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

September 12, 2023

EA-23-044

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

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION INSPECTION REPORT 07201014/2022-201, HOLTEC INTERNATIONAL

Dear Ms. Fleming:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC, Commission) announced routine fabrication inspection conducted December 12-15, 2022, at your Holtec Advanced Manufacturing Division (AMD) in Camden, New Jersey. The lead inspector discussed the inspection results with Holtec International (Holtec) at the conclusion of the on-site portion of the inspection during a debrief, and in subsequent telephonic pre-exit and final exit meetings on August 23 and 30, 2023, respectively.

The inspection assessed the adequacy of Holtec's fabrication activities for spent fuel storage casks with regard to the applicable 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." 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 applicable certificates of compliance (CoCs) Nos. 72-1014 (HI-STORM 100) and 72-1032 (HI-STORM FW). The inspection consisted of an examination of selected procedures and representative quality records, observations of fabrication and inspection activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. Because this violation was of low safety significance, was entered into Holtec's corrective action program, and the issue was not repetitive or willful, it is being treated as a Non-Cited Violation (NCV), consistent with section 2.3.2.a of the Enforcement Policy. The Enforcement Policy (the current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html). The NCV is described in the subject inspection report (Enclosure 2). If you contest the violation or significance of the NCV, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region [Region Number]; (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001; and (3) [Name of the NRC Resident Inspector] at [Plant Name] facility.

In addition, three apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The apparent violations involve:

(1) As required by 10 CFR 72.48(c)(2)(viii), “Changes, tests, and experiments, Holtec failed to obtain CoC amendments pursuant to 10 CFR 72.244 prior to implementing proposed design changes to multi-purpose canister (MPC) continuous basket shims (CBS) for four spent fuel cask designs (i.e., MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS basket variants) that resulted in a departure from the method of evaluations described in the HI-STORM 100 and HI-STORM FW Final Safety Analysis Reports (updated) used in establishing the design bases;

(2) As required by 10 CFR 72.48(d)(1), “Changes, tests, and experiments, Holtec failed to maintain records of changes that included written evaluations that provided an adequate bases for the determination that changing to the MPC CBS basket variants did not require CoC amendments pursuant to 10 CFR 72.48(c)(2); and

(3) As required by 10 CFR 72.146(c), “Design control,” Holtec failed to subject design changes for the MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS basket variants to design control measures commensurate with those applied to the original design.

These apparent violations are listed in Enclosure 1 and are described in the subject inspection report (Enclosure 2). Since the NRC has not made a final determination in this matter, no Notice of Violation is being issued for these inspection findings at this time.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violations addressed in this inspection report within 30 days of the date of this letter, (2) request to participate in a Pre-decisional Enforcement Conference (PEC), or (3) 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 provide a written response, it should be clearly marked as a “Response to Apparent Violations in NRC ISFSI Inspection Report 07201014/2022-201; EA-23-044” and 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. Your response may reference or include previously docketed correspondence if the correspondence adequately addresses the required response. Your written response must be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a pre-decisional enforcement conference. Additionally, your response should be sent to the NRC’s Document Control Center, with a copy mailed to Jacob Zimmerman, Deputy Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852-2738 within 30 days of the date of this letter.

If you choose to request a PEC, the conference will afford 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 would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. If you choose to request a PEC, the conference will afford you an 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 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 NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in assessing adequate corrective actions. 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 written response or PEC, you may request Alternative Dispute Resolution (ADR) with the NRC in an attempt to resolve this issue. 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 Scheinman 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 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 alternative dispute resolution program can be obtained at: http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html, as well as 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 ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through alternative dispute resolution. If you choose to pursue 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, NRC typically issues a publicly available Confirmatory Order to document the agreement.

If you decide to participate in a PEC or pursue ADR, you must contact Natreon Jordan, Acting Chief, Inspection and Oversight Branch, via e-mail at Natreon.Jordan@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 within 10 days regarding your participation in either a PEC or ADR or have not submitted a written response within 30 days, 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 as a result 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 of the NRC's "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 Publicly Available Records component of the NRC's Agencywide Documents Access and Management System (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 NRC should be clearly labeled on the first page with the case reference number: EA-23-044, and should be sent to the NRC's Document Control Center (Ref: 10 CFR 30.6 Communications, https://www.nrc.gov/reading-rm/doc-collections/cfr/part030/part030-0006.html), with a copy mailed to, Jacob Zimmerman, Deputy 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 Natreon Jordan, via email at Natreon.Jordan@nrc.gov.

Sincerely,

Jacob I. Zimmerman on behalf of
Shana Helton, Director
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket Nos. 72-1014 and 72-1032

Enclosures:

1. Apparent Violations Being Considered for Escalated Enforcement
2. Inspection Report 07201014/2022-201
3. NRC Information Notice 96-28

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

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION INSPECTION REPORT 07201014/2022-201, HOLTEC INTERNATIONAL

DOCUMENT DATE: September 12, 2023

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ADAMS Accession Number: ML23145A175

OFFICE	NMSS/DFM	NMSS/DFM	NMSS/DFM	NMSS/DFM (prior to EC & OE)
NAME	ELove	JCurry	NJordan	JZimmerman for SHelton
DATE	8/10/23	8/11/23	8/10/23	8/10/23
OFFICE	NMSS/EC	OE	OGC	NMSS/DFM (final signature)
NAME	MBurgess	JPeralta	SKirkwood	JZimmerman for SHelton
DATE	8/15/23	8/21/23	8/21/23	9/12/23

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APPARENT VIOLATIONS BEING CONSIDERED FOR ESCALATED ENFORCEMENT

Apparent Violation A:

Per 10 CFR 72.48(c)(2)(viii), "Changes, tests, and experiments," requires, in part, that "a certificate holder shall obtain a CoC amendment pursuant to 10 CFR 72.244, prior to implementing a proposed change that would result in a departure from a method of evaluation described in the [Final Safety Analysis Report], (FSAR) as updated used in establishing the design bases or in the safety analyses."

Contrary to the above, the certificate holder Holtec International (Holtec) failed to obtain a Certificate of Compliance (CoC) amendment pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Section 72.244, prior to implementing proposed changes that would result in a departure from a method of evaluation (MOE) described in the FSAR used in establishing the design bases or in the safety analyses. Specifically, from November 6, 2020, to July 19, 2021, Holtec made design changes to four multi-purpose canister (MPC) fuel baskets from the standard MPC 68M, 32M, 89, and 37 baskets to the MPC 68M-continuous basket shims (CBS), MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS basket variants that resulted in a departure from methods of evaluation described in the FSARs (as updated) used in establishing the design bases and failed to submit CoC amendment applications prior to implementing the changes.

Apparent Violation B:

Per 10 CFR 72.48(d)(1), "Changes, tests, and experiments," requires, in part, that the licensee and certificate holder shall maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and 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 does not require a CoC amendment pursuant to paragraph (c)(2) of this section.

Contrary to the above, Holtec failed to maintain records of changes in the spent fuel storage cask design made pursuant to paragraph (c) of 10 CFR 72.48 that included a written evaluation which provided the bases for the determination that the change does not require a CoC amendment pursuant to 10 CFR 72.48(c)(2). Specifically, for the MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS variants, as of February 17, 2021, July 19, 2021, May 13, 2020, and November 6, 2020, Holtec's written evaluations failed to provide an adequate bases for the determination that incorporation of the CBS design fuel basket variants did not require a CoC amendment. Holtec did not clearly and thoroughly discuss the impacts on departures from elements of the methods of evaluation (MOEs) described in the FSARs for the original design (all-welded stainless steel fuel basket) that were affected by the changes to the CBS design fuel basket variants (MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS). The impacted elements included the demonstration of the design criteria of the fuel basket; mathematical model associated with material performance and tip-over analysis; calculational framework on connections between fuel basket and shims; use of revised version of software; new assumptions, etc.

Apparent Violation C:

Per 10 CFR 72.146(c), “Design control,” requires, in part, that a certificate holder shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license or CoC require prior NRC approval.

Contrary to the above, Holtec failed to subject design changes, including field changes, to design control measures commensurate with those applied to the original basket design. Specifically, in four examples prior to February 17, 2021, July 19, 2021, May 13, 2020, and November 6, 2020, Holtec failed to subject design changes from the MPC 68M, 32M, 89, and 37 standard basket designs to the MPC 68M-CBS, 32M-CBS, 89-CBS, and 37-CBS basket variants to design control measures commensurate with those applied to the original design, and made changes in the conditions specified in the license that required prior NRC approval. Holtec failed to perform adequate tip-over calculations and to model the basket shim bolts for the four CBS basket variants. In addition, material strength assumptions were different, the deflection design criteria of the fuel baskets were not demonstrated, and thermal expansion interference was not calculated in the CBS baskets.

U.S. NUCLEAR REGULATORY COMMISSION

Office of Nuclear Material Safety and Safeguards
Division of Fuel Management

Inspection Report

Docket No.:	72-1014
Report No.:	72-1014/2022-201
Certificate Holder:	Holtec International
Facility:	Holtec Advanced Manufacturing Division (AMD)
Location:	One Holtec Boulevard Camden, New Jersey 08104
Inspection Dates:	December 12, 2022, through December 15, 2022, onsite Through August 30, 2023 in-office
Inspectors:	Jon Woodfield, Transportation and Storage Safety Inspector, Team Leader Earl Love, Senior Transportation and Storage Safety Inspector Matthew Learn, Transportation and Storage Safety Inspector Azmi Djapari, Transportation and Storage Safety Inspector in Training
Approved by:	Natreon Jordan, Acting Branch Chief Inspection and Oversight Branch Division of Fuel Management Office of Nuclear Material Safety and Safeguards

Enclosure 2

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

EXECUTIVE SUMMARY

Holtec International
NRC Inspection Report 72-1014/2022-201

On December 12, 2022, through December 15, 2022, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an announced onsite inspection at the Holtec Advanced Manufacturing Division in Camden, New Jersey. The NRC team continued the inspection activities with an in-office review of outstanding inspection questions and conducted subsequent telephonic pre-exit and final exit meetings on August 23 and 30, 2023, respectively.

The purpose of the inspection was to verify and assess the adequacy of Holtec's activities associated with the storage of radioactive material and determine if they were performed in accordance with the 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," Holtec's NRC-approved Certificate of Compliance (CoC) and Quality Assurance Program (QAP), and selected portions of 10 CFR Part 21, "Reporting of Defects and Noncompliance."

Based on the results of this inspection, the NRC determined that the implementation of Holtec's QAP did not meet certain NRC requirements in the areas of design control, 10 CFR 72.48 evaluations, and implementing procedures.

This resulted in the identification of three apparent violations, which are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy and one Severity Level IV violation (a nonescalated enforcement action).

The apparent violations relate to Holtec's implementation of design changes to NRC-approved spent fuel cask systems that resulted in departures from methods of evaluation (MOE) described in the final safety analysis report (FSAR) used in establishing the design bases, or in the safety analyses; Holtec's failure to maintain adequate evaluations that provided the bases for their determination that the design changes did not require a CoC amendment pursuant to 10 CFR 72.48(c)(2); and, not subjecting the changes to design control measures that commensurate with those applied to the original design. The apparent violations are further described in the applicable sections of this inspection report. Since the NRC has not made a final determination in this matter, therefore no final action is being issued at this time.

As summarized in table 1 below, three Apparent Violations and one Severity Level IV Non-Cited Violation (NCV) of NRC requirements were identified.

Table 1
Summary of Inspection Findings

Regulatory Requirement 10 CFR Section	Subject	Number of Findings	Type of Finding	Report Section(s)
72.48(c)(2)(viii)	Changes, tests, and experiments	4	Apparent Escalated Violation	1.1.2
72.48(d)(1)	Changes, tests, and experiments	4	Apparent Escalated Violation	1.1.2
72.146(c)	Design Control	4	Apparent Escalated Violation	1.1.2
72.150	Instructions, procedures, and drawings	1	Severity Level IV Non-Cited Violation	1.4.2

Design Control

The team determined, for the MPC enclosure vessel fabrication, assembly and testing processes selected for review, that the fabrication specifications were consistent with the design commitments and requirements documented in the FSAR, CoC, and technical specifications (TS) for the approved designs. The team did identify three apparent violations regarding the honeycombed fuel basket for spent nuclear fuel storage design modifications for four different casks that had not been approved by the NRC. The first apparent violation is of 10 CFR 72.48(c)(2)(viii) with four examples under regulation 10 CFR 72.48, “Changes, tests, and experiments” for Holtec’s failure to correctly conclude that the structural analysis of four multi-purpose canister (MPC) basket design changes resulted in a change in the MOE to qualify the design changes, thus requiring a CoC amendment and prior NRC review and approval before implementation. The second apparent violation is of 10 CFR 72.48(d)(1) with four examples for Holtec’s failure to document a detailed description/evaluation of why there was not a departure from the MOEs (as described in the FSARs) in order to justify that design modifications MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS did not require a CoC amendment. The third apparent violation with four examples is against regulation 10 CFR 72.146(c), “Design control,” where Holtec implemented a design change from the MPC 68M, 32M, 89, and 37 standard basket designs to the MPC 68M-CBS, 32M-CBS, 89-CBS, and 37-CBS basket variant designs without ensuring that design control measures were commensurate with those applied to the original design. (section 1.1)

Corrective Action and Non-Conformance Report

- The team determined that Holtec effectively implemented its corrective action and non-conformance control programs and has adequate procedures in place to ensure compliance with the applicable regulations and quality assurance (QA) requirements. (section 1.2)

Personnel Training and Certifications

- The team determined that Holtec/AMD trained and certified individuals performing quality-related activities as required by the Holtec QAP. (section 1.3)

Human Performance

- The team determined that Holtec/AMD personnel were familiar with the Dry Cask Storage System (DCSS) designs, designated fabrication techniques, testing requirements, and quality controls (QC) associated with the construction of the specific DCSS MPC components. The team identified one Severity Level IV NCV of regulation 10 CFR 72.150, “Instructions, procedures, and drawings” for Holtec’s failure to follow its procedure, HSP-477, revision 4, “Digital Radiographic Weld Examination,” while performing Digital Radiography (DR) which requires digital detector array (DDA) detector pixel corrections at the commencement of an inspection period of not more than 24 hours. Contrary to this, pixel mapping was not being performed every 24 hours, but instead at approximately 2-week intervals. (section 1.4)

Procurement

- The team determined that materials, components, and other equipment received by AMD met DCSS design procurement specifications, and that the procurement specifications conform to the design commitments and requirements contained in the FSAR, CoC, and TS. (section 1.5)

Implementing Procedures

- The team determined that AMD generally fabricated and inspected DCSS MPC components in accordance with 10 CFR Parts 21 and 72 requirements and implemented their QAP with the associated procedures and fabrication specifications. In addition, the team concluded that Holtec effectively implemented its measuring and test equipment (M&TE) control program and has adequate procedures in place to ensure compliance with the applicable regulations, industry standards and quality requirements. (section 1.6)

10 CFR Part 21

- The team determined that fabrication activities were conducted under an NRC-approved QAP (10 CFR 72.140); the provisions of 10 CFR Part 21 were implemented; the fabricator's personnel were familiar with the reporting requirements of 10 CFR Part 21; and the fabricator complied with 10 CFR 21.6, “Posting requirements.” (section 1.7)

Oversight and Audits

- The team determined that for the items selected for review, Holtec is performing oversight and audits in accordance with their QAP. (section 1.8)

REPORT DETAILS

1.0 ISFSI Component Fabrication by Outside Fabricators (Inspection Procedure 60852)

1.1 Design Control

1.1.1 Inspection Scope

The team determined whether the fabrication specifications were consistent with the design commitments and requirements documented in the FSAR, CoC, and TSs.

The team reviewed HI-STORM 100 and HI-STORM Flood/Wind (FW) licensing drawings against the design and fabrication drawings to verify the consistency of critical dimensions and material specifications as well as testing and inspection requirements to determine whether they were consistent with the design. Specifically, the team focused on design commitments and requirements for important-to-safety (ITS) category A and B components of the HI-STORM 100 and HI-STORM FW MPC designs. The team reviewed the process of converting Holtec design drawings to licensing and fabrication drawings, and subsequent development of shop manufacturing travelers.

The team evaluated the design controls that were in place for the transmittal and handling of design drawings received from Holtec engineering. In addition, the team evaluated how the Holtec AMD transitioned from the design to fabrication, as applicable. The team also evaluated the process for distributing controlled drawings either electronically or in hard copy, to various shop locations, and retrieval of electronic or hard copy revisions to verify that old or uncontrolled versions were not being used.

The team verified design control was performed in accordance with Holtec's NRC-approved Quality Assurance Manual (QAM), section 3, "Design Control," revision 15 and the requirements of 10 CFR Part 72. In addition, the team reviewed the following quality procedure documents associated with design control:

- HQP 3.0, "Design Control," revision 29
- HSP 5.0, "Instructions, Procedures, and Drawings," revision 0
- HSP 100202, "Project Planning, Product Realization, and Project Execution," revision 3
- HSP 100301, "Design Control," revision 5
- HSP 100302, "Design Specifications and Design Criteria Documents," revision 0
- HSP 100501, "Engineering Drawings," revision 8

1.1.2 Observations and Findings

The team did not identify any discrepancies between the design and fabrication specifications and the FSAR licensing drawings. The team noted that the Holtec AMD captured all requirements that were applicable to fabrication. The team also noted that the fabrication drawings contained the relevant information needed for fabrication and had adequate document control and storage of QA records.

Overall, the team did not identify any issues of concern in the translation of design information with the sample selected. The team noted fabrication drawings, shop travelers, and procedures were available at various shop locations, either in hard copy or electronically, for each component being fabricated, and that the documents reflected the correct revisions, as applicable.

During the inspection, the team observed that Holtec had made a design change to MPC baskets through the 72.48 design control process. The team expanded the inspection scope to review this design change. The design change was from the standard non-welded Metamic-HT co-planar slotted plate basket design held together only by welded outside cell corners, to a completely non-welded Metamic-HT co-planar slotted plate basket design, held together by continuous shims running the total outside length of the basket and bolted to top and bottom basket plate extensions. Hereafter, 'the standard non-welded Metamic-HT co-planar slotted plate basket design' is generally referred to as the 'original design.' In addition, as part of the basket design change, several continuous shims, that are smaller in size, are bolted to plate extensions at a standard spacing along the total length of the basket to also help hold the basket assembly together. This basket design change was designated as the CBS variant and has been applied to four different multi-purpose canisters. For the HI-STORM FW system, Holtec has designed the MPC-37-CBS and MPC-89-CBS variants, and, for the HI-STORM 100 system, the MPC-68M-CBS, and MPC-32M-CBS variants. In this inspection report, the four basket design changes are sometimes referred to, singularly or collectively, as the 'CBS variant.'

Holtec performed separate 72.48 evaluations for each CBS variant design change. The staff requested all four 72.48 evaluations to verify that Holtec appropriately considered the screening criteria in 10 CFR 72.48(c)(2) when determining that the change did not require prior NRC review and approval. The team reviewed the following engineering change orders (ECOs), calculations, and FSAR revisions that included the CBS licensing drawings associated with the CBS variant design changes:

MPC Basket (CBS)	72.48 No.	Date Performed	ECO	Analysis	Applicable UFSAR Revisions / CoC Amendments
68M	1502 Rev 0	02/17/2021	5014-320 Rev 0	HI-2012787 (revision 39) "Structural Calculation Package for MPC"	HI-2002444 revision 22 "HI-STORM 100" CoC 1014 A(15)
32M	1532 Rev 0	07/19/2021	5014-327 Rev 0	HI-2188448 (revision 4) "Analysis of Non-Mechanistic Tip-over of the Loaded HI-STORM 100S Version E Storage Cask"	HI-2002444 revision 23 "HI-STORM 100" CoC 1014 A(15)
89	1446 Rev 0	05/13/2020	5018-105 Rev 1	HI-2094353 (revision 18) "Analysis of Non-Mechanistic Tip-over and Drop Events of	HI-2114830 revision 7 "HI-STORM FW" CoC 1032 A(4)

				the Loaded HI-STORM FW Storage Cask" HI-2094400 (revision 18) "Thermal Evaluation of HI-STORM FW"	
37	1498 Rev 0	11/06/2020	5018-122 Rev 0	HI-2094353 (revision 18) "Analysis of Non-Mechanistic Tip-over and Drop Events of the Loaded HI-STORM FW Storage Cask" HI-2200503 (revision 3) "Analysis of the Non-Mechanistic Tip-over Event of the Loaded HI-STORM FW Version E Storage Cask"	HI-2114830 revision 9 "HI-STORM FW" CoC 1032 A(5)

For the CBS variants, the team reviewed Holtec's evaluations, the applicable sections of the FSARs (as updated), and tip-over calculations supporting the design changes to the CBS basket variants. The team noted that the Finite Element Analysis computer models (FEA) used for the original standard basket designs had been changed for the assessment of the CBS variant designs. FEAs are considered 'a method of evaluation,' which is one of the eight criteria listed in 10 CFR 72.48(c)(2). The changed FEAs were used to analyze a tip-over accident which is a design basis condition for the casks. The team noted that Holtec made several element changes to the MOEs described in Holtec's HI-STORM 100 and HI-STORM FW FSARs (as updated).

The team reviewed the four 72.48 evaluations performed and listed in the table above and assessed the original standard basket structural MOEs against the CBS basket variant structural MOEs. The team was looking for new or different MOEs (e.g., input parameter and element changes for the CBS basket variants with respect to the standard basket analysis) to determine if there was a departure from the MOE described, outlined, or summarized in the FSAR (as updated) which stated the design bases for the original standard basket design.

The team used the guidance described in NRC inspection manual chapter 0335, "Changes, Tests, and Experiments," effective date January 29, 2021, Regulatory Guide (RG) 3.72, revision 1, and Nuclear Energy Institute (NEI) 12-04, "Guidelines for 10 CFR 72.48 Implementation," revision 2 (endorsed in RG 3.72). The team used criteria from these documents (presented below) to assess whether the changes resulted in a departure from a MOE described in the Holtec FSARs:

- If the changes to one or more elements of the MOE yielded results that were not conservative or not essentially the same using the results from the analysis of record, or

- Whether Holtec's use of a new or different MOE was approved by the NRC for the intended application.

The inspection team identified three apparent violations associated with Holtec's implementation of modifications that impacted the HI-STORM 100 and HI-STORM FW spent fuel cask systems. The detail of each apparent violation is described as follows:

Details regarding Apparent Violation A

Apparent Violation A involves design changes to four MPC fuel baskets; the standard MPC 68M, 32M, 89, and 37 baskets were modified to the MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS basket variants.

For the HI-STORM 100 (FSAR No. HI-2002444), Basket MPC 68M-CBS (72.48 Evaluation No. 1502, Revision 0)

1. As described in FSAR revision 22, section 3.III.4.4.3.1(iii), Holtec tied the nodes of the shim to the basket panel at the bolt hole locations to replicate bolted connections at the bolt hole locations the resultant of which changed the way the connections are modeled between the fuel basket and the shims in the FEA model and did not explicitly model the new bolts. Holtec implemented the modification and revised FSAR revision 21, section 3.III.4.4.3.1 (original design) in which the corner welds between the standard basket and shims were modeled by bonding the corner elements and assigning them the elastic material properties of the weld, effectively modeling the welds in the FEA. The team considered this an element change because it was a change to the overall FEA model associated with the tip-over analysis.

2. As described in FSAR revision 22 section 3.III.4.4.3.1(iii), the impact load between the fuel basket and the shims is directly transferred between shims and the horizontal basket panel adjacent to them, without inducing shear in the bolts. Additionally, for the modified design, calculation HI-201787-R39, supplement 79, evaluates the bolts for solid shims using an applied 60-g bounding lateral deceleration load from the weight of the basket and fuel assembly, the resultant of which changed the way the strength evaluation was performed for the connections between the fuel basket and the shims. Previously, for the standard basket design, Holtec evaluated basket welds using outputs from the FEA to determine the applied moment and shear load as documented in attachment 2 to supplement 65 of Holtec calculation HI-201787-R38. The team considered this a new or different MOE because Holtec changed the calculational framework on how to evaluate the shims.

3. As described in section 3.III.4.4.3.1(ii) of FSAR revision 22, Holtec used a bilinear material model (which required calculating a tangent modulus for plastic behavior) to define the material stress-strain curve for the basket shims in the CBS FEA, the resultant of which changed the way material property models were developed for the basket shims. In the original design, as described in section 3.III.4.4.4.3.1 of FSAR revision 21, Holtec described the material model for the basket shims as elastic with no plastic deformation in the shims. The team considered this an element change because it was a change to the mathematical model associated with the material performance of the shims.

4. As described in supplement 79 of HI-2012787 revision 39, Holtec modified the way in which a structural integrity tip-over/side drop analysis for the CBS basket shims was performed by comparing the stress in the shims to the ultimate stress. In the original design, as stated in FSAR revision 21, section 2.III.0.1.i, the basket shims are designed to remain below the yield limit of the selected aluminum alloy. The team considered this a different MOE because it was a change to how the analysis was applied and was outside the conditions and limitations in which Holtec received NRC approval.

5. As described in FSAR revision 22, section 3.III.6.2, structural analysis of the CBS basket design was performed using FEA code engineering simulation software ANSYS, version 17 in lieu of ANSYS version 11.0, which was used to analyze the standard basket design. In addition, Holtec did not compare the results of the previous version to the current version to determine if the revised software produces comparable results. The team considered this an element change because Holtec adopted a later version of the ANSYS code.

For the HI-STORM 100 (FSAR No. HI-2002444), Basket MPC 32M-CBS (72.48 Evaluation No. 1532, Revision 0)

6. As described in appendix E.1 of HI-2188448-R3, the impact load between the fuel basket and the shims is directly transferred between the shims and the horizontal basket panel adjacent to them without inducing shear in the bolts. For the standard basket design, Holtec evaluated the welds using an applied 100-g bounding fuel deceleration load in appendix C of HI-218848-R3 (as referenced in HI-STORM FSAR revision 23, section 3.II.4.4.2(ii)). The team considered this a different MOE because Holtec changed the way the strength evaluation was performed for the connections between the fuel basket and the shims by using a different assumption, which was inconsistent with the previous licensing basis assumptions. (similar to AV A.2)

For the HI-STORM FW (FSAR No. HI-2114830), Basket MPC 89-CBS and 37-CBS (72.48 Evaluation Nos. 1446 and 1498, Revisions 0, respectively)

7. As described in appendix N of HI-2094353, “Analysis of Non-Mechanistic Tip-Over Event of Loaded HI-STORM FW Storage Cask,” Holtec used a nodal constraint to tie the shims to the basket panels at the bolt hole locations, the resultant of which changed the way that the connections are modeled between the fuel basket and the shims in the FEA model. In addition, Holtec did not model the bolts for the CBS design. Previously, Holtec modeled the corner welds between the standard basket and shims by bonding the corner elements and assigning them the elastic material properties of the weld, effectively modeling the welds in the FEA. The team considered this an element change because it was a change to the overall FEA model associated with the tip-over analysis. (similar to AV A.1)

8. FSAR HI-2114830, revision 7, section 3.4.4.1.4b, states that lateral deflections from the tip-over analysis of the CBS basket comply with the deflection criterion in FSAR table 2.2.11. However, Holtec did not include lateral defections of the CBS fuel basket design of the FSAR. Instead, Holtec documented that the maximum local plastic strains of the 89-CBS basket reached the rupture strain and depicted

small plastic deformation in the active fuel region. For the 37-CBS basket, Holtec reported the maximum local plastic strains and provided figures of the maximum plastic strains, which showed small plastic deformation in the active fuel region of the MPC 37-CBS basket. Despite these results, Holtec incorrectly concluded that the fuel baskets did not experience any permanent deformation in the active fuel region in appendix N of HI-2094353. The team considered this a different MOE because Holtec stated there was no plastic deformation. However, the changes being considered now show plastic deformation.

9. Holtec made changes to the cold gap assumptions (i.e., requiring a cold gap be maintained to no cold gap) and did not provide justification for the FSAR conclusion that the combined radial gap between the basket, the shims, and the enclosure vessel is sized to prevent distortion in basket panels, as described in FSAR revision 7, section 3.1.2.2.a, Design Basis Loads and Load Combinations. However, appendix V of Holtec calculation HI-2094400, states that the differential thermal expansion closed the radial cold gap between the fuel basket and the MPC vessel for the MPC 89-CBS, therefore, there are unanalyzed interference stresses. The staff considers this a new assumption in the MOE because this change was outside the conditions and limitations in which Holtec received NRC approval.

The team assessed the changes made to the CBS fuel basket variants and determined that changes 2, 4, 6, 8 and 9 were different MOEs while 1, 3, 5 and 7 were changes in elements of the MOE. The team noted that Holtec failed to consider the cumulative impacts from all the changes and Holtec made changes to more than one element of the MOE that were not consistent with the constraints and limitations of the fuel basket's design licensing basis. The team also noted that Holtec adopted different aspects of different approved MOEs and did not apply these changes in the same manner as the original MOE (e.g., how the shims were originally modeled). The guidance provided in NEI 12-04 considers that form of mixing attributes of a different and existing MOE to be an overall change to an element of an MOE. Further, the results should be compared to the analysis of record. The team noted that Holtec did not demonstrate, in the 10 CFR 72.48 evaluations, whether the results were conservative or essentially the same. The team determined that Holtec made changes to elements of MOEs that were not conservative or not essentially the same as the results of the analysis of record and therefore departed from the original MOEs. The staff concluded that Holtec did not adopt the original MOEs in their entirety and did not apply them consistently with the applicable terms, conditions, and limitations as the original MOEs. By not submitting the CBS variant design changes for NRC review and approval, the changes to the existing MOEs for the tip-over accident analysis impacted the NRC's ability to perform the appropriate evaluation to confirm that the design changes met safety requirements.

The staff determined that the potential consequence of an improper tip-over analysis is the failure of the MPC CBS basket variants to satisfy their design bases requirements following a tip-over accident. This could result in a critically event or the inability to remove a spent fuel assembly from a basket cell that has permanent deformation after the design basis accident condition occurred.

The team assessed that this was an apparent violation of NRC requirements. Specifically, 10 CFR 72.48(c)(2)(viii), "Changes, tests, and experiments," requires, in part, that a certificate holder shall obtain a CoC amendment pursuant to 10 CFR 72.244,

prior to implementing a proposed change that would result in a departure from a MOE described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.

Contrary to the above, Holtec failed to obtain a CoC amendment pursuant to 10 CFR 72.244, prior to implementing proposed changes that would result in a departure from a MOE described in the FSAR used in establishing the design bases or in the safety analyses. Specifically, from November 6, 2020, to July 19, 2021, Holtec implemented design changes to MPC standard baskets 68M, 32M, 89, and 37 to the MPC 68M-CBS, 32M-CBS, 89-CBS, and 37-CBS basket variants by replacing the standard non-welded Metamic-HT co-planar slotted plate basket design with mechanically fastened (bolted) extensions in the basket panels that protrude outside the fuel assembly cells.

Based on the team's assessment, the team identified this as one apparent violation of NRC requirements with four examples (MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS). The team characterized this as an apparent violation (in accordance with NRC Enforcement Policy) for which the NRC staff has not made a final enforcement determination.

Details regarding Apparent Violation B

As discussed above for the apparent violation of regulation 10 CFR 72.48(c)(2)(viii), "Changes, tests, and experiments" (apparent violation #1), for 72.48's 1502, 1532, 1446 and 1498; Holtec determined that the proposed activity did not result in a departure from a MOE described in the FSAR used in establishing the design basis or in the safety analyses.

In the "Explanation," section of all four 72.48 evaluations, Holtec used boiler plate statements that all evaluations of the proposed activity use the same methods of evaluation previously described in the HI-STORM 100 (or FW) FSAR, and did not provide a specific bases within their explanations that the changes did not depart from methods of evaluations as described in the FSARs used in establishing the design basis or in their safety analysis reports for the standard basket designs.

The team assessed that this was an apparent violation of NRC requirements. Specifically, 10 CFR 72.48(d)(1) which 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 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 does not require a CoC amendment pursuant to paragraph (c)(2) of this section.

Contrary to the above, Holtec failed to maintain records of changes in the spent fuel storage cask design made pursuant to paragraph (c) of 10 CFR 72.48 that included a written evaluation which provided the bases for the determination that the change does not require a CoC amendment pursuant to 10 CFR 72.48(c)(2). Specifically, for the MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS variants, as of February 17, 2021, July 19, 2021, May 13, 2020, and November 6, 2020, Holtec's written evaluations failed to provide an adequate bases for the determination that

incorporation of the CBS design fuel basket variants did not require a CoC amendment. Holtec did not clearly and thoroughly discuss the impacts on departures from elements of the methods of evaluation (MOEs) described in the FSARs for the original design (all-welded stainless steel fuel basket) that were affected by the changes to the CBS design fuel basket variants (MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS). The impacted elements included the demonstration of the design criteria of the fuel basket; mathematical model associated with material performance and tip-over analysis; calculational framework on connections between fuel basket and shims; use of revised version of software; new assumptions, etc.

This was due to Holtec not clearly and thoroughly discussing the impact on departures from elements (mathematical model associated with material performance and tip-over analysis; calculational framework on connections between fuel basket and shims; use of revised version of software; new assumptions, etc.) of MOEs described in the standard fuel basket FSARs for the MPC 68M, MPC 32M, MPC 89, and MPC 37.

Based on the team's assessment, the team identified this as one apparent violation of NRC requirements with four examples (MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS); specifically, each of the 72.48s performed. The team characterized this as an apparent violation (in accordance with NRC Enforcement Policy) for which the NRC staff has not made a final enforcement determination.

Details regarding Apparent Violation C

The staff determined that in all four tip-over calculations supporting the design changes to the CBS basket variant designs, there were changes to the boundary conditions to the FEA models. Previously, for the standard basket designs the basket corner welds were modeled as elastic elements. In the CBS design change, the welds have been eliminated and bolts are now used to hold the baskets together. The bolts are not modeled in the CBS FEA models and instead the models simply tie the nodes of the shims to a basket panel at the bolt hole locations. Therefore, there are no tip-over evaluations of the basket shim bolts.

For the MPC 68M-CBS tip-over analysis, the stress in the shims is compared to their material ultimate strength while the stress in the shims for the standard baskets was compared to the shim material yield strength. In addition, the strength evaluation for the CBS bolts has several differences from the strength calculation for the welds of the standard basket design. For example, the weld evaluation uses force and moment outputs from the FEA, while the bolt analysis uses an applied 60-g load. For the CBS basket design, Holtec calculated a bilinear modulus of elasticity for the shims following a method not used in the standard basket tip-over analysis.

For the MPC 32M-CBS, the method in which the strength evaluation was performed for the connections between the fuel basket, bolts and the shims was revised. The impact load was assumed to be directly transferred between the shims and the horizontal basket panel adjacent to them without inducing shear in the bolts. The calculational framework on how to evaluate the shims was inconsistent with the previous licensing basis assumptions.

For the MPC 89-CBS and MPC 37-CBS tip-over analysis, the results show large local strains in the fuel basket, reaching the rupture stain for the MPC 89-CBS basket. These results do not support Holtec's conclusion that there was no permanent deformation in the active fuel region and there is no effect on the fuel assembly spacing. The tip-over stress results for the bolts and shims for the CBS baskets were not reported or evaluated in the calculations.

For all four CBS baskets, there is no analysis of the differential thermal expansion between the basket panels and the MPC shell to ensure the gaps are sufficient to prevent stresses from thermal expansion. Also, none of the analysis results address the design criteria for the fuel basket, which requires the maximum total deflection of the basket be less than the allowable values in the FSARs.

The team assessed that this was an apparent violation of NRC requirements. Specifically, 10 CFR 72.146, "Design control," which requires, in part, that a certificate holder shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license or CoC require prior NRC approval.

Contrary to the above, Holtec failed to subject design changes, including field changes, to design control measures commensurate with those applied to the original basket design. Specifically, in four examples prior to February 17, 2021, July 19, 2021, May 13, 2020, and November 6, 2020, Holtec failed to subject design changes from the MPC 68M, 32M, 89, and 37 standard basket designs to the MPC 68M-CBS, 32M-CBS, 89-CBS, and 37-CBS basket variants to design control measures commensurate with those applied to the original design, and made changes in the conditions specified in the license that required prior NRC approval. Holtec failed to perform adequate tip-over calculations and to model the basket shim bolts for the four CBS basket variants. In addition, material strength comparisons were different and thermal expansion interference was not calculated in the CBS baskets.

Based on the team's assessment, the staff identified this as one apparent violation of NRC requirements with four examples (MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS): specifically, each of the four tip-over calculations supporting the MPC CBS basket design changes. The team characterized this as an apparent violation (in accordance with NRC Enforcement Policy) for which the NRC staff has not made a final enforcement determination.

1.1.3 Conclusions

The team determined, for the items selected for review, that the design and fabrication specifications were consistent with the design commitments and requirements documented in the FSAR, CoC, and TS.

The staff identified three apparent violations related to Holtec's HI-STORM 100 tip-over analysis for the MPC 68M-CBS and MPC 32M-CBS design changes and Holtec's HI-STORM FW tip-over analysis for the MPC 89-CBS and MPC 37-CBS design changes.

For apparent violation 1, staff identified that Holtec's tip-over evaluations departed from a MOE described in the HI-STORM 100 and HI-STORM FW FSARs to another method that was not approved by the NRC for the intended application and Holtec did not obtain CoC amendments prior to implementing the proposed changes in accordance with 10 CFR 72.48(c)(2)(viii).

For apparent violation 2, the staff identified for 72.48 evaluations 1502, 1532, 1446, and 1498, that Holtec did not maintain records of changes in the spent fuel storage cask design made pursuant to paragraph (c) of 10 CFR 72.48 that included a written evaluation that provided the bases for the determination that the changes did not require a CoC amendment pursuant to 10 CFR 72.48(c)(2). Holtec did not include a detailed written evaluation which provided the bases for the determination that the addition of the MPC 68M-CBS, 32M-CBS, 89-CBS, and 37-CBS basket design changes do not require a CoC amendment pursuant to 10 CFR 72.48 (c)(2).

For apparent violation 3, the staff identified that Holtec failed to subject the MPC 68M-CBS, 32M-CBS, 89-CBS, and 37-CBS basket design changes to design control measures commensurate with those applied to the original design for the MPC 68M, 32M, 89, and 37 standard basket designs. Changes in the conditions specified in the CoC require prior NRC approval in accordance with 10 CFR 72.146(c).

1.2 Corrective Action and Non-Conformance Reports

1.2.1 Inspection Scope

The team reviewed Holtec's QAM and the following implementing procedures for its corrective action and non-conformance programs:

- HQP 16.0, "Corrective Action," revision 24
- HSP 101601, "Corrective Action," revision 3
- HSP 101502, "Control of Nonconforming Conditions," revision 6
- HSP 101503, "Manufacturing Condition Control," revision 7

The team reviewed selected records and interviewed personnel to verify that Holtec effectively implemented its corrective action program (CAP) in accordance with the requirements of 10 CFR Part 72 and Holtec's corrective action procedures. The team requested a sample of corrective action reports to review.

The team also reviewed selected records and interviewed personnel to verify that Holtec effectively implemented a non-conformance control program in accordance with the requirements of 10 CFR Part 72 and Holtec's non-conformance procedures. The team requested a sampling from a list of non-conformance reports (NCRs) to review and verify that the NCRs were identifiable, traceable, and the disposition of the non-conformance was adequate. The team chose eight NCRs to review and evaluated if the disposition for each was appropriate, adequately performed as necessary, and properly closed out.

1.2.2 Observations and Findings

For all the corrective actions reviewed, conditions adverse to quality were adequately documented. Each corrective actions report included the determination and recording of

the significance, risk, and uncertainty levels. The evaluation of the investigation class (A-D) was documented, and the type of investigation was completed. The corrective action reports reviewed included corrective actions and actions to prevent recurrence of the issue as necessary. The team found the actions taken appropriate and completed in a timeframe commensurate with the issue's importance.

Overall, no concerns were identified with the Holtec CAP, and the team assessed that conditions adverse to quality were appropriately documented, evaluated, corrected, and closed.

The team also assessed that Holtec adequately dispositioned and, if applicable, closed each NCR reviewed in accordance with the requirements of HSP 101502, as applicable. No issues of significance were identified with the corrective action and non-conformance reports reviewed or programs.

1.2.3 Conclusions

The team concluded that Holtec effectively implemented its corrective action and non-conformance control programs and had adequate procedures in place to ensure compliance with the applicable regulations and QAP requirements.

1.3 Personnel Training and Certifications

1.3.1 Inspection Scope

The team assessed and determined whether individuals performing quality-related activities were trained and certified where required. The team reviewed the records of quality inspectors that performed nondestructive examinations (NDE) and welders. The team reviewed various production work route plans (PWRP), fabrication drawings, inspection reports, weld records, and interviewed AMD personnel.

1.3.2 Observations and Findings

The team noted welder performance qualifications and welder continuity conformed to section IX of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code. For the welding qualification records reviewed, the team noted that AMD qualified welders in accordance with procedures in each applicable process, and that AMD maintained welding continuity for each of the welding processes qualified. In addition, the inspector noted that personnel performing NDE were qualified in accordance with the American Society for Nondestructive Testing Recommended Practice No. SNT–TC-1A. This standard includes the required training, experience, medical testing, and education for NDE personnel at AMD. The inspectors observed welding and inspections in the shop and reviewed a sample of welder qualifications and NDE Level II and III, certification records (e.g., visual, liquid penetrant, helium leak test, ultrasonic, and digital radiograph).

No findings were identified.

1.3.3 Conclusions

The team accessed that AMD had adequately trained and certified individuals performing quality-related activities for fabrication of ITS DCSS MPC components.

1.4 Human Performance

1.4.1 Inspection Scope

The team assessed and determined whether AMD personnel were familiar with the specified design, designated fabrication techniques, testing requirements, and QC associated with the construction of the DCSS the team assessed AMD's control of the fabrication process through observations, examinations of records, and personnel interviews in the areas of fabrication and assembly, test and inspection, and familiarity with measuring tools and equipment.

The inspectors reviewed AMD's fabrication drawings, various PWRP's, and associated procedures. Specifically, for welding activities, the inspectors observed various MPC shell welding processes (e.g., gas tungsten arc and submerged arc welding), reviewed PWRP's, weld procedure specifications (WPSs), supporting procedure qualification records, weld data sheets, and welder qualifications. For NDE, the inspectors observed, and reviewed examination reports associated with visual, DR, helium leak, and mechanical testing. The inspectors reviewed examiner and welder qualifications along with AMD's process for welding material control, interviewed shop personnel, and reviewed applicable records used for material control process implementation, including the welding material control log and welding material issue cards.

The team observed visual testing (VT) and Penetrant Testing (PT) examinations of MPC lift lugs, VT of fuel tube welds of a basket assembly, basket plate gauge test, MPC outer lid fit-up, MPC vs HI-TRAC mockup fixture fit verification, submerged arc welding (SAW), digital radiograph of a baseplate weld, and reviewed an examination record of helium leak test of a MPC shell assembly.

1.4.2 Observations and Findings

Overall, the team noted that AMD personnel performed fabrication activities adequately and that AMD staff were knowledgeable about the specified design, designated fabrication techniques, testing requirements, and QC associated with the construction of the DCSSs and MPCs. The team determined that the work was well controlled, individuals were knowledgeable of the applicable fabrication process, and the work was being performed in accordance with the applicable fabrication procedures, PWRPs and WPSs. The team observed the following activities, procedures, and records:

- VT/PT examination of Lift Lugs and MPC Shell Welds
- MPC straight line tape measurement outside diameter at enclosure vessel opening; Lid fit-up
- MPC vs HI-TRAC mockup fixture fit verification
- MPC Submersible Arc Welding
- Digital Radiography MPC-32MCBS Shell Assembly (S/N: 915)
- HSP-1104, revision 8, Visual Weld Examination

- HSP-1105, revision 9, Liquid Penetrant Examination
- HSP-477, revision 4, “Digital Radiographic Weld Examination”
- DS-391, dated September 21, 2018, Holtec Position Paper: “Real Time Digital Radiography for the Volumetric Inspection of MPC Austenitic Stainless Steel Containment Boundary Welds”
- Industrial Testing Laboratory Services, LLC, Procedure No. 204, revision 15, dated July 20, 2015, “Helium Leak Testing”
- Weld Procedure Specification: 227HC, revision 4, “Machine SAW on Stainless Steel Base Metals”
- Weld Procedure Qualification Record No. CE-4B, revision 1, dated January 27, 2015, “Machine SAW on P-No. 8 Stainless Steel”
- Welder Performance Qualifications and welder maintenance of proficiencies
- Helium Leak Test Report MPC-32M CBS Shell Sub-Assembly
- DR Level II NDE Certification Record
- Certificate of Qualification, Leak Testing Level II and Vision Acuity Certification
- Calibration of Primary Gas Leak Standard, ID #: ITLS-0188
- Calibration of Temperature/Humidity Meter, ID#: ITLS-0209

The American Society of Testing and Materials defines DR as the radiological application where film or paper is not used to record exposure. To create an image, a beam of electromagnetic radiation of short wavelength is projected through an object being inspected toward a DDA and dependent upon the test object density, composition, or presence of defects, a two-dimensional image is immediately displayed on a viewing screen or video monitor. The digital radiographic system configured at AMD uses an isotope radiation source and a DDA plate.

The team noted Holtec’s procedure, HSP-477, revision 4, “Digital Radiographic Weld Examination,” requires DDA detector pixel corrections at the commencement of an inspection period of not more than 24 hours prior to the examination. A DDA detector must undergo a calibration (an offset and gain correction) to remove non-uniformities or artifacts. However, pixel mapping was performed at approximately 2-week intervals instead of every 24 hours as prescribed by procedure. The team noted HSP-477 uses the term “calibration” in various locations, however, the activities prescribed are actual standardizations or verifications (ASME, section V, Article 2, mandatory appendix IX, “Radiography Using Digital Detector Systems,” 2021 edition). The team determined the failure to perform pixel mapping was a violation of NRC requirements.

Per 10 CFR 72.150, “Instructions, procedures, and drawings” requires, in part, that the certificate holder (Holtec) shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed.

Contrary to the requirements in 10 CFR 72.150, Holtec failed to adequately implement a procedure for an activity affecting quality. Specifically, procedure, HSP-477, revision 4, “Digital Radiographic Weld Examination,” specified that DDA calibration (pixel mapping) be performed at the commencement of an inspection period and not more than 24 hours as required, instead, Holtec performed the DDA calibrations at 2-week intervals.

The team assessed the significance of the violation using the NRC Enforcement Policy and Enforcement Manual. The team dispositioned the violation using the traditional

enforcement process in section 2.3 of the Enforcement Policy. The team characterized the violation as a Severity Level IV violation in accordance with the NRC's Enforcement Policy, section 6.5. Holtec entered the issue into its CAP under quality issue (QI) No. 3285. The team assessed that because this violation was of low safety significance and was entered into Holtec's CAP, the issue was not repetitive or willful, it is being treated as a NCV, consistent with section 2.3.2.a of the Enforcement Policy.

1.4.3 Conclusions

Overall, the team determined that AMD personnel were familiar with each specific DCSS design, designated fabrication techniques, testing requirements, and QC associated with the construction of the DCSS MPC components. The team noted that AMD had an adequate QI program in place to address the one violation of NRC requirements concerning the failure by Holtec to comply with a procedural requirement to complete the bad pixel mapping on a daily (24-hour frequency) basis.

1.5 Procurement

1.5.1 Inspection Scope

The team assessed and determined whether AMD received materials, components, and other equipment that met the DCSS MPC design procurement specifications and that the procurement specifications conform to the design commitments and requirements contained in Holtec's design and operations of the cask system FSAR, CoC, and TS.

The team reviewed AMD's processes that address procurement, including traceability and receipt inspection. The team reviewed selected drawings and records and interviewed selected personnel to verify that the procurement specifications for materials, fabrication, inspection, and services performed at AMD met design requirements. The team verified that Holtec used a graded approach for identifying ITS components during the design process and applied this graded quality to components and material procurement documents for AMD. The team selected ITS MPC components such as weld wire/flux, top lids, and baseplates. The team reviewed the following procurement documents, specifications and implementing procedures:

- Welding Material Specification PS-235, revision 1, dated March 11, 2015, "Procurement of ASME Section III SAW ER308L"
- Welding Material Specification PS-238, revision 0, dated November 20, 2014, "Procurement of ASME Section III GTAW E308L/880 Flux"
- Purchase Specification No. PS-201, revision 3 dated September 10, 2020 "Spec for ASME SA240 Alloy X Plate (ASME Section III, Subsection NB) for MPC Lid Top Plate Assembly"
- Top Lid Material Identification Report (MIR): No. 9925-2608 dated July 11, 2022
- MPC Baseplate
- Purchase Specification No. PS-105, revision 10 dated September 10, 2020 "Spec for ASME SA240 Alloy X Plate (ASME Section III, Subsection NB) Except for MPC Lids"
- MPC Baseplate MIR No.: 9925-22581 dated January 24, 2022, HT # SD52830
- Purchase Specification No. PS-506, revision 0, "Procurement Specification for NDE and Auditing Services of Safety Significant Applications"
- HSP-100705, revision 7, dated August 22, 2022, "Procurement of Items and Services When Commercial Grade Dedication, Upgrading or Utilization of Unqualified Source Material Applies"
- Top Lid and Baseplate Commercial Grade Dedication Reports

1.5.2 Observations and Findings

The team observed that AMD had adequate control of the procurement processes for the ITS components reviewed. Overall, AMD procured ITS components consistent with design requirements and their implementing procedures. Further, AMD's material traceability, procurement, and receipt inspection controls were adequate. The team determined that the purchase orders were adequate and specified the applicable criteria and requirements including 10CFR Part 21. The material ordered and received by AMD met the design requirements, the critical characteristics if commercially dedicated and were adequate based of the receipt inspection verification. Additionally, AMD verified and maintained the traceability throughout the procurement and receipt process. The team determined that AMD purchased the components from vendors on the AMD approved vendors list.

No findings were identified.

1.5.3 Conclusions

The team determined that materials, components, and services received by AMD met the DCSS MPC design procurement specifications, and the procurement specifications conform to the design commitments and requirements contained in the FSAR, CoC, and TS.

1.6 Implementing Procedures

1.6.1 Inspection Scope

The team assessed whether AMD fabricated DCSS MPC components in accordance with their QAP, fabrication specifications, and specific requirements of 10 CFR Part 21. The team evaluated AMD's control of the fabrication process through observations, examinations of records, and personnel interviews in the areas of fabrication and assembly, test and inspection, handling, and storage as well as tools and equipment.

As noted in the previous sections, the team reviewed procedures and specifications associated with procurement, welding, assembly, and testing used in manufacture of DCSS MPC's.

The team also reviewed the control of M&TE program to evaluate how Holtec identified, specified, and controlled tools and equipment in accordance with applicable sections of the QAM, quality procedures, and regulatory requirements. Specifically, the team reviewed the following quality Holtec documents:

- HQP-12.0, "Control of Measuring and Test Equipment," revision 29
- HSP 101201, "Control and Measuring of Test Equipment," revision 7
- HSP 101202, "Calibration of Measuring and Test Equipment," revision 9
- HSP 101001, "Qualification of Inspection Personnel," revision 2

The team selected a sample of the M&TE used during the fabrication of the HI-STORM 100 and HI-STORM FW MPC's and Overpacks. The sample included a review of travelers that identified the use of specific M&TE that the team selected such as a caliper, tape measure, light meter, surface contact probe, thermometer, pressure gauge

and welding power supply. The team reviewed the calibration records to verify calibration dates, testing standards, and traceability of the associated M&TE.

1.6.2 Observations and Findings

The team observed that AMD fabricated DCSS MPC components in accordance their quality procedures. The team observed for the items selected that the procedures contained the appropriate quantitative and/or qualitative acceptance criteria for determining that ITS activities have been satisfactorily accomplished. The team observed that staff performing ITS activities were adequately following procedures based on the limited fabrication activities assessed during the inspection.

The team verified that AMD stored weld wire used in quality applications for the Holtec projects in accordance with procedure and AMD personnel stored stainless steel and carbon steel tools separately and the tools had the appropriate markings.

The team assessed that Holtec established controls on M&TE in accordance with their quality requirements, industry standards and regulatory requirements. The team assessed that Holtec personnel provided the appropriate information on shop travelers in accordance with approved procedures. The team verified that personnel used M&TE within their rated capacities and sensitivities as documented in calibration records. In addition, the team verified that the calibration status of M&TE was current, all documentation signed off by qualified inspection personnel, and all M&TE sampled was in the proper condition for use.

No findings were identified.

1.6.3 Conclusions

The team determined that AMD fabricated and inspected DCSS MPC components in accordance with their QAM, 10 CFR Part 21 procedures and other implementing procedures, and fabrication specifications.

In addition, the team concluded that Holtec effectively implemented its M&TE control program and has adequate procedures in place to ensure compliance with the applicable regulations, industry standards and quality requirements.

1.7 **10 CFR Part 21**

1.7.1 Inspection Scope

The team reviewed the 10 CFR Part 21 quality procedure, HSP 101501, “Reporting Defects per 10 CFR 21 or 10 CFR 50.55e,” revision 1, to verify if provisions were in place for reporting defects that could cause a substantial safety hazard and for completing the required notifications in a timely manner. The team requested any 10 CFR Part 21 evaluations and notifications associated with the fabrication activities and at the time of the inspection none had been written. The team also verified if Holtec complied with 10 CFR 21.6, “Posting requirements.”

1.7.2 Observations and Findings

The team assessed the procedure contained detailed responsibilities for individuals associated with Part 21. The team determined that all Part 21 Postings were placed in visible locations for employees to read.

No issues of significance were identified.

1.7.3 Conclusions

The team concluded that Holtec had adequate procedures and controls in place for reporting defects which could cause a substantial safety hazard, as required by 10 CFR Part 21, and complied with 10 CFR 21.6, “Posting requirements.”

1.8 Oversight and Audits

1.8.1 Inspection Scope

The team evaluated whether Holtec provided adequate supervision with QC/QA personnel for appropriate oversight during fabrication activities.

The team reviewed Holtec’s audit program to determine if Holtec scheduled, planned, and performed audits in accordance with approved implementing procedures. The team selected internal and external audits from 2020 to 2022 and reviewed the audit results to determine if Holtec identified deficiencies and addressed the deficiencies within their CAP. Also, the team verified audits were performed in accordance with Holtec’s NRC-approved QAM, section 18, “Audits,” revision 15 and the requirements of 10 CFR Part 72. In addition, the team reviewed the following quality procedure documents associated with audits:

- HQP 18.0, “Audits,” revision 0
- HSP 101802, “Audits,” revision 7
- HSP 101801, “Certification of Audit Personnel,” revision 1
- HSP 101803, “Internal QA Surveillance and Document Reviews,” revision 0

The team reviewed the qualifications, training records, and annual evaluations for Holtec lead auditors to determine if they met the procedure requirements for lead auditor.

The team reviewed selected internal audits to determine if they were performed in accordance with Holtec procedures, if Holtec identified deficiencies, and whether Holtec addressed these deficiencies within their CAP.

The team reviewed a sample of external audits for ITS-A suppliers and verified that the audits were performed in accordance with the Holtec procedures. The team verified that any follow up action for audit findings that has not been closed out has been documented through written communication between Holtec and the vendor.

1.8.2 Observations and Findings

The team reviewed internal audit reports from 2020 through 2022 and verified that the audits were performed in accordance with the Holtec procedures, and that any findings were documented and followed up through corrective action reports.

The team also reviewed a sample of external audit reports for approved suppliers of ITS-A welding material and steel plates. The team assessed that, all of the supplier audit reports that were reviewed used the correct forms, and that they were properly filled out. All reports contained the audit plan, audit checklists, and any supplier finding reports.

The team determined that the internal and external audit implementing procedures are adequate and used effectively.

Overall, the team assessed that Holtec adequately implemented their audit program as described in HQP 18.0. The team determined that Holtec appropriately identified issues and implemented corrective actions for findings and observations during their audits.

The team assessed after reviewing the 2020 through 2022 internal audit reports that all 18 criteria were audited every 2 years. The team also assessed that all the Holtec lead auditor qualifications, training records, and annual evaluations reviewed met the procedural requirements for lead auditor.

From field observations the team assessed that Holtec was providing adequate supervision with QC/QA personnel for appropriate oversight during fabrication activities.

No issues of significance were identified.

1.8.3 Conclusions

The team determined that Holtec is performing oversight and audits in accordance with their QAP. The team concluded that Holtec has adequately conducted internal and external audits in accordance with written procedures and checklists. The team determined that Holtec used qualified personnel and evaluated all appropriate aspects of their QA program and ITS-A vendor QA programs.

2.0 Entrance and Exit Meeting

On December 12, 2022, the NRC inspection team discussed the scope of the inspection during an entrance meeting with Holtec Vice President of Quality, Mark Soler and other members of the Holtec staff. On December 15, 2022, the NRC inspection team presented the inspection results and observations during a preliminary onsite debrief meeting with Mark Soler and other members of the Holtec staff. The inspection continued at the NRC headquarters, during which time the NRC held another virtual inspection debrief with Holtec on April 21, 2023, and August 23, 2023, to inform Holtec of potential violations. On August 30, 2023, the NRC inspection team leader conducted a final virtual exit

meeting with Mark Soler and other members of the Holtec staff to inform Holtec of three apparent violations from the inspection. Section 1 of the attachment to this report shows the attendance for the entrance, debrief at AMD, virtual debrief, and virtual exit meetings.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES AND INDIVIDUALS INTERVIEWED

Name	Title	Affiliation	Entrance	Debrief at AMD	Virtual Debrief	Virtual Exit
Jon Woodfield	Inspection Team Leader	NRC/DFM	X	X	X	
Earl Love	Senior Inspector	NRC/DFM	X	X		
Matthew Learn	Inspector	NRC/DFM	X	X	X	
Azmi Djapari	Inspector in Training	NRC/DFM	X	X		
Aida Rivera-Varona	Branch Chief of Inspection and Oversight Branch	NRC/DFM			X	
Jacob Zimmerman	DFM Deputy Director	NRC/DFM			X	
Mark Soler	Vice President of Quality	Holtec	X	X	X	
Chad Coda	Operations Manager	Holtec	X	X		
Vaughn Curcio	Quality Manager of Manufacturing	Holtec	X	X		
Steve Stawisuck	Advanced Manufacturing Division Quality Manager	Holtec	X			
Stefan Anton	Vice President of Engineering	Holtec			X	
Chuck Bullard	Director of Structural Mechanics	Holtec			X	
Jean Fleming	Vice President of Licensing, Regulatory and Probabilistic Safety Analysis	Holtec			X	
Kimberly Manzione	Director of Licensing	Holtec			X	

2. INSPECTION PROCEDURES AND OTHER NRC DOCUMENTS USED

IP 60852	"ISFSI Component Fabrication by Outside Fabricators"
NUREG/CR-6407	"Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety"
NUREG/CR-6314	"Quality Assurance Inspections for Shipping and Storage Containers"

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
71-1014/2022-201-01	Closed	NCV	Failure to follow digital radiograph procedure

4. LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
AMD	Advanced Manufacturing Division

ASME	American Society of Mechanical Engineers
CAP	Corrective Action Program
CBS	Continuous Basket Shim
CFR	Code of Federal Regulations
CMTR	Certified Material Testing Report
CoC	Certificate of Compliance
DCSS	Dry Cask Storage System
DDA	Digital Detector Array
DFM	Division of Fuel Management
DR	Digital Radiography
ECO	Engineering Change Order
FEA	Finite Element Analysis
FSAR	Final Safety Analysis Report
HQP	Holtec Quality Procedure
HSP	Holtec Standard Procedure
ITLS	Industrial Testing Laboratory Services, LLC
ITS	Important-to-Safety
ITS-A	Important-to-Safety Category A
METAMIC-HT	High Temperature Aluminum Boron Carbide Metal Matrix Composite Material
MIR	Material Identification Report
MPC	Multi-purpose Canister
M&TE	Measuring and Test Equipment
NCR	Non-conformance Report
NCV	Non-cited Violation
NDE	Nondestructive Examination
NRC	Nuclear Regulatory Commission
PO	Purchase Order
PT	Penetrate Testing
PWRP	Production Work Route Plans
QA	Quality Assurance
QAM	Quality Assurance Manual
QAP	Quality Assurance Program
QC	Quality Control
QI	Quality Issue
SAW	Submerged Arc Welding
TS	Technical Specifications
UT	Ultrasonic Testing
VT	Visual Testing
WI	Work Instruction or Weld Instruction
WPS	Weld Procedure Specifications

5. DOCUMENTS REVIEWED

Certificate holder documents reviewed during the inspection were specifically identified in the report details above.

6. THE FOLLOWING QI REPORTS WERE OPENED BY HOLTEC DURING THE INSPECTION DUE TO DISCUSSIONS WITH THE INSPECTION TEAM

Item Number	Status	Description
QI-3283	Opened	NRC Form 3 not posted per 10 CFR 72.10.
QI-3284	Opened	HSP-106, “Interface Procedure for Holtec Manufacturing Activities,” revision 34 is not current with how Holtec uses electronic copies of drawings to perform fabrication activities.
QI-3285	Opened	Calibration of Digital Radiographer is not being performed In accordance with procedure HSP-477, “Digital Radiographic Weld Examination,” revision 4.

Based on the results of a NRC inspection conducted at Holtec International (hereafter referred to as Holtec), on December 12 through December 15, 2022, with exiting on August 30, 2023, a team of inspectors identified three apparent violations of NRC requirements. In accordance with the NRC Enforcement Policy, the apparent violations are listed below:

APPARENT VIOLATIONS BEING CONSIDERED FOR ESCALATED ENFORCEMENT

Apparent Violation A:

Per 10 CFR 72.48(c)(2)(viii), "Changes, tests, and experiments," requires, in part, that a certificate holder shall obtain a CoC amendment pursuant to 10 CFR 72.244, prior to implementing a proposed change that would result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.

Contrary to the above, the certificate holder (Holtec) failed to obtain a CoC amendment pursuant to 10 CFR 72.244, prior to implementing proposed changes that would result in a departure from a MOE described in the FSAR used in establishing the design bases or in the safety analyses. Specifically, from November 6, 2020, to July 19, 2021, Holtec made design changes to four MPC fuel baskets from the standard MPC 68M, 32M, 89, and 37 baskets to the MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS basket variants that would result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases and failed to submit CoC amendment applications prior to implementing the changes.

Apparent Violation B:

Per 10 CFR 72.48(d)(1), "Changes, tests, and experiments," requires, in part, that the licensee and certificate holder shall maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and 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 does not require a CoC amendment pursuant to paragraph (c)(2) of this section.

Contrary to the above, Holtec failed to maintain records of changes in the spent fuel storage cask design made pursuant to paragraph (c) of 10 CFR 72.48 that included a written evaluation which provided the bases for the determination that the change does not require a CoC amendment pursuant to 10 CFR 72.48(c)(2). Specifically, for the MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS variants, as of February 17, 2021, July 19, 2021, May 13, 2020, and November 6, 2020, Holtec's written evaluations failed to provide an adequate bases for the determination that incorporation of the CBS design fuel basket variants did not require a CoC amendment. Holtec did not clearly and thoroughly discuss the impacts on departures from elements of the methods of evaluation (MOEs) described in the FSARs for the original design (all-welded stainless steel fuel basket) that were affected by the changes to the CBS design fuel basket variants (MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS). The impacted elements included the demonstration of the design criteria of the fuel basket; mathematical model associated with material performance and tip-over analysis; calculational framework on connections between fuel basket and shims; use of revised version of software; new assumptions, etc.

Apparent Violation C:

Per 10 CFR 72.146(c), “Design control,” requires, in part, that a certificate holder shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license or CoC require prior NRC approval.

Contrary to the above, Holtec failed to subject design changes, including field changes, to design control measures commensurate with those applied to the original basket design. Specifically, in four examples prior to February 17, 2021, July 19, 2021, May 13, 2020, and November 6, 2020, Holtec failed to subject design changes from the MPC 68M, 32M, 89, and 37 standard basket designs to the MPC 68M-CBS, 32M-CBS, 89-CBS, and 37-CBS basket variants to design control measures commensurate with those applied to the original design, and made changes in the conditions specified in the license that required prior NRC approval. Holtec failed to perform adequate tip-over calculations and to model the basket shim bolts for the four CBS basket variants. In addition, material strength assumptions were different, the deflection design criteria of the fuel baskets were not demonstrated, and thermal expansion interference was not calculated in the CBS baskets.

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 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, 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, 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 NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as “Non-cited Violation” 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* Section 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 predecisional enforcement conference 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 predecisional enforcement conference with the licensee and the level of sanction proposed or imposed.

Discussion

Comprehensive corrective action is required for all violations. In most cases, 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.

4.

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?

5. Has your staff been adequately trained on the applicable requirements?

6. 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?

7. Has your staff been notified of the violation and of the applicable corrective action?

8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?

9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?

10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?

11. Is a system in place for keeping abreast of new or modified NRC requirements?

12. Does your staff appreciate the need to consider safety in approaching daily assignments?

13. 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?

14. Have work hours affected the employees' ability to safely perform the job?

15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?

16. 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?

17. Has management established a work environment that encourages employees to raise safety and compliance concerns?

18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?

19. Has management communicated its expectations for safety and compliance?

Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?