14TH CDC INTERNATIONAL SYMPOSIUM ON BIOSAFETY

BIOSAFETY MANAGEMENT

PLANNING FOR THE FUTURE BY LEARNING FROM THE PAST

2016 14TH CDC International Symposium on Biosafety
BIOSAFETY MANAGEMENT
Planning for the Future by Learning from the Past

NSF/ANSI 49

Changes and Updates

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NSF/ANSI std. 49

- Current Version
  - NSF/ANSI 49-2014
    - Published September 19, 2014
    - Updated February 2015
- Continuous Update Process
  - Issue Statements
  - Annually publish competed statements if substantial changes completed

NSF/ANSI 49 releases

- June 1976
- May 1983
- June 1987
- May 1992
- March/ Nov. 2002
- Feb 2004
- Sep 2004
- July 2007

Oct. 2008
Jun 2009
Sep 2010
Nov 2010
Nov 2011
Jul 2012
Feb 2015

www.CETAinternational.org

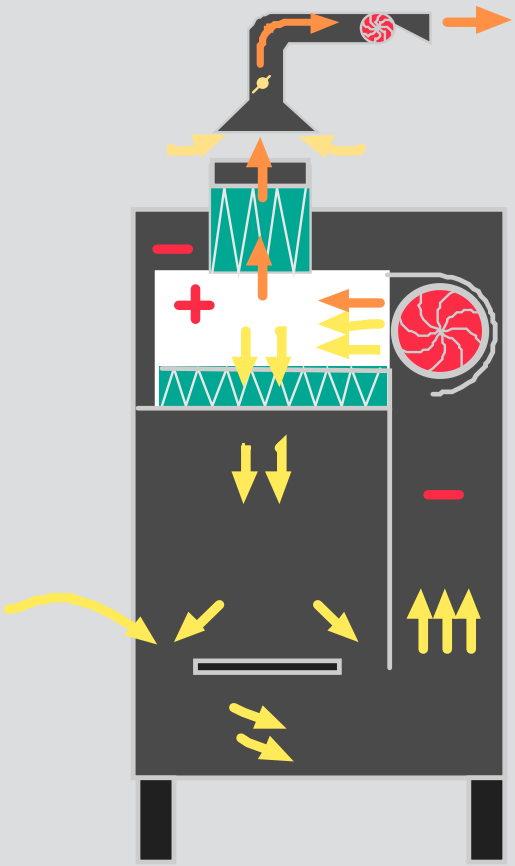
February 2015 Issue Revisions

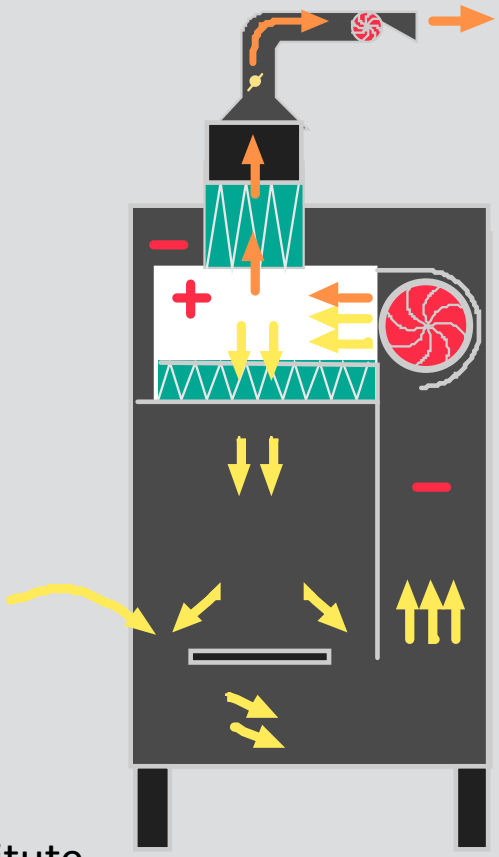
- 48 motor stability test
- 49 sealant language
- 50 new language for new fans
- 51 new language for BSC blower startup
- 52 revision to DOP Challenge port location
- 53 adds definitions for shell penetrations, cable ports
- 55 updates instrumentation language
- 60 updates airflow grid language
- 61 adds sash too low alarm
- 72 updates figures throughout to improve clarity

Field Certification of Direct Connected BSCs

- October 15, 2015 Letter from NSF
  - Effective April 15, 2016, NSF Accredited field certifiers shall no longer certify either direct-connected Type A cabinets or canopy connected Type A cabinets without alarms, even if specifically asked to do so by the customer.
  - Any NSF Accredited individual who field certifies a direct-connected Type A biosafety cabinet or a non-alarmed canopy connected Type A cabinet after April 15, 2016 will be considered in violation of the NSF Code of Ethics.

Type A BSC Venting



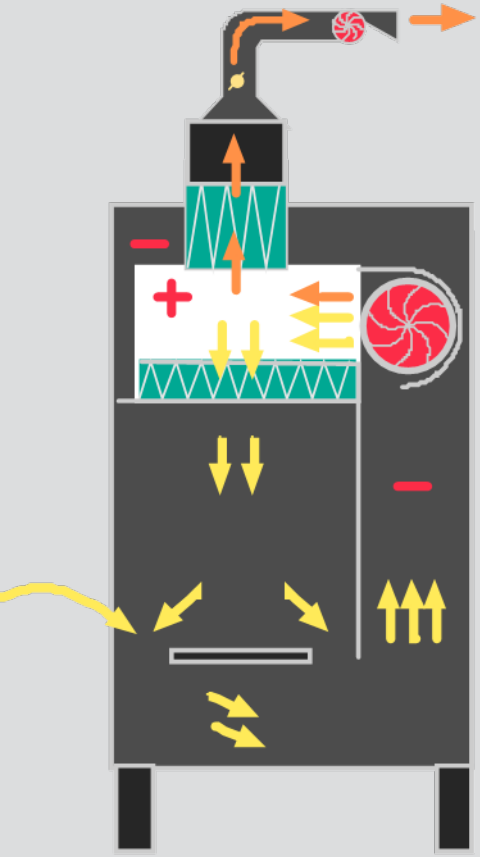


Courtesy of
Eagleson Institute

Type A BSC Venting Issues

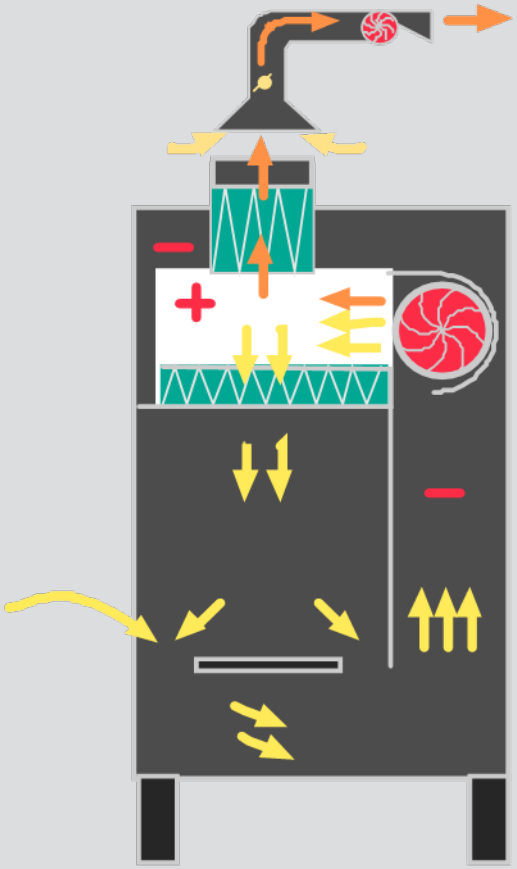
- Direct connected
  - Balance to exhaust fan must be exact
  - Exhaust fan failure results in air escape from front access opening
  - BSC and exhaust fans must be interlocked
  - Effect of BSC fan turned off when exhaust fan is operational
    - Contamination to downstream face of supply HEPA filter
    - Reverse fan rotation
  - Ganged system
- Canopy connected
  - Wide range of acceptable exhaust volume – gap velocity not critical (SG404_460-845)
  - Exhaust fan failure results in air escape from exhaust gap AFTER exhaust HEPA filter
  - BSC and exhaust fans must NOT be interlocked
  - Affect of BSC fan turned off when exhaust fan is operational
    - Minimal
  - Ganged sytems

Type A Venting History



- Pre 1992
  - No consistently reliable method to determine inflow velocity on Type A cabinets vented through a canopy connection
- 1992
  - Direct Inflow Measurement (DIM) methods introduced
- 2002
  - NSF States that Type A cabinets <u>should</u> be connected to the exhaust via canopy connection.

Type A Venting History



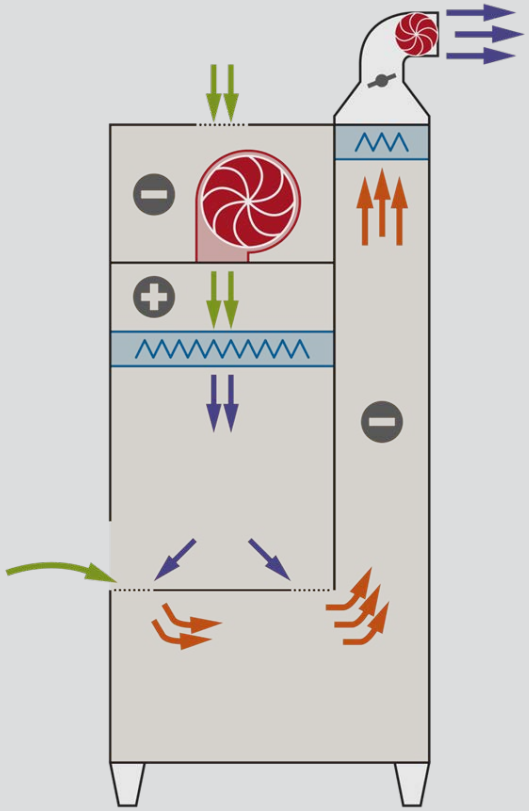
- 2010
- 2011
- 2015/16

- NSF States that Type A cabinets shall be connected to the exhaust via canopy connection and that existing installations must convert to canopy connections and must have an exhaust alarm if vented outside.
- May 17, 2011 letter stating that older installations can be certified to the edition of the standard in place when installed
- Firm position that direct connected A cabinets and A cabinets without an exhaust alarm cannot be certified by an NSF accredited certifier
  - 2015 letter for April 15, 2016 implementation

References

- NSF
  - www.nsf.org
    - NSF/ANSI 49 – 2014
- CETA
  - www.cetainternational.org
  - NSF Updates
  - CAG-010-2011
    - Notes to meet the NSF/ANSI 49:2010a
  - CAG-007-2010
    - Exhaust system requirements for Type B Cabinets

Other BSC Issues



- 2002/2010
- CBV for Type B Cabinets
  - Duct volume + loading factor published for all B cabinets
    - CFM + 0.3”w.c. for B1 cabinets
    - CFM +0.7” w.c. for B2 cabinets
  - Use CBV not the certification set points for HVAC design and balance
  - CETA CAG-007
    - Venting Type B BSCs