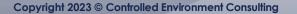
# **NSF/ANSI STANDARD 49**

Date Adopted & Effective	Issue Statements/ Annexes
March 2023	<u>135, 142, 143, 161, 162, 166, 167, 168, 170, 171</u>
March 2021	<u>130, 141, 151, 153, 154, 155, 156, 157, 159, 160</u>
March 2020	<u>54, 82, 92, 120, 122, 127, 130, 133, 136, 138, 139, 140, 146, 147, 148, 149</u>
January 2019	<u>47, 59, 77, 105, 108, 109, 110, 111, 112, 115, 117, 118, 121, 125</u>
March 2017	<u>45, 56, 73, 76, 78, 79, 81, 86, 88, 90, 96, 99</u>
February 2015	<u>48, 49, 50, 51, 52, 53, 55, 60, 61, 72</u>
July 2012	<u>44</u> , <u>46</u>
<u>November 29, 2010</u>	<u>23</u> , <u>29</u>
September 16, 2010	<u>23, 24, 37/38, 41</u>
<u>June 2009</u>	<u>Annex G</u> , <u>15</u> , <u>28</u> , <u>30</u> , <u>34</u> , <u>35</u> , <u>36</u>
<u>April 2008</u>	<u>12, 13, 14, 16, 17, 18, 19, 20, 21, 22, 25, 26, 31</u>

NSF position statement dated May 17, 2011 (see CETA CAG-010-2011)

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ControlledEnvironmentConsulting

March 2023

# CHANGES TO NSF/ANSI 49: MARCH 2023 CHANGES

**Changes Effective March 2023** 

The following is based on the changes outlined in the Foreword of NSF/ANSI 49 The topics were discussed in committee as issue numbers which form the basis of discussion.

• Issue 135, 142, 143, 161, 162, 166, 167, 168, 170, 171

• Only completed issues are discussed.

This revision added language regarding the power failure stability for Type B and C1 cabinets in Section N-1.13.4.3.

### N-1.13.4.3 Power failure stability

The difference between the initial inflow velocity and the final inflow velocity shall not exceed 3 ft/min (0.015 m/s). The difference between the initial downflow velocity and the final downflow velocity shall not exceed 3 ft/min (0.015 m/s). The cabinet lights shall come back on automatically when power is restored. The cabinet blower shall come back on automatically when power is restored, except in the cases of all Type B or those C1 cabinets connected to an exhaust system in which sensors determine when there is insufficient exhaust flow. Alarm parameters (if so equipped) shall remain unchanged from the set points prior to power loss. The cabinet shall provide the user with a visual indication that there was a loss of power.

This section was **modified**. The <u>highlighted</u> language was added to the Power failure stability requirement to prevent cabinets shut down because of insufficient exhaust from automatically restarting.

This revision adds language regarding field tests related to specific industry use of BSCs as Section N-5.1.3.

### N-5.1.3 Tests related to specific industry use

When field testing any Class II BSC, the certifier should take into consideration any additional testing required by a specific industry use. Examples include but are not limited to pharmaceuticals and electronics. Any additional testing completed is an adjunct to, and not a substitute for, the minimum testing required to consider a BSC field tested in accordance with NSF/ANSI 49.

This section **was added** to accommodate differences in applications of BSC from industry to industry. For example, the sterile compounding industry specifically requires particle counting to be done in all Primary Engineering Controls (PECs) which includes Class II BSCs. When certifying to USP Chapter <797> tests beyond those needed for compliance with NSF/ANSI standard 49 are required but those tests must be done in addition to the NSF tests, not in place of.

This revision modifies language regarding performance testing of Noise Level in Sections N-1.3 and N-5.11.

### N-1.3 Noise level test

### N-1.3.1 Purpose

This test provides a uniform method for measuring the noise level produced by the cabinet. The methods can be performed in most acoustically ordinary rooms, such as a factory, where walls are neither sound absorbing nor completely sound reflecting. The cabinet shall be operated at the manufacturer's recommended nominal set points  $\pm 2$  ft/min (0.01 m/s).

This section was modified from +/- 3 ft/min to +/- 2 ft/min.

This revision modifies language regarding performance testing of Noise Level in Sections N-1.3 and N-5.11.

### N-1.3 Noise level test

### N-1.3.1 Purpose

This test provides a uniform method for measuring the noise level produced by the cabinet. The methods can be performed in most acoustically ordinary rooms, such as a factory, where walls are neither sound absorbing nor completely sound reflecting. The cabinet shall be operated at the manufacturer's recommended nominal set points  $\pm 2$  ft/min (0.01 m/s).

This section was modified from +/- 3 ft/min to +/- 2 ft/min.

This revision modifies language regarding performance testing of Noise Level in Sections N-1.3 and N-5.11.

#### N-1.3.3 Method

- a) Turn on the cabinet blower and lights.
- b) Set the instrument to the "A" weighting mode.

c) **Position the noise level meter** 12 in (0.30 m) in front of the cabinet **front** edge of the access opening and 15 in (0.38 m) above the plane of the work surface, in line with the vertical centerline of the cabinet (see Figure 12).

- d) Measure the gross noise level.
- e) Measure the background noise level with the cabinet blower(s) and light(s) off and, if applicable,

the exhaust blower on.

f) Correct the gross noise level in accordance with curves or tables provided in the instrument

operator's manual to determine the net noise level.

N-1.3.4 Acceptance

The net noise level in front of the cabinet shall not exceed 67 dBA.

Item c) was modified for clarity. Items d),e),f) and N-1.3.4 Acceptance were rewritten or added for clarity Note that the process and acceptance criteria did not change.

This revision modifies language regarding performance testing of Noise Level in Sections N-1.3 and N-5.11.

#### N-5.11.3 Method

a) Operate the cabinet within 5 ft/min (0.025 m/s) of the nominal set point with lights on.

b) Set the instrument to the "A" weighting mode.

c) Position the noise level meter 12 in (300 mm) in front of the cabinet (front edge of the access opening) and 15 in (380 mm) above the plane of the work surface, in line with the vertical centerline of the cabinet (Annex N-1, Figure 13).

d) Measure the gross noise level.

e) Measure the background noise level with the cabinet blower(s) and light(s) off and, if applicable, the exhaust blower on.

f) Correct the gross noise level in accordance with curves or tables provided in the instrument operator's manual to determine the net noise level.

g) Reported values shall be:

- gross sound level reading;
- background sound level reading;
- net sound level;
- pass or fail; and
- name of test (noise level tests).

Highlighted items d),e),f) and g) were rewritten for clarity Note that the process did not change.

This revision modifies language regarding performance testing of Noise Level in Sections N-1.3 and N-5.11.

N-5.11.4 Acceptance

The net noise level in front of the cabinet shall not exceed 70 dBA.

The new language above replaced the old language below. The language was changed for clarity, but the effective acceptance criteria did not change.

### N-5.11.4 Acceptance

Overall noise level in front of the cabinet shall not exceed 70 dbA when measured where the maximum ambient sound level is no greater than 60 dbA. When the ambient sound level is greater than 60 dbA, the reading obtained in Section N-5.11.3.c) shall be corrected in accordance with curves or tables provided in the instrument operator's manual. If this information is not available, standard correction curves or tables shall be used (see following table).

This revision modifies language regarding performance testing of Noise Level in Sections N-1.3 and N-5.11.

### N-5.11.4 Acceptance

The noise correction table below was eliminated from this version of NSF/ANSI 49 in favor of correction curves found in the instrument operators manual.

Difference between total and background sound readings in db/	
<mark>0 to 2</mark>	reduce background levels
<mark>3</mark>	3
<mark>4 to 5</mark>	2
6 to 10	1
> 10	<del>Q</del>

This revision updates language regarding the use of volatile chemicals in Type A1 BSCs in Sections 3.8.2.1, I-1.3.1.3, and I-1.11.8.2.1.

#### 1. Class II Type A1 cabinets (formerly designated Type A): Cabinets that:

- maintain minimum average inflow velocity of 75 ft/min (0.38 m/s) through the work access opening;

- have HEPA/ULPA filtered downflow air that is a portion of the mixed downflow and inflow air from

a common plenum (i.e., a plenum from which a portion of the air is exhausted from the cabinet and the

remainder supplied to the total work area);

- may exhaust HEPA/ULPA filtered air back into the laboratory or to the environment through an

external exhaust system connected to the cabinet with a canopy connection;

- have all biologically contaminated ducts and plenums under negative pressure or surrounded by

negative pressure ducts and plenums; and

— type A1 BSCs are not designed for work with volatile chemicals and are not suitable to be used

#### for handling these chemicals.

The highlighted language above was added and the language below was eliminated from the standard to avoid misapplication of the Type A1 cabinet. A1 cabinets are NOT to be used with volatile materials.

If using chemicals with toxic vapors, the unit shall be connected to an external exhaust system. Type A1 cabinets may be used for work with volatile chemicals if deemed appropriate by a chemical risk assessment

(refer to Section I-1.3.1.3).

NOTE — Type A1 BSCs manufactured prior to 2010 are not suitable for work with volatile chemicals due to

the contaminated positive pressured plenums that are not surrounded by negative pressure plenums.

#### I-1.3.1.3, and I-1.11.8.2.1

Similar changes to those described for 3.8.2.1 were made to I-1.3.1.3 and I-1.11.8.2.1 to prohibit the use of Class II Type A1 cabinets with volatile materials.

### **Issue 162**

This revision adds language regarding the feet per minute tolerance for the airflow velocity testing in Sections 6.9 and 6.17, and throughout Normative Annex 1.

### 9. Downflow and inflow velocities

1. The average downflow velocity (uniform downflow) or velocities (nonuniform downflow) and the calculated and measured average inflow velocities of the cabinet shall be set at the manufacturer's recommended nominal set points  $\pm 2$  ft/min (0.01 m/s) for testing or alternative set points as the test method requires. Subsequent production models of the test cabinets of the initial model and size conforming to Section 6.7 may also qualify when the inflow and average downflow velocity (or velocities, if so specified) operate within  $\pm 5$  ft/min ( $\pm 0.025$  m/s) (see Section N-1.9) of the manufacturer's recommended nominal set points of the unit being tested.

This section was modified from +/- 3 ft/min to +/- 2 ft/min. and minor rewording where indicated. Previous wording *nominal set points ± 3 ft/min (0.015 m/s)* for testing unless otherwise noted.

#### **Issue 162**

This revision adds language regarding the feet per minute tolerance for the airflow velocity testing in Sections 6.9 and 6.17, and throughout Normative Annex 1.

### 6.17 Air velocity stability

Air velocity stability shall be determined with the cabinet operating at the manufacturer's recommended nominal set points **± 2 ft/min (0.01 m/s)** 

This section was modified from +/- 3 ft/min to +/- 2 ft/min.

Previous wording Air velocity stability shall be determined with the cabinet operating at the nominal set point velocities **± 3 ft/min (0.015 m/s).** 

#### Issue 166

This revision updates language regarding the various uses of the term "dedicated" in Sections 3.8, I-1.3.1.4, and Table I-1.2.

I-1.3.1.4 Question four: If the BSC requires an exhaust system, is there an appropriate location for the cabinet and its ductwork?

— canopy-connected Types A and C1 require a consistent, low static pressure. While an exhaust duct
 dedicated to that individual cabinet is preferred, they may share a common exhaust system with other exhausted laboratory devices, if properly balanced;

This section was modified from — canopy-connected Types A and C1 require a consistent, low static pressure. **While a dedicated exhaust system** is preferred, they may share a common exhaust system with other exhausted laboratory devices, if properly balanced;

The new language is intended to specify that dedicated in this case implies "to that specific cabinet" as apposed to "to that building" or "to Class II BSCs. etc. This is only one example of where the standard further defines "dedicated" to mean "to that individual cabinet"

#### **Issue 166**

This revision updates language regarding the various uses of the term "dedicated" in Sections 3.8, I-1.3.1.4, and Table I-1.2.

I-1.3.1.4 Question four: If the BSC requires an exhaust system, is there an appropriate location for the cabinet and its ductwork?

— Type B BSCs require a higher static pressure that must increase as their exhaust filters load. They must be on an exhaust duct and fan **dedicated to that individual cabinet**, and not be ganged with other Type B BSCs, or other exhausted laboratory devices requiring a lower static pressure (e.g., fume hoods, canopy-connected BSCs);

This section was modified from — Type B BSCs require a higher static pressure that must increase as their exhaust filters load. They must be on **a dedicated exhaust system**, and not be ganged with other Type B BSCs, or other exhausted laboratory devices requiring a lower static pressure (e.g., fume hoods, canopy-connected BSCs);

The new language is intended to specify that dedicated in this case implies "to that specific cabinet" as apposed to "to that building" or "to Class II BSCs. etc.

#### **Issue 166**

This revision updates language regarding the various uses of the term "dedicated" in Sections 3.8, I-1.3.1.4, and Table I-1.2.

### Table I-1.2 Characteristics of Type B1 and Type B2 BSCs

exhaust system type - Must have an exhaust duct and fan **dedicated to each BSC** - Must have an exhaust duct and fan **dedicated to each BSC**.

This section was modified from

exhaust system type - Must have **dedicated ductwork and exhaust blower for each BSC** - Must have **dedicated ductwork and exhaust blower for each BSC**.

The new language is intended to specify that dedicated in this case implies "to that specific cabinet" as apposed to "to that building" or "to Class II BSCs. etc. This is very moderate change to the language to be consistent with changes made elsewhere.

Note that similar changes are made elsewhere in this table.

#### **Issue 167**

This revision modifies language regarding the resistance to tipping, distortion and deflection of work surface under load tests in Section 6.8 and Normative Annex 1. It also removes former Figures 21 through 24.

### 8. Stability

The cabinet shall be designed and constructed to resist overturning and distortion under applied forces, resist deflection of the work surfaces under load, and resist tipping under workload.

### 1. Resistance to overturning

Cabinets shall conform to the requirements of UL 61010-117 or current edition, Section 7.3.

The sections above remain unchanged as posted here. The sections below were removed in their entirety to reduce the cost of cabinet accreditation. Stability testing is adequately covered in UL 61010-117.

- 2. Resistance to distortion
- 3. Resistance to deflection of work surface
- 4. Resistance to tipping

### **Issue 168**

This revision adds language regarding ammonium carbonate in Section I-2.1.4.1.

### I-2.1.4.1 Paraformaldehyde

CAUTION — All sources of hydrogen chloride must be removed from the cabinet before decontamination. Hydrogen chloride in the presence of formaldehyde, at ambient air conditions, will form the carcinogen Bis(chloromethyl)ether (BCME).

a) Calculate the total volume of the cabinet by multiplying the height, width, and depth.

b) Multiply the total volume of the cabinet by 0.30 g/ft3 (11 g/m3) of space to determine the gram weight of paraformaldehyde required [CHECK CONCENTRATION]. Determine the stoichiometric amount of **ammonium carbonate** [(NH4)2CO3] or alternative to neutralize the resulting formaldehyde gas with ammonia gas. The ammonium carbonate should be weighed out so that it is 10% greater than the weight of paraformaldehyde used for the decontamination to ensure completion of the reaction.

The words **ammonium carbonate** were added to any reference to the scientific notation **[(NH4)2CO3]** throughout I-2.1.4.1. This is just one example.

### **Issue 170**

This revision updates language regarding the airflow smoke patterns test in Sections N-1.10.4.2 and N-5.4.4.2

### N-1.10.4.2 Sash retention test

The visible aerosol or mist shall show smooth downward flow with no dead spots or reflux. No visible aerosol or mist shall escape from the cabinet.

### N-5.4.4.2 Sash retention test

The visible aerosol or mist shall show smooth downward flow with no dead spots or reflux. No visible aerosol or mist shall escape from the cabinet.

Both above changes were to rename this test "**Sash**" retention from "**View Screen**" retention for consistency.

### **Issue 171**

This revision updates the definitions of *Class II* and *decontamination* in Sections 3 and I-1-11. It also adds a footnote regarding HVAC in Sections 5.25.5 and I-1.3.1.

### 3.8.2 Class II: ...

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

The **highlighted** section above was changed from **previous language below** for clarity. This same change was made in I-1.11

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

# ISSUE 171(CONTINUED)

**Issue 171** 

This revision updates the definitions of *Class II* and *decontamination* in Sections 3 and I-1-11. It also adds a footnote regarding HVAC in Sections 5.25.5 and I-1.3.1.

Section 5.25.5

<sup>22</sup> ASHRAE Laboratory Design Guide: Planning and Operation of Laboratory HVAC Systems, Second edition (2015) or latest edition. American Society of Heating, Refrigeration, and Air-Conditioning Engineers, Inc. 1791 Tullie Circle, NE, Atlanta, GA 30329. <<u>www.ashrae.org</u>>

<sup>23</sup> Sheet Metal and Air Conditioning Contractors' National Association. 4201 Lafayette Center Drive, Chantilly, VA 20151. <u>www.smacna.org</u>

The **highlighted** footnote (22) was added. Footnote (23) is carried over.

# **ISSUE 171(CONTINUED)**

**Issue 171** 

This revision updates the definitions of *Class II* and *decontamination* in Sections 3 and I-1-11. It also adds a footnote regarding HVAC in Sections 5.25.5 and I-1.3.1. Section I-1.3.1

<sup>57</sup> Specifications taken from Military Specification MIL-F-51068 (Cancelled), Gasket Assembly.
<a href="mailto:system:specification-system:specif

The **highlighted** section above was changed from the **bold** section below

<sup>57</sup> Specifications taken from Military Specification MIL-F-51068 (Cancelled), Gasket Assembly.
<a href="https://www.defenselink.mil/pubs/>www.defenselink.mil/pubs/

# NSF/ANSI 49: MARCH 2021 CHANGES

**Changes Effective March 2021** 

The following is based on the changes outlined in the Foreword of NSF/ANSI 49 The topics were discussed in committee as issue numbers which form the basis of discussion.

- Issue 130, 141, 151, 153, 154, 155, 156, 157, 159, 160
- Only completed issues are discussed.

This revision updated language throughout the standard regarding use of the previously added terms total work area and usable work area.

- N-1.6.1 Purpose
  - These tests determine whether aerosols will be contained within the cabinet, outside contaminants will not enter the cabinet usable work area, and aerosol contamination of other equipment in the cabinet will be minimized.

### N-1.8.4 Acceptance

- The average downward airflow velocity through the cross section of the unobstructed usable work area (with removable acceptable option components removed) at the level 4 inches (100 mm) above the bottom of the sash of cabinets meeting the requirements of Section N-1.6 shall be the values specified by the manufacturer.
- I-1.3.1.1 Question one: What needs to be protected?
  - ...The Class I BSC will protect the operator and the lab, however, because room air constantly washes over the usable work area, the product is exposed to airborne contaminants.

I-1.7.1.5 Effective usable work area layouts will minimize reach to avoid neck and shoulder stress and fatigue. Rotating tables are available to minimize reach.

### I-1.7.4 BSC techniques

• ...and (2) airborne contamination generated in the usable work area is controlled by flow of airstreams in a top-to-bottom direction;

### I-1.7.5 BSC start up procedure

• ...This will minimize the shedding of skin flora into the usable work area and also protect hands and arms from viable microbial contamination.

### I-1.11.2.3 downflow velocity profile:

 ...Airflow velocities and the average of the airflow through the usable work area may be calculated as a whole (uniform) or may be separated into two or more adjoining areas (zoned) with averages calculated for each zone.

Note there are 92 instances of the use of "total work area". Too numerous to list here.

### This revision updated multiple definitions in Section 3

- Some definitions moved from other sections into the definitions section 3.
- **3.8 cabinet classification**: Although this standard covers only Class II BSCs, Class I and Class III cabinets are currently defined and known to be commercially available.
  - $\succ$  This definition was modified.
- Other minor changes throughout the standard

This issue modified language in Section N-1.6 regarding the occurrence of positive control plates.

This revision updated language in Sections 3.19.1, 6.11, 6.15, and N-1.6.5.1 regarding use of the term *smoke*.

- The word "smoke" was removed from the standard because the visible medium used is not truly a smoke.
  - > 3.19.1 Changed smoke particles to aerosol particles
  - 6.11, 6.15 Changed "Airflow smoke patterns" to "Airflow pattern test" and removed any reference to "smoke"
  - > 6.1.6.5.1 Changed reference to "smoke" to "visible medium"

This revision modified language in Sections N-1.8, N-1.9, N-5.2, N-5.3, and N-5.12 regarding air velocity measurements and the field certification label.

- N-1.8 added "The anemometer probe shall not be hand held for any downflow velocity measurements."
- N-1.9 added "The anemometer probe shall not be hand held"
- N-5.2 added "The anemometer probe shall not be hand held for any downflow velocity measurements."
- N-5.3 added "The anemometer probe shall not be hand held. Acceptable methods include a ring-stand and clamp, manufacturer supplied probe holder or when the BSC manufacturer has made provisions for accurately locating the anemometer sensing element by resting the probe on the exhaust collar and a second lip for stability.
- N-5.12 added "Technician NSF listing number, if applicable." to the Field certification label requirements.

### This revision updated language in Section 5.25.6 regarding the warm up period.

 This sentence was changed as follows: When starting the cabinet blowers from a dead stop, the inflow alarm must activate a visual indication until the cabinet either enters into a visually indicated warm up period not to exceed 2 minutes or the appropriate inflow velocity is achieved to ensure proper alarm system function.

This revision affirms language in Section N-1.6 regarding the placement of biological test control plates.

 Added to N-1.6.5.1.4.b) "A visible aerosol or mist test may be performed to determine where the test organism will be best captured in the areas described above, allowing unnecessary control plates to be eliminated."

This revision further clarifies language in Section N-1.6 regarding biological tests.

### This revision modifies language regarding electrical safety in Section 6.14.

Added "For the purposes of this requirement, an "authorized testing laboratory" shall be either a US Occupational Safety and Health Administration (OSHA) Nationally Recognized Testing Laboratory (NRTL) or an International Electrotechnical Commission for Electrical Equipment CB Testing Laboratory (CBTL)."

### 3.8.2

• This sentence was eliminated <u>"Class II BSCs provide the microbe-free work environment</u> necessary for cell culture propagation and also may be used for the formulation of nonvolatile antineoplastic or chemotherapeutic drugs."

# **ISSUE 160 CONTINUED**

#### This revision adds clarifying language to definitions in Sections 3.5.3 and 3.8.2.

• 3.8.3 Class III: The Class III BSC was designed for work with highly infectious microbiological agents and other hazardous operations. It provides maximum protection for the environment and the worker. It is a gas-tight (no leak greater than 1 × 10-7 mL/s with 1% test gas at 3 inches (750 Pa) pressure water gauge)21 enclosure with a viewing window that is secured with locks, or requires the use of tools to open, or both. Access for passage of materials into the cabinet may be through any of the following: a dunk tank that is accessible through the cabinet floor, a double-door pass-through box that can be decontaminated between uses, integrated double door autoclaves, and portable docking stations with double sealing connecting mechanisms that can be decontaminated between uses. Reversing that process allows materials to be removed from the Class III BSC. Both supply and exhaust air are HEPA/ULPA filtered. Exhaust air must pass through two HEPA/ULPA filters in series, before discharge to the outdoors. Airflow is maintained by an exhaust system exterior to the cabinet, which keeps the cabinet under negative pressure according to manufacturer design pressure criteria. Sometimes because of laboratory conditions an optional exhaust fan may be required. This exhaust fan should generally be kept separate from the exhaust fans of the facility ventilation system. If a cabinet exhaust system is required it should be equipped with an appropriate alarm system which both notifies the cabinet user and shuts down the cabinet exhaust system in the event of a facility exhaust system failure. This exhaust fan should generally be kept separate from the exhaust fans of the facility ventilation system and be equipped with an appropriate alarm system which both notifies the cabinet user and shuts down the cabinet exhaust system in the event of a facility exhaust system failure.

# **ISSUE 160 CONTINUED**

### 3.8.3 Class III:

### This paragraph was modified as noted:

 Rubber gloves / sleeves or equivalent glove material, are sealed to ports in the cabinet and allow direct manipulation of the materials isolated inside. The glove material shall be compatible for use with the materials being used in the cabinet. The exhaust system for the cabinet shall provide inflow to the cabinet arm port in the event of a rubber glove / sleeve breach. The minimum breach velocity shall be measured with a hot wire in the middle of the arm port and shall be no less than 100 ft/min (0.51 m/s). It is not a requirement for the work area to be free of turbulence or cross contamination.

# NSF/ANSI 49: MARCH 2020 CHANGES

**Changes Effective March 2020** 

The following is based on the changes outlined in the Foreword of NSF/ANSI 49 The topics were discussed in committee as issue numbers which form the basis of discussion.

- Issue 54, 82, 92, 120, 122, 127, 130, 133, 136, 138, 139, 140, 146, 147, 148, 149
- Only completed issues are discussed.

This revision affirms new and updated language in Annex N-5 (formerly Annex F) concerning the use of the Secondary method for measuring airflow.

This revision affirms new language in Annex I-1 (formerly Annex E) regarding the term percent recirculation.

This revision affirms new and updated language in Section 3 and Annex N-5 (formerly Annex F) regarding canopy field testing.

This revision affirms new language in Section 3 regarding the addition of the newly proposed term *plenum*.

This revision affirms new and revised language in Annex N-5 (formerly Annex F) regarding the Certification Label.

This revision affirms revised language regarding the use of the term NOTE.

This revision affirms revised language regarding the definition of the term work area.

This revision affirms revised language in Section 5 regarding the data plate.

This revision affirms revised language in Annex N-1 (formerly Annex A) and Annex N-5 (formerly Annex F) regarding the sash seal smoke test.

This revision affirms revised language regarding the range of measurement for vibration frequency.

This revision affirms revised language in Annex I-1 (formerly Annex E).

This revision affirms revised language in Annex N-1 (formerly Annex A) regarding accuracy requirements for the manometer used for the pressure decay and motor blower performance tests.

This revision addresses inconsistencies of incubation times and temperatures during the various biological tests in Annex N-1.

This revision affirms revised language in Annex N-1 (formerly Annex A) regarding filter porosity for filtering impinger water.

This revision affirms revised language in Annex N-1 (formerly Annex A) regarding the confirmation requirements for the Cross Center test.

This revision affirms revised language in Section 2 regarding Normative References.

# NSF/ANSI 49: MARCH 2020 CHANGES

#### Annexes

Annexes	
Previously known as:	Now known as:
Annex A	Normative Annex 1 (N-1)
Annex B	Normative Annex 2 (N-2)
Annex C	Normative Annex 3 (N-3)
Annex D	Normative Annex 4 (N-4)
Annex E	Informative Annex 1 (I-1)
Annex F	Normative Annex 5 (N-5)
Annex G	Informative Annex 2 (I-2)
Annex H	Informative Annex 3 (I-3)
Annex I	Informative Annex 4 (I-4)
Annex J	Informative Annex 5 (I-5)
Annex K	Informative Annex 6 (I-6)

## NSF/ANSI 49: JANUARY 2019 CHANGES

The following is based on the changes outlined in the Foreword of NSF/ANSI 49 The topics were discussed in committee as issue numbers which form the basis of discussion.

- Issue 47, 59, 77, 105, 108, 109, 110, 111, 112, 115, 117, 118, 121, and 125
- Only completed issues are discussed.

Revised and added new language in Annex A regarding the cross contamination test procedure.

Revised and added new language for the airflow alarm requirement language for all cabinet types.

Added language to Annex A regarding confirmation tests when there is a test failure.

Added new language in Annex E regarding risk assessment of biosafety cabinets exhaust system pressurization in the event of an exhaust system failure.

Added new language in Annex F regarding exhaust airflow alarms

Revised and added new language referring to the term Certification throughout this standard.

Revised language in Section 1.3 regarding the identification of major software changes to biosafety cabinets.

Added new and revised language to Section 3 regarding the terms visible and viewable, and added provisions for the optional use of digital data plates to Section 5.

Revised and added new language in Annex G regarding the generation and dispersion of decontamination gas.

Added new language in Section 6.10 regarding inflow requirements for Type C1 Cabinets.

Updates the language throughout this Standard regarding the use of the term "and/or".

Revised language in Section 5.25.3 and Annex F regarding the exhaust alarm in Type B biosafety cabinets.

Revised language in Section 5.26.2 regarding electrical wiring.

Revised language in Section 5.26.2 regarding the term "running power".

# NSF/ANSI 49: MARCH 2017 CHANGES

#### **Changes Effective March 2017**

Note: That in addition to this summary, CETA published an applications guide to provide a more detailed explanation including rationale for the changes.

The following is based on the changes outlined in the Foreword of NSF/ANSI 49 The topics were discussed in committee as issue numbers which form the basis of discussion.

- Issue 45, 56, 73, 76, 78, 79, 81, 86, 88, 90, 96, and 99
- Only completed issues are discussed.

Changes were made to Annex G covering the addition of Vaporized Hydrogen Peroxide as a decontamination agent in Biosafety Cabinetry, as well as clarifying the use of Chlorine Dioxide.

Language in section 6.14 was added regarding certification to IEC 61010-1 or a national standard based on it.

Updated/unified all cabinet definitions, Sections 5, 6, Annex A and F for the type C1.

Updated language was added referencing audible and visual alarms.

Metric conversions throughout the Standard were reviewed and updated.

Decontamination procedures in Annex G were updated.

Updated Annex E. Included all definitions from section 3, updated risk assessment, cabinet placement, cleaning procedures, usage procedures and added type C1.

Updates were made in Annex A to the incubation time and temperature prior to the micro check.

Section 5.32 was updated regarding cabinet height and width.

Redundancies about sliding sash alarms in subsections 5.19.4 and 5.25.1 were removed.

Language involving preparation of the spore suspension of Bacillus atrophaeus 9372 in Annex A was updated.

Update Soap bubble leak test procedure in Annex A to require manufacturers to provide metal seal plates and limits NSF test personnel time to seal leaks found.

# NSF/ANSI STANDARD 49: FEBRUARY 2015 CHANGES

#### **Changes effective February 2015**

Note that in addition to this summary, CETA published an applications guide to provide a more detailed explanation including rationale for the changes.

Issues 48, 49, 50, 51, 52, 53, 55, 60, 61, 72

# **ISSUE 48: MOTOR STABILITY TEST PROCEDURE**

This revision adds a motor stability test procedure for motor speed control systems.

## **ISSUE 49: SEALANT USE LANGUAGE**

#### This revision updates the sealant use language in Annex H, Section H.6.

- Updated recommended sealants for the BSCs.
  - > SAE AMS-S-8802 or equivalent
  - > Dow Corning RTV 732, 781,734, or RRTV 112 self leveling or equivalent

### **ISSUE 50: FANS**

This revision affirms new language regarding the type of fans used in biosafety cabinets.

## **ISSUE 51: BIOSAFETY CABINET BLOWER STARTUP**

This revision affirms new language regarding the type of biosafety cabinet blower startup.

# **ISSUE 52: DOP PORT LOCATION**

#### This revision clarifies details surrounding the DOP port location in section 5.22

• Moved the challenge port from the top of the BSC on the outside to the inside under the work surface. The intent is to ensure that the challenge port is opened in negative pressure.

#### **ISSUE 53: DEFINITIONS**

This revision adds definitions to clarify biosafety cabinet shell penetrations and cable ports with consideration given to service technicians and cabinet users relating to safety.

# **ISSUE 55: INSTRUMENTATION LANGUAGE**

This revision updates the instrumentation language.

# **ISSUE 60: AIRFLOW GRID LANGUAGE**

This revision updates the airflow grid language in sections A.8.3.1 and A.8.3.2, and the related figure A15

- Clarifies minimum spacing and number of readings determination.
- Clarifies different zone dimensions for cabinets with sloped sash for different sash height

### **ISSUE 61: SASH POSITION**

This revision updates the language in sections 5.19.4 and 5.25.1 to include a section requiring the use of a sash position "too low" alarm.

• Now must alarm for more than 1" above and below

### **ISSUE 72: FIGURES**

This revision updates multiple figures throughout the Standard to improve clarity.

# NSF/ANSI STANDARD 49: JULY 2012 CHANGES

Changes effective July 2012

• <u>Issues 44, 46</u>

### **ISSUE 44: CABINETS LESS THAN 3 FEET**

Updates the language in the Standard to include a test method for biosafety cabinets with an interior sidewall dimension of three feet or less.

#### **ISSUE 46: DIRECT INFLOW MEASUREMENT (DIM) & EXHAUST CLEARANCE**

Updates the Standard to include a reference to non-back pressure compensated readings used in a Direct Inflow Measurement (DIM) in Annex A, Annex B, and Annex F

Updates the language in Annex A, Annex E and Annex F for the 12 in (30 CM) clearance requirement used for measuring an exhaust HEPA filter

# NSF/ANSI 49: NOVEMBER 2010 CHANGES

Changes effective November 29, 2010

The following summary of changes is based on the changes outlined in the Foreword The issues were discussed in committee as issue numbers which form the basis of discussion.

- <u>Issue 23, 29</u>
- Only completed issues are discussed.
- Note that these two simple changes are addendum to the other 2010 changes

### **ISSUE 23: B2 DEFINITION**

Errors in the September 2010 version were corrected. B2 Cabinet description is now correct.

# **ISSUE 29: UNIFORM AND ZONED DOWNFLOW**

#### 1. Uniform downflow cabinets

• No change to this section

#### 2. Non-uniform downflow (zoned) cabinets

- The grid must have equidistant spacing
- Each zone must have at least 7 points within it
- The distance between test points shall not be less than 4" nor more than 8" inches apart
- The area defined by the perimeter of the test points must equal at least 30% of the total area of the plane in which the readings are taken.
- Each zone shall be taken at least 6 in away from the walls and sash enclosing the work area.

# NSF/ANSI 49: SEPTEMBER 2010 CHANGES

Changes effective September 2010

The following summary of changes is based on the changes outlined in the Foreword The issues were discussed in committee as issue numbers which form the basis of discussion.

- Issue 23, 24, 37/38, 41
- Only completed issues are discussed.

One additional item was added and not listed as with an issue number.

• <u>Annex K</u>

# **ISSUE 23: HARD DUCTING CABINETS**

- 2. "The canopy connection type of BSC exhaust connection is required for externally vented Class II, Type A1 or A2 BSCs."
  - Minor changes to wording from previous version of standard.
- F.7.3.3 "Direct connected A1 or A2 BSCs shall not be considered in compliance with the Standard."
  - New language intended to end "grace period" for conversion of old installation direct connections for type A1 and A2 cabinets.
    - Strong recommendation since 2002 now becomes a requirement. All externally vented A cabinets now must be connected with a canopy exhaust connection or they cannot be certified to be in compliance with the standard.

## **ISSUE 23: HARD DUCTING CABINETS**

F.7.3.3 "Using a visible medium source positioned to demonstrate containment of BSC exhaust by the canopy, reduce the external exhaust until the alarm signals audibly. The alarm shall sound before visible canopy containment is lost."

- New language for testing canopy connections.
- It should be noted that new language for this is anticipated that will be consistent with other alarm requirements (within 15 seconds).

## **ISSUE 23: ULPA FILTERS**

HEPA references now are HEPA/ULPA

### **ISSUE 24: ALARMS**

5.23.4 "Any Type A1 or A2 cabinet when canopy connected shall have audible and visual alarm indication notifying the user of a potential loss in canopy containment"

# **ISSUE 37/38: ILLUSTRATIONS**

New illustrations throughout the document

## **ISSUE 41: IEC 61010**

"The standard was revised to be more inclusive of markets outside North America by modifying section 6 – Performance of the standard."

#### 6.14 Electrical safety

"The cabinet shall be tested by a National Recognized testing Laboratory (NRTL) for compliance to the requirements of the current edition of any national standard that is based on IEC 61010-1. Compliance is demonstrated by cabinet listing, i.e. UL, CSA, or IECEE CB Scheme certificate."

#### ANNEX G: AMMONIUM CARBONATE (NOT A NUMBERED ISSUE)

1. "The <u>ammonium carbonate</u> should be weighed out so that it is 10% greater than the weight of paraformaldehyde used for the decontamination to ensure completion of the reaction."

- Changed from <u>Ammonium bicarbonate</u> to reflect Dr. Luftman's work published in "Applied Biosafety 10(2)-2005."
  - > Bicarbonate should be 1.6:1 according to this article.

# **ANNEX K**

A "<u>Protocol for the Validation of Alternative Biosafety Cabinet Decontaminating Methods and Agents</u>" was added in the form a new annex (Annex K).

• This is an informative annex

### NSF/ANSI 49: JUNE 2009 CHANGES

Changes effective June 2009

The following summary of changes is based on the changes outlined in the Foreword The issues were discussed in committee as issue numbers which form the basis of discussion.

• Annex G, Issue 15, 28, 30, 34, 35, 36

• Only completed issues are discussed.

### ANNEX G

New section in 2008 largely unchanged.

# **ISSUE 15: AEROSOL INTRODUCTION POINT**

A2.3.1a) "The manufacturer shall determine the aerosol introduction point that provides the most uniform distribution"

• Same as 2008

### New language for 2009

- The location of the aerosol introduction point shall be clearly described or indicated in a manner readily available to the certifier.
  - > On the cabinet data plate (or)
  - > With the electrical schematic if the schematic is affixed to the cabinet

### **ISSUE 28: ILLUSTRATIONS**

Illustrations throughout the document were updated to take advantage of modern technology.

• Thanks to Jim Hunter, Labconco Corporation

### **ISSUE 30: BIOLOGICAL VS. BIOSAFETY**

The term "biosafety" is now used throughout the standard. The title was changed previously but there were some cases where old terminology remained in the 2008 version.

### **ISSUE 34: ACCEPTANCE STATEMENTS**

#### Correct the acceptance statements in Annex F for consistency with Annex A.

- F2.4 Format change. Use of word "shall"
- F3.4 Use of word "shall"
- F4.4 No change
- F5.4 No change
- F6.1.5 Use of word "shall"
- F7 N/A
- F8 N/A
- F9.4 Use of word "shall"
- F10.4 Use of word "shall"
- F11.4 Use of word "shall"

### **ISSUE 35: MULTIPLE ISSUES**

#### 3.26 Added a definition for w.g. (water gauge)

• "Another common name for inch of water column. The word "gauge" after a pressure reading indicates that the pressure stated is actually the difference between the absolute or total pressure and the air pressure at the time of the reading".

#### UL References were updated throughout.

- 1. First reference to NSF/ANSI 49-2002 changed to NSF/ANSI 49 to clarify.
  - With exception of downflow velocity test, all cabinets will be field tested to current version of Annex F regardless of manufacture date.

### **ISSUE 36: PLENUM DESIGN**

- 5.4 All biologically contaminated ducts and plenums in Type A1, A2, B1, and B2 cabinets shall be maintained under negative pressure or enclosed within a negative pressure zone.
  - Match the definition for a type A1 cabinet as in the 2008 version of NSF/ANSI 49. Removed contradictory language.
    - > A1 cabinets can no longer have positive pressure contaminated plenum.

### NSF/ANSI STANDARD 49: APRIL 2008 CHANGES

Changes effective April 2008

• Issue 12, 13, 14, 16, 17, 18, 19, 20, 22, 25, 26, 31

### **ISSUE 12: HEPA FILTERS**

3.14\* High efficiency air filters (for use in class II biosafety cabinets)

• Added (for use in class II biosafety cabinets) to the title to make it clear that the language in the standard only addresses filters as they pertain to BSCs.

\*Note that this is NOT section 3.13 as stated in the foreword.

# **ISSUE 13, 21: CABINET DESCRIPTIONS - TYPE A**

#### Change for Class II Type A1

- All biologically contaminated plenums under negative pressure or surrounded by negative pressure ducts and plenums.
  - > Positive pressure exterior plenums are no longer allowed on any Class II BSC.
- 1. Tests directly related to containment cabinet integrity test
  - Old A1 cabinets only
  - New positive pressure plenum cabinets only

## **ISSUE 14: CONCURRENT BALANCE VALUE**

### Added definition for CBV (3.10)

- For all direct-connected BSCs
- Compares the primary (DIM) value to a duct traverse.
  - ➤ Traverse per ASHRAE std. 111-2008
- Requirements for listing now specified
  - > Exhaust volume @ filter load value (pressure)
  - Allowance for filter loading added to measured value
    - B1 0.3" w.c.
    - B2 0.7" w.c.

### **ISSUE 16: STANDARD TITLE**

### Biosafety Cabinetry: Design, Construction, Performance, and Field Certification

• Remove reference to Class II to include all types of cabinets

### **ISSUE 17, 20: INTERLOCKS FOR TYPE B CABINETS**

### Section F.7.3.2

- Changed requirement for interlock verification to Type B cabinets from Type B2 cabinets.
  - Significant impact for B1 cabinet testing!

## **ISSUE 18: DOWNFLOW VELOCITY MEASUREMENT**

#### 1. clarification language

• Downflow velocity readings shall be taken 4" above the bottom edge of the window only when so stated on the manufacturers data plate or when the manufacturers data plate label indicates the cabinet was listed to NSF 49-2002 or later.

## **ISSUE 19: SOUND LEVEL MEASUREMENTS - ANNEX F**

#### F.11.4 Acceptance (sound level)

- Cabinet passes when overall noise level does not exceed 70 dbA when ambient is not greater than 60 dbA.
  - $\succ$  When ambient exceeds 60 dbA, correction curves are used.

Difference between total and background sound readings in dbA	Number to subtract from total to yield corrected noise level
0-2	Reduce background levels
3	3
4-5	2
6-10	1
>10	0

### Certification Report - F.12.2

- A certification report that will carry the language "certified in accordance with the NSF annex F" or any similar language shall, at a minimum, include the following:
  - BSC Model Number
  - BSC Serial Number
  - BSC Location
  - > BSC Venting Information
    - Ducted or not ducted
      - Type of connection (canopy, direct, or none)
  - > Type of BSC
  - Test equipment used for each test
    - Manufacturer, model, serial number, calibration date
  - Specific test data as detailed in annex F
  - Acceptance criteria for each test
  - Printed name of certification technician
  - Retest date

- Annex F
  - > Requirements for "Reported Values" are now delineated for each test in Annex F.
    - Downflow Velocity for Uniform Downflow Cabinets F.2.3.1
      - Individual velocity readings in the applicable grid
      - Overall average of velocity readings
      - Minimum velocity reading
      - Maximum velocity reading
      - Acceptance criteria for average airflow velocity
      - Acceptance criteria for airflow velocity uniformity
      - Name of test (Uniform Downflow Velocity Test)

- Annex F
  - > Requirements for "Reported Values" are now delineated for each test in Annex F.
    - Downflow velocity for Non-Uniform Downflow Cabinets for each zone F.2.3.2
      - Individual velocity readings in the applicable grid
      - Overall average of velocity readings
      - Minimum velocity reading
      - Maximum velocity reading
      - Acceptance criteria for average airflow velocity
      - Acceptance criteria for airflow velocity uniformity
      - Name of test (Uniform Downflow Velocity Test)

- Annex F
  - > Requirements for "Reported Values" are now delineated for each test in Annex F.
    - Intake Velocity using the Direct Measurement Method F.3.3.2
      - Individual volume readings
      - Overall average of the volume
      - Calculated inflow volume
      - Work access opening area
      - View screen opening height
      - Correction factor used (if applicable)
      - Acceptance criteria for average inflow volume
      - Acceptance criteria for calculated inflow velocity
      - Inflow velocity test method
      - Name of test (Inflow velocity test)

#### **Reported Values**

Annex F: Requirements for "Reported Values" are now delineated for each test in Annex F.

- Intake Velocity using a thermal anemometer to measure exhaust velocity to determine inflow velocity – F.3.3.3.1
  - Individual exhaust velocity readings
  - Overall average of the exhaust velocity readings
  - Calculated exhaust volume
  - Calculated inflow volume
  - Exhaust opening dimensions
  - Exhaust opening effective area
  - Work access opening area and dimensions
  - View screen opening height
  - Correction factor used (if applicable)
  - Acceptance criteria for calculated inflow velocity
  - Acceptance criteria for calculated inflow velocity
  - Inflow velocity test method
  - Name of test (Inflow velocity test)

- Annex F
  - > Requirements for "Reported Values" are now delineated for each test in Annex F.
    - Intake Velocity using a thermal anemometer to measure velocity through a constricted access opening to determine average inflow velocity – F.3.3.3.2
      - Individual constricted velocity readings
      - Overall average of the inflow velocity readings
      - Calculated inflow volume
      - Work access opening dimensions and area
      - Correction factor used (if applicable)
      - Acceptance criteria for average inflow velocity
      - Inflow velocity test method
      - Name of test (Inflow velocity test)

- Annex F
  - > Requirements for "Reported Values" are now delineated for each test in Annex F.
    - Intake Velocity using a thermal anemometer to measure velocity through the access opening to determine average inflow velocity (B1) – F.3.3.3.3
      - Individual velocity readings
      - Overall average of the inflow velocity readings
      - Calculated inflow volume
      - Work access opening dimensions and area
      - Correction factor used (if applicable)
      - Acceptance criteria for average inflow velocity
      - Inflow velocity test method
      - Name of test (Inflow velocity test)

### **Reported Values**

Annex F: Requirements for "Reported Values" are now delineated for each test in Annex F.

- Intake Velocity using an anemometer and pitot tube F.3.3.3.4
  - Individual duct velocity readings
  - Overall average of the duct velocity readings
  - Calculated exhaust volume
  - Duct size shape and area
  - Calculated inflow volume
  - Work access opening dimensions and area
  - Dimensions and area of the supply velocity measurement locations used to determine supply volume
  - Individual supply velocity readings (not to be confused with downflow velocities)
  - Calculated supply velocity and volume
  - Calculated inflow velocity and method used for calculations
  - Correction factor used (if applicable)
  - Acceptance criteria for calculated inflow velocity
  - Inflow velocity test method
  - Name of test (Inflow velocity test)

- Annex F
  - > Requirements for "Reported Values" are now delineated for each test in Annex F.
    - Airflow Smoke Pattern Test F.4.3
      - Name of each test
      - Pass or fail for each test

#### **Reported Values**

- Annex F
  - > Requirements for "Reported Values" are now delineated for each test in Annex F.

### • HEPA Filter Leak Test – F.5.3.1

- Upstream Aerosol Challenge Concentration
- Method used to report concentration (measured or calculated)
- Maximum leak penetration in percent
- Method used (scanned or Probe tested)
- Name of test (HEPA filter leak test)

- Annex F
  - > Requirements for "Reported Values" are now delineated for each test in Annex F.
    - Pressure decay / soap bubble test F.6.1.3
      - Pressure range maintained during test
      - Pass or fail
      - Name of test (Pressure Decay Test)

- Annex F
  - > Requirements for "Reported Values" are now delineated for each test in Annex F.
    - $\circ~$  Site installation assessment tests F.7 ~
      - Reported values are not specified in standard

- Annex F
  - > Requirements for "Reported Values" are now delineated for each test in Annex F.
    - Lighting Intensity Test F.9.3
      - Individual background readings
      - Individual lighting intensity readings
      - Average background intensity
      - Average lighting intensity
      - Acceptance criteria
      - Pass or fail
      - Name of test (Lighting intensity test)

#### **Reported Values**

- Annex F
  - > Requirements for "Reported Values" are now delineated for each test in Annex F.

### • Vibration Test – F.10.3

- Unit "On" vibration reading
- Background vibration reading
- Net vibration
- Pass or fail
- Name of test (Vibration Test)

#### **Reported Values**

- Annex F
  - > Requirements for "Reported Values" are now delineated for each test in Annex F.

### • Noise Level Tests – F.11.3

- Unit "On" sound level reading
- Background sound level reading
- Net sound level
- Pass or fail
- Name of test (Noise level test)

### ISSUE 22, 25: ANNEX G

#### Informative annex expanded from formaldehyde decontamination to include:

- G.1 Biosafety Consultation prior to BSC purchase
- G.2 Risk Assessment procedures
- G.3 Cabinet selection
- G.4 Prior to the Purchase
- G.5 Inspection (of new cabinets)
- G.6 Moving a BSC
- G.7 Decontamination procedures
  - Expanded to include Chlorine Dioxide procedures
- G.8 HEPA Filter Disposal Procedures
- G.9 Lifespan of BSCs
- G.10 Decommissioning process

### **ISSUE 31: HELIUM AND SULFUR HEXAFLUORIDE TESTS**

Annex J created as informational annex because there are no longer any exterior positive pressure contaminated plenum designs. Material removed from Annex A.

- J.1 Helium Leak Test
  - Previously section A.1
- J.2 Sulfur Hexafluoride (SF6) Leak Test
  - Previously section A.2

### **SUMMARY**

Both minor and major changes were made to NSF/ANSI 49-2008. The most substantive changes were elimination of Type A cabinets with exterior positive pressure contaminated plenums, listing requirements for the Concurrent Balance Value, inclusion of chlorine dioxide decontamination procedures, and requirements for minimum reported values for field certification. Minor changes were made in 2009. The most substantive change made in 2010 is strengthening of language relating to external venting of class II Type A cabinets and specific new guidance for testing canopy connections.