FM Approvals

CLASS NUMBER 4920

Examination Standard for Filters Used in Clean Room Facilities

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Foreword

This standard is intended to verify that the products and services described will meet stated conditions of performance, safety and quality useful to the ends of property conservation. The purpose of this standard is to present the criteria for examination of various types of products and services.

Examination in accordance with this standard shall demonstrate compliance and verify that quality control in manufacturing shall ensure a consistent and reliable product.

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1. INTRODUCTION

1.1 PURPOSE

1.1.1 This standard states testing and certification requirements for filter assemblies used in clean room facilities.

1.1.2 Testing and certification criteria may include performance requirements, marking requirements, examination of manufacturing facility(ies), audit of quality assurance procedures, and a surveillance program.

1.2 SCOPE

1.2.1 This standard applies to filters assemblies for use in clean room facilities. The filter assembly typically consists of frames, filter media, gaskets, sealing gel material and potting compounds.

1.2.2 This standard covers certification of final stage wall filters, ceiling filters and prefiltration units.

1.3 BASIS FOR REQUIREMENTS

1.3.1 The requirements of this standard are based on experience, research and testing and/or the standards of other organizations. The advice of manufacturers, users, trade associations and loss control specialists was also considered.

1.3.2 The requirements of this standard reflect tests and practices used to examine characteristics of clean room filters and pre-filters for the purpose of obtaining certification.

1.4 BASIS FOR CERTIFICATION

Certification is based upon satisfactory evaluation of the product and the manufacturer in the following major areas:

1.4.1 Examination and tests on production samples shall be performed to evaluate

- the suitability of the product;
- the performance of the product as specified by the manufacturer and required for certification;
- the durability and reliability of the product.

1.4.2 An examination of the manufacturing facilities and audit of quality control procedures may be made to evaluate the manufacturer's ability to consistently produce the product which is examined and tested, and the marking procedures used to identify the product. Subsequent surveillance may be required by the certification agency in accordance with the certification scheme to ensure ongoing compliance.

1.5 BASIS FOR CONTINUED CERTIFICATION

The basis for continual certification may include, but is not limited to, the following based upon the certification scheme and requirements of the certification agency:

- production or availability of the product as currently certified;
- the continued use of acceptable quality assurance procedures;
- compliance with the terms stipulated by the certification;
- satisfactory re-examination of production samples for continued conformity to requirements; and
- satisfactory surveillance audits conducted as part of the certification agency's product surveillance program.

1.6 EFFECTIVE DATE

The effective date of this certification standard mandates that all products tested for certification after the effective date shall satisfy the requirements of this standard.

The effective date of this standard is the date of publication.

1.7 SYSTEM OF UNITS

Units of measurement used in this Standard are United States (U.S.) customary units. These are followed by their arithmetic equivalents in International System (SI) units, enclosed in parentheses. The first value stated shall be regarded as the requirement. The converted equivalent value may be approximate. Conversion of U.S. customary units is in accordance with ANSI/IEEE/ASTM SI 10.

1.8 NORMATIVE REFERENCES

The following standards, test methods, and practices are referenced in this standard:

ANSI/IEEE/ASTM SI 10, American National Standard for Metric Practice.

ANSI/FM 4920, American National Standard for Testing Filters Used in Clean Room Facilities.

1.9 TERMS AND DEFINITIONS

For purposes of this standard, the following terms apply:

Efficiency Value the ratio of the number of particles captured by the filter to the number of the particles challenging the filter.

HEPA Filter High Efficiency Particulate Air filter having an efficiency value 99.97% and able to remove airborne particles with a size of 0.3 microns or greater in size.

ULPA Filter Ultra Low Penetration Air filter having an efficiency value of 99.9995% and able to remove airborne particles with a size of 0.12 microns or greater in size.

Pack Height The height of the filter media housed in the filter frame

2. GENERAL INFORMATION

2.1 PRODUCT INFORMATION

The clean room filter assemblies are typically constructed from pleated fiberglass or polytetrafluorethylene (PTFE) media and housed within a frame. The filter media is secured and sealed to the frame with an adhesive. The folded portion of the media is typically held in position at the apex of the fold maintaining the pleat spacing by adhesive. The finished filter assembly can be used in the clean room in either a horizontal (ceiling) or vertical (wall) position. In either position, the filter assembly is held in position using a grid system. The filter is sealed against the grid system with either a gasket or silicone gel material. The filters are supplied in a variety of pack heights and widths to fit the application and room size.

Pre-filters assemblies are used upstream of the finished clean room filters and are positioned within the duct work. Normally, there are two stages of pre-filtration. The first stages of pre-filters are constructed with a low cost filter media assembled in pressed cardboard. These filters are positioned at the intake of the air stream. The second stage pre-filters use a micro fiberglass media and is secured in a plastic box frame. The second stage filters are located downstream of the first stage filters.

2.2 CERTIFICATION APPLICATION REQUIREMENTS

The manufacturer shall provide the following preliminary information with any request for certification consideration:

- a complete list of all models, types, sizes, and options for the products or services being submitted for Approval consideration;
- complete set of assembly drawings, materials list, anticipated marking format, nameplate format, brochures, sales literature, spec. sheets, installation procedures
- the number and location of manufacturing facilities.

All documents shall identify the manufacturer's name, document number or other form of reference, title, date of last revision, and revision level. All documents shall be provided with English translation.

2.3 REQUIREMENTS FOR SAMPLES FOR EXAMINATION

2.3.1 Following authorization of a certification examination, the manufacturer shall submit samples for examination and testing based on the following:

- Sample requirements to be determined by the certification agency.

2.3.2 Requirements for samples may vary depending on design features, results of prior or similar testing, and results of any foregoing tests.

2.3.3 The manufacturer shall submit samples representative of production.

2.3.4 It is the manufacturer's responsibility to provide any necessary test fixtures, such as those which may be required to evaluate the filter assembly with a ceiling or wall grid system.

2.3.5 For all filter assemblies, the manufacturer must supply details, or a method of securement, to the certification agency.

3. GENERAL REQUIREMENTS

3.1 REVIEW OF DOCUMENTATION

3.1.1 During the initial investigation, and prior to physical testing, the manufacturer's specifications and details shall be reviewed to assess the ease and practicality of installation and use. The certification examination results may further define the limits of the final certification.

3.2 PHYSICAL OR STRUCTURAL FEATURES

3.2.1 The sides and ends of the filter media pack shall be secured to the filter frame in accordance with the manufacturer's written instructions.

3.2.2 Each filter assembly shall be supplied with its maximum filter pack media height.

3.2.3 A complete grid system with all the necessary gaskets or sealant gel materials shall be supplied for each filter type (style) being tested for certification.

3.2.4 If the manufacturer is seeking certification of a filter assembly that uses a sealant gel, the Material Safety Data Sheet (MSDS) must be submitted prior to shipping the product to the certification agency.

3.2.5 Instructions for mixing the sealant gel, and required tooling to combine the ingredients of the sealant gel, must be submitted prior to assembling the material sample.

3.3 MARKINGS

3.3.1 Marking on the product or label accompanying the product, shall include the following information:

- name and address of the manufacturer or marking traceable to the manufacturer;
- date of manufacture or code traceable to date of manufacture or lot identification;
- model number, size, rating, capacity, etc., as appropriate.

3.3.2 The model or type identification shall correspond with the manufacturer's catalog designation and shall uniquely identify the certification agency's mark of conformity.

3.3.3 The certification agency's mark of conformity shall be displayed visibly and permanently on the product and/or packaging as appropriate and in accordance with the requirements of the certification agency. The manufacturer shall exercise control of this mark as specified by the certification agency and the certification scheme.

3.3.4 All markings shall be legible and durable.

3.4 MANUFACTURER'S INSTALLATION AND OPERATION INSTRUCTIONS

The manufacturer shall:

- prepare instructions for the installation, maintenance, and operation of the product;
- provide facilities for repair of the product and supply replacement parts, if applicable; and
- provide services to ensure proper installation, inspection or maintenance for products of such nature that it would not be reasonable to expect the average user to be able to provide such installation, inspection or maintenance.

3.5 CALIBRATION

3.5.1 Each piece of equipment used to verify the test parameters shall be calibrated within an interval determined on the basis of stability, purpose, and usage. A copy of the calibration certificate for each piece of test equipment is required. The certificate shall indicate that the calibration was performed against working standards whose calibration is certified and traceable to an acceptable reference standard and certified by an ISO/IEC 17025 accredited calibration laboratory. The test equipment shall be clearly identified by label or sticker showing the last date of the calibration and the next due date. A copy of the service provider's accreditation certificate as an ISO/IEC 17025 accredited calibration laboratory should be available.

3.5.2 When the inspection equipment and/or environment is not suitable for labels or stickers, other methods such as etching of control numbers on the measuring device are allowed, provided documentation is maintained on the calibration status of thus equipment.

4. PERFORMANCE REQUIREMENTS

- Tests of alternate constructions may be waived if considered less hazardous than those previously tested.
- Confirming tests may be required, at the sole discretion of the certification agency, depending on design features and results of any foregoing tests.
- Following a test failure, a re-test of an identical or similar assembly shall be at the sole discretion of the certification agency and with a technical justification of the conditions or reasons for the failure. When a test specimen fails to meet the certification acceptance criteria for a given classification/rating, two successful test specimens of the same or similar construction must meet the certification acceptance criteria to qualify for the given classification/rating.
- Prior to testing, assemblies shall be permitted to cure for a maximum period of 28 days.

4.1 FIRE EXPOSURE (FOR HORIZONTAL, VERTICAL, WALL FILTERS OR PREFILTERS)

4.1.1 Requirement

The test sample is a field installed horizontal, vertical (wall) filter or pre-filter assembly consisting of finished filter units placed in the vertical parallel panel test fire fixture. Four 4 ft. (1.2 m) high by 2 ft. (0.6 m) wide filter assemblies are secured to the fixture with the vertical surfaces facing each other spaced 1 ft. (0.3 m) apart. The parallel panels are subjected to a 57 BTU/s (60 kW) propane sand burner placed at the base of the panels. The filters will be tested with their maximum filter pack height and associated grid suspension (if applicable) system with gaskets or sealant gel (if appropriate).

4.1.2 Test/Verification

The fire exposure test is conducted to determine if the sample filters meet the acceptance conditions as stated in section 4.1.3. Testing of the filter assembly shall be in accordance with ANSI/FM 4920.

4.1.3 Conditions of Acceptance of the Fire Exposure Test

1. The visual flame height shall not exceed 6 feet (1.83 m).
2. The heat release rate, measured 2 minutes after the burner is shut off is to be at or below 25% of the maximum heat release rate observed up to 10 seconds before the burner is shut down.
3. The cumulative smoke generated shall be less than or equal to 0.13 lb (60 g).
4. The smoke generation rate shall be less than or equal to 0.0005 lb/s (0.23 g/s).
5. The smoke generation rate at 12 minutes shall be less than or equal to 0.0002 lb/s (0.07 g/s).

5. MANUFACTURER'S REQUIREMENTS

5.1 DEMONSTRATED QUALITY CONTROL PROGRAM

5.1.1 A quality assurance program is required to assure that subsequent filter assemblies produced by the manufacturer shall present the same quality and reliability as the specific filter assemblies examined. Design quality, conformance to design, and performance are the areas of primary concern.

- Design quality is determined during the examination and tests and may be documented in the certification report.
- Continued conformance to this standard is verified by the certifier's surveillance program.
- Quality of performance is determined by field performance and by periodic re-examination and testing.

5.1.2 The manufacturer shall demonstrate a quality assurance program which specifies controls for at least the following areas:

- existence of corporate quality assurance guidelines;
- incoming quality assurance, including testing;
- in-process quality assurance, including testing;
- final inspection and tests;
- equipment calibration;
- drawing and change control;
- packaging and shipping; and
- handling and disposition of non-conforming materials.

5.1.3 Documentation/Manual

There should be an authoritative collection of procedures/policies. It should provide an accurate description of the quality management system while serving as a permanent reference for implementation and maintenance of that system. The system should require that sufficient records are maintained to demonstrate achievement of the required quality and verify operation of the quality system.

5.1.4 Records

To assure adequate traceability of materials and products, the manufacturer shall maintain a record of all quality assurance tests performed, for a minimum period of two years from the date of manufacture.

5.1.5 Drawing and Change Control

- The manufacturer shall establish a system of product configuration control that shall allow no unauthorized changes to the product. Changes to critical documents, identified in the certification report, may be required to be reported to, and authorized by the certification agency prior to implementation for production.
- Records of all revisions to all certified products shall be maintained.

5.2 SURVEILLANCE AUDIT

5.2.1 An audit of the manufacturing facility may be part of the certification agencies surveillance requirements to verify implementation of the quality assurance program. Its purpose is to determine that the manufacturer's equipment, procedures, and quality program are maintained to ensure a uniform product consistent with that which was tested and certified.

5.2.2 Certified products or services shall be produced or provided at, or provided from, location(s) disclosed as part of the certification examination. Manufacture of products bearing a certification mark is not permitted at any other location prior to disclosure to the certification agency.

5.3 INSTALLATION INSPECTIONS

Field inspections may be conducted to review an installation. The inspections are conducted to assess ease of installation, and conformance to written installation and operating specifications. When more than one installation technique is used, one, or all, may be inspected at the sole discretion of the certification agency.

5.4 PRODUCT MODIFICATIONS

The manufacturer shall notify the certification agency of changes in product construction, components, raw materials, physical characteristics, coatings, component formulation or quality assurance procedures prior to implementation.

6. BIBLIOGRAPHY

ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories.