EAGLESON INSE/ANSI STANDARD 49

Changes adopted effective January 2019 March 2017 February 2015 July 2012 November 29, 2010 September 16, 2010 June, 2009 and April, 2008

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

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> > SLIDE 1

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NSF/ANSI STANDARD 49

• Changes Effective January 2019

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

Changes to 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 STANDARD 49

• 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.

Changes to NSF/ANSI 49 March 2017 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.

<u>Issue 45, 56, 73, 76, 78, 79, 81, 86, 88, 90,</u> <u>96, and 99</u>

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.

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• 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.

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

lssue 72 Figures

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

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• Changes effective July 2012

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) and 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 STANDARD 49

• Changes effective November 29, 2010



Changes to NSF/ANSI 49 November 2010 changes

- 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

- A.8.3.1 Uniform downflow cabinets
 - No change to this section
- A.8.3.2 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 STANDARD 49

• Changes effective September 2010



Changes to NSF/ANSI 49 September 2010 changes

- 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, 24, 37/38, 41</u>

- 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

- **5.2** "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.
 - <u>Strong recommendation</u> since 2002 now becomes a <u>requirement</u>. All externally vented A cabinets now <u>must be</u> connected with a canopy exhaust connection or they cannot be certified to be in compliance with the standard. SLIDE 52

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)

- G.1.3.1 "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</u> <u>Biosafety Cabinet Decontaminating Methods and</u> <u>Agents</u>" was added in the form a new annex (Annex K).
 - This is an informative annex

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• Changes effective June 2009



Changes to NSF/ANSI 49

- 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.
- **F.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.



• Changes effective April 2008

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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.
- F.1.1 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

- F.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.
 - 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

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- 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

SI IDF **77**

- Specific test data as detailed in annex F
- Acceptance criteria for each test
- **Printed** name of certification technician
- Retest date

- Reported Values
 - 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)

- Reported Values
 - 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)

Reported Values

- 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

SI IDF **81**

- » 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)

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 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)

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 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)

- Reported Values
 - 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)

- Reported Values
 - 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)

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

Site installation assessment tests – F.7

» Reported values are not specified in standard

- Reported Values
 - 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.