Worldwide Headquarters • Esco Micro Pte Ltd • 21 Changi South Street 1 • Singapore 486777
Phone +65 6542 0833 • Fax +65 6542 6920 • mail@escoglobal.com • www.escoglobal.com
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COMPARISON BETWEEN EN12469:2000 AND ANSI/NSF49:2002 STANDARDS

Lin Xiang Qian | Esco Micro Pte. Ltd.

Abstract

The EN12469:2000 is the harmonized European standard for microbiological safety cabinets. It specifies requirements for both safety cabinet construction and performance criteria. In 2000, the year of its introduction, it replaced the former German, British and French standards in the same field.

The ANSI/NSF49 is the American National Standard which also specifies requirements for both cabinet construction and performance criteria. It gained official ANSI (American National Standards Institute) recognition in 2002, the date of the most current revision. The NSF49 has been in existence since the 1970s and is arguably the most established standard in this field in the world.

These 2 standards are unequivocally of the greatest importance today in the field of biological safety cabinets. This technical paper attempts to highlight and discuss the differences between each standard:

1. Nomenclature

The EN12469 is relevant to Class I, Class II and Class III biological safety cabinets, whereas the NSF49 only applies to Class II safety cabinets. However, this difference, while easily apparent, is not of very great significance since practically all the safety cabinets used in the world today are Class II safety cabinets.

It should be noted by the reader that a "European standard Class II cabinet" and an "American standard Class II cabinet" are basically identical. At the most fundamental level, both types of cabinets provide protection for the product, the operator and the environment - operating via the same principles i.e. HEPA filtered vertical downflow over the work zone, inward airflow at front aperture, HEPA filter exhaust etc.

The most significant difference in this area is that the NSF49 defines various Class II cabinet subtypes i.e. Class II Type A1, Class II Type A2, Class II Type B1 and Class II Type B2 - whereas the EN12469 defines only a "general" Class II cabinet.

Class II Type A1 and Class II Type B1 cabinets are rarely used in the US nowadays. The only other type of cabinet, the Class II Type B2 cabinet, which is used widely in the US for certain applications, is not at all used in Europe.

Interestingly, the Class II cabinets available on the European market conforming to EN12469 are virtually identical in terms of construction principles (albeit with some minor differences) to American Class II Type A2 cabinets. It should also be noted that these 2 classes of cabinets are in general the most prevalent of any type of safety cabinet (whether Class I, Class II or Class III) used today in the world.

2. Similar emphasis on performance criteria and physical measurement / testing

Both the EN12469 and NSF49 are performance based standards - in other words, the emphasis of the standard is not on construction requirements i.e. telling the manufacturer how to build the cabinet within a narrow set of specifications. Rather, the manufacturer is allowed a large degree of freedom in determining the design of his cabinet, as long as it meets the performance test criteria. Examples of performance tests would be: microbiological tests for operator, product and cross contamination protection, airflow velocity readings, airflow smoke pattern tests (the differences between which are discussed in detail below) etc. The bulk of the EN12469 and NSF49 is to do with specifying the test parameters and acceptance criteria (probably more than 70% of the standard).

3. Physical performance tests and acceptance criteria

Both the NSF49 and EN12469 have a very demanding set of physical performance test methods and criteria, the differences between which shall be analyzed in detail below:

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a. Microbiological challenge tests for operator, product and cross contamination protection

The EN12469 basically adopted the NSF49 test methods in this area. Acceptance criteria are also the same. However the EN12469 has one distinct difference in the operator protection test, since it recognises an alternative test method (the KI-Discus test, see the Esco technical paper on that subject), in addition to the conventional microbial challenge test.

The KI-Discus test is one area in which the European standard is arguably superior to the NSF49, since KI-Discus testing is the only way to validate, in the field, the containment of the cabinet. Unlike the conventional microbial challenge test for operator protection which only gives one a pass / fail result, the KI-Discus test enables the aperture protection factor of the cabinet to be calculated, and requires an aperture protection factor of more than 10,000. This means only 1 particle out of 10,000 particles, generated at the weakest point in the cabinet inward airflow curtain, may escape the cabinet.

(Esco cabinets have an average aperture protection factor of more than 100,000 as independently tested by CAMR in the UK - exceeding the standards requirement by a factor of more that 10. This average a.p.f. was established in the CAMR test laboratory on an Esco cabinet based on a replicate of 5 identical tests.)

b. Downflow velocity

The EN12469 specifies an allowable downflow velocity range of 0.25-0.50m/s, whereas the NSF49 does not specify any downflow velocity requirement. The downflow velocity has a direct effect on the product and cross contamination protection of the cabinet. For example, typically, downflow velocities that are too low can cause loss of product protection. However, since both European and American design cabinets have to pass the same product and cross contamination microbial challenge tests, this difference is immaterial.

In terms of downflow measurement methods both standards are very similar (the general principle in fact is identical). However the NSF49 does require a larger number of test points, which means a greater level of accuracy. The NSF49 also specifies that a thermoanemometer with a certain level of accuracy must be used whereas the EN12469 does not specify the test instrument accuracy and type.

In general, the reader should note that the NSF49 tends to be more precise / accurate in terms of testing instrument accuracy and type, as well as testing methods. This is a trend which we will notice for all the performance tests.

(Even for our European cabinets Esco has adopted the downflow test methodology from the NSF49 to ensure the highest accuracy possible.)

c. Inflow Velocity

In terms of methodology, the NSF49 is very specific about the inflow velocity test - and if the author may be allowed to make a personal comment - is greatly superior to the EN12469 in this respect. The NSF49 uses a direct inflow measurement method as a primary standard which gives an extreme high level of accuracy and reproducibility compared to the European method of taking measurements above the exhaust filter.

In fact the method of taking measurements above the exhaust filter is a method that was widely used in the US on cabinets certified in the 1980s and 1990s. To a certain extent the European standard lags behind at least a decade in this respect.

Both the EN12469 and NSF49 specify minimum inflow velocity requirements. We shall discuss only Class II Type A2 and "general" European Class II cabinet requirements here. The NSF49 specifies a minimum inflow velocity of 0.5m/s for Class II Type A2 cabinets whereas the European standard requires 0.4m/s for Class II cabinets.

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(Even for our European cabinets Esco utilises ONLY the NSF49 direct inflow measurement method since our own research has proven this method to be inherently more reliable compared to the European method of taking readings above the exhaust filter.)

c. Performance envelope

The performance envelope of a biological safety cabinet is the set of airflow setpoints (inflow velocity range, and downflow velocity range) within which the cabinet will pass all the microbial challenge tests.

The NSF49 is very strict in this area and requires that the cabinet be set to within +/-0.025m/s of the inflow and downflow setpoints during quality control testing by the manufacturer at the factory, and in the field. The European standard on the other hand does not have such a requirement (the EN12469 only requires the cabinet airflows to be within the generic velocity ranges above).

(Even for our European cabinets Esco publishes inflow and downflow setpoints and as part of our internal quality control program we require the airflows to fall within the setpoint before a unit is shipped from our factory.)

d. Secondary tests for worker comfort: noise, light, vibration

Again, the NSF49 and EN12469 are largely similar in these areas.

For the noise test the EN test method specifies a distance further away from the cabinet (1m from the centre of the work opening) as compared to the NSF49 (approximate operator head position). Consequently, the EN12469 allows a maximum of 65dBA whereas the NSF49 allows a maximum of 67dBA. Consequently European manufacturers have tended to have lower published noise levels. However, internal research at Esco indicates that both measurement methods and acceptance criteria are at the end of the day equal (i.e. if a cabinet will pass NSF noise level, it will also pass EN noise level test, and vice versa).

For the vibration test both NSF49 and EN12469 are identical in all respects.

For the light level test the NSF49 allows a slightly lower lighting level of 650 lux whereas the EN standard requires 750lux. Again the EN standard is not completely precise about background lighting levels, the accuracy of the measurement instrument, and the test point grid.

(Our Airstream Class II cabinets have a typical noise level with clean filters, at nominal airflow setpoints, of 61.5dBA as per NSF, and 57.0dBA as per EN - greatly exceeding the requirements of both standards.)

e. Filter leak test

The NSF49 requires filter leak testing with a generated aerosol challenge (for example, DOP, Emery 3004 / PAO), on the other hand the European standard (although referring to this same test method) also allows an alternative test using the natural aerosol challenge test method. Internal Esco research indicates that that natural aerosol challenge test method cannot reliably detect all leaks.

(All Esco cabinets are scan tested with a generated aerosol source.)

f. Airflow smoke pattern tests

Both NSF49 and EN12469 are identical in terms of test methodology and acceptance criteria.

g. Soap bubble pressure leak test

The NSF49 requires this as a routine test by the manufacturer on all units produced, whereas the EN12469 requires this as only a "type-test" in the independent certification laboratory.

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h. Other miscellaneous tests

The NSF49 specifies some other miscellaneous type-tests (i.e. conducted by NSF during the certification process). These include tests for chemical and abrasion resistance of the cabinet external paintwork, and a motor / blower performance test. While these tests help to establish certain minimum construction criteria they do not have a direct effect on the safety of the cabinet.

4. Cabinet construction requirements

The NSF49 tends to be more detailed in terms of construction requirements, and there is a great emphasis on cleanability issues. Some of the more important differences though are that the NSF49 does not allow noise insulation materials inside contaminated areas in the cabinet (American cabinets therefore have tended to be noisier). The NSF49 also does not require an airflow alarm system, which is required in the EN12469.

This is to a certain extent a direct effect of the nature of the industry in the US, where a cabinet certifier technician is readily available no matter where one's cabinet is located in the field. On the other hand, the European market, due to its greater degree of fragmentation, has had to rely (to a certain extent) on airflow alarming devices since certification companies may not always be available in some regions.

(Nevertheless, all Esco biosafety cabinets are equipped with an airflow alarming system.)

Conclusion: while both standards have differences, the similarities are greater. It is the author's opinion that cabinets built to both standards offer an identical level of quality and safety for the user. The disadvantages of the European standard (for example, being less precise in terms of testing methods) are outweighed by its own advantages such as the requirement of an airflow alarming system - as long as cabinets are operated following manufacturer's instructions by properly trained individuals - and especially in the case of Esco who has adopted the strong points of each standard into our range of biological safety cabinets.