration. Insider note: A Class III BSC is a certain type of glovebox. So while all Class III BSCs are gloveboxes, not all gloveboxes are Class III BSCs. (adapted from NSF/ANSI 49-2008, Section 3.4.3)

Cleanroom: A room or suite of rooms with controlled limits set for air cleanliness/pressures/airflows/temperature/operating procedures.

Concurrent Balance Value: Field certifiers in North America use different methods to measure BSC exhaust than used by air balancers and the traditional HVAC engineers. The concurrent balance value is the exhaust flow measurement from the BSC (usually a Type B1 or B2) as if measured by the air balancer or HVAC engineer.

Containment: The use of HEPA filters to control airflow and pressure within a cabinet or other enclosure or room to capture hazardous aerosols.

Containment Level 3 Laboratory (also called Physical Containment Level 3 Laboratory and in the UK a Cat III or Category III Laboratory): As described in the European Standard EN 12128:1998 “Biotechnology – Laboratories for research development and analysis, containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements.” This is generally analogous to the US or WHO BSL3 Laboratories. This document addresses the physical containment elements of the microbiology laboratory so it does not describe what classes of BSC should be present. EN 12128:1998 has the following requirements for Cat III laboratories (this is only a partial list):

- The exhaust (extract) air from the laboratory must be HEPA filtered.
- The laboratory can be sealed for disinfection (fumigation).
- The laboratory is negatively pressurized relative to outer areas.

COSHH (also called Control of Substances Hazardous to Health Regulations 2002): One of the key regulatory documents addressing biological safety provisions in the UK. Schedule 3 of this document is “Additional Provisions Relating to Work with Biological Agents”. Biological agents are classed into Group 1 through Group 4 analogous to the Risk Group system used by the WHO. Based on the Group of the biological agent, they are assigned to minimum containment levels. In Schedule 3 addressing containment in health and veterinary care facilities, laboratories and animal rooms, the document requires “Infected material, including any animal, is to be handled in a safety cabinet or isolator or other suitable containment” for Containment Levels 2 and 3 when aerosols are produced and in Containment Level 4 all the time.

Contaminated Plenum (usually more correctly called Potentially Contaminated Plenum): The space in which a gas, usually air, is contained at a pressure different from atmospheric pressure. This plenum contains potentially contaminated air as the air originated within the work area of a BSC and has not been filtered. (adapted from the “NIOSH Alert – Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings – September 2004”)

Cross Contamination: Contamination from other products or processes at the same process time or during (from) earlier operations.

Cytotoxic or Chemo: Sometimes Class II BSCs are used for the preparation of antineoplastic drugs (chemotherapeutic agents that control or kill cancer cells) and some believe these dangerous chemicals can off-gas or vaporize and pass through HEPA filters. It is the recommendation of NIOSH that for the safe preparation of the drugs under aseptic (clean) conditions, one of the following ventilated cabinets must be used; Class II BSC (Type B2 is preferred, but Types A2 and B1 are allowed under certain conditions), Class III BSC, or aseptic containment isolators. In Europe, according to DIN12980 it is recommended to use a Triple Filter BSC with a single piece work-top, which is externally exhausted through a Thimble connection. (adapted from the “NIOSH Alert – Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings – September 2004”)

Damper: A device installed in a duct to control airflow volume. For a BSC external exhaust, they may specify an “air-tight” or “gas-tight” damper so when the external exhaust duct is closed off with this damper, there will be no flow of air. Typically, this is done to seal the BSC for decontamination or fumigation. Some BSCs have an internal damper or choke to regulate the amount of air from the single BSC fan that goes to the exhaust filter rather than the downflow filter. (adapted from SEFA 1-2006, Section 9.0)

Decibels: Unit of sound measurement.

Decontamination: The destruction or removal of living organisms (this does not imply either total destruction or total removal). Also, the the removal or neutralization of toxic agents or chemical carcinogens. (adapted from OSHA’s Bloodborne Pathogen Standard – 29 CFR 1910.1030)

DIM or Direct Inflow Measuring Device: A volumetric airflow measuring device consisting of a capture hood with a sensing component that provides a readout as a single value for volumetric flow rate. (adapted from NSF/ANSI 49-2008, Section 3.12)

Direct Connection (also called Hard Connection): A BSC exhaust connection where the connection between the BSC and the external exhaust system is solid with no designed gaps or openings. The external exhaust draws air sufficient to capture all exhaust from the BSC and maintain a negative pressurization in the exhaust duct. The direct connection type of BSC exhaust connection is required for Class II, Type B1 or B2 BSCs.

Diocetyl Phthalate (DOP): Used as an aerosol to test for integrity of HEPA filters. Now PAO (poly alpha olefin) is often used but the use is identical. Sometimes the term “DOP test” is used to describe a HEPA filter leak test without intending to specify the use of DOP as the aerosol.

Downflow Air (also called Supply Air): Air that moves down through the BSC work area through a HEPA filter and protects the product.

Duct: Round, square or rectangular tube used to enclose moving air. (adapted from SEFA 1-2006, Section 9.0)

EN 12469: The mandatory European performance criteria for microbiological safety cabinets. It is the current and only CEN (European) norm standard for microbiological safety cabinets. This replaced ALL previous European standards (BS British, DIN Germany and CEN France). In the UK, it replaced parts 1 and 3 of BS 5726. Parts 2 and 4 were recommendations.

Exhaust (also called Exhaust Flow): The flow of air exiting or being exhausted from the BSC. For all Class II BSC except type B2s, the inflow equals the exhaust. For B2s, the exhaust flow or volume is equal to the downflow plus the inflow. This is usually expressed in cfm/cmh. Note, a room or building can also have “exhaust.”

Exhaust Alarm: The alarm on the BSC exhaust flow that will signal when the exhaust flow drops outside (usually below) acceptable quantities. For our purposes, there are two types of exhaust alarms. One is associated with the cabinet and will signal when the BSC exhaust is incorrect. For direct connected BSCs, like B1s or B2s, this is required by NSF and only one exhaust alarm is needed or required. For A2s without thimble connections (vented into the room), an exhaust alarm would signal when the cabinet blower was not delivering sufficient exhaust (which is the same as inflow). For A2s with a thimble connection (vented into an external exhaust system), an exhaust alarm would signal when the cabinet blower was not delivering sufficient exhaust or that the external exhaust system was not drawing enough for the thimble to allow the BSC to operate AND capture any exhaust coming from the BSC.

Exhaust Connection (also called Exhaust Transition): The physical component allowing the connection of the B1 or B2 BSC to external exhaust which is usually included with the BSC. For A2s, the thimble also serves as the exhaust transition.

Exhaust (also called Extract): Every Class II BSC has exhaust. If a thimble connected A2 or a B1 or B2 BSC is used, they require external exhaust. External exhaust is the building exhaust system including at a minimum an exhaust fan on the roof and exhaust duct connecting the roof exhaust fan to the BSC exhaust connection.

Grade A, B, C, and D Cleanroom Classification: The European system established in “Volume 4 - EU Guidelines to Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use, Annex 1 - Manufacture of Sterile Medicinal Products” (corrected version). Often this is just referred to as Annex 1. Grade A is the local zone for the point at which the product is most at risk of contamination; often a laminar airflow system (BSC, clean bench, isolator, etc.) is the Grade A area. Grade B is the room that the Grade A device or area is surrounded by for aseptic preparation and filling. Grades C and D are for clean areas with less critical stages of pharmaceutical manufacturing.

Grade A Cleanroom Classification: Generally, Grade A areas or equipment provide ISO Class 5 air cleanliness at rest and in operation except a little cleaner for the 5.0 micrometer and larger particle size with 20 particles allowed per cubic meter instead of 29.

Grade B Cleanroom Classification: Grade B areas provide ISO Class 5 air cleanliness at rest for both 0.5 and 5.0 micrometer and larger particles and ISO Class 7 air cleanliness in operation except a little cleaner for the 5.0 micrometer particle size with 2,900 particles allowed per cubic meter instead of 2,930.

Grade C Cleanroom Classification: Grade C areas provide ISO Class 7 air cleanliness at rest except a little cleaner for the 5.0 micrometer particle size with 2,900 particles allowed per cubic meter instead of 2,930 and ISO Class 8 air cleanliness in operation except a little cleaner for the 5.0 micrometer particle size with 29,000 particles allowed per cubic meter instead of 29,300.

Grade D Cleanroom Classification: Grade D areas provide ISO Class 8 air cleanliness at rest except a little cleaner for the 5.0 micrometer particle size with 29,000 particles allowed per cubic meter instead of 29,300, and the requirements are not specified for in operation.

HEPA Filter: A high efficiency particulate air filter.

HPA: Health Protection Agency based in Porton Down is a special health authority and has become the UK’s leading independent type test authority for clean air and containment equipment. Its primary role is “to protect the community (or any part of the community) against infectious diseases and other dangers to health” (HPA Act 2004). HPA will test and validate Class II cabinets to determine whether they meet the requirements of the European Standard EN12469. HPA does not provide any indication of validation of the cabinet design on the cabinet as provided by LNE or TUV.

Hood: Class II BSC or Class I BSC, but usually not a Class III BSC. Could also be a fume hood or a no-flow static containment hood.

Face Velocity: Inward airflow velocity at the cabinet opening.

KI-DISCUSS Test: A fine mist of potassium iodide droplets, produced by a spinning disk, is used as a challenge aerosol to measure the containment of a cabinet or fume cupboard. Centripetal collectors sample the air outside or inside the cabinet – depending on the nature of the test. The collectors deposit any potassium iodide particles that are in the sampled air on to filter membranes. At the end of the sampling period the filter membranes are placed into a solution of palladium chloride whereupon the potassium iodide “develops” to form clearly visible and easily identified grey/brown dots.

Knowledge of the number of droplets in the challenge produced by the mist generator and the number collected in the air samplers enables the protection factor for the cabinet to be calculated. All open-fronted microbiological safety cabinets can be assessed on this protection factor. (adapted from <http://www.kidiscus.com>)

Laminar Air Flow: HEPA-filtered air stream moving within a confined space at uniform velocity, moving along parallel flow lines. Actual correct term should be “unidirectional air flow.” See Unidirectional Air Flow.

Laminar Air Flow Cabinets (also called Horizontal Flow Cabinets or Clean Air Benches): Self-contained laminar work flow stations providing unidirectional airflow and sterile work areas. Used for non-hazardous material. NOT to be used with biological hazard work.

Laboratoire National d’Essais (LNE): Established in 1901 as part of the Conservatoire National des Arts et Métiers (CNAM), France’s most recognized certification institute. It was set up to meet industrial testing and measurement requirements, especially in the fields of materials, machinery and physics. LNE will test and validate Class II cabinets to determine whether they meet the requirements of the European Standard EN12469. Successful validation of the cabinet model by LNE is demonstrated by an NF sticker on the cabinet.

Micron (also called Micrometer): A unit of measurement equal to one-millionth of a metre. Expressed as μm .

Negative Pressure: Air flows from positively pressurized areas into negatively pressurized areas. Negative pressure in a space would cause an inflow of air.

NSF: The NSF certification program is accredited by the American National Standards Institute (ANSI) and the standards council of Canada. It is the leader in validation of Class II cabinets throughout the USA. NSF International tests and validates Class II cabinets to determine whether they meet the requirements of NSF/ANSI 49. Successful validation of the cabinet model by NSF is demonstrated by a NSF sticker on the cabinet.

NSF Listing: A Class II BSC is “NSF listed” when NSF has tested the model to verify it meets the materials, design, construction, and performance requirements of NSF/ANSI 49. If a cabinet is NSF listed, it can have the blue NSF sticker. Some cabinets may claim it meets the requirements of NSF/ANSI 49, but it may not have been tested and officially listed. NSF sends the engineering team a final copy of the confidential test report. The NSF website (www.nsf.org/Certified/Biosafety/) lists the BSCs that have passed their independent testing, and this public posting is what is available to customers as proof of certification pre-sale.

Particle Counter: Electronic instrument used to count the numbers and sizes of airborne particles and determine cleanliness of environment.

Plenum: An enclosure for flowing gases in which the static pressure at all points is relatively uniform.

Positive Pressure: Air flows from positively pressurized areas into negatively pressurized areas. Positive pressure in a space would cause an outflow of air.

Safe Change System: A system which enables filters or filter systems to be changed without hazard to the operator and the back ground environment.

Sterile Air: Air filtered to exclude particles, including microbiological life (e.g. bacteria, viruses).

Supply Air (also called Downflow Air): Downflow air entering the cabinet work area through the downflow filter and diffuser. In Class II cabinets, this air passes through the supply HEPA filter before moving vertically down to the work surface.

Thimble: A BSC exhaust connection where there are one or more openings or gaps in the connection between the BSC and the external exhaust system. The external exhaust draws air sufficient to capture all exhaust from the BSC and to maintain a flow of air into the exhaust connection through the openings or gaps. The flow of air through the openings or gaps provides a buffer between the BSC exhaust and variation in the external exhaust system assuring consistent BSC performance, odor control and/or containment of volatile toxic chemicals, and tracer amounts of radionuclides used in the BSC. The canopy connection type of BSC exhaust connection is required for externally vented Class II, Type A1 or A2 BSCs.

ULPA (Ultra Low Particulate Air) Filter: Provides a higher level of filtration than a HEPA filter. There has been some confusion about whether the European classed H14 filter is actually an ULPA filter. The European Standard EN 1822 states the H14 is a “HEPA” (the “H” in H14 stands for HEPA) and the next level filter, U15, is an ULPA (the “U” in U15 stand for Ultra).

Unidirectional Airflow: Where the plane of the air supplied from the HEPA filter is moving in one direction. Although the air velocities within the plane of movement may vary slightly, this term was previously referred to as laminar airflow.

TUV: Technischer Überwachungsverein or Technical Monitoring Association. The German certification board is widely accepted as the most stringent and comprehensive test a safety cabinet can undergo. Periodic retesting is required to comply with TÜV. TÜV will test and validate Class II cabinets to determine whether they meet the requirements of the European Standard EN12469. Successful validation of the cabinet model by TUV is demonstrated by a GS sticker on the cabinet.

Ultra Violent Radiation (UV): Ultra Violet Radiation. Used for disinfection in biosafety cabinet work area.

Validation: A set of procedures to create documented evidence that something meets design, construction, and performance specification.

Work Area: The area within the BSC intended for the user’s work. It extends from the inside edge of the front grill to the front edge of the rear grill, from the bottom side of the diffuser to the top side of the work surface and within the interior walls of the BSC. This is sometimes called the sample chamber. Certifier’s consider the work area the plane at sash level for BSCs NSF listed before 2002 and 4 inches above the sash for BSCs NSF listed after used for the measurement of downflow velocities for certification.

Work Surface: The stainless steel platform within the BSC intended for the user’s work. It extends from the inside edge of the front grill to the front edge of the rear grill and within the interior walls of the BSC.

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