LICENSEES IDENTIFIED WITH SIGNIFICANT PERFORMANCE ISSUES

NUCLEAR FUEL SERVICES, INC.

1. IDENTIFICATION

Location:	Erwin, TN
License No.:	SNM-124
Docket No.	70-143
License Status:	Active

2. STATUS SUMMARY

Nuclear Fuel Services, Inc. (NFS) was discussed during the 2009 Agency Action Review Meeting (AARM) because NFS had multiple and repetitive program issues that warranted additional U.S. Nuclear Regulatory Commission (NRC) oversight as described in the AARM criteria established in SECY-08-0135. Specifically, NFS demonstrated program breakdowns in safety culture, engineering processes, safety decision-making, corrective actions, and work control. While NFS has demonstrated improved performance since January 2010, it has not demonstrated sustained satisfactory performance in each of the aforementioned program areas where weaknesses were identified. The staff issued two escalated enforcement actions against NFS in 2010, both of which were due to self-revealing or NRC identified performance deficiencies in 2008 and 2009. The staff also conducted significant additional oversight in 2010 to verify that improvements were effective before authorizing startup of four individual processing lines at the facility. The staff believes that NFS continues to meet the *Performance Trend* criteria for discussion at the AARM for the same reasons the facility was discussed in 2009. Specifically, the staff believes that NFS warrants discussion at the AARM because:

1. The effectiveness of their corrective actions has not been fully demonstrated,
2. Extensive oversight is planned by the NRC, and
3. The significant issues involving the NFS safety culture have not been fully resolved in a sustainable manner.

Currently, the NRC has verified that NFS implemented sufficient corrective actions to operate all processes in accordance with NRC requirements except for the Uranium Hexafluoride process. Accordingly, NRC's Region II Office, with concurrence from NRC's Office of Nuclear Material Safety and Safeguards (NMSS), approved operation of those processes. To date, NFS has operated the NRC approved processing lines safely. NRC staff will inspect NFS's readiness to operate the Uranium Hexafluoride process when NFS requests NRC authorization for restart of that process.

Background

On August 30, 2010, a Severity Level III violation and $140,000 civil penalty was issued for safety problems identified in the Uranium-Aluminum processing line in 2009. The NRC's reactive inspections of the Uranium-Aluminum processing line event in 2009 and an interim performance review in December 2009 identified a number of notable

concerns which resulted in a decision by NFS to shut down all processing lines until the NRC was satisfied that actions required for restart were completed, which was documented in a Confirmatory Action Letter on January 7, 2010.

On November 16, 2010, the staff issued a Confirmatory Order to document an agreement negotiated using the alternative dispute resolution (ADR) process. The ADR agreement addressed the underlying causes for violations associated with the failure to provide complete and accurate information regarding fire damper inspections in 2008 and 2009. The Confirmatory Order requires NFS to develop a safety culture improvement plan, and demonstrate the effectiveness and sustainability of that plan. Furthermore, the Confirmatory Order requires NFS to assess its current corrective action program against the criteria of NQA-1-2008, enhance the program based on the assessment results and then request that their license be amended to incorporate the enhanced corrective action program by August 16, 2011.

Recommendation

Region II and NMSS recommend that NFS be discussed at the AARM because NFS continues to meet the *Performance Trend* criteria for the same reasons the facility was discussed in 2009.

3. MAJOR TECHNICAL OR REGULATORY ISSUES

Confirmatory Action Letter

In December 2009, NRC management engaged NFS management to discuss issues identified during reactive NRC inspections and an NRC interim performance review. The interaction resulted in a decision by NFS to shut down all processing lines until the NRC was satisfied that actions required for restart were completed. This agreement was documented in a Confirmatory Action Letter (CAL) dated January 7, 2010. The CAL documented a number of performance issues as follows:

- Inadequate management oversight by NFS of facility process changes;
- Perceived production pressures;
- Lack of questioning attitude by workers and management;
- Poor communications; and,
- An unacceptable management decision to resume operation of the process line following an upset condition without identifying or implementing sufficient corrective actions to address the underlying causes.

Since the issuance of the CAL in January 2010, NFS developed and implemented interim corrective actions for four of five processing lines and informed the NRC they were ready for inspection. The NRC conducted an inspection of each of the four processing lines and found that interim corrective actions were sufficient to authorize each of the four lines to restart. An NRC inspection of the licensee's corrective actions in January 2011 has identified that NFS did not adequately address two post-restart CAL items. These items were related to the licensee's ability to conduct thorough root cause analyses and do not affect the NRC's decision

that the licensee was capable of safely operating and restarting four process lines. Additional inspections will be conducted when NFS implements the long term corrective actions.

NRC Oversight Strategy

NRC's planned oversight strategy is designed to ensure safe operational performance and adequate security at NFS. In addition, the NRC oversight strategy is focused on ensuring that the corrective actions implemented by NFS for the issues identified in the NRC CAL dated January 7, 2010, and the NFS 2009/2010 Independent Safety Culture Assessment Report dated June 21, 2010, are effective and sustained. The NRC oversight strategy involves continued increased inspection effort by NRC inspection staff and maintaining a second on-site resident inspector. In addition, to increase the level of NRC management attention to NFS, NRC will transition the existing Safety Culture and Configuration Management Improvement Oversight Panel to an Executive Oversight Panel in the first quarter of calendar year 2011. The Executive Oversight Panel will ensure that the NRC inspection and oversight strategy is adequate to determine whether there are effective and sustainable improvements at the NFS facility, consider the effective implementation of future Commission Policy changes, implement an effective communication strategy, and ensure that the NRC oversight posture is consistent with NFS performance.

Licensee Safety Culture Improvement Strategy

Based on the 2009/2010 Independent Safety Culture Assessment report dated June 21, 2010, NFS identified a number of focus areas needing significant improvement. They have just begun their implementation of corrective actions for these areas. These focus areas included:

- Organization and Individual Accountability;
- Corrective Action Program Effectiveness;
- Resource Management;
- Technical and Professional Competency;
- Questioning Attitude;
- Work Control; and
- Safety Conscious Work Environment.

The NRC staff will evaluate the effectiveness of the NFS improvement plan and verify that improvements implemented are complete and sustainable when NFS indicates the actions taken to address these issues have been completed.

Management Changes

On January 25, 2011, Joseph (Joe) G. Henry was named President of NFS.

On January 17, 2011, Gary Darter was named Acting President replacing David Amerine. Mr. Amerine had served in the position since March 2010 when he replaced

David Kudsin as President of NFS.

On January 17, 2011, Christa Reed assumed a new position as Director of Operations. Ms. Reed replaced Tim Lindstrom, Vice President of Operations.

In March 2010, Mark Elliott was named Director of Quality, Safety and Safeguards. Mr. Elliott replaced David Ward who was serving as the Interim Director, Safety and Regulatory.

U.S. DEPARTMENT OF VETERANS AFFAIRS

1. IDENTIFICATION

Location: North Little Rock, Arkansas.
License No.: 03-23853-01VA
Docket No.: 030-34325
License Status: Active

2. STATUS SUMMARY

The U.S. Department of Veterans Affairs (VA), a master materials licensee, was discussed during the 2010 AARM based in part, on the identification of significant performance issues related to numerous medical events at the VA Philadelphia Medical Center. An enforcement action associated with these medical events was issued in March 2010 that included a Notice of Violation and a $227,500 civil penalty. Additional performance related issues were identified at other VA facilities and the extent of conditions and concerns were still being evaluated at the time of the 2010 AARM.

The NRC continued its increased oversight of the VA licensed activities and conducted inspections at all of the other VA facilities with prostate cancer treatment programs to gain an assurance that these facilities did not have the same degree of problems as VA Philadelphia. In addition, the NRC conducted inspections of the National Health Physics Program (NHPP) to determine the circumstances that led to NHPP inspectors' failure to identify significant performance problems in the VA Philadelphia brachytherapy program. Under the VA's master material license, the NHPP is responsible for issuing permits, conducting inspections and event follow-up, investigating incidents, allegations, and enforcement.

The results of the additional inspections identified five violations involving four VA facilities: G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi; VA Sierra Nevada Healthcare System, Reno, Nevada; VA New York Harbor Healthcare System, Brooklyn, New York; and the VA Boston Healthcare System, Boston, Massachusetts. A pre-decisional enforcement conference was held on June 30, 2010, and on August 20, 2010, the NRC issued a Notice of Violation and $39,000 civil penalty to the VA for the violations.

Two violations assessed civil penalties involved the failure to develop, implement, and maintain written procedures that addressed methods to verify that the administrations were in accordance with the written directive (G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi; VA Sierra Nevada Healthcare System, Reno, Nevada; and the VA Boston Healthcare System, Boston, Massachusetts); and the failure to report a medical event by the next calendar day after discovery of the medical event (VA New York Harbor Healthcare System, Brooklyn, New York).

Three additional violations were identified that were not assessed civil penalties because they were either outside of the Statute of Limitations for civil penalty or were of lesser significance. These violations involved the failure to develop, implement, and maintain written procedures that addressed methods to verify that the administrations were in accordance with the written directive (VA Boston Healthcare System, Boston,

Massachusetts); a 15-day report that did not contain all the information required (VA New York Harbor Healthcare System, Brooklyn, New York); and a written directive that did not specify the radionuclide, the treatment site, the number of sources, and the total source strength or the total dose (VA Sierra Nevada Healthcare System, Reno, Nevada).

The NRC escalated the civil penalty to underscore that the VA, as a whole, must improve not only the performance of individual VA facilities, but also the performance of the NHPP and the National Radiation Safety Committee (NRSC) in implementing their regulatory oversight responsibilities under the master material license. The NRSC has the responsibility for providing oversight of the VA's implementation of its Master Material License (MML) and associated individual facility (permittee) activities.

In June of 2010, Chairman Jaczko met with the VA's Under Secretary for Health, Robert Petzel, M.D. This meeting, which focused on mutually agreed upon responsibilities for both the NRC and the VA, was a key point in establishing more open and transparent lines of communication between the two agencies. A subsequent meeting was held on September 20, 2010, during which Mark Satorius, Regional Administrator, Region III and Charles Miller, Director, Office of Federal and State Materials and Environmental Management Programs met with senior VA leadership to discuss the VA's MML and Letter of Understanding.

In October 2010, Region III established a VA Task Group to provide focused increased oversight and performance monitoring of the VA's improvement activities developed in response to the multiple performance issues identified during the previous inspections and subsequent enforcement actions. The goal of the VA Task Group is to enhance the communications between the NRC and the VA in order to establish a consistent understanding of roles and responsibilities and provide the oversight guidance necessary for the VA to effectively implement the MML. The VA Task Group conducted independent and accompaniment inspections of VA facilities to ascertain the effectiveness of the VA's corrective actions and to determine the likely sustainability of the corrective actions. Further, the VA Task Group and Region III Senior Management have attended VA NRSC meetings to enhance communications between the NRC and the VA at a higher level and determine the extent of the NRSC's effectiveness in managing the implementation of corrective actions at the individual facilities and at the NHPP.

3. MAJOR TECHNICAL OR REGULATORY ISSUES

The major issues are:

a. On October 14, 2008, the NRC issued a Confirmatory Action Letter (CAL 3-08-004) to the VA as a result of multiple medical events that were identified at several VA facilities involving permanent prostate brachytherapy treatments. The CAL required the VA to: 1) conduct reactive inspections of all the active prostate brachytherapy programs; 2) develop and implement standardized procedures for conducting prostate brachytherapy treatments; 3) correct incompatible data transmission problems; 4) identify root causes and corrective actions to prevent recurrence; 5) immediately suspend any prostate brachytherapy program where medical events are identified for 20 percent or more of the prostate treatments performed and develop enhanced criteria for suspending prostate brachytherapy programs; 6) NHPP

conduct an inspection prior to restart of a suspended prostate brachytherapy program to confirm implementation of all corrective actions and provide notification to the NRC; and 7) before start-up of any new prostate brachytherapy programs at VA facilities, the NHPP conducts an inspection to confirm implementation of the standardized procedures, the individuals involved in the treatments have completed training on medical events, methods to verify needle placement in the prostate prior to seed implantation, preparation of written directives, pre-treatment and post-treatment planning, dose verification, and provide notification to the NRC. The VA has completed Items 1 through 6 of the CAL. Additionally, the VA has established the criteria required in Item 7 of the CAL for a new program; however, they have not established a new prostate brachytherapy program to date. Based on this information, the CAL will be closed prior to the date of the AARM.

b. Assessment of the sustainability of the VA's corrective actions and performance improvements instituted as a result of the previously issued escalated enforcement actions.

c. There are no pending or open escalated enforcement actions.