U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Design Control Inspections

Taiwan ISFSI Workshop
December 8, 2008

Jim Pearson, SFST Inspector
301-492-3337 Jim.Pearson@nrc.gov

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Outline

- Design Control Basis
- Inspection Procedure 60851
- Inspection Findings
- Summary

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Design Control Basis

- Design Submittal for Certificate
- NRC Review and Approval Process
- Certificate of Compliance and Technical Specifications
- Quality Assurance Program

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Why Inspect?

- To determine that the design control program described in a licensee's or certificate of compliance (CoC) holder's quality assurance program (QAP) is effectively implemented.

- Trust, but verify through inspection, that the design is properly controlled.

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Inspection Procedure 60851

- Inspection Objectives
  - Determine that the design control program described in a licensee's or certificate of compliance (CoC) holder's quality assurance program (QAP) is effectively controlling the design.
  - Determine that design changes implemented by the licensee or CoC holder have been properly evaluated for their impact on the function of dry cask storage system (DCSS) components used in an independent spent fuel storage installation (ISFSI).

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

60851 Inspection Objectives (Continued)

- Determine that any design changes have been evaluated to ensure that the change does not:

  a. Require a change to the conditions in the license or the CoC;

  b. Require prior U.S. Nuclear Regulatory Commission (NRC) approval;

  c. Create a significant increase in occupational exposure; or

  d. Have a significant unreviewed environmental impact.

60851 Inspection Requirements

- Determine whether the licensee's or CoC holder's QAP implementing procedures are in place and used effectively.
  - Determine whether:
    - a. A method exists to ensure that design changes initiated by the vendor or CoC holder are communicated to the licensee;
    - b. The licensee was notified of the design changes in a timely manner to minimize production or operations impacts; and

60851 Inspection Requirements (Continued)

c. The licensee has reviewed and/or approved these design changes that were approved by the vendor or CoC holder

- Determine whether any nonconforming conditions, which were resolved by design changes, have been reviewed and approved by the licensee or CoC holder (if authorized by the CoC).

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

60851 Inspection Requirements (Continued)

- Determine whether all nonconforming conditions identified before completion of fabrication were appropriately resolved before the DCSS components affected were released to the licensee.
- Determine whether the licensee, vendor, and fabricator personnel have established an effective method for tracking, evaluating, and dispositioning changes or modifications to the DCSS component design.

60851 Inspection Requirements (Continued)

– For selected design changes, determine whether the applicable documentation is complete and accurate, including relevant 10 CFR 50.59 or 72.48 evaluations.

60851 Inspection Guidance

– Definitions.

a. Participants. The terms licensee, vendor, CoC holder, fabricator, general licensee, and site-specific licensee are terms the inspectors will commonly encounter while reviewing ISFSI activities. Refer to Inspection Manual Chapter (IMC) 2690, Inspection Program for Dry Storage of Spent Reactor Fuel at Independent Spent Fuel Storage Installations, Section 03, for definitions of these terms.

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

60851 Inspection Guidance (Continued)

- Definitions (Continued)

b. Safety Classification. ISFSI systems, structures, and components (SSCs) are classified as either important to safety or not important to safety by the ISFSI designer. If important to safety, the SSC will typically either:

1. Maintain the functions or conditions (i.e., confinement, criticality, shielding, and heat removal) necessary to store spent fuel safely;

2. Prevent significant damage to the spent fuel container (DCSS) during handling and storage; or

3. Provide reasonable assurance that spent fuel can be received, handled, packaged, stored, and retrieved without undue risk to public health and safety.

60851 Inspection Guidance (Continued)

- **General Guidance.**

- a. Additional Assistance. The inspectors may obtain additional assistance for both technical and design questions from the cognizant Spent Fuel Storage and Transportation (SFST) project manager (PM). For questions involving ISFSI operations and how the ISFSI design can affect overall site operations, contact the SFST PM who may request Nuclear Reactor Regulation (NRR) assistance if needed. Note that additional guidance for review of ISFSI storage pad designs is located in Appendix A of inspection procedure (IP) 60856, Review of 10 CFR 72.212(b) Evaluations.

60851 Inspection Guidance (Continued)

- **General Guidance**.

- b. ISFSI SSCs Safety Classification. Before performing an inspection of ISFSI SSCs, the inspectors should review the licensee's design basis documents to determine whether the licensee has applied an appropriate safety classification to a particular SSC. Note that site-specific variations in ISFSI designs may affect the safety classification of some SSCs.

60851 Inspection Guidance (Continued)

- c. ISFSI SSCs Not Important to Safety. For this class of SSCs, the licensee's use of generally accepted commercial-grade standards, practices, and materials in design, fabrication, and construction activities is acceptable. However, these SSCs must still conform to the design requirements described in the safety analysis report (SAR) and supporting engineering documents.

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

60851 Inspection Guidance (Continued)

- d. Design Changes. Each DCSS design has been approved by the NRC through the licensing process, for a site-specific license, or the 10 CFR Part 72, Subpart L, process for a general license. All changes to the design described in the SAR must be approved by the licensee or CoC holder. Approval authority for changes can be difficult for the inspectors to determine. In such cases, the inspectors can find additional guidance in IMC 2690, Section 05.09.

60851 Inspection Guidance (Continued)

- e. Component Functionality. Functionality is the ability of a component to meet its design requirements. Some components may have multiple design requirements and several functions. These requirements and functions are defined in the SAR, safety evaluation report (SER), and, as applicable, the CoC or the site-specific license and technical specifications (TS) for the DCSS. For example, the cask support basket that separates the individual fuel bundles serves several functions: structural integrity, criticality control, heat transfer, and radiation shielding. Assistance in identifying the function(s) of a given component may be obtained from SFST.

60851 Inspection Guidance (Continued)

- f. Document Review. Before any onsite inspection activity, for each DCSS in use, review (as applicable) the:

  1. SAR and corresponding NRC SER;

  2. CoC;

  3. Site-specific license and TS; and

  4. 10 CFR 72.48 evaluations performed since the last update to the DCSS SAR.

60851 Inspection Guidance (Continued)

- f. Document Review (Continued) .

  and also review SERs describing DCSS components which have been written for each type of approved DCSS.

  Information on operational commitments for a particular DCSS may also be found in the CoC or the site-specific license and TS. As DCSS designs vary, be careful to review the appropriate documentation.

  The inspectors can obtain copies of these documents from the appropriate regional division or cognizant SFST PM.

60851 Specific Guidance

- a. Inspection Requirement 02.01. The licensee's or CoC holder's QAP should have been previously reviewed and approved by the NRC. Verify that design control and related activities (e.g., document control, special processes, or resolution of nonconforming conditions) are conducted under an approved QAP. Review completed audits and fabrication records, interview selected personnel, and/or review procedures. Review any related licensee quality assurance (QA) audits or SFST inspections regarding DCSS design changes and determine whether corrective actions for the audit or inspection findings have been effectively implemented.

60851 Specific Guidance

- b. Inspection Requirement 02.02 (Continued).

  If the licensee has imposed requirements on the vendor or CoC holder to notify it of any design changes initiated by the vendor or CoC holder, determine whether the vendor or CoC holder is complying with these requirements. Review QA audits of the vendor's or CoC holder's activities in this area.

60851 Specific Guidance (Continued)

- c. Inspection Requirement 02.03. No specific guidance.

- d. Inspection Requirement 02.04. Determine whether there is a process in place under the QAP to keep track of design changes. Assess the adequacy of design interface activities, communications, evaluations and safety screenings, and documentation of changes.

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

60851 Specific Guidance (Continued)

- e. Inspection Requirement 02.05. Determine, through review of records, inspection of equipment and components, and/or interviews with selected personnel, whether the licensee or CoC holder has performed design changes and modifications. Evaluate the quality and timeliness of such documentation. Assess the thoroughness of documentation and the independence of reviews, particularly for those design changes that resolve nonconformances and field change requests. Check that evaluations contain a discussion of the effect on component functionality. The inspectors can find information on component functionality in the SAR, SER, CoC, or, as applicable, the site-specific license and TS.

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

60851 Specific Guidance (Continued)

- Determine the adequacy of the timing of design change reviews. Ideally the licensee or CoC holder should complete the reviews before the component is fabricated. However, if the licensee elects to proceed with fabrication "at risk," verify that the licensee does not use the DCSS until all design changes have been evaluated and appropriately dispositioned.
- f. Inspection Requirement 02.06. Design-basis accidents, such as a DCSS tip-over or a drop from a maximum specified height, are addressed in the SAR; however, the inspectors may obtain assistance from the cognizant SFST PM in determining whether a change requires NRC approval for a particular DCSS design.

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

60851 Inspection Resources

- To prepare for these inspections each inspector should spend approximately 32 hours on in-office review.
- Inspection activities will require approximately 40 hours, each, by three inspectors.
- Documentation is estimated to require 32 hours for each inspector.
- SFST vendor inspection staff is expected to have the lead in inspecting CoC holders, and any associated vendors or fabricators, with assistance from regional inspection staff.
- Regional inspection staff is expected to have the lead in inspecting licensees, with assistance from SFST Staff.

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

60851 Sample Inspection Findings

Example 1: **INSPECTION REPORT NO. 72-1014/01-201 & NOV**

- 10 CFR 72.140, .Quality Assurance Requirements,. requires, in part, that each certificate holder obtain Commission approval of its quality assurance program before commencing fabrication or testing of a spent fuel storage cask.
- Contrary to the above, vendor adopted Revision 12 of their Quality Assurance Manual on January 2, 2001, and performed fabrication activities prior to receiving NRC approval of the revised program. The vendor submitted Revision 12 to the NRC for approval on June 20, 2001.
- This is a Severity Level IV violation (Supplement VI)

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

60851 Sample Inspection Findings

Example 2: INSPECTION REPORT NO. 72-1014/01-201 & NOV

- 10 CFR 72.150, “Instructions, procedures, and drawings,” requires, in part, that a certificate holder prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances.
- Contrary to the above, the vendor’s procedures were not of a type appropriate to the circumstances in that quality assurance personnel performed activities affecting quality, internal quality assurance surveillances, which were not prescribed by a documented procedure. Fourteen surveillances were performed between February 14, and August 20, 2001, before an appropriate procedure, HQP-18.5, Internal Surveillance, was issued on September 5, 2001.
- This is a Severity Level IV violation (Supplement VI).

60851 Sample Inspection Findings

Example 3: INSPECTION REPORT NO. 72-1014/01-201 & NOV

- C. 10 CFR 72.172, “Corrective action,” requires, in part, that the certificate holder shall establish measures to ensure that conditions adverse to quality are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must ensure that corrective action is taken to preclude repetition.
- Contrary to the above, corrective actions for a significant condition adverse to quality did not preclude repetition. In 2000 and 2001, the vendor’s corrective action program had documented numerous examples of problems involving the incorporation of engineering change orders (ECOs) onto controlled drawings. For example, Corrective Action Report (CAR) 59 and Quality Procedure Violation Form (QPVF) 98, document the significant condition adverse to quality. As detailed in NRC Inspection Report 72-1014/01-201, the NRC identified numerous ongoing repetitive errors regarding the incorporation of ECOs onto controlled drawings.
- This is a Severity Level IV violation (Supplement VI).

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Summary

- **Design Control Basis**

  Design Submittal for Certificate

  NRC Review and Approval Process

  Certificate of Compliance and Technical Specifications

  Quality Assurance Program

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Summary
(Continued)

- Inspection Procedure 60851
  - Determine that the design control program described in a licensee's or certificate of compliance (CoC) holder's quality assurance program (QAP) is effectively controlling the design.
  - Determine that design changes implemented by the licensee or CoC holder have been properly evaluated for impact on the function of DCSS components used in an independent spent fuel storage installation (ISFSI).

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Summary
(Continued)

- Determine that any design changes have been evaluated to ensure that the change does not:
  a. Require a change to the conditions in the license or the CoC;
  b. Require prior U.S. Nuclear Regulatory Commission (NRC) approval;
  c. Create a significant increase in occupational exposure; or
  d. Have a significant unreviewed environmental impact.

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Summary
(Continued)

- Inspection Findings

  A Notice of Violation (NOV) is initiated by the NRC for an inspection finding that does not meet the regulations under Part 72.

  While some NOVs are more safety significant than others, it is important to address each with proper corrective action measures.

  NOVs associated with design issues are important because much of the completed work in fabrication relies on a flawless design as a basis for fabricating a flawless storage cask.