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Terminology Changes in the 2002 Revision of NSF 49
NSF/ANSI Standard # 49 – 2002
Class II Biological Safety Cabinets Types

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INTRODUCTION

For more than 20 years there has been confusion concerning Class II biological safety cabinet (BSC) terminology. This has lead to problems in understanding just what the types of Class II BSCs are, and how they should be installed and used. The changes in the NSF/ANSI Standard 49 - 2002 are intended to resolve many of these issues. A good way to grasp all of this is to become familiar with the evolution of Class II BSC terminology. Achieving this should enable us to properly interpret the relevant literature which contains a myriad of terms that have been applied to Class II BSCs. Additionally, it will make it possible for us to understand each other when we discuss BSCs.

THE EVOLUTION OF CLASS II BIOLOGICAL SAFETY CABINET TERMINOLOGY

The idea for a "laminar flow" cabinet that would provide personnel, product and environmental protection against infectious agents grew out of Baker Company's experience up to 1965 of designing and manufacturing cabinets in response to similar requirements for handling potent compounds for pharmaceuticals. Manuel Barbeito, who worked at Fort Detrick at the time, tells of when a Baker Company representative named Max Hesselgesser brought the concept for such a cabinet to Dr. Wedum and his biosafety staff.(1) The National Cancer institute (NCI) commissioned the Pitman/Moore division of Dow Chemical Company to develop a cabinet while the Baker Company developed one independently. Resulting cabinets were microbiologically tested, as published in 1968, (2,3) and called Laminar Flow Biological Safety Cabinets (**LFBSC**s).(4) See Figure 1.

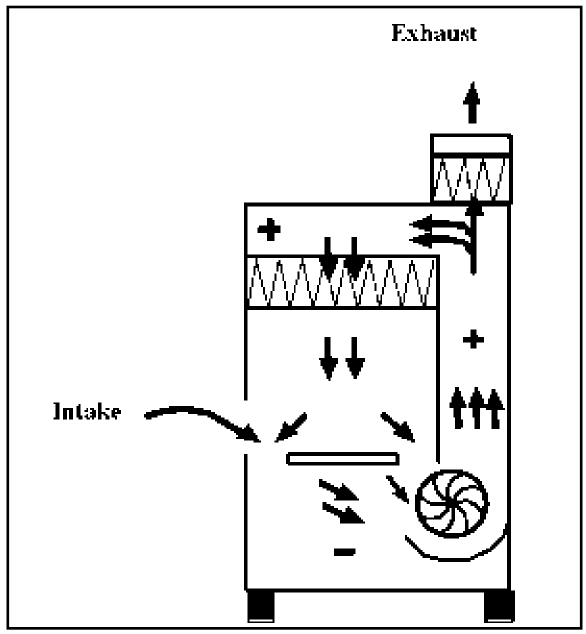


Figure 1. LFBSC, Type 1, Type A, Type A1

Terms used for types of Class II BSCs are in **BOLD.**

In 1974 the National Institutes of Health (NIH) published their purchase specification (5) calling this cabinet a Class II **Type 1** biological safety cabinet. (Figure 1) At the time, these cabinets were generally hard ducted when they were vented to the outdoors. The 1976 NIH slide presentation entitled "Selecting a Biological Safety Cabinet" (6) called this BSC a Class II **Type A** biological safety cabinet. (Figure 1) The Type A had a minimum of 75 fpm intake air velocity, 70 % re-circulation from a common plenum and biologically contaminated ducts that were under positive pressure to the room. These cabinets were built with heavy gauge metal and enough hardware to enable them to withstand a rigorous tracer gas leak test under 2” water column of positive pressure.

A variation on the Type A theme was developed that had 100 fpm intake air velocity, 70% re-circulation from a common plenum and biologically contaminated ducts and plenums under negative pressure, or surrounded by negative pressure. See Figure 2.

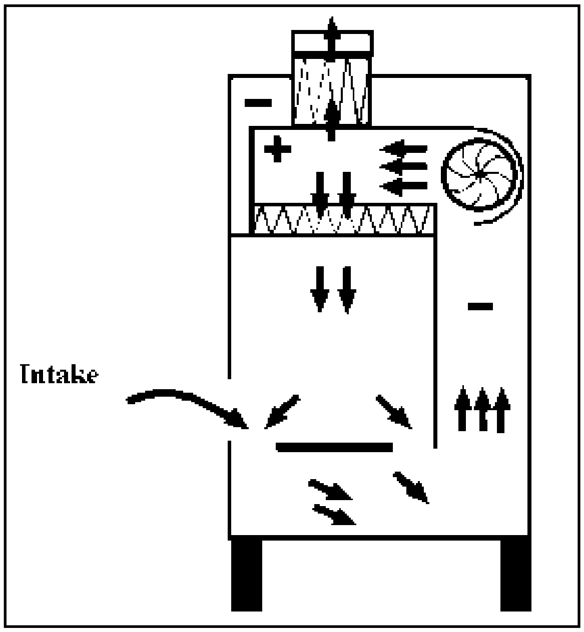


Figure 2. Type A, Type A/B3, Type A2

Thus, any leak in the shell of the cabinet would be inward. This was an alternative approach to solving the cabinet integrity issue. For many years this cabinet was also called a **Type A**.

The advent of the thimble exhaust connection (7) had a large impact on the understanding and implementation of BSC terminology, as we shall see later. Hard connection of a Type A cabinet to the building exhaust system creates problems associated with certifying the cabinet and the performance of the cabinet. The cabinet blower does all the work required to operate the Type A cabinet and pushes the exhaust air out through the exhaust filter. Therefore, all the building exhaust system has to do is carry the cabinet exhaust air away. By setting the building exhaust system to pull more air than the cabinet is putting out, room air coming through a thimble gap (the space between the cabinet and the exhaust system) entrains the cabinet exhaust air and all of it is vented to the outdoors. See Figure 3. The thimble gap also provides a buffer between the behavior of the exhaust system and the cabinet. According to NSF/ANSI Standard 49 - 2002, no Type A cabinet should ever be hard ducted to the building exhaust system.

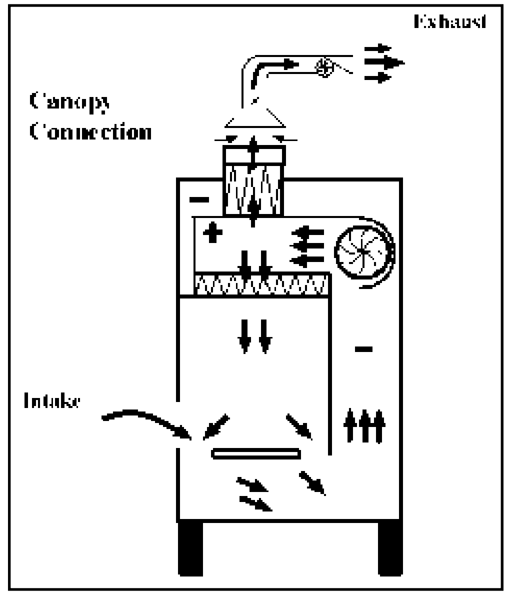


Figure 3. Type B3. Type A2 vented to outdoors

A different approach to Class II cabinetry (Figure 4) was developed by Dr. W. Emmett Barkley who was then at NCI.

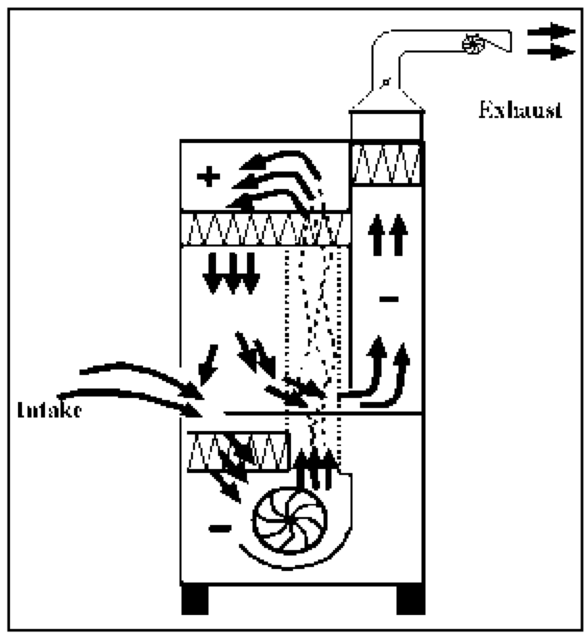
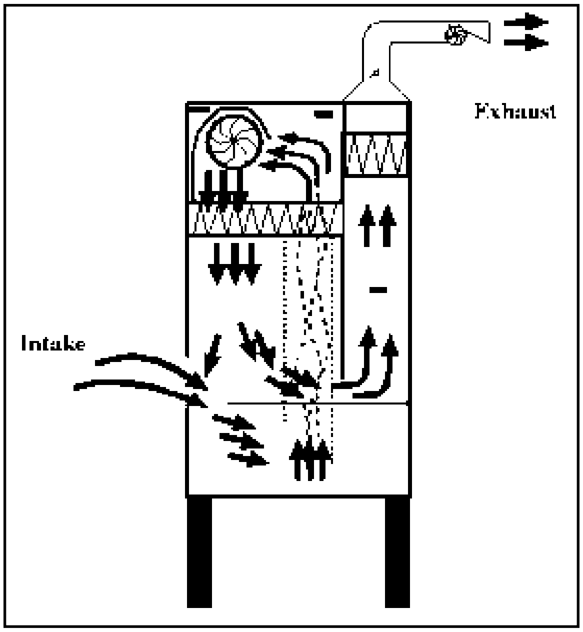


Figure 4. Type 2, Type B, Type B1

His goal was to provide a cabinet that would be better for use with chemicals required as an adjunct to microbiological work.(8) The design included a minimum of 100 fpm intake air velocity, 30 % re-circulation through a plenum separate from a dedicated exhaust plenum, and biologically contaminated ducts and plenums were under negative pressure. Air behind the smoke split was immediately exhausted to the outdoors through a HEPA filter. There was a HEPA filter placed immediately below the work surface to prevent biological and chemical aerosols from contaminating the inside of the cabinet. This BSC was called a Class II **Type 2** in the purchase specification put out by the National Cancer Institute in 1976.(9) This cabinet was already being called a **Type B** that same year.(6) This term was used for this cabinet design until 1983.

Another cabinet design came on the market that was claimed to be **convertible** from a Type A to a Type B (Figure 5).



Figire 5. Convertible cabinet, Type B1

By changing the physical makeup of the cabinet, the airflow characteristics were changed from those of a Type A to those of a **Type B**. The HEPA filter below the work surface was not installed, however.

In 1978 a **100% exhaust** BSC was introduced. See Figure 6. This completed the trend in Class II BSC design from 70% through 30% to 0% re-circulation of air within the cabinet. This design included a minimum 100 fpm intake air velocity, 0 % re-circulation, and biologically contaminated ducts and plenums were all under negative pressure. All aerosols and vapors were immediately exhausted from the cabinet work area. There was no HEPA filter placed immediately below the work surface.

Unlike the blower in the **Type A** cabinet that pushes the exhaust air out of the top of the cabinet, the blower in the **Type B** cabinet only re-circulates the air within the cabinet. The **100% exhaust** cabinet blower only pushes room air down through the supply HEPA into the top of the work area. Creation of intake air in both the **Type B** cabinet, and the **100% exhaust** cabinet, requires the building exhaust blower to <u>pull air out of the cabinet</u>. This precludes the use of a thimble with these cabinets, because, virtually all of the room air would come in through the thimble gap, not into the work access opening and through the cabinet. Therefore, these cabinets MUST be hard connected to the building exhaust system. This must be understood and remembered in order to follow the discussion to come.

At this point in the evolution there were three types of Class II cabinets: **Type A** cabinets (Figures 1 and 2), **Type B** cabinets (Figures 4 and 5) and **100% exhaust** cabinets (Figure 6). However, the original NSF Standard 49 in 1976 talked only of Class II biological safety cabinets and made no mention of types of cabinets. Hence there was a need for the NSF Joint Committee revising the standard, starting in 1978, to define the different types of Class II BSCs. The following terms were applied to the various Class II BSCs in the revised standard when it came out in 1983: (10)

The 100 % exhaust cabinet (Figure 6) was called a **Type B2**.

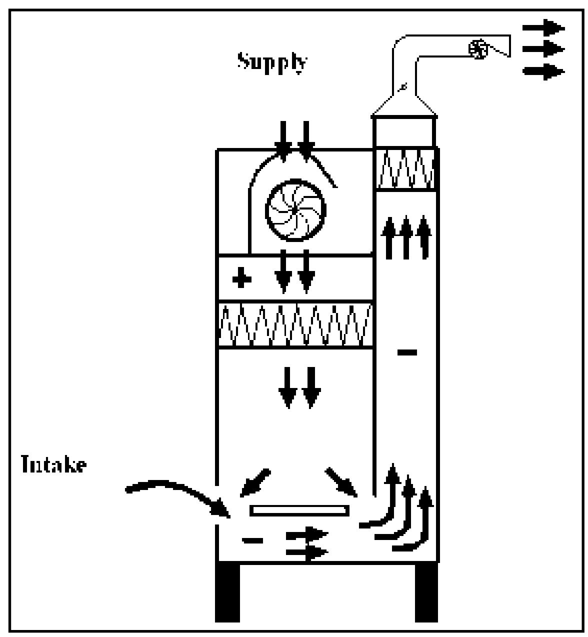


Figure 6. 100 % exhaust (total exhaust), Type B2

The definition for a Type B1 was written to include the NCI Type B (Figure 4) so this cabinet became a **Type B1**. The Type B1 definition did not include a requirement for a primary HEPA below the work surface so the "B style" of the convertible cabinet (Figure 5) became a **Type B1** also.

The old NIH Type A design (Figure 1) remained a **Type A.** It was decided that toxic vapors should not be used in this cabinet whether it were vented to the outdoors or not.

The Type A design that had 100 fpm calculated intake air velocity and negative plenums to the room (Figure 2) was called an **A/B3**. When this cabinet was vented back into the room (Figure 2) it was still called a **Type A**. This seemed logical. Toxic vapors were not to be used in this cabinet “while it was a Type A cabinet” (venting back into the room).

However, if this cabinet were connected to a building exhaust system and vented to the outdoors (Figure 3) it became a **Type B3** and minute amounts of toxic vapors could be used in it as long as they did not interfere with the work when re-circulated into the work area. Calling a Type A cabinet a Type B cabinet has always been very difficult to understand because it is a direct contradiction of terms. How did this happen?

In 1975 a pamphlet called “National Cancer Institute Safety Standards for Research Involving Chemical Carcinogens” appeared.[11] It said, “Laminar flow biological safety cabinets may be used for the containment of *in vitro* procedures involving the use of chemical carcinogens providing that (1) the exhaust air flow is sufficient to provide an inward air flow at the face opening of the cabinet equal to 100 feet per minute times the face opening area, (2) contaminated air plenums that are under positive air pressure are leak tight and (3) the cabinet exhaust air is discharged outdoors.”

The Type A cabinet with 100 fpm intake, and biologically contaminated plenums that were under negative air pressure to the room so they definitely would not leak outward, met the requirements in the NCI pamphlet as long as it was vented to the outdoors. Therefore, “NCI said chemical carcinogens could be used in it”.

Opinions were voiced to the effect that: if NCI said chemical carcinogens could be used in a BSC, that made it a Type B cabinet. These “Type B cabinets” were found in the market place at the time. Looking back over what has been discussed here, it should be clear that venting a Type A cabinet to the outdoors does not make it into a Type B cabinet. However, most of the NSF Joint Committee agreed that when a Type A cabinet had 100 fpm intake, negative pressure to the room (Figure 2), and was vented to the outdoors, it would be called a **Type B3** (Figure 3).

Not only was this terminology difficult to understand because it was a contradiction of terms, i.e. a Type A being called a Type B(3), there was a great debate as to whether a cabinet could be a Type B3 when it was thimble connected to the building exhaust system rather than hard ducted. Our industry was divided in the positions taken on this issue.

One position was: NSF 49 - 1983 made it clear that the preferred exhaust connection for a Type A cabinet was a thimble. Since the cabinet was a Type A, until it was connected to an exhaust, it made sense that it should be thimble connected.

However, the literature, including NSF 49, contained statements saying that “Type B cabinets Must be Hard connected to the exhaust system”. This is a true statement, as discussed earlier in this paper. The other position was then: if the cabinet were to be used as a Type B3, it was a Type B and therefore had to be hard connected to the exhaust because of being a Type B.

In one instance, a large research grant was held up because the granting agency project officer asked if the cabinets were to be used as Type B3s. When the question was answered in the affirmative, the grant would not be approved if the A/B3s were not hard connected. The institution applying for the grant knew that there would be many problems if the A/B3 cabinets were hard connected and did not want to do this. There were experts in the field writing letters of support, some on one side and some on the other of the issue. These kinds of problems had to be resolved by the 2002 revision of the NSF Standard 49 which is called, “NSF/ANSI 49 - 2002”.[12]

In the 2002 revision, **Types B1** and **B2** remained the same. The **Type B1** may be used with minute amounts of toxic chemicals, that might vaporize, as an adjunct to the microbiological work as long as vapors re-circulating within the cabinet will not cause a problem. The **Type B2** may be used with volatile toxic chemicals as an adjunct to the microbiological work.

The original Type A became **Type A1** and still could not be used with toxic vapors.

The A/B3 became a **Type A2**. When venting back into the room, this cabinet cannot be used with toxic vapors.

If the **Type A2** cabinet is **vented to the outdoors via a properly functioning canopy (thimble) connection**, it may be used with minute amounts of toxic chemicals, that might vaporize, as an adjunct to the microbiological work as long vapors re-circulating within the cabinet will not cause a problem.

SUMMARY:

In Summary, we now have **Type A1**, **Type A2**, **Type B1** and **Type B2** Class II BSCs. The above should make the meanings of these terms clear. It is important to realize that this terminology is now in effect,(13) and that the Type B3 **is no longer in existence**. All existing Type B3s are now to be considered **Type A2s vented to the out doors**.(14) Because of this, the problems associated with the Type B3 terminology should be resolved. A chart that shows how Baker cabinets fit into this scheme(15) is available from the Baker Company. (www.bakerco.com)

REFERENCES

1. Personal communication with Manuel S. Barbeito. Biosafety Consultant. 7004 Runny Meade Court. Frederick, MD 21702.

2. Coriell, L.L., and G.J. McGarrity. 1968. Biohazard hood to prevent infection during microbiological procedures. *Appl. Microbiol*. **16:**1895-1900.

3. McDade, J.J., F.L. Sabel, R,L. Akers and R.J. Walker. 1968. Microbiological Studies on the performance of a laminar airflow biological safety cabinet. *Appl. Micrbiol*. **16:**1086-1092.

4. U.S. Department of Health and Welfare. National Cancer Institute. Office of Biohazard and Environmental Control. 1972. Laminar Flow Biological Safety Cabinets - A Training Manual for Biomedical Investigators. Bethesda, MD 20014.

5. U.S. Department of Health and Welfare. National Institutes of Health. 1974. Class II, Type 1 Safety Cabinet. Specification No. NIH-03-112c. Bethesda, MD 20014.

6. U.S. Department of Health and Welfare. National Institutes of Health. Office of Research Safety. 1976. Selecting a Biological Safety Cabinet. Bethesda, MD 20014.

7. Jones, R.L. Jr., B. Tepper, T.J. Greenier, D. G. Stuart, S.M. Large and D. Eagleson. 1989. Effects of thimble connections on biological safety cabinets. Abstracts of 32nd Biological Safety Conference. New Orleans, LA.

8. Barkley, W. Emmett. 1972. Evaluation and Development of Controlled Airflow Systems for Environmental Safety in Biomedical Research. Ph.D. Thesis. Minneapolis, MN. University of Minnesota.

9. National Cancer Institute. 1976. NCI Purchase Specification: General Purpose Clean Air Biological Safety Cabinet (Class II Type 2 Safety Cabinet). Bethesda, MD 20014.

10. National Sanitation Foundation. 1983. Standard No. 49 for Class II (Laminar Flow) Biohazard Cabinetry. Ann Arbor, MI 48106.

11. National Cancer Institute, Office of Research Safety. 1975. National Cancer Institute Safety Standards for Research Involving Chemical Carcinogens. Bethesda, MD 20014.

12. NSF International. 2002. NSF/ANSI Standard No. 49 -2002: Class II (laminar flow) biosafety cabinetry, NSF International Standard/American National Standard. Ann Arbor MI 48113-0140.

13. NSF International. 2002. NSF Listings, Class II Biosafety Cabinetry. NSF International Web Page at www.nsf.org on the Internet.

14. Partial Adoption of the 2002 standard was made official in an Addendum designated as "NSF/ANSI 49-2002, Addendum 1.0 Class II (*laminar flow*) biosafety cabinetry". NSF Memorandum of December 12, 2002, SUBJECT: Published Biosafety Standard Addendum. NSF International. Ann Arbor, Michigan.

15. The Baker Company. 2002. "Guide To Biological Safety Cabinets And Associated Products". Available from the Baker Company. www.bakerco.com.

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