



# NSF INTERNATIONAL

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789 N. Dixboro Road, Ann Arbor, Michigan 48105 USA



# Biosafety Cabinets – primary containment devices for biomedical and microbiological laboratories

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# Who is NSF International?

- NSF International is an independent, not-for-profit, non-governmental public health and safety organization.
- *Our mission and focus is to protect and improve human health!*





# NSF International – Summary of Services

STANDARDS • GMP AUDITING • TESTING • CERTIFICATION • TRAINING • CONSULTING • REGULATORY COMPLIANCE



# Respected Professional Staff and Facilities

- 2,000+ experienced professionals:
  - Microbiologists
  - Toxicologists
  - Chemists
  - Engineers
  - Public Health Experts
- 250,000 ft<sup>2</sup> of laboratories in
  - Ann Arbor, Michigan, USA
  - China
  - India
  - Peru
  - UK
  - Brazil
- Innovative Information Technology and Research and Development capabilities.



# Goals for this Webinar

- Provide a brief overview of biosafety cabinets and how they function
- Examine issues related to technology selection, use and maintenance
- Review the field tests required for annual maintenance
- Review the tests performed on new models for NSF Certification or other third-party certification
- Understand how the field tests relate to the initial qualification test for certified models
- Discuss what actions to take when biosafety cabinets are found to be out of specification
- Review some of the international standards that relate to biosafety cabinets (not just NSF's)
- Notify the group of new training/testing center in Gurugram, India

# Risk Assessment

## PPE required depends on BSL level

**E.11.7 Biosafety Levels (BSLs):** The essential elements of the four BSLs for activities involving infectious microorganisms and laboratory animals are summarized in *Biosafety in Microbiological and Biomedical Laboratories*

The levels are designated in ascending order, by degree of protection provided to personnel, the environment, and the community. Standard microbiological practices are common to all laboratories. Special microbiological practices enhance worker safety, environmental protection, and address the risk of handling agents requiring increasing levels of containment. BSLs should not be considered the same as microorganism Risk Groups.



# Risk Assessment

## BSL-1

**E.11.7.1 Biosafety Level 1 (BSL-1):** Basic BSL-1 laboratory is suitable for work involving well characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. BSL-1 laboratories are not necessarily separated from the general traffic patterns in the building. Work is typically conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required, but may be used as determined by appropriate risk assessment. Laboratory personnel must have specific training in the procedures conducted in the laboratory and must be supervised by a scientist with training in microbiology or a related science.





# Risk Assessment

## BSL-2

**E.11.7.2 Biosafety Level 2 (BSL-2):** Containment BSL-2 laboratory builds upon BSL-1. BSL-2 is

suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that:

- laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures;
- access to the laboratory is restricted when work is being conducted; and
- all procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.



# Risk Assessment

## BSL-3

**E.11.7.3 Biosafety Level 3 (BSL-3):** High Containment BSL-3 laboratory is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with agents that may cause serious or potentially lethal disease through inhalation route exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and associated procedures. Secondary barriers for this level include controlled access to the laboratory and ventilation requirements that minimize the release of infectious aerosols from the laboratory.



# Risk Assessment

## BSL-4



**E.11.7.4 Biosafety Level 4 (BSL-4):** Maximum Containment BSL-4 laboratory is required for work with agents that pose a high individual risk of life-threatening disease, aerosol transmission, or related agent with unknown risk of transmission. Agents with a close or identical antigenic relationship to agents requiring BSL-4 containment must be handled at this level until sufficient data are obtained either to confirm continued work at this level, or re-designate the level. Laboratory staff must have specific and thorough training in handling extremely hazardous infectious agents. Laboratory staff must understand the primary and secondary containment functions of standard and special practices, containment equipment, and laboratory design characteristics. All laboratory staff and supervisors must be competent in handling agents and procedures requiring BSL-4 containment. Access to the laboratory is controlled by the laboratory supervisor in accordance with institutional policies.

There are two models for BSL-4 laboratories:

- Cabinet Laboratory where all handling of agents must be performed in a Class III BSC; and
- Suit Laboratory where personnel must wear a positive pressure protective suit.

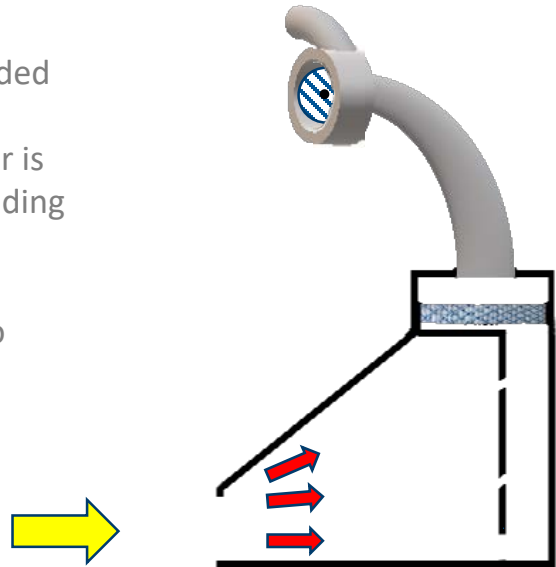
BSL-4 Cabinet and Suit Laboratories have special engineering systems

# Class I BSC



**3.8.1 Class I:** A Class I BSC provides personnel and environmental protection without product protection. Personnel protection is provided as a minimum velocity of 75 lfpm (0.38 m/s) of unfiltered room air is drawn through the front opening and across the work surface. The air is then passed through a HEPA/ULPA filter in the exhaust plenum, providing environmental protection.\*

The classic Class I BSC is connected to an external exhaust system (no internal blower) with a remotely mounted exhaust fan.



**Right side view**

\* NSF/ANSI 49-2018 - Biosafety Cabinetry: Design, Construction, Performance, and Field Certification

# Class II BSC



**3.8.2 Class II:** Class II (Type A1, A2, B1 and B2) BSCs are partial barrier systems that rely on the movement of air to provide personnel, environmental, and product protection. Personnel and product protection is provided by the combination of inward and downward airflow captured by the front grille of the cabinet.

Side-to-side cross-contamination of product is minimized by the internal downward flow of HEPA/ULPA filtered air moving towards the work surface and then drawn into the front and rear intake grills.

Environmental protection is provided when cabinet exhaust air is passed through a HEPA/ULPA filter. When used as designed, the cabinet exhaust air may be recirculated to the laboratory (Type A1 and A2 BSCs) or discharged from the building via a canopy connection (Type A1 and A2 BSCs). Exhaust air from Types B1 and B2 BSCs must be discharged to the outdoors via a sealed connection.

All Class II cabinets are designed for work involving procedures assigned to BSLs 1, 2 and 3. Class II BSCs may be used with procedures requiring BSL-4 containment if used in a BSL-4 suit laboratory by a worker wearing a positive pressure protective suit.

Class II BSCs provide the microbe-free work environment necessary for cell culture propagation and also may be used for the formulation of nonvolatile antineoplastic or chemotherapeutic drugs.\*

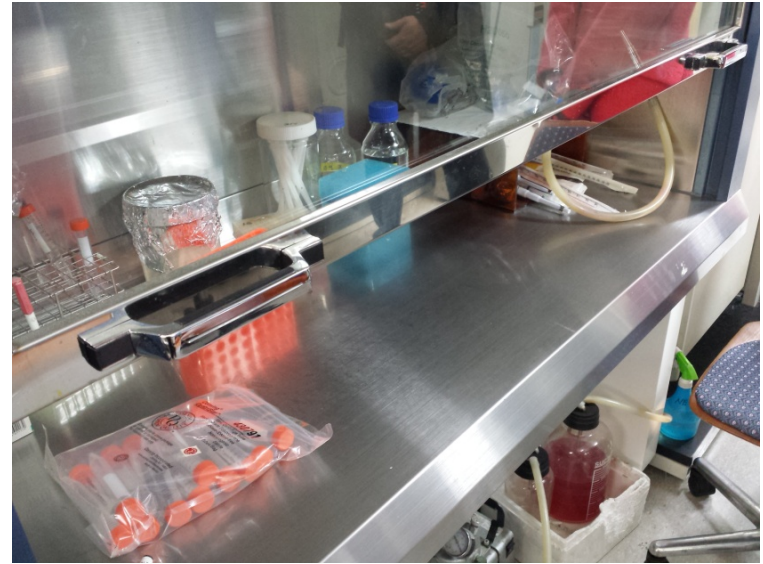
\* NSF/ANSI 49-2018 - Biosafety Cabinetry: Design, Construction, Performance, and Field Certification



# Global Problems – both resource and education related

Lack of understanding of how BSCs work - there may be an assumption of universal inflow and downflow velocities, or an assumption that air flows into the unit but not out of it.

Improper equipment selection - for example, using a clean bench (photo) when personnel protection is needed



# Global Problems (continued)

## User issues:

- Mistakenly store boxes/materials on top of BSC, blocking exhaust airflow
  - See photo – although this is a clean bench, not a BSC, this storage scenario is common
- Placing BSCs in high traffic areas
  - Air currents can disrupt the air curtain along the front opening
- Not working from clean to dirty
- Too many users per BSC - this may create air currents, or their arms may block the intake grille

## Maintenance issues:

- No maintenance plans / budget
- Careless or inexperienced field certifiers

## Facility issues:

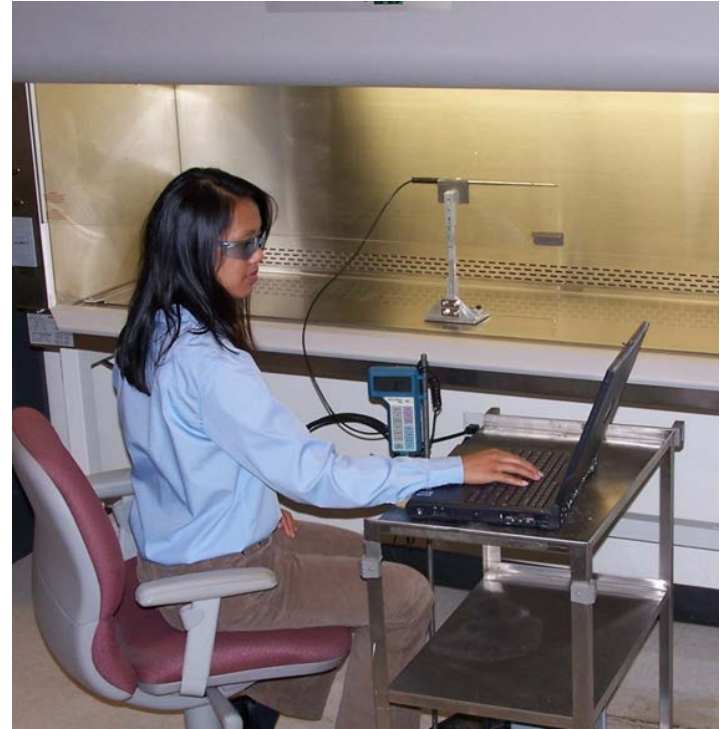
- Management is unfamiliar with “proper” field certification” and what testing looks like – unable to determine if field certifiers are knowledgeable or doing a bad job (see next slide)



## Global Problems (continued)



Vs.



## Global Problems (continued)



Not enough clearance above the BSC to the left – workers in this cleanroom were told to use furniture dollies to move around the room (while sitting cross legged and pushing off the floor with their hands).

Not pictured, but found on Youtube: BSCs operating with UV lights on and the front window wide open. NSF/ANSI 49 and other standards require an interlock for UV lights – so when the window is opened, they automatically turn off, protecting laboratory workers.

## Global Problems (continued)



Torn or damaged HEPA filters



## Global Problems (continued)



Poor installation (collapsed transition to external exhaust on a type B2 BSC)

## A Biological Safety Cabinet Certification Program: Experiences in Southeast Asia

Toni Whistler,<sup>1,2</sup> [Anek Kaewpan](#),<sup>1</sup> and [Stuart D. Blacksell](#)<sup>3,4</sup>

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“In a survey of biosafety level (BSL) 2 and 3 laboratories in 7 countries in the Asia-Pacific region, 30% of Class II BSCs tested were poorly designed, incorrectly installed, not certified, or being operated improperly. In Thailand, an estimated 600 BSCs need annual certification, and in 2013, only 1 accredited certifier was registered with the NSF International for BSC field certifications, and only 1 local company was known to perform these services to NSF standards.”

More than 30% of Class II BSCs evaluated in the study conducted by Dr. Whistler and colleagues were poorly designed, incorrectly installed, not certified, or being operated improperly.

More than 40% of all BSCs are sold into countries with no routine field certification.

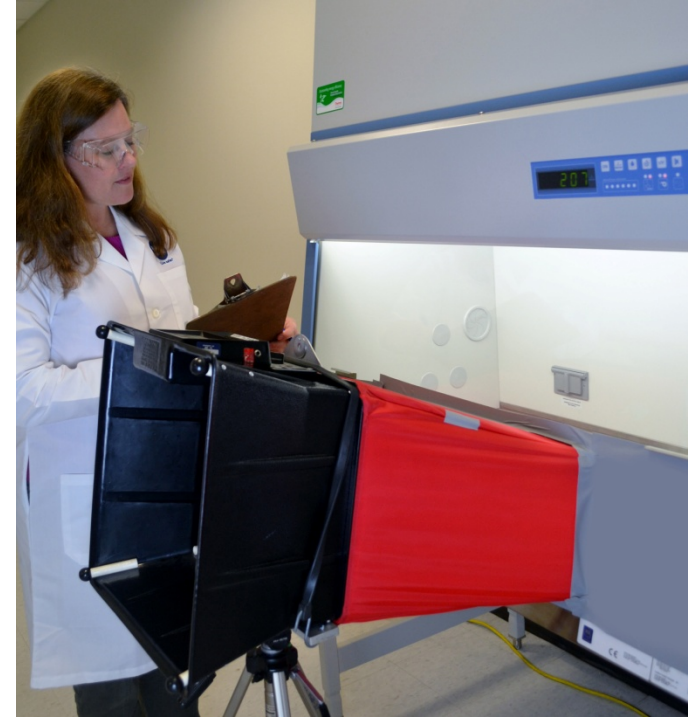
Current framework (esp. related to training and accreditation of qualified personnel) leads authorities to believe that the costs required to start routine maintenance programs are too prohibitive.

# NSF Biosafety Cabinetry Program

NSF's Biosafety Cabinetry Program was established in the 1970s in response to a request from:

- National Institutes of Health (NIH)
- U.S. Centers for Disease Control (CDC)
- National Cancer Institute (NCI).

A former bid specification for the NIH was developed into an American National Standard by NSF International through the guidance of a Joint Committee of experts in the field (public health / regulatory officials, manufacturers and users).



# NSF Biosafety Cabinetry Program

NSF's program was established in three phases:

- 1) Establishment of Joint Committee to provide input and development of national standard
- 2) Certification program for biosafety cabinets – BSCs are tested at NSF headquarters
- 3) **Accreditation Program for field certifiers of biosafety cabinets (started in 1993 in North America, split into two programs in 2017)**



# What is Certification (Type Testing)?

- Tests BSCs at both nominal airflow settings and out-of-balance conditions
- Microbiological challenge tests are extensive (see personnel protection test to right)
- Motor / blower performance tests with different input power supplies
- Structural integrity tests
- Verification of secondary measurement methods, that alarms are functioning as intended (sash height, exhaust airflow volume, etc)





# What is Field Certification?

- Subset of tests required for product certification
- Detailed in NSF/ANSI 49 (Annex F)
- Ensures airflow settings are correct
- Verifies HEPA filters are not damaged or loaded to the point that the airflow balance is impacted
- Visualizes airflow with smoke tests
- Verification that alarms are functioning as intended (sash height, exhaust airflow volume, etc)
- Optional user-comfort tests
- Decontamination test is forthcoming in program



# Accreditation Programs for Field Certifiers



## The old, “North American Model”

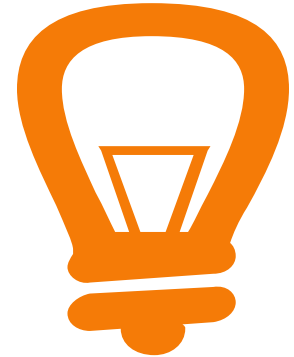
- Minimum education requirements
- Requires at least one year of experience
- Requires experience on both type A and type B biosafety cabinets
- Requires passing results on both written (theoretical) and practical examinations
- Proof of calibrated test equipment
- Signed ethics statement

# NSF's Basic Accreditation Program

There are now **two** NSF accreditation programs for BSC field certifiers:

- 1) The former program was rebranded as the Enhanced Accreditation Program. Field certifiers living and working in North America may **only** obtain accreditation to the enhanced program because of the prominence of type B2 BSCs in the region. It is also still available for international customers.
- 2) A new program was developed to offer training/testing in country at low cost. It does not address type B BSCs, but does have an additional performance test related to EN 12469 (European Standard). This is called the Basic Accreditation Program.

The NSF website continues to provide Listings of all accredited individuals. The two programs have separate Listing pages.



# Basic Accreditation Program - Benefits

Training addresses international standards, not just NSF/ANSI 49

A shorter, more concise written examination can be translated into native language

Fewer practical examination tests – no tests related to type B BSCs (this also makes it easier to find suitable practical exam test locations)

More Cost Effective

- Training and testing can take place in country
- Participants do not have to travel to U.S., nor are two training sessions required as is typical under the Enhanced program
- Personnel time for NSF team member may be donated (costs are minimized)
- Fewer pieces of test equipment are required (including more portable devices)

# Basic Accreditation Program – “Basic” yet Still Rigorous

As compared to the original NSF Accreditation Program, it is very similar:

- Has minimum education requirements
- Encompasses training on biosafety cabinets (type A2)
- Requires passing results on both written and practical examinations
- Requires proof of calibrated test equipment
- Requires signed ethics statement
- Additional requirements that are specific to the Basic Accreditation Program:
  - Field certifiers must submit test reports to NSF each year for review and comment
  - Field certifiers are expected to be aware of multiple international standards (NSF, EN, YY, etc)





# Bangkok, Thailand – September 2017



# Singapore – November 2018



Porton Down, England – January 2019



Noida, India – April 2019



# Addis Ababa, Ethiopia – September 2019





# Singapore – November 2019





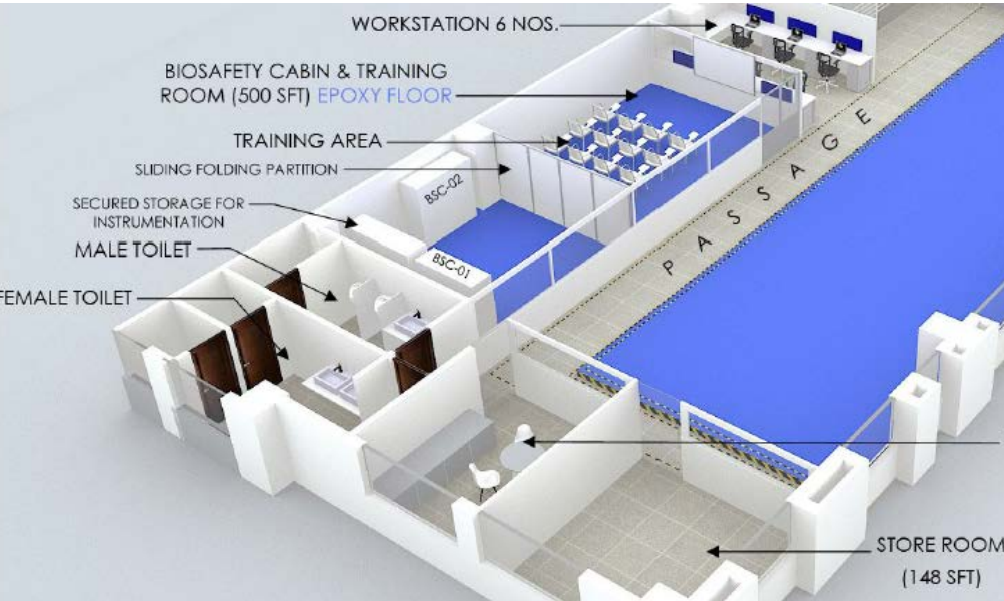
# Lessons Learned

- Power to the test facility was lost several times during test sessions in both India and Ethiopia. Future test sessions will be designed to include extra time in regions where electricity supplies may be subject to interruptions.
- Access to secure test facilities may be limited – need personnel available on-site to let test candidates in and out of test space.
- Allow extra time for test set up. One BSC in Ethiopia had been recently been disassembled for training and was reassembled with loose connections – one hour of troubleshooting was required prior to starting test set up.
- Specifications for test equipment must be clear and concise. Nonfunctional aerosol generators and photometers rented from a third party in India were initially received, causing delays in testing.

## Lessons Learned (continued)

- Communication is key between all different parties – sponsors, coordinators, host facilities, equipment providers, training organization, and testing organization (NSF).
- Billing has been somewhat complicated for NSF when funding sources are different than the entities who will be responsible for annual fees in the future and when intercompany billing must be used (for countries that require invoices from NSF divisions based within their borders).
- Give technicians input re. the expectations they should have for the course – not everyone will pass the tests or receive a certificate of accreditation. It is not unusual to have to retake individual practical exam tests.
- Allow time for examination retests (when policies allow). People have often travelled a long way to the workshop – maximize the use of the time allotted.

# What's Next?



- NSF's India office will have dedicated test space for Accreditation Program testing
- NSF has developed a training program for field certifiers as well!

# Resources

## Videos of field tests

English only playlist:

[https://www.youtube.com/playlist?list=PL9gmGvEk371MWyWOuV1OY8zaL3iJMRz\\_-](https://www.youtube.com/playlist?list=PL9gmGvEk371MWyWOuV1OY8zaL3iJMRz_-)

Spanish playlist: [https://www.youtube.com/playlist?list=PL9gmGvEk371PskOef-0\\_i6r-AGXPwJisj](https://www.youtube.com/playlist?list=PL9gmGvEk371PskOef-0_i6r-AGXPwJisj)

Chinese playlist:

<https://www.youtube.com/playlist?list=PL9gmGvEk371MXSQa7KFR1ho0XX5COMXt7>

## NSF Website

<https://www.nsf.org>



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