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

November 29, 2018

EA-18-151

Dr. K. P. SINGH
President and CEO
Holtec International
Krishna P. Singh Technology Campus
1 Holtec Boulevard
Camden, NJ 08104

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION INSPECTION REPORT 07201014/2018-201, HOLTEC INTERNATIONAL

Dear Dr. Singh:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) announced routine inspection at your Holtec International (Holtec) corporate office in Camden, New Jersey from May 14-18, 2018. The inspection assessed the adequacy of Holtec's activities with regard to the design of spent fuel storage casks 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." The staff examined activities conducted under your NRC approved Quality Assurance (QA) 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). Within these areas, the inspection consisted of an examination of selected procedures and representative records, observations of activities, and interviews with personnel. The inspector discussed the preliminary inspection findings with you at the conclusion of the on-site portion of the inspection, and in subsequent telephonic discussions on July 19, 2018, September 5, 2018, and November 26, 2018.

Based on the information developed during the inspection, two apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

The apparent violations involve: (1) failure to establish adequate design control measures as a part of the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are important to safety, in accordance with 10 CFR 72.146(a), "Design control", and (2) failure to perform a 10 CFR 72.48 evaluation when required. The apparent violations, and associated inspection report, are listed in Enclosures 1 and 2.

During a November 26, 2018, telephonic exit meeting, you and Mr. Earl Love of the NRC, discussed these apparent violations, the significance of the issues, and the need for lasting and effective corrective action.

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

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

If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. If you decide to participate in a PEC or pursue ADR, please contact Ms. Patricia Silva at 301-415-7399 or e-mail (patricia.silva@nrc.gov) within 10 days of the date of this letter. A PEC or ADR should be held within 30 days of the date of this letter.

The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to assist the NRC in making an enforcement decision. This 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. The conference will include an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. The information should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. This information may reference or include previously docketed correspondence. In presenting any corrective actions, you should be aware that the promptness and comprehensiveness of the actions will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed (Enclosure 3) excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in assessing adequate corrective actions.

Following the PEC, you will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding the apparent violations is required at this time.

In lieu of a PEC, you may request 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 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 ADR program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. You must contact ICR at (877) 733-9415 within ten (10) calendar days of the date of this letter if you are interested in pursuing resolution of this issue through ADR. If you choose to request 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 Confirmatory Order to document the agreement. The Confirmatory Order is typically publicly available.

If you do not contact us regarding your participation in either a PEC or ADR within the time specified above and the NRC has not granted an extension of the contact time, we will make an enforcement decision based on available information.

In addition, please be advised that the number and characterization of apparent violations described in the enclosures may change 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 2.390 of the NRC's "Rules of Practice," 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 or from the NRC's Agencywide Documents Access and Management System, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. 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-18-151, 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, Michael C. Layton, Director, Division of Spent 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 Ms. Patricia Silva, of my staff at (301) 415-7399 or e-mail (patricia.silva@nrc.gov)

Sincerely,

/RA/

Michael C. Layton, Director
Division of Spent Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No. 72-1014

Enclosures:
1. Apparent Violations Being Considered for Escalated Enforcement
2. Inspection Report 07201014/2018-201
3. NRC Information Notice 96-28

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION IINSPECTION REPORT 07201014/2018-201, HOLTEC INTERNATIONAL, DOCUMENT DATE: November 29, 2018

DISTRIBUTION:
DSFM r/f NMSS r/f YDiaz-Sanabria/NMSS PSilva/NMSS ELove/NMSS
MBurgess/NMSS RPowell/RI JKatanic/RIV

ADAMS Accession Number: ML18306A853

OFFICE	NMSS/DSFM	NMSS/DSFM	NMSS/DSFM	NMSS/DSFM (prior to OE)	NMSS/EC
NAME	ELove	WWheatley	PSilva	MLayton	MBurgess Via email
DATE	11/01/18	11/02/18	11/01/18	11/07/18	11/08/18
OFFICE	OE	OGC	NMSS/DSFM (final signature)		
NAME	DFurst (acting BC) via email	LBaer via email	MLayton		
DATE	11/16/18	11/16/18	11/29/18		

OFFICIAL RECORD COPY

APPARENT VIOLATIONS BEING CONSIDERED FOR ESCALATED ENFORCEMENT

Apparent Violation A:

10 CFR 72.146(a), “Design control,” requires, in part, that measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are important to safety.

Contrary to the above, Holtec failed to establish adequate design control measures as a part of the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are important to safety. Specifically, on or after August of 2016, Holtec failed to establish adequate design control measures as a part of the selection and review for suitability of application for alternative four-inch stainless steel standoff pins. The standoff pins are essential to the function of the fuel basket to maintain support and ensure that the shims stay elevated to allow airflow to the fuel assemblies within the multi-purpose canister.

Apparent Violation B:

10 CFR 72.48(d)(1) 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, as of July 19, 2018, the certificate holder (Holtec) failed to maintain records of changes that included a written evaluation that provided the bases for the determination that the change does not require a CoC amendment pursuant to 10 CFR 72.48(c)(2). Specifically, Holtec failed to perform a written evaluation to demonstrate that a design change for multi-purpose canister stainless steel standoff pins did not require a CoC amendment. Holtec completed a 72.48 screening and incorrectly determined that a written evaluation was not needed.

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

Inspection Report

Docket:	72-1014
Report:	72-1014/2018-201
Certificate Holder:	Holtec International Krishna P. Singh Technology Campus 1 Holtec Boulevard Camden, NJ 08104
Inspection Dates:	May 14, through July 19, 2018
Inspection Team:	Earl Love, Senior Transportation & Storage Safety Inspector, Team Leader Marlone Davis, Senior Transportation & Storage Safety Inspector Carla Roque-Cruz, Safety Inspection Engineer Meraj Rahimi, Acting Branch Chief, Inspections & Operations Branch Darrell Dunn, Senior Materials Engineer, Renewals & Materials Branch Anthony Rigato, Structural Engineer, Containment, Structural and Thermal Branch
Approved by:	Patricia Silva Inspections and Operations Branch Division of Spent Fuel Management Office of Nuclear Material Safety and Safeguards

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

EXECUTIVE SUMMARY

Holtec International
NRC Inspection Report 721014/2018-201

On May 14, 2018, to May 18, 2018, the U.S. Nuclear Regulatory Commission (NRC) staff performed an inspection at Holtec International (Holtec) corporate office in Camden, NJ. The staff continued the inspection activities and completed the in-office review on July 19, 2018. The purpose of the inspection was to assess Holtec's activities with regard to the design of spent fuel storage casks 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." The inspection scope included reviews of Holtec's implementation of the 10 CFR 72.48 change process, including an on-going Holtec root cause investigation of a cask system design change made that modified the support structure of their multi-purpose canister (MPC) fuel baskets as documented in Holtec's 72.48 Nos. 1212. Specifically, Holtec made a design change to the MPC fuel basket shims under the 10 CFR 72.48 change process.

Based on the results of this inspection, the NRC staff assessed that the implementation of your Quality Assurance (QA) program did not meet certain NRC requirements in the areas of design control and 10 CFR 72.48 evaluations. This resulted in one apparent Severity Level IV violation of NRC requirements, with two examples. Specifically, Holtec failed to obtain license amendments prior to implementing changes: a) to specifications incorporated in the CoC, and (b) that would create a possibility for a malfunction of a different result than any previously evaluated in the final safety analysis report (FSAR).

In addition, two apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The apparent violations are described in the subject inspection report and are applicable to the possibility of unanalyzed design basis heat load conditions of multi-purpose canisters and failure to perform a 10 CFR 72.48 evaluation when required. Since the NRC has not made a final determination in this matter, no final action is being issued at this time.

As summarized in Table 1 below, one Apparent Severity Level IV and two Apparent Escalated Violations 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	Changes, tests, and experiments	2	Apparent SLIV Violation	3.4.2
72.146	Design Control	1	Apparent Escalated Violation	3.4.2

72.48	Changes, tests, and experiments	1	Apparent Escalated Violation	3.4.2

REPORT DETAILS

1.0 Inspection Scope

On May 14 - 18, 2018, the NRC conducted an announced inspection at the corporate headquarters of Holtec International (Holtec) in Camden, NJ. The inspection focused on an assessment of Holtec's activities with regard to the design of spent fuel storage casks (Table 1) with the requirements of Title 10 CFR Part 72, as well as, a review of various Holtec 10 CFR 72.48 reports, including, Holtec's root cause investigation of a cask system design change made that modified the support structure of multipurpose canister fuel baskets as documented in Holtec's 72.48 Nos. 1212.

Table 1
List of Holtec Storage Design Models

Storage Design Model #	Docket / Certificate #	Amendment	FSAR (as updated)
HI-STAR 100	07201108	2	HI-STAR, Revision 3
HI-STORM 100	07201014	10	HI2002444, Revision 14
HI-STORM FW	07201032	3	HI2114830, Revision 5
HI-STORM UMAX	07201040	2	HI2115090, Revision 4

1.1 Inspection Procedures and Guidance Documents Used

IP 60851, "Design Control of ISFSI Components," dated 1/16/08
IP 60857, "Review of 10 CFR 72.48 Evaluations," dated 10/24/07
NUREG/CR 6314, "Quality Assurance Inspections for Shipping and Storage Containers"
RG 3.72, "Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments"

1.2 List of Acronyms Used

ACPL	Approved Computer Program List
AVL	Approved Vendor List
CFR	Code of Federal Regulations
CGD	Commercial Grade Dedication
CoC	Certificate of Compliance
DSFM	Division of Spent Fuel Management
ECO	Engineering Change Order
FSAR	Final Safety Analysis Report
HQP	Holtec Quality Procedure
HSP	Holtec Standard Procedure
IP	Inspection Procedure
ITS	Important to Safety
ISFSI	Independent Spent Fuel Storage Installation
kW	Kilowatt
MPC	Multi-purpose canister
NEI	Nuclear Energy Institute
NOV	Notice of Violation

NRC	Nuclear Regulatory Commission
PO	Purchase Order
PS	Purchase Specification
QA	Quality Assurance
QAM	Quality Assurance Manual
QI	Quality Issue
RRTI	Response to Request for Technical Information
SER	Safety Evaluation Report
SMDR	Supplier Manufacturing Deviation Reports
SONGS	San Onofre Nuclear Generating Station
SSC	Structure, Systems, and Components
TS	Technical Specification
VVM	Vertical Ventilated Module
VYNPS	Vermont Yankee Nuclear Power Station

1.3 Persons Contacted

The team held an entrance meeting with Holtec personnel on May 14, 2018, to present the purpose and scope of the NRC inspection. On May 18, 2018, the team held a briefing to discuss the primarily results on the inspection. On July 19, 2018, the inspection team leader conducted a telephone exit with Holtec's Vice President of Quality Assurance, Mr. Mark Soler. Table 2 documents the individuals present at these meetings.

Table 2
Entrance and Exit Meetings Attendees

NAME	AFFILIATION	ENTRANCE	EXIT (Debrief)	TELEPHONE EXIT
Earl Love	NRC/DSFM	X	X	X
Marlone Davis	NRC/DSFM	X	X	
Carla Roque-Cruz	NRC/DSFM	X	X	
Darrell Dunn	NRC/DSFM	X	X	
Anthony Rigato	NRC/DSFM	X	X	
Meraj Rahimi	NRC/DSFM	X	X	
Dr. K. P. Singh	Holtec		X	
Mark Soler	Holtec	X	X	X
Debu Mitra Majumdar	Holtec	X	X	
P. Stefan Anton	Holtec	X		
Chuck Bullard	Holtec	X	X	
Pankaj Chaudhary	Holtec	X		
Robert Tindal	Holtec	X		
Adam Kabo	Holtec	X	X	
John Griffiths	Holtec	X	X	
Christoper O'Mullane	Holtec		X	

2. Management Controls

2.1 Quality Assurance Policy

The team assessed the adequacy of management controls in the areas of Holtec's QA Program implementation, nonconformance controls, control of conditions adverse to quality, 10 CFR Part 21 reporting, documentation controls, and audit program. The team reviewed Holtec's practices and procedures, and their implementation, to determine the effectiveness of management controls.

2.1.1 Scope

The team reviewed Holtec's quality assurance manual (QAM) and implementing procedures and assessed the effectiveness of the QA Program implementation. The team conducted reviews of Holtec's quality QAM manual, policies, plan, and procedures, and discussed portions of the reviewed documents with selected employees to determine whether activities subject to 10 CFR Part 72 were adequately controlled and implemented under Holtec's NRC approved QA program. Further, the team interviewed Holtec QA personnel and assessed if they had appropriate independence from cost, schedule, and production activities. The team noted that the NRC-approved QA Program is applied at both the Holtec corporate offices located in Camden, NJ, and at the Holtec Manufacturing Division located in Turtle Creek, PA. The team reviewed Holtec's Quality Procedure HQP 1.0, "Organization and Responsibilities", Revision 44, dated January 10, 2018, and HQP 2.0, "Quality Assurance Program", Revision 25, dated April 27, 2018.

2.1.2 Observations and Findings

The team noted that Holtec's procedures are organized in tiers with the Holtec's QAM as the first tier followed by the Holtec Quality Procedures (HQPs). Holtec Standard Procedures (HSPs) are developed as needed to provide implementation details to support the HQPs. These implementing procedures were all in place, used, and effective. Further, the team interviewed Holtec personnel responsible for these QA Program areas, noted that they were knowledgeable of the program requirements, and were implementing the program as required.

The team noted that Holtec's QA Program and manual is in accordance with 10 CFR Part 72, Subpart G, "Quality Assurance." Implementation of the QA Program is achieved through the HQPs, HSPs and Holtec's project procedures (HPPs). The team also reviewed Holtec's organizational charts, staff responsibilities and QA organization independence. The team noted that the QA department has direct access to Holtec's upper management and is independent from the areas it oversees.

Holtec's QA Program uses a graded approach for classification of components important to safety (ITS) as one of three classification categories (A, B, or C). HQP 7.0, "Control of Purchased Items and Services", Revision 21, dated November 10, 2018, addresses the evaluation and selection for use of approved vendors as required by the category or the items and services. Holtec's HSPs and HPPs identify where and when graded approach is implemented and the required activities and processes to follow.

The team reviewed procedures and documents regarding training, qualification, and certification of personnel. The team interviewed the QA Manager about training and the dissemination of information to the necessary personnel in a timely manner. A sample of annual training was

corroborated through document review. The team noted that the system used does not allow the respective personnel to access their respective procedures to perform their work until the associated training activity is completed for the updated document.

2.1.3 Conclusions

The team determined that QA controls at Holtec were adequate and that activities associated with QA organization, independence, and roles and responsibilities were in accordance with Holtec's NRC approved QA Program.

2.2 Nonconformance Controls

2.2.1 Scope

The team reviewed selected records and interviewed personnel to verify that Holtec effectively implemented a nonconformance control program in accordance with their NRC approved QA Program, and the requirements of 10 CFR Part 21 and Part 72. Specifically, the team reviewed Holtec's approved procedure HSP-101502, "Control of Nonconforming Conditions," Revision 0. The team selected a number of nonconformance reports (NCRs) to verify that the NCRs were identifiable, traceable, and the disposition of the nonconformance was adequate. The team reviewed NCRs since the previous 2014 inspection and concentrated on issues involving ITS structures, systems, and components (SSCs). The team reviewed these NCRs to evaluate if the disposition was appropriate, adequately performed as necessary, and properly closed out in accordance with the approved procedure. The team focused the review on "accept-as-is" and "repair" dispositions because generally these NCRs require a technical justification or engineering evaluation. This also included a review of supplier manufacturing deviation reports (SMDRs).

In addition, the team reviewed Holtec's approved procedure HSP-101501, "Reporting of Defects per 10 CFR 21 or 10 CFR 50.55e," Revision 0, to determine if provisions were in place for reporting defects that could cause a substantial safety hazard from the NCRs and quality issues (QIs) identified. This review also included an assessment of NCRs and QI logs for compliance with 10 CFR 72.242(d).

2.2.2 Observations and Findings

The team assessed that Holtec adequately dispositioned and closed each selected NCR and SMDR in accordance with the requirements of procedure HSP-101502, as applicable.

In addition, the team noted that there were no Part 21 reports issued for the past four years. The team noted that Holtec performed a 10 CFR Part 21 evaluation for the deviation and noncompliance for the shim standoffs as a part of QI 2418. The team noted QI 2418 concluded that the shim standoffs would not result in a substantial safety hazard and therefore, the deviation was not reportable. The team had lengthy discussions on the Part 21 evaluation for a design change associated with the fuel basket shims. The discussions centered on the reporting requirements of 10 CFR Part 21 for a deviation in a basic component that Holtec delivered to several purchasers. The team also emphasized the definition of "defect" to Holtec in that based on an evaluation, a deviation could create a substantial safety hazard and not that it actually created a substantial safety hazard. The team mentioned this aspect of the definition because general licensees with empty MPCs that are stored in the warehouse could have

loaded up to their maximum heat load with noncompliant shim standoffs. Further discussion on the Part 21 evaluation performed by Holtec is in Section 3.4.2 of this report.

2.2.3 Conclusions

The team concluded Holtec effectively implemented its nonconformance control program and has adequate procedures in place to ensure compliance with the applicable regulations and approved QA Program requirements. The team also concluded that Holtec has provisions in place for reporting defects that could cause a substantial safety hazard and contain design deficiencies that affects the SSCs ITS to perform their intended safety function, as required by 10 CFR Part 21 and 10 CFR 72.242(d), respectively. The Part 21 postings in Holtec's Camden, NJ facility met the approved implementing procedure and the applicable requirements of 10 CFR Part 21.

2.3 Corrective Actions

2.3.1 Scope

The team reviewed selected records and interviewed personnel to verify that Holtec effectively implemented a corrective action control program in accordance with the NRC approved QA Program and the requirements of 10 CFR Part 72. Specifically, the team reviewed Holtec's approved procedure HSP-101601, "Corrective Actions," Revision 1. The team reviewed QIs since the previous 2014 inspection and concentrated on issues involving ITS SSCs. The team reviewed selected records and interviewed selected personnel to verify that Holtec completed corrective actions for identified deficiencies in a technically sound and timely manner. Additionally, the team followed up on a concern the NRC technical staff had on a design change Holtec performed on the HI-STORM UMAX for the Vertical Ventilated Module (VVM) version B closure lid. Holtec documented the concern in QI 2297.

2.3.2 Observations and Findings

Round vs Square Lid for the HI-STORM UMAX

The team assessed how Holtec evaluated a concern the NRC technical staff discovered regarding the VVM closure lid dose rate measurements described in HI-STORM UMAX technical specifications (TS). The team reviewed QI 2297 and the UMAX TS, Sections 5.3.4 and 5.3.8. The TS compliance issue concerned how the general licensees may take dose rate measurements on the new lid because there was no technical basis for this limit in the shielding analysis of the HI-STORM UMAX FSAR (as updated) performed to demonstrate compliance with 10 CFR 72.236(d).

The team noted that Holtec had changed the design of the UMAX lid that provides shielding and thermal cooling for the canisters during storage using a 72.48 evaluation. Specifically, the team noted a design change from a circular to a square lid (Version B). TS Section 5.3.4 limited the average dose rates allowed on the top of the loaded VVM closure lid to 30 mrem/hr (gamma+neutron). TS 5.3.8 specifies the location the general licensee shall measure the VVM lid for dose rates (i.e., 18 inches from the edge of lid) to ensure limits are not exceeded. This location was intended to be in the area of the VVM annulus. If the general licensee exceed the dose rate limits, then they must evaluate for a possible off normal loading event or evaluate whether a change to their offsite dose calculations are necessary. General licensees also use these TS dose rate limits in their emergency action level schemes to declare an unusual event.

The team and the technical staff noted that the new square lid measurement location, as specified by TS 5.3.8, would be taken approximately 10 inches further away from the annulus than that of the round lid. Therefore, if the general licensee used the square lid, then the dose rate measurement would be in a different location than the round lid. In order to resolve any uncertainty, Holtec requested NRC staff to review the enhanced lid version for compliance with the HI-STORM UMAX system SER and CoC (ADAMS ML17286A702). However, since this document was not submitted for a regulatory purpose (licensing action, corrective action, etc.) the NRC staff did not conduct a review.

The team discussed the methodology for performing the dose rate measurements in accordance with TS Sections 5.3.4 and 5.3.8 using the square closure lid with Holtec. The team noted that the dose rate of 30 mrem/hr was not derived from an analysis supported in the FSAR. The team noted that the QI 2297 captured the staff concerns and that Holtec committed to submitting an analysis to calculate, measure and document dose rates specific to the particular closure lid as part of a future amendment submittal for the HI-STORM UMAX system to satisfy the intent of TS Section 5.3 (ADAMS ML18024A451, ML18156A134, and ML18241A092).

2.3.3 Conclusions

Overall, the team assessed that Holtec had an adequate corrective action program in place to resolve deficiencies. The team determined that Holtec, in general, completed corrective actions for identified deficiencies in a technically sound and timely manner.

2.4 Documentation Controls

2.4.1 Scope

The team reviewed Holtec's documentation control program and procedures to assess the effectiveness of controls established for the approval, issuance, revision and use of quality documents. The team reviewed a sample of Holtec documents (general procedures, records, drawings, and specifications) to verify that Holtec performed and controlled the quality activities suitably. The team reviewed the following documents:

- HQP 6.0, "Document Control," Revision 14,
- HQP 17.0, "Quality Assurance Records," Revision 27,
- HSP 100201, "Quality Assurance Manual and Procedures," Revision 1, and
- HSP 100502, "Standard and Project Procedures", Revision 1

The team also interviewed QA personnel regarding documentation controls.

2.4.2 Observations and Findings

The above mentioned documents establish the processes for the preparation, approval, revision, distribution and control of Holtec's QAM, QA procedures and procedures for safety significance activities. The team noted that the Vice President of Quality is responsible for writing some of the procedures and for reviewing and approving procedures developed by other QA staff. The Vice President of Quality is also responsible for adding the new procedures or new version of a procedure in the appropriate folder in Holtec's QA software and sending an email to the company with the information and location for the new procedure. Once this is

done, previous versions of procedures are removed to an archive within the QA software. Currently, Holtec keeps all QA records electronically. Record retention guidance can be found in the HQPs and HSPs and in the QA software.

2.4.3 Conclusions

The team concluded that Holtec conducts its activities associated with QA documentation controls in accordance with their NRC approved QA program.

2.5 Procurement Controls

2.5.1 Scope

The team assessed Holtec's process of material procurement, which included the review of procurement documents, material traceability, drawings and procedures, and receipt inspection records.

2.5.2 Observations and Findings

The team verified that procurement of ITS, Category A items and services were made to suppliers listed on Holtec's approved vendors list (AVL) for that procurement scope. The team reviewed a sample of procurement documents. Specifically, the team reviewed Holtec's commercial grade dedication (CGD) for the procurement (purchase order (PO) No. 111656) of SA240 "Alloy X" plate used on various MPC's (68, 68M and 37) shell, baseplate, closure ring and port covers. The team noted Holtec commercially dedicated the components and maintained traceability from receipt of items until completion of CGD and receipt inspection. Additional layers of traceability were added by association with a numbered CGD report and quality plan, purchase specification, material test and examination reports, and a receipt inspection report.

The team reviewed ITS-A procurement of SA240 "Alloy X" plate (PO No. 110310) used for the basket shell plate. The team noted the procurement was made to a vendor that was audited, approved and maintained on Holtec's AVL. The team noted that the procurement of the items complied with the requirements of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, Section III, as applicable, and Holtec's procurement requirements (e.g., POs and specifications), 10 CFR Part 72, Subpart G, and Holtec's QAM. Overall, the team noted ITS-A procurement and CGD activities were satisfactorily identified and controlled in accordance with HSP-100705, "Procurement of Items and Services from Unqualified Vendors," HSP-100402, "Purchase Specification," HSP-100401, "Processing of Purchase Orders," and HSP-100701, "Receipt Inspection."

The team reviewed Holtec's external audit program to determine if Holtec scheduled and performed supplier audits and annual evaluations in accordance with approved quality procedures. Specifically, the team reviewed HSP-100704, Revision 1, "Approved Vendors List," HQP-7.0, Revision 21, "Control of Purchased Items and Services," HSP-100702, Revision 0, "Vendor Surveillances," and HSP-100703, Revision 0, "Vendor Selection." The team reviewed a material supplier commercial grade survey (Outokumpu Americas Inc.) and an external vendor audit (Forge Monchieri). Overall, the team identified no concerns with Holtec's supplier survey, audit and supplier evaluation program. The team verified that for the audit sampled, Holtec conducted the audit and survey with qualified and certified personnel, scheduled and

evaluated applicable elements of the QA Program, and resolved findings and observations in a timely manner.

2.5.3 Conclusions

The team assessed that Holtec is satisfactorily implementing its procurement control program and have adequate procedures in place to ensure compliance with the applicable regulations and QA program requirements. In addition, supplier audits were assessed to be comprehensive and contained findings and observations. No concerns were identified with procurement controls and Holtec's external audit process.

2.6 Audit Program

2.6.1 Scope

The team reviewed Holtec's audit program to determine whether plans, procedures, and records were available. In addition, the team assessed Holtec's performance of internal QA audits for compliance to approved quality procedures and audit checklists; auditor independence and qualifications, appropriate level of management reviews, and corrective actions in those areas found to be deficient.

2.6.2 Observations and Findings

The team reviewed Holtec's internal audit program to determine if Holtec scheduled, planned, and performed internal audits in accordance with approved quality procedures. Specifically, the team reviewed HSP-101802, Revision 0, "Audits," and HSP-101801, "Certification of Lead Auditor Qualifications". The team selected an internal audit (No. 2018-I01) of the Holtec Camden, NJ facility performed January-March 2018. The team noted the audit included both Corporate (design, project management, procurement, etc.) and the manufacturing facility. The team reviewed the audit results to determine if Holtec identified deficiencies and addressed the deficiencies with their corrective action program. The team noted that the auditors identified twelve (12) QI's during the audit and that all the issues were captured on QI reports. The team noted the status of the QI's in that six (6) were closed and evidence provided included appropriate corrective actions and that the additional six (6) QI's were open in which the majority were pending QA verification of implementation of corrective actions.

2.6.3 Conclusions

Overall, the team determined that the audit reviewed was conducted by a qualified and certified auditor, was thorough and encompassed sufficient objective evidence satisfying all the elements of Holtec's QA Program.

3. Design Controls

3.1 General

The team assessed the design control program described in Holtec's governing procedures to determine whether Holtec implemented design controls and design changes to their dry cask storage system components used at independent spent fuel storage installations. The team reviewed selected design change packages, and interviewed Holtec personnel involved in the design control process.

3.2 Design Development

3.2.1 Scope

The team reviewed the design control section of the Holtec QAM Revision 14 and specifically reviewed the following Holtec quality and standard procedures associated with design control to verify that Holtec properly implemented their design control program. The design procedures are as follows:

- HQP-2.0, "Quality Assurance Program," Revision 25
- HQP-3.0, "Project Planning, Design Control, Product Realization and Project Execution," Revision 29
- HSP-100202, "Project Planning, Product Realization and Project Execution," Revision 0
- HSP-100301, "Design Specifications and Design Criteria Documents," Revision 0
- HSP-100302, "Design Control," Revision 0
- HSP-100303, "Design and Analysis Personnel Qualifications," Revision 1
- HSP-101101, "Computer Programs," Revision 0

3.2.2 Observations and Findings

The team verified that design responsibilities were assigned appropriately and verified that the responsible parties were performing acceptable reviews. The team interviewed personnel at the manager, project manager, and engineer levels. The team noted Holtec implements an electronic system for document distribution, tracking, and design development and control.

The team reviewed selected drawings, calculation packages, design verification checklists, design specifications, purchasing specifications and other design control records to verify that materials, equipment, and services met design requirements, Holtec's CoC No. 1014, Amendment 10, FSAR No. HI-2002444, Revision 14, for the HI-STORM 100 Cask System; CoC No. 1032, Amendment 3, FSAR No. HI-2004830, Revision 5, for the HI-STORM FW Cask System; and CoC No. 1040, Amendment 2, FSAR No. HI2115090, Revision 4, for the HI-STORM UMAX Cask System to assure compliance with approved methods, procedures, and specifications. The team noted that Holtec uses a network database that organizes information needed to maintain configuration control for licensing and design basis documentation.

The team reviewed purchase specification (PS) 1601, "Purchase Specification for the Damaged Fuel Container (Ancillary No. 601)" Revision 9 dated May 6, 2018." The team noted that the Damaged Fuel Container was evaluated and classified as ITS-C and that the PS defined and addressed adequate technical and quality requirements as defined by HSP-100402.

The team assessed Holtec's methods for the development, control, verification, validation, and documentation of computer programs used for safety significant activities and noted an Approved Computer Program List (ACPL) as maintained on the network. Computers that run a safety significant computer program (those identified on the ACPL) are run using the operating system and version identified on the ACPL for that particular computer code. The ACPL identifies the computer program; safety designation; individuals qualified to use programs; operating subsystem and version; and any limitations/restrictions. The team reviewed Holtec's ACPL, dated April 20, 2018, and noted that codes on the list required validation under Holtec's QAP. The team noted that the program list was categorized by software title (e.g., ANSYS (A),

Fluent (A), LS-Dyna (A)), applicable docket number, version, users, any special limitations, operating system and version, and identification of approved computers.

3.2.3 Conclusions

Overall, PS's define and address technical and quality requirements and Holtec's methods for the development, control, verification, validation, and documentation of computer programs used for safety significant activities were adequate. No concerns were identified.

3.3 Project Planning

3.3.1 Scope

The team reviewed customer project plans that were written to guide project management, project execution, and project controls in order to satisfy the project execution. The team noted plans contained project based objectives and provided descriptions of equipment, components, and pool to pad services to accommodate implementation of the HI-STORM 100S Version B system and UMAX, respectively.

3.3.2 Observations and Findings

The team noted the plans translated Client's technical and quality requirements into the execution phase and evaluated the risks to the project, including licensing risk. In addition, both plans used the proper forms, were compliant with procedural requirements, signed off by the Project Manager and an independent reviewer, and had received proper approval by a QA representative.

3.3.3 Conclusions

Overall, no concerns were noted, each project plan contained necessary information to enable the project team to execute the project in a controlled manner and to assure that products and services meet customer requirements.

3.4 Design Changes

3.4.1 Scope

The team reviewed selected records and interviewed personnel to assess Holtec's design change process associated with modifications. The team focused its review in the following areas: 1) adequacy of Engineering Change Orders (ECOs) and 2) adequacy of 10 CFR 72.48 screenings and evaluations. The team reviewed Holtec procedures related to the implementation instructions for 10 CFR 72.48 evaluations and control of modification activities. Specifically, the team reviewed Holtec's approved procedure HSP-321, "Screening and Evaluation of Changes," Revision 5. The team reviewed a list of screenings and evaluations performed by Holtec to meet the regulatory requirements associated with 10 CFR 72.48. The team selected a representative sample of screenings and evaluations based on a judgement of risk significance and the potential impact on the functionality of the dry cask storage systems.

The team reviewed selected ECOs and 72.48 screenings and evaluations performed since the last inspection in June 2014, as well as, 2016 and 2018, 10 CFR 72.48(d)(2) reports, "Biennial

Summaries of Changes, Tests, and Experiments," relating to HI-STAR 100, HI-STORM 100, HI-STORM FW, and HI-STORM UMAX Dry Cask Storage Systems.

3.4.2 Observations and Findings

As a part of the scope for this inspection, the team specifically selected a design change related to a discovery of a broken shim standoff pin in a delivered MPC to one of Holtec consumers. The team evaluated the design change Holtec made in August 2016 to the fuel basket shims fabrication activities. The team reviewed and assessed ECO 102-23, 72.48 evaluation number 1212, and the licensing and fabrication drawings associated with this design change. Holtec used the ECO and 72.48 evaluation process to allow for the use of alternative four-inch stainless steel standoff pins instead of machining the shim bottom to form cutouts for helium flow. The fuel basket shims have two ITS functions: (1) to provide structural support of the fuel basket and (2) to ensure that the shims stay upright to allow helium flow for thermal heat transfer within the MPC.

The team identified a number of deficiencies with Holtec's design control process. The team noted that the ECO did not consider all the impacts that would affect the functionality of the shims such as the installation, general MPC handling and manufacturing operations, the potential for lateral loads based on existing gaps within the MPC, and conditions adverse to quality identified during installation, when personnel discovered issues with the shim standoff pins. This design change affected three MPC types (37, 89 and 68M) and several general licensees because Holtec had delivered a number of systems to several purchasers. Holtec identified and documented the results for this problem in a root cause evaluation as described in QI 2418. However, the team determined that based on these design deficiencies identified in the ECO, and the 72.48 evaluation, Holtec needed prior NRC approval to make this design change prior to implementation because under a design basis earthquake, this change created a possibility for a malfunction of an SSC ITS with a different result than that evaluated in the FSAR. Holtec had determined in the 72.48 evaluation that this was a non-credible failure. However, with the potential for lateral loads based on existing gaps within the MPC and standoff pins installed missing, bent, or broken, the loss of redundant shim standoff pins was a credible failure mode.

The team assessed that this was a violation of NRC requirements. Specifically, 10 CFR 72.146(a), "Design control," requires, in part, that measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are ITS.

Contrary to the above, on August 26, 2016, Holtec did not establish measures for the selection and review for suitability of the application of alternative stainless steel standoff pins (i.e., instead of machining the shim bottom to form cutouts) which were essential to the function of the fuel basket and MPC that are ITS. Specifically, Holtec failed to establish adequate design control measures as a part of the selection and review for suitability of application for alternative four-inch stainless steel standoff pins. The standoff shims are essential to the function of the fuel basket to maintain support and ensure that the shims stay elevated to allow airflow to the fuel assemblies within the multi-purpose canister. During the design review process for the change, Holtec did not consider all the impacts that would affect the functionality of the shims such as the installation; general MPC handling and manufacturing operations (e.g., peening the canisters); the potential for lateral loads based on existing gaps within the MPC; and conditions adverse to quality identified during installation when personnel discovered defects with the shim standoff pins. The team determined that this violation was more than minor because these

design deficiencies during the selection and review could affect the ability of the fuel basket shims to perform their intended safety function.

In addition, with respect to casks currently in operation, the NRC recognizes that Holtec informed licensees of the need to restrict the operation of MPCs to decay heat loads below NRC's approved design basis limits. The NRC will verify if all applicable MPC's have been loaded at or below Holtec restricted heat limits. The NRC will need additional information in order to evaluate and determine whether or not NRC agrees that the MPCs will not exceed the peak cladding temperature (PCT) under the restricted loading limits. As such, the staff considered all relevant examples in the Enforcement Policy based on the potential consequence of the violation creating a credible accident and exposure scenario. The potential consequence was a loss of all redundant shim standoff pins in a MPC following an external event. This could present a challenge to the integrity of the fission product barrier because it would restrict airflow to the stored fuel assembly inside the MPC resulting in increased PCT and pressure. Therefore, the potential safety consequence is damage to the fuel cladding and a potential release.

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.

10 CFR 72.48 Screenings and Evaluations

The team assessed a sample of twenty-three 10 CFR 72.48 evaluations and screenings to verify that Holtec appropriately concluded that changes did not require prior NRC approval or a full evaluation following a screening in accordance with NRC requirements and Holtec procedures. Based on the team's assessment, the team identified issues in the following areas:

- Incorrectly concluded that a change did not affect the technical specification incorporated in the CoC;
- Incorrectly determined that a change did not meet one of the 10 CFR 72.48 criteria and therefore required prior NRC review and approval before implementing the change; and
- Did not conduct a full evaluation for a change after performing a 10 CFR 72.48 screening indicated the need for an evaluation.

The team identified three apparent 10 CFR 72.48 violation examples The details of each example are described below.

HI-TRAC VW Version V

The team evaluated the HI-STORM FW, FSAR, HI-2114830, and assessed the 72.48 evaluation number 1303 associated with a design change to the transfer cask (HI-TRAC VW) for the CoC No. 1032. Holtec made a change that introduced a new HI-TRAC VW. This new version of the HI-TRAC VW, Version V, included an airflow inlet into the bottom lid to improve thermal performance. The addition of the inlet and outlet airflow vents required continuous monitoring by operator personnel and operator action if the vents became blocked. The team noted that the addition of these new inlet and outlet vents could have an impact on thermal performance of the HI-TRAC VW and on radiation protection for the workers.

The team also noted similarities between 72.48 No. 1303 and the example in Regulatory Issue Summary 2006-22, "Lessons Learned from Recent 10 CFR Part 72 Dry Cask Storage Campaign." Specifically, the team had questions related to the TS requirements for the HI-

TRAC surface dose rates and the thermal analysis with the addition of the new operator actions. The team asked whether this constituted a change in the method of evaluation and if the blockage of the vents constitute a new off normal or accident condition. Holtec stated that the routine visual observation of the ventilation flow paths is similar to an approved method of confirming that operator personnel maintained the thermal performance of the HI-STORM overpack, so requiring visual observation of the HI-TRAC Version V vents does not constitute a new method of evaluation. Holtec also stated that the blockage of the inlet vents was determined to be a non-credible event because operators would not leave the loaded HI-TRAC Version V unattended. Holtec stated that the addition of the vents necessitated a change in procedure (i.e., requirement for constant inspection of the vents). Holtec considered both elements of the proposed activity interdependent, and evaluated them together. Holtec concluded that collectively these two changes did not increase the likelihood of an accident, malfunction, or create a new accident.

The response from Holtec did not agree with the guidance in NEI 96-07 Appendix B (as endorsed by RG 3.72, "Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments"). For example, NEI 96-07 Appendix B 4.3, states, in part, that an increase in frequency or likelihood of occurrence cannot be compensated for by additional mitigating actions (i.e., operator actions). Additionally, NEI 96-07 4.3.2, Example 7, identifies that permanently substituting a manual action for an automatic action for performing FSAR-described design function is an example of a case that would require prior NRC approval because they would result in more than a minimal increase in the likelihood of occurrence of a malfunction. Prior to this change, the HI-TRAC did not need operator actions to perform its FSAR described design function. The team determined that the requirement for an operator to be continuously present and to verify that vents remained free of debris would meet the more than minimal increase in the likelihood of occurrence of a malfunction (e.g., human performance errors). The change also would affect the technical specifications in that it would require an additional surveillance requirement to verify inlet and outlet vents are free of blockage and administrative controls for new surface does rates for the HI-TRAC.

The team assessed that this was a violation of NRC requirement 10 CFR 72.48(c)(1)(ii)(A), which requires, in part, that a certificate holder may make changes in the facility or spent fuel storage cask design as described in the FSAR (as updated), make changes in the procedures as described in the FSAR (as updated), and conduct tests or experiments not described in the FSAR (as updated), without obtaining A CoC amendment submitted by the certificate holder pursuant to § 72.244 (for general licensees and certificate holders) if:

> (A) A change to the technical specifications incorporated in the specific license is not required.

Contrary to the above, as of July 19, 2018, the certificate holder (Holtec) did not obtain a license amendment pursuant to 72.244 for a storage cask design as described in the FSAR because the new HI-TRAC VW, Version V, required a change to the TS incorporated in the CoC. Specifically, Holtec made a change to the HI-TRAC VW that required new operator actions with new dose rates that affected the FSAR design function and specifications. The team determined that the violation was more than minor because permanently substituting a manual action for an automatic action for performing FSAR described design function would require prior NRC approval because it would result in more than a minimal increase in the likelihood of occurrence of a malfunction and a change to the TS, respectively.

This is example one of an apparent Severity Level IV violation (NRC Enforcement Policy Section 6.1.d.2).

MPC Lift Cleat at Pilgrim

On January 21, 2015, at the Pilgrim Nuclear Power Station, Holtec pool to pad personnel reduced the length of one of four MPC lift cleat studs because personnel could not remove the stud from the lifting hole in the MPC lid due to damage. The reduction of one of the MPC lift cleat stud's length was an interim compensatory measure for a degraded and nonconforming condition. Holtec prepared a 72.48 evaluation, #1121, in response to the interim compensatory measure while Holtec prepared to schedule and perform a repair to restore the functionality of the lifting hole. Holtec had proposed to repair the affected lifting hole by removing a section of the MPC lid where the defective stud was and decided to replace it with a welded bushing. The team assessed the 72.48 evaluation and identified issues related to the interim compensatory measure for this degraded and nonconforming condition.

Based on the review of the NRC's HI-STORM 100 SER and the generic unloading procedure in the HI-STORM FSAR, the team noted that Holtec incorrectly concluded that reducing the length of one of four MPC lift cleat studs and continuing to transport the cask to the ISFSI pad required prior NRC review and approval. The SER discussed ready retrieval throughout the structural section and a number of other sections. Additionally, Holtec designed the MPC lift cleats in accordance with NUREG-0612 and American National Standard Institute (ANSI) N14.6 to meet the requirements of single failure proof. There is also a section in the HI-STORM FSAR that discusses repairs following a normal or off-normal condition. The team noted that this would be a new repair as described in the FSAR. The team also noted that the 72.48 evaluation did not discuss the requirements for ANSI N14.6 for the MPC lift cleat studs for meeting single failure proof requirements as described in the HI-STORM FSAR. The team determined that this was a departure from a design standard.

Additionally, the team noted that the NRC, in the SER, relied upon the four MPC lift cleat studs to provide reasonable assurance that the as-design cask system performed its design function, without any repairs, following a normal or off-normal condition. The NRC staff, during the initial review, assumed an intact MPC to allow for safe removal (i.e. ready retrieval) from the overpack or HI-TRAC without any repair. The staff also assumed that it would not pose operational safety problems with respect to its removal that could expose workers to additional dose and would not affect the confinement boundary.

This activity, therefore, requires prior NRC approval because the activity results in the possibility for a malfunction of an ITS SSC to have a different result than any previously evaluated in the FSAR. The team determined that Holtec incorrectly concluded that reducing the length of one of four MPC lift cleat studs and continuing to transport the cask to the ISFSI pad required prior NRC review and approval before implementing such a change. The team assessed that this was a violation of NRC requirements.

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

Contrary to the above, as of July 19, 2018, the certificate holder (Holtec) did not obtain a license amendment after removing one of the four MPC lift cleat studs. The removal of the MPC lift cleat stud created a possibility for a malfunction of a different result than any previously evaluated in the FSAR and SER. Additionally, the change was a departure from the requirements of ANSI N14.6 for single failure proof without performing a repair.

This is an example of an apparent Severity Level IV violation (NRC Enforcement Policy Section 6.1.d.2).

Fuel Basket Shim Standoff Pins for San Onofre Nuclear Generating Station (SONGS) and Vermont Yankee Nuclear Power Station (VYNPS)

On or after August 2016, Holtec conducted a design change (ECO No. 102-23, Revision 1) to the fuel basket shims for the MPC using the 10 CFR 72.48 (No. 1212) evaluation process, to use stainless steel standoff pins at the bottom of the shims instead of machining the shim bottoms to form cutouts for helium flow. On February 18, 2018, during a receipt inspection of the MPCs at SONGS, Holtec discovered a broken shim standoff (initially characterized as a foreign material). As a part of an extent of condition review, Holtec conducted additional inspections on several other SONGS's purchased MPCs and identified more broken and bent shim standoffs. On March 5, 2018, SONGS informed the NRC Region IV office of a potential issue with the broken and bent shim standoff pins. During this period, Southern California Edison (owner/operator) asked Holtec for a response to request for technical information (RRTI) No. RRTI-2464-04. The RRTI provided the technical disposition for accepting the case of a single Alloy X shim standoff becoming detached from one of the hollow basket shims and remaining inside a loaded MPC-37 at SONGS during normal, off-normal, and accident conditions. Holtec also performed a RRTI to accept the loaded MPC at VYNPS.

The team reviewed the RRTIs and Holtec's 72.48 reports (No. 1319 & 1321) used to evaluate the nonconforming and degraded conditions at both SONGS and VY, respectively. The team noted that the report used to evaluate this nonconforming and degraded condition stopped at the 72.48 screening process. The team noted that the loss of the redundant shim standoffs created an adverse impact on the heat transfer design function of the shim and per the Holtec procedure and NEI guidance in 96-07 would have "screened in" to a full evaluation against the eight criteria. The team assessed that this was a violation of NRC requirements related to 10 CFR 72.48(d)(1).

10 CFR 72.48(d)(1) 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, as of July 19, 2018, the certificate holder (Holtec) did not maintain records of changes that included a written evaluation that provided the bases for the determination that the change does not require a CoC amendment pursuant to paragraph (c)(2) of 72.48. The team determined that the violation was more than minor because Holtec did not perform a 10 CFR 72.48 written evaluation when required. The team noted that Holtec initiated QI 2471 to address this issue.

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.

3.4.1 Conclusions

The team identified that Holtec did not correctly conclude that a change did not affect the technical specification incorporated in the CoC; Holtec did not determine that a change met one of the 10 CFR 72.48 criteria and therefore required prior NRC review and approval before implementing the change; and Holtec did not conduct a full evaluation for a change after performing a 10 CFR 72.48 screening.

4. Exit Meeting

On May 18, 2018, the NRC inspection team presented the inspection results and observations during an on-site preliminary exit meeting. On November 26, 2018, the NRC inspection team leader conducted a final telephone conference exit with Mark Solar. Table 2 of this report, shows the attendance for all entrance and exit meetings.

Based on the results of an U.S. Nuclear Regulatory Commission (NRC) inspection conducted at Holtec International (hereafter referred to as Holtec), on May 14, 2018, through July 19, 2018, a team of inspectors identified two Apparent Violations and one Severity Level IV violation of NRC requirements with two examples. In accordance with the NRC Enforcement Policy, the violations are listed below:

APPARENT VIOLATIONS BEING CONSIDERED FOR ESCALATED ENFORCEMENT

Apparent Violation A:

10 CFR 72.146(a), "Design control," requires, in part, that measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are important to safety.

Contrary to the above, Holtec failed to establish adequate design control measures as a part of the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are important to safety. Specifically, on or after August of 2016, Holtec failed to establish adequate design control measures as a part of the selection and review for suitability of application for alternative four-inch stainless steel standoff pins. The standoff pins are essential to the function of the fuel basket to maintain support and ensure that the shims stay elevated to allow airflow to the fuel assemblies within the multi-purpose canister.

Apparent Violation B:

10 CFR 72.48(d)(1) 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, as July 19, 2018, the certificate holder (Holtec) failed to maintain records of changes that included a written evaluation that provided the bases for the determination that the change does not require a CoC amendment pursuant to 10 CFR 72.48(c)(2). Specifically, Holtec failed to perform a written evaluation to demonstrate that a design change for multi-purpose canister stainless steel standoff pins did not require a CoC amendment. Holtec completed a 72.48 screening and incorrectly determined that a written evaluation was not needed.

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" violations as provided in Section VI.A of the Enforcement Policy. Minor violations are not subject to formal enforcement action. Nevertheless, the root cause(s) of minor violations must be identified and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as required by 10 CFR 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?

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