**Department of Energy**

Washington, DC 20585

June 15, 2010

The Honorable Peter S. Winokur
Chairman
Defense Nuclear Facilities Safety Board
625 Indiana Avenue NW, Suite 700
Washington, D.C. 20004-2901

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2010 JUN 17 PM 3:33
DNF SAFETY BOARD

Dear Mr. Chairman:

The purpose of this letter is to report on the status of actions contained in the Department of Energy's (DOE), *Plan of Action to Address Increased HEPA Filter Rejection Rates* dated July 23, 2008. This plan was provided to the Defense Nuclear Facilities Safety Board (DNFSB) in response to the DNFSB's letter dated March 17, 2008 regarding the increased contribution of manufacturing defects to the rejection rate of filters tested at the Filter Test Facility (FTF).

At the time the plan was developed, the Office of Health, Safety and Security convened a working team that progressively implemented the various actions in the plan as summarized in the enclosed table. These included upgrading the FTF reporting requirements; gathering information on the quality control and testing performed by the filter media and filter manufacturers; reviewing the major filter manufacturer's root cause analysis of defects and corrective actions; visiting its manufacturing facility and evaluating the quality assurance and quality control practices; and monitoring FTF inspection and testing results for over one year to determine the efficacy of filter manufacturer's corrective actions.

Copies of the reports documenting completion of each action, which were previously provided to the DNFSB staff, are enclosed. As a result of the DOE Plan of Action, the rejection rate has reduced from its Fiscal Year (FY) 2007 peak of 21.5 percent to approximately 6.6 percent for the first six months of FY 2010. DOE will continue to monitor the performance of High Efficiency Particulate Air filter manufacturers regarding the rejection rate of filters from FTF inspection and testing.

Questions may be directed to me or Andrew Lawrence Director, Office of Nuclear Safety, Quality Assurance, and Environment at (202) 586-5680, or your staff may contact Subir Sen, Office of Quality Assurance Policy and Assistance, at (301) 903-6571.

Sincerely,

A large, stylized handwritten signature in black ink, appearing to read "G. Podonsky".

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



Enclosures

1. Summary of the Plan of Action to Address Increased HEPA Filter Rejection Rate
2. July 24, 2008, Safety Advisory on HEPA Filter Rejection Rates, Action 1.5
3. August 27, 2008, Quality Assurance Points-of-Contact for High Efficiency Particulate Air Filter Information, Action 1.3
4. July 10, 2009, Plan of Action to Address Increased HEPA Filter Rejection Rate, Action 1.4, 3.1 and 3.2
5. April 16, 2010, Plan of Action to Address Increased HEPA Filter Rejection Rate, Action 1.1, 1.2, 2.1 and 2.2

cc: Mari-Jo Campagnone, HS-1.1

SEPARATION

PAGE

Summary of the DOE Plan of Action to Address Increased HEPA Filter Rejection Rate

| # | Action | Status |
|-----|--|------------------------------|
| 1.1 | Filter manufacturers to determine causes and corrective actions | Completed April 16, 2010 |
| 1.2 | DOE review of filter manufacturers' response, develop recommendation and monitor FTF testing | Completed April 16, 2010 |
| 1.3 | DOE & contractor POCs identified for HEPA filter-related data/info | Completed August 27, 2008 |
| 1.4 | Review HEPA filter data reporting processes | Completed July 10, 2009 |
| 1.5 | Issue Safety Advisory – Quality Assurance on increased rejection rates | Completed July 24, 2008 |
| 2.1 | DOE review of filter manufacturers' QA and qualification programs and develop recommendations | Completed April 16, 2010 |
| 2.2 | DOE review of filter manufactures protocols for reporting failed filter qualification tests | Completed April 16, 2010 |
| 3.1 | Conduct site survey to document testing of non-safety related HEPA filters including test sampling | Completed July 10, 2009 |
| 3.2 | Evaluate test sampling to ensure it meets DOE-STD-3020 | Completed July 10, 2009 |

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Department of Energy

Washington, DC 20585

July 10, 2009

MEMORANDUM FOR DISTRIBUTION

THROUGH:

~~GLENN S. PODONSKY~~
 CHIEF HEALTH, SAFETY AND SECURITY OFFICER
 OFFICE OF HEALTH, SAFETY AND SECURITY

FROM:

ANDREW C. LAWRENCE
 DIRECTOR
 OFFICE OF NUCLEAR SAFETY, QUALITY
 ASSURANCE AND ENVIRONMENT
 OFFICE OF HEALTH, SAFETY AND SECURITY

SUBJECT:

Concurrence on Three Actions Completed to Address
 Increased High Efficiency Particulate Air Filter Rejection
 Rates

The Department of Energy's (DOE) *Plan of Action to Address Increased High Efficiency Particulate Air (HEPA) Filter Rejection Rates* (Plan) was submitted to the Defense Nuclear Facilities Safety Board (DNFSB) on July 23, 2008. The Plan was developed in response to the March 17, 2008, DNFSB letter regarding its concerns on the increased contribution of manufacturing defects to the rejection rates of filters tested at the Filter Test Facility (FTF).

In response to the DNFSB letter, a review team comprised of Federal and contractor employees experienced in HEPA filter testing, procurement, quality assurance (QA), engineering, and operations, drafted a plan of action to address the increase in rejection rates.

Action 1.4 of the Plan required DOE to review the flow of information between filter manufacturers, the FTF, and DOE and site contractor personnel to determine if quality-related issues emerging from HEPA filter inspection and testing can be identified and communicated in a more timely manner.

Actions 3.1 and 3.2 of the Plan required DOE to conduct a site survey to:

- (1) document protocols for testing non-safety related HEPA filters used in facility ventilation systems for confinement of radioactive particles as defined in DOE-STD-3020, *Specification for HEPA Filters Used by DOE Contractors*, and
- (2) to identify the technical basis for any tailored filter testing program being used. All survey respondents indicated that a tailored QA testing program is not being used and that 100 percent of the subject filters are being sent to the FTF for inspection and testing, or that a program is being implemented to do so.



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The enclosed reports document the results of the above actions and will be submitted to the DNFSB indicating completion of the specific action items of the plan.

If you have any questions, you may contact me at (202) 586-5680 or your staff may contact Subir Sen at (301) 903-6571 or subir.sen@hq.doe.gov.

Attachments

cc: Dae Chung, EM-60
Sandra L. Waisley, EM-64
Michael A. Thompson, NA-17
Samuel D. Johnson, NA-173
Frank B. Russo, NA-3.6
Robert G. Lange, NE-34
Carl R. Sykes, NE-43
Marc E. Jones, SC-31
Matt B. Cole, SC-31.1
Timothy J. Dwyer, DNFSB

Distribution:

Ines Triay, EM-1
R. Shane Johnson, NE-1
Gerald L. Talbot Jr., NA-17
George J. Malosh, SC-3

**RECOMMENDATIONS FOR
IMPROVING THE REPORTING OF
HEPA FILTER INSPECTION AND
TEST DATA**

**PLAN OF ACTION TO ADDRESS INCREASED HEPA
FILTER REJECTION RATES
ACTION 1.4**



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

July 2009

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EXECUTIVE SUMMARY

On March 17, 2008, the Department of Energy's (DOE) Office of Health, Safety and Security (HSS) was issued a letter by the Defense Nuclear Facilities Safety Board (DNFSB) requesting actions 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 by the DOE site contractors to assess and report on the efficacy of the HEPA filter manufacturers' quality assurance programs.

In response to the DNFSB letter, a plan of action was developed to address the increase in rejection rates. A team was formed comprised of Federal and contractor employees with experience and expertise in HEPA filter testing, procurement, quality assurance, engineering, and operations. The team reviewed the flow of information between and among interested stakeholders including, the FTF, and DOE and site contractor personnel (e.g., quality assurance, engineering and procurement) to evaluate the HEPA filter data reporting processes to improve the flow of information to the stakeholders from HEPA filter inspections and testing. The objective of the review was to develop a list of recommendations to improve flow of information between and among the stakeholders and in certain instances the filter manufacturers, and to strengthen the causal analysis and corrective action processes to improve HEPA filter quality.

The recommendations focus on the FTF Test and Inspection Report and include the following:

- Maintain a list, through DOE, of complex-wide HEPA filter points of contact
- Share results of DOE site contractors' periodic supplier quality assurance evaluations and source verifications of the filter manufacturers among DOE stakeholders
- Share contractors' receipt inspection nonconformance reports related to filters inspected and tested at the FTF among DOE stakeholders
- Specify in site contractor's purchase orders that manufacturers provide nonconformance reports to the site contractors for filters rejected by the FTF
- Modify the FTF process for reporting the results of the HEPA filter inspection and testing
- Modify the FTF filter rejection label and the HSS monthly and semi-annual reports to incorporate rejection codes recommended in this report

Implementing the above recommendations will significantly improve the exchange of HEPA filter inspection and testing information between and among interested stakeholders. This will enable DOE and the site contractors to institute consistent reporting of HEPA filter quality assurance related information to facilitate analysis and trending in order to take timely and appropriate corrective actions.

1.0 INTRODUCTION

1.1 *Background*

On March 17, 2008, the Department of Energy's (DOE) Office of Health, Safety and Security (HSS) was issued a letter by the Defense Nuclear Facilities Safety Board (DNFSB) requesting actions 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 by the DOE site contractors to assess and report on the efficacy of the HEPA filter manufacturers' quality assurance programs.

In response to the DNFSB letter, a review team comprised of Federal and contractor employees experienced in HEPA filter testing, procurement, quality assurance (QA), engineering, and operations, drafted a plan of action to address the increase in rejection rates. In July 2008, the *Plan of Action to Address Increased HEPA Filter Rejection Rates* was submitted to the DNFSB. One of the actions in the plan required a review of the flow of information between and among interested stakeholders, including, the FTF, site contractor personnel (e.g., QA, engineering and procurement) and DOE (Headquarter and Field offices) to determine if quality related issues could be identified and communicated among these stakeholders, and in certain instances the filter manufacturers in a timely manner.

Several weaknesses in communication were identified that impacted taking appropriate corrective actions. For example: (1) FTF test reports were routinely sent to the contractor purchasing organization; however, this information was typically not distributed to the site QA personnel responsible for supplier quality; (2) DOE Field Offices and site contractor personnel were not receiving monthly FTF reports that would provide more timely and detailed indication of potential quality problems; (3) semi-annual reports on FTF testing were typically not distributed to site QA organizations; (4) site contractors were not receiving sufficiently detailed descriptions of causes for filter rejections; (5) site contractors were not generating nonconformance reports (NCRs) for filters rejected by FTF as rejected filters are not sent to the site; (6) FTF was not receiving site contractor NCRs resulting from receipt inspections; and (7) site contractors' periodic supplier quality audit results of the HEPA filter manufacturers were not shared with other DOE site contractors. The plan of action therefore called for a review to improve communication of HEPA filter inspection and test data between and among interested stakeholders.

1.2 *Review Purpose, Scope, and Objectives*

The purpose of the review was to evaluate the HEPA filter data reporting processes to improve and accelerate the flow of information from HEPA filter testing and inspections. The scope of this review included information related to QA inspection and testing of

Recommendations for Improving the Reporting of HEPA Filter Inspection and Test Data

HEPA filters at the FTF, reporting of the HEPA filter rejection rates and associated trending, and also inspections and QA related actions taken by site contractors. The objective of the review was to develop a list of recommendations that will improve flow of information and strengthen the corrective action and causal analysis processes to enhance HEPA filter quality and thereby reduce the rejection rate for filters from inspection and testing at the FTF.

2.0 REVIEW METHODS

2.1 APPROACH

The review focused on the adequacy of specific data collection and dissemination from FTF filter inspection and tests and other inspections conducted by site contractors. The current reporting processes were examined, specifically in light of the weaknesses highlighted in Section 1.1. The review also considered specific data/information submittal requirements specified in DOE-STD-3020-2005, *Specification for HEPA Filters Used by DOE Contractors*, and DOE-STD-3025-2007, *Quality Assurance Inspection and Testing of HEPA Filters*.

The review included examining the distribution of information (was it getting to the right person in a timely fashion?) and the data content to ensure the right data and an appropriate level of detail were being captured. The interaction among various stakeholders (i.e., DOE, site contractors, manufacturers, and FTF) was examined to assure that: (1) there were clear requirements for monitoring manufacturer's quality performance and corrective actions related to manufacturing defects; (2) QA-related information was shared among site contractors and (3) the results of site receipt inspection of filters were shared with the FTF. The reporting processes were then evaluated for improvements and several recommendations were developed.

2.2 Reference Documents

The following documents were used to determine the basic requirements for the review:

- *Plan of Action to Address Increased HEPA Filter Rejection Rates*, July 2008
- DOE-STD-3020-2005, *Specification for HEPA Filters Used by DOE Contractors*
- DOE-STD-3025-2007, *Quality Assurance Inspection and Testing of HEPA Filters*

3.0 REVIEW RESULTS

3.1 Recommendations

The evaluation performed pursuant to Section 2.1 resulted in recommending the following six specific improvements to the current reporting processes. The focus of the recommendations is to institute consistent reporting of FTF and other inspection and test results to facilitate analysis and trending as well as taking timely and appropriate corrective actions.

3.1.1 *Maintain a list of DOE complex-wide High Efficiency Particulate Air filter points of contact*

One of the DOE plans of action (Action 1.3) specified that HSS establish a list of DOE and contractor QA points of contact (POC) for receiving HEPA filter-related data/information, such as the FTF monthly and semi-annual reports, to enable appropriate and timely response to quality issues. The QA POC list has been developed and it is recommended that HSS maintain the list and circulate it annually to obtain updates from the Program Secretarial Offices (PSOs) and Field Elements.

3.1.2 *Share results of site contractors' periodic supplier quality assurance evaluations and supplier source verifications of filter manufacturers*

It is recommended that the site contractors through the Field Elements share information on the supplier (filter manufacturer) QA audit/evaluations and supplier source verifications performed by the site contractors. As these QA audits and verifications of the HEPA filter manufacturers are performed, the site contractors, a copy of the results should be provided to HSS for distribution to the HEPA filter QA POCs. Sharing this information may eliminate some duplication of effort with QA evaluations and will notify other sites of potential issues with the manufacturers' QA programs.

3.1.3 *Share site contractors' receipt inspection nonconformance reports related to Filter Test Facility testing*

It is recommended that the site contractors through the Field Elements provide HSS with a copy of contractor on-site HEPA filter receipt inspection nonconformance reports (NCRs) related to the inspection and test activities performed by the FTF. HSS will then forward the NCRs to the FTF for action. Also, Field Elements will specify that the site contractors should categorize their receipt inspection rejections using the same rejection codes as indicated in Appendix A, Page 4 of 4. This will allow HSS to monitor post FTF inspection and testing DOE-wide. This data may also be valuable in evaluating FTF inspection and testing protocols.

3.1.4 *Specify in site contractor's purchase orders that manufacturers provide nonconformance reports for filters rejected by the Filter Test Facility*

It is recommended that the site contractors specify in their purchase orders that filter manufacturers issue NCRs for filters rejected by FTF. Additionally, the contractor's purchase orders should specify that the manufacturer maintain a customer specific rejection rate by the same rejection codes used in the FTF inspection and test report. This should also include filters rejected from contractors' receipt inspections and reported to the manufacturer. As an ASME NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications*, qualified supplier, the manufacturer should already be performing this activity in accordance with its approved QA program. The contractor's purchase

Recommendations for Improving the Reporting of HEPA Filter Inspection and Test Data

orders should also specify that the supplier provide information related to the disposition of filters returned (i.e., rejected) by the FTF, including corrective actions taken, when requested. This will ensure that the manufacturers are taking appropriate action to supply NCRs for filter rejections, and DOE will have documented evidence that appropriate corrective actions are occurring. The contractors should request such documentation when audits are conducted or on an as needed basis to ascertain the effectiveness of the corrective actions taken by the manufacturers as well as the effectiveness of the filter manufacturer's QA program.

3.1.5 Modify the Filter Test Facility process for reporting the results of High Efficiency Particulate Air filter inspections and tests

Critical to the trending of HEPA filter rejections is the monitoring of the HEPA filter quality by the FTF. The FTF conducts quality inspections and tests for each HEPA filter and records the results (including details on rejections) in the FTF inspection and test report. In addition to providing results and details of rejections for each filter, the FTF inspection and test report provides the source data for the DOE monthly and semi-annual reports.

It is recommended that DOE revise the FTF format for reporting the results of the HEPA filter inspections and tests as follows: (1) the FTF inspection and test report will be modified as shown in Appendix A, Page 1 of 1 to report results for each filter inspection and test; (2) the FTF will include a separate sheet (see Appendix A, Page 3 of 3) to record the rejection code and supplemental description to document the details of the filter rejection and, (3) the FTF should use a standardized set of rejection codes (see Appendix A, Page 4 of 4). The FTF will use the inspection checklist (see Appendix A, Page 2 of 2) to document the inspection for the specific purchase order but will not be required for each filter. The distribution of the FTF inspection and test report will remain with the site contractor procurement contact.

3.1.6 Modify the Filter Test Facility filter rejection label and the HSS monthly and semi-annual reports to incorporate recommended rejection codes

It is recommended that the FTF modify the rejection codes generated in its monthly and semi-annual reports to match the rejection codes identified in Appendix A, Page 4 of 4 (see attached Inspection and Test Report). This will ensure that the contractors receive sufficiently detailed descriptions of causes for filters rejected from FTF testing. It is expected that the contractors will also use these rejection codes during their receipt inspection for consistency from site to site. See Appendix B for an example of the use of the rejection codes for a FTF generated monthly report.

4.0 CONCLUSIONS

The team made six recommendations resulting from evaluation of the reports and data required by the DOE HEPA filter Standards. Implementing the recommendations will significantly improve the exchange of FTF inspection and testing information. This will enable DOE to institute consistent timely reporting of HEPA filter QA related information to facilitate analysis and trending in order to take timely and appropriate corrective actions.

| Recommendation | Responsibility |
|---|-------------------------------------|
| 3.1.1 Maintain a list, of DOE complex-wide HEPA filter points of contact | HSS |
| 3.1.2 Share results of site contractors' periodic supplier QA evaluations and supplier source verifications of the filter manufacturers | Site contractors/Field Elements/HSS |
| 3.1.3 Share site contractors' receipt inspection NCRs related to FTF testing | Site contractor/Field Elements/HSS |
| 3.1.4 Specify in site contractor's purchase orders that manufacturers provide NCRs for filters rejected by the FTF | Site contractors |
| 3.1.5 Modify the FTF process for reporting the results of HEPA filter inspections and tests | FTF |
| 3.1.6 Modify the FTF filter rejection label and the HSS monthly and semi-annual reports to incorporate recommended rejection codes | FTF |

Appendix A

FTF Inspection and Test Report (Page 1 of 4)

PAGE 1 OF 1

| | | | |
|--|--|------------------------------------|----------------------------|
| CUSTOMER Fluor Hanford | TEST CRITERIA | NUMBER ORDERED 7 | DATE RECEIVED 10 Apr 08 |
| | DOP PENETRATION | | |
| PURCHASE ORDER NO. 00034833 | LINE No. <input type="checkbox"/> | NUMBER RECEIVED 7 | DATE TESTED 22 Apr 08 |
| REPLACEMENTS: Yes <input type="checkbox"/> No <input type="checkbox"/> | .03 % @ RATED FLOW / .03 % @ 20 % RATED FLOW RESISTANCE 1.3 IN., W.G. @ 100 % RATED FLOW | | |
| FILTER MODEL NUMBER 0-007-D-43-05-NU-51-23-CC-DU5 | SPECIFICATION HNF-S-0552 Rev. 5 & Data Sheet | NUMBER ACCEPT 4 | DATE SHIPPED 22 Apr 08 |
| MANUFACTURER Flanders | TEST CONDITIONS | REJECTION SUMMARY | |
| FILTER DESCRIPTION Mtl 12x12x5.88 GRDX2 FS Up | TEMPERATURE 68° F | TEST FLOW (ACFM) 125/25 | PENETRATION 1 |
| PO reviewed by JKF/DWC/JAS | RATED FLOW 125 CFM | Barometer 757 mm hg. | Humidity 50% RH |
| | | TRANS/PACKAGING DAMAGE 1 | LABELING |
| | | RESISTANCE | PO/SPEC |
| | | | FILTER DEFECT 1 |

| ITEM No. | FILTER SERIAL NUMBER | VISUAL INSPECTION | | TEST RESULTS | | | DISPOSITION | | | |
|----------|----------------------|-------------------------------------|-------------------------------------|--------------|---------------|------------|-------------------------------------|-------------------------------------|-------------------------------------|------------------------|
| | | Pass | Fail | RESISTANCE | % PENETRATION | | ACCEPT | ACCEPT W/WAIVER | REJECT | PRIMARY REJECTION CODE |
| | | | | | @ 100% FLOW | @ 20% FLOW | | | | |
| 1 | 133457 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.0 | 0.002 | 0.003 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | - |
| 2 | 133458 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.0 | 0.002 | 0.003 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | - |
| 3 | 133459 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.1 | 0.004 | 0.005 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | - |
| 4 | 133460 | <input type="checkbox"/> | <input checked="" type="checkbox"/> | 1.1 | 0.005 | 0.007 | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | - |
| 5 | 133461 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 0.9 | 0.005 | 0.006 | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | P |
| 6 | 133462 | <input type="checkbox"/> | <input checked="" type="checkbox"/> | N/A | N/A | N/A | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | F |
| 7 | 133463 | <input type="checkbox"/> | <input checked="" type="checkbox"/> | N/A | N/A | N/A | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | T |
| 8 | | <input type="checkbox"/> | <input type="checkbox"/> | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | - |
| 9 | | <input type="checkbox"/> | <input type="checkbox"/> | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | - |
| 10 | | <input type="checkbox"/> | <input type="checkbox"/> | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | - |

| | |
|--|--|
| DISTRIBUTION Marge A Palfrey e-mailed 22 Apr 08 | Tested BY:  Approved BY:  |
|--|--|

Appendix A

FTF Inspection and Test Report (Page 3 of 4)

FTF HEPA Test/Inspection Comment Form

| Part I: Reference Information | | | | | | | | | |
|---|---------------|------------------------------|--|--|---------------|--|-----------------------------|---|--|
| P.O. Number | P.O. Revision | P.O. Line | Specification Number | Spec. Revision | Other: | | | | |
| 34833 | 0 | 1 | HNF-S-0552 | 5 | PO Data Sheet | | | | |
| Part II: Initial Receipt Inspection for Carrier Damage | | | | | | | | | |
| Carrier Damage Noted? | | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | Picture Available? | | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> | |
| If yes, describe type and extent of damage Below: N/A | | | | | | | | | |
| Part III: Purchase Order /Specification Compliance Review | | | | | | | | | |
| Is quantity of filters received consistent with purchase order? | | | | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> | | | | | |
| Are filter attributes (material, size, construction, etc.) consistent with Purchase Order? | | | | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> | | | | | |
| Are Buyer-specified (special) tests performed as required per the Purchase Order? | | | | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> | | | | | |
| Is Buyer-specified (special) labeling applied as required per the Purchase Order? | | | | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> | | | | | |
| Is Buyer-specified documentation provided with the shipment? | | | | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> | | | | | |
| Other: N/A | | | | Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/> | | | | | |
| Part IV: Detailed Inspection/Test Report and FTF | | | | | | | | | |
| Item # | Serial Number | (Primary) Rejection Code | | (Secondary/Other) Defect/Deficiencies | | FTF Inspection/Test Comments: | Inspector Initials | Photo Available | |
| | | Type | Class | Type | Class | | | | |
| <i>Note: Unlock form and copy additional rows as necessary. Ensure all data entries are performed in "Locked" mode.</i> | | | | | | | | | |
| 4 | 133460 | - | - | F | 3 | Small dent located on side of filter case . Affected area is less than 3/4 inch in diameter approximately 1/32 inch deep. It appears the filter was bumped against a sharp corner/ object during handling. The dent is located near the sealing face and is unlikely to have impacted the filter pack. Per J. Jones E-mail dated 10/18/08, filter buyer has requested a rejection waiver and has accepted the filter as-is. Rejection Waiver is on file. | J.M. | Yes | |
| 5 | 133461 | F | 10 | - | - | Two small gouges in gel seal on upstream side. 1/2" and 3/4" on each side of corner. | J.F. | Yes | |
| 6 | 133462 | F | 11 | L | 3 | Frame channel is not adequately filled with sealant to assure proper seal during installation. Sealant on one edge of the channel is less than 1/8 inch deep. Lower corner of Filter label is torn. Portion of label showing UL-586 compliance is missing. | D.C. | No | |
| 7 | 133463 | T | 1 | - | - | Box damage resulting in damage to faceguard. | D.C. | Yes | |
| | | - | - | - | - | | - | - | |
| | | - | - | - | - | | - | - | |

Appendix A
FTF Inspection and Test Report (Page 4 of 4)

HEPA Filter Rejection Codes

Filter Description Codes

Rejection Type

Note: Data in the Semi-Annual report will be binned using the following five rejection types.

- P – Penetration
- R – Resistance
- S – Specification/Purchase Order
- T – Transportation/Packaging
- F – Filter Defect/Deficiency

| Code | Description |
|---------|--|
| MTL | Metal Filter |
| WD | Wood Filter |
| SEPLESS | Separatorless Filter Pack |
| GRD | Face Guards, X1 = 1 faceguard, X2 = 2 faceguards |
| GSK | Gasket |
| FS | Fluid Seal |
| UP | Upstream for either the gasket or the fluid seal |
| DN | Downstream for either the gasket or fluid seal |
| NIP | Nipple ended connection X1 one connection X2 two connections |
| CYL | Cylindrical Units |

Rejection Class

Note: To enable detailed comparisons between sites/contractors data, Monthly reports will include the following rejection classes.

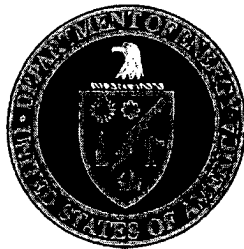
| <u>Penetration</u> | <u>Filter Defects</u> |
|---|--|
| P1 Excessive penetration at 100% rated flow | F1 Filter media pack (i.e. uneven pleats, etc.) |
| P2 Excessive penetration at 20% rated flow | F2 Filter media (i.e., damages, holes, etc.) |
| P3 Excessive penetration at both flows | F3 Frame, damage |
| <u>Resistance</u> | F4 Frame, out of square |
| R1 Excessive resistance at rated flow | F5 Frame, dimensional tolerances (excluding out of square) |
| <u>Specification/Purchase Order</u> | F6 Frame, other |
| S1 Special test or unique requirements not met | F7 Gasket, adherence |
| S2 Material of construction | F8 Gasket, damage |
| S3 Labeling, (purchase order wide) | F9 Gasket, other |
| S4 Filter attributes (i.e. no faceguards when required, etc.) | F10 Fluid seal, damage |
| S5 Documentation (C.O.C. not included, etc.) | F11 Fluid seal, other |
| S6 Label error | F12 Faceguard |
| S7 Label missing or damaged | F13 Separator |
| S6 Other | F14 Other |
| <u>Transportation/Packaging</u> | |
| T1 Container/carton damage | |
| T2 Improper packaging | |
| T3 Other | |

Appendix B Monthly Report Format

| Purchaser | Purchase Order Number | Item # | Mfg. | Size (cfm) | Model # | Quantity Tested | Testing Completed | Date Shipped | Number Rejected | Rejection Cause |
|---------------|-----------------------|--------|------|------------|--------------------------------|-----------------|-------------------|--------------|-----------------|-----------------|
| LANL | 64657-001-08-9B | 1 | F | 1500 | 0-007-U-43-03-NU-12-23-GG-FU5 | 2 | 6-Aug-08 | 7-Aug-08 | 0 | |
| WSR | AC65795A | 2 | F | 350 | X-007-8-42-01-NU-13-13-Z96687B | 1 | 11-Aug-08 | 12-Aug-08 | 0 | |
| WSR | AC65832A | 1 | F | 1000 | D-007-W-42-R1-NU-13-13-Z07185 | 2 | 11-Aug-08 | 12-Aug-08 | 0 | |
| WSR | AC64161A | 1 | F | 1000 | 0-007-W-04-00-NU-11-13-GG-FU5 | 20 | 29-Jul-08 | 5-Aug-08 | 2 | 1-F7, 1-F3 |
| WSR | AC64161A | 2 | F | 1000 | 0-007-W-04-00-NU-11-13-GG-FU5 | 16 | 29-Jul-08 | 5-Aug-08 | 1 | F4 |
| WSR | AC64161A | 3 | F | 1500 | T-007-W-04-05-NU-51-13-GG-FU5 | 8 | 29-Jul-08 | 5-Aug-08 | 0 | |
| WSR | AC64161A | 4 | F | 1000 | 0-007-W-43-03-NU-11-23-GG-FU5 | 5 | 30-Jul-08 | 5-Aug-08 | 1 | F5 |
| WSR | AC64161A | 5 | F | 50 | 0-007-D-42-03-NU-11-00-BB-DU5 | 6 | 30-Jul-08 | 5-Aug-08 | 0 | |
| WSR | AC64161A | 6 | F | 1000 | 0-007-W-04-00-NU-13-13-GG-FU5 | 4 | 29-Jul-08 | 5-Aug-08 | 1 | F7 |
| WSR | AC64161A | 7 | F | 1000 | 0-007-W-42-N2-NU-00-13-Z77180J | 10 | 30-Jul-08 | 5-Aug-08 | 2 | 2-P3 |
| INL/CH2M-WG | 711789 | 1 | F | 1000 | T-007-W-43-05-NU-51-23-GG-FU5 | 4 | 5-Aug-08 | 6-Aug-08 | 0 | |
| Fluor Hanford | 35619 | 1 | F | 125 | 0-007-D-43-05-NU-51-23-CC-DU5 | 3 | 7-Aug-08 | 12-Aug-08 | 2 | 2-P3 |
| WSR | AC65229A | 1 | F | 1000 | T-007-W-12-05-NU-51-23-GG-FU5 | 5 | 5-Aug-08 | 7-Aug-08 | 0 | |
| WSR | AC65229A | 2 | F | 1000 | T-007-W-12-05-NU-51-23-GG-FU5 | 1 | 5-Aug-08 | 7-Aug-08 | 0 | |
| WSR | AC65229A | 3 | F | 1000 | 0-007-W-04-00-NU-11-13-GG-FU5 | 8 | 5-Aug-08 | 7-Aug-08 | 2 | 2-F4 |
| Fluor Hanford | 35670 | 1 | F | 1500 | T-007-U-43-05-NU-51-23-GG-FU5 | 48 | 11-Aug-08 | 12-Aug-08 | 0 | |
| WSR | AC67709A | 1 | F | 1000 | 0-007-W-04-05-NU-52-12-GG-FU5 | 5 | 6-Aug-08 | 7-Aug-08 | 0 | |
| INL/CH2M-WG | 715077 | 1 | F | 1000 | T-007-U-43-05-NU-51-23-GG-FU5 | 60 | 12-Aug-08 | 20-Aug-08 | 8 | 6-P3, 2-F4 |
| WSR | AC67709A | 2 | F | 1000 | 0-007-W-04-05-NU-52-12-GG-FU5 | 20 | 11-Aug-08 | 12-Aug-08 | 1 | F5 |
| WSR | AC67356A | 1 | F | 1500 | T-007-W-04-05-NU-51-13-GG-FU5 | 16 | 12-Aug-08 | 13-Aug-08 | 0 | |
| WSR | AC67726A | 1 | F | 50 | 0-007-C-04-00-NU-13-00-BB-DU5 | 13 | 20-Aug-08 | 20-Aug-08 | 2 | 1-P1, 1-F4 |
| | | | | | | 257 | | | 22 | |
| Notes: | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
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**SURVEY OF PROTOCOLS FOR
TESTING NON-SAFETY RELATED
HEPA FILTERS**

**PLAN OF ACTION TO ADDRESS INCREASED HEPA
FILTER REJECTION RATES
ACTIONS 3.1 & 3.2**



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

July 2009

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1.0 INTRODUCTION

1.1 *Background*

On March 17, 2008, the Department of Energy's (DOE) Office of Health, Safety and Security (HSS) received a letter from the Defense Nuclear Facilities Safety Board (DNFSB) requesting actions 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 by the DOE site contractors to assess and report on the efficacy of the HEPA filter manufacturers' quality assurance programs.

In response to the DNFSB letter, a review team comprised of Federal and contractor employees experienced in HEPA filter testing, procurement, quality assurance (QA), engineering, and operations, drafted a plan of action to address several concerns expressed by the DNFSB regarding the increase in rejection rates from testing at the FTF. In July 2008, the *Plan of Action to Address Increased HEPA Filter Rejection Rates* was submitted to the DNFSB. One of the concerns raised by the DNFSB related to the testing of non-safety related HEPA filters in the facility ventilation system that have a confinement function for radioactive material as defined in DOE-STD-3020, *Specification for HEPA Filters Used by DOE Contractors*. A robust testing plan based on testing a sample of such filters is permitted by DOE-STD-3020 whereby the filter samples are tested at the FTF. However, the DNFSB cited the increased rejection rate and the prudence of using a test sampling program because of the increased rejection rates. To assess the existing protocols for testing such non-safety HEPA filters, Action 3.1 in the plan required that a site survey be conducted to (1) document protocols for testing the subject non-safety-related HEPA filters, and (2) identify the technical basis for any filter test sampling program that might be in use. Action 3.2 in the plan required the team to evaluate test sampling programs that may be in use to ensure that approaches meet DOE expectations for statistical sampling as specified in DOE-STD-3020.

1.2 *Survey Purpose, Scope, and Objectives*

On October 6, 2008, a letter (See Appendix A) with survey questions was sent to Program Secretarial Officers and Site Office Managers. The purpose of the survey was to assess the adequacy of sampling programs used by DOE site contractors for testing the non-safety related HEPA filters. Sites were requested to provide the following information:

- A description of any tailored QA testing program used, including scope and applicability, and the technical basis for establishing the current statistical sampling program to tailor the FTF testing.
- If the site contractor's program does not specify that a sample of non-safety related HEPA filters be tested at the FTF, describe what testing is done to meet the provisions of DOE-STD-3020.

1.3 Survey Reference Documents

- *Plan of Action to Address Increased HEPA Filter Rejection Rates, July 2008*
- *DOE-STD-3020-2005, Specification for HEPA Filters Used by DOE Contractors*

2.0 SURVEY RESULTS

The results of the survey are shown in Appendix B. All survey respondents indicated that a tailored QA testing program is not being used and that 100 percent of the subject filters are being sent to the FTF for inspection and testing, or that a program is being implemented to do so.

3.0 CONCLUSIONS

Based on the survey results, test sampling programs are not being used for non-safety related HEPA filters used in confinement ventilation systems at DOE defense nuclear facilities and 100 percent of the filters are or will be sent to the FTF for inspection and testing. This eliminates any concern regarding the adequacy of any sampling program to detect potentially defective filters that would not have been otherwise tested at the FTF.

APPENDIX A
LETTER TO PSOs AND SITE OFFICE MANAGERS



Department of Energy
Washington, DC 20585

October 6, 2008

MEMORANDUM FOR DISTRIBUTION

THROUGH: ~~GLENN S. PODONSKY~~
~~CHIEF HEALTH, SAFETY AND SECURITY OFFICER~~
~~OFFICE OF HEALTH, SAFETY AND SECURITY~~

FROM: ANDREW C. LAWRENCE *Andrew C. Lawrence*
DIRECTOR
OFFICE OF NUCLEAR SAFETY, QUALITY
ASSURANCE AND ENVIRONMENT
OFFICE OF HEALTH, SAFETY AND SECURITY

SUBJECT: Request for Information on Filter Test Facility Testing
Non-Safety High Efficiency Particular Air Filters Used
For Radioactive Confinement

On July 23, 2008, the Department of Energy (DOE) submitted a plan of action (Plan) to the Defense Nuclear Facilities Safety Board (DNFSB) to address several issues regarding the increased rejection rate of High Efficiency Particulate Air (HEPA) filters tested at the Air Techniques International Filter Test Facility (FTF). One of the issues relates to a specific category of filters that are designated as non-safety related but are providing radioactive material confinement in DOE nuclear facilities. These filters are not required by DOE to be 100 percent tested at the FTF. Since the increased rejection rate indicates problems in the manufacturers' quality assurance (QA) programs and filter manufacturing processes, the DNFSB requested information on actions planned by DOE to reassess the adequacy of the less than 100 percent testing provision for these non-safety-related filters.

The Secretary of Energy's letter to the DNFSB dated June 4, 2001, (and DOE-STD-3020-2005, *Specification for HEPA Filters Used by DOE Contractors*) 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." It is this category of HEPA filters about which the DNFSB has expressed concerns regarding the effectiveness of tailored QA sampling programs used to assure acceptable levels of quality and performance.

To assess the adequacy of any sampling program used for testing the aforementioned category of HEPA filters, a site survey is needed as outlined in Action 3.1 of the Plan. The survey will be used to gather information on what tailored filter testing programs are being used by DOE site contractors. Accordingly, please provide us with the following information:

1. A description of any tailored QA testing program used, including its scope and applicability, and the technical basis for establishing the current statistical sampling program for FTF testing.
2. If the site contractor's program does not specify that a sample of non-safety-related HEPA filters be tested at the FTF, describe what testing is done to meet the requirements specified in the Secretary's letter.

The Team that developed the Plan will evaluate the submitted information and will assess if the sampling programs meet DOE expectations for statistical sampling as specified in the Secretary of Energy's letter. Based on this assessment, appropriate recommendations will be made regarding the efficacy of any sampling program.

Please provide the above information no later than October 29, 2008. Questions may be directed to me at (301) 903-3777 or your staff may contact Subir Sen, at subir.sen@hq.doe.gov or (301) 903-6571.

cc: Richard H. Lagdon, US
Michael A. Kilpatrick, HS-1
C. Russell H. Shearer, HS-1
Mark B. Whitaker, HS-1.1
Robert J. McMorland, HS-1.1
Frank B. Russo, NA-3.6
Don F. Nichols, NA-1
Michael A. Thompson, NA-173
Samuel D. Johnson, NA-173
Marc Jones, SC-31
Matt Cole, SC- 31.1
Dae Chung, EM-60
Sandra L. Waisley, EM-64
Gary T. Staffo, EE-3C
Robert G. Lange, NE-34
Carl Sykes, NE-43
Colette A. Broussard, HS-23
Subir K. Sen, HS-23
David Grover, DNFSB

Distribution:

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Dennis Spurgeon, NE-1
James Slutz, FE-1
Edward F. Sproat, III, RW-1
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Gerald L. Talbot, NA-17
George Malosh, SC-3
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Michael D. Holland, Brookhaven Site Office
David C. Moody III, Carlsbad Field Office
Donna M. Perez, East Tennessee Technology Park
Elizabeth D. Sellers, Idaho Operations Office
Steve C. Taylor, Kansas City Site Office
Camille Yuan-Soo-Hoo, Livermore Site Office
Donald L. Winchell Jr., Los Alamos Site Office
Stephen Mellington, Nevada Site Office
Karen L. Boardman, NNSA Service Center
Gerald G. Boyd, Oak Ridge Operations Office
Steve Erhart, Pantex Site Office
Shirley J. Ojinger, Office of River Protection
David A. Brockman, Richland Operations Office
Patrice M. Wagner, Sandia Site Office
Jeffrey M. Allison, Savannah River Operations Office
Ralph Kevin Hall, Savannah River Site Office
Bryan C. Bower, West Valley Demonstration Project
Theodore D. Sherry, Y-12 Site Office
Michael J. Weis, Pacific Northwest Site Office

APPENDIX B

SURVEY RESPONSES ON FILTER TEST FACILITY TESTING

NON-SAFETY HEPA FILTERS USED FOR RADIOACTIVE CONFINEMENT IN DEFENSE NUCLEAR FACILITIES

| Organization/Site | Summary of Response | Test 100% of all filters at FTF | Alternate Testing Program |
|--|---|---|---------------------------|
| National Nuclear Security Administration (NNSA) | | | |
| Kansas City Plant | Kansas City Plant does not have non-safety HEPA filters used for radioactive confinement. We do not have any processes that involve radioactive airborne particulate. | N/A | N/A |
| Savannah River Site Office | The two primary contractors send 100% of HEPA filters covered by the scope of the Secretary of Energy's June 4, 2001 letter to the DNFSB and DOE-STD-3020-2005 to the FTF for testing. A tailored Quality Assurance testing program is not used. | Yes | No |
| Pantex | <p>The ventilation systems in Pantex nuclear facilities are not classified as confinement ventilation systems; therefore, they are not required to meet DOE-STD-3020-2005 criteria.</p> <p>Pantex does have facilities applicable to Section 4.1 of DOE-STD-3020-2005 and is in the process of implementing a HEPA filter program to address habitability systems and test sampling program for confinement ventilation systems for airborne radioactive particulate which will require 100% testing at the FTF for these HEPA filters.</p> | Yes Revised program requiring 100% testing implemented | No |
| Lawrence Livermore National Laboratory (LLNL) | Lawrence Livermore National Laboratory (LLNL) is implementing 100% testing of all non-safety related | Yes Revised | No |

| Organization/Site | Summary of Response | Test 100% of all filters at FTF | Alternate Testing Program |
|---------------------------------------|--|--|---------------------------|
| | HEPA filters used in radioactive confinement systems. LLNL does not have a tailored HEPA filter QA testing program which specifically addresses statistical sampling of non-safety-related filters. | program requiring 100% testing implemented | |
| Nevada Test Site (NTS) | The Nevada Test Site (NTS) does not currently have a statistical sampling program for FTF testing of HEPA filters. There are currently 19 non-safety related HEPA devices (vacuums and air handlers) used in NTS facilities for radiological purposes, but only a few are in active use. Because of the small number of HEPA filters that are purchased on an annual basis, the current procurement policy of the NTS Management & Operations Contractor requires that all HEPA filters purchased for radiological purposes in facilities that are designated as non-safety related shall be tested at the Air Techniques International Filter Test Facility prior to delivery at the NTS. | Yes | No |
| Los Alamos National Laboratory (LANL) | LANL requires 100% of non-safety related HEPA filters intended for use in radioactive confinement applications to be tested at the Department of Energy (DOE) Filter Test Facility FTF) in accordance with ASME AG-1, Article FC-5200 and DOE-STD-3025-99. | Yes | No |
| Y-12 | <p>The Y-12 policy has been, and continues to be 100 percent testing of all HEPA filters (safety and non-safety related) at the FTF.</p> <p>Y-12 continues to address HEPA filter quality by implementation of our maximum life criteria, initial and periodic aerosol testing of installed HEPA filters, and 100 percent testing of all HEPA filters at the FTF.</p> | Yes | No |
| Sandia National Laboratory | Sandia National Laboratories (SNL) has a single | Yes | No |

| Organization/Site | Summary of Response | Test 100% of all filters at FTF | Alternate Testing Program |
|--|---|---------------------------------|---------------------------|
| (SNL) | <p>testing program for all High Efficiency Particulate Air (HEPA) filters which are used in safety related and non-safety applications for radioactive confinement. All HEPA filters within the scope of DOE-STD-3020-2005 are 100% tested through the FTF. A statistical sampling program is not used because the number of HEPA filters in non-safety-related applications is small and a 100% testing program was considered SNL policy.</p> <p>SNL provides 100% testing for all HEPA filters. This includes those non-safety-related HEPA filters used in confinement ventilation systems for Hazard Category III and radiological facilities.</p> | | |
| Office of Environmental Management (EM) | | | |
| Office of River Protection (ORP) | <p>The WTP contractor is not yet in procurement of production HEPA filters. However, ORP verified that the WTP HEPA filter specifications require 100% testing at the FTF.</p> <p>For the TFOC, all HEPA filters, regardless of safety class, with a system flow rate greater than 20 acfm are sent to the FTF prior to delivery for site use. Filters with less than 20 acfm flow are exempted by language in Section 1.2 of DOE-STD-3020-2005</p> | Yes | No |
| Richland Operations Office (RL) | As a policy, all RL contractor HEPA filters used in confinement ventilation systems are tested at the FTF regardless of safety classification; therefore, tailored Quality Assurance (QA) testing programs are not used. DOE-RL oversees three contractors which | Yes | No |

| Organization/Site | Summary of Response | Test 100% of all filters at FTF | Alternate Testing Program |
|------------------------------|--|----------------------------------|-------------------------------|
| | use non-safety HEPA filters used in confinement ventilation systems; CH2M HILL Plateau Remediation Company LLC (CHPRC), Fluor Hanford Inc., (FHI), and Washington Closure Hanford LLC (WCH). | | |
| Oak Ridge Office | <p>Responses for the three primary ORO-EM contractors are as follows:</p> <ul style="list-style-type: none"> • Isotek Systems, LLC, has affirmed that they only use HEPA which have been tested at the FTF whether that use is for safety systems or for use in radiological material confinement. • EnergX TN, LLC, operator of the Transuranic Waste Processing Center, has confirmed that all safety system HEPA filters are tested at the FTF. EnergX did not have a requirement for FTF testing for HEPA filters that provide radioactive material confinement under abnormal conditions (positive pressure) for three process areas; the box breakdown area (BBA), the glove boxes, and the hot cell. These filters were certified by the supplier to a specification in the procurement which occurred prior to the issuance of DOE-STD-3020. EnergX has since confirmed that all replacement filters whether used in a credited or non-credited (i.e., inlet filters) application within confinement ventilation systems will in the future meet the requirements specified in DOE-STD-3020. | <p>Yes</p> <p>Yes</p> <p>Yes</p> | <p>No</p> <p>No</p> <p>No</p> |
| Carlsbad Field Office (CBFO) | The WIPP managing and operating (M&O) contractor, Washington TRU Solutions (WTS), is not using a tailored QA testing program for HEPA filters used in confinement ventilation systems. All HEPA | Yes | No |

| Organization/Site | Summary of Response | Test 100% of all filters at FTF | Alternate Testing Program |
|--|---|---|---------------------------|
| | filters used at the WIPP site for any functional class of confinement ventilation are drop-shipped to and tested at the FTF. This includes safety-related and non-safety-related HEPA filters used at the WIPP site. | | |
| Idaho Operations Office | Responses from the two site contractors are as follows: <ul style="list-style-type: none"> • CWI tests 100% of HEPA filters at the Filter Test Facility (FTF). • BBWI is implementing a program to require 100% testing at the FTF. | Yes for CWI BBWI implementing program requiring 100% testing | No |
| Office of Science (SC) | | | |
| Pacific Northwest National Laboratory (PNNL) | PNNL is implementing a program to send all Non-Safety Related Filters, that are used for radioactive confinement function in the ventilation systems, to the DOE approved Filter Test Facility (FTF). Currently PNNL's procedures for purchasing these types of filters do not require this process. PNNL will revise its procedures to ensure that those types of filters are sent to the FTF. | PNNL implementing program requiring 100% testing | No |

SEPARATION

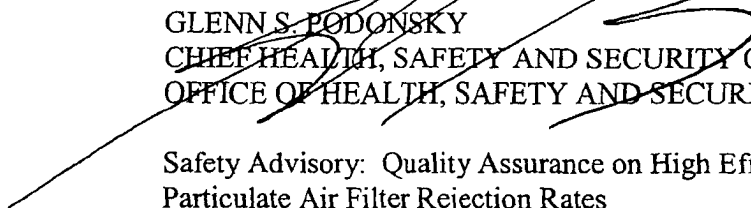
PAGE



Department of Energy
Washington, DC 20585

July 24, 2008

MEMORANDUM FOR DISTRIBUTION

FROM:  GLENN S. PODONSKY
CHIEF HEALTH, SAFETY AND SECURITY OFFICER
OFFICE OF HEALTH, SAFETY AND SECURITY

SUBJECT: Safety Advisory: Quality Assurance on High Efficiency
Particulate Air Filter Rejection Rates

The attached Safety Advisory provides information on quality assurance concerns related to the increased rejection rates of High Efficiency Particulate Air (HEPA) filters during testing at the Filter Test Facility (FTF) near Baltimore, MD. The increased filter rejection rates are primarily due to manufacturing defects, and this was highlighted in the two FY 2007 semi-annual reports. This increase in the rejection rates was also noted by the Defense Nuclear Facilities Safety Board in a letter to my office dated March 17, 2008.

The defective HEPA filters are rejected and returned to the manufacturers and are not shipped to Department of Energy (DOE) sites. The rejected filters are either replaced or repaired by the manufacturers and are then re-inspected and tested at the FTF prior to shipping to DOE sites. It is important for the DOE community to be aware of the increased rejection rate, indicating problems in quality programs and manufacturing processes, and be informed of the actions proposed to correct the problem.

Please provide this advisory to your managers to assist them in their continuing oversight of DOE contractor activities related to HEPA filters.

Attachment



Distribution

Office of the Secretary of Energy

Thomas P. D'Agostino, Under Secretary for Nuclear Security, National Nuclear Security Administration, US
C. H. Albright Jr., Under Secretary of Energy, Under Secretary, Office of the Under Secretary, US
Raymond L. Orbach, Under Secretary for Science, Office of the Under Secretary for Science, S-4

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Alexander A. Karsner, Assistant Secretary, Office of Energy Efficiency and Renewable Energy, EE-1
James A. Rispoli, Assistant Secretary, Office of Environmental Management, EM-1
James Slutz, Acting Principal Deputy Assistant Secretary, Office of Fossil Energy, FE-1
Dennis R. Spurgeon, Assistant Secretary for Nuclear Energy, Office of Nuclear Energy, NE-1
Edward F. Sproat III, Director, Office of Civilian Radioactive Waste Management, RW-1

Other DOE DAS / Directors

George J. Malosh, Deputy Director for Field Operations, Office of the Deputy Director for Field Operations, SC-3

cc:

Frank Russo, Senior Advisor, NA-3.6
Chuan-Fu Wu, Chief Safety Office, EM-41
Robert C. Wunderlich, Manager, Office of Science Chicago Office
Elizabeth D. Sellers, Manager, Idaho Operations Office
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William C. Gibson, Jr., Manager, Strategic Petroleum Reserve Project Office
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Cynthia K. Baebler, Manager, Ames Site Office
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M. Patrice Wagner, Manager, Sandia Site Office
Ralph Kevin Hall, Acting Manager, Savannah River Site Office
James A. Turi, Manager, Thomas Jefferson Site Office
Theodore D. Sherry, Manager, NNSA Y-12 Site Office
David Grover HS-1.1

Safety Advisory

Quality Assurance

HEPA FILTER REJECTION RATES

2008 – 04

July 2008

PURPOSE

This Advisory provides information on quality assurance (QA) concerns related to the increased rejection rates of High Efficiency Particulate Air (HEPA) filters during testing at the Filter Test Facility (FTF) operated by Air Techniques International near Baltimore, MD. The defective HEPA filters are rejected and returned to the manufacturers and are not shipped to Department of Energy (DOE) sites. The rejected filters are either replaced or repaired by the manufacturers and are re-inspected and then tested at the FTF prior to shipping to DOE sites. It is important for the DOE community to be aware that the increased rejection rates indicate problems in quality programs and manufacturing processes, and be informed of the actions proposed to correct the problem.

BACKGROUND

The past two semi-annual reports (FY 2007) on HEPA filter testing at the FTF, issued by the DOE Office of Health, Safety and Security (HSS), indicated an overall rejection rate of 20%, far above the historical average rate of approximately 7%. This increase in rejection rate was also noted by the Defense Nuclear Facilities Safety Board (DNFSB) in a letter to HSS dated March 17, 2008. The letter requested a plan of action to address the increased contribution of manufacturing defects to the rejection rate. HSS convened a working team comprised of Federal and contractor employees to develop a plan of action to respond to this situation.

ANALYSIS OF REJECTED FILTERS

HEPA filter manufacturers have indicated that they have been analyzing the increased rejection rates and are taking corrective actions for their specific quality issues. The working team will be reviewing the results of the analyses and will conduct supplemental analysis as necessary to develop a thorough and complete understanding of the increase in rejection rates for various types of defects.

COMMUNICATION WEAKNESSES

The working team identified communication weaknesses related to distribution of FTF test reports. Some examples include: (1) FTF test reports are routinely sent to the contractor purchasing organization; however, in some instances this information is not reaching the QA personnel responsible for overseeing supply chain quality, and (2) DOE Field Offices and site contractor personnel are not receiving monthly FTF reports that would provide more timely and detailed indication of potential quality problems. The working team will review and address the communication weaknesses within the DOE community. This will include requesting each

site to identify QA points-of-contact for receiving HEPA filter related data/information.

ACTIONS PLANNED

The working team has developed a plan of action to address the HEPA filter testing issues identified by the DNFSB which includes:

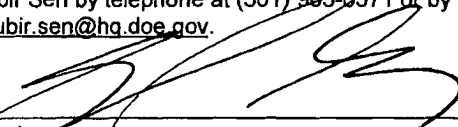
- Reviewing and making recommendations on the filter manufacturers' analyses of causes for manufacturing defects and QA process weaknesses that contributed to the increased rejection rates, including identification of corrective actions taken or planned.
- Assessing the manufacturers' production-related quality control tests and inspections of HEPA filters and determine if improvements are warranted.
- Assessing the adequacy of sites' use of a test sampling program for non-safety related HEPA filters that are not subject to 100% testing at the FTF and making recommendations.

The plan of action will be issued this summer and will recommend specific actions by Field Elements and site contractors based on the working team's findings.

ADDITIONAL SOURCES OF INFORMATION

- <https://www.hss.energy.gov/deprep/2008/FB08M17A.PDF>

If you have any questions regarding these issues, please contact Subir Sen by telephone at (301) 903-6571 or by e-mail at subir.sen@hq.doe.gov.


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



SEPARATION

PAGE



Department of Energy

Washington, DC 20585

August 27, 2008

MEMORANDUM FOR DISTRIBUTION

THROUGH: GLENN S. PODONSKY
 CHIEF HEALTH, SAFETY AND SECURITY OFFICER
 OFFICE OF HEALTH, SAFETY AND SECURITY

FROM: ANDREW C. LAWRENCE *Andrew C. Lawrence*
 DIRECTOR
 OFFICE OF NUCLEAR SAFETY, QUALITY
 ASSURANCE AND ENVIRONMENT
 OFFICE OF HEALTH, SAFETY AND SECURITY

SUBJECT: Quality Assurance Points-of-Contact for High Efficiency
 Particulate Air Filter Information

On July 23, 2008, the Department of Energy (DOE) submitted a plan of action to the Defense Nuclear Facilities Safety Board to address the increased rejection rate of High Efficiency Particulate Air (HEPA) filters tested at the Air Techniques International Filter Test Facility (FTF). The increased rejection rate is of concern to DOE because it indicates problems in quality assurance (QA) programs and filter manufacturing processes.

The Team that developed the plan of action reviewed the flow of information between filter manufacturers, the FTF, DOE and DOE 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 several weaknesses in communication that impacted taking proactive corrective actions, such as: (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 indication of potential quality problems; and (3) semi-annual reports on FTF testing are typically not getting to site QA organizations.

To remedy in part these weaknesses, the Team developed Action 1.3 in the plan which requires DOE and site contractors to appoint QA points-of-contact (POCs) who will receive and be responsible for forwarding HEPA filter-related data/information to appropriate site personnel. The data/information will be



provided primarily by the Office of Quality Assurance Policy and Assistance who will also ensure that monthly filter test data are sent to these QA POC's so that appropriate action can be taken in a timely manner if the test data indicates any potential quality problems. The distribution of the HEPA filter testing semi-annual report will also be augmented to include the QA POCs.

Please provide your DOE and site contractor POCs to Subir Sen, of my office, by September 12, 2008. Questions may be directed to me at (202) 586-5680 or have your staff contact Subir Sen at subir.sen@hq.doe.gov or (301) 903-6571.

cc:

Richard H. Lagdon, US
Frank B. Russo, NA-3.6
Don F. Nichols, NA-1
Gerald Talbot, NA-17
Michael A. Thompson, NA-173
Samuel D. Johnson, NA-173
Robert Malosh, SC-3
Matt Cole, SC- 31.1
Dae Chung, EM-60
Sandra L. Waisley, EM-64
Gary T. Staffo, EE-3C
Robert G. Lange, NE-34
Carl Sykes, NE-43
David Grover, DNFSB
Richard Frounfelker, ORO

bcc:

Michael A. Kilpatrick, HS-1
C. Russell H. Shearer, HS-1
Mark B. Whitaker, HS-1.1
Robert J. McMorland, HS-1.1
Colette A. Broussard, HS-23
Subir K. Sen, HS-23

Distribution:

Thomas P. D'Agostino, NA-1
C. H. Albright, Jr., US
Raymond L. Orbach, US
James A. Rispoli, EM-1
Dennis Spurgeon, NE-1
Alexander Karsner, EE-1
James Slutz, FE-1
Edward F. Sproat, III, RW-1
Ingrid Kolb, MA-1
Robert C. Wunderlich, Chicago Operations Office
Michael D. Holland, Brookhaven Site Office
David C. Moody III, Carlsbad Field Office
Donna M. Perez, East Tennessee Technology Park
Elizabeth D. Sellers, Idaho Operations Office
Steve C. Taylor, Kansas City Site Office
Camille Yuan-Soo-Hoo, Livermore Site Office
Donald L. Winchell Jr., Los Alamos Site Office
Stephen Mellington, Nevada Site Office
Karen L. Boardman, NNSA Service Center
Gerald G. Boyd, Oak Ridge Office
Steve Erhart, Pantex Site Office
Shirley J. Olinger, Office of River Protection
David A. Brockman, Richland Operations Office
Patrice M. Wagner, Sandia Site Office
Jeffrey M. Allison, Savannah River Operations Office
Ralph Kevin Hall, Savannah River Site Office
Bryan C. Bower, West Valley Demonstration Project
Theodore D. Sherry, Y-12 Site Office
Michael J. Weis, Pacific Northwest Site Office

Site HEPA Points-of-Contact

| Site | Organization | Name | Phone | Email |
|-------------|------------------------------|--------------------------|----------------|--|
| LANL | LASO | Ted Wald | (505) 667-5793 | twald@doeal.gov |
| LANL | M&O Contractor | Kim Clement | (505) 606-2014 | kclement@lanl.gov |
| Y12 | M&O Contractor - QA | Ty Nemeth | TBD | nemethtir@y12.doe.gov |
| Y12 | M&O Contractor - Engineering | Robert Hamby | (865) 574-2204 | hambyrs@y12.doe.gov |
| Y12 | Site Office - QA | Ken Guay | (865) 241-6446 | guaykp@yso.doe.gov |
| SRS | Site Office | William Rowland | (803) 952-8202 | bill.rowland@srs.gov |
| SRS | Site Office | Gary Borba | (803) 208-3396 | gary.borba@srs.gov |
| SRS | LWO/WSRC | Gerry Eide | (803) 208-3406 | gerald.eide@srs.gov |
| ID | DOE - ID | Chauntel Robbins | 208-526-5897 | robbincm@id.doe.gov |
| ID | BBWI | Kevin Bake | TBD | bakeka@amwtp.inl.gov |
| ID | BBWI | Neil Brill | TBD | brilna@amwtp.inl.gov |
| ID | CWI | Kim Poole | (208) 351-9741 | R.Poole@icp.doe.gov |
| ID | BEA - Nuclear Maintenance | Mike Love | (208) 533-4310 | Michael.Love@inl.gov |
| ID | DOE - ID | Lee Beidelman | TBD | beideldl@id.doe.gov |
| WVDP | Site Office | Christopher J. Eckert | (716) 942-4783 | christopher.j.eckert@wv.doe.gov |
| ORP | Site Office | Pat Carier | (509) 376-3574 | patrick_p_carier@rl.gov |
| ORP | BNI | Dave Jantosik | (509) 371-2377 | djjantos@bechtel.com |
| ORP | WRPS | Dave Shugars | (509) 372-9972 | David.L.Shugars@rl.gov |
| OCRWM | DOE - YMP | Richard Spence | (702) 794-1455 | dick_spence@ymp.gov |
| LLNL | Site Office | Adeliza Cordis | (925) 422-9585 | adeliza.cordis@oak.doe.gov |
| LLNL | M&O Contractor | Gary Ream | (925) 423-1210 | ream2@llnl.gov |
| Kansas City | Site Office | Kent Kerr | (816) 997-5571 | kkerr@kcp.com |
| Kansas City | FM&T Honeywell | Kenny Speer | (816) 997-7133 | kspeer@kcp.com |
| HQ | DOE - EM | Kriss Grisham | (301)-903-8478 | kriss.grisham@em.doe.gov |
| RL | Site Office | Mark Hahn | (509) 373-9872 | mark_r_hahn@rl.gov |
| RL | Fluor Hanford | Pat O'Brien | (509) 373-3929 | Patrick_m_Obrien@rl.gov |
| RL | Washington Closure | Bob Gregonis | (509) 372-9979 | Ragregon@wch-rc.com |
| ORO | Site Office | Rick Swatzell | (865) 754-0216 | swatzellr@oro.doe.gov |
| OR | ORNL | Mike Woods | (865) 576-7327 | woodsmr@ornl.gov |
| OR | UT-Battelle | Debbie Jenkins | (865) 576-0647 | jenkinsdl@ornl.gov |
| OR | USEC | Randy Devault | (865) 241-8277 | devaultrm@oro.doe.gov |
| OR | DOE - EM | Scott Foster | (865) 576-9564 | fosterps@oro.doe.gov |
| OR | BJC | Susan Kimmerly | (865) 574-8242 | lowesh@bechteljacobs.org |
| OR | Energx | Jerry Erpenbach | (865) 574-3436 | jerry.erpenbach@truproject.com |
| SNL | Site Office | Daniel Dilley | (505) 845-6246 | pddilley@doeal.gov |
| SNL | Site Office | Michael Ortega | (505) 845-6673 | mortega@doeal.gov |
| SNL | M&O Contractor | John Scott | (505) 844-2482 | jwscott@sandia.gov |
| PNSO | Site Office | Russ Haffner | (509) 372-4890 | Russ.haffner@pns0.science.doe.gov |
| PNNL | Contractor | Alice Lewis | TBD | alice.lewis@pnl.gov |
| WIPP | Washington TRU Solutions | Roy Byrd | (575) 234-8999 | roy_byrd@wipp.ws |
| Chicago | DOE - SC | William (Chuck) Salsbury | (630) 252-3484 | William.Salsbury@ch.doe.gov |
| HQ | DOE - SC | Matt Cole | (301) 903-8388 | Matt.Cole@science.doe.gov |
| HQ | DOE - NNSA | Sam Johnson | (301) 903-5220 | Samuel.Johnson@nnsa.doe.gov |
| HQ | DOE - NE | Carl Sykes | (301) 903-5708 | Carl.Sykes@nuclear.energy.gov |

Site HEPA Points-of-Contact

| | | | | |
|--------|-------------|------------------|----------------|--|
| NTS | Site Office | Thomas Enyeart | (702) 295-4312 | enyearrt@nv.doe.gov |
| NTS | NSTec | Michael Eshleman | (702) 295-0478 | eshlemmj@nv.doe.gov |
| NTS | NSTec | Jerry Clark | TBD | clarkjw@nv.doe.gov |
| Pantex | PXSO | Gregory Baker | (806) 477-3246 | gdbaker@pantex.doe.gov |
| Pantex | B&W Pantex | Courtney Olson | (806) 477-4707 | colson@pantex.doe.gov |
| Golden | DOE - EE | Karen Harness | (303) 275-4743 | Karen.Harness@go.doe.gov |

Updated 3/23/2010

SEPARATION

PAGE

**Department of Energy**

Washington, DC 20585

April 16, 2010

MEMORANDUM FOR DISTRIBUTION

THROUGH: ~~GLENN S. PODOMSKY~~
~~CHIEF HEALTH, SAFETY AND SECURITY OFFICER~~
~~OFFICE OF HEALTH, SAFETY AND SECURITY~~

FROM: ANDREW C. LAWRENCE *Andrew C. Lawrence*
DIRECTOR
OFFICE OF NUCLEAR SAFETY, QUALITY
ASSURANCE AND ENVIRONMENT
OFFICE OF HEALTH, SAFETY AND SECURITY

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





Department of Energy

Washington, DC 20585

April 16, 2010

MEMORANDUM FOR DISTRIBUTION

THROUGH: ~~GLENN S. PODOMSKY~~
~~CHIEF HEALTH, SAFETY AND SECURITY OFFICER~~
~~OFFICE OF HEALTH, SAFETY AND SECURITY~~

FROM: ANDREW C. LAWRENCE *Andrew C. Lawrence*
DIRECTOR
OFFICE OF NUCLEAR SAFETY, QUALITY
ASSURANCE AND ENVIRONMENT
OFFICE OF HEALTH, SAFETY AND SECURITY

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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



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

cc: Richard H. Lagdon, US
Donald F. Nichols, NA-1
Steven L. Krahn, EM-20
Robert Murray, EM-64
Michael A. Thompson, NA-17
Samuel D. Johnson, NA-172.3
Frank B. Russo, NA-3.6
Robert G. Lange, NE-34
Michael Worley, NE-43
Marcus E. Jones, SC-31
Matthew B. Cole, SC-31.1
Mark Hahn, RL
Werner Bergman, Aerosol Science
Alan Flanders, SRNS
Julie Stormo, ATI
Timothy J. Dwyer, DNFSB

Distribution:

Ines R. Triay, EM-1
Warren Miller, NE-1
James J. McConnell, NA-171
George J. Malosh, SC-3

**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

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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 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 to 10.2 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.

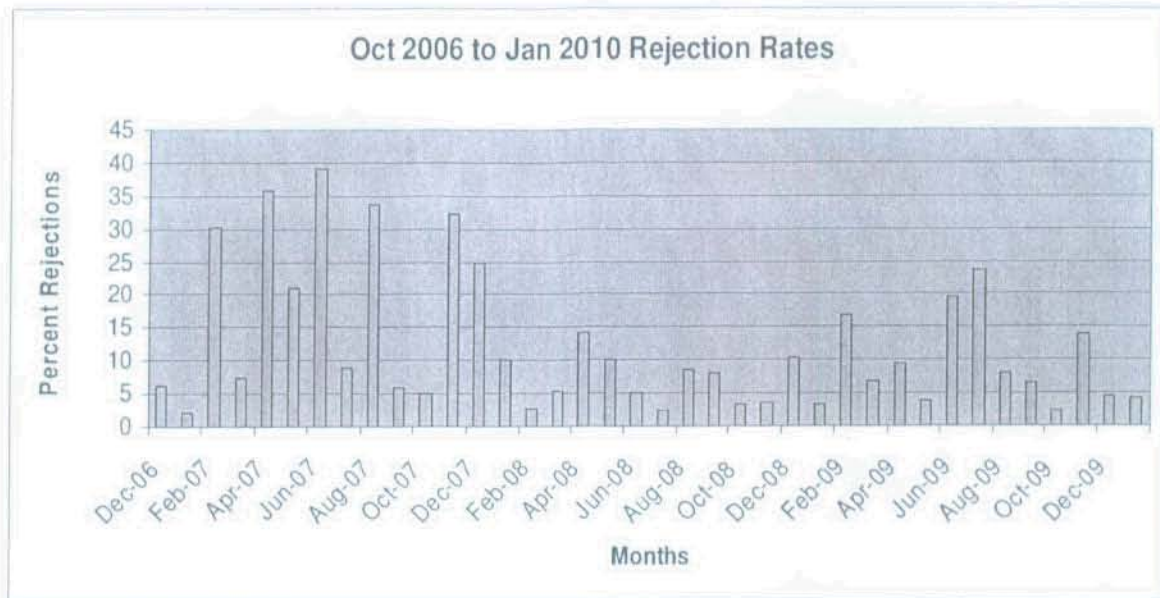


Figure 1: FTF Rejection Rate for FFI Filters

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 handling 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) | <p>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.</p> <p>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.</p> |
| Spot flame (no flame propagation) | <p>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.</p> <p>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.</p> |

| Critical Qualification Test Parameters | QC Tests and Inspections during Manufacturing |
|---|--|
| <p>Overpressure test (demonstrates filter pack blow-out capability)</p> | <p>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.</p> <p>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.</p> |
| <p>Rough-handling test (demonstrates that the filter can handle mechanical stresses)</p> | <p>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.</p> <p>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.</p> <p>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.</p> |

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:



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.

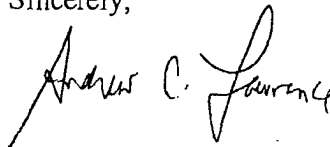
DOE will review the submitted information to determine what further action is needed to improve the quality of the filters furnished to DOE.

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
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