Biosafety Cabinets

Must be certified (tested) on regular basis to balance airflows and prevent leaks in the HEPA filters
Eagleson Institute

Nonprofit educational organization with a mission to globally promote the principles and practices of health and safety in the life sciences community
Global Biosafety Cabinet Certification Training Program

CHALLENGES IN CERTIFYING BIOSAFETY CABINETS
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Challenges

• **PART I**: Challenges in the United States
• **PART II**: Challenges in Low Resource Countries
Challenges in United States

1. Staying up-to-date on changes to NSF/ANSI 49

<table>
<thead>
<tr>
<th>Year</th>
<th>Changes</th>
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<tbody>
<tr>
<td>2008</td>
<td>• Chlorine dioxide added as a decontamination agent</td>
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<td>2010</td>
<td>• No longer allows Type A1 BSCs to have exterior positive pressure contaminated plenums</td>
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<td>• Type A1 and A2 BSCs need to be canopy connected, and direct connected ones shall no longer be considered in compliance (enforcement began in 2015)</td>
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<td>• NSF accredited certifiers can lose accreditation if they certify Type A BSCs that are direct connected (enforcement began in 2015)</td>
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<td>• Canopy connected BSCs need to have exhaust alarms, which must be tested</td>
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### Challenges in United States

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<th>Year</th>
<th>Changes</th>
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| 2017 | - Type C1 BSCs were added  
      | - Vaporized Hydrogen Peroxide added as a decontamination agent |
| 2018 | - New standard – minor changes |
Challenges in United States

2. Determining if BSC certifiers are qualified

• Are they accredited?
• Do they leave detailed documentation for each BSC tested?
What Should A Certification Report Include?

- General information
  - Type of cabinet
  - Manufacturer, Model, Serial number
  - Location
  - Venting criteria
    - To room, to roof, exhaust fan, type of damper, BMS, other hoods on same system?
- Name of certifier
  - Print and sign
What Should A Certification Report Include?

- **Basic Information on Tests Performed**
  - Brief description of each test
    - This can be provided on a referenced SOP
    - Refer to any appropriate industry standards
  - Acceptance criteria for each test
  - Pass/Fail statement for each test and for the unit overall
What Should A Certification Report Include?

• Detailed Information on Tests Performed
  • Airflow readings per NSF
    - Each reading in a corresponding grid
    - Average of readings
    - Methods used to determine the readings
  • HEPA filter
    - Upstream aerosol challenge and how determined (calculate vs measure)
    - Maximum leak penetration in percent and method used (scan vs probe)
    - Diagram showing location of leaks
What Should A Certification Report Include?

- Test equipment used for each test
  - Manufacturer
  - Model and Serial number
  - Calibration date and calibration due
## Resources

**NSF**

**NSF/ANSI 49 – 2018 Annex E and F**
- E: Biosafety Cabinet Selection, Installation, Lifespan, and Decommissioning
- F: Field Tests

**CDC/NIH**

**BMBL – Appendix A**
- Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets
Challenges in Low Resource Countries

- Very few trained personnel
- BSCs come from all parts of the world
- BSCs built to different standards
- BSCs may not be working at all
- Certifiers need to figure out how they work, diagnose problems, and develop strategy for repairing without manual
- Difficult to obtain parts
Every Country Has It’s Own Story
Success Stories

- Significant increase in number of BSCs being certified.
- Much more training related to proper use of BSCs is taking place.
- Certification programs are starting to grow roots.
Challenges

• Certifier Credibility
Challenges

- Calibration of testing equipment
Challenges

- Obtaining Consumable Supplies and Replacement Parts
Challenges

- Program Leadership Needed
  - System for keeping track of BSCs and certification reports
  - System for professional development and oversight of certifiers
  - System for storing, transporting and calibrating certification equipment
  - Budget for supplies
  - Time planned into work schedule
Thank you!

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