



Department of Energy

Washington, DC 20585

July 23, 2008

The Honorable A.J. Eggenberger
 Chairman
 Defense Nuclear Facilities Safety Board
 625 Indiana Avenue, NW, Suite 700
 Washington, D.C. 20004-2901

Dear Mr. Chairman:

This is in response to your March 17, 2008, letter regarding your concerns on the increased contribution of manufacturing defects to the rejection rates of filters tested at the Filter Test Facility (FTF). Specifically, your letter requested a report on (1) actions planned by the Department of Energy (DOE) to investigate and correct the root cause of increased rejection rates of High Efficiency Particulate Air (HEPA) filters at the FTF, (2) actions planned by DOE to assess the potential degradation of critical quality program components supporting HEPA filter manufacturing attributes that are not explicitly tested at the FTF (e.g., resistance to pressure and heated air, water repellency, tensile strength), and (3) actions planned by DOE to reassess the adequacy of those non-safety-related HEPA filters providing radioactive material confinement in DOE nuclear facilities that are not subjected to 100 percent testing at the FTF, given the relatively high rejection rates observed during 2007.

The Office of Health, Safety and Security convened a working team made up of DOE Federal and contractor employees, an outside expert and FTF personnel experienced in the use, testing, and qualification of HEPA filters. On May 8, we requested additional time to respond to your letter in order to allow the assembled working team to conduct further discussions with filter/filter media manufacturers and more analysis of the available information. The working team has now developed the attached document which outlines the actions planned by DOE to address the above three issues. An overview of the actions planned was presented to your staff on June 24, 2008.

If you have any questions or concerns, please contact me at (301) 903-3777 or your staff may contact Andrew Lawrence, Director, Office of Nuclear Safety, Quality Assurance, and Environment at (202) 586-5680 or Subir Sen, Office of Quality Assurance Policy and Assistance at (301) 903-6571.

Sincerely,

Glenn S. Podonsky
 Chief Health, Safety and Security Officer
 Office of Health, Safety and Security

Enclosure

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**PLAN OF ACTION TO ADDRESS
INCREASED HEPA FILTER
REJECTION RATES**



**Department of Energy
Office of Health, Safety and Security**

July 2008

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1.0 INTRODUCTION

On March 17, 2008, the Department of Energy (DOE) Office of Health, Safety and Security (HSS) received a letter from the Defense Nuclear Facilities Safety Board (DNFSB) requesting actions planned to address the increased high-efficiency particulate air (HEPA) filter rejection rates as reported in the FY 2007 semi-annual reports issued by the HSS Office of Corporate Safety Programs. These semi-annual reports provided the results of HEPA filter inspection and testing performed at the Filter Test Facility (FTF) and recommended further actions. As indicated in the DNFSB letter, increased rejection rates indicate problems in quality control (QC) programs and manufacturing processes.

This plan of action responds to the DNFSB concerns and identifies actions planned by DOE to:

1. Investigate and correct the root cause of increased rejections rates of HEPA filters at the FTF.
2. Assess the potential degradation of critical quality program components supporting HEPA filter manufacturing attributes that are not explicitly tested at the FTF (e.g., resistance to pressure and heated air, water repellency, and tensile strength).
3. Reassess the adequacy of those non-safety-related HEPA filters providing radioactive material confinement in DOE nuclear facilities that are not subjected to 100 percent testing at the FTF, given the relatively high rejection rate.

2.0 BACKGROUND

Air Techniques International (ATI) provides HEPA filter testing services for the Department at the ATI Filter Test Facility outside Baltimore, MD. These testing services include independent quality assurance (QA) inspections and tests of HEPA filters in addition to those performed by filter manufacturers.

HEPA filters are purchased by the DOE site contractors primarily from three major manufacturers. DOE-STD-3020, *Specification for HEPA Filters Used by DOE Contractors*, and The American Society of Mechanical Engineers (ASME) AG-1, *Code on Nuclear Air and Gas Treatment*, provide the necessary guidance. Filter manufacturers assemble the HEPA filters, per the purchase order specifications, and inspect and test the filters prior to shipment to the FTF. Inspections performed at the FTF verify that there has been no shipping damage, that there are no manufacturing defects, and that the filters meet purchase order specifications. Filters that pass inspection are then tested for penetration and resistance. Filters passing the inspections and tests are re-packaged and shipped to the site. Rejected filters are returned to the manufacturer by FTF after informing the site purchasing organization.

The FTF reports the results of filter inspection and testing by purchase order to the DOE site purchasing organization. Monthly reports are provided to HSS by the FTF, and HSS produces semi-annual reports based on inspection and test results provided by the FTF. These semi-annual reports are distributed to Program Secretarial Offices and DOE Field Elements.

The FY 2007 semi-annual reports noted that the overall rejection rates of HEPA filters were significantly higher than the ten-year historical average. The increase in the rejection rates is the result of increased filter manufacturing defects and filters not meeting purchase order specifications.

3.0 DISCUSSION

DOE convened a Working Team (Team) comprised of Federal and contractor employees, an outside expert, and FTF personnel experienced in the use, testing and qualification of HEPA filters. The Team met on April 15 and 16, 2008, to develop a plan of action in response to the DNFSB letter. FTF testing data were evaluated to develop an understanding of the increased rejection rate. Additionally, teleconference interviews were conducted with the three major HEPA filter manufacturers and two other filter media manufacturers. Team members also visited the FTF on April 17, 2008 and witnessed actual inspection and testing of HEPA filters and examined samples of rejected filters.

Discussions with HEPA filter manufacturers were conducted to understand the HEPA filter manufacturing QA processes, causes of specific recent filter rejections, and to identify any recent changes to the manufacturing or QA programs. These manufacturers indicated that in recent months a number of steps have been taken to address HEPA filter manufacturing or quality problems. For example, during the teleconference with the largest filter supplier, the Directors of QA and Engineering acknowledged the existence of quality issues in their manufacturing process in FY 2007. This resulted in several upper management changes in the latter part of 2007 along with assigning a new QA manager in early 2008. This manufacturer is also performing an analysis of the causes of the defects that resulted in the increased rejection rate. Defects categorized as manufacturing deficiencies primarily included damage/defects in the filter gasket or gel seals and out-of-square filters. According to the same manufacturer, the manufacturing defects related to gaskets can be attributed to packaging, which has recently been redesigned to eliminate this problem. Also, this manufacturer installed a heated tunnel on the filter production line to ensure proper setting of the gasket glue and BLU-JEL® to eliminate damage to these sealing elements during packaging. The cause of some rejections, such as out-of-square filters and fluid seal problem, is still being investigated. According to the same manufacturer, one corrective action being considered is to rectify the out-of-square condition to ensure filters are held to the correct dimensions while pouring the urethane sealant. The use of shock sensors in the filter packaging is also being considered to determine if the out-of-square condition is occurring during shipping. Other initiatives reported to have been implemented by the manufacturer since the beginning of 2008 include: tracking of FTF rejected filters through their non-

conformance report (NCR) process re-inspection of ten percent of filters after packaging, and providing additional training for inspectors. Also, the manufacturer's representatives recently visited the FTF to inspect rejected filters and discuss inspection and testing activities.

Discussions with other major filter manufacturers revealed that they are also using NCR processes and have conducted preliminary analyses to determine the causes for filters being rejected by the FTF.

The Team also discussed filter qualification testing with the manufacturers. Filters are qualified for various combinations of filter sizes, frame material, media, gaskets, etc. The qualification test filters are manufactured in the standard production line and are required to be re-qualified every 5-years according to DOE-STD-3020 and ASME AG-1. The largest filter supplier to DOE staggers qualification tests (approximately every eighteen months) for various filters types during the 5-year interval so that all qualification tests are not performed at the same time. This indicates that the qualification tests are being periodically monitored over the 5-year interval.

4.0 PLAN OF ACTION

The following actions are planned to address the three concerns identified by the DNFSB. Table 1 provides a summary of deliverables and completion dates for each action.

DNFSB CONCERN #1: Actions planned by DOE to investigate and correct the root cause of increased rejection rates of HEPA filters at the FTF.

Since the reported FY 2007 rejection rates are higher than the historical average and are indicative of QA and manufacturing problems, the following actions will be taken to determine the extent and causes of these problems:

Action 1.1: DOE will request the filter manufacturers to determine causes of the defects identified by FTF testing and the QA process weaknesses that contributed to the increased rejection rates, and to identify corrective actions taken or planned to rectify the problems.

Action 1.2: The Team will review the manufacturers' responses to Action 1.1 along with inspection and testing procedures related to the quality control of the manufacturing process. Based on this review, the Team will document the causes for rejections and recommend corrective actions to address filter rejection rates. Additionally, the results of the FTF testing will be closely monitored by the Team through January 2009 to determine the efficacy of the corrective actions undertaken by the filter manufacturers.

The Team reviewed the flow of information between filter manufacturers, the FTF, DOE and site contractor personnel (e.g., QA, engineering and procurement) to determine if quality-related issues can be identified and communicated within DOE and to the

manufacturers in a timely manner. The Team identified weaknesses in communication that impacted taking proactive corrective actions. For example: (1) FTF test reports are routinely sent to the contractor purchasing organization; however, this information is typically not distributed to the site QA personnel responsible for supplier quality; (2) DOE Field Offices and site contractor personnel are not receiving monthly FTF reports that would provide more timely and detailed indications of potential quality problems; (3) semi-annual reports on FTF testing are typically not getting to site QA organizations; (4) site contractors are not receiving adequate descriptions of FTF filter rejections; (5) site contractors are not generating NCRs for filters rejected by FTF because the rejected filters are not sent to the site; and (6) site contractors' periodic supplier quality audit results of the HEPA filter manufacturers are not shared with other DOE site contractors. The following actions are planned to address the communication weaknesses:

Action 1.3: DOE and site contractors will appoint and provide HSS with contact information for their QA points-of-contact (POCs) for receiving HEPA filter related data/information. HSS and FTF will ensure that filter test data (monthly) are sent to these QA POCs to inform them of potential quality problems so that appropriate action can be taken in a timely manner. The distribution of the semi-annual report will also be augmented to include the QA POCs for HEPA filters.

Action 1.4: The Team will review HEPA filter data reporting processes (e.g., monthly, semi-annual, NCRs, and audit reports) and develop recommendations as needed.

Action 1.5: To increase awareness of the increased HEPA filter rejection rates and related issues, a Safety Advisory – Quality Assurance will be issued through the DOE Corporate Operating Experience program.

DNFSB CONCERN # 2: Actions planned by DOE to assess the potential degradation of critical quality program components supporting HEPA filter manufacturing attributes that are not explicitly tested at the FTF (e.g., resistance to pressure and heated air, water repellency, tensile strength).

Qualification tests are defined in DOE-STD-3020, *Specification for HEPA Filters Used by DOE Contractors*, and ASME AG-1, *Code on Nuclear Air and Gas Treatment*, and are required to be performed every five years by the manufacturers. These inspections and tests include water repellency, wet and dry tensile strength, resistance to rough handling, spot flame resistance, resistance to heated air, and overpressure. Some of these tests are applicable to the filter media and others apply to the assembled filters. Manufacturers are required to have the qualification tests performed at an independent testing facility. These tests are not duplicated at the FTF. The following actions are planned to assess the potential degradation of critical quality program components supporting HEPA filter manufacturing attributes that are not explicitly tested at the FTF.

Action 2.1: The Team will review the filter and media manufacturers' QA programs, qualification test procedures and results, production related QC test and

inspection procedures, and sampling of test and inspection results to determine if adequate controls are in place to maintain product quality. The review will address the QC of manufacturing and assembling of filter components that can potentially impact the performance of filters confirmed through the qualification tests. Appropriate recommendations will be developed.

Action 2.2: The Team will review the current requirements and protocols for manufacturers to report to DOE any failed filter requalification tests. Appropriate recommendations will be developed.

DNFSB CONCERN # 3: Actions planned by DOE to re-assess the adequacy of those non-safety-related HEPA filters providing radioactive material confinement in DOE nuclear facilities that are not subjected to 100 percent testing at the FTF, given the relative high rejection rate.

Secretary of Energy letter to the DNFSB dated June 4, 2001, as delineated in DOE-STD-3020, requires 100 percent testing at the FTF for (1) HEPA filters that are used in confinement ventilation systems in Category 1 and Category 2 nuclear facilities that perform a safety function in accident situations, or are designated as important to safety (i.e., safety class or safety significant per DOE-STD-3009-94) and, (2) HEPA filters necessary for habitability systems (e.g., filters that protect workers who must not evacuate in emergency situations because of the necessity to shutdown or control the situation). The Secretary's letter (and DOE-STD-3020) further states that "for all other applications where HEPA filters are used in confinement ventilation systems for radioactive airborne particulate, develop and document an independent tailored filter QA testing program that achieves a high degree of fitness for service. The program should include the testing of a sample of filters at the FTF. The size of the sample to be tested should be large enough to provide sufficient statistical power and significance to assure the required level of performance." While the initial indications are that a number of these HEPA filters (i.e., non-safety-related) are tested at the FTF, the following actions are planned to determine what tailored protocols are being used by the site contractors.

Action 3.1: A site survey will be conducted to document protocols for testing non-safety-related HEPA filters as defined in DOE-STD-3020. The survey will include requirements to identify the technical basis for a tailored filter testing program.

Action 3.2: The Team will evaluate the test sampling programs to ensure that approaches meet DOE expectations for statistical sampling as specified in DOE-STD-3020.

Table 1

Summary of Actions to Address Increased HEPA Filter Rejection Rates at the FTF

Number	Action	Completion Date	Deliverable	Responsibility
1.1	DOE will request the filter manufacturers to determine causes of the defects identified by FTF testing and the QA process weaknesses that contributed to the increased rejection rates, and to identify corrective actions taken or planned to rectify the problems.	August 2008 October 2008	Letters to the manufacturers Response from the manufacturers	HSS
1.2	The Team will review the manufacturers' responses to Action 1.1 along with the inspection and testing procedures related to the quality control of the manufacturing process. Based on this review, the Team will document the causes for rejections and recommend corrective actions to address filter rejection rates. Additionally, the results of the FTF testing will be closely monitored by the Team through January 2009 to determine the efficacy of the corrective actions undertaken by the filter manufacturers.	March 2009	Analysis report disseminated to the DOE complex which will include recommended corrective actions	Team
1.3	DOE and site contractors will appoint and provide HSS with contact information for their QA points-of-contact (POCs) for receiving HEPA filter-related data/information. The HSS and FTF will	August 2008	Federal and contractor POCs identified for receiving HSS HEPA filter related data/information	DOE Operations Offices and Site Contractors

Number	Action	Completion Date	Deliverable	Responsibility
	ensure that filter test data (monthly) are sent to these QA POCs to inform them of potential quality problems so that appropriate action can be taken in a timely manner. The distribution of the semi-annual report will also be augmented to include the QA POCs for HEPA filters.			
1.4	The Team will review HEPA filter data reporting processes (e.g., monthly, semi-annual, NCRs and audit reports) and develop recommendations as needed.	September 2008	Develop recommendations for filter data reporting processes	Team
1.5	To increase awareness of the increased HEPA filter rejection rates and related issues, a Safety Advisory – Quality Assurance will be issued through the DOE Corporate Operating Experience program.	August 2008	Safety Advisory – QA	HSS
2.1	The team will review the filter and media manufacturers' QA programs, qualification test procedures and results, production related QC test and inspection procedures, and a sampling of test and inspection results to determine if adequate controls are in place to maintain product quality. The review will address the QC of manufacturing and assembling filter components that can potentially impact the	December 2008	Assessment of Manufacturers' QA/QC programs	Team

Number	Action	Completion Date	Deliverable	Responsibility
	components that can potentially impact the performance of filters confirmed through the qualification tests. Appropriate recommendations will be developed.			
2.2	The Team will review the current requirements and protocols for manufacturers to report to DOE any failed filter requalification tests. Appropriate recommendations will be developed.	December 2008	Assessment of requirements and protocols for manufacturers to report to DOE any failed filter requalification tests	Team
3.1	A site survey will be conducted to document protocols for testing non-safety-related HEPA filters as defined in DOE-STD-3020. The survey will include requirements to identify the technical basis for a tailored filter testing program.	October 2008	Site survey of testing status of non-safety-related HEPA filters	DOE Operations Offices and Site Contractors and Team
3.2	The Team will evaluate the test sampling programs to ensure that approaches meet DOE expectations for statistical sampling as specified in DOE-STD-3020.	December 2008	Recommendations on test sampling program	Team