

REVIEW OF 10 CFR 72.48 EVALUATIONS

PROGRAM APPLICABILITY: 2690

60857-01 INSPECTION OBJECTIVE

In 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste," Section 72.48, "Changes, tests and experiments," contains requirements for the process by which licensees (specific and general) and certificate holders may make changes, under certain conditions, to their facilities (independent spent fuel storage installation or monitored retrievable storage facility), spent fuel storage cask designs, and procedures, as described in the final safety analysis report (FSAR), as updated, without prior U.S. Nuclear Regulatory Commission (NRC) approval.

This procedure is primarily intended to provide guidance to inspectors in assessing the effectiveness of licensee or certificate holder performance of 10 CFR 72.48 evaluations, and in ensuring that any required license or certificate of compliance (CoC) amendments have been obtained. A secondary focus of this inspection procedure is a programmatic review of the licensee or certificate holder's 10 CFR 72.48 procedures and training.

60857-02 INSPECTION REQUIREMENTS

02.01 Inspection Sample Selection

- a. Review a list of evaluations performed by the licensee/certificate holder and select a representative sample. Choose samples from changes to facility or cask design, procedures, FSAR, and tests, based on a judgement of their risk significance.
- b. Select a sample of changes, tests, and experiments that were screened out by the licensee/certificate holder as not requiring performance of 10 CFR 72.48 evaluations.

02.02 Review of Licensee/Certificate Holder Evaluations

- a. With respect to 02.01a, review the selected sample evaluations to verify that the licensee/certificate holder has appropriately considered the conditions under which they may make changes to the facility or procedures, or conduct tests or experiments without prior NRC approval. Review analyses for technical content, methods, and process. Verify that the licensee/certificate holder has appropriately concluded that the change, test, or experiment can be accomplished without obtaining a license or CoC amendment.

- b. With respect to 02.01b, review the selected sample of changes, tests, or experiments (CTEs) for which the licensee/certificate holder determined that evaluations were not required and verify that their conclusions were correct and consistent with 10 CFR 72.48.

02.03 Procedures and Controls

- a. Verify that formal procedural guidance has been established, and procedural responsibility assigned, for implementing the requirements of 10 CFR 72.48 for proposed CTEs. This should include guidance for:
 - 1. Assessing and documenting whether 10 CFR 72.48 applies.
 - 2. Assessing and documenting whether a change to the facility can be made without requiring a license amendment under 10 CFR 72.56 (for specific licensees), or a CoC amendment pursuant to 10 CFR 72.244 (for general licensees and certificate holders).
 - 3. Maintaining records in accordance with 10 CFR 72.48(d)(1) and (d)(3).
 - 4. Formal reporting to the NRC in accordance with 10 CFR 72.48(d)(2).
 - 5. Provisions for updating the FSAR for evaluations and analyses described in 10 CFR 72.48(c)(3).
 - 6. Provisions for the exchange between licensees and certificate holders of records of changes in accordance with 10 CFR 72.48(d)(6)(i)-(iii).
- b. Verify that the licensee/certificate holder's formal procedural guidance for implementing its evaluation program conforms to 10 CFR 72.48 requirements.
- c. Verify that the licensee/certificate holder has established measures to ensure that design information necessary for preparing adequate 10 CFR 72.48 evaluations is available to licensee/certificate holder personnel that prepare 10 CFR 72.48 evaluations.

02.04 Training and Qualifications

- a. Verify that the licensee/certificate holder's training and qualification requirements are consistent with the licensee/certificate holder's commitments established in the NRC-approved quality assurance program including, as applicable, training and qualification requirements for licensee/certificate holder personnel that prepare, review, or approve 10 CFR 72.48 evaluations and applicability determinations, and for personnel that conduct 10 CFR 72.48 training.
- b. Verify that training materials are consistent with the licensee/certificate holder's current procedural guidance for preparing 10 CFR 72.48 evaluations and making 10 CFR 72.48 applicability determinations. Determine whether the licensee/certificate holder has established a process for assessing training effectiveness.

60857-03 INSPECTION GUIDANCE

Definitions

- a. Refer to 10 CFR 72.48(a)(1) through (7) for the definition of various terms that are specific in their applications to the 10 CFR 72.48 process.
- 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. Further guidance can be found in NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety."

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 [dry cask storage system(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.

If an SSC does not perform any of the preceding functions, it may be classified as "not important to safety."

General Guidance

This procedure is intended to guide inspectors in evaluating licensee/certificate holder compliance with the requirements of 10 CFR 72.48. The procedure consists of three major elements: implementation (Sections 02.01 and 02.02), procedures and controls (Section 02.03), and training and qualifications (Section 02.04). Sections 02.01 and 02.02 should be performed on all initial licensee/certificate holder inspections and during subsequent inspections as needed. Sections 02.03 and 02.04 should be performed during initial licensee/certificate holder inspections and as needed thereafter if the subsequent performance of Sections 02.01 and 02.02 indicates possible programmatic problems in the licensee/certificate holder's implementation of the 10 CFR 72.48 requirements.

- a. This Inspection Procedure (IP) will normally be used to provide inspector guidance in performing reviews of 10 CFR 72.48 evaluations when directed to do so by IPs 60851 through 60856; however, it can be used as a stand-alone IP if needed.
- b. Technical questions on ISFSI change activities under 10 CFR 72.48 should be referred to the cognizant Spent Fuel Project Office project manager (SFPO PM) who will then determine whether the issue should be referred to the SFPO 10 CFR 72.48 working group for resolution or to the cognizant Office of Nuclear Reactor Regulation project manager if the issue involves safety-related reactor SSCs.
- c. In preparation for inspecting the DCSS used by the licensee, review the commitments and key requirements in the safety analysis report (SAR), the NRC's safety evaluation report (SER), and the CoC. SARs and SERs have been written for each type of approved DCSS and describe the operations of DCSS components. Information about commitments for a particular DCSS may also be found in the associated CoC. In some cases, the CoC may have an attached "Conditions of Use/Technical Specifications" document and design bases. DCSS designs vary and care must be taken to review the correct documentation. Copies of these documents may be obtained from the region or the cognizant SFPO PM. (Note: Although the SER can document or clarify commitments made by the licensee or vendor, the SER is not an independent basis for enforcement actions.)
- d. The cognizant SFPO PM should be contacted to determine if they have identified any 72.48 evaluations, from their review of the licensee/certificate holder's biannual submittals, that should be considered for further review during the inspection.

- e. The inspector should review, and have available during the inspection, a copy of NUREG/CR-6407, Regulatory Guide 3.72, "Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments," and NEI-96-07, Appendix B, "Guidelines for 10 CFR 72.48 Implementation." These documents should be referred to when evaluating licensee/certificate holder evaluations against the criteria of 10 CFR 72.48(c)(1)-(4). It is particularly important for the inspector to have a good working knowledge of NEI-96-07, Appendix B, in reviewing and assessing the adequacy of 10 CFR 72.48 screenings and evaluations.

Specific Guidance

03.01 Inspection Sample Selection

- a. Include in the sample selection (where possible) evaluations that involve calculations, revisions, design modifications, or content changes, as they relate to the six primary function categories (as defined in Table 3 of NUREG/CR-6407) of spent fuel storage casks. These are: containment, criticality control, shielding, heat transfer, structural integrity, and operations support. Inspector judgment should be used in determining an appropriate and representative sample size for review. As described further in 03.02a, some sampled evaluations should be complex in nature.
- b. No specific guidance.

03.02 Review of Licensee/Certificate Holder Evaluations

- a. As noted above, in "General Guidance", when reviewing licensee/certificate holder evaluations against the 10 CFR 72.48(c) criteria, refer to RG 3.72 and NEI-96-07, Appendix B, for guidance and examples in assessing whether the licensee/certificate holder evaluations are appropriate.

In the review of the 10 CFR 72.48 analyses, the review effort should focus on the technical content of the analyses. Although it is recognized that inspection resources may be limited, consider reviewing some analyses that are more complex to provide an indication of licensee/certificate holder abilities in performing such analyses. NOTE: Assistance is available from the SFPO Technical Review Directorate should technical questions arise that cannot be resolved with the licensee/certificate holder during the inspection. Requests for assistance should be made through the cognizant SFPO PM.

- b. No specific guidance.

03.03 Procedures and Controls

- a. The inspector should verify that the licensee/certificate holder has approved procedures that include guidance for conducting the activities described in Section 02.03 of this procedure. Although the licensee/certificate holder should have a controlled process for implementing the requirements of 10 CFR 72.48, this process may not be confined to a single procedure or document. The inspector must, therefore, identify which procedures define the licensee/certificate holder's 10 CFR 72.48 implementation process. To do this, review and become familiar with as many of the following licensee/certificate holder procedures, guidance documents, and NRC requirements as needed for understanding how the licensee/certificate holder complies with 10 CFR 72.48:

1. 10 CFR 72.48 implementation program procedure.
 2. Guidance for preparing 10 CFR 72.48 evaluations. This should include controls for coordinating the preparation of 10 CFR 72.48 evaluations for design changes involving multiple engineering disciplines or diverse parts of the licensee/certificate holder's organization.
 3. Guidance for making 10 CFR 72.48 applicability determinations and for answering the questions in 10 CFR 72.48 that determine whether a CTE can be made without requiring prior NRC approval.
 4. Procedures for making facility modifications (permanent and temporary).
 5. The NRC-approved quality assurance program.
 6. Procedures for preparing FSAR updates.
 7. Procedures for making changes to procedures.
 8. Procedures for preparing and conducting tests (or experiments) not described in the FSAR.
 9. Procedures for document control (procedures, design documents, etc.).
- b. The inspector should verify that the licensee/certificate holder's procedures for implementing 10 CFR 72.48 clearly designate, by position title, the individuals in their organization responsible for the accomplishment of the activities listed above in 03.03a.
- c. No specific guidance.

03.04 Training and Qualifications

- a. 10 CFR 72.144(d) requires that a licensee or certificate holder provide for indoctrination and training for personnel performing activities affecting quality as necessary to ensure that suitable proficiency is achieved and maintained. The performance of 10 CFR 72.48 applicability determinations and evaluations falls under this requirement.

Interview cognizant licensee/certificate holder training program personnel to determine how their training program addresses the 10 CFR 72.48 process. Determine if refresher training is provided and how additional training needs are identified.

- b. Review the licensee/certificate holder's lesson plans, training materials, tests, etc., and determine whether they are consistent with their current controls, procedures, and guidance for preparing 10 CFR 72.48 applicability determinations and evaluations. Determine if a feedback process is used for identifying training effectiveness and weaknesses, and how any identified weaknesses are resolved.

60857-04 INSPECTION RESOURCES

Inspection resources are expected to vary. Reviews associated with new cask designs (vendors/certificate holders) or first-time use of a cask design at an ISFSI (licensees) should require one inspector spending 24 hours on in-office review and 36 hours at the site. Subsequent inspections involving the same cask design should require one inspector spending 8 hours on in-office review and 12 hours at the site.

60857-05 REFERENCES

RG 3.72, "Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments," March 2001 (draft was issued as DG-3020)

NEI-96-07, Appendix B, "Guidelines for 10 CFR 72.48 Evaluations," March 5, 2001

NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety", February 1996

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