

## Quality Assurance

# HEPA FILTER REJECTION RATES

2008 – 04

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### 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/dep/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](mailto:subir.sen@hq.doe.gov).

(signed by)

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