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**DOE-STD-3026-99
February 1999**

**Superseding
DOE NE F 3-44
July 1986**

DOE STANDARD

FILTER TEST FACILITY QUALITY PROGRAM PLAN



**U.S. Department of Energy
Washington, D.C. 20585**

FSC 4460

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FOREWORD

This Department of Energy standard supercedes DOE NE F 3-44 and is approved for use by all DOE components and their contractors.

This standard was developed primarily for application in U.S. Department of Energy programs. It contains specific direction for HEPA filter testing performed at a DOE-accepted HEPA Filter Test Facility (FTF). Beneficial comments (recommendations, additions, deletions) and any pertinent data that may improve this document should be sent to the Office of Nuclear Safety Policy and Standards (EH-31), U.S. Department of Energy, Washington, D.C. 20585, by letter or by using the self-addressed Document Improvement Proposal form (DOE F 1300.3) appearing at the end of this document.

DOE technical standards, such as this standard, do not establish requirements. However, all or part of the provisions in a DOE standard can become requirements under the following circumstances:

- (1) they are explicitly stated to be requirements in a DOE requirements document; or,
- (2) the organization makes a commitment to meet a standard in a contract or in an implementation plan or program plan required by a DOE requirements document.

Throughout this standard, the word "shall" is used to denote actions that must be performed if the objectives of this standard are to be met. If the provisions in this standard are made requirements through one of the two ways discussed above, then the "shall" statements would become requirements. It is not appropriate to consider that "should" statements would automatically be converted to "shall" statements as this action would violate the consensus process used to approve this standard.

NOTICE

The "Preparing Activity" wishes to establish continuity between this standard (DOE-STD-3026-99) and its direct predecessor, entitled "DOE Filter Test Facilities Quality Program Plan (NE F 3-44)." The original standard was first issued by DOE as a Nuclear Energy (NE) standard on June 1984.

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1. SCOPE

1.1 Introduction

DOE Order 5700.6C requires that all DOE contractor programs be conducted under established quality assurance programs. Basic requirements for DOE quality assurance activities appear in "Quality Assurance Program Requirements for Nuclear Facilities" ANSI/ASME NQA-1 as specifically applied to DOE Filter Test Facilities (FTF) and their operation.

1.2. Definitions

1.2.1 Acceptance Test. Inspection and testing of a nuclear grade filter to verify certain characteristics or properties which determine acceptance or rejection of that filter.

1.2.2 Airflow Resistance. An index of the energy required to maintain airflow through a filter. Airflow resistance is measured in terms of the air pressure difference (pressure drop) across a filter at a specified flow rate (e.g. see section 5.2.2, Table-1, Standard DOE-STD-3020-97).

Note: The initial airflow resistance of a new filter serves as an index of the filter's potential loading capacity.

1.2.3. Filter Test Facility (FTF). A facility accepted by the DOE specifically to conduct quality assurance inspections and tests of HEPA filters.

1.2.4 High Efficiency Particulate Air (HEPA) Filter. A throwaway, extended-media, dry type filter with a rigid casing enclosing the full depth of the pleats. Aerosol collection efficiency of the filter shall be at least 99.97% for 0.3 micrometer diameter particles. The maximum airflow resistance shall be as specified in Section 5.2.2, Table 1 of DOE Standard 3020-97.

1.2.5 Penetration. The downstream test aerosol concentration, expressed as a percentage of the upstream test aerosol concentration.

- 1.2.6 Preparing Activity. The DOE organization responsible for issue and interpretation of this standard.
- 1.2.7 Quality Program Plan (QPP). The basic document which identifies actions necessary to ensure that High Efficiency Particulate Air (HEPA) filter test and inspection data are reliable, accurate, and reproducible.
- 1.2.8 Quality Control. Those checks and balances imposed on FTF procedures and operations which implement the QPP.

2. APPLICABLE DOCUMENTS

The following documents are a part of this standard to the extent specified herein. Unless otherwise stated, the current issue date and revision number of a referenced document shall apply, including addenda and/or amendments. In the event of a conflict between provisions of this standard and provisions of the referenced documents, the text of this standard shall take precedence. Appeals in this matter may be addressed to the DOE "Preparing Activity," which is designated as the DOE entity responsible for issue and interpretation of this standard.

2.1 Department of Energy (DOE)

DOE Order 5700.6C - Quality Assurance

DOE-STD-3020-97 - Specification for HEPA Filters used by DOE Contractors

DOE-STD-3022-98 - DOE HEPA Filter Test Program

DOE-STD-3025-99 - Quality Assurance Inspection and Testing of HEPA Filters
(formerly DOE NE F 3-43)

2.2 American National Standards Institute (ANSI)

ANSI/ASME NQA-1 - Quality Assurance Program Requirements for Nuclear
Facilities

3. QUALITY PROGRAM PLAN PREPARATION

3.1 General

Each FTF shall be operated under a site-specific and documented Quality Program Plan (QPP) that provides for assessing of all FTF operations. The QPP shall be written and implemented in concert with applicable site quality programs, insofar as practicable, including on-site assessment activities. Independent inspections or surveillance of FTF activities, including provisions of this document, shall be conducted at appropriate intervals by the FTF managers or designees. Independent assessments shall be conducted periodically using on-site QA programs as deemed necessary. Findings and recommendations resulting from these activities shall be documented and satisfactorily resolved as determined by the assessor. Records of findings, recommendations, and corrective action shall be prepared and maintained.

3.2 Preparation

Each FTF shall prepare a written QPP that provides for assessing of all FTF operations. The QPP shall identify and apply to activities affecting inspection and testing of HEPA filters at each FTF. Measures presented in the following sections of this document shall be applied as necessary.

3.3 Implementation

Preparation, implementation, and maintenance of the QPP is the responsibility of the FTF manager, including provisions for purchase of suitable equipment and training of personnel.

4. REQUIREMENTS

4.1 General

This Quality Program Plan was prepared by reviewing the 18 elements of ANSI/ASME NQA-1 and selecting those elements which were directly applicable to a Quality Plan for Filter Test Facilities; therefore, this Plan is traceable to

NQA-1. The following items shall be addressed in the QPP. If certain items are determined to be not applicable, the QPP shall contain a short statement explaining and justifying each determination.

4.2 Control Measures

- 4.2.1 Design Control. Design activities associated with FTF operations shall be defined, verified, controlled, and documented. Design activities include design or modification of facilities, facility systems, test equipment, and support equipment. The use of appropriate engineering methods is required and shall be documented. The technical rationale or “basis for design” that supports planned design activities shall also be documented. (Examples of applicable systems or equipment include the High Flow Alternative Test System [HFATS], exhaust air handling systems with air cleaning capabilities, penetrometers, and associated hardware, such as chucks or calibration devices.)
- 4.2.2 Control of Purchased Items and Services. Procurement of those items and services important to testing activities shall be controlled to the extent necessary to assure quality of items or services purchased. The following are considered important procurement activities and services: source evaluation, vendor inspection, tests or certifications, and receipt inspection. Examples of applicable items that require procurement services are: test equipment, laser spectrometers, diluter boards, and calibration services. Post-receipt activities such as monitoring performance as an indicator of procured equipment/service quality.
- 4.2.3 Identification of Items. Items requiring identification and control shall be specified in the QPP. Identification requirements can be met either by marking items or maintaining documents traceable to these items. (Examples of applicable items are rejected filters and "as built" or "as modified" drawings.)
- 4.2.4 Control of Measuring and Test Equipment. Measuring and test equipment, including manometers, gages, meters, and other measuring devices, shall be controlled and calibrated within specified time periods to maintain the required

accuracy of HEPA filter test systems. Calibration of measuring devices critical for completion of HEPA filter performance tests shall be performed prior to initial use, following repairs/alterations, and periodically, as specified in the QPP.

Sources of calibration devices or services shall be specified in the QPP. Depending on the importance to the testing system, calibration sources or standards must be traceable to the National Institutes of Standards Technology (NIST) or other recognized industrial standards, including on-site standards.

Records of calibration shall be prepared and maintained as required in accordance with site procedures.

- 4.2.5 Inspection and Testing Activities. Inspections and tests of HEPA filters shall be conducted only in accordance with approved FTF procedures. Monitoring and documentation of FTF inspection and testing activities shall be accomplished in accordance with Sections 10 and 11 of DOE-STD-3020-97. The results of inspection and test activities shall be identified, either on the tested items themselves (filters), or in documents directly traceable to the items. The QPP shall provide assurance that HEPA filters that have failed to pass inspections are segregated and cannot be installed in operating air handling systems. The QPP shall provide assurance that critical test components that have failed calibration, or are out of calibration, shall not be used for testing, pending completion of corrective action. Disposition instructions for non-complying items shall be provided in the QPP.

4.3 Records Management and Document Control

- 4.3.1 Records Management. Specifications for records transmittal, distribution, and retention shall be established in the QPP. Records shall be legible, readily identifiable and retrievable. They shall be protected against damage, deterioration or loss and shall be available for assessment at any time. Retention periods for stored records shall be compatible with on-site records storage

retention periods, but in no case shall records of HEPA filter test activities and results be stored for less than three years from time of test.

- 4.3.2 Document Control. Preparation, issuance, and change of documents relating to HEPA filter test activities shall be controlled to ensure the documents are correct, current, properly reviewed, and approved. Documents and changes thereto shall be reviewed for adequacy and approved at appropriate management levels.
- 4.3.3 Procurement Documents. Documents related to the purchase of critical items, including records of inspection visits to vendors, item acceptance, and assessment of vendor quality programs (if applicable) shall be maintained by the FTF and shall be made available to authorized persons on request.
- 4.3.4 Instructions, Procedures, and Drawings. Activities performed at the FTF shall be as specified by approved written procedures covering, as a minimum, topics addressed in this standard. Operating procedures and records to show compliance with their requirements shall be retained at the FTF. Reports and/or records to customers, as specified by DOE, shall be prepared and retained at the FTF. "As built" drawings of facilities, equipment, etc., shall be kept current and retained at the FTF.
- 4.3.5 Certification Records. Records that furnish documentary evidence of FTF certification shall be specified, prepared, and maintained.

5. CORRECTIVE ACTIONS AND CONTROL OF NON-CONFORMING ITEMS

Test equipment, items, or activities identified as in non-compliance with specifications of the overall HEPA Filter Test Program, as defined in this document and related procedures, shall be corrected in a timely manner. Provisions for corrective actions, including written procedures and documentation of corrective actions, shall be included in the QPP. Documentation of non-conformance shall include a discussion of cause, identification of corrective action techniques, and a conclusion that corrective actions have been adequately completed.

HEPA filters which have failed applicable tests shall be clearly identified as non-conforming items and stored separately from filters which have been tested and found acceptable, or from filters which are awaiting testing. Disposition of non-conforming filters shall be completed according to provisions of the QPP.

6. ASSESSMENTS

FTF management staff shall conduct periodic self-assessments of filter testing activities. QA specialists not normally associated with day-to-day filter test activities shall perform periodic assessments of the FTF test program and provide results to FTF management and to the DOE. DOE, or a DOE-appointed representative, may perform assessments of FTF activities at DOE's discretion. Assessors shall be qualified by training and experience to perform the assessments. Records of all assessment or inspection activities, including identification and correction of non-conformance issues, shall be retained on site according to local records retention requirements.

7. TRAINING

Personnel qualifications shall be established and all FTF personnel shall be adequately trained to perform assigned tasks. A formal training program for various levels of FTF personnel shall be established. The training program(s) shall be described in site procedures, and records shall be maintained to indicate satisfactory trainee performance. FTF personnel shall not be allowed to test filters for penetration and resistance without supervision until they have completed their designated training. Records of training participation and performance shall be prepared and properly maintained. Levels and intensity of training shall be equivalent to that received by Non-Destructive Test (NDT) personnel.

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CONCLUDING MATERIAL

Review Activity:

DOE

DP-21/23/25/31/33

EH-11/30/63

EM-23

NE-44

ER-8.1

Field Offices

AL

CH

ID

NV

OR

SR

RF

Preparing Activity:

DOE-DP-45

Project Number:

4460-0006

National Laboratories

INEL

Area Offices

Amarillo Area Office

Kirtland Area Office

