UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

EAF-NMSS-2025-0102
EA-23-044

July 18, 2025

Ms. Jean Fleming
Vice President of Licensing, Regulatory
and Probabilistic Safety Analysis
Holtec International
Krishna P. Singh Technology Campus
1 Holtec Boulevard
Camden, New Jersey 08104

SUBJECT: HOLTEC INTERNATIONAL, INC. – NUCLEAR REGULATORY COMMISSION INSPECTION REPORT NO. 72-1014/2024-201

Dear Ms. Jean Fleming:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) announced inspection at the Holtec International (Holtec) corporate office in Camden, New Jersey during the week of October 21-25, 2024. This inspection assessed the adequacy of Holtec's design activities associated with your dry cask storage systems (DCSSs) to meet requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-level Radioactive Waste, and Reactor-related Greater Than Class C Waste," and select portions of 10 CFR Part 21, "Reporting of Defects and Noncompliance." The NRC staff examined activities conducted under your NRC-approved quality assurance program to determine whether Holtec implemented the requirements associated with the Commission's rules and regulations and with the conditions of the applicable DCSSs certificates of compliance.

The inspection consisted of an examination of selected procedures and official records, as applicable, and interviews with personnel. The NRC staff discussed the preliminary results of the inspection with you and other Holtec representatives at the conclusion of the on-site portion of the inspection on October 25, 2024, and conducted a pre-exit meeting on January 3, 2025, after Holtec provided additional information related to 10 CFR 72.48 screenings and evaluations. Subsequently, the final exit meetings took place on May 12, 2025, and on July 2, 2025, with you and other Holtec representatives.

Based on the information reviewed during the inspection, the team identified five apparent violations, two of which are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The NRC's website includes the current Enforcement Policy at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

The apparent violations involve:

1) As required by 10 CFR 72.48(c)(2)(vi), “Changes, tests, and experiments (CTEs),” a failure to obtain a certificate of compliance (CoC) amendment pursuant to 10 CFR 72.244 prior to implementing a proposed design change that created a possibility for a malfunction of the HI-STORM FW version E1 and multi-purpose canister with a different result than any previously evaluated in the Final Safety Analysis Report (FSAR) (as updated).
2) As required by 10 CFR 72.146, “Design control,” a failure to subject design changes made on the HI-STORM FW overpack to design control measures commensurate with those applied to the original design.
3) As required by 10 CFR 72.48(d)(1), “CTEs,” a failure to include a written evaluation which provided the bases for the determination that operating the HI-STORM 100 overpack without a lid outside the fuel handling building does not require a CoC amendment pursuant to paragraph (c)(2) of this section.
4) As required by 10 CFR 72.48(d)(1), “CTEs,” a failure to include a written evaluation which provided the bases for the determination that the introduction of an alternative storage overpack for the HI-STORM FW Version F and common lid using an updated finite element analysis code version.
5) As required by 10 CFR 72.172, “Corrective Actions,” a failure to establish measures to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected.

Enclosures 1 and 2 include a summary of the apparent violations and associated inspection report, respectively.

NRC staff member, Mr. Marlone Davis, discussed the circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action with you and members of your staff at the conclusion of the inspection and during the May 12, 2025, telephonic exit meeting.

As discussed with you, the NRC has not made a final determination regarding the apparent violations or that enforcement action will be taken against Holtec; therefore, a final action is not being issued at this time. In addition, please be advised that the characterization of the apparent violations may change because of further NRC review.

Before the NRC makes its enforcement decision, we are providing you with an opportunity to: (1) request to participate in a Pre-decisional Enforcement Conference (PEC), or (2) request to participate in an Alternative Dispute Resolution (ADR) mediation session. These options are discussed further in subsequent paragraphs in this letter.

If you choose to request a PEC, the conference will offer you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether the violations occurred, information to determine the significance of the violations, information related to the identification of the violations, and information related to any corrective actions taken or planned. The conference will include an opportunity for you to

provide your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision.

The information should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. This information may reference or include previously docketed correspondence. In presenting any corrective actions, you should be aware that the promptness and comprehensiveness of the actions will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed (Enclosure 3) excerpt from the NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in assessing adequate corrective actions. Following the PEC, you will be advised by separate correspondence of the results of our deliberations on this matter. If a PEC is held, it will be open for public observation and the NRC may issue a press release to announce the time and date of the conference.

In lieu of a PEC, you may request an ADR session with the NRC to resolve these issues. An ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC process employs is mediation. Mediation is a voluntary, informal process in which a trained neutral third party (the “mediator”) works with parties to help them reach resolution. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. If the parties agree to use an ADR, they select a mutually agreeable neutral mediator from ICR, who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues.

Additional information concerning the NRC's ADR program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html, as well as the NRC brochure NUREG/BR-0317, “Enforcement Alternative Dispute Resolution Program,” Revision 2 (Agencywide Documents Access and Management System (ADAMS) Accession Number ML18122A101). Please contact the Institute on Conflict Resolution at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through an ADR.

If you choose to pursue an ADR, the ADR will be closed to the public; however, the NRC may issue a meeting notice and/or press release to announce the time and date of this closed mediation. In addition, if the mediation is successful, the NRC typically issues a Confirmatory Order to document the agreement. The Confirmatory Order is typically publicly available.

If you decide to participate in a PEC or pursue an ADR, please contact Gerond George, Chief, Inspection and Oversight Branch, via email at Gerond.George@nrc.gov within 10 days of the date of this letter. A PEC should be held within 30 days of the date of this letter and an ADR mediation session within 45 days of the date of this letter. If you do not contact us regarding your participation in either a PEC or ADR within the time specified above and the NRC has not granted an extension of the contact time, we will make an enforcement decision based on available information.

In addition, please be advised that the number and characterization of apparent violations described in the enclosures may change because of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR Part 2, "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure(s), and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room (PDR) or from the Publicly Available Records component of the NRC's ADAMS. ADAMS is accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. The PDR is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

Any information forwarded to the NRC should be clearly labeled on the first page with the case reference number: EAF-NMSS-2025-0102, and should be sent to the NRC's Document Control Center, with a copy mailed to, Shana Helton, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852-2738.

Should you have any questions, please contact Gerond George, via email at Gerond.George@nrc.gov.

Sincerely,

SHANA HELTON

Digitally signed by SHANA HELTON
Date: 2025.07.18 11:33:59 -04'00'

Shana Helton, Director
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No. 72-1014

Enclosures:
1. Apparent Violations Being Considered for Enforcement
2. Inspection Report 07201014/2024-201
3. NRC Information Notice 96-28

SUBJECT: HOLTEC INTERNATIONAL, INC. – NUCLEAR REGULATORY COMMISSION INSPECTION REPORT NO. 72-1014/2024-201

DOCUMENT DATE: July 18, 2025

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APPARENT VIOLATIONS BEING CONSIDERED FOR ENFORCEMENT

Apparent Violation A:

10 CFR 72.48(c)(2)(vi) “Changes, tests, and experiments (CTEs),” requires, in part, that a certificate holder shall obtain a Certificate of Compliance (CoC) amendment pursuant to 10 CFR 72.244, prior to implementing a proposed change, test, or experiment if the change, test, or experiment would create a possibility for a malfunction of a structure, system, or component (SSC) important to safety (ITS) with a different result than any previously evaluated in the Final Safety Analysis Report (FSAR) (as updated).

Contrary to the above, from September 2021 to present, Holtec failed to obtain a certificate of compliance (CoC) amendment pursuant to 10 CFR 72.244, prior to implementing a change that created a possibility for a malfunction of a SSC ITS with a different result than any previously evaluated in the Final Safety Analysis Report (FSAR) (as updated).

Specifically, Holtec failed to obtain a CoC amendment pursuant to 10 CFR 72.244, prior to implementing a design change that raised the air inlet vents from the bottom of the HI-STORM FW overpack to above ground positions, which created a low point for water to collect in the overpack after normal rainfall. When Holtec made this change and evaluated the design change with their design control change process, Holtec failed to recognize that this created a possibility for all air inlet vents to become blocked for a period greater than what was analyzed in the FSAR when rainwater entered the overpack. The HI-STORM FW FSAR sections 4.6.2.4 (100% Blockage of the Air Inlets), 12.2.13 (100% Blockage of Air inlets), and table 12.2.1, “Accident Events and Their Probability of Occurrence,” had considered an extended period where all air inlet vents are blocked and that this was a non-credible event, respectively. However, this design change created a possibility for all air inlet vents to become blocked for a period greater than what was analyzed in the FSAR and made what was deemed as a non-credible event to a credible event that would create a possibility for a malfunction of the HI-STORM FW overpack and MPC with a different result than any previously evaluated in the FSAR as updated. The malfunction of the HI-STORM FW overpack could result in the fuel within the MPC exceeding temperature limits and the MPC exceeding pressure limits during normal operation.

Apparent Violation B:

10 CFR 72.146(c), “Design Control,” requires, in part, that the certificate holder shall subject design changes to design control measures commensurate with those applied to the original design.

Contrary to the above, from September 2021 to March 2024, Holtec failed to subject a design change made to the HI-STORM FW overpack to design control measures commensurate with those applied to the original design. Specifically, Holtec made a change to the original HI-STORM FW overpack design using their design change control process to raise the air inlet vents from the bottom of the overpack to above ground positions. However, Holtec failed to identify that rainwater that enters the overpack can remain trapped inside of the overpack blocking the air inlets for an extended period due to the elevated position of the air inlet vents. This trapped rainwater could result in a condition where air inlet vents are blocked longer than previously analyzed in the FSAR, thereby causing a potential for the fuel to exceed peak cladding temperatures and to exceed the internal pressure limits in the MPC. This design change also does not allow operators to visually

observe the trapped rainwater from the outside due to the configuration of this new design making this a more active versus a passive design function. This condition could create the possibility of an unanalyzed condition where an event considered non-credible in the FSAR is now a credible event.

Apparent Violation C:

10 CFR 72.48(d)(1) “Changes, tests, and experiments” requires, in part, that the certificate holder shall maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test, or experiment does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section.

Contrary to the above, as of May 2025, the certificate holder (Holtec) failed to maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. The records did not include a written evaluation which provided the bases for the determination that the moving of the HI-STORM 100 overpack version E and E1 without a lid outside the fuel building does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section. Specifically, Holtec stopped at their procedural 10 CFR 72.48 screening process step and did not perform a full evaluation. The inspectors determined that Holtec should have screened this design change for a full evaluation under Holtec’s screening questions a. and c. since (1) the proposed activity could adversely affect the design function of the MPC and (2) there was no method of evaluation used in supporting an updated FSAR analysis that demonstrates the intended design function will be accomplished under design basis conditions such as natural phenomena.

Apparent Violation D:

10 CFR 72.48(d)(1) “Changes, tests, and experiments” requires, in part, that the certificate holder shall maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test, or experiment does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section.

Contrary to the above, as of May 2025, the certificate holder (Holtec) failed to maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. The records failed to include a written evaluation which provided the bases for the determination that the introduction of an alternative storage overpack for the HI-STORM FW Version F and common lid using an updated method of evaluation does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section. Specifically, Holtec used a different version of the ANSYS finite element analysis (ANSYS 2020 R2) for the new overpack and lid than what was previously approved for the standard HI-STORM FW (ANSYS 11). Holtec performed a verification and validation of the ANSYS 2020 R2 with favorable results. However, Holtec did not reanalyze one or more representative cases using the revised software (ANSYS 2020 R2) to compare those cases with those in the FSAR to determine if the current results produced results that are conservative, non-conservative, or essentially the same, as the previous values in the FSAR for the overpack and common lid.

Apparent Violation E:

10 CFR 72.172 “Corrective action” requires, in part, that the certificate holder shall establish measures to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition identified as adverse to quality, the measures must ensure that the cause of the condition is determined, and corrective action is taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

Contrary to the above, prior to October 22, 2024, the certificate holder (Holtec) failed to establish measures to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. Specifically, Holtec failed to promptly identify and correct a quality issue (QI) for the Holtec position paper (DS-331) credited in the storage and transportation system design basis of the FSARs for the development of stress and strain curves. Holtec used the wrong value, which would place the systems in an unanalyzed state or outside their storage and transportation systems licensing basis. However, when identified during the EA-23-044 cited violation issue and HI-STORM FW amendment review in December 2023, Holtec failed to initiate a QI and correct the deficiencies and nonconformances.

U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Division of Fuel Management

Docket:	72-1014
Report.:	72-1014/2024-201
Enterprise Identifier:	I-2024-201-0054
Certificate Holder:	Holtec International, Incorporated
Facility:	1 Holtec Boulevard
Location:	Camden, New Jersey
Inspection Dates:	October 21, - October 25, 2024 (Onsite) October 28, 2024 - January 3, 2025 (In-office)
Inspection Team:	Marlone Davis, Senior Transportation and Storage Safety Inspector, Team Leader Earl Love, Senior Transportation and Storage Safety Inspector Andres Rowe, Transportation and Storage Safety Inspector In-Training
Approved By:	Gerond George, Branch Chief Inspection and Oversight Branch Division of Fuel Management Office of Nuclear Material Safety and Safeguards

U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Division of Fuel Management

EXECUTIVE SUMMARY

Holtec International, Inc.
NRC Inspection Report 72-1014/2024-201

On October 21, 2024, through October 25, 2024, the U.S. Nuclear Regulatory Commission (NRC) conducted an announced onsite team inspection at the Holtec International, Inc. (Holtec) corporate office in Camden, New Jersey. The NRC inspection team (team) continued the inspection activities with an in-office review while the team waited for Holtec to respond to questions on several Title 10 of the *Code of Federal Regulations* (10 CFR) 72.48 evaluations. The team discussed the preliminary results of the inspection with Holtec at the conclusion of the onsite inspection, October 25, 2024, and on January 3, 2025, after receiving additional information from Holtec. The team conducted an initial exit meeting on May 12, 2025, and a final exit meeting on July 2, 2025.

The purpose of the inspection was to verify and assess Holtec's implementation and compliance with 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-level Radioactive Waste, and Reactor-related Greater Than Class C Waste," for the design, modification, procurement, and design changes of their dry cask storage systems (DCSSs). The team assessed Holtec's quality related activities based on examination of permanent quality records and other supporting documentation under their NRC approved quality assurance program (QAP). The team also reviewed 10 CFR 72.48 evaluations and screenings performed since the last corporate inspection and followed up on a traditional enforcement notice of violation (EA-23-044).

The NRC inspection team identified that Holtec failed to meet certain elements of their QAP. As a result, the team identified five apparent violations (AV), two of which are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy and Enforcement Manual. The apparent violations are further described in the applicable sections of this inspection report.

Quality Assurance Program

- The team determined that Holtec generally had adequate QAP controls. The team determined that Holtec conducts activities with a quality assurance organization that has independent responsibilities and uses a graded approach to quality in accordance with their NRC approved quality assurance manual and implementing quality procedures (section 1.1).

Nonconformance and Corrective Action Programs

- The team determined that Holtec, in general, effectively implemented its nonconformance and corrective action control programs. The team determined that Holtec has adequate procedures in place to ensure compliance with applicable regulations and quality assurance requirements. However, as a part of the review of Holtec's corrective actions for the Continuous Basket Shim (CBS) issue and Holtec's quality issues (QIs) process, the team identified an apparent violation because Holtec failed to initiate a quality issue for the Holtec position paper (DS-331) credited in the

storage and transportation system design basis of the Final Safety Analysis Reports (FSARs) for the development of stress and strain curves. (sections 1.2 and 1.4).

Design Control

- The team determined that Holtec, in general, has established an effective method for tracking, evaluating, and dispositioning changes or modifications to DCSSs structure, system, or components (SSCs). However, the team identified several apparent violations related to Holtec's failure to establish measures to ensure that design changes met applicable regulatory requirements and maintained design basis as specified in the certificate of compliance (CoC) (section 1.3).

Follow-up on Traditional Enforcement Action (EA-23-044)

- The team determined that Holtec implemented adequate corrective actions for the root cause analysis associated with an escalated traditional enforcement violation (EA-23-044). However, as a part of the review of Holtec's corrective actions for the CBS issue and Holtec's QIs process, the team identified an apparent violation because Holtec failed to initiate a quality issue for the Holtec position paper (DS-331) credited in the storage and transportation system design basis of the FSARs for the development of stress and strain curves. (section 1.4).

REPORT DETAILS

1.0 Inspection Procedure (IP) 60851 Design Control of Independent Spent Fuel Storage Installation (ISFSI) Components (Selected Portions)

1.1 Quality Assurance Program

1.1.1 Inspection Scope

The team reviewed the Holtec Quality Assurance Manual (QAM), Revision 15 and various Holtec implementing procedures designated as Holtec Quality Procedures (HQPs) and Holtec Standard Procedures (HSPs) to assess the effectiveness of their Quality Assurance (QA) program implementation. The team conducted reviews of Holtec's quality program, policies, and procedures, to determine whether Holtec adequately controlled and implemented activities under their NRC approved QA program and activities subject to 10 CFR Part 72 regulations. The team reviewed procedures to verify if Holtec clearly defined and documented the quality program authorities and responsibilities and that the quality assurance organization functioned as an independent group. The team also reviewed procedures for the use of a graded approach for identifying Important-to-Safety (ITS) components and whether Holtec applied this graded quality level to procurement documents. The team reviewed procedures and documents regarding training, qualification, and certification of personnel involved in quality activities. Additionally, the team reviewed training records of a random selection of employees in quality related positions to determine if they received the required QA indoctrination and QA program revision training. The team reviewed the following specific HQPs and HSPs:

- HQP-1.0, "Organization and Responsibilities," Revision 45
- HQP-2.0, "Quality Assurance Program," Revision 25
- HSP-100101, "Organization," Revision 4
- HSP-100201, "QA Manual and Procedures," Revision 2
- HSP-100203, "Training Program," Revision 2
- HSP-100204, "Measurement and Analysis of QA Program Effectiveness," Revision 2

1.1.2 Observation and Findings

The team assessed that Holtec had a QA program and implementing procedures in place that were effective for conducting activities in accordance with their DCSS CoCs as well as their NRC approved QA program. The team verified that the quality assurance program authorities and responsibilities were clearly defined and documented, and the quality assurance organization functioned as an independent group. The team also determined that for the sample of Holtec staff member training records reviewed and selected that each staff member completed the required training and attained the applicable qualifications to perform their duties. Additionally, the team verified Holtec's quality assurance procedures discussed a graded approach for identifying ITS components for their DCSS components.

Additionally, the team evaluated the quality program status report and noted that this report was an effective tool for the Holtec management to review the status and adequacy of the overall QA program.

There were no findings of significance identified.

1.1.3 Conclusions

The team determined that Holtec generally had adequate QA controls in place. The team also determined that Holtec conducts activities with an organization that is independent of schedule and pressure and with a graded approach in accordance with their NRC approved QA program.

1.2 Nonconforming and Corrective Actions Control Programs

1.2.1 Inspection Scope

Nonconforming Control Program

The team reviewed selected records and interviewed personnel to verify that Holtec effectively implemented a nonconformance control program in accordance with their NRC approved QA program, and the requirements of 10 CFR Parts 21 and 72. Specifically, the team reviewed Holtec's approved procedure HSP-101502, "Control of Nonconforming Conditions," Revision 4. The team selected several nonconformance reports (NCRs) associated with 10 CFR 72.48 screenings and evaluations to verify that the NCRs were identifiable, traceable, and the disposition of the nonconformance was adequate. The team reviewed NCRs since the previous 2021 inspection and concentrated on issues involving ITS SSCs. The team reviewed these NCRs to evaluate if the disposition was appropriate, adequately performed as necessary, and properly closed out in accordance with the approved procedure, HSP-1010502. The team focused the review on "accept-as-is" and "repair" dispositions because generally these NCRs require a technical justification or engineering evaluation dispositioned with 10 CFR 72.48 requirements. This also included a review of supplier manufacturing deviation reports (SMDRs).

In addition, the team reviewed Holtec's approved procedure HSP-101501, "Reporting of Defects per 10 CFR 21 or 10 CFR 50.55e," Revision 2, to determine if provisions were in place for reporting defects that could cause a substantial safety hazard from the NCRs and QIs identified. This review also included an assessment of NCRs and QIs logs for compliance with 10 CFR 72.242(d).

Corrective Action Control Program

The team reviewed selected records and interviewed personnel to verify that Holtec effectively implemented a corrective action control program in accordance with the NRC approved QA program and the requirements of 10 CFR Part 72. Specifically, the team reviewed Holtec's approved procedure HSP-101601, "Corrective Actions,"' Revision 4. The team reviewed QIs since the previous 2021 inspection and concentrated on issues involving ITS SSCs. The team reviewed selected records and interviewed selected personnel to verify that Holtec completed corrective actions for identified deficiencies in a technically sound and timely manner. Additionally, the team included a review of two QIs numbers 3095 and 3326 based on items that occurred during loading campaigns.

1.2.2 Observation and Findings

The team assessed that Holtec adequately dispositioned and closed selected NCR and SMDR in accordance with their quality procedure requirements. The team noted that there were no Part 21 or 10 CFR 72.242(d) reports issued for the period assessed. Holtec failed to promptly identify and correct a QI for the Holtec position paper (DS-331) credited in the storage and transportation system design basis of the FSARs for the development of stress and strain curves (see section 1.4).

1.2.3 Conclusions

Overall, the team determined that the licensee, in general, effectively implemented its nonconformance and corrective action control programs and has adequate procedures in place to ensure compliance with applicable regulations and QA requirements. However, as a part of the review of a design deficiency issue for the Continuous Basket Shim (CBS), the team identified an apparent violation because Holtec failed to initiate a quality issue for the Holtec position paper (DS-331) credited in the storage and transportation system design basis of the FSARs for the development of stress and strain curves.

1.3 Design Control

1.3.1 Inspection Scope

The team reviewed the design control program described in Holtec's QAM and governing procedures to determine whether Holtec implemented design controls and design changes to their DCSSs for use at independent spent fuel storage installations. The team reviewed selected design change packages, including engineering change orders (ECOs) and 10 CFR 72.48 screenings/evaluations, and the team interviewed Holtec personnel involved in their engineering design control process.

Design Changes

The team reviewed selected records and interviewed personnel to determine whether Holtec implemented and evaluated design changes for their impact on the functionality of DCSS components. The team focused its review on the complete and accurate documentation and appropriate evaluation of ECOs and 10 CFR 72.48 screenings and evaluations. The team reviewed Holtec's procedures related to the implementation instructions for 10 CFR 72.48 evaluations and control of modification activities. Specifically, the team reviewed Holtec's approved procedure HSP-321, "Screening and Evaluation of Changes," Revision 7.

The team reviewed a list of ECOs, screenings and evaluations performed by Holtec to meet the regulatory requirements associated with 10 CFR 72.48 based on the last corporate inspection in May 2021. The team selected a representative sample of screenings and evaluations from the biennial summary reports and a more recent list provided by Holtec using the guidance in Inspection Procedure 60857, "Review of 10 CFR 72.48 Evaluations," and Appendix E to Inspection Manual Chapter (IMC) 2690, "Guidance for Risk-Informed Review of 72.48 Evaluations." The team reviewed biennial reports from 2022 and 2024 titled 10 CFR 72.48(d)(2) reports, "Biennial Summaries of

Changes, Tests, and Experiments," pertaining to the HI-STAR 100, HI-STORM 100, HI-STORM FW, and HI-STORM UMAX Dry Cask Storage Systems (NRC Docket Nos. 72-1008, 72-1014, 72-1032, and 72-1040).

The team used the guidance in NRC IMC 0335, "Changes, Tests, Experiments;" Nuclear Energy Institute (NEI) 12-04, Revision 2; and NEI 96-07, Appendix B, "Guidelines for 10 CFR 72.48 Evaluations," dated September 2018 and March 5, 2001, respectively to evaluate the screenings and evaluations. The NRC endorsed both NEI documents in Regulatory Guide 3.72, "Guidance for Implementation of 10 CFR 72.48, "Changes, Tests, and Experiments". The team also reviewed the NRC safety evaluation reports (SERs) associated with each DCSS.

The team reviewed design changes that the licensee (as applicable) and Holtec initiated to determine whether a method existed to ensure that both the licensee and Holtec communicated design changes in a timely manner, minimize production or operational impacts, and if the design changes received the necessary approvals.

The team selected a sample of approximately thirty 10 CFR 72.48 screenings (10) and evaluations (20) to verify that Holtec appropriately concluded that changes did not require prior NRC review and approval or a full evaluation, if Holtec personnel determined that the change screened out during the screening process in accordance with the NRC requirements and Holtec procedure HSP-321, respectively.

1.3.2 Observation and Findings

HI-STORM FW Overpack Version E1

Apparent Violation A: 72-1014/2024-201-01, Failure to obtain a CoC amendment pursuant to 10 CFR 72.244

The team reviewed a design change associated with the introduction of a new overpack version for the HI-STORM FW storage system. The HI-STORM FW storage system has two major storage components: the multi-purpose canister (MPC) and the storage overpack. The MPC is a welded and bolted pressure vessel that maintains the confinement boundary for the stored spent nuclear fuel assemblies. The HI-STORM FW storage overpack provides structural protection, cooling, and radiological shielding for the MPC while stored on the ISFSI pad. Holtec made a design change to the standard overpack design of the HI-STORM FW storage system that elevated the air inlet vents from the bottom of the circumference of the overpack to raised positions. For this inspection activity, the team reviewed the design change from the standard HI-STORM FW overpack to version E1, but identified that Holtec made similar changes to other overpacks and designated those changes as versions E and F.

As part of this design change review, the team reviewed the 10 CFR 72.48 evaluation number (No.) 1541 revisions 0 and 1, specific sections of the HI-STORM FW FSAR revisions 7, 8, and 9, the HI-STORM FW technical specifications (TSs), ECO No. 5018-130 revisions 0 and 1, and the NRC's SER for the HI-STORM FW storage system. As described above, the design change raised the inlet vents of the HI-STORM FW overpack above ground level to preclude floodwater ingress into the cask system. Changing the height of the inlet vents created a potential for water to remain trapped in

the lower portion of the overpack after a normal rainfall occurrence while in storage. If enough water enters the overpack it could block airflow to the air inlet vents and result in an adverse thermal effect on the fuel assemblies and the MPC.

The team noted that Holtec had performed evaluations of these scenarios in sections 4.6.1.3 (Partial Blockage of Air Inlets/Outlets), 4.6.2.4 (100% Blockage of the Air Inlets), and 12.2.13 (100% Blockage of Air inlets) of the HI-STORM FW FSAR. Additionally, the FSAR contained the thermal impact results presented in the HI-STORM FW system tables 4.6.5, 4.6.7, and 12.2.1 in the FSAR.

Additionally, as provided in the TS bases contained in the FSAR, the TS assumed that under normal storage conditions the inlet and outlet air ducts are unobstructed and have full air flow (i.e., maximum heat transfer for the given ambient temperature). The team noted rainwater could enter through either the inlet or outlet vents, and it would be undetectable when performing the daily TS surveillance to ensure vents remain unblocked. The water would not be seen from the outside because the water would gather in low points inside of the overpack. The team had gathered additional insights from the NRC inspection staff in Region IV. There was actual operating experience, that rainwater would enter the HI-STORM FW overpack internal cavity, but the rainwater would not immediately exit the cavity through the inlet vents as it would with the original configuration. Subsequently, the team discussed the design change related to the HI-STORM FW overpack with the Region IV counterparts and gathered more information on the operating experience associated with the new overpacks deployed at various sites.

The team also noted that the 100 percent (%) blockage of the air inlet vents may exceed the 32 hours stated in section 4.6.2.4 of the FSAR analysis, if the water trapped inside the overpack goes undetected because it cannot be seen from the outside. The team noted that additional operator actions would be needed to remove the water from inside the overpack if detected. If undetected, then for normal storage conditions this would lead to an off-normal and accident condition, essentially changing the frequency category from normal to off-normal or accident conditions. The team noted that this was like an example in section 6.1 of NEI 12-04, which states, in part, that a change from one frequency category to a more frequent category is clearly an example of a change that results in more than a minimal increase in the frequency of occurrence of an accident (see Criterion 1 of the 10 CFR 72.48 evaluation criteria). However, Holtec did not identify the direct and indirect impacts in their 10 CFR 72.48 evaluation nor as a part of their ECO.

Furthermore, the HI-STORM FW FSAR table 12.2.1, “Accident Events and Their Probability of Occurrence,” had considered this a non-credible event. The team noted that operating experience showed the presence of water in the overpacks at several different sites related to this design change. Subsequently, this design change increases the likelihood of a malfunction previously thought to be non-credible to the point where it became a credible event with a different result (Criterion 6 of 10 CFR 72.48 evaluation criteria). The team had reviewed the industry endorsed guidance document NEI-12-04, revision 2 to gain insights on what changes are permissible without prior NRC review and approval that could create a new result from a malfunction. The team noted that section 6.6 of NEI 12-04, stated, in part, that a proposed change or activity that increases the likelihood of a malfunction previously thought to be incredible to the point

where it becomes as likely as the malfunctions assumed in the updated FSAR, could create a possible malfunction with a different result.

Holtec implemented compensatory measures in revision 1 of the ECO and 10 CFR 72.48 evaluation to remove the plugs from the drain lines if the overpack has a separate drain line near the baseplate of the overpack. However, the team noted that these drain lines could still get clogged, so removing the plugs mitigates but doesn't eliminate the issue. Furthermore, this would need an active operator action to permanently substitute to maintain what should be a passive cooling system. The team determined that Holtec needed to seek prior NRC review and approval for this design change to the HI-STORM FW overpack because this change would create a possibility for a malfunction of a SSC ITS with a different result than any previously evaluated in the FSAR (as updated).

10 CFR 72.48(c)(2)(vi), "Changes, tests, and experiments (CTEs)," requires, in part, that a certificate holder shall obtain a CoC amendment pursuant to 10 CFR 72.244, prior to implementing a proposed change, test, or experiment if the change, test, or experiment would create a possibility for a malfunction of a SSC ITS with a different result than any previously evaluated in the FSAR (as updated).

Contrary to the above, from September 2021 to present, Holtec failed to obtain a CoC amendment pursuant to 10 CFR 72.244, prior to implementing a proposed change that created a possibility for a malfunction of an SSC ITS with a different result than any previously evaluated in the FSAR as updated. Specifically, Holtec failed to obtain a CoC amendment pursuant to 10 CFR 72.224, prior to implementing a design change that raised the air inlet vents from the bottom of the HI-STORM FW overpack to above ground positions, which created a low point for water to collect in the overpack after a normal rainfall. When Holtec made this change and evaluated the design change with their design control change process, Holtec failed to recognize that this created a possibility for all air inlet vents to become blocked for a period greater than what was analyzed in the FSAR when rainwater entered the overpack. The HI-STORM FW FSAR sections 4.6.2.4 (100% Blockage of the Air Inlets), 12.2.13 (100% Blockage of Air inlets), and table 12.2.1, "Accident Events and Their Probability of Occurrence," had considered an extended period where all air inlet vents are blocked and that this was a non-credible event, respectively. However, this design change created a possibility for all air inlet vents to become blocked for a period greater than what was analyzed in the FSAR and made what was deemed as a non-credible event to a credible event that would create a possibility for a malfunction of the HI-STORM FW overpack and MPC with a different result than any previously evaluated in the FSAR as updated. The malfunction of the HI-STORM FW overpack could result in the fuel within the MPC exceeding temperature limits and the MPC exceeding pressure limits during normal operation.

<u>Apparent Violation B: 72-1014/2024-201-02, Failure to establish adequate design control</u>

10 CFR 72.146 (c), "Design Control," requires, in part, that the certificate holder shall subject design changes to design control measures commensurate with those applied to the original design.

Contrary to the above, from September 2021 to March 2024, Holtec failed to subject a design change made to the HI-STORM FW overpack to design control measures

commensurate with those applied to the original design. Specifically, Holtec made a change to the original HI-STORM FW overpack design using their design change control process to raise the air inlet vents from the bottom of the overpack to above ground positions. However, Holtec failed to identify that rainwater that enters the overpack can remain trapped inside of the overpack blocking the air inlets for an extended period. The trapped rainwater could result in the fuel exceeding peak cladding temperatures and increase the internal pressure limits in the MPC if there is no operator action taken to drain the water. This design change also does not allow operators to visually observe the trapped rainwater from the outside due to the configuration of this new design making this a more active versus a passive design function. Furthermore, this condition could create the possibility of an unanalyzed condition where an event considered non-credible in the FSAR is now a credible event.

HI-STORM 100 Movement of MPC without Lid Outside Fuel Building (Version E and E1)

Apparent Violation C: 72-1014/2024-201-03, Failure to include a written evaluation which provided the bases for the determination that a CoC amendment pursuant to paragraph (c)(2)

The team assessed Holtec's 10 CFR 72.48 screening no. 1591 associated with a design change to allow movement of the lidless HI-STORM 100 (Version E and E1) overpack with loaded MPC configuration outside of the fuel handling building. The inspectors determined that this design change would have screened in for a full evaluation under Holtec's screening questions a. and c. since (1) the proposed activity could adversely affect the design function of the MPC and (2) there was no method of evaluation (MOE) used in supporting the updated FSAR analysis that demonstrates the intended design function will be accomplished under design basis conditions such as natural phenomena. Holtec initially screened the activity out of the 10 CFR 72.48 evaluation process. Holtec originally required a full evaluation but later revised the evaluation to just a screening. Holtec took credit for two MOEs in the FSAR and stated, that although different, both together bounded the activity (i.e., a combination of two tornado missile analysis), one with the vertical HI-STORM 100 Version E and E1 with the lid bolted on, and the other with HI-TRAC in the horizonal orientation with the MPC exposed (see FSAR-R23: Subsections 3.48.2 and 3.II.4.4.2).

10 CFR 72.48(d)(1), "Changes, tests, and experiments" requires, in part, that the certificate holder shall maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test, or experiment does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section.

Contrary to the above, as of May 2025, the certificate holder (Holtec) failed to maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. The records did not include a written evaluation which provided the bases for the determination that the moving of the HI-STORM 100 overpack version E and E1 without a lid outside the fuel building does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section. Specifically, Holtec stopped at their procedural 10 CFR 72.48 screening process step and did not perform a full evaluation.

The inspectors determined that Holtec should have screened this design change for a full evaluation under Holtec's screening questions a. and c. since (1) the proposed activity could adversely affect the design function of the MPC and (2) there was no method of evaluation used in supporting the updated FSAR analysis that demonstrates the intended design function will be accomplished under design basis conditions such as natural phenomena.

HI-STORM FW Overpack and Common Lid Version F

Apparent Violation D: 72-1014/2024-201-04, Failure to include a written evaluation which provided the bases for the determination that a CoC amendment pursuant to paragraph (c)(2)

The team assessed Holtec's 10 CFR 72.48 evaluation no. 1516, revision 1, specific sections of the HI-STORM FW FSAR (HI-2114830) revisions 8 and 9, the HI-STORM FW TSs bases document, ECO No. 5018-126 revision 1 and the NRC's SER for the HI-STORM FW storage system for a design change associated with a new storage overpack and common lid. Holtec performed a full evaluation of the design change because Holtec used a different version of the finite element analysis (ANSYS) code thus impacting an element of the MOE used in establishing the design bases.

The team assessed the evaluation using the endorsed industry guidance document NEI 12-04, revision 2. Section 6.8.1 of NEI 12-04 provides guidance when changing one or more elements of the MOE. As stated in the 10 CFR 72.48 evaluation, the team noted that the analysis of the common lid used a different version of ANSYS (ANSYS 2020 R2 vs ANSYS 11). The NRC previously approved (ANSYS 11) for the standard HI-STORM FW lid. Holtec performed a verification and validation (V&V) of the finite element analysis. However, Holtec did not reanalyze one or more representative cases using the revised software (ANSYS 2020 R2) to compare those cases with those in the FSAR to determine if the current results produced results that are conservative, non-conservative, or essentially the same, as the previous values in the FSAR for the overpack and common lid.

The team explained to Holtec that comparing one or more representative cases using the revised software to those cases in the FSAR to determine if the new MOE results produced conservative, non-conservative, or essentially the same, as the previous values in the FSAR is consistent with the NEI 12-04, revision 2 guidance document after Holtec performed the V&V of the software. Specifically, section 6.8.1, "Guidance for Changing One or More Elements of a MOE," provides a similar example of a code version change and provides the steps necessary to determine whether prior NRC review and approval is required. Holtec did not complete all the steps described in the guidance document to compare those cases with those in the FSAR to determine if the current results produced results that are conservative, non-conservative, or essentially the same, as the previous values in the FSAR. The team assessed that Holtec's failure to compare representative cases with those in the FSAR to determine if the current results produced results that were conservative, non-conservative, or essentially the same, as the previous values in the FSAR was a violation of NRC requirements 10 CFR 72.48(d)(1).

10 CFR 72.48(d)(1) requires, in part, that the certificate holder shall maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test, or experiment does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section.

Contrary to the above, as of May 2025, the certificate holder (Holtec) failed to maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. The records did not include a written evaluation which provided the bases for the determination that the introduction of an alternative storage overpack for the HI-STORM FW Version F and common lid using an updated MOE does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section. Specifically, Holtec used a different version of the ANYSYS finite element analysis (ANSYS 2020 R2 vs 11) for the new overpack and lid than what was previously approved for the standard HI-STORM FW (ANSYS 11). Holtec performed a V&V of the ANSYS 2020 R2 with favorable results. However, Holtec did not reanalyze one or more representative cases using the revised software (ANSYS 2020 R2) to compare those cases with those in the FSAR to determine if the current results produced results that are conservative, non-conservative, or essentially the same, as the previous values in the FSAR for the overpack and common lid. Since Holtec did not compare the results to those in the FSAR, the evaluation did not have an adequate written bases to determine if prior NRC review and approval was needed.

1.3.3 Conclusions

The team determined that Holtec has established an effective method for tracking, evaluating, and dispositioning changes or modifications to DCSSs SSCs. However, the team identified several apparent violations related to Holtec's failure to establish measures to ensure that design changes met applicable regulatory requirements and maintained design basis as specified in the CoC.

1.4 Follow-up on Traditional Enforcement Action (EA-23-44)

1.4.1 Inspection Scope

The team reviewed the root cause analysis associated with the traditional enforcement Severity Level IV notice of violation (EA-23-44) issued to address CBS design change issue. The team reviewed Holtec's extent of condition and extent of cause evaluations to verify that the root cause analysis had sufficient breadth. The team reviewed the corrective actions Holtec took to address the identified causes and evaluated Holtec's effectiveness of those actions. The team also held discussions with Holtec personnel to ensure that the root and contributing causes, as well as any contribution of safety culture components, were understood and that corrective actions taken were appropriate to address the causes and preclude repetition.

1.4.2 Observation and Findings

Apparent Violation E: 72-1014/2024-201-05, Failure to promptly identify and correct a condition adverse quality

The team assessed that Holtec, generally, provided adequate corrective actions for the cited traditional enforcement violation (EA-23-44). The team verified that Holtec performed a root cause evaluation that focused on the causal factors, extent-of-condition, and extent-of-cause, as necessary. The team noted that Holtec updated several program documents and provided training to necessary personnel.

However, as a part of the corrective action review for this condition, the team identified that the Holtec position paper DS-331 used to determine the design basis criteria, used the incorrect value for the true ultimate strength of the Metamic-HT to determine the maximum stress intensity limit that established the design basis limits. Specifically, Holtec used the fracture stress of the material instead of the ultimate strength. The NRC discovered the wrong value while reviewing documents for the CBS enforcement issue and HI-STORM FW amendment request in December 2023. The team determined that Holtec failed to promptly identify and correct the deficiencies and nonconformances as this impacted several storage and transportation systems. The team assessed that this was a violation of NRC requirements 10 CFR 72.172, “Corrective actions.”

10 CFR 72.172 “Corrective action” requires, in part, that the certificate holder shall establish measures to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition identified as adverse to quality, the measures must ensure that the cause of the condition is determined, and corrective action is taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

Contrary to the above, prior to October 22, 2024, the certificate holder (Holtec) failed to establish measures to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. Specifically, Holtec failed to promptly identify and correct a QI for the Holtec position paper (DS-331) credited in the storage and transportation system design basis of the FSARs for the development of stress and strain curves. Holtec used the wrong value, which would place the systems in an unanalyzed state or outside their storage and transportation systems licensing basis. However, once identified during the EA-23-044 cited violation issue and HI-STORM FW amendment review in December 2023, Holtec failed to initiate a QI and correct the deficiencies and nonconformances.

1.4.3 Conclusions

The team determined that Holtec, generally, implemented adequate corrective actions for the root cause analysis associated with the cited traditional enforcement violation. However, the team did identify an apparent violation because Holtec failed to initiate a quality issue for the maximum primary stress limit.

2.0 Meetings

On October 21, 2024, the NRC inspection team discussed the scope of the inspection during an entrance meeting with Ms. Jean Fleming and other members of the Holtec staff. On October 25, 2024, the NRC inspection team discussed the preliminary results and observations during an onsite debrief meeting with the Holtec staff. The team continued the inspection activities with an in-office review while the team waited for Holtec to provide additional information on questions related to three 10 CFR 72.48 screenings/evaluations. Once the team received the additional information and completed their review, the team discussed the preliminary results of the inspection with Ms. Jean Fleming and other Holtec representatives on January 3, 2025. Subsequently, the final exit meetings took place on May 12, 2025, and on July 2, 2025.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES AND INDIVIDUALS INTERVIEWED

Name	Title	Affiliation	Entrance	Debrief	Debrief	Exit
Marlone Davis	Team Leader	NRC	X	X	X	X
Earl Love	Sr. Safety Inspector	NRC	X	X		
Andres Rowe	Safety Inspector In-Training	NRC	X	X	X	X
Gerond George	Branch Chief, Inspection & Oversight Branch	NRC				X
Jean Fleming	Vice President of Licensing, Regulatory and Probabilistic Safety Analysis	Holtec	X	X	X	X
Mark Soler	Vice President of Quality	Holtec	X	X	X	X
Kimberly Manzione	Director of Licensing	Holtec	X	X	X	X
Chuck Bullard	Director of Engineering	Holtec	X	X		

2. INSPECTION PROCEDURES (IP) and GUIDANCE DOCUMENTS USED

IP 60851	Design Control of Independent Spent Fuel Storage Installation (ISFSI) Components
IP 60857	Review of Title 10 of the *Code of Federal Regulations* Part 72.48 Evaluations
NUREG/CR-6314	Quality Assurance Inspections for Shipping and Storage Containers
NUREG/CR-6407	Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
72-1014/2024-201-01	Open	AV	Failure to obtain a CoC amendment pursuant to 10 CFR 72.244
72-1014/2024-201-02	Open	AV	Failure to establish adequate design control
72-1014/2024-201-03	Open	AV	Failure to include a written evaluation which provided the bases for the determination that a CoC amendment pursuant to paragraph (c)(2)
72-1014/2024-201-04	Open	AV	Failure to include a written evaluation which provided the bases for the determination that a CoC amendment pursuant to paragraph (c)(2)
72-1014/2024-201-05	Open	AV	Failure to promptly identify and correct a condition adverse quality

4. LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
ADR	Alternate Dispute Resolution
CAP	Corrective Action Program
CBS	Continuous Basket Shim
CFR	*Code of Federal Regulations*
CoC	Certificate of Compliance
CTE	Change, Test, and Experiment
DCSS	Dry Cask Storage System
DS	Design Specification
ECO	Engineering Change Order
FSAR	Final Safety Analysis Report
IMC	Inspection Manual Chapter
IP	Inspection Procedure
ISFSI	Independent Spent Fuel Storage Installation
ITS	Important to Safety
MOE	Method of Evaluation
NCR	Nonconformance Report
NEI	Nuclear Energy Institute
NRC	Nuclear Regulatory Commission
PEC	Pre-decisional Enforcement Conference
QA	Quality Assurance
QAM	Quality Assurance Manual
QI	Quality Issue
QP	Quality Procedure
SER	Safety Evaluation Report
SMDR	Supplier Manufacturing Deviation Report
TS	Technical Specification

V&V Verification and Validation

5. DOCUMENTS REVIEWED

Certificate holder documents reviewed during the inspection were specifically identified in the Report Details above.

NRC INFORMATION NOTICE 96-28

UNITED STATES

NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR MATERIAL SAFETY AND
SAFEGUARDS WASHINGTON, D.C. 20555

May 1, 1996

NRC INFORMATION NOTICE 96-28: SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of the NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action or written response is required.

Background

On June 30, 1995, the NRC revised its Enforcement Policy, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, the NRC encourages and expects identification and prompt, comprehensive correction of violations.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without the NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section VI.A of the Enforcement Policy. Minor violations are not subject to formal enforcement action.

Nevertheless, the root cause(s) of minor violations must be identified, and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response,

as required by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence.

In some cases, such violations are documented on Form 591 (for materials licensees) which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a Pre-decisional Enforcement Conference (PEC) may be held to discuss those actions.

The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a PEC with the licensee and the level of sanction proposed or imposed.

Discussion

Comprehensive corrective action is required for all violations. In most cases, the NRC does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation.

It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation.

Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the particular case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation. Typically, such reviews include:

   Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers.

   Tours and observations of the area where the violation occurred, particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that may have contributed to the violation as well as those items that may result in future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred.

Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its overall objectives and requirements are clearly stated and implemented.

Procedures should be reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the current requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to provide a record that can be audited and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

   Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns and prevent recurrence of the violation.

   It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, immediate corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

In evaluating the root causes of a violation and developing effective corrective action, consider the following:

1. Has management been informed of the violation(s)?
2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?
3. Have precursor events been considered and factored into the corrective actions?
4. In the event of loss of radioactive material, should security of radioactive material be enhanced? Has your staff been adequately trained on the applicable requirements?
5. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?
6. Has your staff been notified of the violation and of the applicable corrective action?

7. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?
8. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?
9. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?
10. Is a system in place for keeping abreast of new or modified the NRC requirements?
11. Does your staff appreciate the need to consider safety in approaching daily assignments?
12. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?
13. Have work hours affected the employees' ability to safely perform the job?
14. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?
15. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?
16. Has management established a work environment that encourages employees to raise safety and compliance concerns?
17. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?
18. Has management communicated its expectations for safety and compliance?
19. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?