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July 29, 1996

NIOSH Docket Office Robert A. Taft Laboratories M/S C34
4676 Columbia Parkway Cincinnati, OH 45226

Please accept these comments in response to the May 16, 1996 Federal Register (Volume 61, Number 96; Page 24740-24743) proposed rules for revising current National Institute for Occupational Safety and Health (NIOSH) procedures for certifying respiratory devices used to protect workers in hazardous environments.

The comments provided represent those of NSF International, an independent, private, not-for-profit organization providing third-party conformity assessment programs and consensus standards development in the areas of public health safety and the environment. Our services span a wide range of program areas, including the assessment of products, individuals, and organizations, collectively representing over 2,500 clients in 60 countries worldwide.

We believe that NSF, through our experiences, expertise, and worldwide recognition as the leader in public health related standards development and conformity assessment programs, can provide assistance to NIOSH for implementation of the necessary changes needed to accomplish the intended goals of improved respiratory device certification.

NSF, with over 52 years of service, has been involved with many similar projects, improving upon existing government programs and development of new opportunities. We offer the means by which to facilitate, through assembly of the stakeholder community, the development of consensus standards and certification programs. Requests for development of private sector conformity assessment programs can come from a variety of sources, but quite commonly arise from the needs of regulatory authorities, like that of NIOSH. NSF has worked with many federal agencies over the years to provide this very same area of expertise, including EPA, FDA, USDA, CDC, NIH, NCI, and many similar authorities internationally.

The need for credible, third-party, private sector programs, such as those administered by NSF, are expected to now grow as a result of the legislatively mandated policy under the National Technology Transfer and Advancement Act of 1995, PL 104-133. Signed into law by President Clinton on March 7, 1996, federal agencies are now directed to use private sector resources for standards and conformity assessment programs rather than administering their own.

In order to provide a greater understanding of NSF's role, and the similarities to that of NIOSH, I am providing a brief overview of NSF's current services. Following, I will elaborate on how NSF proposes to work with NIOSH to answer the many pertinent questions posed and to accomplish the intended goals related to the certification of respiratory devices. C B I V B D

Personnel Accreditation

Pertaining to the assessment of individuals, NSF operates the only program in the US accredited internationally to the European Norm (EN) Standards. The NSF accreditation program enables individuals to demonstrate their knowledge and skills, through both a written and practical examination. The current program is specifically directed at those service providers who perform field evaluations of biological safety cabinets used in various laboratory environments.

Organizational Accreditation/Registration

In regards to the assessment of individual organizations, NSF has programs directed at both management practices and technical operations. As an example of demonstrating technical competence, NSF was the first, recognized, third-party private entity to provide for the assessment of drinking water laboratories, as federally mandated by the USEPA under the Safe Drinking Water Act. The accreditation program provides all of the necessary laboratory assessments, relieving the state authorities of this role. The assessments include facility and operation inspections, method compliance, personnel qualifications, quality assurance, sample performance evaluation, and related areas, according to the USEPA requirements for certification of laboratories analyzing drinking water. NSF's independent assessment and recommendation to the state authority is the basis for state certification.

In the area of assessing management systems capability and compliance, NSF provides registration programs using the internationally recognized ISO (International Organization for Standardization) standards for both quality systems (ISO 9000) and environmental management (ISO 14000). The ISO 9000 standards were created to promote consistent quality practices as a proactive management tool, assuring product quality and facilitating international trade. It defines the minimum critical elements that must be implemented within an organization to assure consistent quality. Similarly, ISO 14000 was created to promote consistent environmental management practices across international borders to recognize and address the impact of products, services, and processes on the environment. NSF was a lead organization in the development of these standards, and accredited nationally and internationally for registration to the ISO 9000 series standards and working towards the same for the newly adopted ISO 14000 standards.

Product Certification

NSF's programs certify products to 45 NSF standards, in addition to other national and international standards. Consensus product standards development and accompanying product certification is the service area for which NSF is most widely known.

All of the NSF programs are operated on a voluntary basis. Many regulatory authorities, user groups and the like, however, have elected to require NSF Certification for demonstration of initial and continued product conformance. Throughout all of our processes NSF uses a consensus approach to determine the components of the certification programs and for development of related standards. As a result, whether truly voluntary or required through external authorities, all participants have a represented voice in the process.

NSF currently provides product certification programs in the areas of commercial food equipment, chemicals and materials in contact with drinking water, residential water filtration

devices, alternative residential wastewater treatment systems, plastic pipe, swimming pools, and laminar flow biological safety cabinets.

NSF is accredited nationally by the American National Standards Institute (ANSI), and internationally by the Dutch Council for Accreditation (Raad voor Accreditatie; RvA) for operation of all product certification programs, complying with the recognized standards for third-party conformity assessment organizations. In addition, our product standards development process is accredited by the ANSI.

NSF has been recognized by many organizations and authorities for our services and their impact upon public health safety and the environment. Most recently, NSF's credibility and expertise in water-related product certification was recognized and endorsed by the World Health Organization (WHO), selecting NSF as the Collaborative Center for Drinking Water Safety and Treatment. In this role, NSF will provide technical guidance to the international community on a variety of water related programs. We will also take the lead in development of several WHO international guidelines for establishing drinking water quality.

Numerous programs currently operated by NSF were developed as a result of the need to address similar issues as those under review by NIOSH for program administration and private sector involvement. One, however, stands out because it is so nearly identical. The Biohazard Cabinet Certification Program, directed specifically at Class II laminar flow biological safety cabinets, originated through a request from the National Institute of Health (NIH) and the National Cancer Institute (NCI). Both of these agencies operated programs for assessing Class II biological safety cabinets. However, due to financial constraints and limited resources, a request was made to have a third-party organization develop a national, consensus standard and implement a certification program against that standard. NSF was selected as the organization of choice for developing and operating such a program.

Beginning in 1973, NSF assembled representative experts from across the country, representing the manufacturing industry, regulatory authorities, and user groups. Enclosed is a list of those original members. The process was completed in June of 1976 with the adoption of the first edition of NSF's Standard 49 Class II (Laminar Flow) Biohazard Cabinetry. Now in its fourth edition, this document continues to be the recognized standard for evaluation of Class II cabinets. It is referenced in numerous publications used by laboratories and hospitals across the country, including CDC•NIH publications Biosafety in Microbiological and Biomedical Laboratories and Primary Containment for Biohazards: Selection, Installation, and Use of Biological Safety Cabinets. Enclosed is a current copy of Standard 49.

All of the NSF standards contain requirements for more than simply demonstration of performance. Standard 49, as an example, contains very detailed, additional requirements for materials, design and construction. Collectively, the standard sets minimum requirements of which all must be satisfied.

Regarding performance requirements, all Certified cabinets are required to meet the following: personnel, product, and environmental protection; reliable operation; durability; cleanability; stability; HEPA filter leak; velocity profile; airflow smoke patters; noise level limitations; Page

acceptable light intensity; limitation on temperature rise; acceptable vibration limits; and electrical leakage ground, circuit resistance and polarity. Appendix A of the standard defines the specific test methods for demonstrating compliance with the performance requirements.

The individual tests are performed not only at NSF, but are also required by the standard to be performed at the point of production by the manufacturer as well. Every cabinet bearing the NSF Mark, prior to leaving the manufacturing facility, must be performance tested for those areas affecting user safety, while every tenth cabinet must be tested for areas of worker comfort.

In addition, requirements for materials must also be met, demonstrating their ability to withstand normal wear, including abrasion and chemical resistance, protection from breakage, et cetera. Interior and exterior surfaces, work surfaces, windows, gaskets and sealants all have individual requirements.

Lastly, the standard addresses requirements for design and construction. Briefly, the cabinet must be demonstrated to function properly and operate in a safe manner, minimize contamination, provide personnel and product protection, and be capable of being cleaned and decontaminated.

With the standard in place, the second phase of NSF's role began through implementation of the product certification program. NIH and NCI assisted in the process by supplying NSF with performance test equipment. All of the remaining costs were absorbed by NSF. The certification program has since evolved, both with advancements in the standard and in the cabinet and test equipment industries. Many of the original manufacturers continue to be the leaders in the industry, and continue to be Certified by NSF. Enclosed is a current Listing Book. The NSF Listing Book for Biohazard Cabinetry is published three times per year and distributed to over 3,000 users.

The certification program has many elements, of which certainly the foundation is product conformance to the standard. However, many other aspects of the program have an equal impact upon the ability of a manufacturer to use the NSF Mark on their product(s). These requirements are defined in the NSF International Certification Policies for Biohazard Cabinetry (copy enclosed).

The Certification Policies address the conformity assessment process of NSF, including such areas as use of the NSF Mark, record keeping practices, confidentiality, advertising, investigation of complaints, corrective action and enforcement, appeals, fees, and on-site inspections. Of all the policy issues, the on-site inspection is the most significant relative to product compliance. The inspection process is conducted annually at all facilities and production locations to ensure that the Certified product is being produced to the same specifications as that

which was evaluated, including dimensions, materials, construction, components, etc. Only qualified, trained NSF auditors are authorized to perform these inspections.

The conformity assessment program for Class II Biohazard Cabinetry, like that of all NSF Certified products, ensures that the cabinets fulfill their intended function, providing for the safety and comfort of those who use them.

Many of the questions posed by NIOSH in the Federal Register regarding standards and program administration mirror those of NIH and NCI over twenty years ago. It was their decision at that time to allow the stakeholder community, as facilitated by NSF, to answer these same questions through the consensus process. A similar process would serve to accomplish the same for NIOSH, leading to accomplishment of their goals. Although the Federal Register process of public comment can be a sounding board for raising comments and awareness, it lacks the necessary dynamics of a facilitated discussion among the representative people and organizations.

Perhaps the one difference between the questions posed by NIH/NCI and NIOSH is in regards to international recognition and acceptance. This difference is likely due to the change in international relations over the last two decades and the recognized need for global harmonization of standards. NSF, more than any other organization in the US, has carried the vision for international public health and environmental standards development and acceptance. Through expansion of the stakeholder representation, bringing international participants to the table, it is possible to address global acceptance. Certainly ISO has been very effective in this process. We would be happy to investigate with ISO the possibility of developing an international standard to meet the needs of assessing respiratory devices.

We propose to NIOSH, based upon what you now know of NSF, the goals you wish to accomplish, and the desire to involve private organizations, that NSF and NIOSH meet to discuss how we can mutually serve the stakeholder community. NSF is capable today of developing an internationally recognized standard and implementing a product certification program to that standard. Our experience and established credibility and integrity in this area, as recognized and accredited nationally and internationally, is proof of our capability.

I will be in contact with NIOSH near the completion of your August 16, 1996 deadline. This will allow time for internal discussions relative to our proposal and the review and assessment of other commentary offered.

Please distribute this information to all those you feel appropriate, allowing them an opportunity to learn of NSF and our possible contribution towards meeting NIOSH's goals. Please direct all questions and communications regarding NSF's possible role in the area of respiratory device certification to my attention. I will personally see that the appropriate representatives within NSF are brought into the process as necessary.

I look forward to the opportunity to meet with representatives of NIOSH and to working closely towards accomplishing the goals of NIOSH, for creation of a credible, nationally and internationally recognized respiratory device certification program.

Sincerely,

Ann Marie Gebhart, Ph.D.

Vice President, Technical Operations

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NSF *International*Certification Policies for Biohazard Cabinetry



TABLE OF CONTENTS

SECTION I. GENERAL POLICIES FOR ALL PRODUCTS PAGE											
INTRODU	CTION										
	DEFINITIONS 1										
AUTHORI	ZATION FOR CERTIFICATION										
GP - 1.	Eligibility										
GP - 2.	Application for NSF Certification										
GP - 3.	Contract for NSF Certification										
GP - 4.	Responsibility of Company										
GP - 5.	Written Authorization for Certification and Use of the Mark										
GP - 6.	Notification of NSF Certification										
GP - 7.	Transfer of Authorization for Certification and Use of the Mark										
GP - 8.	NSF Acknowledgement of Certified Products										
GP - 9.	Use of the Mark for Products Shown in the Official Listing										
GP - 10.	Trade Designations										
GP - 11.	Use of the Mark for New Products										
GP - 12.	Use of the Mark at Authorized Production Locations										
GP - 13.	Product Modification										
GP - 14.	Implementation of Revisions to Standards										
GP - 15.	Certification of Distributors										
GP - 16.	Private Labeling of Certified Products										
	č										
AUDIT											
GP - 17.	Requirement and Purpose of Audits										
GP - 18.	Access for Audits										
GP - 19.	Cooperation with NSF										
GP - 20.	Cooperation with NSF5Sample Collection5										
GP - 21.	Audit Report 5										
GP - 22.	Correction of Items of Noncompliance from Audits										
TESTING											
GP - 23.	Conduct of Testing										
GP - 24.	Test Report										
GP - 25.	Periodic Testing of Certified Products										
GP - 26.	Unsatisfactory Test Results for Certified Products										
GP - 27.	Unsatisfactory Retest Results for Certified Products										
GP - 28.	Disposal of Test Samples										
RECORDS											
GP - 29	Documentation Reports										
GP - 30.	Company Records of Materials and Components										
GP - 31.	Company Records of Production, Shipment, and Inventory										
GP - 32.	Company Records of Complaints About its Certified Products										
CONFIDE	N/TF A T 1/TS/										
	NTIALITY Confidentiality8										
GP - 33.	Separate Confidential Disclosure Agreement										
GP - 34.	Separate Confidential Disclosure Agreement										

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GP - 35.	Procedures Upon Receipt of Subpoena for Confidential Business Information 8							
ADVERTIS	SING							
GP - 36.	Use of the Mark: Advertising, Packaging, and Literature							
INVESTIG	ATION OF COMPLAINTS							
GP - 37.	Complaints							
GP - 38.	Investigation of Complaints - Sample Selection and Handling9							
CORRECT	TIVE ACTION AND ENFORCEMENT							
GP - 39.	Corrective Action For General Noncompliance9							
GP - 40.	Enforcement Action For Use of the Mark on a NonCertified Product							
GP - 41.	Enforcement Action for Unauthorized Change to a Certified Product							
GP - 42.	Enforcement Action For Unauthorized Shipment							
	or Disposal of Products Placed on Hold							
GP - 43.	Enforcement Action For Bribes Offered to NSF							
GP - 44.	Enforcement Action: Recall of Products							
GP - 45.	Enforcement Action: Administrative Hearings							
GP - 46.	Enforcement Action: Withdrawal of Certification							
GP - 47.	Public Notice							
GP - 48.	Reinstatement							
APPEALS								
GP - 49.	Administrative Review							
GP - 50.	Formal Appeal Through an Appeals Officer							
GP - 51.	Final Appeal By a Panel							
FEES								
GP - 52.	Application Fee							
GP - 53.	Standards Maintenance Fee							
GP - 54.	Certification Fee							
GP - 55.	Reinstatement Fee							
GP - 56.	Additional Charges							
GP - 57.	Collection Fee							
CDECTAT	DOLLGING							
	POLICIES							
GP - 58.	Lead							
GP - 59.	Use of Accreditation Marks							
ATTACH								
Application	r Certification Services							
Contract fo	r Certification by NSF International							
Application	for Another Name For (ANF) Listing							
Ancillary C	Contract for Another Name For (ANF) Listing							
Application	for Distributor Listing							
Ancillary C	Contract for a Distributor Listing							
Agreement	for Nondisclosure of Confidential Information							

SECTION II. PROGRAM SPECIFIC POLICIES

MARKING	PAGE
PP - 1. NSF Certification Marks for Biohazard Cabinets	
OFFICIAL LISTING	
PP - 3. General Format	. 21
EVALUATION AND TESTING	
PP - 4. Reevaluation and/or Periodic testing of Certified Products	. 21
INFORMATION REQUIRED FOR CERTIFICATION	
PP - 6. Product Design and Engineering Information	. 22
ENFORCEMENT	
PP - 7. Inaccurate, Incomplete, or False Quality Control Testing or Records	22

NSF CERTIFICATION POLICIES FOR BIOHAZARD CABINETRY

INTRODUCTION

As a public service, NSF International (NSF) offers to any Company, Certification of Products subject to the requirements of the general and program specific policies.

The general policies (Section I) apply to all Products being Certified against any Standard, within the scope of an NSF Certification program. There are additional program specific policies (Section II) that further define requirements under each NSF Certification program. The general and program specific policies must be considered in their entirety, and shall be applied within the context of the Standard referenced in the contract between the Company and NSF. For clarity and ease of reference, these policies are presented as individually numbered items with appropriate headings.

SECTION I. GENERAL POLICIES FOR ALL PRODUCTS

DEFINITIONS

- Alternate Testing Laboratory (ATL) A laboratory that has been evaluated by NSF and found to operate in accordance with established policies and procedures; determined by NSF to be qualified to perform testing in accordance with NSF requirements; and selected by a Company and accepted by NSF for testing leading to Certification by NSF of the Company's Products.
- Company Any public or private organization, group, individual, or other entity contracting with NSF, or a subsidiary or division of such an entity.
- Compliance Conformance with all NSF requirement(s).
- Contract Any authorized written agreement between the Company and NSF. An authorized agreement is any agreement signed by a corporate officer of NSF.
- Certified Company A Company that has a contract with NSF for Certification and manufactures, designs, sells, assembles, distributes, or markets Certified Products.
- Certified Product Product authorized by NSF for Certification and use of the Mark.
- Certification NSF attestation that a representative sample of a Product has been determined to meet all applicable NSF requirements, and is authorized for use of a designated Mark as long as it continues to conform with all NSF requirements.
 - THE TERMS "LISTING" OR "LISTED" ARE SYNONYMOUS WITH CERTIFICATION OR CERTIFIED.
- Mark A registered NSF Certification Mark. In this instance "registered" means a formal process with an appropriate official agency.

Noncompliance - Lack of conformance with any NSF requirement.

NSF - NSF International, its staff, or other authorized representatives.

- NSF Requirements Requirements of the relevant Standards, the general and program specific policies, and any agreements or contracts upon which NSF's Certification is based. There shall be only two documents applicable to Certification for a Product: One Standard and one program policy document. In all instances where this term is used, it is understood this means the requirements that are appropriate and applicable to the specific Product.
- Production Location Any point of final production or assembly. Facilities within a ten (10) mile or 16 kilometer radius of a single location are considered one production location.
- Product Any goods, equipment, component, system, service, material, facility, compound, or ingredient covered by a Standard for which NSF offers Certification.

Public Notice

- For new Certifications, the issuance of a copy of an Official Listing to a Company which
 may distribute this information.
- For enforcement purposes, distribution of a written notice for noncompliance.
- Standard The document that is the basis for the Certification. This document may be an NSF Standard, an ANSI/NSF Standard, another voluntary standard, an NSF Criteria or other criteria, a government regulation, or other specifications.

It shall be one document and be referenced in the contract.

Subcontract Laboratory (SCL) - A laboratory that has been evaluated and contracted by NSF to perform testing for NSF in accordance with established policies and procedures.

AUTHORIZATION FOR CERTIFICATION

Eligibility

GP-1. A Company with Products covered by a Standard for which NSF offers Certification is eligible for evaluation and/or testing, and Certification by NSF.

Application for NSF Certification

GP-2. An application provided by NSF shall be submitted by the Company to NSF for each production location.

Contract for NSF Certification

GP - 3. Upon satisfactory completion of all requirements for Certification, a contract provided by NSF shall be executed by the Company and NSF. A separate contract for services is required for Certification under each Standard, and each subsidiary or division of a Company requesting separate invoicing.

Responsibility of Company

GP - 4. The Company shall represent as Certified, by use of the Mark or otherwise, only Products which are in full compliance with all applicable NSF requirements, and only after the Product has been Certified by NSF.

Written Authorization for Certification and Use of the Mark

GP - 5. NSF and the Marks are registered marks of NSF *International*. No Company or person shall apply or use the Mark in connection with a Product, or represent in any way that the Product is Certified, until receipt of written authorization from NSF. NSF may pursue legal recourse if the Mark is misused.

Notification of NSF Certification

GP - 6. The Company shall be advised in writing of the Certification, and the Certification shall be made public by NSF.

Transfer of Authorization for Certification and Use of the Mark

GP - 7. Upon request and with documentation of continued compliance with all applicable NSF requirements, NSF may transfer authorization for continued Certification of specific Products to another Company for the purpose of a name change, change of ownership, or change of a production location.

NSF Acknowledgement of Certified Products

GP - 8. Certified Products (other than ingredients, materials, or Products specifically exempted by policy) shall bear the Mark or be otherwise represented as Certified. Certified Products that do not bear the Mark shall specify how the Product will be represented as Certified in the Official Listing.

Use of the Mark for Products Shown in the Official Listing

GP - 9. A Company shall place the Mark only on Products with a trade designation or model designation shown in the Official Listing.

Trade Designations

GP - 10. A Company shall not use the letters "NSF" in its trade designation (e.g., name, model number, or other identification assigned by the Company) for a Certified or nonCertified Product.

A Company shall not have a trade designation for a Certified Product that directly or indirectly states or implies an end use application for which the Product is not Certified.

A Company shall not have a trade designation for a Certified Product that includes the designation of a Standard, (e.g., NSF or ANSI Standard), or official regulation (e.g., the Codex Alimentarius).

Use of the Mark for New Products

GP-11. The Company shall place the Mark only on new Products fully complying with all NSF requirements, unless prior written authorization from NSF allows otherwise. In the context of this policy, "new" means Products manufactured or assembled after the date of authorization for Certification.

Use of the Mark at Authorized Production Locations

GP - 12. The Mark shall be placed on Products only at authorized production locations, unless prior written authorization from NSF permits placement at another location.

Product Modification

GP - 13. The Company shall notify NSF in writing prior to any changes related to NSF requirements for a Certified Product. The change shall be reviewed by NSF and the Company advised of any required evaluation or testing. The Company shall not make such changes to a Certified Product without prior written acceptance by NSF.

Implementation of Revisions to Referenced Standards or Regulations

GP - 14. Upon adoption of a revision to a Standard referenced in the contract for NSF Certification, NSF shall promptly implement all changes in requirements.

"New Products" is defined as any Products not Certified as of the date of adoption of a revision to a referenced Standard. All new Products shall comply with the current revision prior to Certification, except that for all new Products requiring laboratory testing and received by the laboratory prior to the date of adoption of the revised Standard, the Company shall be given the option of having the Products tested and Certified against either or both versions of the Standard.

Products Certified as of the date of adoption of a revision to a referenced Standard or regulation (or Products Certified to the previous version as allowed under this policy), shall be reevaluated and retested for compliance against the revised Standard within a reasonable period of time as established and announced by NSF.

Certification of Distributors

GP - 15. A Company distributing a Certified Product with a trade designation other than that of the original manufacturer shall obtain NSF Certification (separate contract and fees are required), or the Certified Company making the Product shall conform with the policy for private labeling.

Private Labeling of Certified Products

- GP 16. A Company shall be authorized to label Certified Products with another name and designation under one of the following provisions:
 - The original Certified Company's name, address, and trade designation shall also be included on the label or data plate, and in any advertising literature (no separate contract or charges are required); or
 - The Certified Company shall include the trade designation of the private labeled Product in its Official Listing (no separate contract or charges required); or
 - The Certified Company shall Certify and private label the Product as "Another Name For" the Certified Company (a separate contract and fees are required).

AUDIT

Requirement and Purpose of Audits

GP - 17. Physical audit of all facilities and production locations of the Company may be required before Certification is authorized, and one or more unannounced audits may be conducted each calendar year. However, NSF reserves the right to conduct announced or unannounced audits as needed to monitor for compliance with all NSF requirements.

Access for Audits

GP - 18. Access for NSF audits shall be granted promptly by the Company upon NSF's request during any operating hours. However, NSF shall make every attempt to accommodate plant vacations, inventory shut-downs and other non-productive periods or plant closings where NSF has been notified in advance. NSF shall be granted access to all facilities and production locations of the Company, except where precluded from doing so by restrictions included in agreements between the Company and NSF or by government regulations, and where NSF has been notified in advance and is satisfied as to the validity of these restrictions. Refused or delayed access may result in withdrawal of Certification and in other appropriate actions by NSF, including but not limited to issuing a public notice.

If audits are to be conducted by non-NSF employees, NSF shall so notify the Company and provide the name(s) of the individual(s) who will conduct the audit.

Cooperation With NSF

GP - 19. Audit and sampling of Products by NSF is for the benefit of the Company as well as in the public interest. While engaged in the performance of these duties, NSF shall be given every assistance necessary, and shall have the right to examine all records bearing upon the duties and responsibilities of NSF or the Company with respect to compliance with NSF requirements. No NSF representative shall be required, nor authorized to make any agreements, waive any rights or privileges, or enter into any compromises as a condition of audit. While in a Company's facility, NSF representatives shall comply with all applicable health and safety rules and be accompanied by authorized Company personnel.

Sample Collection

GP - 20. The Company shall permit NSF to select samples for testing and retesting. The samples shall be provided without charge, appropriately identified by NSF, and shipped promptly (or at such time as requested by NSF), prepaid by the Company. If samples selected by NSF are not received within the time limit specified at the time of collection, NSF shall revisit the plant to recollect samples for testing.

Audit Report

GP - 21. At the conclusion of an audit, NSF shall provide a written report to the Company.

Correction of Items of Noncompliance from Audits

GP - 22. The Company shall promptly (or within a reasonable time agreed to by NSF) correct any and all items of noncompliance and shall submit, in writing within 30 days of the date of the audit report, an explanation of planned and/or actual corrective action. NSF shall verify compliance.

Note: This policy does not relieve a Company of its continuing responsibility to use the Mark (or otherwise represent as Certified) only on Products complying with all NSF requirements. The 30 days applies to the report, not to the date for corrective action.

TESTING

Conduct of Testing

- GP 23. At the election of NSF, testing shall be conducted at one or more of the following locations:
 - NSF
 - · The Company's facilities under NSF's supervision
 - · A prior designated alternate testing laboratory
 - · A subcontract laboratory
 - · Another site or arrangement acceptable to NSF

Test Report

GP - 24. Upon completion of testing, NSF shall report the results to the Company. NSF shall provide pertinent data and test results to the Company.

Periodic Testing of Certified Products

GP - 25. Periodic testing of Certified Products by NSF may be required to maintain Certification. The frequency of testing shall be sufficient to monitor for compliance with all NSF requirements.

Unsatisfactory Test Results for Certified Products

- GP 26. Upon receipt of written notification from NSF that the results of its testing of a Certified Product are "unsatisfactory," the Company shall promptly take reasonable measures to prevent use of the Mark on any noncomplying Product. The measures shall include:
 - Investigation to determine that any continuing production is in compliance
 - · Corrective action to bring the Product into compliance; and
 - Review of inventory of Product bearing the Mark to verify that it is in compliance.

The Company shall determine the cause of the unsatisfactory results, and report the findings and corrective action in writing to NSF within 30 days of notification of noncompliance. NSF shall verify that corrective action has been taken and retest the Product. The Company shall be responsible for any additional costs necessary to verify compliance.

Note: This policy does not relieve a Company of its continuing responsibility to use the Mark (or otherwise represent as Certified) only on Products complying with all NSF requirements. The 30 days applies to the report, not to the date for corrective action.

Unsatisfactory Retest Results for Certified Products

GP - 27. If the results of retesting of a Certified Product due to failure are "unsatisfactory," NSF shall withdraw Certification of the Product. Other appropriate action may be taken by NSF, including, but not limited to, ordering a Product recall and issuing a public notice.

Disposal of Test Samples

GP - 28. All test samples not returned to the Company will be disposed of by NSF in accordance with all applicable federal, state, and local laws, statutory regulations, rules, ordinances and orders.

RECORDS

Documentation Reports

GP - 29. A Company may submit a documentation report to NSF that documents that a Product (or family of Products) fully conforms with all applicable requirements for Certification. The documentation report shall be reviewed by NSF and, if acceptable, shall be Registered by NSF. Registration is accomplished by labeling each page in a manner that allows any unauthorized changes to be identified by NSF. A Registered copy shall be maintained by NSF and at each production location for use by NSF to verify that there are no changes to the Product. For Products with a Registered documentation report, periodic testings by NSF may not be required for continuing Certification.

Company Records of Materials and Components

GP - 30. The Company shall maintain, at the production location, records of the purchase of ingredients, materials, and components used in the production and/or assembly of all Certified Products. Such records shall be made available to NSF upon request. These records shall be maintained for the preceding three (3) year period.

Company Records of Production, Shipment, and Inventory

GP - 31. The Company shall keep up-to-date records of production, shipment, and inventory of Certified Products at the production location. Upon request, the Company shall provide NSF prompt and full access to such records. These records shall be maintained and made available for the preceding three (3) year period.

Company Records of Complaints About Its Certified Products

GP - 32. The Company shall retain a record of complaints and remedial actions taken by the Company since the last on-site audit performed by NSF, and shall make the record available to NSF upon request.

Only complaints received in writing by the Company, the subject of which is under the Company's control, and referring to Certified Products or services covered by the scope of the Certification provided by NSF, are included in this policy. At a minimum, the record shall include:

- The nature of the complaint;
- Identification of the Product and/or services pertinent to the complaint;
- Confirmation that remedial action(s) have been taken
- The status (open or closed) of the complaint, as known to the Company.

More detailed information and the identity of the complainant need not be provided to NSF.

All records and other information provided to NSF shall remain the property of the Company and be handled by NSF as confidential information.

If the complaint record required by this policy is not retained by the Company at the plant location being audited, NSF shall be advised by the Company in writing of the location of the record. The Company shall provide the record to NSF upon request by whatever means selected by NSF.

CONFIDENTIALITY

Confidentiality

GP - 33. NSF shall not disclose without the Company's prior written consent and shall keep confidential any information supplied to it by the Company about the Company and its Products, including formulations, components, processes, ingredients, or the identity of the Company's suppliers or vendors. NSF shall keep confidential all information regarding Procedures and equipment gained during plant audits. NSF shall release information required by law to be disclosed. NSF shall release the information only to those persons or agencies authorized or required by law to receive such information. Confidentiality does not apply to any information known to NSF independently, generally available to the public, or obtained by NSF from a third party under no obligation to the Company not to disclose said information.

Separate Confidential Disclosure Agreement

GP - 34. Upon request by the Company, NSF may execute a separate, uniform, and standard written confidential disclosure agreement with a Company or with a Company's supplier(s).

Procedures Upon Receipt of Subpoena for Confidential Business Information

GP - 35. NSF shall notify the Company promptly of a subpoena or request for production of the Company's confidential business information, seek the Company's consent to release the information, and inquire whether the Company asserts a proprietary interest in the information. If the Company does not assert a proprietary interest, NSF shall release the information to parties requesting the information.

If the Company advises that it does assert a proprietary interest and does not consent to release, NSF and the Company shall, through designated counsel, take appropriate steps to quash the subpoena or request, including the filing of motions and attendance at hearings where necessary. Such steps shall be taken at the Company's expense, including attorney's fees. If the Court orders release of the information covered by the subpoena or production request, NSF shall release the information only to parties entitled by the Court's order to receive such information.

ADVERTISING

Use of the Mark: Advertising, Packaging, and Literature

- GP 36. Use of a Mark on sales literature, technical publications, promotions, materials, packaging, catalogs, and in advertising of Certified Products is acceptable, provided the Company complies with the following:
 - The Company shall code literature and packaging to indicate date of printing;
 - The Company shall not directly or indirectly represent, advertise, imply, or claim that any
 of its nonCertified Products are Certified by NSF;

- The Company shall not directly or indirectly represent, advertise, imply, or claim that any Product is Certified for an end use application for which it is not Certified; and
- A nonCertified company may advertise Products as Certified provided the nonCertified company complies with these requirements, and includes the name of the Certified Company and the trade designation and/or model designation of the Certified Products, or includes specific instructions to obtain the name of the Certified Company and the trade designation and/or model designation of the Certified Products.

INVESTIGATION OF COMPLAINTS

Complaints

GP - 37. NSF shall investigate complaints related to Certified Products, misuse of a Mark by a Certified Company, or use/misuse of a Mark by a nonCertified company. Complaints are classified as formal or informal.

For formal complaints, a Request for Investigation (RFI) form provided by NSF must be completed and signed by the complainant. NSF shall acknowledge receipt of an RFI, promptly investigate the complaint, and take appropriate action. NSF may advise the subject of the complaint of the allegation. NSF shall confirm to the complainant that the allegation has, or has not, been verified as correct. For formal complaints from another Certified or nonCertified Company, signing of the RFI constitutes agreement by the complainant to bear the costs of the investigation if the complaint is not verified. If the complaint is verified, the subject of the complaint shall be responsible for the costs of the investigation. NSF shall not identify the complainant except as required by law.

If the complainant does not submit an RFI, or does not agree to bear the costs of the investigation (if required by NSF), the complaint shall be considered informal. NSF shall investigate informal complaints on or before the next regular plant audit, but has no obligation to acknowledge informal complaints, identify the complaining party, or to notify the complainant of the results of any investigation that may be conducted.

Investigation of Complaints - Sample Selection and Handling

GP - 38. NSF shall not test for enforcement purposes, any samples submitted by a complainant, or select samples for testing that are under the control or influence of the complainant, or test samples if NSF has reason to believe that the samples may have been altered in a way that may affect the outcome. Samples for testing for enforcement purposes shall be selected by NSF and handled in accordance with established procedures.

CORRECTIVE ACTION AND ENFORCEMENT

Corrective Action for General Noncompliance

GP - 39. A Company shall be advised in writing of all items of noncompliance. The Company shall promptly (or within a reasonable time agreed to by NSF), effect correction of all items of noncompliance. The Company shall submit, in writing within 30 days of the date of receipt of written notice, an explanation of corrective action. NSF shall verify compliance.

Note: To prevent any misunderstanding, this policy does not relieve a Company of its continuing responsibility to use the Mark (or otherwise represent as Certified) only on Products complying with all NSF requirements. The 30 days applies to the report, not to the date for corrective action.

When subsequent audits, evaluations, and/or testing indicate that corrective actions have not been effected, or for repeated recurrence of an item of noncompliance, NSF may withdraw Certification and take other appropriate action, including, but not limited to, ordering a Product recall and issuing a public notice.

Enforcement Action for Use of the Mark on a NonCertified Product

GP - 40. NSF may order an administrative hearing to determine the appropriate response to use of the Mark on a nonCertified product. For a second such occurrence within a period of two (2) years, NSF may withdraw Certification for all Products for the production location. Other appropriate action may be taken by NSF, including, but not limited to, ordering a Product recall and issuing a public notice.

Enforcement Action for Unauthorized Change to a Certified Product

- GP 41. Upon determination by NSF of unauthorized changes related to NSF requirements for a Certified Product (including, but not limited to, changes in design, components, or materials), the Company shall hold the changed Product in its inventory until released by NSF in writing. Other appropriate action may be taken by NSF, including, but not limited to, ordering a Product recall and issuing a public notice.
 - For the first occurrence, NSF may require the Product to be held until the change is authorized;
 - For recurrence within a period of two (2) years, NSF may order an administrative hearing;
 and
 - For a third occurrence within a period of two (2) years, NSF may withdraw Certification for all Products for the production location. Other appropriate action may be taken by NSF, including, but not limited to, ordering a Product recall and issuing a public notice.

Enforcement Action for Unauthorized Shipment or Disposal of Products Placed on Hold

GP - 42. NSF shall order an administrative hearing for unauthorized shipment or disposal of Products placed on hold by NSF. For a second occurrence within two (2) years, NSF shall withdraw Certification for all Products for the production location. Other appropriate action may be taken by NSF, including, but not limited to, ordering a Product recall and issuing a public notice.

Enforcement Action for Bribes Offered to NSF

GP - 43. Any attempt by a Company or its employees or agents to offer inducement or bribes to NSF may result in immediate withdrawal of Certification and/or other action deemed appropriate by NSF, including issuing a public notice.

Enforcement Action: Recall of Products

GP - 44. NSF may order the recall of Products from distribution if Products bear the Mark or are represented as Certified, but do not comply with all NSF requirements.

The Company shall furnish to NSF, or at the option of NSF, permit prompt and full access to:

- Its production records to determine quantity and dates of production, and marking (identification) on Products; and
- Its shipping records to identify customers receiving the Products, quantity and dates of shipment, and marking (identification) on Products.

The Company, at the demand of NSF, shall in good faith draft a voluntary recall notice, acceptable to NSF, and promptly transmit the notice to each known purchaser and recipient of the Product. The Company shall provide satisfactory evidence to NSF that the recall notice was received by each customer.

The Company shall provide evidence satisfactory to NSF that the recall notice was received by each customer, identify the quantity of Products returned from each customer, marking (identification) of the Products returned, and dates returned. The Company shall hold the inventory of returned Products for verification by NSF.

If the recall is incomplete or cannot be conducted, NSF may make public notice of the recall.

Enforcement Action: Administrative Hearing

GP - 45. As a result of a Company's non-compliance, NSF may order the Company to appear at an administrative hearing at NSF in Ann Arbor, Michigan, USA. The purpose of the hearing is to review the noncompliance and to specify conditions for continued Certification, which may include, but is not limited to, increased monitoring by NSF.

The Company shall be represented at the hearing by a person with authority to speak and act for the Company. The Company may have other representatives present, including legal counsel. However, the Company shall notify NSF, at least five (5) days before the hearing or other time as specified by NSF, of the name and title or position of any and all Company representatives, agents, employees, or counselors who plan to attend the hearing. If the Company chooses to have legal counsel present at the hearing, NSF reserves the right to ask its counsel to attend as well.

If the Company does not attend, is represented by a person without authority to act for the Company, or is represented by any person(s) without prior notice to NSF, the hearing may be cancelled and Certification may be withdrawn. Other appropriate action may be taken by NSF, including, but not limited to, Product recall and public notice.

If the Company does not agree to the conditions for continued Certification, Certification shall be withdrawn. Again, other appropriate action may be taken by NSF, including, but not limited to, ordering a Product recall and issuing a public notice.

The Company shall be responsible for the costs of the hearing, including NSF travel costs and reasonable attorneys' fees necessitated by the Company electing to have its legal counsel at the hearing.

Enforcement Action: Withdrawal of Certification

GP - 46. NSF may withdraw Certification of any Product, at any time, for failure to comply with any NSF requirements.

NSF shall notify the Company, in writing, of withdrawal of Certification. Upon notice by NSF (whether written or oral) to the Company of withdrawal of Certification, the Company shall immediately stop applying the Mark to the Product. If directed by NSF, the Company shall notify its distributors and outlets that the Certification has been withdrawn. The Company shall confirm these actions to NSF. NSF may make public notice of withdrawal of Certification and the reason for such action.

Upon withdrawal of Certification of a Product, NSF may require the Company to isolate, dispose of, modify, or destroy all of the Product, by means acceptable to NSF, to assure that it is not sold, used, or represented as Certified. The disposal, modification, or destruction of the Product shall be completed within 20 calendar days of notification to dispose. The disposal shall be verified by NSF.

Upon withdrawal of Certification of all Products, NSF may require the Company to dispose of, modify, destroy, or surrender to NSF all Marks, marking devices, and marked materials, by means acceptable to NSF. The disposal, modification, destruction, or surrender of the Marks and/or marked materials shall be completed within 20 calendar days after NSF notifies the Company that it requires the action, and shall be at the Company's expense. No credit or refunds shall be provided for Marks disposed of, modified, destroyed, or surrendered. The Company shall confirm the disposal in writing to NSF, and shall also acknowledge in writing that it is not authorized to use the Mark or otherwise represent that any of its Products are Certified.

Public Notice

- GP 47. NSF may issue a public notice for noncompliance with any NSF requirement. The Company shall cooperate in good faith with NSF in determining who should receive copies of a public notice. The content and distribution of the notice shall be in accordance with the following conditions for a Class I, II, or III notice.
 - A Class I notice shall be issued for a noncomplying Product that results in a high risk of serious, adverse health consequences or death (e.g., acute toxicity, reproductive toxicity).

If the Product is not under the direct control of the Company for immediate and complete recall (within 48 hours), NSF shall issue a notice that includes the name of the Company, a description of the Product, including its trade or model designation, and may explain the cause for concern.

NSF shall issue a press release of the notice to appropriate print and broadcast media. NSF shall distribute a written notice to those appropriate persons, agencies and entities, which may include known purchasers and recipients of the Product; appropriate federal, state, and local regulatory officials in the United States and other countries; NSF's Council of Public Health Consultants; the appropriate Joint Committee(s); Certified Companies; and other individuals routinely receiving the appropriate Certification information.

 A Class II notice may be issued for a noncomplying Product that poses a known risk of long- or short-term adverse health consequences (e.g., contributing levels of toxic substances to food or water that exceed regulated or established maximum acceptable levels). The notice shall include the name of the Company, a description of the Product, including its trade or model designation, and may explain the cause for concern.

NSF may distribute a written notice to those appropriate persons, agencies, and entities, which may include known purchasers and recipients of the Product; appropriate federal, state, and local regulatory officials in the United States and other countries; NSF's Council of Public Health Consultants; the appropriate Joint Committee(s); Certified Companies; and other individuals routinely receiving the appropriate Certification information; and

 A Class III notice may be issued for noncompliance that, in the opinion of NSF, is unlikely to pose any adverse health consequence. The notice shall include the name of the Company, a description of the Product, including its trade or model designation, and state the Certification status of the Company and its Product(s).

NSF may distribute a written notice to those appropriate persons, agencies, and entities, which may include known purchasers or recipients of the Product; NSF's Council of Public Health Consultants; the appropriate Joint Committee(s); Certified Companies, and other individuals routinely receiving the appropriate Certification information.

Reinstatement

GP - 48. Following withdrawal of Certification, Products may not be reCertified until NSF has reevaluated and/or retested the Product, has verified that any other items of noncompliance have been satisfactorily resolved, and has notified the Company in writing that it is authorized to use the Mark in connection with the Product. The Company shall be responsible for any costs associated with reinstatement, and for any additional costs necessary to verify compliance with NSF requirements.

APPEALS

Administrative Review

GP - 49. A Company, or any other party, directly affected by a decision or action of NSF related to Certification by NSF, may request an administrative review. The request shall be in writing to the Secretary, Certification Council of NSF, and state the reasons for requesting the review. The request shall be acknowledged within ten (10) calendar days of receipt, and shall state the name of the NSF staff person assigned to conduct the review. NSF may, at its discretion, hold in abeyance any enforcement action against a Company until the administrative review has been conducted. A request for an administrative review shall not entitle the requesting party to be provided any information to which it is not otherwise entitled by applicable law, regulation, NSF policy, or NSF procedure. NSF shall, within 30 calendar days of receipt of the written request, inform the Company or the party in writing of the results of the review.

NSF may, at its discretion, hold in abeyance any action required as a result of the administrative review during the time prescribed in the policy for requesting a formal appeal.

Formal Appeal Through an Appeals Officer

- GP 50. A Company, or any other party, directly affected by a decision or action of NSF related to Certification by NSF that has requested and been granted an administrative review, but that is not satisfied with the results of the administrative review, may request a formal appeal.
 - 1. The request for formal appeal shall:
 - Be in writing to the President of NSF;
 - Be received at NSF within 30 calendar days of receipt of written notification by NSF of the results of the administrative review; and
 - · Indicate reasons why the action is being disputed.

Along with the request, the appellant shall pay \$5,000.00 U.S. to NSF for NSF's fee for the formal appeal. If the decision of the President is for the appellant, NSF shall reimburse this payment to the appellant.

- 2. The request for formal appeal shall be acknowledged by NSF within ten (10) calendar days of receipt. The request may be rejected if, in the opinion of the President of NSF, the Company or the party is not directly affected by the action. NSF may, at its discretion, hold in abeyance any enforcement action against a Company until a decision has been made in response to this appeal.
- 3. If the President determines that the appeal relates primarily to the language of an NSF Standard or application or an interpretation thereof, and cannot be resolved to the satisfaction of the appellant by NSF staff, the President may refer the appeal to the NSF Joint Committee with jurisdiction for the Standard (reference NSF Standards Development and Maintenance Policies).
- 4. If the President determines that the appeal relates primarily to the language of an NSF Certification policy or an application or interpretation thereof, and cannot be resolved to the satisfaction of the appellant by NSF staff, the President may refer the appeal to the NSF Certification Council (reference NSF Certification Council Policies).
- 5. If the appeal has not been referred to the Joint Committee or Certification Council and cannot be resolved by NSF staff to the satisfaction of the appellant, the President shall appoint an appeals officer. The appeals officer shall be from NSF staff and have had no direct involvement in the NSF action being appealed.
 - The appellant and NSF shall support their positions in writing to the President of NSF. The appellant and NSF shall send three (3) copies of the written submittals to the President of NSF within 45 calendar days of receipt of NSF's acknowledgement of the formal appeal. Written submittals are limited to 50 pages, including appended referenced documentation. Supporting documentation, as appropriate, should be made a part of the written submittal, and may include notes, correspondence, memoranda, legal or technical opinions, Standards, policies, or any other items which bear on or relate to NSF's disputed decision, so long as the documents are not protected by confidentiality agreements that prohibit their disclosure.

- The President shall, within seven (7) calendar days of receipt, distribute the written submittals to the appeals officer, the appellant and the NSF representative, and shall set a meeting date. Unless otherwise agreed to by both parties, the meeting shall occur within 30 days of distribution of the written submittals.
- The formal appeal meeting is not a legal hearing. Each party will be represented by one person only for the purposes of oral presentations. Legal counsel may not attend. Up to four (4) representatives of each party will be permitted, inclusive of the respective presenter. There shall be no electronic recording or verbatim transcription of the proceedings unless agreed to in advance by both parties.
- Each party will be provided one hour for oral presentation. Questions by the appeals officer may follow. Each party will be provided 20 minutes for rebuttal.
- The appeals officer shall provide a written recommendation to the President within 15 calendar days of the meeting.
- The President's decision shall be transmitted in writing to both parties within 30 calendar days of the meeting.
- NSF may, at its discretion, hold in abeyance any action required as a result of the formal appeal during the time prescribed in the policy for requesting a final appeal.

Final Appeal by a Panel

- GP 51. The appellant may request a final appeal by an appeals panel if it is not satisfied with the decision of the formal appeal. A final appeal shall not be recognized (or acknowledged) until completion of a formal appeal.
 - 1. The request for final appeal shall:
 - Be a written appeal to the President of NSF;
 - Be received at NSF within 30 calendar days of receipt of written notice of the President's decision of the formal appeal; and
 - Indicate the reasons why the decision of the formal appeal is being disputed.

Along with the request, the appellant shall pay \$10,000.00 U.S. to NSF for NSF's fee for the appeal. NSF shall compensate each appeals panel member \$1,000.00 U.S. and pay for the travel, housing, and meal expenses of the panel members to attend the meeting. If the decision of the President is for the appellant, NSF shall reimburse this payment, and the payment for the formal appeal, to the appellant.

- 2. The request for the final appeal shall be acknowledged by NSF within ten (10) calendar days of receipt. NSF may, at its discretion, hold in abeyance any enforcement action against a Company until a decision has been made in response to this appeal.
- 3. The final appeal shall be heard by a three (3) member appeals panel. The appeals panel shall be appointed by the Chair of the Certification Council from a list of acceptable candidates agreed to by both parties.

Within ten (10) calendar days of receipt of the acknowledgement letter, each party shall submit, to the Secretary of the Certification Council, a list of names of five (5) candidates to serve on the appeals panel. The candidates shall have had no direct involvement with the action being appealed. The Secretary of the Certification Council

shall provide to each party a list of candidates for the appeals panel that shall include all members of the Certification Council and the names of the additional candidates submitted by the appellant and NSF. Each party shall within ten (10) calendar days of receipt of the list, cross off any names it objects to, and return the list to the Secretary of the Certification Council. The appeals panel shall be appointed by the Chair of the Certification Council from the marked-up list of candidates provided by each party. If any panel member declines the appointment, the Chair of the Certification Council shall appoint another panel member from the lists.

- 4. Before the appeal may go forward, the appellant shall agree in writing to hold harmless, defend, and indemnify each member of the appeals panel for matters arising out of the appeals process.
- 5. Each party shall prepare a written submittal supporting its position but is limited to addressing the decision of the formal appeal or the issues in the written submittals presented in the formal appeal. New information supporting the issues presented in the formal appeal may be provided, but the appellant and NSF shall not raise any new issues. Five (5) copies of the written submittals shall be received by the Secretary of the Certification Council within 15 calendar days of the acknowledgement. Written submittals are limited to ten (10) pages maximum, including references and documentation, which shall be considered with the written submittals provided for the formal appeal. Supporting documentation, as appropriate, shall be made a part of the written submittal and may include notes, correspondence, memoranda, legal or technical opinions, Standards, policies, or any other items which bear on or relate to NSF's disputed decision, so long as the documents are not protected by confidentiality agreements that prohibit their disclosure.
- 6. The Secretary of the Certification Council shall, within seven (7) calendar days of receipt, distribute the written submittals to both parties and each member of the appeals panel, and set a meeting date. Unless otherwise agreed to by both parties and the appeals panel members, the meeting shall occur within 30 days of distribution of the written submittals.
- 7. The final appeal meeting is not a legal hearing, and may not involve legal counsel except with the advance agreement of both parties. If agreed, each party may have legal counsel present, but the oral argument shall not be made by the legal counsel. Each party shall be represented by one person only for purposes of the oral presentations and rebuttal. Up to four (4) representatives of each party shall be permitted to attend, inclusive of the respective presenter and legal counsel. There shall be no electronic recording or verbatim transcription of the proceedings unless agreed to in advance by both parties.
- 8. Unless otherwise agreed to by both parties, the Secretary of the Certification Council shall provide administrative support to the appeals panel, and shall attend the meeting for the purpose of assuring proper conduct of the meeting. In this capacity, the Secretary shall not be considered one of the representatives of NSF as it relates to the subject matter of the appeal, and the Secretary shall not question any presenters, participate in discussions, or otherwise influence the decision of the panel.

9. If appeals panelists do not agree, the majority opinion shall be reported. The appeals panel shall provide a written recommendation to the President, endorsed by at least two (2) of the appeals panel members within 15 days of the meeting.

Note: By intent, there is no chair of the appeals panel. If there is a unanimous or majority recommendation, the panel members shall agree upon one member to write the opinion; however, the final recommendation shall be agreed to and signed by all concurring panel members.

10. The President's decision shall be transmitted in writing to both parties within 30 calendar days of the meeting.

FEES

Application Fee

GP-52. The Company shall submit payment of the application fee, if applicable, with the signed application form. This fee, if applicable, shall be paid once by each Company for each NSF program. For conglomerates and large corporations with operating subsidiaries or independent divisions desiring separate Certification (and invoicing), the fee shall be paid by each subsidiary or independent division. This fee is nonrefundable.

Charges for services for initial Certification (including audits, toxicological assessment, testing, or evaluation) shall be invoiced as services are provided.

Standards Maintenance Fee

GP - 53. An annual standards maintenance fee, if applicable, shall be charged to each Certified Company for each program area in which it participates. Each Company shall be invoiced annually, on or about December 1; the invoice shall be dated January 1, payable 30 days net.

Certification Fee

GP - 54. For initial Certification, the Company shall submit payment of the Certification fee and any outstanding fees (e.g., audit, toxicological assessment, testing or evaluation) prior to the Official Certification being granted. The Company shall be responsible on an annual basis for continued conformance and for fees for continued Certification. The Company shall be invoiced for annual services for a calendar year on or about December 1 of each preceding year; the invoice shall be dated January 1 payable 30 days net. The Certification fee shall be paid for each plant location for each Standard.

Reinstatement Fee

GP - 55. The Company shall be invoiced and pay for reinstatement of a Certified Product (a single item, a Product line, or a series) that was deCertified for noncompliance, after satisfactory corrective action has been taken and NSF has verified compliance and reCertified the Product.

Additional Charges

GP - 56. The Company shall be responsible for any additional fees and costs incurred by NSF to monitor the Company's compliance with NSF requirements.

Collection Fee

GP - 57. The Company shall be responsible for any fees and costs incurred by NSF in collection of fees in arrears.

SPECIAL POLICIES

Lead

GP - 58. There shall be no lead as an intentional ingredient in any material contacting food or drinking water, except brass meeting the definition of "lead free" under the specific provisions of the Safe Drinking Water Act of the United States, as amended in 1986. In the absence of further regulatory guidance, the EPA Action Level of 15 ppb shall be used for purposes of establishing the maximum extraction levels for Products contacting food or drinking water.

Use of Accreditation Marks

- GP 59. A Company with Products Certified by NSF, for a Certification program that is accredited by the American National Standards Institute (ANSI), and the Raad voor de Certificatie (RvC), the Dutch Council for Certification, may use the Accreditation Mark in combination with the NSF Mark only, as follows:
 - The Accreditation Mark(s) shall be used in a manner that clearly communicates the
 meaning of the Accreditation Mark in regard to the NSF Certification Mark, and does
 not imply that the Product is Certified by the Accreditation body.
 - The Accreditation Mark(s) shall be in a smaller size than the NSF Certification Mark, shall be in direct proximity to the NSF Certification Mark, and shall state, "The NSF Certification program is accredited by (state either `The Dutch Council for Certification' or `ANSI' or both)," or equivalent language.
 - The Accreditation Mark(s) may be used on a Company's literature, packaging, or on the Product.

The ANSI Accreditation Mark is:



The RvC Mark is:



NSF is accredited by both ANSI and RvC for the following Product Certification programs:

Food Equipment
Drinking Water Additives
Plastics and Plumbing Products

Drinking Water Treatment Units
Biohazard Cabinetry (excluding the field certifier accreditation)
Swimming Pools, Spas and Hot Tubs
Bottled Water and Packaged Ice
Wastewater Treatment Units

SECTION II. PROGRAM SPECIFIC POLICIES

MARKING

NSF Certification Marks for Biohazard Cabinets

PP - 1. Certified biohazard cabinets (cabinets) shall bear a Mark as follows:



The Mark shall be a legible, authorized facsimile of the Mark and included on the data plate; or shall be a laminated "foil" Mark with an identifying number obtained from NSF.

- NSF Marks are laminated, blue "foil" labels, 13/16" x 1" (20.6 mm x 25.4 mm), and bear a serial number comprised of a letter and six numeric digits.
- If a Company requests customized foil labels bearing the appropriate Mark and serial number, the labels shall be obtained from NSF.

If a Company is known to have removed a Mark, NSF may make public notice.

Model Designations

PP - 2. Each Certified cabinet shall have a model designation. A Company shall not use the same trade designation and/or model designation on Certified and nonCertified products. If a cabinet has been manufactured and distributed prior to Certification, it shall be assigned a new model designation that distinguishes it from earlier, noncertified cabinets. Redesigns of Certified cabinets shall have a different model designation.

OFFICIAL LISTING

General Format

- PP 3. The Listing format shall include, at the minimum, the following information:
 - Company name and address,
 - production location (city and state or a production location number followed by the state, province, or country),
 - model number,
 - cabinet type,
 - cabinet style,
 - window height,
 - window type,
 - inflow velocity,
 - downflow velocity,
 - · acceptable options,
 - bench height.

EVALUATION AND TESTING

Reevaluation and/or Periodic Testing of Certified Products

- PP 4. For continued Certification, products shall be reevaluated and/or tested at intervals not to exceed five years. For products without variations in design and construction, the following periodic test parameters shall be evaluated;
 - physical evaluation
 - halogen and/or soap bubble leak
 - HEPA filter leak
 - personnel protection
 - product protection
 - cross contamination
 - inflow velocity
 - downflow velocity
 - supply air volume (type B2 only)
 - decontamination

Ouality Control Testing

- PP 5. Quality control testing shall be conducted by the Company on all Certified biohazard cabinets with the results being maintained on file for a minimum of three years. Upon request, the Company shall provide NSF immediate access to such records. The required tests are as follows:
 - halogen/soap bubble, HEPA(DOP), velocity profile, face velocity, and smoke tests shall be conducted on each cabinet.
 - noise, lighting, and vibration shall be conducted on every tenth cabinet.

INFORMATION REQUIRED FOR CERTIFICATION

Product Design and Engineering Information

PP - 6. As specifically requested by NSF, the Company shall provide design, materials, and engineering information, including blueprints and parts lists, to adequately document the product for evaluation and Certification.

ENFORCEMENT

Inaccurate, Incomplete, or False Quality Control Testing or Records

- PP 7. In-plant quality control testing is essential for demonstrating that Certified products comply with all NSF requirements. Inaccurate, incomplete, or false quality control testing or records compromise the integrity of the Mark on a product and constitutes a serious breach of contract with NSF.
 - for a recurrence of noncompliance for inaccurate or incomplete testing or records within a period of two years, NSF may order an administrative hearing.
 - for a third occurrence of noncompliance for inaccurate or incomplete testing or records within a two year period, NSF may withdraw Certification for all products for a production location.
 - for falsifying quality control testing or records, NSF may immediately withdraw
 Certification for all products for a production location. In all cases, other appropriate
 actions may be taken by NSF, including but not limited to, product recall and public
 notice.

In all cases, other appropriate action may be taken by NSF, including, but not limited to, product recall and public notice.

EXAMPLE (not for use)

APPLICATION FOR CERTIFICATION SERVICES

То	be completed by a	pplicant:							
1.	Company Name:	Name: (Name as it is to appear in published Listing.)							
Mailing Address:									
	Telephone:		800:	Fax:		Telex:			
	Address for Publi	shed Listing:	Location Address: (🗸)	: 🗆	Mailing Address: (✔): □				
	Name of Corresp	ondence Cont	tact: Mr. □ Mrs. □ Ms	s. 🗆 Dr. 🗆	-1				
2.									
	Mailing Address:	(All production facilities for Certified products. If more than one facility involved, attach an application for each facility.) Mailing Address:							
	Ü	(If different from	location address)	Fax:		_ Telex:			
	Name of Plant Contact: Mr. □ Mrs. □ Ms. □ Dr. □								
	Operating Hours:								
	Holidays/Closings:(Attach a separate list if necessary)								
3.	NEW PROPOSE	D LISTINGS	: Standard/Criteria	Complet	e the reverse side of this appli	cation.			
4.	inspections, toxic	check in the amount of \$ is enclosed for the non-refundable application fee*. Charges for regional services, spections, toxicological review, and laboratory testing will be invoiced as rendered. A Contract for Certification Services ll be executed upon satisfactory completion of all requirements for Certification.							
*	Bottled Water/Pa	Water/Packaged Ice Programs enclose \$ for the Annual Listing fee.							
5.	and program-spec	able standard, criteria, or regu am authorized by the compan urther authorized to agree tha e company in the initial evalu	y to apply on behalf of t the company will pay						
	S	ignature	D	ate	Name and Title (prin				

Enclosed with the application information is a current copy of the published Listing for similar products. In the space below, present/indicate how you propose the Listing for your company to appear in this publication. In addition to using examples in the published Listing book, you should also check the program-specific NSF Certification Policies for Listing format. Prior to actually achieving Listing, you will be provided a "Proposed Official Listing" for final review and sign-off.

By completing this part of the application form, you will help us to better understand what you anticipate receiving as an end product from NSF. This Listing information will assist in providing better service to you.

To be completed by NSF: Date Issued:By:	
Standard/Criteria/Registration: Application for New: Company Plant Standard	
Revised Application for:	

CONTRACT for CERTIFICATION by NSF International

A contract made and entered into this <day> day of <month> <year> between NSF International, a corporation organized and existing under the laws of the State of Michigan, with its principal office in the City of Ann Arbor, Michigan, (herein after called "NSF") and <Company name and address> (herein after called "COMPANY").

- 1. Certified product(s) are any goods, equipment, component(s), system(s), service(s), material(s), compound(s), or ingredient(s) that have been specifically authorized by NSF for Certification and use of an NSF Mark. The terms Certification and Certified are synonymous with the terms Listing or Listed.
- 2. The COMPANY hereby certifies and represents that it has received and read <the standard that is the basis for Certification>, as revised <date>. The COMPANY acknowledges that it has received the Certification Policies for cprogram> dated <date>.
- 3. Upon determination by NSF that the evaluated products comply with the applicable requirements of the documents referenced in item 2 of this contract, and upon execution of this contract and payment of the annual Certification fee and other outstanding fees, NSF agrees to authorize the COMPANY for Certification and use of an NSF Certification Mark (Mark) on the COMPANY's Certified products.
- 4. The COMPANY expressly acknowledges and agrees that execution of this contract, of and by itself, is not authorization to use an NSF Mark. In accordance with the documents referenced in item 2 of this contract, NSF will notify the COMPANY in writing of Certification and authorization to use the Mark.
- 5. The COMPANY hereby certifies and represents that if authorized to use an NSF Mark, the Mark will be placed only on products fully complying with all NSF requirements. The COMPANY further certifies and represents that it will abide by all NSF requirements, as specified in the documents referenced in item 2 of this contract.
- 6. It is understood and agreed that the documents referenced in item 2 of this contract shall be periodically revised in accordance with procedures that expressly provide for representation and comment by all parties of interest. Any revision shall be announced by NSF by written notice to the COMPANY. Upon receipt of notice of any applicable revision, the COMPANY agrees that it will abide by the announced revision; or, at its option, the COMPANY may terminate this contract in accordance with the provisions of this contract.
- 7. The COMPANY agrees that its use of the Mark is its representation that its products are Certified by NSF and comply with all NSF requirements. The COMPANY assumes full and complete responsibility for its use of the Mark or other representation that its products are Certified. NSF assumes no liability for any claims arising from the COMPANY's misuse of the Mark or misrepresentation of the Certification status of its products.
- 8. It is understood and agreed that a Mark on a product and its Certification are invalid if, as determined by NSF, the product has been significantly altered or has been represented as being Certified for any purpose or end use other than that Certified by NSF. NSF assumes no liability for any claims arising from such alteration, misuse, or misrepresentation by the COMPANY.
- 9. NSF assumes no liability for any claims for damages of any kind occurring to any person or entity as a result of sale, resale, or use of the COMPANY's products, whether or not the products are Certified.
- 10. The COMPANY assumes no liability for any claims arising from the content of the documents referenced in item 2 of this contract.
- 11. The COMPANY agrees that, in the event that NSF is not a named party but is involved in legal proceedings (including receipt of subpoenas for documents or testimony) concerning the COMPANY or its products or services, NSF shall notify the COMPANY and the COMPANY will reimburse NSF for all reasonable expenses related to those proceedings.
- 12. If it is necessary to revise this uniform contract, it shall be revised in accordance with procedures that expressly provide for comment by any parties of interest, then NSF shall provide the new contract or contract modifications to be executed by the COMPANY and NSF.

- 13. The COMPANY may terminate this contract at any time upon thirty (30) days written notice to NSF, but shall be liable for costs for services provided by NSF through the date of receipt of notice, and for any additional costs necessary to terminate services. NSF shall repay only pre-paid fees for services that were not provided. NSF may terminate this contract at any time upon thirty (30) days written notice to the COMPANY for noncompliance or nonpayment by the COMPANY, or when replaced by a new contract or contract revision provided by NSF.
- 14. Unless terminated by either party, this contract shall continue in effect from year to year. The COMPANY shall notify NSF by December 30 if it wishes to cancel the contract for the next year. If NSF has not received such notice in writing by December 30, the COMPANY agrees to submit the required annual fees by January 31. The COMPANY agrees that all payments are 30 days net.
- 15. After termination of this contract for any reason, the COMPANY shall promptly confirm, in writing, to NSF that the COMPANY has discontinued use of an NSF Certification Mark on its products and/or in its product literature and advertising. The COMPANY further agrees that, upon termination of the contract for any reason, it will, surrender, efface, or otherwise dispose of in a manner acceptable to NSF any unused Marks and data labels, dies, molds, stencils, marking devices, literature, advertisement, or other information bearing a Mark or referencing NSF Certification. If NSF has reason to question conformance by the COMPANY with this provision of the contract, the COMPANY agrees to allow NSF reasonable access to the COMPANY's facilities to conduct inspections to verify conformance.
- 16. NSF agrees to provide the COMPANY written notice of nonconformance with any NSF requirement. NSF reserves the right to withdraw authorization for Certification and use of a Mark for any product, at any time, for the COMPANY's failure to correct the nonconformance within a reasonable time.
- 17. This contract shall be interpreted in accordance with the laws of the State of Michigan, of the United States of America.
- 18. The invalidity or unenforceability of any particular provision(s) of this contract and/or the documents referenced in item 2 of this contract shall not affect the other provisions.
- 19. This contract and referenced policies constitute the entire agreement between the parties with respect to the subject matter hereof and supersede all previous communications, representations or agreements, whether oral or written, between the parties with respect to said subject matter. No modification will be binding upon either party unless it is made in writing and is signed by duly authorized representatives of both parties.

For NSF International	For <company name=""></company>
Signature	Signature
Typed Name and Title	Typed Name and Title
Date	Date

APPLICATION FOR ANOTHER NAME FOR (ANF) LISTING

Standard or

			Criteria No		
			Date Issue	ed:	
То	be completed by the Certified (Base) Com	npany: (Please p	int or type).		Initials
1.	ANF Company Name:(Name and address as it is to appear in published	Listing)			
	Address:				
	City:	State/0	Country:	Zip Code	
	Telephone: (As it is to appear in the published Listing)	_			
	Plant Location:				
		state/Province, Cou gnation (e.g. Pla			
				Designation	
 3. 	 □ The ANF Company is wholly owner the ANF Company is not wholly own the Certified Company (supporting the Certified Company will be invoiced for toxicological review or laboratory testing or literature review will be invoiced as a will be signed by the Base Company. 	rned by the Base of documentation of one ANF Listing of charges for the rendered. A sep-	e Company, but has on attached). g fee at the time of l is Listing. Any add	Listing. There are no itional charges such a	inspection, as labelling
4.	Please attach the proposed ANF Listin	ng, as you wish i	to appear in NSF	Listings, and correlat	te Listed to
	Return the completed application a	and attachment	s to:		
	CERTIFICATION RI NSF International 3475 Plymouth Roa PO Box 130140 Ann Arbor, Michigar FAX: (313) 769-801	d n 48113-0140		·	
	Signature	Date	Name and Title (Corr	respondence contact of Ba	use Company)
			Base Company Nam	ne	

ANCILLARY CONTRACT FOR "ANOTHER NAME FOR" (ANF) LISTING

A contract made and entered into this <day> of <month>, <year> between NSF International, a corporation organized and existing under the laws of the State of Michigan, with its principal office in the City of Ann Arbor, Michigan (herein after called "NSF"), and the Certified Base Company <Company Name and Address> (herein after called COMPANY) for the "another name for" (ANF) Listing as <ANF Company name and address> for the production location at:

<pi< th=""><th>ant</th><th>Nam</th><th>e></th></pi<>	ant	Nam	e>

<Plant Address>

- 1. This agreement exists solely as an ancillary agreement to the existing Contract for Certification Services of the COMPANY.
- 2. The COMPANY certifies and represents that it will fully comply with all clauses of its Contract for Certification Services for <Standard>, as revised <date>; and Certification Policies for cprogram> dated <date>.
- 3. This agreement and the referenced Contract for Certification Services of the COMPANY constitute the entire agreement between the parties with respect to the subject matter hereof and supersede all previous communications, representations or agreements, whether oral or written between the parties with respect to said subject matter. No modification will be binding upon any party unless it is made in writing and is signed by the duly authorized representatives of all parties.

For NSF International	For <company name=""></company>	
Signature	Signature	
Typed Name and Title	Typed Name and Title	
Date	Date	

APPLICATION FOR DISTRIBUTOR LISTING

A company that has its own Listing which is another company's Certified products DISTRIBUTOR Company: labelled with the distributor company's trade designation. The Certified company that is the actual manufacturer. BASE Company: Standard or Criteria No._____ To be completed by the DISTRIBUTOR Company: (Please print or type.) 1. Distributor Name: (Name and address as it is to appear in published Listing) State/Country: _____Zip Code: _____ Plant at: _____("City, State", or "Plant at: #____Country") Telephone: _ (As it is to appear in the published Listing) 2. Check (✓) all applicable statements: The Distributor is already Listed for a production facility under the same Certification Program and this application is for an additional plant location. The Distributor is not currently Listed for a production facility under the same Certification Program. Enclosed is a check in the amount of \$______for the non-refundable application fee. THE DISTRIBUTOR'S PRODUCT IS IDENTICAL TO AND DEPENDENT ON THE BASE COMPANY'S CERTIFIED PRODUCT: *Complete and enclose the Ancillary Contract for a Distributor Listing - attached *Attach documentation of the model-to-model correlation. 3. Affidavit: The BASE COMPANY agrees to release and authorize NSF to communicate directly with the DISTRIBUTOR COMPANY about any noncompliance, including formulation variations or test failures, and that the BASE COMPANY will release NSF from any claim for this disclosure. The DISTRIBUTOR COMPANY signee is further authorized to agree that the DISTRIBUTOR COMPANY will pay NSF for any charges billed for the Listing and audit fees. The BASE COMPANY and DISTRIBUTOR COMPANY each certify that they have read and agree to comply with the applicable standard, regulation, or other governing document that is the basis for Certification and use of an NSF Mark, and that each party is authorized by their respective company to apply on behalf of the company for this Distributor Listing. For <Distributor Company> <Base Company> NSF International Signature Signature Kevan P. Lawlor Treasurer and Controller Name and Title Name and Title Date Date Date

Example (not for use)

ANCILLARY CONTRACT FOR A DISTRIBUTOR LISTING

This Agreement between NSF I	international, (herein after called I	ISF), (herein
after called the DISTRIBUTOR		(herein after
called the BASE COMPANY) i	s entered into for the BASE COM	PANY'S production location at:
	e de la companie de l	
<plant name=""> <plant< td=""><td>Address></td><td></td></plant<></plant>	Address>	
Flair Name	Address	
		!
This agreement exists as a dependent on the BASE CO	certification requirement for the IMPANY Listed product.	DISTRIBUTOR whose product Listing is
Certification Services of the	ely as an ancillary agreement to BASE COMPANY and an ancilla ervices of the DISTRIBUTOR.	the current or subsequent Contract for ry agreement to any current or subsequent
DISTRIBUTOR about any r	agrees to release and authorize noncompliance, including formula ease NSF from any claim for this of	NSF to communicate directly with the ion variations or test failures, and that the isclosure.
DISTRIBUTOR COMPAN matter hereof and supersede written between the parties v	Y constitute the entire agreement be all previous communications, repr vith respect to said subject matter.	Services of the BASE COMPANY and the tween the parties with respect to the subject esentations or agreements, whether oral or No modification will be binding upon any horized representatives of all parties.
	•	. , .
For	For	For
NSF International	<base company=""/>	<distributor company=""></distributor>
<u></u>		
Kevin P. Lawlor Controller and Treasurer	BASE Correspondence Signature	DISTRIBUTOR COMPANY Correspondence Signature
	Name and Title (print or type)	Name and Title (print or type)
	Date	Date

Example (not for use)

AGREEMENT FOR NONDISCLOSURE OF CONFIDENTIAL INFORMATION

THIS AGREEMENT is made by and between NSF Internation	onal ("NSF"), at 3475 Plymouth Road, Ann Arbor, Michigan
48105, and	("Company")
at	

The Company may disclose to NSF certain information regarding its operations, processes, or products, including the chemical composition of materials or ingredients, or submit to NSF samples, for the purpose of evaluating the Company's products for disposal in water treatment systems for certification, registration, or for specific end uses. Any such disclosures or submissions to NSF are subject to the following terms and conditions.

- 1. "Confidential Information" may include manufacturing techniques, compositions, samples, specifications, processes, applications, formulae, equipment, inventions, and related information, whether first gained orally, visually, or in written form.
- 2. As used in this Agreement, "Confidential Information" does not include information which (a) was in the public domain prior to disclosure to NSF, (b) becomes part of the public domain through no unauthorized act or omission of NSF, (c) as evidenced by written records, was lawfully in NSF's possession prior to disclosure by the Company, or (d) was obtained on a non-confidential basis by NSF from a third party under no obligation to the Company not to disclose the Confidential Information.
- 3. The Company shall designate and label "CONFIDENTIAL" any written Confidential Information that it considers to be confidential and proprietary. In order to designate as confidential information which is first disclosed orally or visually, Company shall summarize the information and submit the summary to NSF within thirty days after such disclosure.
- 4. If NSF disagrees with the confidential designation, it shall notify the Company in writing within seven (7) calendar days of receipt of the information stating its reasons. Until any questions about the confidential designation are resolved, as documented in writing to both parties, the Confidential Information shall be maintained by NSF as "Confidential Information".
- 5. NSF agrees it will not disclose without the Company's prior written consent and will keep confidential any Confidential Information supplied to it by the Company.
- 6. NSF agrees that it will notify the Company promptly of a subpoena or request for production of the Company's Confidential Information, or of any situation in which NSF believes release of the Company's Confidential Information is required by law, that NSF will seek the Company's consent to release the information, and that NSF will inquire whether the Company asserts a proprietary interest in the information. If the Company does not assert a proprietary interest, NSF will release the information to parties requesting the information. If the Company does assert a proprietary interest, NSF will provide the Company an opportunity to intervene and dispute the alleged requirements for disclosure or seek a protective order covering the Company's Confidential Information. Steps taken at the request of Company, including any costs to NSF, will be taken at the Company's expense, including attorney's fees. If the Court orders release of the information covered by the subpoena or production request, NSF will release the information only to parties entitled by the Court's order to receive such information.
- 7. The Confidential Information shall be used by NSF only in connection with evaluating the Company's products for disposal in water treatment systems; no other use shall be made of it.

- 8. NSF will limit disclosure of and access to the Confidential Information to employees who are directly involved with the Product and the disclosure and access shall only be to the extent necessary and essential for purpose of this agreement. The employees shall preserve the confidential nature of the Confidential Information.
- 9. No license or right is granted hereby to NSF, by implication or otherwise, with respect to the confidential information, including, without limitations, any right or license under any patent application, patent, claims of patent or any other proprietary or intellectual property rights of the Company. NSF agrees that all rights, title and interest in and to any and all inventions (including discoveries, ideas and improvements, whether patentable or not), which are conceived or made during or after the term of this Agreement and are derived from or utilized in the Confidential Information, shall belong to the Company.
- 10. This Agreement shall be in effect from the date of execution thereof and shall continue until terminated by either party.
- 11. Either party may terminate this agreement at any time upon thirty (30) days written notice to the other party.
- 12. At the expiration of the Agreement, any and all records of Confidential Information in possession of NSF, except for that information required to legally protect NSF, will be destroyed or, at the request and expense of the Company, will be returned to the Company. NSF staff will be bound to maintain confidential any knowledge of retained records of Confidential Information learned or received during the term of this Agreement and for 10 years thereafter.

This Agreement shall be governed by and construed in accordance with the laws of the State of Michigan.

NSF International	COMPANY:
By:	By:
Typed Name:	Typed Name:
Title:	Title:
Date:	Date:

CLASS II (LAMINAR FLOW) BIOHAZARD CABINETRY

NSF International Standard

NSF 49 - 1992



MISSION STATEMENT

9.32.1-1-

The mission of NSF is to provide, for the benefit of all our clients, third-party standardization services in public health safety and in systems management, including quality and environmental specialties.

This Standard is subject to revision.

Contact NSF to confirm this revision is current.

Users of this Standard may request clarifications and interpretations, or propose revisions by contacting:

NSF International 3475 Plymouth Road, P.O. Box 130140 Ann Arbor, Michigan 48113-0140 USA Phone: (313) 769-8010 Telex: 753215 NSF INTL FAX: 313-769-0109

NSF International (NSF)

STANDARD 49

CLASS II (LAMINAR FLOW) BIOHAZARD CABINETRY

As Prepared by

The NSF Joint Committee on Biohazard Cabinetry

and

Recommended for Adoption by

The NSF Council of Public Health Consultants

Adopted by

The NSF Board of Trustees

June 1976

Revised May 1983 Revised June 1987 Revised May 1992

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STANDARDS AND CRITERIA

The following standards and criteria established and adopted by NSF as minimum voluntary consensus standards are used internationally:

- 1 Soda Fountain and Luncheonette Equipment
- 2 Food Equipment
- 3 Commercial Spray-Type Dishwashing Machines
- 4 Commercial Cooking, Rethermalization and Powered Hot Food Holding and Transport Equipment
- 5 Water Heaters, Hot Water Supply Boilers, and Heat Recovery Equipment
- 6 Dispensing Freezers
- 7 Food Service Refrigerators and Storage Freezers
- 8 Commercial Powered Food Preparation Equipment
- 12 Automatic Ice Making Equipment
- 13 Refuse Compactors and Compactor Systems
- 14 Plastics Piping Components and Related Materials
- 18 Manual Food and Beverage Dispensing Equipment
- 20 Commercial Bulk Milk Dispensing Equipment
- 21 Thermoplastic Refuse Containers
- 24 Plumbing System Components for Manufactured Homes and Recreational Vehicles
- 25 Vending Machines for Food and Beverages
- 26 Pot, Pan, and Utensil Washers
- 29 Detergent and Chemical Feeders for Commercial Spray-Type Dishwashing Machines
- 30 Cabinetry and Laboratory Furniture for Hospitals
- 35 Laminated Plastics for Surfacing Food Service Equipment
- 36 Dinnerware
- 37 Air Curtains for Entranceways in Food and Food Service Establishments
- 40 Individual Aerobic Wastewater Treatment Plants
- 41 Wastewater Recycle/Reuse and Water Conservation Devices
- 42 Drinking Water Treatment Units Aesthetic Effects
- 44 Cation Exchange Water Softeners
- 49 Class II (Laminar Flow) Biohazard Cabinetry
- 50 Circulation System Components and Related Materials for Swimming Pools, Spas/Hot Tubs
- 51 Plastic Materials and Components Used in Food Equipment
- 52 Supplemental Flooring
- 53 Drinking Water Treatment Units Health Effects
- 54 Flexible Membrane Liners
- 55 Ultraviolet Microbiological Water Treatment Systems
- 56 Pitless Well Adapters
- 58 Reverse Osmosis Drinking Water Treatment Systems
- 59 Food Carts
- 60 Drinking Water Treatment Chemicals Health Effects
- 61 Drinking Water System Components Health Effects
- 62 Drinking Water Distillation Systems
- 100 Environmental Auditing Principles and General Practices
- 110 Environmental Management Systems Guiding Principles and Generic Requirements
- C-2 Special Equipment and/or Devices
- C-9 Evaluation of Special Processes, Components, or Devices Used in Treating Wastewater

NSF PURPOSE AND ORGANIZATION

NSF is a nonofficial and noncommercial agency. It is incorporated under the laws of Michigan as a not-for-profit organization devoted to research, education, and service. It seeks to solve problems involving man and his environment. It wishes to promote health and enrich the quality of life through conserving and improving that environment. Its fundamental principle of operation is to serve as a neutral medium in which business and industry, official regulatory agencies, and the public come together to deal with problems involving products, equipment, procedures, and services related to health and the environment.

NSF is perhaps best known for its role in the developing of standards and criteria for equipment, products, and services that bear upon health. The NSF Mark is widely recognized as a sign that the article to which it is affixed complies with the applicable NSF standard. NSF conducts research; tests and evaluates equipment, products, and services for compliance with NSF standards and criteria; and grants and controls the use of the NSF Mark.

A brochure is available discussing in some detail the purpose, objectives, and philosophy of NSF and its standards and certification programs. It describes the way in which distinguished leaders from business, industry, public health, and related professions give generously of their time and talent in helping achieve NSF objectives. The brochure is available upon request.

DISCLAIMERS

NSF, in performing its functions in accordance with its objectives, does not assume or undertake to discharge any responsibility of the manufacturer or any other party. The opinions and findings of NSF represent its professional judgement. NSF shall not be responsible to anyone for the use of or reliance upon this standard by anyone. NSF shall not incur any obligation or liability for damages, including consequential damages, arising out of or in connection with the use, interpretation of, or reliance upon this standard.

NSF standards provide basic criteria to promote sanitation and protection of the public health. Provisions for mechanical and electrical safety have not been included in this standard because governmental agencies or other national standards-setting organizations provide safety requirements.

Participation in NSF standards development activities by regulatory agency representatives (federal, local, state) shall not constitute their agency's endorsement of NSF or any of its standards.

Preference is given to the use of performance criteria measurable by examination or testing in NSF standards development when such performance criteria may reasonably be used in lieu of design, materials, or construction criteria.

The illustrations, if provided, are intended to assist in understanding their adjacent standard requirements. However, the illustrations may not include <u>all</u> requirements for a specific product or unit, nor do they show the only method of fabricating such arrangements. Such partial drawings shall not be used to justify improper or incomplete design and construction.

Unless otherwise referenced, the appendices are not considered an integral part of NSF standards. The appendices are provided as general guidelines to the manufacturer, regulatory agency, user, or certifying organization.

CONTENTS

NSF P	t NSF Standards and Criteria
	SECTION 1. GENERAL
1.0	Scope 1
1.1	Minimum Requirements
1.2	Variations in Design and Construction
	1.2.1 Modifications
1.3	Standard Review
1	Canada Rossow
	SECTION 2. DEFINITIONS
2.0	Accessible 1
	2.0.1 Readily Accessible
2.1	Biohazard
2.2	Biosafety Levels
4.4	2.2.1 Level 1
	2.2.2 Level 2
	2.2.3 Level 3
2.0	
2.3	Cabinet Classification
	2.3.1 Class I
	2.3.2 Class II
	2.3.3 Class III
2.4	Cleaning 4
	2.4.1 Cleanable
	2.4.2 Easily Cleanable
2.5	Closed
2.6	Chemical Resistance
2.7	Decontamination
2.8	High Efficiency Particulate Air (HEPA) Filter
2.9	Laminar Airflow
2.10	Nominal Set Point Velocities
2.11	Removable
	2.11.1 Readily Removable
2.12	Sealed 5
2.13	Smooth
2.15	2.13.1 Interior Work Surfaces and Exposed Interior Surfaces
	2.13.2 Other Interior Surfaces and Exterior Surfaces
2.14	Surfaces
2,17	
	2.14.2 Exposed Interior Surfaces
	2.14.3 Other Interior Surfaces
	2.14.4 Exterior Surfaces
2.15	Toxic

SECTION 3. MATERIALS

3.0	Conclusion and the contract of	7
3.1		7
3.2		7
3.3	- Chile Hilleria and Exiction Surfaces	7
3.4	- Midicilain aimi l'impinga	7
	3.4.1 Windows	7
	3.4.2 Protective Coatings	7
	3.4.3 Plastics	8
	3.4.4 Welding	8
	3.4.5 Gaskets and Sealants	8
	3.4.6 Sound Dampening	8
	3.4.7 Hard Solder	8
	3.4./ Hard Solder	~
	SECTION 4. DESIGN AND CONSTRUCTION	
4.0	General	9
4.1	Cleanability	9
4.1	Decontamination	9
	Plenum Design	9
4.3		9
		9
	4.5.2 Types D1 and D5	9
	4.3.3 Type B2	9
4.4	Internal Corners and Angles	9
	4.4.1 Interior Work Surfaces	י 10
4.5	External Corners and Angles	10 11
4.6	Julius and Seams	11 11
	4.0.1 Interior Work and Exposed Interior, Surfaces	
	4.0.2 Other filterior and exterior surfaces	11
4.7	rastering retriods	11
	4,/.1 Expused Pasterings	11
	4.7.2 Extend Pasterings	11
	4./.5 Interior rasterings	11
4.8	WEIGS	11
4.9	301061	11
4.10	Removable Lancis	11
4.11	MIZIBILLY A A A A A A A A A A A A A A A A A A	11
4.12	Provision for Mounting	12
	4.12.1 Mounting	12
	4.12.2 Clear Space Beneath	12
4.13	Legs and Feet	12
4.14	Reinforcing and Framing	13
4.15	Fixed Panels	13
4.16	Doors and Covers	14
4.10	4.16.1 Single Panel	14
	4.16.2 Double Panel	14
	4.16.3 Viewing Panel	15
	4.16.4 Sliding Sash Alarm	15
4 17	Louvers and Openings	15
4.17	Lunyers and Openings	

4.18	Tracks and Guides	15
4.19	Filters	15
4.20	Gaskets and Sealants	16
4.21	Stopcocks and Service Outlets	17
4.22	Fans	17
4.23	Electrical Components	17
	4.23.1 Motor	17
	4.23.2 Electrical Wiring, Switches, etc	17
4.24	Lighting	18
	4.24.1 Work Lighting	18
	4.24.2 Ultraviolet Lighting	18
4.25	Gauges	18
4.26	Drain Spillage Trough	18
4.27		18
	Diffuser Placement	
4.28	Height and Width	18
4.29	Data Plate(s)	19
	ADCETON & DEDECTOR (ANGE	
	SECTION 5. PERFORMANCE	
5.0	General	20
5.1	Soap Bubble/Halogen Leak	20
5.2	HEPA Filter Leak	20
5.3	Temperature Rise	20
5.4	Noise Level	20
		20
5.5	Lighting Intensity	20
5.6	Vibration	20
5.7	Personnel, Product, and Cross-Contamination Protection	20
	5.7.1 Personnel Protection	21
	5.7.2 Product Protection	
	5.7.3 Cross-Contamination Protection	21
5.8	Stability	21
	5.8.1 Resistance to Overturning	21
	5.8.2 Resistance to Distortion	21
	5.8.3 Resistance to Deflection of Work Surface	21
5.9	Velocity Profile	
	5.9.1 Uniform Downflow Velocity	21
	5.9.2 Nonuniform Downflow Velocity	21
5.10	Inflow Velocity	21
5.11	Airflow Smoke Patterns	22
5.12	Drain Spillage Trough Leakage	22
5.13	Motor/Blower Performance	22
5.14	Electrical Leakage, Ground Circuit Resistance and Polarity	22
5.15	Performance Data	22
5.16	Record Maintenance	23
Annex	A - Performance Tests	A1
A	B. Marked for Calibration of Davigos for Direct Messurement of Inflow	R1

Annex C - Nebulizer Selection and Calibration	C1
Annex D - Evaluation of Cleanability, Chemical Resistance, and Abrasion Resistance of Surfaces	
Annex E - Recommendations for Installation	E1
Annex F - Field Tests	F1
Annex G - Recommended Microbiological Decontamination Procedure	G1
Annex H - Recommended Materials, Finishes and Construction	H1
Annex I - Reference Standards and Specifications Pertinent to Class II Biohazard Cabinetry	I1
Participating Committees NSF Joint Committee on Biohazard Cabinetry NSF Council of Public Health Consultants	

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STANDARD 49 FOR CLASS II (LAMINAR FLOW) BIOHAZARD CABINETRY

SECTION 1. GENERAL

- 1.0 SCOPE: This standard applies to Class II (laminar flow) biohazard cabinetry designed to minimize hazards inherent in work with agents assigned to biosafety levels 1, 2 or 3 and defines the tests which shall be passed by such cabinetry to meet this standard. This standard includes basic requirements for design, construction, and performance that are intended to provide personnel, product, and environmental protection, reliable operation, durability, cleanability, noise level, illumination, limitations on temperature rise, vibration, and electrical leakage ground circuit resistance and polarity.
- 1.1 MINIMUM REQUIREMENTS: Cabinets qualifying under this standard shall have passed all of the designated tests. Units with component parts covered under existing NSF standards or criteria shall comply with those applicable requirements.
- 1.2 VARIATIONS IN DESIGN AND CONSTRUCTION: Cabinetry varying in design, construction, or installation of accessory equipment may qualify under this standard provided appropriate tests and investigations indicate the equipment is durable, reliable, can be cleaned and decontaminated, and performs in compliance with this standard. Such equipment shall meet the requirements for materials and finishes in this standard.
 - MODIFICATIONS: Major modifications require appropriate tests for compliance. Major modifications include changes in location or capacity of blower/motor(s), positioning of High Efficiency Particulate Air (HEPA) filters, positioning or redesign of work surface, window placement or design, access opening size, location and size of exhaust port, and built-in accessory equipment (centrifuges, ultraviolet [U.V.] lighting, etc.). Relocation of utility service equipment (electrical outlets, petcocks, etc.) is not considered a major modification if other provisions of this standard are not compromised.
- 1.3 STANDARD REVIEW: A complete review of this standard shall be conducted at least every five years. These reviews shall be conducted by the NSF Joint Committee on Biohazard Cabinetry which is comprised of representatives from industry, public health and user agencies.

SECTION 2. DEFINITIONS

- 2.0 ACCESSIBLE: Fabricated to be exposed for cleaning and visual inspection using simple tools (screwdriver, pliers, open-end wrench, etc.).
 - 2.0.1 READILY ACCESSIBLE: Fabricated to be exposed for cleaning and visual inspection without using tools.

- 2.1 BIOHAZARD (A contraction of the words biological and hazard): Infectious agent(s), or part thereof, presenting a real or potential risk to the well-being of man, animals, and/or plants, directly through infection or indirectly through disruption of the environment.
- 2.2 BIOSAFETY LEVELS: The combination of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed and the hazard posed by the infectious agents and the laboratory function or activity. These biosafety levels are described in "Biosafety in Microbiology and Biomedical Laboratories."²
 - 2.2.1 BIOSAFETY LEVEL 1: Practices, safety equipment, and facilities are appropriate for undergraduate and secondary educational training and teaching laboratories and for other facilities in which work is done with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. Bacillus subtilis, Naegleria gruberi, and infectious canine hepatitis virus are representative of those microorganisms meeting these criteria. Many agents not ordinarily associated with disease processes in humans are, however, opportunistic pathogens and may cause infection in the young, the aged, and in immunodeficient or immunosuppressed individuals. Vaccine strains which have undergone multiple in vivo passages should not be considered avirulent simply because they are vaccine strains.
 - 2.2.2 BIOSAFETY LEVEL 2: Practices, equipment, and facilities are applicable to clinical, diagnostic, teaching and other facilities in which work is done with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity. With good microbiological techniques, these agents can be used safely in activities conducted on the open bench, provided the potential for producing aerosols is low. Hepatitis B virus, the salmonellae, and toxoplasma spp. are representative of microorganisms assigned to this containment level. Primary hazards to personnel working with these agents may include accidental autoinoculation, ingestion, and skin or mucous membrane exposure to infectious materials. Procedures with high aerosol potential that may increase the risk of exposure of personnel must be conducted in primary containment equipment or devices.
 - 2.2.3 BIOSAFETY LEVEL 3: Practices, safety equipment, and facilities are applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents where the potential for infection by aerosols is real and the disease may have serious or lethal consequences. Autoinoculation and ingestion also represent primary hazards to personnel working with these agents. Examples of such agents for which biosafety level 3 safeguards are generally recommended include Mycobacterium tuberculosis, St. Louis encephalitis virus, and Coxiella burnetii.

¹Previously referred to as risk levels (low, moderate, and high).

²U.S. Department of Health and Human Services, HHS Publication No. (NIH) 88-8395, U.S. Government Printing Office, Washington, DC 20402.

- 2.2.4 BIOSAFETY LEVEL 4: Practices, safety equipment, and facilities are applicable to work with dangerous and exotic agents which pose a high individual risk of life-threatening disease. All manipulations of potentially infectious diagnostic materials, isolates, and naturally or experimentally infected animals pose a high risk of exposure and infection to laboratory personnel. Lassa fever virus is representative of the microorganisms assigned to level 4.
- 2.3 CABINET CLASSIFICATION: Although this standard covers only Class II biohazard cabinetry, Class I and Class III cabinets are currently defined and known to be commercially available:
 - 2.3.1 CLASS I: A ventilated cabinet for personnel and environmental protection, with an unrecirculated inward airflow away from the operator. Class I cabinets are suitable for work with agents assigned to biosafety levels 1, 2 or 3 where no product protection is required.
 - NOTE: The cabinet exhaust air passes through filters to protect the environment before it is discharged to the outside atmosphere.
 - 2.3.2 CLASS II: A ventilated cabinet for personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA filtered exhausted air for environmental protection. Class II cabinets are suitable for work with agents assigned to biosafety levels 1, 2 or 3 containment.

NOTE: When toxic chemicals or radionuclides are used as adjuncts to biological studies or pharmaceutical work, Class II cabinets designed and constructed for this purpose should be used.

- CLASS II TYPE A CABINETS (Formerly designated Type 1): (1) maintain minimum (calculated or measured) average inflow velocity of 0.38 m/s (75 ft/min) through the work access opening; (2) have HEPA 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 work area); (3) may exhaust HEPA filtered air back into the laboratory; and (4) may have positive pressure contaminated ducts and plenums. Type A cabinets are suitable for work with agents assigned to biosafety levels 1, 2, or 3 in the absence of volatile toxic chemicals and volatile radionuclides.
- CLASS II TYPE B1 CABINETS (Formerly designated Type 2): (1) maintain a minimum (calculated or measured) average inflow velocity of 0.5 m/s (100 ft/min) through the work access opening; (2) have HEPA filtered downflow air composed largely of uncontaminated recirculated inflow air; (3) exhaust most of the contaminated downflow air through a dedicated duct exhausted to the atmosphere after passing through a HEPA filter; and (4) have all biologically contaminated ducts and plenums under negative pressure, or surrounded by negative pressure ducts and plenums. Type B1 cabinets may be used with

agents assigned to biosafety levels 1, 2, or 3 treated with minute quantities of volatile toxic chemicals and tracer amounts of radionuclides required as an adjunct to microbiological studies if work is done in the direct exhausted portion of the cabinet, or if the chemicals or radionuclides will not interfere with the work when recirculated in the downflow air.

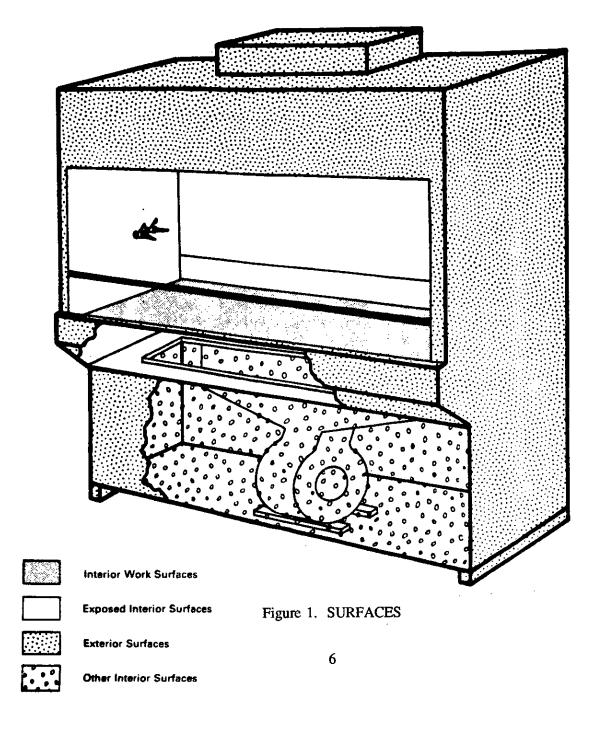
- CLASS II TYPE B2 CABINETS (Sometimes referred to as "Total Exhaust"): (1) maintain a minimum (calculated or measured) average inflow velocity of 0.5 m/s (100 ft/min) through the work access opening; (2) have HEPA filtered downflow air drawn from the laboratory or the outside air (i.e., downflow air is not recirculated from the cabinet exhaust air); (3) exhaust all inflow and downflow air to the atmosphere after filtration through a HEPA filter without recirculation in the cabinet or return to the laboratory; and (4) have all contaminated ducts and plenums under negative pressure, or surrounded by directly exhausted (nonrecirculated through the work area) negative pressure ducts and plenums. Type B2 cabinets may be used with agents assigned to biosafety levels 1, 2, or 3 treated with volatile toxic chemicals and radionuclides required as an adjunct to microbiological studies.
- CLASS II, TYPE B3 CABINETS: (1) maintain a minimum (calculated or measured) average inflow velocity of 0.5 m/s (100 ft/min) through the work access opening; (2) have HEPA filtered downflow air that is a portion of the mixed downflow and inflow air from a common exhaust plenum; (3) discharge all exhaust air to the outdoor atmosphere after HEPA filtration; and (4) have all biologically contaminated ducts and plenums under negative pressure, or surrounded by negative pressure ducts and plenums. Type B3 cabinets may be used with agents assigned to biosafety levels 1, 2, or 3 treated with minute quantities of volotile toxic chemicals and tracer amounts of radionuclides required as an adjunct to microbiological studies that will not interfere with the work when recirculated in the downflow air.
- 2.3.3 CLASS III: A totally enclosed, ventilated cabinet of gas-tight construction. Operations in the cabinet are conducted through attached rubber gloves. The cabinet is maintained under negative air pressure of at least 120 Pa (0.50 in wg). Supply air is drawn into the cabinet through HEPA filters. The exhaust air is treated by double HEPA filtration, or by HEPA filtration and incineration.³ Class III cabinets are suitable for work with agents assigned to Biosafety levels 1, 2, 3, and 4.
- 2.4 CLEANING: Physical removal of dirt, dust, or other soiling materials.
 - 2.4.1 CLEANABLE: Fabricated of materials, designed, and constructed that soil is accessible for removal by normal cleaning methods.

³National Institute of Health,"Supplement to Recombinant DNA Guidelines," Laboratory Safety monograph, January 1979.

- 2.4.2 EASILY CLEANABLE: Fabricated of materials, designed, and constructed that soil is readily accessible for removal by normal cleaning methods.
- 2.5 CLOSED: Fabricated with no openings exceeding 0.8 mm (1/32 in).
- 2.6 CHEMICAL RESISTANCE: Capability of materials to maintain their original surface characteristics under prolonged contact with cleaning compounds, decontaminating agents, and normal conditions of the use environment.
- 2.7 DECONTAMINATION: Removal or destruction of infectious agents; removal or neutralization of toxic agents.
- 2.8 HIGH EFFICIENCY PARTICULATE AIR (HEPA) FILTER: A throwaway, extended/pleated medium, dry-type filter with: (1) rigid casing enclosing the full depth of the pleats; (2) minimum particulate removal of 99.97% for thermally generated monodisperse dioctylphthalate (DOP) smoke particles or equivalent with a diameter of 0.3 µm; (3) maximum pressure drop of 250 Pa (1.0 in wg) when clean and operated at rated airflow capacity; and no area showing a penetration exceeding 0.01% when scan-tested with a polydisperse aerosol having a light scattering median size of 0.7 µm and a geometric standard deviation of 2.4.
- 2.9 LAMINAR AIRFLOW: Unidirectional airflow through the work area often referred to as: (a) turbulence-free airflow; (b) steady, unidirectional micro-turbulence flow; or (c) mass airflow.
- 2.10 NOMINAL SET POINT VELOCITIES: The cabinet downflow and inflow velocities that the manufacturer designates as the settings at which the cabinet is intended to operate and the settings at which it passed the tests listed in item 5.7 and Section VIII of Annex A.
- 2.11 REMOVABLE: Capable of being taken away from the main unit using simple tools (screwdriver, pliers, open-end wrench, etc).
 - 2.11.1 READILY REMOVABLE: Capable of being taken away from the main unit without using tools.
- 2.12 SEALED: Fabricated with no openings that will permit entry or leakage of air.
- 2.13 SMOOTH: A surface free of pits and inclusions, with a cleanability equal to or exceeding the following:
 - 2.13.1 INTERIOR WORK SURFACES AND EXPOSED INTERIOR SURFACES: Number 3 (100 grit) finish on stainless steel.
 - 2.13.2 OTHER INTERIOR SURFACES AND EXTERIOR SURFACES: Commercial grade hotrolled steel free of visible scale.
- 2.14 SURFACES: (Figure 1)
 - 2.14.1 INTERIOR WORK SURFACES: Surfaces used when performing a task, operation, or

activity.

- 2.14.2 EXPOSED INTERIOR SURFACES: Exposed interior surfaces, other than work surfaces, which are subject to splash, spillage, and contamination during normal uses.
- 2.14.3 OTHER INTERIOR SURFACES: Interior surfaces not exposed to splash and spillage, but exposed to vapor.
- 2.14.4 EXTERIOR SURFACES: All exposed surfaces.
- 2.15 TOXIC: Having an adverse physiological effect on biological systems.



SECTION 3. MATERIALS

- 3.0 GENERAL: Materials shall withstand normal wear, corrosive action of gases or liquids, cleaning compounds, and decontaminating agents and procedures. Materials shall be structurally sound, dimensionally stable, fire and moisture resistant, and compatible with other materials used in the laboratory.⁴
- 3.1 INTERIOR WORK SURFACES: Interior work surfaces shall be smooth 300-series stainless steel.
- 3.2 EXPOSED INTERIOR SURFACES: Exposed interior surfaces shall be smooth, abrasion and corrosion resistant, or shall be rendered corrosion resistant with nontoxic material which resists crazing, cracking, and chipping. Recirculated air diffuser materials shall be tested in accordance with Underwriters Laboratories (UL) Standard 94.5 Nonrigid diffuser materials shall conform to Class 94HBF; rigid diffuser materials shall conform to Class 94HB.
- 3.3 OTHER INTERIOR AND EXTERIOR SURFACES: Other interior and exterior surfaces shall be smooth, abrasion and corrosion resistant, or shall be rendered corrosion resistant with nontoxic materials which resist crazing, cracking, and chipping.

3.4 MATERIALS AND FINISHES:

- 3.4.1 WINDOWS: Windows shall be optically clear and not adversely affected by accepted cleaning methods and decontaminating agents. Glazing materials shall be laminated glass, tempered glass, safety plastic, or equal. Edges shall be ground or provided with protective stripping.
 - FLAMMABILITY: Safety plastic view screens shall be tested in accordance with UL Standard 94 and conform to Class 94HB.
 - ABRASION RESISTANCE: Safety plastic view screens shall be abrasion resistant, and show no more than 5% change in haze when tested in accordance with Item 5.17, Test No. 17 of American National Standards Institute (ANSI) Standard 226.1.6

3.4.2 PROTECTIVE COATINGS:

CHEMICAL RESISTANCE: Protective coatings shall be resistant to prolonged contact to liquids, cleaning compounds, and procedures. Specifically, the protective coatings used shall be resistant to the following chemicals, when tested

⁴See Annex H for material selection guidance.

⁵Underwriters Laboratories, Inc. 333 Pfingsten Road, Northbrook, IL 60062.

⁶ANSI, 11 West 42nd St., New York, NY 10018.

in accordance with Annex D:

- 4% hydrochloric acid
- 4% sodium hydroxide
- 1% quaternary ammonium compound
- 5% formaldehyde
- 5,000 ppm hypochlorite
- 2% iodophor
- 5% phenol
- 70% ethyl alcohol (ethanol)

When exposed to these chemicals and following the test methods in Annex D, there shall be no visible effect on the finish other than a slight change of gloss, discoloration, and/or temporary softening of the finish, with no loss of adhesion or film protection.⁷

ABRASION RESISTANCE: Protective coatings for exposed interior, other interior, and exterior surfaces shall meet the following requirements when tested in accordance with Annex D:

Maxim	nii
Weight	Loss

Minimum Wear Value

100 mg

500 cycles

- 3.4.3 PLASTICS: Plastics may be used if they meet the applicable requirements of Items 3.0, 3.2, 3.3, and 3.4.1.
- 3.4.4 WELDING: Welded seams and deposited weld material shall meet the applicable requirements of Items 3.0, 3.1, 3.2, and 3.3.
- 3.4.5 GASKETS AND SEALANTS: Gaskets and sealants shall be made of materials which do not release halogens, are nonhardening, nontoxic, stable, odor free, not detrimentally absorbent, and which are unaffected by exposure to gases, liquids, cleaning compounds, and decontamination agents listed in Item 3.4.2. Exposed surfaces of gaskets for all access panels, doors, structural seams, and windows shall be skinned and smooth. Gaskets supplied with HEPA filters shall be exempt from this requirement.
 - 3.4.6 SOUND DAMPENING: Sound dampening materials shall comply with the requirements for the area in which used. They shall not be used in areas subject to contamination. Nonhardening and porous types are not acceptable.
 - 3.4.7 HARD SOLDER: Hard (silver) solder shall be formulated to be corrosion resistant.

⁷When special chemical solutions are intended to be used, the resistance of the material thereto should also be evaluated.

SECTION 4. DESIGN AND CONSTRUCTION

- 4.0 GENERAL: Cabinets shall be designed and constructed to function properly and operate in a safe manner, minimize contamination, provide personnel and product protection, and be capable of being cleaned and decontaminated. Burrs and sharp edges shall be eliminated from those parts of the cabinet subject to cleaning and maintenance.
- 4.1 CLEANABILITY: Interior work, exposed interior, and the other interior surfaces subject to splash or spillage shall be readily accessible and easily cleanable as assembled or when removed. Interior work, exposed interior, and other interior surfaces, including plenums, shall be capable of being vapor or gas decontaminated.
- 4.2 DECONTAMINATION⁸: Cabinets shall be designed to be decontaminated with formaldehyde gas or equivalent inactivating agent without being moved. Closure to contain decontaminating agents should be limited to gas-tight sealing of air intake and exhaust openings with metal plates, or plastic film and tape, or equal.
 - 4.2.1 DECONTAMINATION: Pressure tight valves, if provided, suitable for decontamination, shall be located on the clean side of the HEPA filter.

4.3 PLENUM DESIGN:

- 4.3.1 TYPE A: Type A cabinets can have biologically contaminated plenums under positive or negative pressure to the room.
- 4.3.2 TYPE B1 AND B3: All biologically contaminated ducts and plenums in Types B1 and B3 cabinets shall be maintained under negative pressure, or enclosed within a negative pressure zone.
- 4.3.3 TYPE B2: Plenums or ducts carrying contaminated air shall be maintained under negative pressure, or enclosed within a directly exhausted (nonrecirculated) negative pressure zone.

4.4 INTERNAL CORNERS AND ANGLES:

4.4.1 INTERIOR WORK SURFACES:

- TWO-PLANE INTERSECTION: An internal angle of 2 rad (110°) or less formed by the intersection of two planes, which is subject to manual cleaning, shall have a minimum continuous and smooth radius of 3.2 mm (1/8 in).
- THREE-PLANE INTERSECTION: An internal corner formed by the intersection of three planes at 2 rad (110°) or less, subject to manual cleaning, shall have a minimum continuous and smooth radius of 6.3 mm (1/4 in) for a vertical or horizontal intersection. The alternate intersections shall have a minimum continuous and smooth radius of 3.2 mm (1/8 in).

⁸See Annex G.

• FILLET MATERIAL: Parent material or hard solder may be used as fillet material in structurally sound seams.

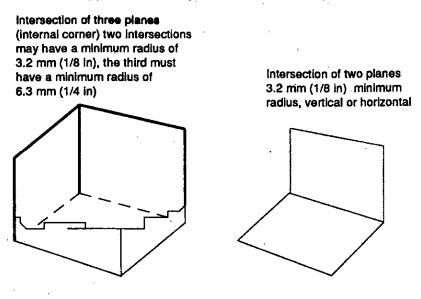


Figure 2. INTERNAL CORNERS AND ANGLES

4.5 EXTERNAL CORNERS AND ANGLES: All external comers and angles subject to splash and spillage shall be sealed as smooth as the surfaces being joined, and formed to eliminate sharp edges which may interfere with use, cleaning, or maintenance.

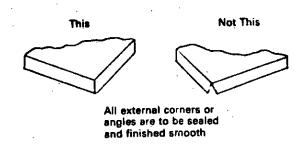


Figure 3 EXTERNAL CORNERS OR ANGLES

4.6 JOINTS AND SEAMS:

- 4.6.1 INTERIOR WORK AND EXPOSED INTERIOR SURFACES: All joints and seams subject to manual cleaning shall be sealed as smooth as the surfaces being joined. Perimeter drain spillage trough joints and seams shall be welded and sealed. All other seams shall be sealed. Wherever practical, equipment parts shall be stamped, extruded, formed, or cast in one piece. Joints shall be fabricated to eliminate dirt-catching horizontal ledges.
- 4.6.2 OTHER INTERIOR AND EXTERIOR SURFACES: All joints and seams subject to routine splash and spillage shall be sealed and smooth. All other seams shall be closed.

4.7 FASTENING METHODS:

- 4.7.1 EXPOSED FASTENINGS: Exposed screw threads, projecting screws, and studs shall not be used on interior work surfaces. They shall only be used on exposed interior and other interior surfaces when other fastening methods are impractical.
- 4.7.2 EXTERIOR FASTENINGS: Fasteners for exterior removable panels, that are gasketed and subject to pressure, shall be studs with solid acorn nuts or equal. Fasteners for other removable panels may be low profile-type fasteners (truss, round counter sunk, flat counter sunk head) or studs with solid acorn nuts.
- 4.7.3 INTERIOR FASTENINGS: In areas subject to cleaning, interior fastenings and joinings shall be fabricated to minimize projections, ledges, and recesses.

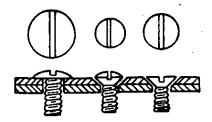


Figure 4 LOW PROFILE TYPE FASTENERS

- 4.8 WELDS: Welds shall meet the smoothness requirements of the applicable surface.
- 4.9 SOLDER: Solder shall only be used to seal structurally sound seams or as a fillet material (see Item 4.4.1 Fillet Material).
- 4.10 REMOVABLE PANELS: The design and construction of removable panels shall minimize projections and openings. Removable panels for access into contaminated areas shall be designed so that upon reassembly, a seal is provided as required in Item 5.1.
- 4.11 STABILITY: Cabinets shall stand on the floor or bench top in a stable and secure manner, and

not tip or fall when tested in accordance with Annex A, Section VIII.

- 4.12 PROVISION FOR MOUNTING: Provision shall be made for cleaning, and where necessary, cleaning underneath the unit. All cabinets shall be designed and constructed with one of the following provisions for mounting:
 - 4.12.1 MOUNTING: The cabinet base shall be designed to be sealed to the mounting surface (floor, raised base, bench top).
 - 4.12.2 CLEAR SPACE BENEATH: The cabinet shall be mounted on adjustable legs, or other acceptable means, to assure a minimum of 10 cm (4 in) of unobstructed clearance beneath the unit. A 5 cm (2 in) minimum clearance beneath the ends of the cabinet is acceptable if the front is open for cleaning, and the side panel is equal to or less than 5 cm (2 in) thick.
- 4.13 LEGS AND FEET: Legs and feet shall be sufficiently rigid to provide support with a minimum of cross bracing. They shall be fastened to the cabinet and shaped at floor or bench top contact to minimize the accumulation of splash and spillage. Legs and feet shall be of simple design, with no exposed threads.

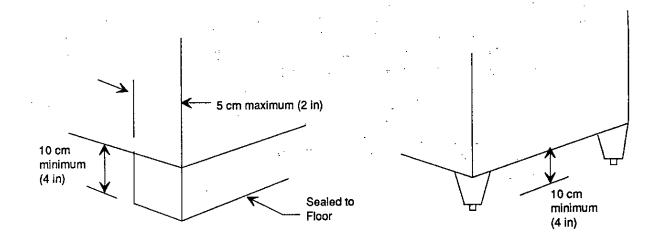


Figure 5. CLEAR SPACE BENEATH

Figure 6. CLEAR SPACE BENEATH

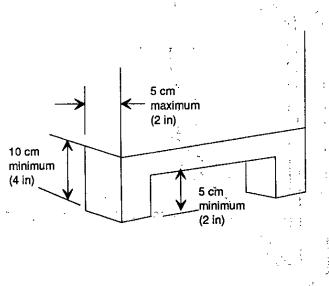
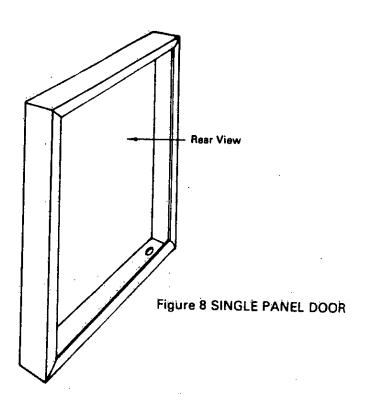


Figure 7. CLEAR SPACE BENEATH

CAV37/STD49FIG.GRF

- 4.14 REINFORCING AND FRAMING: Reinforcing and framing members, not totally enclosed or within walls, shall be easily cleanable. Reinforcing and framing members shall not provide harborage for vermin. The ends of all hollow sections, not subject to gas decontamination, shall be closed. Reinforcing and framing members subject to splash and spillage shall be sealed. Horizontal angle reinforcing and gussets shall not be placed where soil may accumulate. Where angles are used horizontally, they shall have one leg turned down wherever the equipment permits, or be formed integrally with the sides. All vertical channel sections shall be completely closed or open.
- 4.15 FIXED PANELS: Fixed panels shall be designed, constructed, and fastened to eliminate projections and openings.

- 4.16 DOORS AND COVERS: Doors and covers shall fit and close properly. Horizontal sliding doors shall not be used for the work area. When used for storage areas, doors shall slide easily and be readily removable. Piano and butt-type hinges are acceptable. Handles shall be designed, constructed, and installed to eliminate sharp edges or unnecessary projections. Latches and hold-open mechanisms shall provide even and secure support.
 - 4.16.1 SINGLE PANEL: Single panel doors and covers shall be fabricated to minimize the collection of foreign matter, and if possible, be designed without channel sections at the bottom. Channel sections, if used, shall be inverted, or shallow and wide enough to be easily cleanable. Clean-out holes shall be provided in all channels which are not inverted.



4.16.2 DOUBLE PANEL: Double panel doors and covers shall be fabricated to minimize the collection of foreign matter. Openings to hollow sections shall be closed. If subject to splash or spillage, openings shall be sealed.

- 4.16.3 VIEWING PANEL: Viewing panels shall be fabricated to prevent particles from entering the work space by induction through joints, tracks, or guides.
- 4.16.4 SLIDING SASH ALARM: Sliding sash enclosures shall include an audible alarm, actuated when the sash is raised above the manufacturer's specified opening height.
- 4.17 LOUVERS AND OPENINGS: All louvers and openings outside the work area and air plenums shall:
 - 4.17.1 Be of drip deflecting design; or
 - 4.17.2 Not be subject to routine splash, spillage, or overhead drippage; or
 - 4.17.3 Designed and constructed to be readily accessible, and the space behind easily cleanable; or
 - 4.17.4 Louvers through double panel doors and covers shall be sleeved.
- 4.18 TRACKS AND GUIDES: All tracks and guides for doors, window covers, and access panels shall be designed and constructed to be easily cleaned.

4.19 FILTERS:

- 4.19.1 HEPA filters are required for the downflow and exhaust air systems.
- 4.19.2 The HEPA filters for downflow and exhaust systems shall conform to the materials, construction, and aerosol efficiency requirements of IES-RP-CC-001-86 for type C filters. Filter media shall conform to MIL-F-51079B. Filter units of sizes not covered by these specifications shall be of the same type, materials, and construction as filters which have been qualified for the filter manufacturer. In addition, HEPA filters shall be scan tested for a leakage not to exceed 0.01% when tested in accordance with Annex A, Section II.
- 4.19.3 The cabinet shall be designed to provide accessibility for easy filter installation, testing, and sealing.

⁹Institute of Environmental Sciences, "Recommended Practice for HEPA Filters-1986" 940 East Northwest Highway, Mount Prospect, IL 60056.

¹⁰U.S. Department of Defense, "Filters, Particulate, High Efficiency, Fire Resistant, Biological Use," Navy Publishing and Printing Service Office, 700 Robins Ave., Philadelphia, PA 19111-5094.

- 4.19.4 HEPA filters shall be mounted to prevent air by-pass of the filters. When required, one or more 1 cm (3/8 in) I.P.S. threaded plugged penetrations shall be located in the plenum upstream of the HEPA filters and accessible from the front of the cabinet. These penetrations are used to measure the aerosol concentration upstream of the HEPA filters during the HEPA filter leak test (Item 5.2). When the penetration enters a potentially contaminated space, it shall be labeled "Decontaminate Cabinet Before Opening."
- 4.19.5 Cabinets exhausting into the room shall be provided with a perforated exhaust filter guard or airflow sensor providing equal protection, to prevent damage to the filter and blockage of exhaust air.

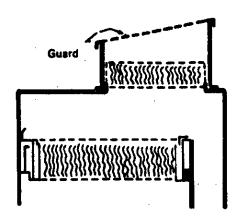


Figure 9 EXHAUST FILTER GUARD

- 4.19.6 HEPA filter patches shall not exceed 5% of the total face area. The maximum width of any one patch shall not exceed 4.0 cm (1.5 in).
- 4.20 GASKETS AND SEALANTS: Exposed surfaces of gaskets shall be easily cleanable and not contain internal angles (angles less than 2.4 rad [135°]). All corner joints and hollow sections of gaskets shall be sealed.
 - 4.20.1 Fixed gaskets shall be securely fastened and sealed in place.
 - 4.20.2 HEPA filter seals shall be leakproof when tested in accordance with Annex A, Section II. Gaskets on HEPA filters shall have interlocking corners or sealed joints.
 - 4.20.3 Gaskets used in cabinet seams or on the facing of service panels shall have sealed joints. Structural strength of seams and service panel joints shall be independent of the seal produced by the gasket.
 - 4.20.4 All joints or assemblies may be made with sealant bonding applied according to the manufacturer's recommendations. The structural strength of joints or assemblies shall be independent of sealants.

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4.21 STOPCOCKS AND SERVICE OUTLETS: Stopcocks and service outlets shall be readily accessible. Electrical outlets on exposed interior surfaces shall have drip-proof caps or gasket seal blade openings.

4.22 FANS:

- 4.22.1 The unit may have a single motor driven fan system for both recirculated and exhaust air. When more than one fan is required, they shall be interlocked so the supply fan shuts off whenever the exhaust fan fails, and an alarm shall signal. If the supply fan fails, the exhaust fan shall continue to run, and the alarm shall signal the failure. If the unit is exhausted by a remote blower, a vacuum or flow sensor, audible alarm, and warning light shall be provided to indicate failure or nonoperation of the remote blower.
- 4.22.2 Fan air connections shall be tight and secure. Sleeves shall conform to Class I material requirements of UL Standard 181.

4.23 ELECTRICAL COMPONENTS:

4.23.1 MOTOR:

- A thermal protector shall be provided. It shall not trip at 115% of the rated voltage, under maximum load and ambient temperature conditions. The motor shall be rated for continuous operation.
- Fan motors shall be sized to operate at a static pressure sufficient to meet the requirements of Item 5.13.
- Variable speed fan motors, if provided, shall have controls that can be secured (set screw, jamnut, etc.). Controls shall be installed behind a removable or locked panel. Motor controls shall permit the adjustment of fan speeds to achieve proper airflow balance.
- Motor and lights shall be separately protected from the receptacles. Circuit overload protection, conforming to the National Electrical Code¹¹, shall be provided. Flexible power cords for single phase power, shall be 3 wire, with the ground wire connected to the frame, unless otherwise specified and sized in accordance with the National Electrical Code for the specified load(s).

4.23.2 ELECTRICAL WIRING, SWITCHES, ETC.:

Replaceable electrical components shall not be located in contaminated air
plenums, except for fan motors, sealed nonporous or jacketed wiring, and
necessary airflow sensors. All wiring penetrations of contaminated spaces shall
be sealed in accordance with Item 5.1. Circuit overload protection shall be
provided for all receptacles. Switches shall be mounted outside the work area.
A wiring diagram showing connection of all electrical components shall be

¹¹National Fire Protection Association, Batterymarch Park, Quincy, MA.

permanently attached to the unit in an accessible location outside of air plenum systems. A statement providing starting current, running power, and circuit requirements shall be provided with the installation instructions.

4.24 LIGHTING:

- 4.24.1 WORK LIGHTING: The light intensity at the work surface shall comply with Item 5.5.1. Lamps, ballasts, and starters shall be accessible and not installed in contaminated areas. Lamps shall be located so reflection does not interfere with visibility through the window, and the operator's eyes are shielded from direct radiation.
- 4.24.2 ULTRAVIOLET LIGHTING:¹² UV lighting is not recommended in class II (laminar flow) biohazard cabinetry. If requested by the purchaser, it shall be installed in such a manner that it does not reduce the required performance as specified in Section 5. This standard does not provide any performance verification of UV lighting.
- 4.25 GAUGES: Pressure gauges indicating the differential pressure across the recirculated air filter, if provided, shall be installed in accordance with the manufacturer's instructions. Hose connections to the gauge and sampling port shall be secured by positive compression clamps. If threaded connections are used to penetrate the plenum, an engagement of three continuous threads is required.
- 4.26 DRAIN SPILLAGE TROUGH: A drain spillage trough shall be provided below the work surface to retain spillage from the work area, and shall be easily cleanable. A drain pipe shall be connected to the drain spillage trough, and fitted with a 9.5 mm (3/8 in) or larger ball valve. The drain pipe and valve shall conform to the material requirements of the drain pan or trough. The drain spillage trough shall accommodate at least 4 L (1 gal). The drain valve shall be identified with a label and operating instructions placed in close proximity to the valve.
- 4.27 DIFFUSER PLACEMENT: Removable diffusers shall be designed and constructed to assure reassembly in the proper operating position.
- 4.28 HEIGHT AND WIDTH: The cabinet, excluding removable light fixtures, exhaust filter housings and guards, and adjustable legs or feet, shall be sized to fit through a 2 m by 0.9 m (6 ft 7 in by 2 ft 11 in) doorway using commonly available furniture moving equipment (jacks and dollies).

¹²In a dynamic airstream, UV lighting is not penetrating, has limited effectiveness, and may produce ozone levels sufficient to affect rubber materials. UV irradiation can cause erythema of skin and eye damage.

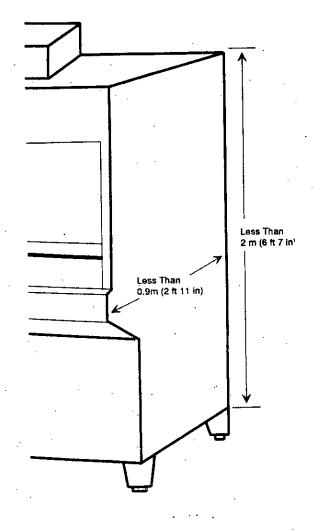


Figure 10. HEIGHT AND WIDTH

- 4.29 DATA PLATE(S): A data plate(s) indicating the following shall be readily visible on the front of the cabinet:
 - manufacturer's name and address
 - cabinet model
 - cabinet serial number
 - nominal set point for downflow and inflow velocities
 - type classification
 - velocity profile test grid dimensions (Annex A, Section IX.C)
 - the cabinet has contaminated plenums that are at positive pressure directly to the room (if applicable)
 - voltage requirements

SECTION 5. PERFORMANCE

- 5.0 GENERAL: For qualification by the standard certifying agency, biohazard cabinetry shall meet the performance requirements listed in items 5.1 through 5.13 when tested in accordance with Annex A. All removeable components within the cabinet that are offered as optional equipment by the manufacturer shall be in place during testing.
- 5.1 SOAP BUBBLE/HALOGEN LEAK: When the cabinet is in normal operation, all biologically contaminated air plenums under positive pressure to the room shall be halogen leak tight. The periphery and penetrations of all other plenums shall be leak tight when tested by the soap bubble test.
 - 5.1.1 All welds, gaskets, penetrations, or seals on exterior surfaces of air plenums shall hold pressure within 10% for 30 min, or shall be soap bubble tight at 500 Pa (2 in wg) pressure.
 - 5.1.2 Halogen leakage shall not exceed 1 x 10⁻⁴ cc/s, which is equal to 5 x 10⁻⁷ cc/s, when the air inside the cabinet at 1 atm is pressurized with 100% Freon R-12 to 500 Pa (2 in wg).
- 5.2 HEPA FILTER LEAK: HEPA filters, filter housings, and mounting frames shall be DOP, or equivalent, leak tight when cabinet is operating at the nominal set point velocities.
 - 5.2.1 Polydisperse DOP, or equivalent, penetration shall not exceed 0.01% at any point when measured on a linear or logarithmic scale photometer.
- 5.3 TEMPERATURE RISE: The temperature rise in the cabinet shall be determined with the cabinet operating at the nominal set point velocities and all fluorescent lights operating.
 - 5.3.1 Temperature rise shall not exceed 8.5°C (15° F) above ambient temperature after 4 h continuous operation.
- NOISE LEVEL: The noise level shall be determined with the cabinet operating at the nominal set point velocities.
 - 5.4.1 The overall noise level 30 cm (12 in) in front of the cabinet, 38 cm (15 in) above the plane of the work surface at the vertical centerline of the cabinet, shall not exceed 67 dbA with a maximum background level of 57 dbA.
- 5.5 LIGHTING INTENSITY: The lighting intensity at the work surface shall be determined with an average background in the room of 210 430 lx (20 40 footcandles) at the work surface level.
 - 5.5.1 Lighting intensity averages from 860 1600 lx (80 150 footcandles) are acceptable. Individual readings shall be between 650 1880 lx (60 175 footcandles).
- 5.6 VIBRATION: The net displacement shall not exceed 0.0002 in rms amplitude, at 10-250 Hz, in the center of the work surface, when the cabinet is operating at the nominal set point velocities.
- 5.7 PERSONNEL, PRODUCT, AND CROSS-CONTAMINATION PROTECTION: The cabinet shall meet the requirements of Items 5.7.1, 5.7.2, 5.7.3, and Section VII of Annex A when operating with the airflows specified in Annex A.

- 5.7.1 PERSONNEL PROTECTION: The system shall be challenged by 1 to 8 x 10⁸ <u>Bacillus subtilis</u> var. <u>niger</u> (B. <u>subtilis</u>) spores. The number of <u>B. subtilis</u> colony forming units (CFU) recovered from the collection suspension of all six all glass impinger samplers (AGI-30) shall not exceed 10 CFU per test. Total slit-type air sampler plate counts shall not exceed 5 <u>B. subtilis</u> CFU for a 30-min sampling period. Three replicate tests shall be performed. The control plate shall be positive for <u>B. subtilis</u> CFU.
- 5.7.2 PRODUCT PROTECTION: The system shall be challenged by 1 to 8 x 10⁶ B. subtilis spores in 5 min. The number of CFU recovered on agar settling plates shall not exceed 5 CFU for each test. Three replicates shall be performed. The control plate shall be positive for B. subtilis CFU.
- 5.7.3 CROSS-CONTAMINATION PROTECTION: The system shall be challenged by 1 to 8 x 10⁴ B. subtilis spores in 5 min. Some agar plates within 35 cm (14 in) from the challenge sidewall will recover B. subtilis CFU and shall be used as controls. The number of CFU recovered on agar plates with centers greater than 35 cm (14 in) shall not exceed 2 CFU per test. Three replicates each shall be performed from the left and right sides of the cabinet.
- 5.8 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 work load.
 - 5.8.1 RESISTANCE TO OVERTURNING: Cabinets shall comply with the requirements of UL 1262, section 12.4.
 - 5.8.2 RESISTANCE TO DISTORTION: The top front edge and the top of the sides shall not move forward more than 1.6 mm (1/16 in) from the static position when a 113 kg (250 lb) lateral force is applied to the top rear edge and top of the opposite side, respectively.
 - 5.8.3 RESISTANCE TO DEFLECTION OF WORK SURFACE: The work surface shall not be permanently deflected by a 23 kg (50 lb) test load distributed uniformly over an area 25 x 25 cm (10 x 10 in) in the center of the work surface.
- 5.9 VELOCITY PROFILE: The average downflow velocity and the calculated or measured average inflow velocity of the cabinet shall be set at the nominal set point for testing. Subsequent production cabinets of the initial mode and size complying with Item 5.7 may also qualify when the average downflow velocity (or velocities, if so specified) is provided within 0.025 m/s (± 5.0 fpm) (see Annex A, Section IX).
 - 5.9.1 UNIFORM DOWNFLOW VELOCITY: Cabinets intended to be operated with a uniform downflow velocity shall have individual point readings that do not vary more than \pm 20% from the average downflow velocity.
 - 5.9.2 NONUNIFORM DOWNFLOW VELOCITY: The manufacturer shall designate the velocity gradient in terms of design velocity and distance from the cabinet front for every zone within which velocity is intended to be uniform. The velocity shall not vary more than ± 20% from the average within each designated zone.
- 5.10 INFLOW VELOCITY: The velocity of the inflow air through the work access opening shall be

determined. Subsequent production cabinets of the initial model and size complying with Item 5.7 may also qualify if the calculated inflow velocity is within \pm .025 m/s (\pm 5.0 fpm) of the nominal set point velocities.

- 5.10.1 The minimum calculated and measured inflow velocity of Type A cabinets shall be 0.35m/s (75 fpm). The minimum exhaust flow volume shall be 0.02 m³/s (45 cfm) per 0.3 m (1ft) of work area width (see Items 5.7 and 5.9).
- 5.10.2 The minimum calculated and measured inflow velocity of Type B cabinets shall be 0.5m/s (100 fpm). The minimum exhaust flow volume shall be 0.03 m³/s (65 cfm) per 0.3 m (1ft) of work area width (see Item 5.7 and 5.9).
- 5.11 AIRFLOW SMOKE PATTERNS: Smoke patterns shall be determined with the cabinet operating at the nominal set point velocities.
 - 5.11.1 Airflow along the entire perimeter of the work access opening shall be inward.
 - 5.11.2 Airflow within the work area of the cabinet shall be downward, with no dead spots or refluxing.
 - 5.11.3 Airflow within the work area of cabinets with sliding sashes shall be downward, with no escape to the outside at the wiper gasket or side channels.
- 5.12 DRAIN SPILLAGE TROUGH LEAKAGE: Drain spillage troughs shall hold a minimum of 4 L (1 gal) of water with no visible leakage after a 1 h holding period.
- 5.13 MOTOR/BLOWER PERFORMANCE: When operating at the nominal set point velocities and without readjusting the fan speed control, a 50% increase in pressure drop across the new filter shall not decrease total air delivery more than 10%.
- 5.14 ELECTRICAL LEAKAGE, GROUND CIRCUIT RESISTANCE AND POLARITY: The electrical leakage shall not exceed 500 ma and the ground circuit resistance shall not exceed 0.15 ohms. Cabinets with primary-circuit filtering complying with UL 1262 shall be considered complying with this requirement.
- 5.15 PERFORMANCE DATA: The manufacturer shall provide a performance data sheet with each cabinet. The following tests shall be conducted in accordance with Annex A and reported for each unit.
 - Soap Bubble/Halogen Leak
 - HEPA Filter Leak
 - Downflow Velocity individual point readings plotted on a grid, and the calculated average for each designated zone (uniform downflow represents a single zone).
 - Inflow Velocity individual point readings plotted on a grid, and the calculated average and/or the direct reading.
 - Airflow Smoke Patterns

The following additional tests shall be conducted in accordance with Annex A and reported on each tenth unit produced:

- Noise
- Lighting
- Vibration
- Electrical leakage, ground circuit resistance and polarity
- 5.16 RECORD MAINTENANCE: Quality control test results shall be maintained on file at the plant location for a minimum of three years.

ANNEX A

PERFORMANCE TESTS

(This Annex is part of Standard 49.)

Test Method I	- Soap Bubble/Halogen Leak	A2
Test Method II	- HEPA Filter Leak	A5
Test Method III	- Temperature Rise	A7
Test Method IV	- Noise Level	A8
Test Method V	- Lighting Intensity	A10
Test Method VI	- Vibration	A11
Test Method VII	- Personnel, Product, and Cross-Contamination Protection (Biological)	A13
Test Method VIII	- Stability	A26
Test Method IX	- Downflow Velocity	A33
Test Method X	- Inflow Velocity (Face Velocity)	A36
Test Method XI	- Airflow Smoke Patterns	A43
Test Method XII	- Drain Spillage Trough Leakage	A 44
Test Method XIII	- Motor/Blower Performance	A4 4
Test Method XIV	- Electrical Leakage, Ground Circuit Resistance and Polarity	A47

ANNEX A

PERFORMANCE TESTS

NOTE: Before running any performance tests, the cabinet shall be properly installed and leveled, and airflows adjusted to the nominal set point. These tests are intended for the qualification of a new cabinet at the point of production or by the standard certifying agency. Recommended field tests are provided in Annex F.

I. SOAP BUBBLE/HALOGEN LEAK TEST

A. Soap Bubble Test

1. Purpose

This test on exterior surfaces of all plenums determines if welds, gaskets, and plenum penetrations or seals are free of leaks.

2. Apparatus

Liquid leak detector (such as "Search," "Leak-Tek," "Snoop," or equal).

3. Method

- a. Prepare the cabinet as a closed system; i.e., seal the front window and exhaust port.
- b. Remove decorative panels, where necessary, to expose plenums to be tested.
- c. Attach a manometer, pressure gauge, or pressure transducer system to the test area to indicate the interior pressure (Figure A-1a).
- d. Pressurize the cabinet with air to a reading of 500 Pa (2 in wg), turn off the pressurizing air and measure the pressure after 30 min. A leakage of 10% of the original pressure is allowable. If a cabinet does not hold 500 Pa (2 in wg) continue to pressurize cabinet as close to the desired pressure as possible while searching for leaks.
- e. If the cabinet leak exceeds 10%, spray or brush the liquid leak detector along all welds, gaskets, penetrations, or seals on exterior surfaces of cabinet plenums. Small leaks will be indicated by bubbles. Large leaks will occur that blow the detection fluid from the hole without forming bubbles, and may be detected by slight feel of airflow or sound.

4. Acceptance (Soap Bubble Test)

All welds, gaskets, penetrations, or seals on exterior surfaces of air plenums shall hold 500 Pa (2 in wg) within 10% for 30 min, or shall be free of soap bubbles when at 500 Pa (2 in wg) pressure above atmospheric.

B. Halogen Leak Test

1. Purpose

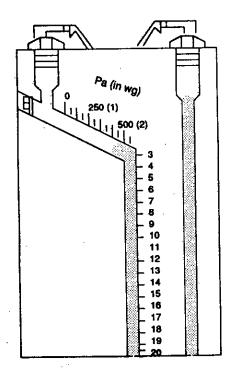
This test on all biologically contaminated air plenums under positive pressure to the room determines if exterior joints made by welding, gasketing, or sealing with sealants are free of leaks that might release potentially hazardous materials into the atmosphere.

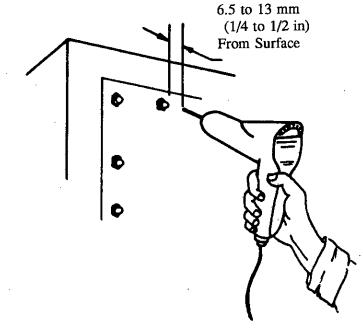
2. Apparatus

- a. An industrial-type halogen leak detector capable of detecting a halide leak of 1×10^{-7} cc/s.
- b. The halogen leak detector shall be calibrated in accordance with the manufacturer's instructions using a calibrated leak standard.

Method

- a. The room where testing will be performed shall be free of halogenated compounds, and air movements kept to a minimum. No smoking should take place in the test area.
- b. Prepare the cabinet as a closed system (Sections I.A.3.a, b, and c).
- c. Pressurize the cabinet with air to 500 Pa (2 in wg). If the cabinet holds this pressure without more than ± 10% loss for 30 min, release pressure. If the cabinet does not hold this pressure, examine for gross leaks with liquid leak detector (Section I.A.2), repair, and retest.
- d. Pressurize the air filled cabinet at atmospheric pressure to 500 Pa (2 in wg) with halide gas (dichlorodifluoromethane).
- e. Turn on the cabinet blower for 30 s to circulate gas.
- f. Adjust the halogen leak detector to a sensitivity setting of 5 x 10⁻⁷ cc/s, in accordance with the manufacturer's instructions.
- g. Move the detector probe over seams, joints, utility penetrations, panel gaskets, and other areas of possible leakage. The detector probe shall be held at the surface of cabinet, being careful not to jar the instrument. Move the detector probe over the surface at a rate of approximately 2.5 cm/s (1.0 in/s), keeping the probe 6.5 to 13 mm (1/4 to 1/2 in) away from the surface (Figure A-1b).





a. Inclined Manometer

b. Scanning for Halide Leaks

FIGURE A-1. HALOGEN LEAK TEST

4. Acceptance (Halogen Leak Test)

Absolute leakage from any point in the cabinet shall not exceed a leak rate of 5 \times 10⁻⁷ cc/s to compensate for the dilution of halide gas.

II. HEPA FILTER LEAK TEST

A. Purpose

This test determines the integrity of supply and exhaust HEPA filters, filter housings, and filter mounting frames. The cabinet shall be operated within ± 0.01 m/s (2 fpm) of the nominal set point.

B. ... Apparatus

- 1. An aerosol photometer with linear or expanded logarithmic scale. The instrument shall be capable of indicating 100% upstream concentration with an aerosol of 10 µg/L of polydisperse dioctylphthalate (DOP) particles, or an equivalent fluid which provides the same particle size distribution (e.g., foodgrade com oil, di(2-ethylhexyl), sebecate, polyethylene glycol, and medicinal-grade light mineral oil)¹ produced by the generator described in Section II.B.2 and shall be capable of detecting an aerosol of 1 x 10³ µg/L of the same particles. The sampling rate of air shall be at least 5 x 10⁴ m³/s ± 10% (1 cfm). Probe diameter shall not exceed 2.5 cm (1 in). The photometer shall be calibrated in accordance with the photometer manufacturer's instructions or IES-RP-CC-013-86t² if instructions are not provided.
- 2. An aerosol generator of the Laskin Nozzle type conforming to Figure A-2 or equivalent shall be used to create an aerosol by flowing air through liquid DOP or suitable substitute. The compressed air supplied to the generator should be adjusted to a minimum of 140 kPa (20 psi), measured at the entrance of the nozzle, downstream of all restrictions. The nozzles shall be covered with liquid to a depth not to exceed 2.5 cm (1 in).

¹Hinds, W., Macher, J., First M.W., "Size Distributions of Aerosols Produced from Substitute Materials by the Laskin Cold DOP Aerosol Generator," presented at the 16th Dept. of Energy Nuclear Air Cleaning Conference; and Yan, X., First, M.W., Rudnick, S.N. "Characteristics of Laskin Nozzle Generated Aerosols," Proc. 21st Nuclear Air Cleaning Conf., M.W. First, Ed., N.T.I.S., Springfield, VA. Feb. 1991. p.116.

²Recommended Practice, Tentative (August, 1986). Institute of Environmental Sciences, 940 East North West Highway, Mt. Prospect, IL 60056.

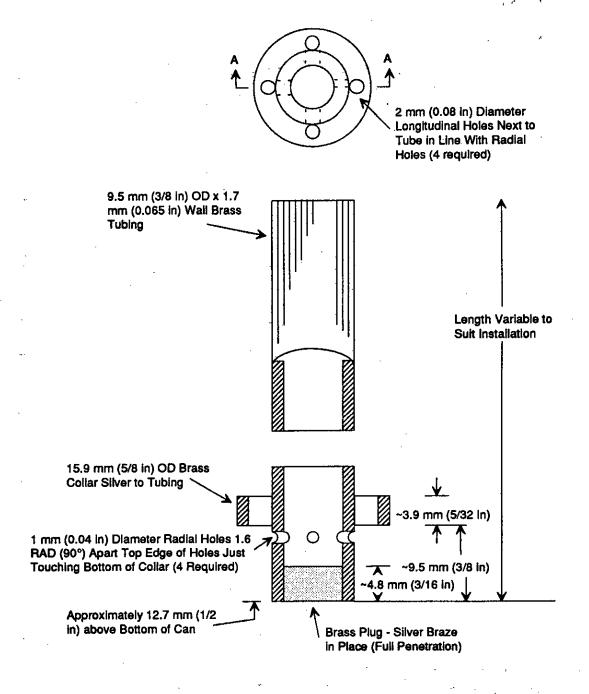


FIGURE A-2. DETAILS OF LASKIN NOZZLE

C. Method

- 1. Place the generator so the aerosol is introduced into the cabinet, upstream of the HEPA filter.
- 2. Turn on the photometer and adjust in accordance with the manufacturer's instructions.
- 3. Measure aerosol concentration upstream of the HEPA filter.

Section 18 Section 18

- a. An aerosol concentration shall be used that is at least equal to the concentration at which the photometer sensitivity was verified during the calibration against the photometer manufacturer's instructions or IES-RP-CC-013-86t if instructions are not provided.
- b. For logarithmetic photometers, set the photometer by measuring the upstream concentration to be at least 10⁻⁴ above the concentration for one scale division (using the instrument calibration curve).
- 4. With the nozzle of the probe not more than 2.5 cm (1 in) from the surface, scan the downstream side of the HEPA filters and the perimeter of each filter pack by passing the photometer probe in slightly overlapping strokes over the entire surface of the HEPA filter. Scan the entire periphery of the filter and the junction between filter and filter mounting frame. Scanning shall be done at a transverse rate of not more than 5 cm/s (2 in/s).

D. Acceptance

Aerosol penetration shall not exceed 0.01% at any point, and for logarithmetic readout photometers, penetration shall not exceed 0.01% using the calibration curve.

III. TEMPERATURE RISE TEST

A. Purpose

This test determines the maximum temperature rise in the cabinet when the fan, motor, and lights are operating. The test shall be performed in an area where the temperature is between 20 and 30°C (70 and 80°F). The cabinet shall be operated within \pm 0.01 m/s (2 fpm) of the nominal set point velocities.

B. Apparatus

- 1. Calibrated dry bulb thermometer graduated in 1°C (2°F) divisions; or
- 2. Calibrated chart type temperature recorder graduated 1°C (2°F) divisions. The sensing element is the only part of the instrument located in the airflow stream within the cabinet.

C. Method

- 1. Place one thermometer or one sensing element 8 cm (3 in) upstream of the center of the front work access opening outside the cabinet to measure ambient temperature.
- 2. Place the second thermometer or sensing element 30 cm (12 in) above the geometric center of the work tray within the cabinet.
- 3. Record the ambient temperature and the temperature in the cabinet.
- 4. Turn on the blower and lights. Report the temperature rise as the difference between the stabilized temperature in the cabinet and the ambient temperature at the work access opening, at the end of the test.

D. Acceptance

Temperature rise in the cabinet shall not exceed 8.5°C (15°F) above ambient temperature after 4 h continuous operation, with lights and fans or blowers operating.

IV. NOISE LEVEL TEST

A. 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 nominal set point velocities within \pm 0.01 m/s (2 fpm).

B. Apparatus

The measuring instrument shall be a sound level meter with a range of at least 50 to 100 db, and an "A" weighting scale calibrated in accordance with the manufacturer's instructions.

C. Method

- 1. Turn on the cabinet blower and lights.
- 2. Set the instrument to the "A" weighting mode.
- 3. Measure noise level 30 cm (12 in) in front of the cabinet and 38 cm (15 in) above the plane of the work surface, in line with the vertical centerline of the cabinet (see Figure A-3).
- 4. To measure the ambient noise level, turn blower and lights off, and measure as in Item 3.

D. Acceptance

Overall noise level in front of the cabinet shall not exceed 67 dbA when measured where the maximum ambient sound level is 57 dbA. When the ambient sound level is greater than 57 dbA, the reading obtained in Section IV.C.3 shall be corrected in accordance with standard correction curves or tables.

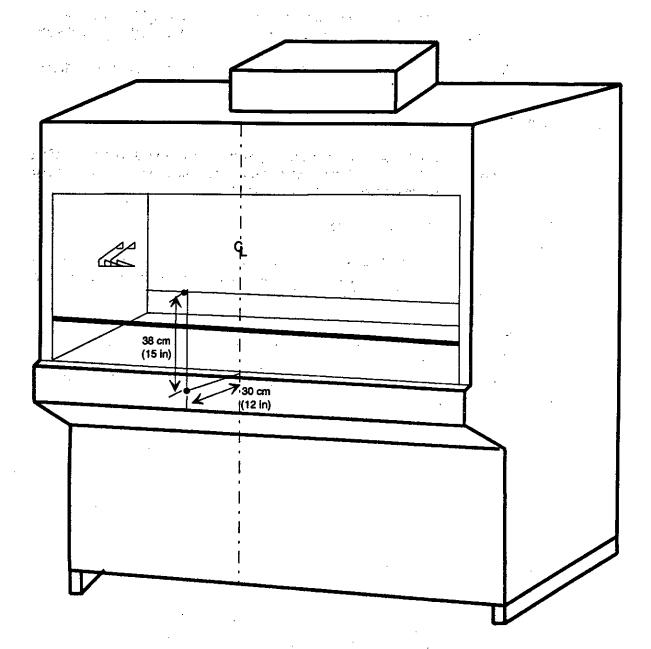


FIGURE A-3 NOISE LEVEL TEST

V. LIGHTING INTENSITY TEST

A. Purpose

This test determines the light intensity at the work surface of the cabinet in lx (foot-candles).

B. Apparatus

- 1. Portable photoelectric illumination meter approved for field measurement in accordance with the Illuminating Engineering Society (IES) Lighting Handbook.³
- 2. The illumination meter shall be calibrated in accordance with the manufacturer's instructions.

C. Method

- 1. Measure the background lighting intensity along the side-to-side centerline of the work tray at 30 cm (12 in) increments, with no measurements made closer than 15 cm (6 in) from the side wall (see Figure A-4).
- 2. Turn on the lights and blower.
- 3. Measure the light intensity along the side-to-side centerline of the work tray at 30 cm (12 in) increments, with no measurement made closer than 15 cm (6 in) from the side wall (see Figure A-4).

D. Acceptance

Lighting intensities averaging 860 to 1600 lx (80 to 150 foot-candles) at the work surface are acceptable, if individual readings are between 650 and 1880 lx (60 and 175 foot-candles) when measured where background light levels average 210 to 430 lx (20 to 40 foot-candles) at the work surface.

³Illuminating Engineering Society, 345 E. 47th St., New York, NY 10017.

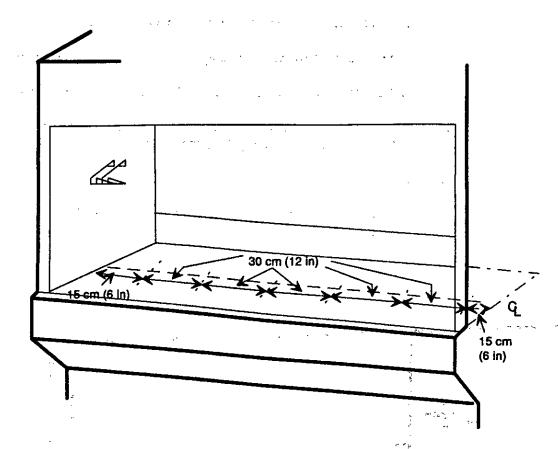


FIGURE A-4. LIGHTING INTENSITY TEST

VI. VIBRATION TEST

A. Purpose

This test determines the amount of vibration in the operating cabinet. The cabinet shall be operated within ± 0.01 m/s (2 fpm) of the nominal set point velocities:

B. Apparatus

A vibration analyzer with a minimum sensitivity of 1 x 10⁻⁴ in rms amplitude, calibrated in accordance with manufacturer's instructions.

C. Method

- 1. Clamp, bolt, or use integral magnet with petroleum jelly film, or a double-faced adhesive tape, to affix the sensing element of the vibration pickup unit firmly onto the work surface.
- 2. Test positions are shown in Figure A-5.

To determine the vibration displacement on the vertical axis, attach the sensing

element to the geometric center of the work surface.

- 3. Determine the gross vibration amplitude with the cabinet operating.
- 24. Determine background vibration amplitude with cabinet not operating.
 - 5. Subtract the background from the gross vibration amplitude to determine the net vibration amplitude attributable to the cabinet.

D. Acceptance

Net displacement shall not exceed 0.0002 in rms amplitude at 10 to 250 Hz in the center of the work surface.

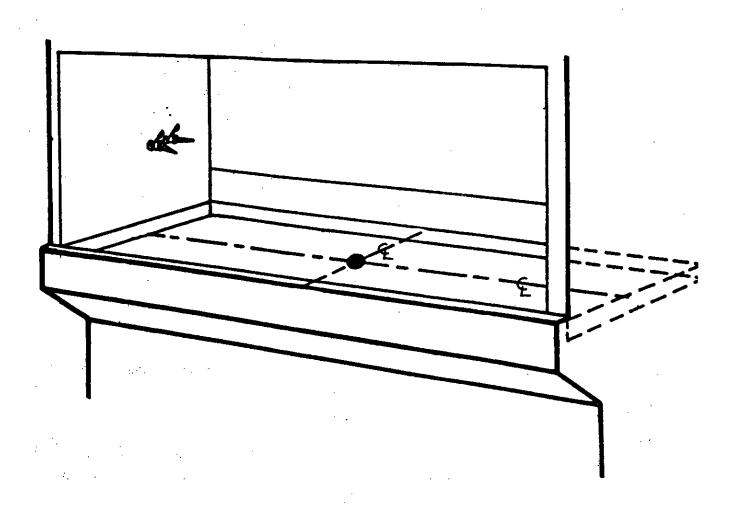


FIGURE A-5. VIBRATION TEST

VII. PERSONNEL, PRODUCT, AND CROSS-CONTAMINATION PROTECTION (BIOLOGICAL) TESTS

A. Purpose

These tests determine if aerosols will be contained within the cabinet, outside contaminants will not enter the cabinet work area, and aerosol contamination of other equipment in the cabinet will be minimized. The cabinet shall be operated at the airflow velocities indicated in the specific test methods. The cabinet shall be turned on at least 30 min before the start of any test, and operated continuously throughout all test methods. Cabinets meeting these tests shall then meet airflow characteristics as measured in Sections IX and X.

B. Materials

- Spores of <u>Bacillus subtilis</u> var. <u>niger</u> (<u>B. subtilis</u>), A.T.C.C. 9372⁴, or N.C.T.C. NO. 10073.⁵
- 2. Sterile diluent prepared as follows:
 - a. Final diluent phosphate buffer solution (PBS)(step 1)
 Dissolve 34 g KH₂PO₄ in 500 mL distilled H₂0
 Adjust pH to 7.2 ± 0.5 with 1 N NaOH at 25°C (77°F)
 Dilute to 1 L with distilled H₂O

Final dilutent PBS (step 2) Distilled H₂O - 1 L Stock PBS step 1 - 1.25 mL

Final Ph - 7.2 ± 0.5 Autoclave at 121° C (250°F) for 15 min

Optional - Magnesium sulfate (50 g MgSO₄ • 7H₂O per L distilled H₂O) - 5.0 mL

OR

b. Distilled $H_2O - 1$ L Adjust pH to 7.0 ± 0.1 at 25°C (77°F) Autoclave at 121°C (250°F) for 15 min

⁴American Type Culture Collection, Rockville, MD.

⁵National Collection Type Culture, London, England.

NOTE: Formula b. is suitable for diluent when spore suspension is prepared for immediate use. When storage of diluent suspension at 4°C (39.2°F) is required, Formula a. should be used.

3. Suspension of <u>B</u>. <u>subtilis</u> var. <u>niger</u> spores prepared as follows:

METHOD A (using previously harvested B. subtilis spores)

- a. Aseptically inoculate by streak plating technique several tryptic soy agar (Difco⁶ or equivalent) petri plates (100 x 15 mm).
- b. Incubate for $48 \pm 2 \text{ h}$ at $37 \pm 0.5^{\circ}\text{C}$ $(99 \pm 1^{\circ}\text{F})$.
- Remove characteristic (pigmented dark orange) colonies and transfer to 10 220 mL sterile screw-capped bottles containing approximately 50 mL of tryptic soy agar.
- d. Incubate for $48 \pm 2 \text{ h}$ at $37 \pm 0.5^{\circ}\text{C}$ (99 $\pm 1^{\circ}\text{F}$).
- e. Add 10 mL of PBS to each slant, and gently wash the bacteria from the agar surface.
- f. Transfer the bacterial suspensions to yield approximately 100 mL in a sterile 150 mL screw-cap bottle. If cell debris interferes with nebulizer dissemination, the suspension may be clarified by washing three times in PBS by centrifugation at 1500 rpm for 10 min. Re-suspend in PBS to the original volume.
- g. Heat shock culture at 65 ± 0.5 °C (149 \pm 1°F) for 15 min.
- h. Determine spore concentration by standard dilution-plate methods⁷ using PBS and tryptic soy agar. Spores prepared as above should yield an average count of 2 to 4 x 10⁹/mL.
- i. Incubate plates for 48 ± 2 h at 37 ± 0.5 °C (99 ± 1 °F).
- j. Dilute the spore suspension with PBS to obtain final spore concentration of 5 to 8 x 10⁸/mL if spores are to be used immediately.
- k. Store the stock spore suspension (2 to 4 x 10°/mL) at 4°C (39°F), or divide into aliquots to store in screw-capped vials at -70°C (-94°F).

⁶Difco Laboratories, Detroit, MI.

⁷Standard Methods for the Examination of Water and Wastewater, Seventeenth Edition, American Public Health Association, 1015 Eighteenth Street N.W., Washington, DC 20036.

Making frequent checks of: spore viability by surface plating; and spore predominance by an acceptable spore staining technique.⁸.

METHOD B

- a. Inoculate 250 mL portions of sterile tryptose broth (Difco or equivalent) with aliquots of previously harvested <u>B. subtilis</u> spores; or rehydrated freeze-dried cultures per A.T.C.C. or N.C.T.C. instructions.
- b. Incubate on a reciprocating shaker for 48 ± 2 h at 37 ± 0.5 °C (99 ± 1 °F).
- c. Heat shock cultures at 65 ± 0.5 °C (149 \pm 1°F) for 15 min.
- d. Transfer suspensions to screw-cap test tubes and wash at least 3 times in sterile distilled H₂O by centrifugation at 1500 mp for 10 min. Use PBS in last washing if storage is required.
- e. Determine spore concentration by standard dilution-plate methods using PBS and tryptic soy agar. Spores prepared as described above should average 1.5 x 109/mL.
- f. Incubate plates for $48 \pm 2h$ at 37 ± 0.5 °C (99 ± 1 °F).
- g. If spore suspension is to be used promptly, dilute the spore suspension with PBS to obtain a final suspension concentration of 5 to 8 x 108/mL.
- h. To store the stock spore culture, divide into aliquots and store at 4°C (39°F) in sterile screw-cap vials, or store in freezer at -70°C (-94°F). Before use, check viability of spore suspension as in Method A, Item 1.
- 4. Petri plates (100 x 15 mm and 150 x 22 mm) containing nutrient agar, trypticase soy agar, or other suitable growth medium with no inhibitors or other additives.
- 5. Six AGI-30 samplers (flow rate calibrated at 12.5 L/min) containing 20 mL of sterile diluent. The AGI-30 samplers shall be Ace Glass Incorporated, Vineland, NJ, Catalog Number 7540-10, air sampling impingers, or equal.
- 6. Two slit-type air samplers operating at a rated flow of 1 ± 0.000472 m³/s (0.05 cfm).
- 7. Refluxing 6-jet modified MRE-type short-form collision nebulizer (available as

⁸APHA Intersociety/agency Committee on Microbiological Methods for Foods, "Compendium of Methods for Microbiological Examination of Foods,"1976,pg.92-93.

⁹BBL Microbiological Systems, Cockeysville, MD.

Model CN-38 Nebulizer from BGI, Inc., Waltham, MA) or any other nebulizer that can be demonstrated to produce a bacterial aerosol of equivalent characteristics.

- 8. One 63 mm (2-1/2 in) outside diameter stainless steel, steel, or aluminum cylinder with closed ends shall be used to disrupt the airflow. The length to be determined by size of cabinet interior. One end butts against the back wall of the cabinet, and the other end protrudes at least 15 cm (6 in) into the room through the work access opening of the cabinet.
- C. Personnel Protection Test (system challenged with 1 to 8 x 10⁸ <u>B. subtilis</u> spores in five min)

1. Method

- a. A nebulizer containing up to 55 mL of spore suspension (5 to 8 x 10⁸ /mL) is centered between side walls of the cabinet. The horizontal spray axis is placed 35 cm (14 in) above the work surface, the opening of the nebulizer is 10 cm (4 in) in back of the front window. The spray axis is parallel to the work surface and directed toward the front window (see Figure A-6).
- b. The cylinder is placed at the cabinet center. The axis of the cylinder is 6.9 cm (2-3/4 in) above the work surface. Around the cylinder, four AGI-30s are positioned with the sampling inlets 6.3 cm (2-1/2 in) outside the cabinet front. Two AGI-30s are placed so their inlet axes are 15 cm (6 in) apart, and in a horizontal plane tangent to the top of the cylinder. Two AGI-30s are positioned so their inlet axes are 5 cm (2 in) apart, and lie in a horizontal plane 2 cm (1 in) below the cylinder. As a positive control, an agar plate is placed under the center of the cylinder, and supported 1 cm (1/2 in) above or below the front intake grill, to minimize the obstruction of airflow into the grill (see Figures A-7 and A-8).
- c. Two slit-type air samplers are placed so the horizontal plane of the air inlets is at the work surface elevation, the vertical axes of the inlets are 15 cm (6 in) in front of the cabinet, and 20 cm (8 in) from each interior side wall. Two AGI-30 samplers are placed so the horizontal plane of the air inlets is 35 cm (14 in) above the work surface, the vertical axes are 5 cm (2 in) outside the front edge of the cabinet, and 15 cm (6 in) on each side of the cabinet centerline (see Figure A-9).
- d. The cabinet shall be set at the nominal set point.

e. Duration of the test is 30 min. The test sequence is as follows:

Time (min)	Activity
30	Start slit samplers
25	Start nebulizer
24	Start impingers
19	Stop impingers
18.5	Stop nebulizer
0	Stop slit samplers

Three replicate tests shall be performed.

- f. Filter the sampling fluid from all of the AGI-30 samplers¹⁰ through a 47 mm diameter 0.22 μm membrane filter, remove the filter aseptically and place on appropriate media. Plates containing the filters and plates from the slit-type air samplers shall be incubated at 37°C (98.6°F). Examine at 24 28 h, and if negative, reincubate and read at 44 48 h.
- g. Repeat the above steps setting the cabinet airflow velocities at $-5 \times 10^4 \pm .01$ M/s (-10 ± 2 fpm) inflow and $+5 \times 10^4 \pm .01$ M/s ($+10 \pm 2$ fpm) supply from the nominal set point. Airflow velocity adjustments shall be made by the adjustment of voltage, blower speed and dampers (if applicable). If the $5 \times 10^4 \pm .01$ M/s (10 ± 2 fpm) adjustments cannot be reached based on cabinet design, the maximum adjustment from the nominal set point shall be used.
- h. Repeat the above steps setting the airflow velocities at $-5 \times 10^4 \pm .01$ M/s (-10 \pm 2 fpm) from the nominal set point for both supply and inflow.

2. Acceptance

The number of <u>B. subtilis</u> colony forming units (CFU) recovered from the 6 AGI-30 samplers shall not exceed 10 CFU per test. Total slit-type air sampler plate counts shall not exceed 5 <u>B. subtilis</u> CFU for a 30-min sampling period. Three replicate tests shall be performed. The control plate shall be positive. A plate is "positive" when it contains greater than 300 CFU of <u>B. subtilis</u>.

¹⁰For research and field applications, the sampling fluid may be filtered separately from each AGI sampler to provide information on specific areas within the cabinet.

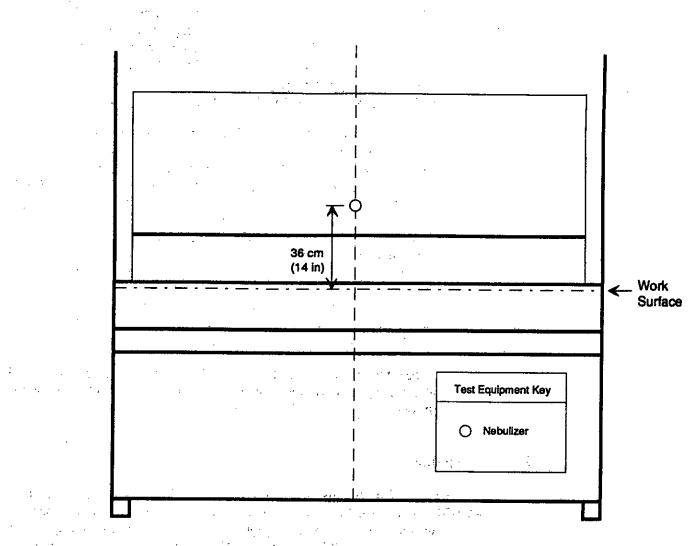


Figure A-6. PERSONNEL PROTECTION TEST

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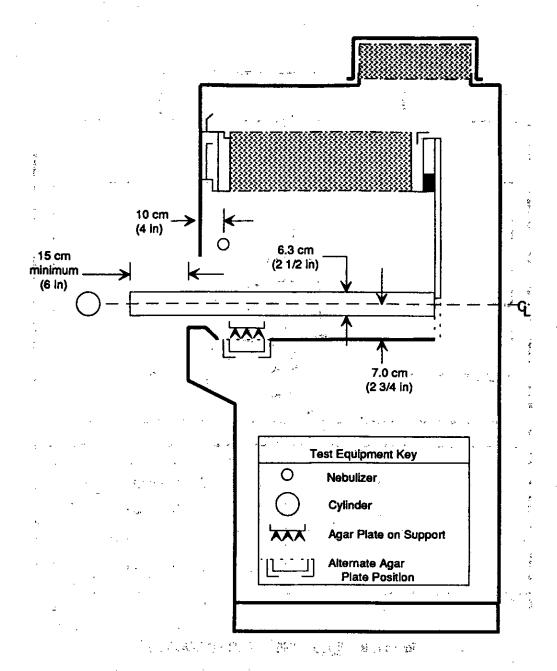


Figure A-7. PERSONNEL PROTECTION TEST

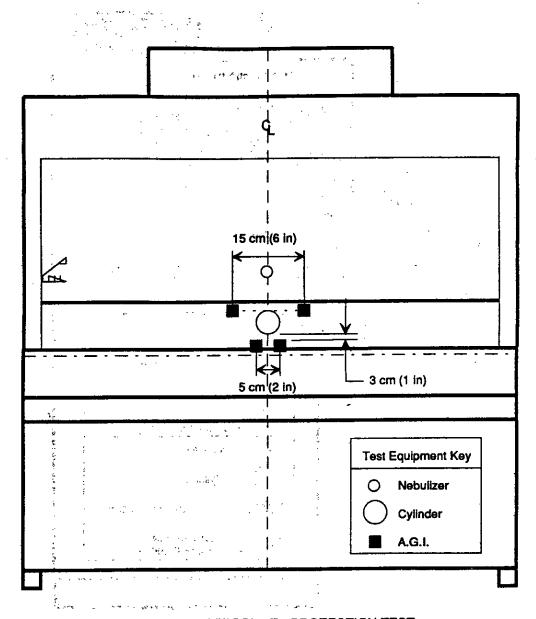


Figure A-8. PERSONNEL PROTECTION TEST

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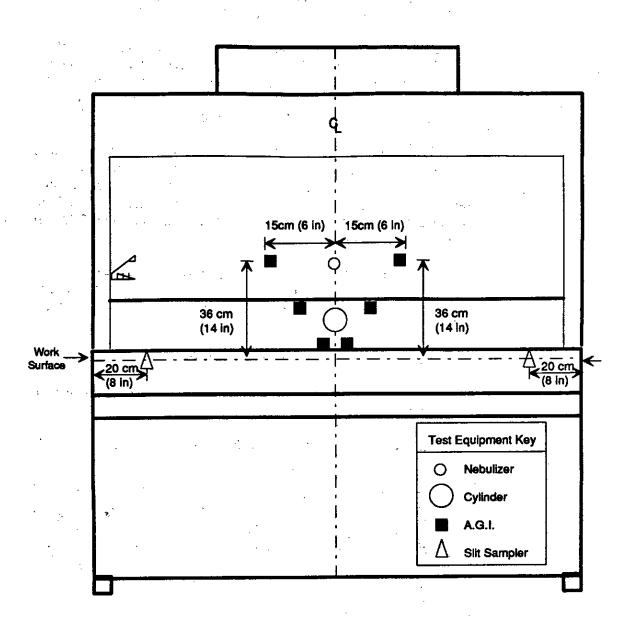


Figure A-9. PERSONNEL PROTECTION TEST

D. Product Protection Test (system challenged by 1 to 8 x 10⁶ B. subtilis spores in 5 min)

1. Method

- a. Cover the work surface with open agar plates (100 x 15 mm) with the cylinder at the midpoint (see Figure A-10).
- b. Position the horizontal spray axis of the nebulizer containing 55 mL of 5 to 8 x 10⁶ spores/mL at the level of the top edge of the work opening, and center between the two sides of the cabinet, with the opening of the nebulizer 10 cm (4 in) outside the window. The spray axis is parallel to the work surface and directed toward the open front of the cabinet.
- c. A 6.3 cm (2-1/2 in) outside diameter cylinder, with closed ends, is placed in the center of the cabinet. The cylinder is positioned in the cabinet so one end butts against the back wall of the cabinet, the other end extends at least 15 cm (6 in) into the room through the front opening of the cabinet, and the axis of the cylinder is 6.9 cm (2-3/4 in) above the work surface.
- d. As a positive control, an agar plate is placed under the center of the cylinder, and supported 1 cm (1/2 in) above or below the front intake grill, to minimize the obstruction or airflow into the grill (see Figure A-11).
- e. The cabinet shall be set at the nominal set point.
- f. Operate nebulizer for 5 min. 5 min after nebulization is terminated, place lids on agar plates.
- Incubate plates at 37°C (98.6°F) and examine them at 24 28 h. If negative, reincubate and read at 44 48 h.
- h. Repeat the above steps at airflow velocities $-5 \times 10^4 \pm .01$ m/s (-10 ± 2 fpm) supply and $+5 \times 10^4 \pm .01$ m/s ($+10 \pm 2$ fpm) inflow from the nominal set point. Airflow velocity adjustments shall be made by the adjustment of voltage, blower speed and dampers (if applicable). If the $5 \times 10^4 \pm .01$ m/s (10 ± 2 fpm) adjustments cannot be reached based on cabinet design, the maximum adjustment from the nominal set point shall be used.

2. Acceptance of the property of the property

The number of \underline{B} , subtilis CFU on agar settling plates shall not exceed 5 CFU for each test. Three replicates shall be performed. The control plates shall be positive. A plate is "positive" when it contains greater than 300 CFU of \underline{B} , subtilis.

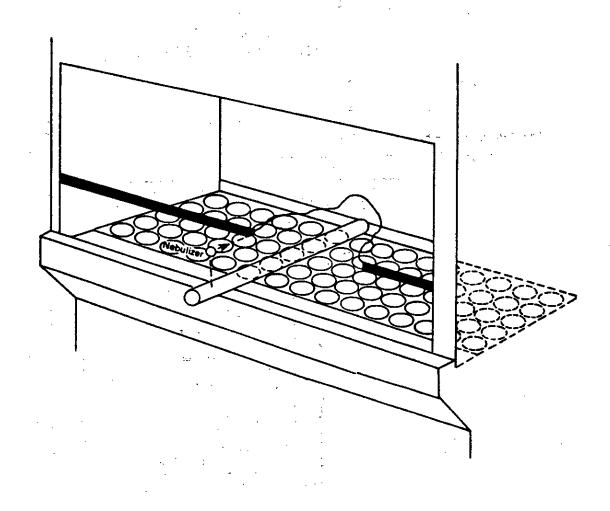


Figure A-10. PRODUCT PROTECTION TEST

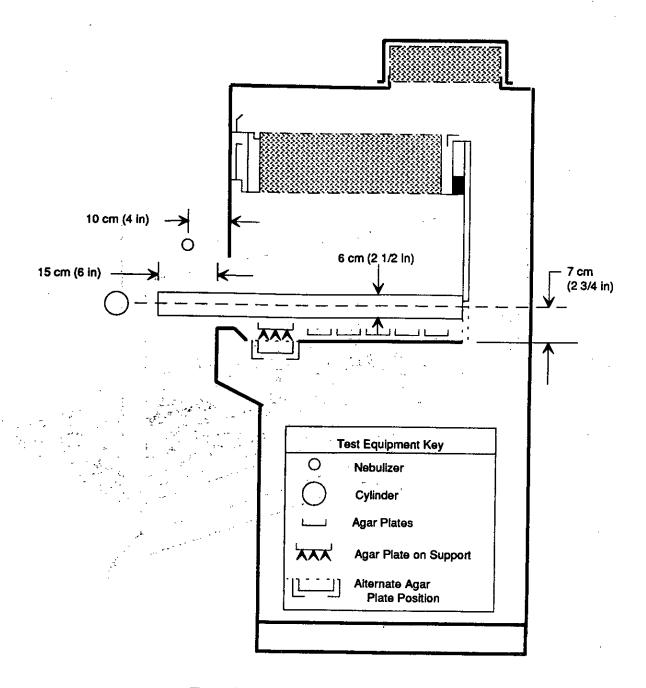


Figure A-11. PRODUCT PROTECTION TEST

33.

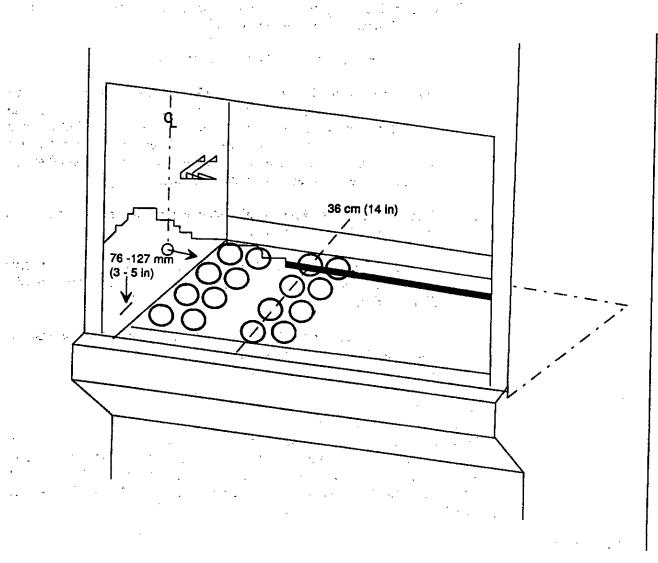


Figure A-12. CROSS CONTAMINATION TEST

E. Cross-Contamination Test (system challenged by 1 to 8 x 10⁴ <u>B. subtilis</u> spores for 5 min.)

1. Method

- a. Position the horizontal spray axis of the nebulizer containing 55 mL of 5 to 8 x 10⁴ spores/mL 76-127 mm (3-5 in) above the work surface, with the back of the nebulizer located against the midpoint of the left interior side wall. The spray axis is parallel to the work surface and is directed toward the opposite side wall.
- b. The cabinet shall be set at the nominal set point.
- c. Place open agar settling plates (100 x 15 mm) on the work surface in the following manner (see Figure A-12). Two rows of control plates with the centerline under the outlet of the nebulizer. One row of plates with their centers on a line drawn front to back 36 cm (14 in) from the side wall being tested. Nest at least one more row of plates beyond the 36 cm (14 in) row; two rows when there is room.
- d. Start the nebulizer. After 5 min, stop the nebulizer but continue to operate the cabinet for 15 min.
- c. Let the cabinet motor run while placing the covers on the open agar plates. Incubate the plates at 37°C (98.6°F) and examine them at 24 28 h. If negative, reincubate and read at 44 48 h.
- f. Perform the same procedure (a e), but place nebulizer against the midpoint of the right interior wall.

2. Acceptance

Some agar plates, from the challenge sidewall to 36 cm (14 in) from the sidewall, will recover <u>B. subtilis</u> CFU and shall be used as controls. The total number of CFU recovered on agar plates with centers greater than 36 cm (14 in) shall not exceed 2 CFU per test. Three replicates each shall be performed from the left and right sides of the cabinet.

VIII. STABILITY TESTS

A. Purpose

These tests demonstrate the structural stability of a biohazard cabinet for:

1. Resistance to overturning under applied forces (refer to UL 1262, cited in section 5.8.1 of this standard).

- Resistance to distortion under applied forces;
- 3. Resistance to deflection of work surfaces under load; and
- 4. Stability with respect to tipping under load.

Tests are performed by applying static force couples or loads, as described below, and measuring the distortion or deflection within the cabinet.

B. Apparatus

- 1. Compression force gauge, calibrated in pounds, with an accuracy of \pm 5% full scale, or
- 2. Extension spring balance, calibrated in pounds, with an accuracy of \pm 5% full scale.

NOTE: Where an extension type spring balance is used, force shall be applied as "pull" at opposite side of device from that specified in methods below.

Test Loads

- a. 113 kg (250 lb) uniformly distributed over an area of 25 x 25 cm (10 x 10 in).
- b. 23 kg (50 lb) uniformly distributed over an area 25 x 25 cm (10 x 10 in).

C. Resistance to Distortion

1. Method

- Bolt device securely to firm base or floor to prevent overturning and lateral movement.
- b. Apply force of 113 kg (250 lb) at top rear and one top side edge. Measure forward deflection of top front edge, and opposite top side edge with dial micrometer (see Figures A-13 and A-14).
- c. Report deflection.

2. Acceptance

The top front edge and the top of the sides shall not move forward more than 0.2 cm (1/16 in) from static position when a 113 kg (250 lb) lateral force is

 applied to the top rear edge and top of the opposite side, respectively.

D. Resistance to Deflection of Work Surface Under Load

1. Method

- a. Measure distance from center point of front edge of work surface to floor.
- b. Place the 23 kg (50 lb) test load at the center of the work surface, distributed over an area 25 x 25 cm (10 x 10 in). Remove the test load and measure the distance from the center point of the front edge of work surface to the floor (see Figure A-15).

2. Acceptance

There shall be no permanent deflection of the work surface after applying and removing the 23 kg (50 lb) test load.

E. Resistance to Tipping (Applicable only to free standing devices with work surfaces)

1. Method

Place the 113 Kg (250 lb) test load centered from right to left of the work surface on the leading edge of the cabinet (see Figure A-16).

2. Acceptance

The rear bottom of the cabinet shall not lift off the floor more than 0.2 cm (1/16 in) when a 113 Kg (250 lb) test load is applied.

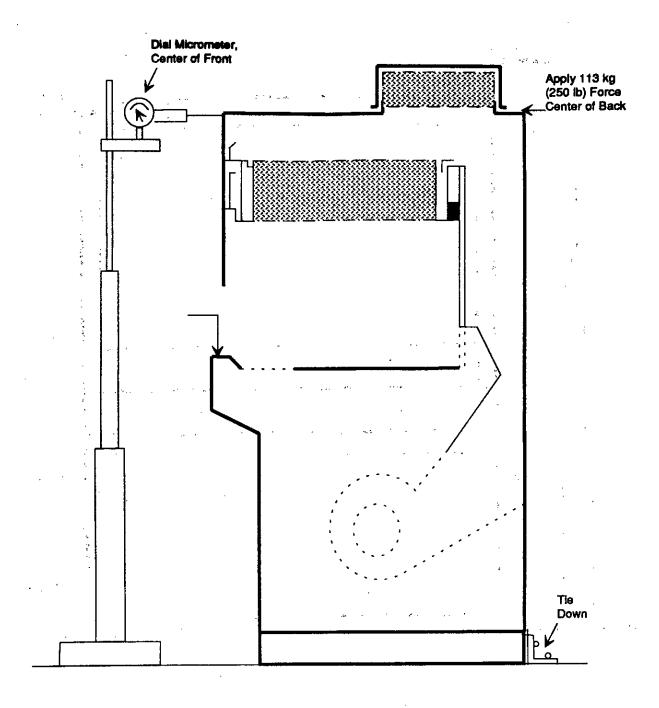


Figure A-13. RESISTANCE TO DISTORTION

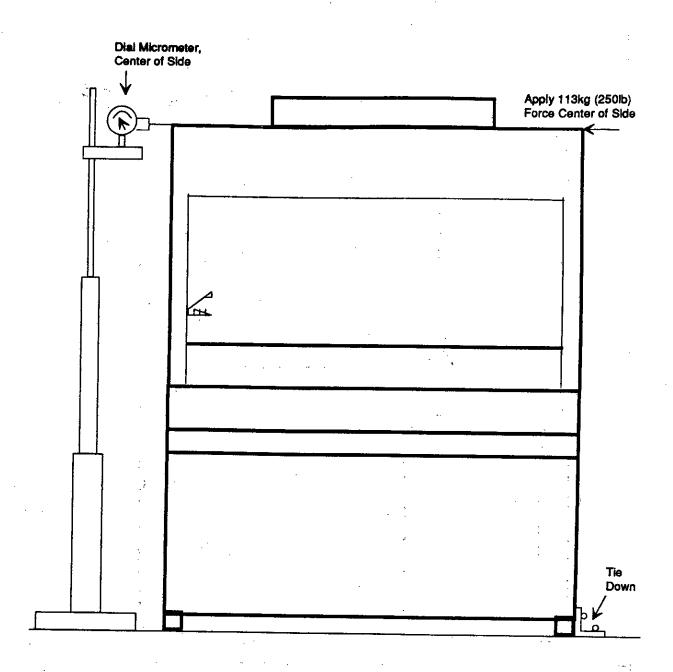


FIGURE A-14. Resistance to Distortion

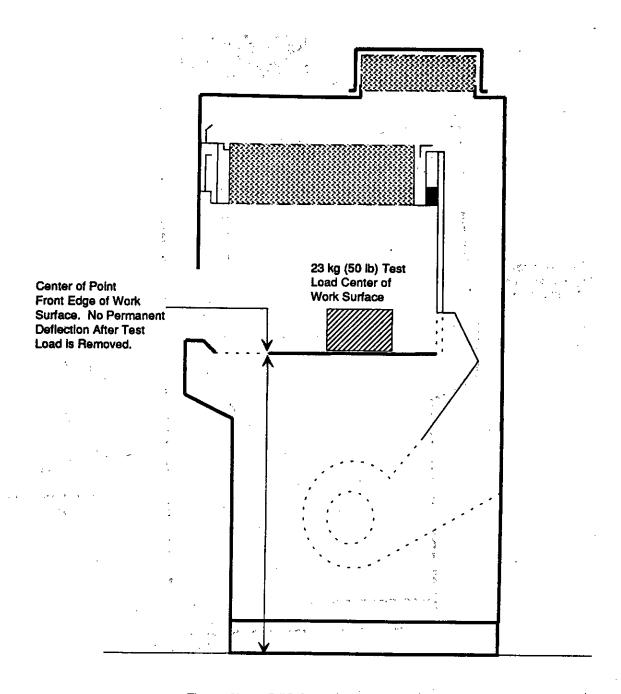


Figure A-15. RESISTANCE TO DEFLECTION

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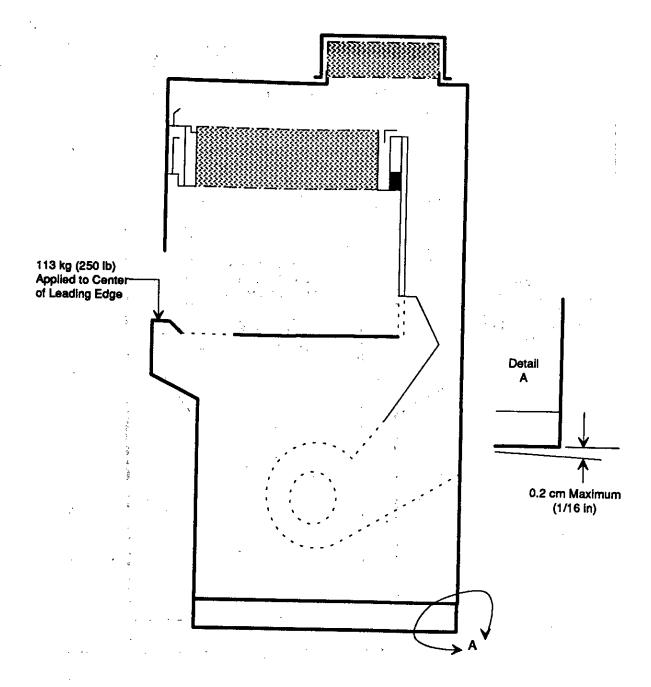


Figure A-16. RESISTANCE TO TIPPING

IX. DOWNFLOW VELOCITY

A. Purpose

This test measures the velocity of air moving through the cabinet work space at the bottom edge of the window, and is performed on all cabinets accepted under Section VII.

B. Apparatus

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A thermoanemometer with an accuracy of \pm 0.01 m/s (\pm 2.0 fpm) or 3% of the indicated velocity, whichever is larger, shall be used. The device shall be calibrated in accordance with the thermoanemometer manufacturer's instructions or IES-RR-CC-013-86t if instructions are not provided. When applicable, an altitude correction factor from the manufacturer's manual for the thermoanemometer shall be consulted for the appropriate correction calculation.

C. Method: downflow velocity

Setting nominal set point

a. Uniform downflow cabinets

Measure the air velocity at multiple points across the workspace, using equal points in the horizontal plane defined by the bottom edge of the window frame using the following spacing:

- A uniform rectangular grid with spacings no greater than 15 x
 15 cm (6 x 6 in) and containing a minimum of 3 rows and 7 readings per row.
- Perimeter air velocity readings shall be taken 15 cm (6 in) away from the walls and window enclosing the work area (See Figure A-17).
- Removeable equipment shall be removed prior to the setting of the nominal set point when instructed by the manufacturer.

The air measurement probe shall be held rigidly in a free-standing fixture that permits accurate positioning and does not distort the airflow pattern (ring stand and clamp). Reported values shall be each of the readings included in the applicable grid, and the overall average of these readings. The nominal set point shall be based on this average.

b. Non-uniform (zoned) downflow cabinets

Measure the air velocity at multiple points across the work space in zones defined by the manufacturer in the horizontal plane defined by the bottom edge of the window frame. Manufacturer's instructions shall

include location of zone boundaries, number of points within each zone, the specific grid to be used with equidistant spacing, and the removeable equipment shall be removed prior to setting the nominal set point when instructed by the manufacturer. When there is a supply air diffuser, either remove it or leave it installed in accordance with the manufacturer's instructions. Reported values shall be each of the readings taken in each of the zones and the average of each zone. The nominal set point shall be based on the above data in accordance with the manufacturers instructions.

2. Zone Uniformity

If previously removed, the diffuser and other removeable components shall be reinstalled. The procedure provided in IX.C.1 shall then be performed using the manufacturer's defined zones. The reported values shall be each of the readings included in each of the zones and the corresponding averages of each zone.

D. Acceptance

The average downward airflow velocity through the cross section of the unobstructed work area at the level of the bottom of the window of cabinets meeting the requirements of Section VII shall be the value specified by the manufacturer. Subsequent production cabinets of the initial model and size complying with Section VII may also qualify if the measured downflow velocity set point is within \pm .025 m/s (\pm 5.0 fpm) of the nominal downflow velocity set point, and any additional velocity readings specified by the manufacturer, are provided. Individual point readings in cabinets with uniform downflow shall not vary more than \pm 20% from the average downflow velocity. Individual point readings shall not vary more than \pm 20% from the average of each gradient zone, when the downflow is specified as non-uniform downflow (zoned) by the manufacturer.

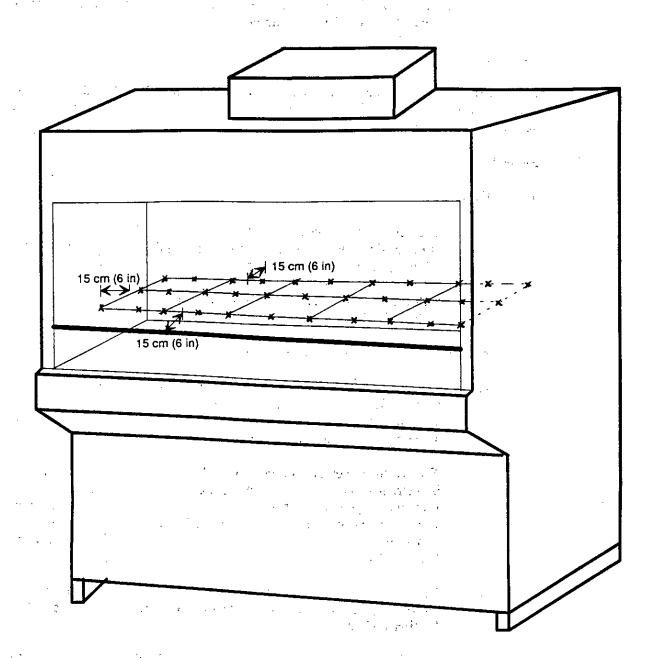


Figure A-17. VELOCITY PROFILE TEST

X. Inflow Velocity (Face Velocity) Test

A: Purpose

This test determines the calculated and measured inflow velocity through the work access opening, and calculated exhaust flow volume rates.

B. Apparatus

A thermoanemometer with an accuracy of \pm 0.01 m/s (\pm 2 fpm) or 3% of the indicated velocity, whichever is larger, and a direct airflow reading instrument calibrated in accordance with Annex B shall be used.

C. Methods

1. General

• The nominal set point average inflow velocity shall be determined by a direct airflow measurement method. In addition for Type A and B3 cabinets, after the nominal set point is determined by a direct measurement method, then readings should be taken by the calculated method. Both of these set point values must meet the requirements of section IX of the standard.

2. Method for Type A cabinets by anemometer measurement

- a. Air velocity measurements shall be taken at multiple points across the exhaust filter face on a 10 x 10 cm (4 x 4 in) grid, with the points approximately 10 cm (4 in) in from the filter frame, and 10 cm (4 in) above the face of the filter (see Figure A-18).
- b. The effective open area of the exhaust HEPA filter or exhaust port shall be measured. Do not include in the measurement blockage of area by filter frame, glue, patches, or any obstructions to airflow. Cabinets in which the exhaust filter is not accessible or exhaust port flow is nonuniform, such as caused by a damper, shall be tested as specified by the manufacturer.
- c. To obtain the exhaust flow volume in m/s (fpm), multiply the average air velocity in m/s (fpm) by the exhaust area in m² (ft²) measured in Section X.C.2.b.
- d. Calculate the average inflow velocity in m/s (fpm) by dividing the exhaust flow volume in m³/s (cfm) by the work access opening area in m² (ft²).

- e. Measure the width of the work area in m (ft) to the nearest 0.3 x 10⁻¹m (0.1 ft). Divide the exhaust flow volume in m³/s (cfm) by this width in m (ft) to determine the exhaust air volume rate in m³/s (cfm) per width of work area in m (ft).
- f. Reported values shall be the point velocity readings, average exhaust velocity, filter dimensions, effective exhaust area, work access opening dimensions and area, calculated average inflow velocity, width of the work area, and exhaust flow volume rate in m³/s (cfm) per m (ft) of work area width.
- g. Reported data shall include the method used for measuring and calculating the inflow velocity and the average calculated inflow velocity.
- 3. Measured method for Type B1 cabinets using an anemometer.

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- a. Turn off blower(s) that recirculate air in the cabinet, if specified in the manufacturer's instructions.
- b. Set sash (viewing window) to manufacturer's recommended operating height.
- c. Two rows of air velocity measurements shall be taken at multiple points in the plane of the access opening. One row shall be taken at a distance below the top of the access opening equal to 25% of the opening height. The second row shall be taken at a distance below the top of the access opening equal to 75% of the opening height (see Figure A-19).
- d. The indicated velocity measurements shall be taken every 10 cm (4 in) across the width of the front work access opening, but no closer than 10 cm (4 in) from sides of the work opening.
- e. Where measurements in the plane of the access opening are not practical, determine the inflow velocity in accordance with the manufacturer's instructions.
- f. Multiply the average inflow velocity in m/s (fpm) by the work access opening area in m² (ft²) to obtain the exhaust flow volume rate in m³/s (cfm).
- g. Measure the width of the work area in m (ft) to the nearest 0.3 x 10¹m (0.1 ft). Divide the exhaust flow volume in m³/s (cfm) by this width to obtain the exhaust air volume rate in m³/s (cfm) per m (ft) of work area width.
 - h. Reported values shall be the point and average exhaust velocities,

2.00

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effective exhaust area, work access opening area, calculated inflow velocity, width of work area, and exhaust flow volume rate per m (ft) of work area width.

- i. Reported data shall include the method used for measuring and calculating the inflow velocity and the average calculated inflow velocity.
- 4. Calculated method for Type B2 cabinets using an anemometer
 - a. Turn on cabinet supply blower and exhaust system blower.
 - b. Set sash (viewing window) at manufacturer's recommended operating height.
 - c. Measure and calculate exhaust volume in accordance with manufacturer's instructions, or American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) standards for air velocity measurements, in round or rectangular ducts.
 - d. Measure the downflow velocity on an approximate 10 x 10 cm (4 x 4 in) grid in a horizontal plane 15 cm (6 in) below the face of the supply diffuser, starting 50.8 mm (2 in) from each perimeter wall. Air measurement probe shall be held rigidly in a free-standing fixture (ring stand and clamp) that permits accurate positioning and does not distort air flow pattern (see Figure A-20). Average velocity readings and multiply by the area in m² (ft²) of the plane in which the velocities were measured, to determine the total filtered air supply in m³ (ft³).
 - e. Subtract the downflow air volume rate in m³/s (cfm) from the exhaust volume rate in m³/s (cfm); the difference represents the calculated inflow volume rate in m³/s (cfm).
 - f. Divide the calculated inflow volume rate by the area of the access opening in m² (ft²) to determine the average inflow velocity in m/s (fpm).
 - g. Reported values shall be point velocities, calculated average exhaust velocity, dimensions of filter, effective exhaust area, calculated exhaust volume, downflow air average velocity, effective downflow air area, calculated downflow air volume, area of the work access opening, calculated inflow air volume, calculated access opening average inflow velocity.

5. Measured method using a direct airflow reading instrument.

The direct airflow reading instrument completely encloses the cabinet face opening and has a constricted inlet section of known area. Reported values when using an instrument of this type are to be air volume rate, m³/s (cfm), work access opening area, m² (ft²), volume rate, m³/s (cfm), and average face velocity, m/s (fpm).

The air velocity measurements shall be taken at multiple points across the exhaust filter face on a 10 cm (4 in) grid, with the points approximately 10 cm (4 in) from the filter frame and 10 cm (4 in) above the face of the filter.

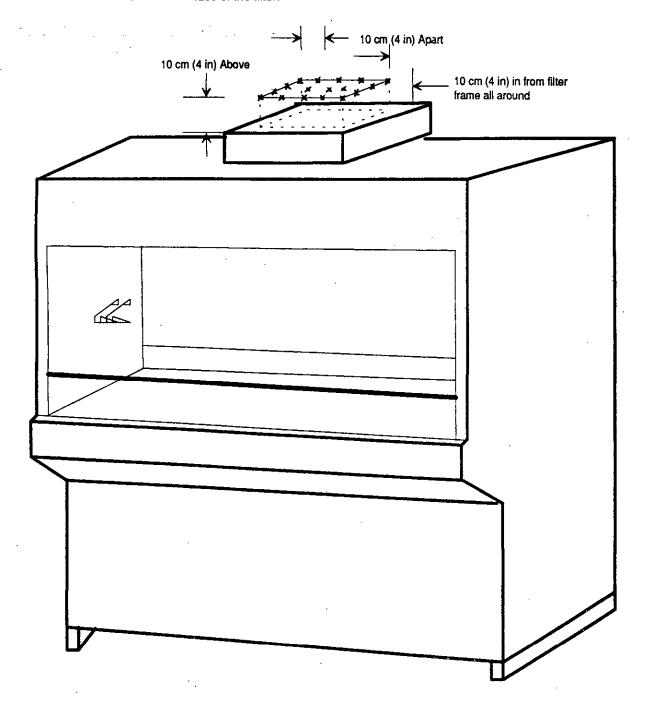


Figure A-18. CALCULATED INFLOW VELOCITY FOR CLASS II TYPE A

Take air velocity measurements at multiple points in the plane of the access opening. Take two rows of air velocity measurements. One row shall be taken at a distance below the top of the access opening equal to 25% of the opening height. The second row shall be taken at a distance below the top of the access opening equal to 75% of the opening height.

Indicated velocity measurements shall be taken every 10 cm (4 in) across the width of front work access opening, but no closer than 10 cm (4 in) from edges of work opening.

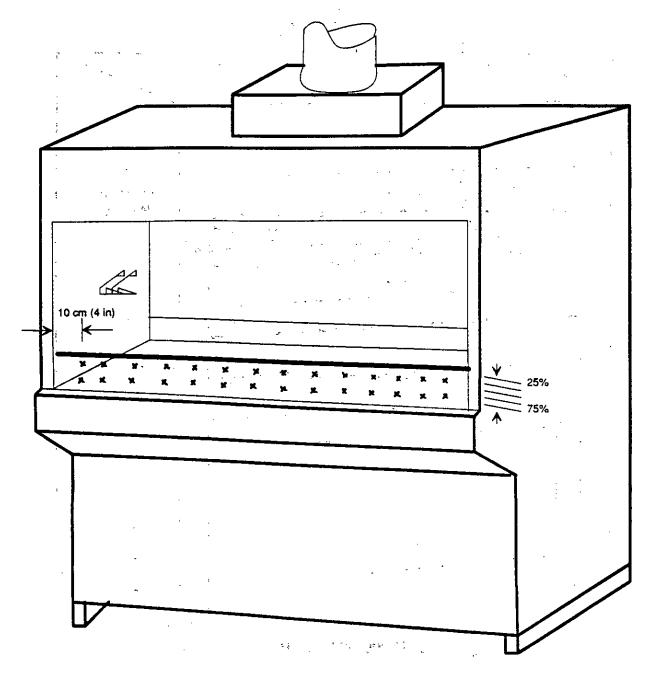
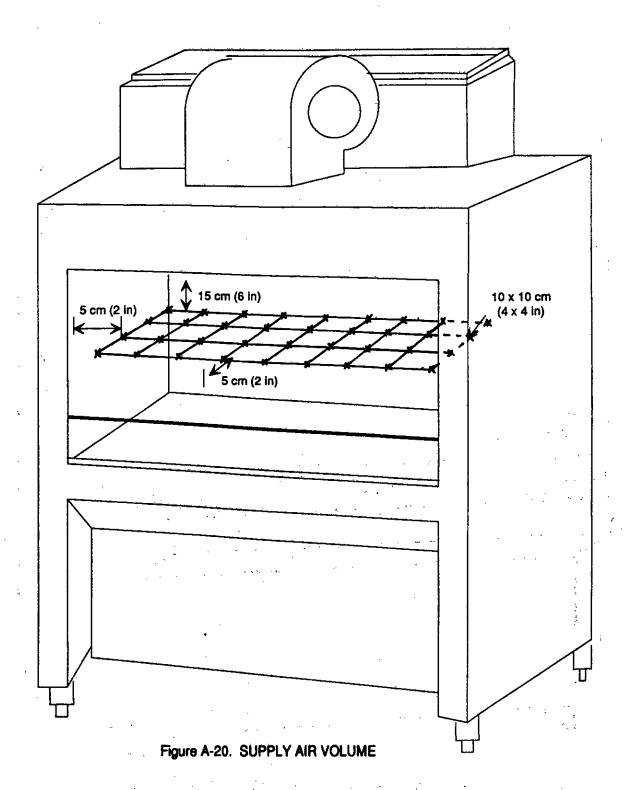


Figure A-19. ANOTHER EXAMPLE OF INFLOW VELOCITY CLASS II TYPE B

5.1



D. Acceptance

The inflow velocity through the work access opening of cabinets meeting the requirements of Section VII shall be calculated and directly measured. Subsequent production cabinets of the initial mode and size may also qualify as meeting Section VII when the calculated or directly measured inflow velocity is provided within $\pm 5 \times 10^{-3}$ m/s (± 5 fpm).

The minimum inflow velocity of Type A cabinets shall be 0.38 m/s (75 fpm). The minimum exhaust flow volume shall be 76 m³/h (45 cfm) per m (ft) of work area width (see Sections VII and IX).

The minimum face velocity of Type B cabinets shall be 0.5 m/s (100 fpm). The minimum exhaust flow volume shall be 110 m³/h (65 cfm) per m (ft) of work area width (see Sections VII and IX).

XI. AIRFLOW SMOKE PATTERNS TEST

A. Purpose

This test determines that the airflow along the entire perimeter of the work access opening is inward, airflow within the work area is downward with no dead spots or refluxing, ambient air does not pass on or over the work surface, and there is no refluxing to the outside at the window wiper gasket and side seals.

B. Apparatus

A source of visible smoke such as titanium tetrachloride.

NOTE: Titanium tetrachloride is corrosive and should be handled with care.

C. Method

- 1. Smoke shall be passed from one end of the cabinet to the other, along the centerline of the work surface at a height of 10 cm (4 in) above the top of the access opening. The smoke shall show smooth downward flow with no dead spots or reflux (upward flow).
- 2. Smoke shall be passed from one end of the cabinet to the other, 25 cm (1 in) behind the view screen, at a height 15 cm (6 in) above the top of the access opening. The smoke shall show smooth downward flow with no dead spots or reflux. No smoke shall escape from the cabinet.
- Smoke shall be passed along the entire perimeter of the work opening edges, approximately 4.0 cm (1.5 in) outside the cabinet. Particular attention should be paid to comers and vertical edges. No smoke shall be refluxed out of the cabinet once drawn in, nor shall smoke billow over the work surface or penetrate onto it

4. For cabinets with sliding sashes, smoke shall be passed up the inside of the window at the side channel seals, and along the inside of the cabinet immediately below the wiper gasket. There shall be no upward refluxing, nor escape of smoke from the cabinet.

D. Acceptance

Directional airflow, as shown by smoke, shall comply with Sections XI.C.1, XI.C.2, XI.C.3, XI.C.4.

XII. DRAIN SPILLAGE TROUGH LEAKAGE TEST

A. Purpose

This test demonstrates the containment capability of the spillage trough under the work surface.

B. Method

Fill drain spillage trough with water and hold it for 1 h. Check for visible signs of water leakage after 1 h.

C. Acceptance

The drain spillage trough shall hold a minimum of 4 L (1 gal) of water, and have no visible leakage after 1 h holding period.

XIII. MOTOR/BLOWER PERFORMANCE

A. Purpose

This test demonstrates that the motor/blower will operate at a static pressure sufficient to meet the requirements of Item 5.13.

B. Apparatus

A thermoanemometer with an accuracy of \pm 0.01 m/s (\pm 2 fpm) or 3% of the indicated velocity, whichever is larger, shall be used. A manometer with an accuracy of \pm 2% of reading shall be used.

C. Method

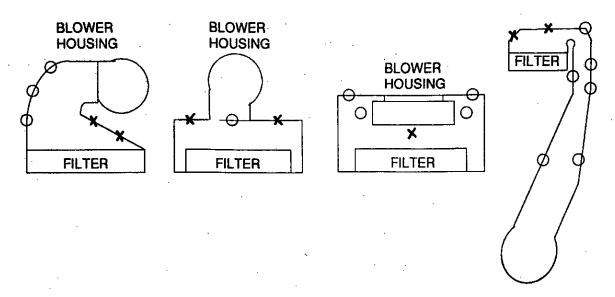
- 1. Set the cabinet at the nominal set point, \pm 0.01 m/s (\pm 2 fpm).
- 2. Measure the total airflow volume rate, m³/s (cfm), the cabinet blower is delivering at the nominal set point. (see section IX and X).

- Locate the manufacturer's supplied¹¹ positive and negative pressure taps. 3. Manufacturer shall locate the positive pressure tap directly above the supply HEPA filter to allow conversion of velocity pressure to static pressure. The positive pressure tap shall not be located in the face of the blower outlet (see Figure A-21). If more than one pressure tap is used, as in a piezometer ring, pressure taps may be connected together for an average reading. Manufacturer shall locate the negative pressure tap not less than one half equivalent diameter from the blower inlet. In the case of double inlet blowers, static measurements shall be made in both blower inlets and connected together for an average static pressure (see Figure A-22). If it is not possible to mount both static pressure taps due to cabinet design, one tap will be sufficient. For negative pressure tap use Dwyer instruments A-300 series pressure tap or equivalent. manometers to each pressure tap and record result. The positive pressure reading is the initial static pressure reference point. The sum of the positive and negative readings without reference sign is the total fan static pressure.
- 4. Increase the negative pressure reading 50% or more of the positive pressure reading by restricting the cabinet front inlet grill with the use of muslin, scott foam, etc., until the new total fan static pressure equals the sum of the initial fan total static pressure plus 50% of the initial fan rate, m³/sec.
- 5. Measure the total volume of airflow (cfm) the restricted cabinet blower is delivering (see sections IX and X).
- 6. Record the initial and final positive and negative pressures and initial and final airflow rates.

D. Acceptance

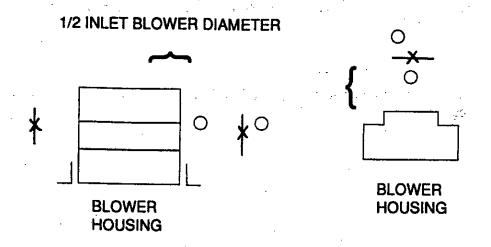
The total airflow volume rate, m³/s (cfm) shall not decrease more than 10% meeting the requirements of section 5.13.

¹¹Manufacturer to supply positive and negative pressure taps (see Figures A-21 and A-22) on units submitted for laboratory certification.



X Correct Location = Acceptable Tap Location
O Incorrect Location = Unacceptable Tap Location

Figure A-21 POSITIVE PRESSURE TAP PLACEMENT



X = Acceptable Tap Locations
O Incorrect Location = Unacceptable Tap Locations

FIGURE A-22 NEGATIVE PRESSURE TAP PLACEMENT

XIV. ELECTRICAL LEAKAGE, GROUND CIRCUIT RESISTANCE AND POLARITY TESTS

A. Purpose

These tests are performed to determine if a potential shock hazard exists by measuring the electrical leakage, polarity, ground fault interrupter function, and ground circuit resistance to the cabinet ground connection.

B. Apparatus

- 1. Electrical safety analyzer (ESA) with 1 K Ω input impedance and 2 leads; one with a sharp point, one with a probe.
- 2. Leviton model 6185 GFI circuit tester, or equivalent.

C. Method

1. Electrical Leakage

- a. Place all cabinet electrical switches in off position.
- b. Plug cabinet main power cord into an adapter plug (a 3-hole electrical receptacle on one end, a two-prong plug on the other) and insert adapter into an electrical outlet.
- c. Insert one lead from ESA into a grounding (round) hole of an adjacent electrical outlet and with the other lead (having a sharp end) make firm contact with the cabinet work surface, and other exposed conductive cabinet surfaces.
- d. Turn the ESA function selector to the microamp scale that gives the best reading.
- e. Repeat steps a-d with all cabinet electrical switches in the on position.
- f. Repeat steps a through e with reversed polarity (reverse two-prong plug of adapter in the outlet).
- g. Repeat steps a through f on the second power cord when cabinet has two.

2. Ground Circuit Resistance

- a. Turn off the blower, lights, and accessories.
- b. Prepare the resistance test portion of the electrical safety tester for use in accordance with the manufacturer's instructions.

- c. Connect a test lead from the electrical safety tester to the work surface. If the tester has additional leads, connect these to other exposed metal surfaces on the front facing of the cabinet. If there are no other leads, move existing lead to other exposed metal surfaces after each resistance reading.
- d. Read the resistance for each lead or location.

3. Polarity and Ground Fault Interrupter

- a. Turn off the receptacle switch when present on the unit. When the unit has a separate line cord for the duplex circuit, plug it in.
- b. Set gfi tester to "polarity" and plug into each duplex outlet in the cabinet. When polarity is correct, the two yellow lights will light equally. Any other combination of lights indicates a defect as identified on the tester.
- c. On units with ground fault interrupters, unplug all accessories and plug the tester into the last receptacle in the gfi protected branch (in a 2 receptacle cabinet this is usually the receptacle that does not have the gfi).

Turn selector switch to 1, 2, and 3 ma positions. If the gfi trips, the lights on the tester will go out indicating leakage in the cabinet wiring that must be located and repaired.

When the lights on the tester do not go out, turn the selector switch to "gfi trip test". The lights on the tester should go out. If they do not, the gfi is defective or the circuit is not gfi protected and there is leakage in the cabinet wiring that must be located and repaired. Turn the selector switch back to "polarity" and reset the gfi. The lights on the tester should turn on as in step 3.b.

D. Acceptance

The electrical leakage shall not exceed 500 ma and the ground circuit resistance shall not exceed 0.15 ohms. Cabinets with primary-circuit filtering may qualify when they comply with UL 1262.

ANNEX B

Method For Calibration Of Devices For Direct Measurement Of Inflow

(This Annex is part of Standard 49.)

- A. Calibrate the basic measuring portion of the device in a wind tunnel with NIST traceable calibration (e.g. for devices with removable hoods, calibrate the device without a hood installed; for devices using thermoanemometers, calibrate the thermoanemometer). A pitot tube constructed according to the dimensions given in the Industrial Ventilation Manual¹ is a primary standard and needs no other verification.
- B. Install the device using one of the two following methods.
 - 1. Seal the device to the front opening of a Class II Type B2 or B3 biological safety cabinet hard connected. Connect the exhaust of the cabinet to a duct containing a calibrated orifice meter or other calibrated flow meter. If a B2 cabinet is used, turn off the downflow blower and seal the supply air opening. If the cabinet has a moveable sash, seal the sash.
 - 2. Seal the device to the front opening of a Class II Type A or B3 biological safety cabinet intended to be thimble connected. Seal a calibrated flow hood, such as Shortridge model CFM-88, to the cabinet exhaust. If the cabinet has a moveable sash, seal the sash. The cabinet exhaust filter open area must be larger than the section of the flow hood where readings are taken [35 x 35 cm (14 x 14 in) for the Shortridge unit].
- C. Run the cabinet at a number of airflow velocities in a range spanning the highest and lowest airflows the device will be required to measure. Record the readings of the device and the flow hood or orifice meter and calculate the difference.
- D. Using the configuration of paragraph B.2, measure the exhaust flow both with the device installed and removed. Take at least 5 readings in each configuration. The difference should not exceed 2%.
- E. The calibration is valid for cabinets of the size used and smaller. It is recommended that 2 m (6 ft) cabinets be used in this procedure.

¹American Conference of Industrial Hygienists, "Industrial Ventilation, A Manual of Recommended Practice," 6500 Glenway Ave., Building D7, Cincinnati, OH 45211.

ANNEX C

NEBULIZER SELECTION AND CALIBRATION

(This annex is part of NSF Standard 49)

I. SELECTION

A. Criteria

Nebulizers are acceptable when they:

- 1. Deliver 1-8 x 10⁸ airborne spores of <u>Bacillus subtilis</u> var. <u>niger</u> in 5 min.
- Deliver $94 \pm 6\%$ single cell spores.
 - 3. Have a spore aerosol discharge velocity of 30.5 m \pm 3 m (100 \pm 10 ft) per minute.

Special Notes:

- 1. Tests performed by First et al. demonstrated that a stainless steel 6-jet collision refluxing nebulizer will deliver the bacterial spore aerosol required in paragraph 5.7.1 when the following conditions are met:
 - Nebulizer equipped with a glass flask 5 cm (2 in) in diameter, 9 cm (3.5 in) high and a 23 mm (0.9 in) ID horizontal discharge spout on top.
 - Operated at 140 kPa (20 psi);
 - 55 mL of a 5 to 8 x 108/mL spore suspension is placed in the flask.
 - The bottom of the 6-jet spray head is 1.8 cm (11/16 in) above the bottom of the flask.
 - Six rosette patterns created by the air jets form on the inside of the glass flask. (These should be observed frequently for size and contour to verify that the jets are not clogged or obstructed.)
- 2. The 6-jet collision refluxing nebulizer need not be retested for performance before use.

¹First, M. W., Stuart, D., Webb, T., <u>Report of NSF Standard Number 49 Ad Hoc Task Group to Recommend Revisions to Appendix C</u>, November 5, 1986.

II. CALIBRATION

A. Purpose

To demonstrate that a nebulizer conforms with all the criteria cited in section I.A.

B. Site

Nebulizer shall be calibrated in the laboratory where it is being used.

C. Frequency

Prior to first use and periodically thereafter.

D. Materials

- 1. A suspension of 5-8 x 108 Bacillus subtilis var. niger spores per mL
- Nebulizer to be calibrated
- 3. One all glass ACI-30 impinger sampler
- 4. Switching timer
- 5. Membrane filter funnel (47 mm filter size) with silicone rubber diaphragms sealed to each end with RTV. Diaphragms are perforated to insert the outlet of the nebulizer at the wider and one impinger sampler at the other end. Insertions shall be tight on the impinger end. Insertion shall be loose on the nebulizer end so that the impinger is operating in atmospheric pressure, not in a closed system.
- 6. Flow meters
- 7. Pressure gauge
- 8. A 37 mm aerosol type membrane filter in sampling cassette with an open face.

E. Method

- 1. Measure nebulizer outlet dimensions and calculate the area in ft².
- 2. Calculate airflow (cfm) through the nebulizer required to result in 100 fpm discharge velocity.
- 3. Add manufacturer's recommended volume of spore suspension to the nebulizer.
- 4. Place the outlet of the nebulizer in the rubber diaphragm of the wide end of the filter funnel. Insert the collecting tube of the impinger sampler through the

rubber diaphragm on the opposite end of the filter funnel. Insure a tight fit at impinger end.

NOTE: The all glass impinger (chemical corps type) comes in two versions: (1) an impinger with tip submerged in liquid 4 mm from flask bottom and passing 6 Lpm at a pressure drop of 8 psig or greater (ACE Glass No. 7541 impinger) and (2) an impinger with tip above the liquid surface and passing 12.5 Lpm at a pressure drop of 8 psig or greater, known as AGI-30, (ACE Glass No. 7540 impinger). Either impinger may be used. When the air delivery rate of the nebulizer is not precisely 6 or 12.5 Lpm, select the impinger that samples at a higher rate and bleed in through an opening around the nebulizer insertion an amount of air equal to the difference in the two airflows. If the nebulizer and the impinger are to be operated at the same flow rate, a snug fit in the diaphragm at both ends is recommended.

- 5. Attach hose to a pressure gauge attached to flow meter, then to nebulizer.
- 6. Simultaneously turn on the nebulizer (maintain airflow through the nebulizer to result in a calculated 30.5 m (100 ft) per minute output velocity based on airflow (cfm) and diameter of the discharge spout 12.5 L/m for the 6-jet collision described in this Annex) and the impinger sampler (operating according to manufacturer's instructions). Operate nebulizer for 5 min (using the switching timer) and the impinger sample for 5 1/4 min.
- 7. Aseptically transfer the impinger sampler collecting fluid to a sterile 500 mL graduated cylinder. Rinse the funnel, impinger stem and bottle with sterile water to insure collection of all spores, and collect all rinse water in the graduated cylinder.
- 8. Measure and record the volume of fluid in the graduated cylinder. Transfer all the fluid aseptically to a sterile flask containing a magnetic stirrer and mix thoroughly.
- 9. Prepare serial dilutions and quantify spore concentration by five replicate platings.
- 10. Actively sample the bacterial aerosol with membrane filter located in its design mode. After sampling is completed, stain the membrane with an appropriate dye. Count the number of deposits containing single and more than one bacterium in representative fields under a microscope.

F. Calculations

- 1. Number of spores delivered in $5 \text{ min} = (\text{dilution factor}) \times (\text{average number of CFUs on the 5 plates}).$
- 2. Velocity of air leaving nebulizer = the air volume measured in IIE3 in cfm

divided by nebulizer outlet area in ft2.

3. Calculate percent of single bacteria in the total aerosol sample.

G. Acceptance

- 1. The average of 5 replicate calibration tests shall fall between 1 and 8 x 10⁸ spores per 5 min nebulizer operation.
- 2. Velocity of air leaving the nebulizer shall be $30.5 \text{ m} \pm 3 \text{ m} (100 \pm 10 \text{ ft})$ per min.

ANNEX D EVALUATION OF CLEANABILITY, CHEMICAL RESISTANCE, AND ABRASION RESISTANCE OF SURFACES

(This Annex is part of Standard 49.)

I. CLEANABILITY OF SURFACES

A. Soil Formulation

The following soil formulation (by weight) will be used, a portion of each ingredient being radioactive.

Triolate

62.5%

Tristearate

37.5%

C14 Triolate

0.5 MCI

B. Apparatus

- Detection, counting, and recording system
- Dishwashing machine capable of delivering the following with only a lower spray arm:

Wash - 2 min at $72^{\circ} \pm 1^{\circ}C$ (162 ± 2°F)

Rinse - 1 min at $72^{\circ} \pm 1^{\circ}C$ (162 ± 2°F)

C. Evaluation Method

1. General

- a. Soiling shall consist of four 4 cm (1.5 in) diameter circles at 90-degree intervals, each independently soiled (see Figure D-1).
- b. Counting areas shall consist of the same four 4 cm (1.5 in) diameter circles.
- c. Samples shall be positioned in the holding device of counting system, in identical positions during initial and residual soil counting sequences.
- d. Samples shall be flat 13 x 13 cm² (5 x 5 in²) sections cut from parent material.

2. Soiling

Soiling of samples and controls shall be performed as follows:

- a. A measured volume, selected to provide a uniform thickness of soil over a defined area, shall be applied using a syringe and 16 gauge needle. The thickness of soil shall permit uniform application and minimize the effects of self-absorption on evaluation of soil quantities.
- b. To assure ease in uniformity of application of soil, the sample and heated soil shall be exposed in a uniform manner to an infrared heating facility for a fixed period of time. Care must be taken to assure that heat intensity shall not modify or alter the material and/or finish of sample being soiled.
- c. Radioactivity of the initial soil shall be determined for each soiled area of each sample.

3. Counting

a. Detection, counting, and recording of radioactive intensity of the initial and residual soils shall use the systems previously specified, or equal.

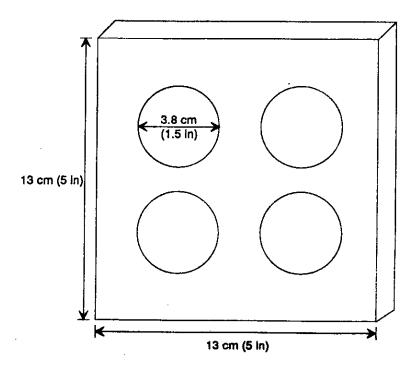


Figure D-1. Diagram of Soiling Areas

b. The following apply:

- All counting shall be based on efficiency of the system for each given material.
- Each counting period shall be of sufficient time to assure statistical significance of results.
- Each sample and control shall be located for counting to assure identical positioning during initial and residual soil determinations.

4. Washing

- a. Following initial soiling and counting, samples are washed in a dishwashing machine.
- b. Cycles and water temperatures are as follows:

72°C (160°F) wash and rinse waters
Wash - 2 min
Dwell - 30 seconds

Rinse - 1 min

During washing, all samples and controls are individually and identically positioned in a specially modified dish rack.

5. Statistical Analysis

Statistical analysis of data shall be accomplished through computer calculation of micrograms of residual soil, and development of 90% confidence levels (average limits P-90) by Students Distribution Method (American Society for Testing and Materials [ASTM] Manual on Quality Control of Materials; Special Technical Publication 15-C, January 1959).

D. Acceptance

Materials used for interior work and exposed interior surfaces shall have a finish with a cleanability at least equal to a Number 3 finish on 300-series stainless steel. Other interior and exterior surfaces shall have a finish with a cleanability at least equal to commercial grade, hot-rolled steel, free of visible scale. Residual soil shall not be more than the soil remaining on the control surface.

II. CHEMICAL RESISTANCE

A. Chemicals

The following chemicals shall be used for resistance testing:

4% hydrochloric acid

4% sodium hydroxide

1% quaternary ammonium compound

5% formaldehyde

5,000 ppm hypochlorite

2% iodophor

5% phenol

70% ethyl alcohol

B. Method

Chemical spot tests shall be made by applying 10 drops (approximately 0.5 mL) of each reagent to the surface to be tested. Each reagent is to be covered by a watch glass, convex side down, in the center of the puddle, to hold reagent in place. Reagents shall be allowed to remain on the surface for 4 h, and tests shall be performed so the testing surface is wet throughout the entire test period. After 4 h, the surface shall withstand scrubbing with a stiff brush and hot water at 72°C (160°F). Samples shall be dried before examination. Surface stains of dyes shall be removed with an alcohol wash before examination.

C. Acceptance

When exposed to the chemicals listed or special chemicals, the surface shall show no visible effect on the finish, other than a slight change of gloss, slight discoloration, or temporary slight softening of the finish, with no loss of adhesion and film protection.

III. ABRASION RESISTANCE

A. Method

A protective coating shall be applied in the recommended manner and properly cured on a panel of the prescribed substrate. It shall be evaluated on a Taber Abrader following the procedures of ASTM D1044-76 using a CS-IOS wheel, and a 1,000 gram load for 500 cycles.

B. Acceptance

The maximum weight loss for 500 cycles shall not exceed 100 mg. The substrate shall not be exposed during the test.

ANNEX E

RECOMMENDATIONS FOR INSTALLATION

(This Annex is not part of Standard 49, but is provided for information only.)

I. RECOMMENDATIONS FOR INSTALLATION

A. LOCATION

- 1. The Class II (laminar flow) biohazard cabinet should be located out of the traffic pattern, and away from room air currents that could disrupt the containment provided by the work access opening air barrier. Figure E-1 shows a suggested location after all air turbulence sources have been considered.
- 2. If there is a window in the laboratory, it should remain closed at all times. Cabinets should not be located where room ventilation air inlets blow across the front opening or onto the exhaust filter.
- 3. Where space permits, a 30 cm (12 in) clearance should be provided behind and on each side of the cabinet. If not feasible, a minimum 8 cm (3 in) clearance on each side and 4 cm (1.5 in) in back are recommended. The electrical outlet for the cabinet should be accessible for the cabinet service and electrical safety testing without moving the cabinet.

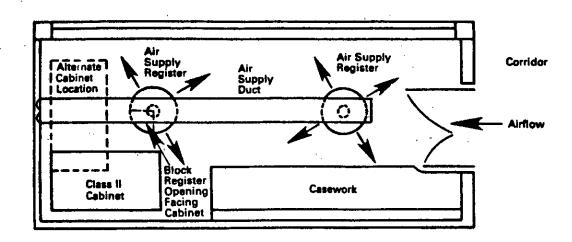


Figure E-1. Suggested laboratory location for Class II (laminar flow) biohazard cabinet.

B. VENTING

- 1. Type A cabinets are designed to return air to the laboratory, and do not generally require external venting. When it is desirous to exhaust air to the atmosphere, it should be via a 100% exhaust system (i.e. a system that does not recirculate its exhaust air into other parts of the building). The recommended exhaust system connection for a type A cabinet is a canopy connection as is shown in Figures E-2 and E-3. When a canopy is used, the opening in the canopy should be checked with a smoke stick when the cabinet is recertified to ensure that internal air turbulence does not cause outward air leakage. If the type A cabinet is hard connected to an exhaust system as is shown in Figures E-4 and E-5, the cabinet should be interlocked with the blower in the duct or the building system to prevent pressurization of the exhaust system. In addition, type A cabinets hard connected to an exhaust system should not be turned off, while the exhaust system is functioning.
- Type B cabinets are to be vented outside the building without recirculation. The 2. venting system should include a leak-tight duct, a damper in the duct near the cabinet to permit flow adjustment closure and decontamination, and an external exhaust fan as the final system component (see Figure E-6). The exhaust fan should be sized to deliver the required exhaust airflow (as specified by the cabinet manufacturer), considering pressure losses in the duct, and allowing at least 500 Pa (2 in wg) for a dirty HEPA filter. If a charcoal filter is used downstream of the HEPA filter, an additional pressure capacity equal to the manufacturer's recommended resistance should be provided. An alarm should be provided at the cabinet to indicate loss of exhaust flow. This can be a differential pressure switch across the exhaust filter, sail switch at the fan discharge, or flow measuring station in the exhaust duct. It is recommended that each Type B cabinet have its own (dedicated) exhaust system. The cabinet should be interlocked with the blower in the duct or the building system to prevent pressurization of the exhaust system. In addition, cabinets hard connected to an exhaust system should not be turned off.

NOTE: Type B cabinets "hard connected" to any exhaust system may require an anti-backflow device to prevent reverse airflow through the HEPA filter.

C. ELECTRICAL

Variations in line voltage may affect the cabinet airflows. A voltage regulator should be installed in order to reduce the potential of variations in airflows.

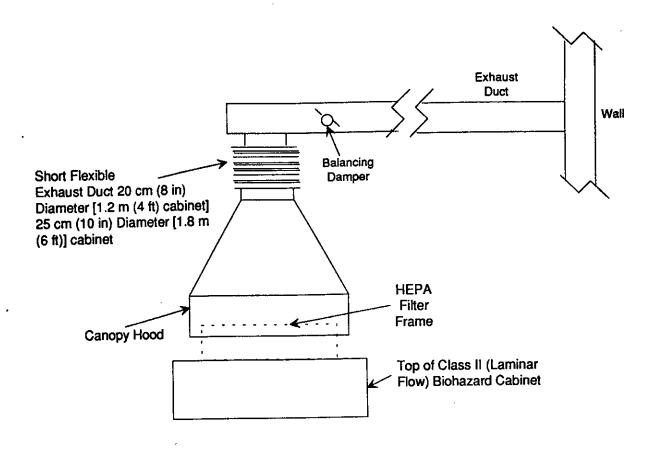
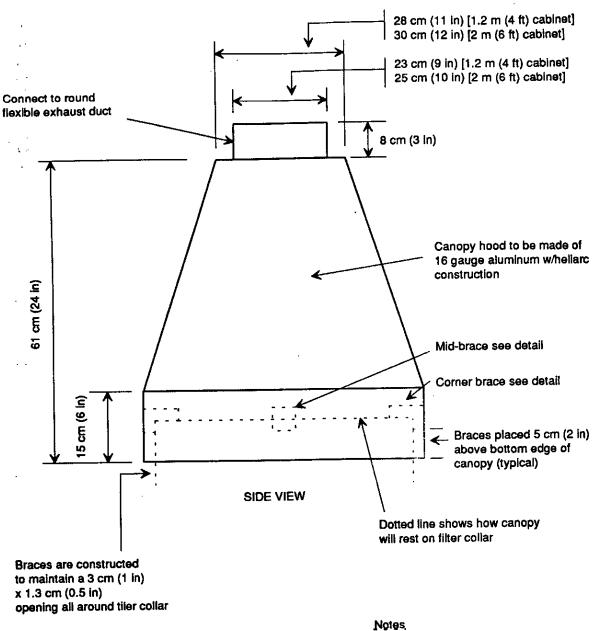


Figure E-2. SUGGESTED CLASS II (LAMINAR FLOW), TYPE A BIOHAZARD CABINET VENTING SYSTEM



1. Actual hood dimensions to be determined by designer

Figure E-3. Suggested canopy venting for Class II (laminar flow) Type A, biohazard cabinet

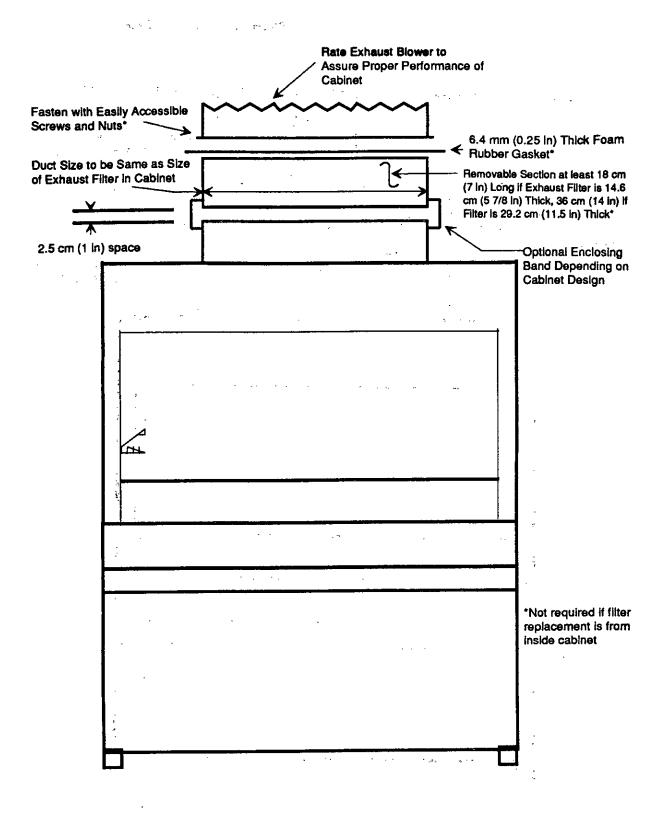


Figure E-4. ALTERNATE VENTING METHODS CLASS II (LAMINAR FLOW) BIOHAZARD CABINET WITH EXHAUST DUCT

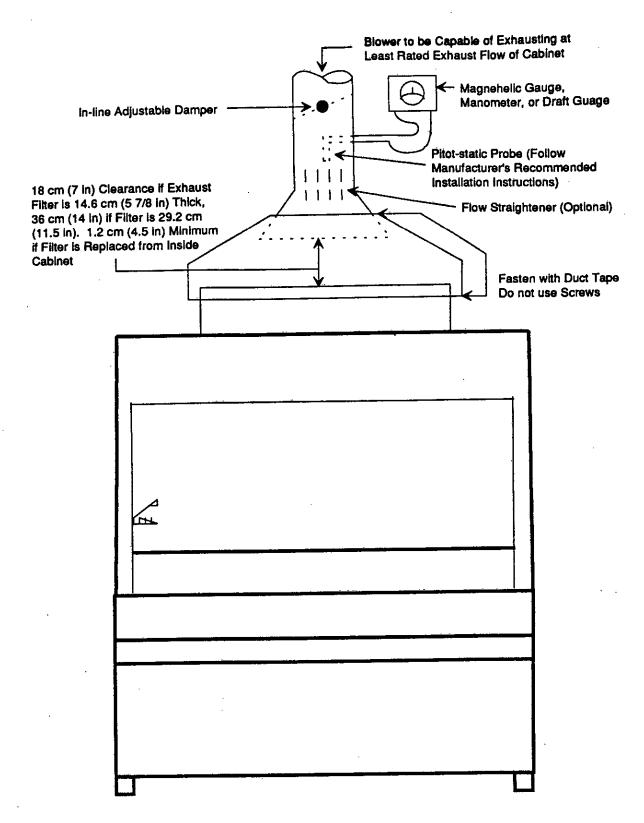


Figure E-5. ALTERNATE VENTING METHODS CLASS II (LAMINAR FLOW) BIOHAZARD CABINET WITH EXHAUST DUCT CONTAINING AIRFLOW MONITORING SYSTEM.

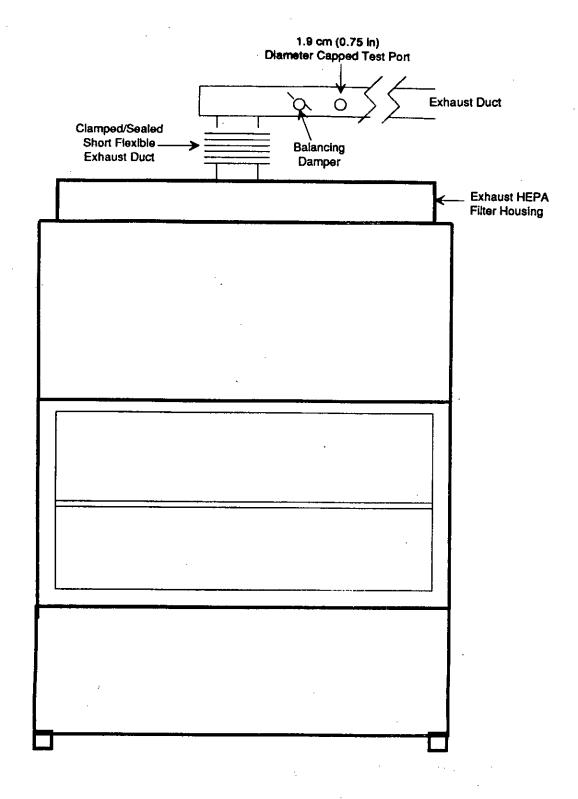


Figure E-6. ALTERNATE VENTING METHODS CLASS II (LAMINAR FLOW), TYPE B, BIOHAZARD CABINET WITH EXHAUST DUCTS.

ANNEX F

FIELD TESTS

(This Annex is not part of Standard 49 but is provided for information only.)

I	Field Certification Preconditions and Intervals F		F1
II	Field Test Procedures	and Acceptance Criteria	F2
	Test Method A	- Downflow Velocity and Volume	F2
	Test Method B	- Inflow Velocity	F4
	Test Method C	- Airflow Smoke Patterns	F8
	Test Method D	- HEPA Filter Leak Test	F9
	Test Method E	- Cabinet Leak Test	F12
	Test Method F	- Electrical Leakage and Ground Circuit Resistance and Polarity	F13
	Test Method G	- Lighting Intensity	F15
	Test Method H	- Vibration	F16
	Test Method I	- Noise Level	F17
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ANNEX F

FIELD TESTS

(This Annex is not part of Standard 49 but is provided for information only)

I. FIELD CERTIFICATION PRECONDITIONS AND INTERVALS

This Annex contains the field tests that define the methods and acceptance criteria that are appropriately applied for determining qualification for field certification of all Class II biological safety cabinets. Field certification is intended to confirm that an installed cabinet listed by NSF¹ as having met all design criteria contained in Sections 2 through 5 of NSF Standard 49 currently meets all criteria contained in this annex.

To assure that all cabinet operating criteria contained in this Annex continue to be met, each cabinet should be field tested at the time of installation, and at least annually thereafter. In addition, recertification should be performed whenever HEPA filters are changed, maintenance repairs are made to internal parts, or a cabinet is relocated². More frequent recertification should be considered for particularly hazardous or critical applications, or workloads. It is customary for the person conducting the designated tests to affix to the cabinet a certificate of satisfactory performance when it meets all field test criteria.

The following physical tests should be performed on-site:

- A. Tests directly related to containment, (i.e. personnel and environmental protection) and product protection.
 - 1. Downflow velocity profile test
 - 2. Inflow velocity test
 - 3. Airflow smoke patterns
 - 4. HEPA filter leak test
 - 5. Cabinet leak test (when cabinet is newly installed, relocated, or after maintenance procedures that require removal of panels)

¹Field certification of a cabinet is not intended to provide complete verification that the cabinet complies with all the requirements of this NSF Standard 49.

²<u>Microbiological</u> equipment that has been used with microorganisms should be decontaminated prior to repair or replacement of components located in contaminated plenums, prior to cabinet relocation, and in some cases prior to recertification. See Annex G, Recommended Microbiological Decontamination Procedure. When equipment has been used with chemical agents, appropriate protective clothing and safety procedures should be used during chemical decontamination.

B. Tests related to worker comfort and safety

- 1. Electrical leakage, ground circuit resistance, and polarity tests
- 2. Lighting intensity test
- 3. Vibration test
- 4. Noise level test

II. FIELD TEST PROCEDURES AND ACCEPTANCE CRITERIA

*A. Downflow Velocity and Volume Tests

1. Purpose

This test is preformed to measure the velocity of air moving through the cabinet workspace, and is to be performed on all cabinets.

2. Apparatus

A thermoanemometer with an accuracy of ± 0.01 m/s (± 2 fpm), or 3% of the indicated velocity, whichever is larger, is to be used.

The device is to be calibrated in accordance with the thermoanemometer manufacturer's instructions or IES-RR-CC-013-86T,³ if instructions are not provided. When applicable, an appropriate altitude correction should be used. The manufacturer's manual for the airflow reading device should be consulted for the appropriate correction calculation.

3. Method: Downflow Velocity

- a. To verify downflow nominal set point setting
 - (1) Uniform downflow cabinets.

Measure the air velocity at multiple points across the workspace, using equal points in the horizontal plane defined by the bottom edge of the window frame using the following spacing:

A uniform rectangular grid with spacings no greater than 15 x 15 cm (6 x 6 in), and containing a minimum of 3 rows and 7 readings per row.

³ IES-RP-CC-013-86T. Recommended Practice, Tentative. Institute of Environmental Sciences, 940 East North West Highway, Mt. Prospect, Illinois 60056, August 1986.

Perimeter air velocity readings are to be taken 15 cm (6 in) away from the walls and windows enclosing the work area (see figure A-17).

The air measurement probe is to be held rigidly in a free-standing fixture, (ringstand and clamp) that permits accurate positioning and does not distort the airflow pattern. Reported values are to be each of the readings included in the applicable grid m/s (fpm), and the overall average of these readings.

(2) Non-uniform (zoned) downflow cabinets

Measure the air velocity at multiple points across the work space in the zones defined by the manufacturer in the horizontal plane defined by the bottom edge of the window frame. The manufacturer's instructions are to include location of zone boundaries, number of points within each zone, the specific grid to be used with equidistant spacing, and the horizontal plane in which the readings are to be taken. When there is a supply air diffuser, either remove it or leave it installed in accordance with the manufacturer's instructions. Removable equipment is to be removed prior to the test when instructed to do so by the manufacturer. Reported values are to be each of the readings m/s (fpm) taken in each of the zones and the average of each zone.

Acceptance

- a. A cabinet Listed by NSF qualifies for field certification when the average downflow velocity through the cross section of the unobstructed work area at the level of the bottom of the window has (1) the average downflow velocity within \pm 0.025 mps (\pm 5 fpm) of the value specified by the manufacturer as that submitted to NSF and (2) has individual point readings that do not vary more than \pm 20% from the average downflow velocity, or
- b. A cabinet Listed by NSF, for which the cabinet manufacturer has specified a nonuniform (zoned) downflow velocity, qualifies for field certification when (1) the individual zone average downflow velocities are within ±0.025 m/s (±5 fpm) of the values specified by the manufacturer as those submitted to NSF and (2) the individual point readings do not vary more than ±20% from the averages of each zone specified by the manufacturer as those submitted to NSF.

B. Inflow Velocity Test

1. Purpose

This test is performed to determine the calculated or directly measured velocity through the work access opening to verify the nominal set point average inflow velocity and to calculate the exhaust airflow volume rate.

2. Apparatus

An anemometer with an accuracy of ± 0.01 m/s (± 2 fpm) or 3% of the indicated velocity, whichever is larger, or a direct airflow reading instrument calibrated in accordance with Annex B.

NOTE: The direct airflow reading instrument completely encloses the cabinet face opening and has a constricted inlet section of known area, making it possible to express the instrument's readings in m³/s (cfm). Reported values when using an instrument of this type are to be air volume rate, m³/s (cfm), work access opening area, m² (ft²), volume rate, m³/s (cfm), and average face velocity, m/s (fpm). These instruments must meet the minimum accuracy required for thermoanemometers.

3. Method

- a. For Type A Cabinets by Anemometer Measurement
 - (1) When the exhaust filter face is accessible
 - (a) Measure air velocity at multiple points across the exhaust filter face on a 10 x 10 cm (4 x 4 in) grid, with measurements 10 cm (4 in) above the face of the filter (see Figure A-18). Perimeter air velocity readings are to be taken 10 cm (4 in) in from the filter frame. The average velocity, m/s (fpm), is the sum of the individual readings divided by the number of readings.
 - (b) Measure the effective open area of the exhaust HEPA filter or the exhaust port taking into account open area blockage by filter frame, glue, patches, or any obstructions to airflow. Cabinets in which the exhaust filter is not accessible or the exhaust port flow is nonuniform are to be tested as specified by the manufacturer.
 - (c) Where measurements in the plane of the access opening are not practical, determine the inflow velocity in accordance with the manufacturer's instructions.

- (d) The exhaust flow volume in m³/s (cfm), is obtained by multiplying the average air velocity obtained in item 3a(1)(a) by the exhaust area measured in item 3a(1)(b).
- (e) The average face velocity in m/s (fps) is calculated by dividing the exhaust flow volume, m³/s (cfm), by the work access opening area, m² (ft²).
- (f) Reported values are to be the average exhaust velocity, m/s (fpm), effective exhaust area, m² (ft²), work access opening area, m² (ft²), and the calculated average face velocity, m/s (fpm).

(2) When the exhaust filter face is not accessible

- (a) Measure the inflow volume rate by the direct airflow measurement method, item IIB2, or with a standard pitot tube and liquid-filled inclined draft gauge in a duct section where the velocity is greater than 5.0 m/s (1,000 fpm) by the method of equal area transverses as defined in Industrial Ventilation³, except in a thimble application.
- (b) Reported values are to be the point readings and average exhaust velocity, m/s (fpm), dimensions, m (ft), and area of the section traversed, m² (ft²), air volume rate, m³/s (cfm), the work access opening area, m² (ft²), and calculated average face velocity, m/s (fpm).

b. Method for Type B1 Cabinets

(1) By anemometer measurement

(a) Turn off the recirculating fan(s) installed inside the cabinet that provide downflow air but keep the fan that exhausts air from the cabinet in full operation.

<u>Note</u>: It may be necessary to bypass for the duration of this test the electrical interlock, if provided, between recirculating and exhaust fans; the interlock must be reestablished at the conclusion of the test.

³ Industrial Ventilation, a Manual of Recommended Practice, 20th ed. (1989) ACGIH, Cincinnati, OH 45211 pp. 9-3 to 9-11.

- (b) Take two rows of air velocity measurements at multiple points in the plane of the access opening when sash (viewing window) is set to the height specified by the manufacturer as that submitted to NSF. Locate one row 25% below the top of the access opening and the second row 75% below the top of the access opening (see Figure A-19). Take the velocity measurements every 10 cm (4 in) across the width of the front work access opening, starting 10 cm (4 in) from the sides of the work opening.
- (c) Where measurements in the plane of the access opening are not practical, determine the inflow velocity in accordance with the manufacturer's instructions.
- (d) Report the individual point velocity measurements, m/s (fps), the average face velocity, m/s (fps), the dimensions, m (ft), and area of work access opening, m² (ft²).
- (2) By the direct airflow measurement method Refer to item IIB2 for method.
- c. For Type B2 Cabinets
 - (1) By anemometer measurements
 - (a) Operate the cabinet supply and exhaust fans while making both downflow and exhaust flow measurements and set the sash at the height specified by the manufacturer as that submitted to NSF.
 - (b) Measure the downflow velocity on an approximate 10 x 10 cm (4 x 4 in), grid in a horizontal plane, 15 cm (6 in), below the face of the supply diffuser, starting 5 cm (2 in) from each perimeter wall. The air measurement probe is to be held rigidly in a free-standing fixture (ringstand and clamp) that permits accurate positioning and does not distort the air flow pattern (see Figure A-20).

Average the velocity readings, m/s (fpm), And multiply by the area m² (ft²), of the plane in which the velocities were measured to determine the total filtered air supply, m³/s (cfm).

Reported values are to be each of the velocity readings, m/s (fpm), and their average, the measurement plane cross sectional measurements, m (ft), and their product, m^2 (ft²), and the product of average velocity and area to give air volume rate in m^3/s (cfm).

- (c) Measure volume exhaust rate by the pitot traverse method specified in item IIB3b of this Annex.
- (d) Calculate inflow air volume as the difference between the measured exhaust flow and the measured downflow volumes.
- (e) Calculate the average inflow velocity as specified in item IIB3a of this Annex.
- (f) Reported values are to be the individual point velocity readings m/s (fpm), for downflow and exhaust, average velocity m/s (fpm), calculated for downflow and exhaust, dimensions m (ft), and cross sectional areas m² (ft²) of locations where downflow and exhaust flow measurements were made, calculated downflow, inflow, and exhaust flow volume rates m³/s (cfm), area of work access opening m² (ft²), and average inflow velocity m/s (fpm).
- (2) Inflow velocity by the direct airflow measurement method, refer to item IIB2 of this Annex for method.
- d. Method for Type B3 Cabinets
 - (1) By anemometer measurementsTest Type B3 cabinets as specified in Annex F item II.B.3.
 - (2) By the direct airflow measurement method refer to item IIB2 of this Annex for method.

Acceptance

a. A cabinet Listed by NSF qualifies for field certification when the average work access opening face velocity is within ±0.025 m/s (±5 fpm) of the nominal set point verified by NSF using the same method.

NOTE: The manufacturer's (or NSF's) published nominal setpoint value that was established when using the same inflow measurement method used in the

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field (i.e., by anemometer point velocity measurements or by a direct airflow reading instrument) should be the value used to determine if the inflow volume qualifies the cabinet for field certification.

C. Airflow Smoke Patterns Tests

1. Purpose

This test is performed to determine that the airflow along the entire perimeter of the work access opening is inward, airflow within the work area is downward with no dead spots or refluxing, ambient air does not pass on or over the work surface, and there is no refluxing to the outside at the window wiper gasket and side seals.

2. Apparatus

A source of visible smoke such as a chemical smoke tube

NOTE: Some chemical smokes are corrosive and irritating and should be handled with care.

3. Method

a. Downflow Test

Pass a smoke source from one end of the cabinet to the other along the centerline of the work surface at a height of 15 cm (6.0 in) above the top of the access opening.

b. View Screen Retention Test

Pass a smoke source from one end of the cabinet to the other, 2.5 cm (1.0 in) behind the view screen, at a height 15 cm (6.0 in) above the top of the access opening.

c. Work Opening Edge Retention Test

Pass a smoke source along the edges of the entire perimeter of the work opening approximately 4 cm (1.5 in) outside the cabinet, with particular attention paid to comers and vertical edges.

d. Sash Wiper Seal Test

For cabinets with sliding sashes, pass a smoke source up the inside of the window at the side channel seals, and along the inside of the cabinet immediately below the wiper gasket.

Acceptance

A cabinet Listed by NSF qualifies for field certification when smoke tests give the following results:

a. Downflow Test

The smoke shows smooth downward flow with no dead spots or reflux. No smoke escapes from the cabinet.

b. View Screen Retention Test

The smoke shows smooth downward flow with no dead spots or reflux. No smoke escapes from the cabinet.

c. Work Opening Edge Retention Test

No smoke refluxes out of the cabinet once drawn in, nor does smoke billow over the work surface, or penetrate onto it.

d. Sash Wiper Seal Test

No upward refluxing, nor escape of smoke from the cabinet.

D. HEPA Filter Leak Test

1. Purpose

This test is performed to determine the integrity of supply and exhaust HEPA filters, filter housings, and filter mounting frames while the cabinet is operated at the nominal set point velocities.

2. Apparatus

a. A total scattering aerosol photometer with a linear or expanded logarithmic scale, or equivalent, that is capable of detecting a 100% upstream concentration with an aerosol concentration of 10 µg/L of polydisperse dioctylphthalate (DOP) particles, or an equivalent fluid that produces the same particle size distribution when generated by a Laskin nozzle generator, or equivalent, and is capable of detecting an aerosol concentration of 1 x 10⁻³ µg/L of the same particles. The photometer is to have an air sampling rate of 5 x 10⁻⁴ m³/s (1 cfm) ±10%. Probe diameter is not to exceed 2.5 cm (1.0 in). When used on potentially contaminated cabinets that have not been decontaminated, a photometer that has an internal reference light that corresponds to the light scattered from a known aerosol concentration generated by a Laskin nozzle generator, or equivalent, may be used to avoid the need to make an

upstream aerosol concentration measurement. The photometer response with the selected aerosol may be calibrated in accordance with the photometer manufacturer's instructions or IES-RP-CC-013-86T⁴ if instructions are not provided.

b. A Laskin nozzle aerosol generator (Figure A-2), or equivalent. The aerosol is to be diluted with air flowing through the cabinet to a concentration not greater than 100 μg/L nor less than 10 μg/L upstream of the HEPA filter undergoing a leak test.

3. Method For Testing Filters

- a. Filters that can be scanned
 - (1) Place the generator so the aerosol is introduced into the cabinet upstream of the HEPA filter under test in a manner to produce good mixing.
 - (2) Turn on the photometer and adjust it for measurements in accordance with the manufacturer's instructions.
 - (3) Sample the aerosol concentration upstream of the HEPA filter and verify that the concentration gives a light scattering intensity at least equal to that produced by 10 µg/L of DOP.
 - (a) For linear readout photometers (graduated 0-100), adjust the instrument to read 100 on the 100% scale.
 - (b) For logarithmic readout photometers, adjust the upstream concentration to 1 x 10⁴ above the concentration needed to produce one scale division (use the instrument calibration curve).
 - (4) With the nozzle of the probe approximately 2.5 cm (1 in) from the surface, scan the downstream side of the HEPA filters, including the perimeter of each filter pack, by passing the photometer probe in slightly overlapping strokes over the entire surface. Also scan the entire periphery of the filter and the junction between filter and filter mounting frame at a scanning rate that does not exceed 5 cm/s (2 in/s).
- b. Filters that cannot be scanned

⁴ IES-RP-CC-013-86T. Recommended Practice, Tentative. Institute of Environmental Sciences, 940 East North West Highway, Mt. Prospect, Illinois 60056, August 1986.

(1) When a cabinet is ducted so that the exhaust filter cannot be scanned, it may be leak tested by drilling a hole approximately 1 cm (3/8 in) in diameter in the duct at a downstream location that will produce a well mixed aerosol and inserting the photometer sampling probe through the hole.

NOTE 1: This method is not suitable for testing exhaust filters in Type A cabinets vented through a thimble connection. Thimble connection should be removed and the filter scanned as in item E.II.d.3.

NOTE 2: After testing, the hole in the duct should be sealed with an expandable plug.

NOTE 3: Filters failing to qualify for acceptance may be repaired in conformity with the requirements of item 4.19.6 of the standard and retested.

NOTE 4: Replacement HEPA filters are to conform to all requirements cited in item 4.19.2.

NOTE 5: Liquids that produce the prescribed aerosol size distribution (±20%) when generated by one or more Laskin nozzles with (20 psig) compressed air include: DOP, food grade corn oil, polyethylene glycol 400, dioctylsebacate, food grade mineral oil, medicinal grade mineral oil 200, and synthetic aliphatic hydrocarbon (Emery 3004). When using an internal reference light for making a calculated upstream photometer gain setting, it has not been confirmed that each liquid produces the same aerosol concentration as does DOP when generated by Laskin nozzles at 140 kPa (20 psig). Therefore, the calibration procedure cited in item F.II.d2a of this Annex is recommended.

4. Acceptance

a. Filters that can be scanned

A cabinet Listed by NSF qualifies for field certification when aerosol penetration does not exceed 0.01% at any point.

Filters that cannot be scanned

⁵ Yan, X., First, M.W. and Rudnick, S.N., Proceedings of the 21st DOE/NRC Nuclear Air Cleaning Conference, NTIS, Springfield, VA, 1991, PP. 116-25.

A cabinet Listed by NSF qualifies for field certification when average aerosol penetration does not exceed 0.005%.

E. Cabinet Leak Test

1. Purpose

The pressure holding test is performed to determine if exterior surfaces of all plenums, welds, gaskets, and plenum penetrations or seals are free of leaks. It need only be performed just prior to initial installation when the cabinet is in a free-standing position (all four sides easily accessible) in the room in which it will be used, after a cabinet has been relocated to a new location, and again after removal of access panels to plenums for repairs or a filter change. This test may also be performed on fully installed cabinets at any other time at the cabinet owners option. The soap bubble test referenced in annex a may be used in place of the following method.

Apparatus

- a. Materials to prepare the cabinet as a closed system
 - (1) Impervious front sealing panels and tightly-sealing dampers provided by a cabinet manufacturer for this purpose, or
 - (2) Heavyweight plastic film and sealing tape for sealing cabinet's open face and exhaust air opening.
- b. A source of compressed air adequate to pressurize the cabinet to 500 Pa (2 in wg) and a surface tap that provides an airflow passage into the interior of plenums.
- c. A pressure gauge capable of reading 500 ± 5 Pa (2 \pm 0.02 in wg) pressure differential.
- d. Liquid leak detector (such as "Search", "Leak-Tek", "Snoop", or equal).

NOTE: Use a pressure regulating valve between compressed air hose and cabinet to avoid accidently pressurizing the cabinet to the full compressed air pressure.

3. Method

- a. Prepare the cabinet as a closed system; i.e., seal the front window and exhaust port.
- b. Remove decorative panels, wherever necessary, to expose plenums to be tested.

- c. Attach a manometer, pressure gauge, or pressure transducer system to the test area to indicate the interior pressure.
- d. Pressurize the cabinet with air to a reading of 500 Pa (2 in wg), turn off pressurizing air, and hold as a sealed system.

NOTE: Temperature increases will increase the pressure.

- e. Measure residual pressure. If the cabinet leak rate exceeds 10% in 30 min, spray or brush liquid leak detector along all welds, gaskets, penetrations, or seals on exterior surfaces of cabinet plenums while pressure is maintained at 500 Pa (2 in wg) by continuous makeup compressed air flow into cabinet. Small leaks will be indicated by bubbles; larger leaks may blow the detection fluid from the hole without forming bubbles. Leaks of this magnitude may be detected by feel of airflow against the skin, or by sound.
- f. After repairing all leaks discovered by bubbles, sound, or cooling effect against the skin, retest by repeating the procedure contained in items E3d.e of this Annex.

4. Acceptance

A cabinet Listed by NSF qualifies for field certification when all welds, gaskets, penetrations, and seals on exterior surfaces of air plenums hold the specified pressure within 10% for 30 min.

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F. Electrical Leakage and Ground Circuit Resistance and Polarity Tests

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1. Purpose

These safety tests are performed to determine if a potential shock hazard exists by measuring the electrical leakage, polarity, ground fault interrupter function, and ground circuit resistance to the cabinet ground connection. It may be performed by an electrical technician other than the field certification personnel at the time the other field certification tests are conducted.

2. Apparatus

- a. Electrical safety analyzer (ESA) with 1 $k\Omega$ input impedance and 2 leads; one with a sharp point, one with a probe.
- b. Leviton model 6185 GFI circuit tester, or equivalent.

Method

a. Electrical leakage

- (1) Place all cabinet electrical switches in off position.
- (2) Plug cabinet main power cord into an adapter plug (a 3-hole electrical receptacle on one end, a two-prong plug on the other) and insert adapter into an electrical outlet.
- (3) Insert one lead from ESA into a grounding (round) hole of an adjacent electrical outlet and with the other lead (having a sharp end) make firm contact with the cabinet work surface and other exposed conductive cabinet surfaces.
- (4) Turn the ESA function selector to the microamp scale that gives the best reading.
- (5) Repeat steps 1-4 with all cabinet electrical switches in the on position.
- (6) Repeat steps 1-5 with reversed polarity (reverse two-prong plug of adapter in the outlet).
- (7) Repeat steps 1-6 on the second power cord when cabinet has two.

b. Ground circuit resistance

- (1) Turn off the blower, lights, and accessories.
- (2) Prepare the resistance test portion of the electrical safety tester for use in accordance with the manufacturer's instructions.
- (3) Connect a test lead from the electrical safety tester to the work surface. If the tester has additional leads, connect these to other exposed metal surfaces on the front facing of the cabinet. If there are no other leads, move existing lead to other exposed metal surfaces after each resistance reading.
- (4) Read the resistance for each lead or location.

c. Polarity and ground fault interrupter

- (1) Turn on the receptacle switch when present on the unit. When the unit has a separate line cord for the duplex circuit, plug it in.
- (2) Set GFI tester to "polarity" and plug into each duplex outlet in the cabinet. When polarity is correct, the two yellow lights will light equally. Any other combination of lights indicates a defect as identified on the tester.

(3) On units with ground fault interrupters, unplug all accessories and plug the tester into the last receptacle in the GFI protected branch (in a 2 receptacle cabinet this is usually the receptacle that does not have the GFI).

Turn selector switch to 1, 2 and 3 ma positions. If the GFI trips, the lights on the tester will go out indicating leakage in the cabinet wiring that must be located and repaired.

When the lights on the tester do not go out, turn the selector switch to "GFI trip test". The lights on the tester should go out. If they do not, the GFI is defective or the circuit is not GFI protected and there is leakage in the cabinet wiring that must be located and repaired. Turn the selector switch back to "polarity" and reset the GFI. The lights on the tester should turn on as in step C(2).

4. Acceptance

A cabinet Listed by NSF qualifies for field certification when the electrical leakage does not exceed 500 ma and the ground circuit resistance does not exceed 0.15 ohms. Cabinets with primary-circuit filtering may qualify when they comply with UL 1262.

G. Lighting Intensity Test

1. Purpose

This test is performed to measure the light intensity on the work surface of the cabinet in lx (foot-candles) as an aid in minimizing cabinet operator's fatigue.

2. Apparatus

A portable photoelectric illumination meter approved for field measurements in accordance with the current edition of the Illuminating Engineering Society (IES) Lighting Handbook and adjusted for measurements in accordance with the manufacturer's instructions.

3. Method

- a. Turn on the lights and blower and measure the light intensity along the side-to-side centerline of the work tray at 30 cm (12 in) intervals beginning 15 cm (6 in) from the side wall (Figure A-4).
- b. Repeat measurements with cabinet lights off.

4. Acceptance

A cabinet Listed by NSF qualifies for field certification when average lighting intensities are within 860-1600 lx (80-150 foot-candles) at the work surface and individual readings are not less than 650 lx (60 foot-candles) when measured where background light levels average 220-430 lx (20 to 40 foot-candles) at the work surface.

H. Vibration Test

1. Purpose

This test is performed to determine the amount of vibration in an operating cabinet as a guide to satisfactory mechanical performance and as an aid in minimizing cabinet operator's fatigue, and to prevent damage to delicate tissue culture specimens.

2. Apparatus

- a. A vibration analyzer with a minimum sensitivity of 1 x 10⁻⁴ in rms amplitude, calibrated immediately prior to testing in accordance with manufacturer's instructions.
- b. Vibration calibrator

Method

- a. Operate the cabinet with lights on and at the nominal set point velocities.
- b. Clamp, bolt, or use an integral magnet with petroleum jelly film, or a double-faced adhesive tape, to affix the sensing element of the vibration pickup unit firmly onto the geometric center of the work surface.
- c. Determine the gross vibration amplitude with the cabinet operating.
- d. Determine background vibration amplitude with cabinet not operating.
- e. Subtract the background from the gross vibration amplitude to determine the net vibration amplitude attributable to the cabinet.

4. Acceptance

A cabinet Listed by NSF qualifies for field certification when net displacement does not exceed 0.002 in (50 µg) rms amplitude at 10 - 200 hertz in the center of the work surface when the cabinet is operating at the manufacturer's recommended airflow velocities.

I. Noise Level Test

1. Purpose

This test is performed to measure the noise levels produced by the cabinet as a guide to satisfactory mechanical performance and an aid in minimizing cabinet operator's fatigue. The procedures can be performed in most acoustically ordinary rooms where walls are neither sound absorbing nor completely sound reflecting.

2. Apparatus

- a. A sound level meter with a range of at least 50 to 100 db, and an "A" weighting scale calibrated in accordance with the manufacturer's instructions.
- b. A sound-level calibrator.

Method

- a. Operate the cabinet at the nominal set point velocities with lights on.
- b. Set the instrument to the "A" weighting mode and adjust with the sound-level calibration.
- c. Measure noise level 30 cm (12 in) in front of the cabinet and 45 cm (15 in) above the plane of the work surface, in line with the vertical centerline of the cabinet (Figure A-3).
- d. Remeasure the ambient noise level as in item 3c with blower and lights off.

Acceptance

A cabinet Listed by NSF qualifies for field certification when overall noise level in front of the cabinet does not exceed 70 dbA when measured where the maximum ambient sound level is no greater than 57 dbA. When the ambient sound level is greater than 57 dbA, the reading obtained in item 3c is to be corrected in accordance with standard correction curves or tables.

J. Record of Field Certification

- 1. A cabinet Listed by NSF that has met all the field test criteria listed in items IIA-F should have the following information posted on the front of the cabinet in a location readily visible to the user, unless otherwise specified by the user.
 - a. Date of certification
 - b. Date cabinet should be recertified: no later than
 - c. Certifier's report number. (Reference document showing tests performed and results.)
 - d. Name, address, and telephone number of certifying company.
 - e. Signature of the person who performed the field certification tests.

ANNEX G RECOMMENDED MICROBIOLOGICAL DECONTAMINATION PROCEDURE¹

(This Annex is not part of Standard 49, but is provided for information only.)

Decontamination is mandatory when maintenance work, filter changes, and performance tests require access to any contaminated portion of the cabinet. All interior work surfaces and exposed interior surfaces should be decontaminated with a suitable disinfectant before certification tests are performed. In addition, it may be desirable to gaseous decontaminate the entire cabinet before performing certification tests when the cabinet has been used with agents assigned to Biosafety Level 2 and is recommended when the cabinet has been used with an agent assigned to Biosafety Level 3. Cabinets potentially contaminated with biological agents should be suitably decontaminated before they are moved to another location. Additionally, after spills and splashes of research agents, contaminated surfaces should be suitably decontaminated. In most instances where gas decontamination is necessary, the procedure described below utilizing depolymerized paraformaldehyde is used. Alternate methods are required in certain instances; e.g., slow disease viruses. Decontamination method should be determined by consultation between user and certification agency.

- 1. Calculate the total volume of the cabinet by multiplying the height, width, and depth.
- 2. Multiply the total volume of the cabinet by 10.6 g/m³ of space (0.3 g/ft³) to determine the gram weight of paraformaldehyde required.
- 3. If the cabinet is equipped with an exhaust duct, this duct must be gas tight. This may be accomplished at the terminal end of the duct, or if present, at the damper located near the cabinet. If the exhaust duct is more than 3 m (10 ft) long, additional paraformaldehyde may be needed to compensate for the increased volume. If the cabinet exhausts into a recirculating building exhaust system, disconnect the cabinet from the building system and form a gas tight seal (plastic film and tape may be used).
- 4. If the cabinet exhaust air is discharged into the room, tape a plastic cover over the exhaust port. A flexible hose can be applied to an opening in the plastic cover to exhaust formaldehyde gas following decontamination. However, the end of the flexible hose must be sealed with plastic film and tape during decontamination. This flexible hose can be directed into the room, another cabinet, or hood exhaust system, provided the exhaust is not recirculated, or it may be placed out a window to exhaust the formaldehyde gas. (When the formaldehyde gas cannot be exhausted through a duct or window, a charcoal or appropriate neutralizing device may be fitted to an exhaust port.)
- 5. A heating device, such as a commercially available electric frying pan or a remote formaldehyde generator/neutralizer, with the thermostat set at 232.2 to 246.1°C (450 to 475°F) is placed on the work tray. The paraformaldehyde is spread evenly over the heating surface of the frying pan.

¹Taylor, L.A., Barbeito, M.S., Gremillion, G.G., 1969. "Paraformaldehydes for Surface Sterilization and Detoxification. Applied Microbiology 17:614-618.

- CAUTION: The auto-ignition temperature of paraformaldehyde is 300°C (572°F).
- 6. A hot plate, beaker of water, and temperature and humidity indicators are placed on the cabinet work tray. Do not connect electrical cords to the internal cabinet electric supply.
- 7. Close the opening to the work area with heavy gauge plastic film and tape. Close all possible leak areas, such as the exit of electrical cords, around the window, and the junction of the plastic film and cabinet.
- 8. Determine temperature and humidity inside the cabinet.
- 9. The temperature should be 21.1°C (70°F) or higher, and humidity should be 60 to 85%. Use the hot plate to heat the beaker of water until the desired temperature and humidity are achieved.
- 10. Plug the cord of the electric frying pan into an outlet not installed on the cabinet.
- 11. After 25% of the paraformaldehyde has depolymerized, turn on the cabinet blower(s) for 10 to 15 sec. Repeat after 50%, 75%, and 100% of the paraformaldehyde has depolymerized.²
- 12. Disconnect the hot plate and frying pan from the electrical outlets.
- 13. Allow the cabinet to stand for a minimum of two hours, preferably overnight.
- 14. If it is not possible to attach a flexible hose add same amount of NH₄HCO₃ as of paraformaldehyde to the frying pan. Turn on the frying pan and the cabinet blower until the NH₄HCO₃ has dissipated.
- 15. Let the cabinet stand for at least 1 h before opening seals.
- 16. During cabinet decontamination, respiratory protection for service personnel is recommended. Only National Institute for Occupational Safety and Health (NIOSH) approved respirators should be used.

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). Refer to NIOSH, Department of Health and Human Services (DHHS) reports in "Hazard Review of Bis(chloromethyl)ether (BCME)."

²Modification by Kruse, R.H., Puckett, W.H. and Richardson, J.H., 1991 "Biological Safety Cabinetry" Clinical Microbiological Review 4:207-241.

ANNEX H RECOMMENDED MATERIALS, FINISHES, AND CONSTRUCTION

(This Annex is not part of Standard 49, but is provided for information only.)

I. SHEET METAL AND FINISHES

- A. All cabinet interior work surfaces, including the drain pan assembly, should be fabricated with corrosion-resistant steel conforming to Federal Specification QQ-S-766 (Class 304, Number 3 Finish).
- B. If carbon steel sheet is used in cabinet fabrication, it should be prime grade, stretcher or roller leveled, conforming to Federal Specification QQ-S-698 (Cold Rolled Sheets, Condition Number 3 Regular Finish).
- C. Before plating, carbon steel surfaces should be free of dirt, oil, and grease. The carbon steel should be given a phosphate coating treatment in accordance with Federal Specifications TT-C-490. Prime and finish coats can be applied by spraying or dipping, and should be baked after each coat for a minimum of 15 min at 148.9°C (300°F). The finish should be uniform, with a minimum thickness of 1 mil. Concealed surfaces or hollow metal sections should be protected by the finish, applied by a suitable method after welding and before assembly. Epoxy coatings may be used to coat all carbon steel surfaces and should conform to Federal Specification TT-C-001224. The finish should be uniform. Polyurethane coating may be used to coat all carbon steel surfaces, and should conform to Federal Specification TT-C-001227. The finish should be uniform.

II. GLASS

- A. If safety glass is used for the window, it should be nominally 6.4 mm (0.25 in) laminated safety plate glass, such as PPG "Duo Lite", or equal.
- B. If tempered glass is used for the window, it should be nominally 6.4 mm (0.25 in) tempered glass conforming to American Society for Testing and Materials C 1048, or equal.
- III. HEPA filter gasket materials should be cellular sheet or molded rubber, or closed cell expanded neoprene gasket materials, as described in Military Specification MIL-F-51068, Paragraph 3.2.2, Gasket Material; and it should be mounted according to Paragraph 3.3.3, Gasket Assembly.
- IV. HEPA Filter Case Type IC (wood type fire retardant treated particle board) is acceptable for the case of the HEPA filter. Military Specification MIL-F-51068 lists other acceptable materials.
- V. Military Specification MIL-F-51068 requires filter mounting tolerances for openings up to 50.8 cm (12 in), ±0, 1.6 mm (-1/16 in); and openings over 50.8 cm (12 in), to be ±0, 3.2 mm (-1/8 in). The squareness of filter mountings shall have diagonals within 1.6 mm (1/16 in) total

allowance. Flatness at the filter gasket seal surface should be \pm 0.4 mm (0.015 in) within any 25.4 cm (10 in) run.

VI. SEALANTS

- A. Two part accelerated synthetic rubber (polysulfide type), temperature resistance, high adhesion aircraft specification grade, Federal Specification MIL-S-8802 or PR-1422 Class B-2, Products Research Company, or equal.
- B. One part silicon base sealant compound, such as Dow Corning RTV 732 Adhesive Sealant, Dow Corning RTV 781 Building Sealant, Dow Corning RTV 734 or RTV 112 Self-leveling Sealants or equal, is acceptable when used in accordance with the manufacturer's recommendations.
- VII. Fan(s) should be direct connected, forward curve centrifugal fans conforming to Air Moving and Conditioning Association (AMCA) standards. The performance curve for the specific fan furnished would be provided with each cabinet. Curves should display cfm (m3/s) vs. static pressure and voltage vs. cfm (m3/s).
- VIII. All electrical components and wiring should conform to the latest edition of the National Electrical Code, National Electrical Manufacturer's Association (NEMA), or Underwriters Laboratories (UL), whichever is applicable and provides the highest standard.

II. FEDERAL SPECIFICATIONS

- A. J#C-145 Cable, Power, Electrical and Wire, Electrical; (Weather Resistant)
- B. W-C-00596 Connector, Plug, Electrical; Connector Receptacle, Electrical
- C. W-S-00896 Switch, Toggle
- D. W-S-893 Switch, Toggle, and Mounting Strap (Interchangeable)
- E. CC-M-636 Motor, Alternating-Current (Fractional Horsepower)
- F. QQ-S-698 Steel, Sheet and Strip, Low-Carbon
- G. QQ-S-776 Steel Plates, Sheets, and Strip-Corrosion Resisting
- H. TT-C-490 Cleaning Methods and Pretreatment of Ferrous Surfaces for Organic Coatings
- I. TT-C-535 Coating, Epoxy, Two-Component, for Interior and Exterior Use of Metal, Concrete and Masonry
- J. TT-C-001224 Coating System, Epoxy, Glaze for Interior Surfaces
- K. TT-C-001227 Coating System, Polyurethane Glaze for Interior Surfaces
- L. PPP-B-601 Boxes, Wood, Cleated-Plywood
- M. PPP-B-621 Boxes, Wood, Nailed and Lock-Corner
- N. PPP-B-640 Boxes, Fiberboard, Corrugated, Triple-Wall
- O. PPP-C-650 Crates, Wood, Open and Covered
- P. PPP-C-843 Cushioning Material, Cellulosic
- Q. PPP-T-60 Tape, Packaging, Waterproof

III. FEDERAL STANDARDS

- A. Federal Standard No. 102 Preservation, Packaging and Packing Levels
- B. Federal Standard No. 123 Marking for Domestic Shipment

IV. MILITARY SPECIFICATIONS

- A. MIL-C-104 Motor, Alternating Current (Fractional Horsepower)
- B. MIL-C-132 Crates, Wood, Open; Maximum Capacity 2,500 pounds
- C. MIL-C-3774 Crates Wood, Open; 12,000 and 16,000 Pound Capacity
- D. MIL-L-10547 Liners, Case and Sheet Overwrap, Water-Vaporproof or Waterproof, Flexible
- E. MIL-P-116 Preservation, Methods of
- F. MIL-R-3065 Rubber, Fabricated Products-Gaskets, Synthetic Rubber
- G. MIL-S-8802 Sealing Compound, Temperature-Resistant Aircraft High Adhesion
- H. MIL-F-51079B Filters, Particulate, High Efficiency, Fire Resistant, Biological Use

ANNEX I REFERENCE STANDARDS AND SPECIFICATIONS PERTINENT TO CLASS II BIOHAZARD CABINETRY¹

(This Annex is not part of Standard 49, but is provided for information only.)

I. MISCELLANEOUS PUBLICATIONS

- A. Air Moving and Conditioning Association (AMCA)
 - 1. AMCA 99 Standards Handbook
 - 2. AMCA 210-67 Test Code for Air Moving Devices
 - 3. AMCA AS 2406 Fans, Designation of Direction of Rotation and Discharge
 - 4. AMCA 211 Fans, Labeling Requirements
- B. American National Standards Institute, Inc. (ANSI)
 - 1. S1.4-1984 Specification for Acoustical Calibrators
 - S2.2-1959 (R1982) Methods for the Calibration of Shock and Vibration Pickups
 - 3. Z26.1983 Safety Glazing Materials for Glazing Motor Vehicles Operating on Land Highways, Safety Code for
 - 4. Z97.1-1984 Performance Specifications and Methods of Test for Safety Glazing Material Used in Buildings
- C. Illuminating Engineering Society (IES)
 - 1. IES Lighting Handbook
- D. National Electrical Code
- E. National Electrical Manufacturers' Association (NEMA)

¹Latest edition in effect at the time of manufacture.

F. Underwriters Laboratories

- 1. UL-62-1965 Flexible Cord and Fixture Wire
- 2. UL-94-1985 Test for Flammability of Plastic Materials for Parts in Devices and Appliances
- 3. UL-181 Factory-Made Air Duct Materials and Air Duct Connectors
- 4. UL-586-1985 Test Performance of High Efficiency Particulate Air Filter Units
- 5. UL-817-1987 Cord Sets and Power Supply Cords
- 6. UL-1262-1984 Laboratory Equipment
- G. U.S. Department of Energy
 - 1. ERDA 76-11 Nuclear Air Cleaning Handbook (March 1976)
- H. U.S. Department of Labor
 - 1. Occupational Safety and Health Administration (OSHA) Safety and Health Standards for Respiratory Protection 29CFR* 1910.134
- I. U.S. Department of Health and Human Services
 - 1. Centers for Disease Control, National Institute of Occupational Safety and Health, Requirements for Respirator, 30CFR* Part II
 - *Code of Federal Regulations
- J. American Conference of Governmental Industrial Hygienists
 - 1. Industrial Ventilation, A Manual of Recommended Practices, Twentieth Edition, 1989 or Later Edition (this publication is updated every two years)
- K. U.S. Naval Research Laboratory
 - 1. Report 5959 (July 1963)
- L. American Society for Testing and Materials (ASTM)
 - 1. C 1048 Specification for Heat Treated Flat Glass, Kind HS, Kind FT Coated and Uncoated Glass

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