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MEMORANDUM FOR DISTRIBUTION

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SUBJECT: Completion of Actions to Address Increased High Efficiency Particulate Air Filter Rejection Rate

The Department of Energy (DOE) had previously reported the completion of several actions in a plan developed by a DOE team to address the concerns of the Defense Nuclear Facilities Safety Board (DNFSB) regarding manufacturing defects resulting in the high efficiency particulate air (HEPA) filters being rejected at a high rate from testing at the Filter Test Facility (FTF). The attached report addresses the completion of the remaining action items.

The DOE team focused its review on the quality assurance program (QA) and quality control (QC) activities related to filter manufacturing by Flanders Filters, Inc. (FFI) who supplies the vast majority of HEPA filters to DOE. The team's review did not reveal any degradation in FFI's QA and QC activities that could potentially impact filter performances that are not explicitly tested at the FTF. Additionally, the team noted that the types of defects observed from FTF testing will also not materially affect the qualification test results. However, the DOE team made several recommendations for improving the quality of filters and reporting to DOE on the results of periodic qualification testing. FFI has started implementing these recommendations through a plan of action as described in the enclosed report.

As a result of DOE's continued efforts to engage FFI to improve the quality of its filters, the overall rejection rate has decreased significantly from observed high rate in mid 2007. DOE will continue to monitor the performance of other filter manufacturers (i.e., American Air Filter and Camfil-Farr) regarding the rejection rate of their filters from the FTF inspection and testing. If the overall rejection

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rate is adversely affected because of a notable increase in defective filters, additional reviews will be conducted.

The enclosed report will be submitted to the DNFSB indicating completion of the specific action items of the plan. If you have any questions, please contact me or have your staff contact Subir Sen at (301) 903-6571 or subir.sen@hq.doe.gov.

Attachment: Review of HEPA Filter Manufacturing, Inspection and Testing

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REVIEW OF HEPA FILTER MANUFACTURING, INSPECTION, AND TESTING

PLAN OF ACTION TO ADDRESS INCREASED HEPA FILTER REJECTION RATES

Department of Energy
Office of Health, Safety and Security

March 2010

TABLE OF CONTENTS

EXECUTIVE SUMMARY 1

1.0 INTRODUCTION 4

1.1. Background 4

1.2 HEPA Filter Use and Testing 5

1.3 Purpose and Scope 6

2.0 DOE TEAM ACTIVITIES 6

3.0 EVALUATION OF QUALITY CONTROL OF HEPA FILTER MANUFACTURING, INSPECTION, AND TESTING 7

3.1. Filter Media 7

3.2. Filter Assembly 8

3.3. Issues Related to Quality Assurance and Quality Control 9

4.0 REVIEW OF CRITICAL ELEMENTS RELATED TO QUALIFICATION TESTS 10

4.1. Review of Critical Qualification Test Parameters and Quality Control Production Tests and Inspections 10

4.2. Analysis of FTF Test Results on Qualification Test Critical Elements 11

4.3. Monitoring of FTF Inspection and Test Results 11

4.4. Review Results 12

5.0 QUALIFICATION TESTING AND NOTIFICATION 12

5.1. Review of Qualification Test Results 12

5.2. Quality Control Issues 13

5.3. Recommendation 14

6.0 FOLLOW-UP ACTIONS 14

7.0 CONCLUSIONS 17

8.0 REFERENCES 18

APPENDIX A Letter to Flanders Filters, Inc. 21

EXECUTIVE SUMMARY

On March 17, 2008, the Defense Nuclear Facilities Safety Board (DNFSB) issued a letter to the Department of Energy's (DOE) Office of Health, Safety and Security (HSS) requesting actions to address the increased rejection rate of high-efficiency particulate air (HEPA) filters, as reported in the Fiscal Year (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 that DOE site contractors assess and report on the efficacy of the HEPA filter manufacturers' quality assurance (QA) programs.

In response to the DNFSB letter, a review team, comprising DOE and contractor employees experienced in HEPA filter testing, procurement, QA, engineering, and operations, drafted a plan of action to address the increase in rejection rate. The DOE team included the following areas in the plan of action which was sent to the DNFSB in July 2008.

- Results of the manufacturers' assessment of the causes of the defects identified by FTF testing, the QA process weaknesses that contributed to the increased rejection rates, and their identification of corrective actions to rectify the problems.

- Evaluation of the manufacturers' filter and media QA programs; qualification test procedures, and results; production-related quality control (QC) test and inspection procedures; and a sampling of test and inspection results to determine if adequate controls were in place to maintain product quality.

- Explanation of the current requirements and protocols for manufacturers to report any failed filter requalification tests to DOE.

To address the above actions, the DOE team contacted three filter manufacturers that provide HEPA filters to DOE facilities and subsequently sent letters requesting information regarding the causes of defects, including any manufacturing deficiencies contributing to the defects, and corrective actions to rectify the problems. Additionally, filter manufactures were requested to provide information on qualification tests. The information was requested to enable DOE to determine how filter manufactures were resolving the high rejection rate of filters tested at FTF. Responses from the three filter manufactures were received in November 2008 and requests for additional information followed to clarify the initial responses. Because Flanders Filters, Inc. (FFI) provided the vast majority of the filters and FFI filters accounted for most of the filters rejected from FTF inspection and testing, the review focused on the actions taken by FFI in manufacturing, inspecting, and testing filters that are supplied to DOE.

The increase in the rejection rate from FTF inspection and testing in mid-2007 was highlighted in the second semi-annual report of Fiscal Year (FY) 2007 and was repeated in the first semi- annual report of FY 2008 which was issued in early 2008. Subsequently, several meetings and discussions were held among DOE, FFI and the FTF

to ascertain the root causes of the defects. With FFI taking an active interest in reducing the defects, the rejection rate from FTF testing showed a general decline during the intervening period from February 2008 through May 2009. However, periodic fluctuations in the monthly rejection rate during this period and high rejection rate observed in subsequent months indicated that a more comprehensive review of FFI's QA and QC program by the DOE team was necessary. The DOE team visited the FFI manufacturing facility in August 2009 to better assess FFI's quality program and the reason for the increased rejection rate.

The DOE team review consisted of interviews with FFI management and staff; review of FFI submitted information and actions related to the HEPA filter rejection rate; and the associated root causes and corrective actions developed by FFI. The DOE team also toured the FFI manufacturing facility and observed many facets of nuclear-grade HEPA filter manufacturing operations. This visit included observation of manufacturing and QC inspection and testing, starting with HEPA filter media and filter media packs to the final filter assembly. In September 2009, FFI submitted a formal action plan to address the issues raised during the DOE team visit. FFI provided updates to the action plan in December 2009 and February 2010.

The DOE team investigated FFI's QC of filter manufacturing, inspection, and testing, as well as the root cause and corrective actions developed by FFI to address the increased filter rejections at the FTF. The DOE team determined that the FFI QC of the filter media manufacturing process included most of the qualification tests specified in the American Society of Mechanical Engineers (ASME) AG-1, *Code on Nuclear Air and Gas Treatment* and DOE Standard 3020-2005, *Specification for HEPA Filters used by DOE Contractors*. These tests provide confidence that the quality of the media is maintained for production filters. However, the review of the filter assembly process identified several opportunities for improving the quality of filters and thereby reducing the rejection rate from FTF testing.

The DOE team assessed the potential degradation of critical quality program components related to filter manufacturing. The team's review did not reveal any degradation in FFI's QA and QC activities that could potentially impact filter performances that are not explicitly tested at the FTF. Additionally, the QC program provides assurance that the filters will continue to pass the qualification tests during the intervening years between the required five-year requalification. The DOE team review indicated that the media and filter pack are being manufactured with adequate QC such that there is assurance that the filters are being manufactured to required specifications. The types of defects observed from FTF testing will not materially affect the qualification test results. However continued improvements in the manufacturing of HEPA filters are needed to reduce the fluctuations in the rejection rate.

The DOE team reviewed the current requirements and protocols for FFI to report any failed filter requalification tests to DOE. FFI is developing and implementing a formal notification process to inform DOE of failed qualification tests. FFI is also determining which filter models are going to be qualified and maintained as qualified filters.

FFI has cooperated fully during the DOE team review and has submitted a plan of action to improve the quality of filters being furnished to DOE. Some of these actions have already been implemented. FFI expects that with the implementation of the various actions outlined in the FFI plan, the rejection rate of the HEPA filters observed during testing at the FTF will significantly improve in the near term. DOE will continue to monitor the efficacy of the FFI actions to see if the HEPA filters manufactured, tested, and inspected under the revised QA program are free from defects. With the continued inspection and testing by the FTF, DOE is assured that no defective filters are being installed in DOE facilities.

1.0 INTRODUCTION

1.1. Background

On March 17, 2008, the Defense Nuclear Facilities Safety Board (DNFSB) issued a letter to the Department of Energy's (DOE) Office of Health, Safety and Security (HSS) requesting actions to address the increased rejection rate of high-efficiency particulate air (HEPA) filters, as reported in the Fiscal Year (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 that the DOE site contractors assess and report on the efficacy of the HEPA filter manufacturers' quality assurance (QA) programs.

In response to the DNFSB letter, a review team comprising Federal and contractor employees experienced in HEPA filter testing, procurement, QA, engineering, and operations drafted a plan of action to address the increase in rejection rate. In July 2008, the *Plan of Action to Address Increased HEPA Filter Rejection Rates* was submitted to the DNFSB (Reference 1). This plan of action responded to the following DNFSB concerns.

1. Actions planned by DOE to investigate and correct the root cause of increased rejections rate of HEPA filters at the FTF.
2. Actions planned by DOE to assess the potential degradation of critical HEPA filter attributes that are not explicitly tested at the FTF (e.g., resistance to pressure and heated air, water repellency, tensile strength).
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 relatively high rejection rate.

To address DNFSB concerns 1 and 2 above the DOE team contacted three filter manufacturers that provide HEPA filters to DOE facilities and subsequently sent letters requesting information regarding the causes of defects, including any manufacturing deficiencies contributing to the defects, and corrective actions to rectify the problems. Additionally, filter manufactures were requested to provide information on qualification tests. An example of the letter sent to the filter manufactures is included as Appendix A. The information was requested to enable DOE to determine how filter manufactures were resolving the high rejection rate of filters tested at FTF. Responses from the three filter manufactures were received in November 2008 and requests for additional information followed to clarify the initial responses. Because Flanders Filters, Inc. (FFI) provided the vast majority of the filters and FFI filters accounted for most of the filters rejected from FTF inspection and testing, the review focused on the actions taken by FFI in manufacturing, inspecting, and testing filters that are supplied to DOE.

The increase in the rejection rate from FTF inspection and testing in mid 2007 was highlighted in the second semi-annual report of Fiscal Year (FY) 2007 and was repeated in the first semi-annual report of FY 2008 which was issued in early 2008. Subsequently several meetings and discussions were held among DOE, FFI and the FTF to ascertain the root causes of the defects. With FFI taking an active interest in reducing the defects, the rejection rate from FTF testing showed a general decline during the intervening period from February 2008 through May 2009. However, periodic fluctuations in the monthly rejection rate during this period and high rejection rate observed in subsequent months indicated that a more comprehensive review of FFI's QA and QC program by the DOE team was necessary. The DOE team visited the FFI manufacturing facility in August 2009 to better assess FFI's quality program and the reason for the increased rejection rate.

In September 2009, FFI submitted a formal action plan to address the issues raised during the DOE team visit. FFI provided updates to the action plan in December 2009 and February 2010. Additionally in July 2009, DOE issued a report on the survey of protocols for testing non-safety related HEPA filters to address DNFSB concern number 3 above (Reference 2).

1.2 HEPA Filter Use and Testing

HEPA filters perform a critical function in the DOE nuclear facilities by providing protection against any unmitigated release of radioactive particulates from postulated accidents as described in the facility safety analysis documents. Because of the critical nature of their use, HEPA filters having safety functions are required to meet, as specified in the purchase order, DOE Standard 3020-2005 (DOE-STD-3020-2005), *Specification for HEPA Filters used by DOE Contractors* (Reference 3) and/or American Society of Mechanical Engineers (ASME) AG-1, *Code on Nuclear Air and Gas Treatment* (Reference 4). The DOE Standard requires that every HEPA filter having specific safety functions (as outlined in DOE-STD-3020-2005) must be tested by the filter manufacturer for aerosol penetration and flow resistance and must undergo independent testing at the FTF. The critical attributes that ensure that HEPA filters perform their intended function during a postulated accident are verified through a series of tests which are designated as qualification tests. Manufacturers are required to have these qualification tests performed on assembled filters at independent test facilities such as US Army Edgewood Chemical Biological Center (Edgewood) and Underwriters Laboratory (UL). Passing these tests allows manufacturers to designate these filters as qualified. Only qualified HEPA filters are allowed to be used in DOE nuclear facilities. In addition to the qualification tests, the filter manufacturers perform various tests on filter components, especially filter media, urethane adhesive, and gel seals. The tests are performed routinely on the filter components to ensure that they are continuously manufactured according to the specifications and provide assurance that the filters will not fail prematurely during periodic qualification tests.

1.3 Purpose and Scope

The purpose of this report is to present the results of the review performed by the DOE team. The report also outlines the specific actions taken to address DNFSB concerns number 1 and 2,in section 1.1. The following actions from the DOE plan served as the basis for this report.

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 rate, including identification of 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 the filter rejection rate. Additionally, the results of the FTF testing will be closely monitored by the team to determine the efficacy of the corrective actions undertaken by the filter manufacturers.

Action 2.1: The team will review the filter and media manufacturers' QA programs, qualification test procedures and results, production-related quality control (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 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.

DOE contractors purchase HEPA filters from several manufacturers. While the scope of the DOE team review focused on the actions taken by FFI in manufacturing, inspecting, and testing filters, DOE will continue to monitor the performance of other filter manufacturers (i.e., American Air Filter and Camfil-Farr) regarding their contribution to the rejection rate of filters from FTF inspection and testing. If the rejection rate increases significantly due to the contribution from the other filter manufacturers, additional reviews will be conducted.

2.0 DOE TEAM ACTIVITIES

The DOE team reviewed the responses provided by FFI and subsequently conducted conference calls with responsible FFI QA and engineering managers, and received additional information. Subsequently the DOE team toured the FFI manufacturing facility on August 24-26, 2009, to support the review required by Actions 1.2, 2.1, and 2.2. The DOE team observed many facets of the nuclear

grade HEPA filter manufacturing. These observations ranged from the production of HEPA filter media and filter media pack QC testing to the final filter assembly, inspection, and testing. The DOE team also reviewed the QC used by FFI during the manufacturing of filters. Interviews were conducted with the Vice President of Operations and Engineering, QA Manager, Plant Manager and their staffs.

3.0 EVALUATION OF QUALITY CONTROL OF HEPA FILTER MANUFACTURING, INSPECTION, AND TESTING

3.1. Filter Media

Of the three major suppliers of HEPA filters to DOE, FFI is the only one that manufactures its own filter media. Approximately 90 percent of the media used in FFI HEPA filters is manufactured by FFI. The remaining media is purchased from other media manufacturers and is used in the HEPA filter designs that have deep pleats and aluminum separators.

Filter media was manufactured by measuring specific amounts of different diameter glass fibers and chopped glass and mixing them with water in batches with the formula for each batch recorded. The filter media fiber slurry was then fed to a continuous belt screen where the water is drained, leaving a fiber mat. A binder solution with water repellency was then sprayed on the fiber mat, which was then partially dried as the media sheet was pulled through an oven. Rollers imprint an embossment on the filter while it was still partially wet to form the separation space in the pleats. Filter media production and pleating occurred in a continuous operation. The edges were trimmed to size prior to pleating. A colored dye was sprayed on the media to show where the operator manually cuts the media with a knife to separate the media into different filter packs. Six filter packs are typically formed per batch of fiber mix. The individual filter packs are packaged to retain their shape and stored for later installation into the filter frame. Each filter pack receives a final inspection and is stamped for use in filters.

FFI manufactures two types of embossed filter media: (1) W media in which the embossment is continuous along the filter media, including over the filter pleats, and (2) U media in which the embossment is intermittent over the filter media and flat over the pleats.

FFI performed a series of production QC tests on samples of the finished media from each production batch. A strip was cut from the media and tested at the FFI test laboratory for the following: flow resistance, aerosol penetration, weight, thickness, dry tensile strength in the machine and cross direction, elongation in the machine and cross direction, weight loss on ignition, stiffness in machine and cross direction, and water repellency. All of the test results were recorded on an FFI form. Any deviations in the media performance were reported, and the defective media batch was identified and not used in the filter production. The production QC tests on the filter media provided a good measure of the filter

media qualification and of a number of critical qualification test parameters in the filter qualification. However, an important media qualification test that was not performed in the production QC tests was the wet tensile strength. ASME AG-1 required that this test be performed every five-years. Performing this as a production QC test would provide additional assurance regarding the wet tensile strength of the media and, in turn, on the performance of the media in the overpressure qualification tests on the finished HEPA filters.

3.2. Filter Assembly

Assembly of filters was a sequential manual operation conducted in an assembly line fashion predominantly using hand tools. Once the media pack was formed (media pleated, folded, and cut), aluminum separators (if required) were placed by hand in between the media pleats. The media pack was then moved to the filter assembly area (nuclear grade filter assembly is segregated from non-nuclear). The filter frame sub-components (top, bottom, and two sides) were fabricated at a separate location and brought to the assembly area. The filter pack was attached to the frame in a four-step process. First, liquid urethane sealant was poured into one of the top/bottom filter frames to form a pool. The corrugated end of the filter pack was then immersed into the liquid. After allowing the urethane time to set in the first step, the same process was then repeated on the opposite corrugated end of the filter pack in a second step. In the third step, liquid urethane was poured on one of the side frames to form a thin film and the frame was then pressed against the side of the filter pack to seal the flat media end to the side frame. The same process is used in a fourth step to seal the remaining flat media end to the final side frame of the filter unit. The frame parts were then fastened together using nails on wooden frames and bolts on metal frames. Once the frame fasteners were secured, the assembly staff measured the length of opposite corners to determine if the frame was square. If adjustments were required, the assembly staff would physically push or pull opposite corners and repeat the measurements while the sealant was curing until the frame was square. The assembly staff then removed the excess urethane sealant from the filter. Additional curing time was allowed before further assembly. As specified by the filter design, faceguards were added, followed by installation of a gasket or gel seal as specified. Tools were used to aid the assemblers; for example, faceguard stretching and retaining tool or hand rollers were used to ensure that the gasket was firmly attached to the frame.

During the filter assembly operation, the team observed the staff perform various inspections and measurements as part of the QC checks. These included; media inspection, adhesive mixture checks, filter frame “squareness” checks, gel mixture checks, gel depth checks and various cleanliness inspections. However, the results of these inspections and measurements were not documented except when a filter had to be scrapped.

The final filter QC tests and inspections were conducted by specially trained and qualified staff and were performed for every nuclear grade filter. First, each filter

was subjected to aerosol penetration and flow resistance testing. The results were added to the filter label. Those that passed testing were inspected for dimensional tolerances, workmanship, cleanliness and conformance to design and purchase order. The inspection procedure and associated checklist were available at the work station. Inspectors had access to acceptance criteria from design drawings available locally on a computer. A signed inspection checklist, with the major inspection areas identified, was required for each filter.

3.3. Issues Related to Quality Assurance and Quality Control

The FFI QC testing of the HEPA filter media during manufacturing was consistent with the governing standards ASME AG-1 and DOE-STD-3020-2005. However, the review of the filter assembly operation identified the following QA and QC issues that could potentially impact the quality of the HEPA filters being manufactured.

1. A systemic approach for evaluating the root causes of observed filter defects was not being implemented. The proper identification of root causes of the filter defects is important so that corrective actions can be properly targeted to eliminate the observed defects.
2. Categorizing, trending, and performing effectiveness reviews of corrective actions were not being performed.
3. A procedure for training personnel that handle the filters during the manufacturing process had not been developed and implemented. The procedure should also address the documentation of completed training.
4. The periodic inspections and maintenance on wear points for Q-107 penetrometer machine (e.g., gasket on fixture and adaptor plate) were not sufficient to maintain the Q-107. Increasing inspection and maintenance frequency will ensure that the test equipment is available and produces accurate results.
5. Independent assessments of the QA Department were not being conducted. This is an important management tool that should be used to augment internal self-assessments including the comparison of assessment results.
6. Checklists containing the acceptance criteria and showing the completion of an operation were not being used on the manufacturing line. The signing or initialing of a checklist document attests to the fact that a particular operation has been completed.
7. The root cause(s) for filters being of the out of square were not fully resolved. The current measurement method, using a metal tape, was subject to error. Use of test fixtures and a go-no-go gauge may reduce errors.
8. Penetration testing using the large Q-107 penetrometer machine for low flow filter testing had the potential for error. This could be the reason for a number of failures of low flow filters at FTF where a smaller machine is used for testing low flow filters.

9. Manufacturing defects due to faceguards touching media and gasket failures attributed to inadequate gluing were not fully resolved. Both of these manufacturing defects contributed to the increase in the rejection rate.
10. Formal training sessions for the filter assembly staff were not being conducted, except to satisfy corrective actions. The current training approach was to require the assembly staff read the procedure.
11. The procedures that were required to be read by the QC inspectors, as shown on the Training Matrix, did not match those required on the corresponding procedure training records for QC inspectors.

Actions being taken by FFI to address the above QA and QC issues are discussed in Section 6.0.

4.0 REVIEW OF CRITICAL ELEMENTS RELATED TO QUALIFICATION TESTS

The DOE team identified a set of critical parameters affecting the qualification tests and also applicable QC production tests and inspections related to the critical parameters. Filters manufactured under an acceptable QA program, together with acceptable production tests and inspections related to the critical parameters, are expected to meet the qualification requirements during the five-year intervals between the required requalification tests. Additional confidence is provided when the multiple qualification tests of different filter models are conducted at various times (i.e., staggered) over the five-year period and involve testing some of the same parameters.

4.1. Review of Critical Qualification Test Parameters and Quality Control Production Tests and Inspections

FFI implements continuous QC in the manufacturing, testing, and inspection of filter media and filter assemblies. This QC program, in part, provides assurance that the filters would continue to be qualified (i.e., would continue to pass the qualification tests if tested) during the intervening years between the required five-year requalification. Table 1 provides a comparison between the critical parameters in the qualification tests and the parameters that are tested in the production QC operations at FFI.

The DOE team was provided with one test each for spot flame and heated air that were conducted by UL in 2008. The review indicated that these tests were successful. For other filters that were submitted to UL for testing, UL had provided certification but no test results. At the request of the DOE team, FFI has asked UL to provide the balance of the test results. However, the only significant failures in the 13 filter models submitted for qualification tests from 2002 to 2009 were not from these two tests.

4.2. Analysis of FTF Test Results on Qualification Test Critical Elements

The primary reasons for the filter rejections at the FTF were defects in gaskets and the T-clips used to clamp the filter onto the filter housing, filters being out of square, incorrect labels, and not meeting purchase order specifications. The type and nature of these defects do not affect the critical parameters influencing the qualification tests.

The defects due to faceguards touching the filter media are also not expected to impact the overpressure qualification test results. Published technical reports show that the failure mode of filters for the wet overpressure test is a ballooning of the filter pleat and a tensile rupture of the pleat end.

HEPA filters used by DOE have to pass the penetration test at the FTF and the defective filters are rejected Any significant defect in the media that could potentially affect filter performance in an overpressure condition will be detected by the FTF testing, and also by the routine in situ leak tests in the field. These testing requirements prevent potentially defective HEPA filters from being relied upon to perform during normal operation or accident conditions.

4.3. Monitoring of FTF Inspection and Test Results

Within HSS, the Office of Quality Assurance Policy and Assistance has been monitoring the results of FTF testing to determine the efficacy of the corrective actions undertaken by the filter manufacturers to improve quality. To date, the FTF test results indicate that the corrective actions taken by FFI have not been effective in systematically reducing the filter rejection rate to acceptable levels. While the overall rejection rate has decreased from its peak of 20.5 percent in FY 2007 to 10.4 percent in FY 2008 and to10.2 percent in FY 2009, there have been some upward fluctuations in the monthly rejection rate since February 2009 (see Figure 1). At the request of DOE, FFI performed a root cause analysis of the defects of the FTF rejected filters during November 2009 and implemented various corrective actions to address the defects.

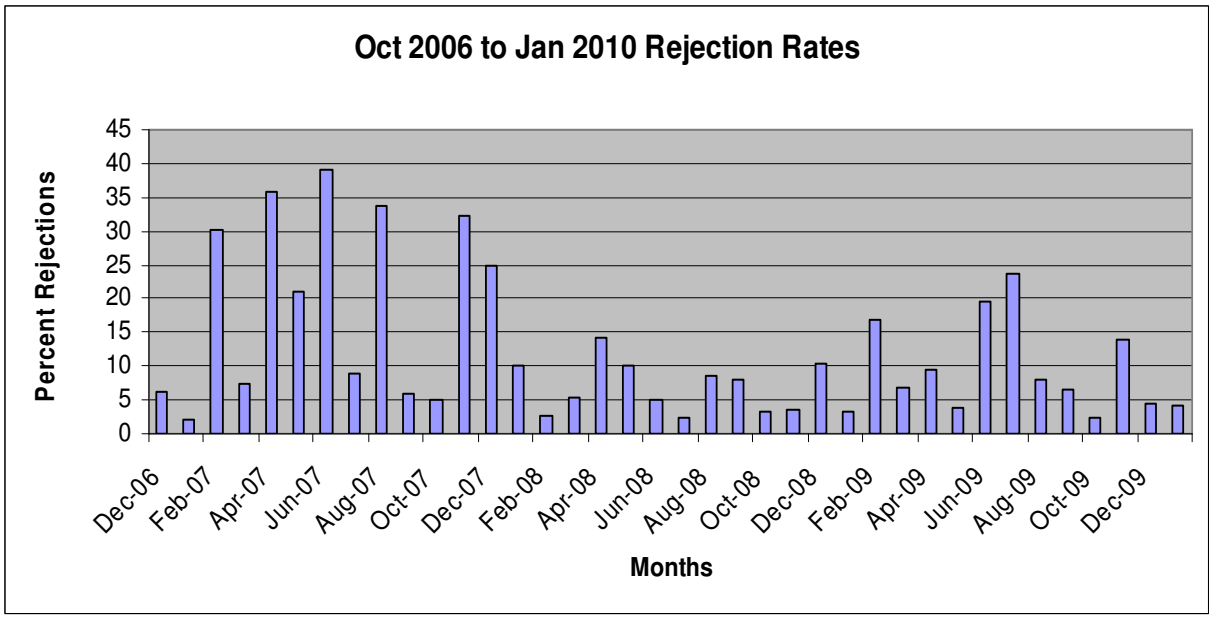

Figure 1: FTF Rejection Rate for FFI Filters

4.4. Review Results

The DOE team review indicated that the media and filter pack are being manufactured with adequate QC such that there is assurance that the filters are being manufactured to required specifications. The types of defects observed from FTF testing will not materially affect the qualification test results. However continued improvements in the manufacturing of HEPA filters are needed to reduce the fluctuations in the rejection rate. FFI recognizes the need for improvements and has undertaken programs to improve the quality of their filters (see Section 6.0).

5.0 QUALIFICATION TESTING AND NOTIFICATION

5.1. Review of Qualification Test Results

The DOE team examined the FFI filter qualification process to determine how FFI qualifies filter models, analyzes the results of qualification testing and notifies HEPA filter purchasers of failed qualification tests. Additionally, the DOE team examined the process used to document HEPA filter model qualification results and, and how these qualification results are conveyed to the purchaser through the Certificate of Conformance (COC).

FFI conducted 13 qualification tests between 2002 and 2009. FFI used the Edgewood and UL facilities as the independent laboratories to conduct the qualification testing. These are the only independent facilities that have the capabilities to conduct these qualification tests. The testing was conducted in accordance with ASME AG-1 specifications. Among the various models that were tested, two models were retested because of previous test failures. The filter

qualification test results from Edgewood on the rough handing and overpressure tests were available for the DOE team to assess compliance with ASME AG-1. The DOE team was not able to obtain sufficient information from FFI to determine that the FFI filters met the qualification requirement for the heated air test and the spot flame test. Only one set of UL heated air test data was available, and that test showed the test temperature did not comply with ASME AG-1 requirements.

Although FFI indicated that it had six qualified filter models, a complete listing of qualified filters was not available. FFI provides qualification information to the purchaser when responding to the request for quotation and then later during the delivery of the filter via the COC. FFI uses the COC to formally document the qualification status in compliance with the procurement specifications. Included in the COC is the qualification status or other applicable qualification tests results that are used to support the qualification pedigree of individual design elements (i.e., materials, components, or subassemblies). This may include qualification results of several other filter models to encompass the components of the filter model purchased.

In determining the filter models to be qualified, FFI uses sales information, as well as the provisions of ASME AG-1 and DOE-STD-3020-2005, to select filter models for qualification testing. ASME AG-1 allows for filter qualification based on qualification of a larger filter using the same materials and fabrication methods. DOE-STD-3020-2005 allowance for qualification is broader and states: "In order to reduce costs associated with qualification testing, successful tests of filters with known material components for filter frames, filter media, cases, and adhesives that have been produced by a single manufacturer can be used to qualify filters of similar construction. Similar construction is defined as manufactured using the same method, material, equipment, and process."

FFI has much of the equipment used to conduct the qualification testing and uses it to internally validate their design and fabrication process prior to independent qualification testing as well as to analyze any qualification failures. FFI relies on the Edgewood and UL facilities to analyze the qualification test results for passing tests and does not witness the testing. When filters fail a qualification test, FFI analyzes the results and conducts a review to determine the cause of the failure. However, FFI has no formal process for analyzing any potential impact of such failures from qualification tests on other filter models except for retesting the failed models. Additionally, FFI has no formal process to notify the filter purchasers or DOE of failed qualification tests. FFI is committed to developing a procedure for notification of DOE and other customers of failed requalification testing of qualified HEPA filters.

5.2. Quality Control Issues

DOE-STD-3020-2005 requires the following: "If failures are noted, the manufacturer, the FTF, and DOE contractor procurement specialists shall be

informed that the failed filter model is no longer acceptable for use in DOE facilities, pending requalification." As stated above, FFI has no formal notification process to inform DOE of failed qualification tests. In addition, any specific filter model qualification failures should be evaluated for impacts on other filter designs that were referenced in the COCs as part of the qualification basis for the specific filter model purchased. Depending upon the specific failure, this may also impact other qualified filters that are manufactured using some variation of the same method, material, equipment, and process as in the failed test.

The one exception to this observation is the failure of the overpressure qualification test for HEPA filters using the W filter pack design. FFI had two filter models using the W filter pack fail the overpressure qualification tests from 2002 to 2009. FFI performed additional testing, and the filters passed. These failures are not the result of deficiencies in the QC program but need further review by FFI as to the efficacy of the design of the W filter pack.

5.3. Recommendations

FFI is in the process of implementing the following recommendations made by the DOE team:

1. Develop a formal process for notifying the FTF, DOE, and DOE contractor procurement specialists of failed qualification tests and that the failed filter model is no longer acceptable for use in DOE facilities, pending requalification.

2. Develop and document a process including the decision logic for qualifying filters based on the qualification of other filter models consistent with the allowance described in DOE-STD-3020-2005.

3. Develop and document a process to conduct an extent-of-condition evaluation for failed qualification tests to determine if the specific component failure may indicate potential failures in other filter models.

4. Obtain records of test results for the filter qualification tests from UL to demonstrate compliance with the ASME AG-1 qualification tests on heated air and spot flame and institute a process for verifying that the filters meet the qualification requirements of ASME AG-1.

6.0 FOLLOW-UP ACTIONS

On September 28, 2009, FFI submitted a Plan of Action to address the QA and QC issues identified during the DOE team visit (Reference 5). FFI updated the Plan of Action on December 7, 2009, and has implemented or is in the process of implementing the following activities to address the QA and QC issues discussed in this report.

1. FFI has purchased and implemented Reason® root cause analysis software and has sent personnel to the software manufacturer for training. The software is used in conjunction with the FFI Non-conformance Reporting and Corrective Action Request programs to provide systematic evaluation and reporting of the root causes of defective filters. (Action Complete)

2. FFI has revised the Corrective Action Program to include categories for each corrective action issued and has formalized the trending and requirements for effectiveness reviews. Follow-up information demonstrating root cause trending has been provided. (Action Complete)

3. FFI has implemented visual work instructions for manufacturing personnel and has developed a procedure for training that also describes the use of the "Train Track" training scheduling and documentation software. (Action Complete)

4. FFI has developed and implemented a controlled work instruction for the periodic inspection and maintenance of wear points on the Q-107 and other test equipment. This should eliminate leaks that contribute to potential errors in filter penetration measurements. Inspection and maintenance activities have been added to the maintenance software package which automatically schedules and generates work orders to maintain the test equipment. (Action Complete)

5. FFI plans to have an independent assessment of the QA Department by an outside audit agency. Internal self-assessments have been performed. (Action Pending; This action has not been completed due to scheduling issues with customer audits of FFI, audits of suppliers and FFI internal QA audits of departments. Completion is expected by March 2010.)

6. FFI has implemented a process in which each filter in the manufacturing line is tagged with an In-Process Checklist. The checklist is initialed at each work station or stage in the manufacturing, assembly, and testing process. This will allow FFI to document acceptance as the filter travels through the manufacturing process and will serve as an indicator that an activity has been completed. (Action Complete)

7. FFI is conducting a detailed review and analysis of the manufacturing and assembly process in an effort to correct the defects caused by filters being out of square. The use of improved assembly methods have been implemented and while improvements have been noted, there are continuing issues with filters being out of square and this issue has not been fully resolved. FFI is now using a gauge to check the dimensional squareness rather than a tape measure. While not a "go-no-go" gauge, it is similar to the measuring device used by the FTF and should provide more consistent results when measuring the squareness of the filter. (Action Complete: However out of square issues

have not been completely eliminated, corrective actions and analysis are ongoing.)

8. FFI is investigating the installation of new test fixtures for the Q-107 penetrometer machine. Preliminary plans outline the installation of three different plenum sizes that more closely approximate the size of the filters being tested. This will allow for full encapsulation of the filters and should reduce the error associated with testing small filters in large plenums. (Action Pending: Dates have not been established for completion due to production schedules and management desire to minimize impact on production during installation of upgrades. Implementation of new Enterprise Resource Planning System has been delayed three months. Completion is expected by May 2010.)

9. FFI has modified the filter assembly process to incorporate an improved technique for attaching the faceguard so that it does not come in contact with the filter media. To correct the gasket failures attributed to inadequate gluing, FFI has incorporated the use of a roller to ensure that sufficient pressure is applied to the gasket after gluing. (Action Complete)

10. FFI is implementing illustrative procedures as part of a new training program. These procedures will be visual-based procedures that illustrate the "Do's and Don'ts" of various steps in the filter manufacturing, assembly and testing processes. The new training program will include the review of procedures and work instructions, "hands-on" training, and performance demonstrations. (Action Pending: Implementation has begun and is ongoing. QA and production personnel are working through existing work instructions and procedures and developing "visual" work instructions).

11. FFI has implemented the use of the "Train Track" training database, and the required training matrix has been updated to list the general training requirements for each department. Employee-specific training is assigned within the "Track Train" system. (Action Complete)

12. FFI is in the process of completing and implementing a procedure for notification of DOE and, where warranted, customers of failed requalification testing of qualified HEPA filters. FFI is currently evaluating the filter qualification process and what filters FFI maintains as qualified filters. (Action Pending: FFI management is currently reviewing sales history to make determinations of what filter models are going to be qualified and maintained as qualified filters. Completion is expected June 2010.)

FFI expects that with the implementation of the various actions outlined in the FFI plan, the rejection rate of the HEPA filters observed during testing at the FTF will significantly improve in the near term. The DOE team reviewed the FFI plan and, in addition to the corrective actions proposed by FFI recommends that FFI

consider conducting additional media tests on the tensile strength of the wet media and the media after heating as part of the media production QC tests. These additional tests will provide increased confidence that the filters will pass the qualification tests.

7.0 CONCLUSIONS

1. The DOE team investigated FFI's QC of filter manufacturing, inspection, and testing, as well as the root cause and corrective actions developed by FFI to address the increased filter rejections at the FTF. The DOE team determined that the FFI QC of the filter media manufacturing process included most of the qualification tests specified in the American Society of Mechanical Engineers (ASME) AG-1, *Code on Nuclear Air and Gas Treatment* and DOE Standard 3020-2005, *Specification for HEPA Filters used by DOE Contractors*. These tests provide confidence that the quality of the media is maintained for production filters. However, the review of the filter assembly process identified several opportunities for improving the quality of filters and thereby reducing the rejection rate from FTF testing. FFI has undertaken a plan of action to improve the quality of their filters.

2. The DOE team assessed the potential degradation of critical quality program components related to filter manufacturing. The team's review did not reveal any degradation in FFI's QA and QC activities that could potentially impact filter performances that are not explicitly tested at the FTF. Additionally, the QC program provides assurance that the filters will continue to pass the qualification tests during the intervening years between the required five-year requalification. The DOE team review indicated that the media and filter pack are being manufactured with adequate QC such that there is assurance that the filters are being manufactured to required specifications. The types of defects observed from FTF testing will not materially affect the qualification test results. However continued improvements in the manufacturing of HEPA filters are needed to reduce the fluctuations in the rejection rate and are currently being addressed by FFI.

3. FFI is developing and implementing a formal notification process to inform DOE of failed qualification tests. FFI is also determining which filter models are going to be qualified and maintained as qualified filters.

4. FFI has submitted a plan of action to DOE to improve the quality of filters being furnished to DOE. Some of these actions have already been implemented. FFI expects that with the implementation of the various actions outlined in the FFI plan, the rejection rate of the HEPA filters observed during testing at the FTF will significantly improve in the near term. DOE will continue to monitor the efficacy of the FFI actions to see if the HEPA filters manufactured, tested, and inspected under the revised QA program are free from defects.

8.0 REFERENCES

1. Plan of Action to Address Increased HEPA Filter Rejection Rates, July 2008.
2. Glenn Podonsky memorandum to distribution, Concurrence on Three Actions Completed to Address Increased HEPA Filter Rejection Rates, July 10, 2009.
3. DOE-STD-3020-2005, *Specification for HEPA Filters used by DOE Contractors*
4. ASME AG-1, *Code on Nuclear Air and Gas Treatment.*
5. Flanders Action Plan for Items of Concern Identified during DOE Site Visit, September 28, 2009, revised December 7, 2009 and updated February 15, 2010.

Table 1
Critical Qualification Test Parameters vs. QC Tests and Inspections during Manufacturing

Critical Qualification Test Parameters	QC Tests and Inspections during Manufacturing
Resistance to airflow (DP)	**Resistance to Airflow:** This parameter is measured for all HEPA filters.
Penetration	**Penetration:** This parameter is measured for all HEPA filters.
Heated air (demonstrates that the filter performs after exposure to heated air)	**Urethane Mixture:** This parameter is measured daily prior to the production start-up. Since improper mixing of the polymer and catalyst can lead to the urethane burning in the heated air test and cause structural damage to the HEPA filter, the production QC test provides assurance of continued qualification. **Media Pack Design:** The loss of binder and softening of the filter media during the heated air test can lead to media pack rupture and qualification failure. This failure mode occurs with mini-pleat pack designs not reinforced with a metal grid backing. The two separatorless filters that FFI produces (W-media pack, U-media pack) are reinforced with metal support plates that prevent the filter pack collapse under heated air conditions.
Spot flame (no flame propagation)	**Media (partly covered by LOI test):** FFI conducts Loss on Ignition (LOI) tests on all of the filter media that it produces as part of its production QC and ensures that the media passes the spot flame test. **Urethane (flammability test):** Mixing of urethane is measured daily prior to production startup. Since improper mixing of the polymer and catalyst can lead to failures in the spot flame test, the production QC test provides assurance of continued qualification.

Critical Qualification Test Parameters	QC Tests and Inspections during Manufacturing
Overpressure test (demonstrates filter pack blow-out capability)	**Media Wet Tensile Strength (not tested):** The wet tensile strength is an important parameter that determines whether the HEPA filter will pass the overpressure test. FFI does perform a dry tensile strength test for each media batch. **Moisture Resistance:** This parameter is tested as part of the FFI QC media production tests and provides assurance that moisture adsorption does not contribute to overpressure failures.
Rough-handling test (demonstrates that the filter can handle mechanical stresses)	**Media Stiffness:** This parameter is measured as part of the FFI QC media production. Stiff media prevents distortion of the filter pack and consequent damage under rough handling conditions. **Media Pack Design (e.g., dimple pleat):** In general, filters with separatorless media are easier to distort and damage during rough handling compared to deep pleated HEPA filters with aluminum separators. The reinforcement bars in the FFI filters help mitigate this tendency. **Media Tensile Strength:** FFI measures the media tensile strength of all its filter media batches. Media with increased tensile strength can withstand greater rough handling without encountering tears.

Appendix A
Letter to Flanders Filters, Inc

Department of Energy
Washington, DC 20585

September 22, 2008

Mr. John Urton
Director of Quality Assurance
Flanders Filters, Inc.
531 Flanders Filter Road
Washington, NC 27889

Dear Mr. Urton:

The Department of Energy (DOE) is continuing with its efforts to review the actions being taken by its suppliers of High Efficiency Particulate Air (HEPA) filters to address the increased rejection rate of filters observed in 2007 during testing at the Air Techniques International, Inc. Filter Test Facility (FTF). Your cooperation and participation in earlier conference calls with the DOE staff is very much appreciated, along with the information you provided regarding the initial investigation by Flanders Filters, Inc. into the causes for the defective filters.

On July 23, 2008, DOE submitted a plan of action to the Defense Nuclear Facilities Safety Board to address the increased rejection rate of HEPA filters. The plan outlined several actions that will be taken by DOE and its site contractors in conjunction with the filter manufacturers over the next several months for improving the quality of filters delivered to DOE by Flanders Filters, Inc. thereby reducing the high rejection rate. The information requested below is essential for DOE to determine how Flanders Filters, Inc. is resolving the problem of the high rejection rate of filters. This will also aid in the evaluation of the Flanders Filters, Inc. quality assurance (QA) program and manufacturing processes that are critical for manufacturing filters to the DOE quality requirements and specifications.

A. The root causes of the increased rejection of filters for manufacturing defects and not meeting specifications need to be investigated, identified and corrected. These rejections are indicative of inherent manufacturing and QA deficiencies. From our past communications, we understand that Flanders Filters, Inc. is pursuing this track. DOE therefore requests that Flanders Filters, Inc. determine the root causes of the defects identified by FTF testing and provide the following information regarding the reasons for the increased rejection rate:

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1. What QA and/or manufacturing process weaknesses, including worker experience, contributed to the rejection of filters tested at the FTF since October 2006?
2. What corrective actions have been taken or are planned to rectify the identified problems and improve the quality of the manufactured filters?

   DOE will review the response and will document the causes for rejections and recommend future steps to ensure that the causes for the increased rejection rate are addressed. Additionally, the results of the FTF testing will be closely monitored by DOE for the next six months (through January 2009) to determine the effectiveness of the corrective actions undertaken by the filter manufacturers.

B. Manufacturers are required to perform qualification tests as defined in DOE-STD-3020, *Specification for HEPA Filters Used by DOE Contractors,* and ASME AG-1, *Code on Nuclear Air and Gas Treatment,* at a frequency not to exceed five years. These 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.

   In order to assess the critical elements of the manufacturing process that can affect filter performance as determined by the filter qualification tests, we are requesting the following information:

1. QA program, inspection and testing procedures for production-related quality control of the filter media and filter manufacturing process, including any special process for filters selected for qualification testing.
2. Any changes made or anticipated in the production inspection and testing procedures that have resulted from the increased rejection rate or from the DOE review.
3. A sampling of production-related inspection and testing results.
4. Filter qualification test procedures, test schedule and summary results for the past ten years. Any failed qualification tests or re-tests results should also be reported including causes for the failure and corrective actions taken. If filters have failed periodic (e.g., five years) qualification re-tests, indicate what actions have been taken to notify DOE users of the failure.
5. Detailed results (including penetration and pressure drop data) of the five most recent qualification tests of which two should be re-tests.

6. For each critical qualification test parameter (e.g. overpressure), identify the associated filter element(s) and the manufacturing and/or assembly process that can have an effect on the qualification test results for that parameter. Identify the related inspections and tests that are performed to control the quality of the filter element(s) and the manufacturing and assembly processes related to that parameter.

DOE will review the submitted information to determine what further action is needed to improve the quality of the filters furnished to DOE.

Your response for items A and B above is requested by October 22, 2008. Requested documents may be sent electronically to Subir Sen at subir.sen@hq.doe.gov .

This request does not represent a commitment by the Government to pay for costs incurred in the preparation and submission of the data or any other costs incurred in response to this letter.

Thank you in advance for your assistance. Questions may be directed to me at (202) 586-5680 or to Subir Sen at subir.sen@hq.doe.gov or (301) 903-6571.

Sincerely,

Andrew C. Lawrence

Andrew C. Lawrence
Director
Office of Nuclear Safety, Quality Assurance
and Environment
Office of Health, Safety and Security

bcc: Mike Kilpatrick, HS-1
Mark Whitaker, HS-1.1
Colette Broussard, HS-23
Subir Sen, HS-23
David Grover, HS-23