DOCKET: 70-143

LICENSEE: Nuclear Fuel Services, Inc.

SUBJECT: SAFETY EVALUATION REPORT – CONFIGURATION MANAGEMENT PROGRAM AMENDMENT (TAC L32632)

BACKGROUND

Since 2002, a growing number of significant violations occurring at the Nuclear Fuel Services Inc. (NFS) facility, in Erwin, TN have been reflected in successive Licensee Performance Reviews. Despite numerous root cause investigations and corrective action plans, NFS continued to experience chronic noncompliance issues. Civil penalties and other sanctions imposed by the Nuclear Regulatory Commission (NRC) did not have the desired effect for improving overall compliance with regulatory requirements. The normal enforcement process did not result in adequate improvement. It was the conclusion of the NRC Headquarters and RII staff and management to focus NFS resources on actions that would improve the licensee's program and reduce repeat violations.

One such issue was a spill of High Enriched Uranyl Nitrate (HEUN) solution on March 6, 2006, resulting in multiple violations, including the failure of the existing configuration management system to evaluate, implement, and track changes in accordance with 10 CFR 70.72(a).

The proposed strategy recommended use of the Alternate Dispute Resolution (ADR) process, which required the licensee to develop an improved Configuration Management (CM) program based on benchmarking they have done, and to amend License SNM-124 to implement the program.

On September 28, and November 30, 2006, the NRC and NFS staff met in ADR sessions facilitated by a professional mediator, arranged through Cornell University's Institute on Conflict Resolution. As a result, the licensee agreed to submit, for NRC approval, a request to amend the license to revise the CM program. The NRC issued a Confirmatory Order on February 21, 2007, requiring submittal of the amendment request within 60 days.

Via letter dated April 20, 2007, NFS submitted a request to amend Part I, Chapter 2, of License SNM-124. On October 17, 2007, the NRC returned a Request for Additional Information (RAI). The licensee responded to the RAI in a letter dated December 14, 2007. This Safety Evaluation includes staff conclusions based on these submittals.

DISCUSSION

The staff reviewed the amendment request using guidance contained in Section 11.3 of NUREG-1520, *Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility.* The licensee's proposed CM program is based on the Nuclear Information & Records Management Association standard ANSI/NIRMA CM 1.0-2006, *Guidelines on Configuration Management for Nuclear Facilities*, as well as that contained in Department of Energy Standard

DOE-STD-1073-2003, *Configuration Management*. While there is no regulatory basis for selection of these standards, the staff selected them as the best approach to evaluate a program with the purpose of preventing a spill situation, similar to the events of March 6, 2006.

The goal of the CM program is to ensure that accurate and current documentation matches the facility's physical/functional configuration, ensuring that items relied on for safety (IROFS) are available and reliable, and the facility complies with regulatory requirements. The licensee commits to a CM program in accordance with the requirements of 10 CFR 70.62(d), 10 CFR 70.64, and 10 CFR 70.72.

The licensee commits to implementing the CM program for new processes throughout facility design, construction, testing, and operation after June 30, 2008. For existing processes (designed, installed, or in operation prior to June 30, 2008) the program will be applied in accordance with the following schedule: (1) revise the CM program documents – March 2008; (2) revise engineering procedures – March 2008; (3) develop procedures for control and storage of CM information – March 2008; (4) revise/develop change control procedures – March 2008; (5) complete mini-prototype for BLEU U-Aluminum Bowl Cleaning– July 2007; (6) roll capabilities throughout BLEU Prep Facility – September 2008; (6) roll capabilities throughout Navy Fuel Operations – June 2009; and -(7) roll capabilities throughout NFS – December 2010. Problem identification categories and criteria for the Problem Identification Resolution and Correction System (PIRCS) system have been developed and are in use. Initial training was completed. The staff has reviewed the amendment request, using the guidance in NUREG-1520, and has concluded with reasonable assurance that the licensee has committed to an acceptable schedule for design reconstitution of the existing areas.

Organizational Structures, Procedures, and Responsibilities

The Engineering organization has overall responsibility for the implementation of the CM program. The CM program will be applied to all NFS organizations, including contractors, who perform construction, operation, maintenance, modification, and decommissioning activities.

The licensee's CM program will apply to IROFS, contained in the Integrated Safety Analysis (ISA), in accordance with design control, document control, and records management procedures. All design changes will undergo formal review, including interdisciplinary reviews, as appropriate. The program addresses the following topics: (1) program management; (2) design control; (3) information control; (4) assessments; (5) training; and (6) performance metrics related to the CM program.

The CM program will be applied to all Systems Structures and Components (SSC's) that the ISA identifies as IROFS, and any SSC's: that process or store a critical mass of U-235; protect off-site personnel; are necessary to meet regulatory requirements for physical protection of special nuclear material; or protect the environment.

The CM program will also apply to design requirements as follows: calculations, safety analyses, design criteria, engineering drawings, system descriptions, technical documents, and specifications that establish the form, fit, or function of Configuration Items (CI), including but not limited to capacities, physical sizes, limits, and set points for process control parameters.

Programmable Logic Controller software that are CIs are managed by the CM program. However, software applications' running on the NFS computer network are addressed by the licensee's Software Quality Assurance Program (SQAP), and is based on the sections of ASME

standard NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications*, applicable to software. The SQAP is implemented through procedures which include appropriate software design verification and validation steps.

The amendment request describes how the CM function relates to other management measures, including records management, maintenance, training and qualifications, incident investigation, audits and assessments, and procedures. Specifically, the Engineering Function establishes the framework for CM, and the records associated with IROFS, or items affecting IROFS. Records are generated and processed in accordance with CM program requirements. The design basis, which will be controlled under CM, establishes maintenance requirements. The objective of the CM function will be to ensure design and operation within the design bases of the IROFS. This will be accomplished by identifying and controlling documentation associated with IROFS, controlling changes to IROFS, and maintaining the physical configuration of the facility, consistent with the approved design.

Changes to the approved design are subject to review and approval to ensure consistency and coordination within the design bases of IROFS. The CM function and the design will be subject to periodic audits and assessments to confirm that the design and physical configuration will be consistent with the design basis Identified problems will be subject to the licensee's PIRCS process, which is identified in the licensee's Quality Assurance (QA) Program and associated implementing procedures. Prompt corrective actions will be developed as a result of incident investigations, or in response to an unfavorable audit or assessment results. CM activities will be conducted and documented under design control provisions and involve the systematic preparation, review, and approval of design and construction documentation for ensuring that consistency is maintained between design and design bases for IROFS. CM activities also provide for operation of IROFS within the limits specified in the ISA and control changes to the facility in accordance with 10 CFR 70.72. Finally, CM activities provide records for certifying that the personnel conducting activities relied on for safety are appropriately trained and qualified, and revisions for ensuring only formally reviewed and approved procedures, specifications, and drawings are used for activities associated with IROFS.

The staff has reviewed the amendment request using the guidance in NUREG-1520, and has concluded with reasonable assurance that the licensee has committed to acceptable organizational structures, procedures, and responsibilities.

Design Requirements

During design and construction, the Engineering organization establishes and maintains design requirements and associated design bases. Design requirements will be documented and maintained in a design bases document, which contains a set of functional requirements, interfaces, and expectations of a facility or item that is based on regulatory requirements, performance requirements, and/or analyses. Each design requirement has a design basis. The design requirements documentation and the design-basis documents will ultimately reside in a single electronic database, utilizing the LINC system, a third party software, and be controlled in accordance with the design control provisions of the CM program. The design documents associated with IROFS, items that affect the function of IROFS, and items required to satisfy regulatory requirements, as well as analyses that constitute the ISA of the design bases, will be subject to interdisciplinary reviews and design verification. Design changes are evaluated to

ensure consistency within the design basis. Qualified individuals will prepare and review design documents, and the responsible manager approves the corresponding design documentation. The QA department conducts audits on the design-control process, using independent, technically qualified staff.

The amendment request includes a design-verification process for design documents where emphasis will be placed on assuring conformance with applicable codes, standards, and license application design criteria. Design verification ensures that design documents are consistent with the design criteria used for IROFS. Design verification will be accomplished through design review by the affected safety organizations. For new facilities, design requirements for an item must be complete before construction or installation. The Baseline Design Criteria in 10 CFR 70.64 are addressed. After verification and approval, the design document will be distributed to the appropriate parties through the document control center. Configuration control will be accomplished, during design, through the use of design-control procedures, which address preparation, review, verification, approval, release, and distribution of design documents for use.

The staff has reviewed the amendment request using the guidance in NUREG-1520, and has concluded with reasonable assurance that the licensee has committed to an acceptable basis for documentation of design requirements supported by analyses.

Change Control

The licensee is mandated by 10 CFR 70.72 to implement a change control function, and associated procedures that control changes to the technical baseline, as part of it's CM program. For each change to the facility or to the activities carried out by personnel, an evaluation of the proposed change will be performed in accordance with the requirements of 10 CFR 70.72, as applicable. The amendment request has described the process of evaluation for every modification to the facility, and how the review will be performed, to determine the need for any required changes or additions to the facility's processes, procedures, personnel training, testing program, or regulatory documents. Changes to the above items will be controlled through procedures. Before a change is implemented, the change control process will require an appropriate level of technical, management, and safety review and approval. During the design phase, changes to the design will include a systematic review of the design bases. Consistency between documents will be ensured through the interdisciplinary review process, which will ensure that design changes do not impact the ISA; or are accounted for in subsequent changes to the ISA; or such design changes will not be approved and/or implemented. The licensee has committed to notify the NRC of potential changes that reduce the level of commitments or the safety margin in the design bases of IROFS.

Proposed changes are to be prepared as a Change Control Package (CCP) and are evaluated by a Change Control Board (CCB), chaired by the CM function manager. The status of pending or temporary changes and work orders are available on the LINC system. One key feature of the LINC software is its ability to cross-reference CIs and their related information. If a modification is required during the implementation of a CCP, a second CCP must be entered, to ensure that all affected documents are identified, revised, and approved prior to implementation of the new change.

The amendment request describes measures that will be implemented to ensure that the quality of facility SSCs are not compromised by planned changes and modifications. Modification procedures will be implemented that will state the requirements that will be met to implement a modification, as well as the requirements for initiating, approving, monitoring, designing, verifying, and documenting modifications. Modification procedures will be written to ensure that policies are maintained to satisfy the licensee's QA requirements. Each modification will be evaluated for any required changes to the facility's procedures, training programs, testing programs, or regulatory requirements described in 10 CFR 70.72. A nuclear criticality safety evaluation will be prepared and approved for any change that involves or could affect on-site uranium. The evaluation of modifications will take into consideration such items as: (a) radiation exposure; (b) cost; (c) lessons-learned; (d) QA aspects; (e) operability issues; (f) maintenance issues; (g) constructability issues; (h) testing requirements; (i) environmental concerns; and (j) human factors.

The staff has reviewed the amendment request using the guidance in NUREG-1520, and has concluded with reasonable assurance that responsibilities and procedures adequately describe how consistency will be maintained among the design requirements, facility configuration, and documentation, as the facility is modified.

Information Control

The CM function will establish a document control program that will be implemented and controlled through procedures. Document control procedures govern the preparation and issuance of, as well as changes to, key documents. In addition to document control procedures, the licensee will utilize an electronic document management system that will file project records and make available, the latest controlled copy of design documents. Controlled documents will be maintained in the system until cancelled or superseded.

The document control and records management procedures will be part of the CM program, and as such, they will capture the following documents, which are listed in approved procedures: (a) regulatory requirements documents; (b) design-bases documents; (c) the ISA and ISA Summary; (d) nuclear criticality safety evaluations and analyses; (e) as-built drawings; (f) specifications; (g) procedures that are IROFS; (h) vendor information; (i) maintenance documents; (j) audit and assessment reports; (k) emergency operating procedures; (l) Process Hazard Analyses (PHAs); (m) system-modification documents; and (n) engineering documents.

The licensee commits to use the LINC software for implementation of the CM program. All information (design requirements, drawings, results of design reviews, including resolution of comments) will be entered into the LINC database. Change requests and change control packages will utilize the LINC system.

The staff has reviewed the amendment request using the guidance in NUREG-1520, and has concluded with reasonable assurance that the licensee has committed to an acceptable program for storing and accessing drawings and related documents.

Assessments

Review of the licensee's CM assessment function included a description of periodic assessments of the CM program which are designed to detect and correct deficiencies in the CM program. This review of assessments will be carried out by the licensee's QA department. The amendment request describes the implementation strategy used for scheduling internal and

external audits/assessments in a manner consistent with the activities status and importance to on-going work activities. These assessments will be based on thorough reviews of the adequacy of documentation and effectiveness of the quality assurance program and system walk-downs of the as-built facility. As stated in the licensee's amendment request, these periodic assessments will confirm the implementation of the CM programmatic elements and verification of compliance and consistency of design with the design bases.

In addition, the licensee's CM program includes periodic reviews of set point analyses to ensure that the safety function, system boundary, assumptions, and process variables accurately reflect current conditions. Also subject to periodic reviews are the results of tests of Safety Related Equipment, to ensure that the tests fully challenge the controls required by the applicable IROFS.

The staff has reviewed the amendment request using the guidance in NUREG-1520, and has concluded with reasonable assurance that the licensee has committed to an acceptable program for initial and periodic assessments of the adequacy of the CM function.

Training

The licensee's training program includes a commitment to provide awareness of CM concepts, terminology, and procedures. The intention is to maintain consistency between design requirements, facility configuration information, and the as-built conditions. The staff finds this commitment to be acceptable.

ENVIRONMENTAL REVIEW

A categorical exclusion is allowed under 10 CFR 51.22 (c)(11) if the following requirements have been satisfied:

i There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite.

ii There is no significant increase in the individual or cumulative occupational radiation exposure.

iii There is no significant construction impact.

iv There is no significant increase in the potential for or no consequences from radiological accidents.

There are no new nuclear fuel manufacturing activities proposed by this request, nor increased throughputs within existing unit processes. The amendment is administrative in nature and applies to authorized activities. There will be no significant increase in the possibility of an off-site release and there will be no significant increase in individual or cumulative occupational radiation exposure. Consequently, there is no significant increase in the potential for, nor consequences from, radiological accidents. There is no construction impact.

The staff has determined that the proposed change does not adversely impact public health and safety or the environment, and is categorically excluded from the requirement to prepare a site-specific environmental assessment. Therefore, in accordance with 10 CFR 51.22(c)(11),

neither an environmental assessment nor an environmental impact statement is warranted for this action.

RECOMMENDATION

The NRC staff has concluded that the licensee's proposed CM program provides reasonable assurance of effective protection against a spill event similar to that of March 6, 2006, and recommends approval of the CM program amendment request.

The Regional inspection staff has reviewed this action and has no objections.

The NRC staff recommends that the schedule of application of the CM program to existing processes be captured in a license condition for existing processes (designed, installed, or in operation prior to June 30, 2008), the program will be applied in accordance with the following schedule: (1) apply throughout BLEU Prep Facility – September 2008; (2) apply throughout Navy Fuel Operations – June 2009; (3) apply throughout NFS – December 2010.

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