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) continues to meet the performance trend criteria established in SECY-08-0135. Specifically, NFS had significant performance issues lasting more than one inspection period involving escalated enforcement actions and that warrant extraordinary NRC oversight (i.e., safety culture inspections and a second resident inspector). Two older enforcement cases resulted in four confirmatory orders in 2009 (i.e., fitness for duty and falsified medical exams). The orders implemented agreements reached during Alternative Dispute Resolution negotiations. During the negotiations, NRC agreed not to cite findings which likely would have resulted in Severity Level II and III violations.

Two Severity Level III violations were issued for security related issues. In addition, an Augmented Inspection Team identified significant performance issues that resulted in a Confirmatory Action Letter. The issues included inadequate evaluation of process changes, poor communication, lack of a questioning attitude, and lack of management oversight. The problems that led to the Confirmatory Action Letter are programmatic in nature and will require a sustained effort by the licensee to address the performance issues. Hence, a sustained period of heightened oversight by the U.S. Nuclear Regulatory Commission (NRC) is also warranted.

3. MAJOR TECHNICAL OR REGULATORY ISSUES

Augmented Inspection Team

An Augmented Inspection Team (AIT) reviewed the circumstances associated with an unexpected exothermic reaction that occurred on October 13, 2009, within the Uranium Aluminum processing portion of the downblending facility at NFS. The preliminary insights from the AIT, combined with a review of recent operations and performance, led the staff to conclude that additional regulatory action was needed. On January 7, 2010, a Confirmatory Action Letter (CAL) was issued to confirm NFS commitments to 1) suspend processing operations in specific areas, 2) complete specific actions required before restart of operations, and 3) provide NRC sufficient time to inspect the actions taken. The AIT report was issued on March 19, 2010. NRC authorized restart of the Navy fuel process line on March 23, 2010, following a multi-week restart readiness inspection. Inspection coverage will be augmented during restart activities. Over the next year, we expect NFS to notify Region II when it is prepared to restart other process lines. Restart readiness inspections will be conducted to confirm fulfillment of CAL actions and other criteria established by NRC.

NFS Safety Culture and Configuration Management Improvement Oversight Panel

The Panel was formed after the February 2007 Order was issued to provide specific oversight of NFS's implementation of the Order. The Panel reviewed the qualifications, plan, and schedule of the independent third party performing the initial safety culture assessment. The Panel's review prompted the licensee to augment their initial assessment strategy, which resulted in NRC granting a 90 day extension for its implementation. The Panel then reviewed the initial assessment report and assessed NFS's plans to address the safety culture issues identified in the assessment. As before, the Panel's review prompted the licensee to clarify and improve its implementation plan. Follow-up inspections have noted progress, but have also identified failures to implement new procedures and raised concerns about the slow pace of improvements. The second safety culture assessment required by the order is in progress. The Panel will review the results when the second assessment is completed.

New Ownership

On December 31, 2008, Amendment 85 to License SNM-124 was issued to reflect an indirect transfer of control of the license from NFS Services, LLC, to NOG-Erwin Holdings, Inc. (a subsidiary of Babcock and Wilcox (B&W)). On January 1, 2009, David Kudsin became the President of NFS. On February 2, 2010, Luis Reyes, Bill Borchardt and Mike Weber met with B&W to discuss its efforts to enhance performance at NFS. On March 1, 2010, David Amerine replaced Mr. Kudsin as President of NFS. In addition, Mark Elliot was appointed the Director of a new Safety and Security Department on March 1. The safety and security organizations had reported to the Vice-President of Operations. Now they report to the Director of the Safety/Security Department.

Department of Veterans Affairs Philadelphia VA Medical Center

1. IDENTIFICATION

Location: Philadelphia, Pennsylvania
License No.: 03-23853-01VA
Docket No.: 030-34325
License Status: Active

2. STATUS SUMMARY

The Department of Veterans Affairs (DVA) holds a master materials license (MML), which was issued in March 2003. An MML is a material (byproduct, source, and/or special nuclear material) license issued to a Federal organization, authorizing the use of material at multiple sites. The MML authorizes the DVA to issue permits for the possession and use of licensed material, and ties the licensee to a framework of oversight consistent with NRC regulations and inspection and enforcement policies, procedures, and guides. The DVA National Radiation Safety Committee (NRSC) has the responsibility for providing oversight of the DVA's implementation of its MML and associated permittee activities. The NRSC has delegated the authority to manage the DVA radiation safety program to its National Health Physics Program (NHPP). The NHPP is responsible for issuing permits, conducting inspections and event follow-up,

investigating incidents, allegations, and enforcement. The Philadelphia VA Medical Center (PVAMC) is one of approximately 115 permits issued by the DVA.

On May 16, 2008, the NHPP notified the NRC of a possible medical event at the PVAMC that involved a prostate brachytherapy treatment in which the total dose delivered differed from the prescribed dose by more than 20 percent. The treatment was performed using iodine-125 seeds of a lower radioactivity than intended. Specifically, iodine-125 seeds were inadvertently ordered and implanted with the wrong radioactivity. As a result, the patient received a dose to the prostate that was less than 80 percent of the prescribed dose.

An expanded review of the program identified additional patients who received doses to the prostate that were less than 80 percent of the prescribed dose. The PVAMC identified that the circumstances for the additional medical events were unrelated to the initial medical event in that these treatments were performed using iodine-125 seeds of the correct radioactivity. However, based on the placement of the seeds by the physician, the treatment site (prostate) received a dose that was less than 80 percent of the prescribed dose. Based on these findings, the PVAMC expanded the review to include all of the patients who received prostate brachytherapy treatments (114) performed since the inception of the brachytherapy program (February 2002). The PVAMC prostate brachytherapy program was suspended on June 11, 2008, with no plans to restart the program.

Between May 16, 2008 and October 2, 2008, the licensee reported 92 medical events that involved I-125 prostate brachytherapy implants that occurred between February 25, 2002, and May 12, 2008 (one of these medical events was reported twice). Six additional medical events were reported to the NRC on August 12, 2009. The PVAMC reported 97 medical events between May 16, 2008 and August 12, 2009. On October 19, 2009, the PVAMC submitted their final dose assessments for the 114 patients that received permanent prostate implants at the medical center. After a comprehensive assessment of patient dose data, the staff identified 17 cases that met the current NRC Abnormal Occurrence (AO) criteria. In all cases the prescribed dose to the prostate was 160 Gy (16,000 rad) and the dose actually delivered to the prostate was in the range of 39 Gy (3,900 rad) to 111 Gy (11,100 rad). The doses to the periprostatic tissues and rectum, which should have received the same dose as the dose prescribed to the prostate (160 Gy (16,000 rad))**,** ranged between 248 Gy (24,800 rad) and 588 Gy (58,800 rad).

Each of the 17 AO cases were considered medical events because: (1) the region of the patient's periprostatic tissue or rectum where the seeds were placed received a dose that was greater than 0.5 Gy (50 rad) and was 50 percent greater than the expected dose the area would have received if the treatment had been administered in accordance with the written directive and treatment plan; and (2) the prostate received 20 percent less than the prescribed dose of 160 Gy (16,000 rad).

An NRC medical consultant reviewed a total of 39 medical events. During the consultants' onsite assessment, he reviewed numerous written directives and treatment plans with the inspectors and the licensee's consulting medical physicist. The medical consultant reviewed the permittee's spreadsheet summarizing the treatments and he provided a statistical analysis of the data. The consultant generally agreed with the licensee's dose estimates to the patients. However, he indicated that erratic seed placement caused a number of patients to have elevated doses to the rectum, bladder,

or periprostatic tissue. The consultant identified specific patients with rectal bleeding where the increased dose to the patients' colon, which resulted from erratic seed placement, may have been a contributing factor to the condition. Five of the 114 patients treated had expired; however, the inspectors confirmed that the cause of death for these 5 patients was not related to their prostate brachytherapy treatments. The PVAMC offered to refer 18 of its patients to the VA Puget Sound Health Care System, Seattle facility for re-implantation. Eight patients received re-implants. The remaining ten patients, who declined a re-implant, received additional follow up through other treatment modalities that did not involve any form of radiation therapy.

NRC Region III Office issued their inspection reports on March 30, 2009 and November 17, 2009. Based on the results of the inspections, eight apparent violations of NRC requirements were identified. The apparent violations involved inadequate procedures, training, and reporting requirements for medical events. A pre-decisional enforcement conference was held on December 17, 2009. The final enforcement action was issued on March 17, 2010.

3. MAJOR TECHNICAL OR REGULATORY ISSUES

The major issues are:

a. 97 medical events occurred between February 2002 and May 2008, which were not identified and reported to the NRC until May 16 through October 2, 2008 and August 12, 2009. Of these 97 medical events, 17 of them met the abnormal occurrence criteria;

b. The authorized user physician and medical physicists failed to take appropriate corrective action when the post treatment plans demonstrated that the administered dose was not in accordance with the written directive and pre-treatment plan;

c. The licensee's written policies and procedures did not provide a procedure to adequately verify that the final treatment plan was in accordance with the written directive;

d. There was inadequate program oversight of the brachytherapy program by the PVAMC's Radiation Safety Officer and Radiation Safety Committee;

e. There was inadequate management oversight and no peer review of the physicians and physicists working under contract to provide brachytherapy services for the PVAMC;

f. The PVAMC failed to provide adequate training to the contractor physicians and physicists that provided brachytherapy services regarding identification and reporting requirements for medical events; and

g. The PVAMC lacked a safety culture for reporting radiation concerns to the appropriate individuals. As an example, interviews of two medical physicists indicated that they had concerns about the quality of an authorized physician user's implants being "suboptimal," but their concerns were never reported to the Radiation Safety Officer or licensee management.