MEETING THE STANDARD:

# INDUSTRY STANDARDS YOUR BIOSAFETY CABINET SHOULD MEET

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Biosafety cabinets are a vital part of research, hospital, and industry laboratories worldwide, creating a clean and ventilated workspace for research, development, diagnosis, and drug preparation. To ensure the best protection for both workers and products/samples, you must be confident that your biosafety cabinets meet industry and regulatory authority approved standards.

## An Introduction To Biosafety Cabinets

Biosafety Cabinets also known as biological safety cabinets or microbiological safety cabinets, provide an enclosed and ventilated workspace. Biosafety cabinets serve two important purposes – to protect workers from potentially toxic or infectious materials, and/or to protect samples and products from environmental contamination.

When biosafety cabinets were first developed, they had basic on/off switches. Now they include many safety features which can all be tracked using software. These can include airflow monitoring and control using airflow sensors, as well as sensors that can monitor window position and motor function.

## Biological Safety Cabinet Classes

Biosafety cabinets are divided into three classes, depending on their design and use: [1]

### Class I

- Protects workers and the environment from aerosols and when handling biological agents, but does not protect products from contamination.
- HEPA filter in the air exhaust.
- Air exhausted externally or room recirculated into the laboratory.

### Class II

- Protects workers, products, and the environment when handling biological agents or handling of Hazardous Drugs (HD's) such as chemotherapeutic agents.
- HEPA filter in the supply and exhaust.
- Air exhausted externally or room recirculated.

### Class III

- Total containment cabinets.
- Gas-tight; protects workers, products, and the environment when handling BSL4 biological agents.
- HEPA filter located in the air supply.
- Typically a double exhaust HEPA filter configuration.

In medical, chemical, and biological research, as well as in biopharma R&D, biosafety cabinets ensure research experiments are carried out in a sterile consistent environment. In medical diagnostics, biosafety cabinets protect both samples and operators from contamination (e.g., bacteria, viruses). For preparation of combination HD drug regimens, such as cancer chemotherapy, the cabinets keep infusion and injection solutions free from contamination and protect operators from the often toxic drugs. Biosafety cabinets can also be used by drug manufacturers to reassure their clients that products have been prepared in sterile environments that adhere to validated safety standards.

## The Biosafety Standards

Biosafety cabinet standards have been published for 40 years or more providing the minimum construction and performance requirements for assurance of a safe working environment. By purchasing cabinets that adhere to international standards, customers can be confident that they are working with cabinets that meet industry guidelines.

The key standards used are NSF/ANSI 49 and EN 12469. NSF International is an accredited independent and not-for-profit organization that develops standards and certification programs on behalf of the American National Standards Institute (ANSI). The NSF/ANSI 49 standard is regarded as the "gold standard" for biosafety cabinets in the US.

In Europe, TÜV (Technischer Überwachungsverein) Nord, one of Europe's leading independent testing agencies that tests to the EN 12469, biosafety cabinet standard. TÜV Nord tests the majority of the biological safety cabinets that were previously tested to EN standard.

The documentation for these standards explains how biosafety cabinets are tested (see Table 1).

**Table One** - Biosafety Standards [2]

| | NSF/ANSI 49 | EN 12469 |
|---|---|---|
| Classes | Covers Class II cabinets; broken down into subtypes | Covers Classes I-III Cabinets<br>Class II requirements are virtually identical to NSF/ANSI 49 |
| Microbiological Challenge Testing for Operator, Cross- and Product Contamination. | Yes | Requirements adopted from NSF/ANSI 49 Include optional test to validate containment in the field (KI-Discus text) |
| Airflow Velocity – Downflow | Includes downflow velocity but no specific requirements; requires larger number of test points<br>Specifies thermoanenometer | Recommended downflow velocity range of 0.25-0.50 m/s<br>Does not specify instrument accuracy and type |
| Airflow Velocity – Inflow | Uses direct inflow measurement (DIM)<br>Minimum inflow velocity of 100 fpm (0.51 m/s) | Recommends airflow measurement above exhaust and calculates inflow<br>Minimum inflow velocity of 0.4 m/s |
| Performance Envelope | Function within +/-0.025 m/s of the inflow and downflow set points, using the airspeed parameters | No specification<br>TUV Nord requires low alarm point to be tested |
| Pressurization Testing | Soap bubble pressure leak test as routine test | Soap bubble pressure leak test as a test type |
| Filter Leak Test | Generated Aerosol Challenge | Generated Aerosol Challenge |
| Airflow Smoke Pattern Tests | Yes | No |
| Room Airflow Patterns in Situ | Not Required | Optional – uses potassium iodide |
| Worker Comfort | Noise – 67 dBA at operator head position<br>Vibration Test – Yes<br>Light level – 650 lux | Noise – 65 dBA 1m away from center of access opening<br>Vibration Test – Yes<br>Light level – 650 lux |
| Other | Measure 'cleanability' of contaminated surfaces<br>No noise insulation inside contaminated areas Chemical/abrasion resistance of paintwork<br>Motor/Blower Test | Airflow alarms<br>Audio and visual alerts for malfunctions |

The biological testing aspect that uses a biological aerosol challenge, is one of the most important parts of both US and European standards. The key difference between the two standards is that the European standard looks for bacterial challenge at nominal set point velocities (i.e. calibrated inflow and downflow air speed), the US standard also tests above and below those levels that allows for variability in the testing processes.

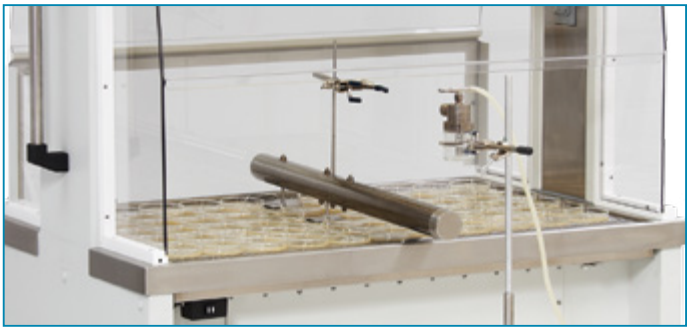
Throughout the world, some countries publish their own standards, and while most of these use are based on the US or European guidelines, they also have their own variations. For example, the standards in Australia does not include biological tests, but require testing on site along with dioctyl phthalate (DOP) or potassium iodide testing for containment performance. The Chinese standards require a coved work zone insert (dual side wall construction) and British standards require two exhaust HEPA filters if the biosafety cabinet is room recirculated.

However, it is important for purchasers and users to remember these standards are just the minimum expectations for safety, performance and construction quality. They also cover how the cabinet performs, but not how it is manufactured.

## Look Beyond the Standards

Customers need to look beyond the standards. For example, Is the cabinet simply fastened together with screws and rivets or smoothly and tightly constructed, welded, and polished? Quality of materials used, stainless steel versus painted steel? Is the biosafety cabinet service friendly (front access)?

Cabinets that exceed the minimum standards, rather than meeting them, provide users with confidence of maximum containment performance with a margin of safety. For example, a vivarium setting may produce additional airflow currents and movements. Dynamic testing of a biosafety cabinet can help identify its limits when placed in a turbulent environment.



*Biological Testing, Generated Aerosol Challenge*

## Testing to Meet the Standards

When buying cabinets that have NSF or EN listings, you know what to expect from a safety and containment perspective. Manufacturers of biosafety cabinets submit their base unit models to the testing organization, which inspects the unit to see if it meets the standards requirements. It is a costly process; for example, NSF testing can cost up to $50,000 per model. The model lines that are approved carry the appropriate labels and are listed on the organization's website. There is still a degree of "buyer beware" for the customer. Some companies submit only one or two models through third-party testing, and then offers similar models for sale, which may not be the ones listed under the NSF or EN standards.

Once a cabinet passes, the standards apply as long as no major changes are made. However, many cabinets are customized to customers' requirements. While minor construction or cosmetic changes do not affect the listing, major customization changes cannot carry the NSF or TÜV labels.

**Major changes include:**

- Producing non-stock size cabinets
- Providing tailored access (e.g., side access)
- Including robotics
- Designing the cabinet to fit a specific space and instrument.

When looking for a customized biosafety cabinet, it is worthwhile finding a manufacturer who will meet this challenge by designing customized solutions as if they were going to be

NSF or TÜV tested. As many cabinet manufacturers will have on-site testing facilities that can replicate third-party testing, these changes can be validated.

## Future Standards

As technology evolves and as research and industry requirements become more stringent, standards will have to also evolve to meet these changes. The Joint Committee on Biosafety Cabinetry at NSF International updates the guidelines continuously based on user submissions. The most recent guidelines were published in 2014. The most recent version of the European standard was published in 2000. Because the EN standards have to be agreed upon across all the countries in Europe, updating them is more challenging.

## References


1) University of Minnesota. *Biosafety: Types (Classes) of Biological Safety Cabinets.* Created: 2010. Last updated: 14 June 2010; Accessed: 21 October 2015; Available from: http://www.dehs.umn.edu/bio_pracprin_biosafecab_types.htm.

2) Qian, L.X. *Biological safety cabinets: Comparison between European and US standards.* Clean Air and Containmnent Review, 2011. (5).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