

February 24, 2011

Dr. K. P. Singh
President and CEO
Holtec International
555 Lincoln Drive West
Marlton, NJ 08053

SUBJECT: NRC INSPECTION REPORT NO. 72-1014/10-201 AND NOTICE OF VIOLATIONS

Dear Dr. Singh:

From October 25, through October 29, 2010, the U.S. Nuclear Regulatory Commission (NRC) conducted an announced inspection at the Holtec International (Holtec) offices in Marlton, NJ. From October 29, 2010, through February 10, 2011, the inspection continued at NRC Headquarters in Rockville, MD, on two open items remaining from the on-site inspection.

The purpose of the inspection was to examine design and quality assurance (QA) activities to determine if they were performed in accordance with the requirements of 10 CFR Part 21 and 10 CFR Part 72, the certificate of compliance (CoC), the applicable safety analysis report (SAR), and the NRC-approved QA program. Within these areas, the inspection consisted of selected examinations of procedures and representative records, observations of activities, and interviews with personnel. The enclosed report presents the results of this inspection.

Based on the results of this inspection, the NRC determined that two Severity Level IV violations of NRC requirements occurred. These violations were evaluated 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 violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations are being cited in the Notice because they were identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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, [Add: if you choose to provide one for cases where a response is not required], will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), 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 or proprietary, information so that it can be made available to the Public without redaction.

Sincerely,

/RA/

Eric Benner, Branch Chief
Rules, Inspections, and Operations Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety
and Safeguards

Docket No. 72-1014

Enclosure:

1. NRC Inspection Report No. 72-1014/10-201
2. Notice of Violation

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, [Add: if you choose to provide one for cases where a response is not required], will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), 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 or proprietary, information so that it can be made available to the Public without redaction.

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Docket No. 72-1014

Enclosure:

1. NRC Inspection Report No. 72-1014/10-201
2. Notice of Violation

Distribution: Docket 72-1014
 V.Ordaz, SFST
 D.Weaver, SFST

NMSS r/f
 R. Woodward, OIG
 C.Faria-Ocasio, OE

SFSTr/f
 R.Wharton, SFST

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OFC:	SFST	E	SFST	E	SFST	E	SFST	E	SFST	E	SFST	E
NAME:	JPearson		MDeBose		JGoshen		JSolis		ELove		GBjorkman	
DATE:	2/10/11		2/15/11		2/15/11		2/14/11		2/17/11		2/17/11	
OFC:	SFST	E										
NAME:	EBenner											
DATE:	2/24 /11											

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**U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Spent Fuel Project Office**

Inspection Report

Docket: 72-1014

Report: 72-1014/10-201

Certificate Holder: Holtec International
555 Lincoln Drive West
Marlton, NJ 08053

Date: October 25, 2010 through February 10, 2011

Inspection Team: Jim Pearson, Team Leader, SFST
Earl Love, Safety Inspector, SFST
John Goshen, Senior Project Manager
Jorge Solis, Technical Reviewer, SFST

Approved by: Eric Benner
Rules, Inspections, and Operations Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety
and Safeguards

EXECUTIVE SUMMARY

Holtec International
NRC Inspection Report 721014/10-201

Overall, as a result of the inspection, the team assessed that programmatic problems exist in Holtec's implementation of its NRC approved QA program. The team noted two violations in the QA program implementation. Specifically, team reviewed Holtec screenings and evaluations performed in accordance with 10 CFR 72.48, Changes, test, and experiments and noted various preparation and process errors. As a result of the process errors the team identified one instance where the final conclusion of an evaluation required prior NRC approval. The NRC is concerned that incorrect processing contributed to an incorrect conclusion and considers this an unacceptable method of evaluation. Because of this, from October 29, 2010 through February 10, 2011, the inspection continued at NRC Headquarters in Rockville, MD. In addition the team determined that Holtec failed to perform adequate verification of analysis to support thermal design functions.

As summarized in Table 1 below, two Severity Level IV violations of NRC requirements was identified.

Table 1
Summary of Inspection Findings

Regulatory Requirement 10 CFR Section	Subject	Number of Findings	Type of Finding	Report Section(s)
72.48	Certificate of Compliance Amendment	1	Violation	3.1.2.4
72.146	Design Control	4	Violation	3.1.2.5

PERSONS CONTACTED

The team held an entrance meeting with Holtec personnel on October 25, 2010, to present the purpose and scope of the NRC inspection. On February 10, 2011, the team held an exit meeting with Holtec to present the results of the inspection. The individuals present at the entrance and exit meetings are listed below in Table 2.

Table 2
Entrance and Exit Meetings Attendance

NAME	AFFILIATION	ENTRANCE	EXIT
Jim Pearson	NRC/SFST	X	X
Earl Love	NRC/SFST	X	
Jorge Solis	NRC/SFST	X	
John Goshen	NRC/SFST	X	
Robert Woodward	NRC/OIG	X	

Debu Mitra-Majumdar	Holtec	X	
P. Stefan Anton	Holtec	X	
Chuck Bullard	Holtec	X	
Pankaj Chaudhary	Holtec	X	
Tammy Morin	Holtec	X	
Mark Soler	Holtec	X	X

INSPECTION PROCEDURES USED

60851, Design Control of ISFSI Components
60857, Review of 10 CFR 72.48 Evaluations
NUREG/CR 6314, Quality Assurance Inspections for Shipping and Storage Containers

LIST OF ACRONYMS USED

AVL	Approved Vendor List
BWR	Boiling Water Reactor
CFR	Code of Federal Regulations
CoC	Certificate of Compliance
DVC	Design Verification Checklist
ECO	Engineering Change Order
FSAR	Final Safety Analysis Report
HMD	Holtec Manufacturing Division
HQP	Holtec Quality Procedure
HSP	Holtec Standard Procedure
kW	Kilowatt
LLNL	Lawrence Livermore National Laboratory
MPC	Multipurpose Canister
NOV	Notice of Violation
NRC	Nuclear Regulatory Commission
PNPP	Perry Nuclear Power Plant
PWR	Pressurized Water Reactor
PSEG	Public Service Electric & Gas
QA	Quality Assurance
QAP	Quality Assurance Program
QPV	Quality Program Violation
QPVF	Quality Program Violation Form
SAR	Safety Analysis Report

REPORT DETAILS

1. Inspection Scope

The team inspected Holtec's activities associated with spent fuel storage to determine if they were conducted in accordance with the requirements of 10 CFR Parts 21, 72, the applicable Certificate of Compliance (CoC) and Safety Analysis Report (SAR), and Holtec's Nuclear Regulatory Commission (NRC) approved quality assurance (QA) program. The team reviewed documentation and interviewed personnel to determine Holtec's performance in these areas.

2. Management Controls

2.1 General

The team assessed the adequacy of management controls in the areas of Holtec's QA program (QAP) 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.

2.2 Quality Assurance Policy

2.2.1 Scope

The team reviewed Holtec's QA manual and implementing procedures and assessed the effectiveness of the QA program implementation.

2.2.2 Observations and Findings

The team conducted reviews of Holtec's quality 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 they had appropriate independence from cost, schedule, and production activities. The team noted that the NRC-approved QAP is applied at both the Holtec corporate offices located in Marlton, NJ, and at the Holtec Manufacturing Division (HMD) located in Turtle Creek, PA.

The team reviewed procedures and documents regarding training, qualification, and certification of personnel. The team interviewed the QA Manager in regard to 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.

2.2.3 Conclusions

The team determined that quality assurance controls at Holtec were adequate.

2.3 Nonconformance Controls

2.3.1 Scope

The team reviewed Holtec Quality Procedure HQP-16.0, "Conditions Adverse to Quality and Corrective Action," Revision 16, the Quality Program Violation Form (QPVF) log, and selected QPVFs. The team also reviewed training and implementing procedures, internal postings, supplier notifications, reporting processes, and program controls in accordance with the provisions of 10 CFR Part 21, "Reporting of Defects and Noncompliance."

2.3.2 Observations and Findings

The team reviewed Holtec's QAP status reports for the year 2009 and mid-year 2010. The 2009 report noted a decrease of 27 QPVs from the year 2008. The mid-year 2010 report indicated that 19 QPVs were issues in the first half of 2010 with eleven (11) reflected in 2009 and three (3) in 2008 as open for a total of 19. For the areas reviewed, the status reports appeared to adequately analyze data for deficiencies and trends.

The team noted that the 2010 Mid-Year Report Executive Summary indicated that "Calculation package errors continue to occur requiring significant amount of additional work in report revisions and extent of conditions evaluations. While additional training has been completed with personnel, we are looking to have technical discipline leaders begin to provide discipline specific refresher training during the course of the year."

The team reviewed HQP-15.1, "Reporting of Defects and Non-compliances per 10 CFR 21," Revision 12 and that a sample of Holtec purchase orders contained requirements for vendors to satisfy in regard to 10 CFR Part 21 and further, 10 CFR Part 21 postings and procedures were accessible and complete in the in common areas.

2.3.3 Conclusions

The team had no findings with respect to corrective action and 10 CFR Part 21 program implementation.

2.4 Documentation Controls

2.4.1 Scope

The team reviewed a sample of Holtec documents (general procedures, records, drawings, and specifications) to determine that the quality activities performed by Holtec were suitably controlled.

2.4.2 Observations and Findings

The team reviewed procedures and documents regarding the control of documentation. The team discussed the capture of records on electronic media with Holtec personnel in regard to the requirements of Holtec procedure HQP-6.0, Revision 10, "Document Control."

2.4.3 Conclusions

The team determined that document and records management controls at Holtec were adequate.

2.5 Audit Program

2.5.1 Scope

The team reviewed Holtec's audit program to determine whether plans, procedures, and records were available. The team determined whether Holtec scheduled and performed internal QA audits in accordance with approved procedures or checklists; whether qualified and independent personnel performed the audits; whether Holtec management reviewed audit results; and whether Holtec took appropriate follow up actions in those areas found to be deficient.

2.5.1 Observations and Findings

The team reviewed audit procedures and internal and external audit packages which included audit checklists, audit reports, and associated documentation. The team noted that five (5) findings were identified during the 2010 internal audit. In addition three (3) observations and one (1) recommendation were identified during this same audit. The team reviewed audit schedules and determined that audits were being performed on a routine basis and in a timely manner. The team noted that audit closure dates were indicated on the audit schedule and overall were prompt. The team also reviewed auditor qualifications, and in one case the acceptable results of an auditor certification test of a lead auditor.

The team reviewed two vendor audits for sources on Holtec's AVL. The team noted that both audits used the NIAC audit checklist and that the audits appeared to be in-depth and thorough. The team verified that the audit acceptance was used to include the two vendors on the Holtec Approved Vendor's List.

The team reviewed QA's internal surveillance report (No. 2010-10, dated July 7, 2010) of five (5) calculation packages and noted that the calculations were determined acceptable according to the requirements of HQPs 3.1, "Design Input Requirements," Revision 10; 3.2, "Design Analysis," Revision 22; and 3.3, Design Verification, Revision 24, as applicable. The team noted the use of a comprehensive checklist and supporting objective evidence within the report.

2.5.2 Conclusions

Overall, the team assessed that Holtec's QA policy, nonconformance controls, document controls, and audit program were adequate. However, the attached notice of violation (NOV) identifies specific concerns in other areas where additional quality oversight may enhance quality implementation.

3.0 Design Controls

3.1.1 Scope

The team reviewed Holtec's procedures governing design controls and design change controls, reviewed selected design change packages, and interviewed Holtec personnel involved in the design control process.

3.1.2 Observations and Findings

3.1.2.1 Design Development

The team reviewed Holtec's NRC approved Quality Assurance Manual (HQAM, Revision 14, dated 01/09/2006) pursuant to the provisions of 10 CFR Part 50 Appendix B, 10 CFR Part 72 Subpart G, and 10 CFR Part 71, Subpart H and various Holtec Quality Procedures (HQPs) that address design development and modification activities as related to Amendment 7 to CoC No. 72-1014 and Final Safety Analysis Report (FSAR) No.: HI-2002444, Revision 9, dated 02/13/2010 for the HI-STORM 100 Cask System.

The team verified that design responsibilities were assigned appropriately and verified that acceptable reviews were being performed by the responsible parties. The team interviewed personnel at the manager, project manager, and engineer levels. These interviews provided a basis for the acceptable determination by the team for the qualification of the personnel as well as their ability to use the electronic system Holtec uses for document distribution, tracking, and design development and control. The interviews also provided the team with the personal insight from the actual engineer performing design control activities.

The team reviewed selected drawings and records to verify that materials, equipment, and services met design requirements, Holtec's Certificate of Compliance No. 72-1014, Amendment 7, and FSAR No. HI-2002444, revision 9, dated 02/13/2010 for the HI-STORM 100 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.

3.1.2.2 Project Planning

The team reviewed various Project Plans applicable to the Perry Nuclear power Plant (PNPP), Project No. 1628, as operated by FirstEnergy Nuclear Operating Co., and Salem Nuclear Generating Station (SNGS) as operated by PSEG Nuclear, LLC, for use of the HI-STORM 100 Dry Cask Storage System (DCSS) and noted that technical and quality roles and responsibilities relating to design and licensing activities were properly defined as required by HQP-3.0. Both adequately defined project planning and project execution with respect to Independent Spent Fuel Storage Installation (ISFSI) construction, fabrication and delivery of DCSS components, and ISFSI startup and operational testing activities, canister loading, and ISFSI operations. The team noted appropriate references within project plans to PNPP Specification No.: PRS 1917, Revision 2 and SNGS Specification No.: S-C-ZZ-NDS-0474, Revision 1, as well as, client purchase orders Nos. 55106812, change order No. 4 and 4500463000, change order No. 30, respectively. Overall, no concerns were noted, each project plan was assessed to contain the 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.

3.1.2.3 Design Changes

The team reviewed ECO 5014-89, various design documents noted elsewhere in this report, and a sample of Design Verification Checklists (DVCs) used during the verification of new and modified design reviews. The team noted that DVCs are used for calculation and report verification of appropriate administrative, quality, and technical perspectives and concerns. The team determined that the DVCs are reviewed by a principal reviewer after completion by the

author. The team also noted that DVCs were not required where the design would be tested by a qualification test.

3.1.2.4 10 CFR 72.48 Evaluations

The team reviewed 72.48 Evaluation, No. 923, which added text to clarify that the integrity of the fuel cladding is assured for design basis accidents analyzed for the HI-STORM system and to present discussion of NUREG-1864 which Holtec asserts to contain information to predict that the fuel cladding can withstand decelerations greater than 45 g limit imposed on the HI-STORM 100 system. The evaluation concluded that the change did not affect a method of evaluation, and therefore, a CoC amendment was not required.

The team noted that the 72.48 change: a) introduced a completely new method as the basis for demonstrating the integrity of the fuel rod cladding during a vertical end drop of the HI-STORM 100 while being transported to the ISFSI pad; b) endorsed a Lawrence Livermore National Laboratory (LLNL) report (No. UCID-21246) for the axial buckling of fuel rods as the basis for demonstrating the integrity of the fuel rod cladding even though NRC technical staff determined that the LLNL report was inaccurate and therefore unacceptable and that the correct guidance is provided in ISG-12, Revision 1, published in 1999; and c) justified a g-load limit of 45gs for the HI-STORM 100 System based on information provided in NUREG-1864 to predict cladding failure even though the information to support a 45g limit does not exist in the NUREG.

The team determined that 72.48 Evaluation No. 923 resulted in a change that is a departure from a method of evaluation described in the FSAR used to establish the safety analysis for cladding integrity during a drop accident event. This failure to comply with the requirements of 10 CFR 72.48(C)(2), (viii) which states, "a certificate holder shall obtain a CoC amendment pursuant to 72.244 prior to implementing a proposed change, if the change 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," is cited in the attached Notice. (Violation 72-01014/2010-201-01)

The team reviewed Holtec's 72.48 Training and Recertification process for 72.48 initiation, review, and approval qualification. This is identified in an electronic matrix maintained by Holtec's QA Manager. The team determined the process of training and recertification to be acceptable.

3.1.2.5 Thermal Evaluation

The inspection team followed-up on a potential generic issue identified by regional inspectors during the performance of a Byron Nuclear Power Plant reactive inspection. The inspection was performed in August/September 2010 (IR No. 05000454/2010007) to assess the circumstances surrounding the loss of cooling to the annulus water of a Holtec multi-purpose canister and transfer cask assembly.

This inspection included NMSS staff evaluation that FSAR safety limits were not exceeded. The reactive inspection noted that FSAR, Revision 5, Table 4.3.1, provides the HI-STORM 100 system material temperature limits. A short-term temperature limit of 1058°F is provided in this table for commercial spent fuel cladding at moderate burn-up levels. During an independent review of the licensee's failure to provide adequate cooling to the Byron ISFSI canister during vacuum drying operations, the staff assessed the Holtec FSAR, HI-2002444, Revision 5, design basis calculation for adequacy. When comparing the results of the staff's model to the results

provided by Holtec’s model, which were subsequently incorporated into FSAR Revision 5, a discrepancy was noted. FSAR, Revision 5, Section 4.5, states that during steady state vacuum drying of an MPC-32 canister with a heat load of 28.74 kW and a shell temperature postulated at 125°F, fuel cladding temperature will not exceed 1040°F. The staff’s model calculated fuel cladding temperatures in excess of 1058°F. At that time, Holtec indicated the vacuum drying analysis results reported in the FSAR had been obtained using Fluent Version 4. To verify that the results from the analysis of record match the results reported in FSAR Revision 5, the staff requested Holtec to provide these analyses. When evaluating the analysis files created using Fluent Version 4 provided by Holtec, the staff noted the maximum calculated temperatures from these analyses did not match the results from FSAR, Revision 5, Table 4.5.9. Peak Cladding Temperature in Vacuum (Moderate Burnup Fuel Only). The following table compares the results as obtained from the two-dimensional (2-D) analysis files provided by Holtec and Table 4.5.9 of the FSAR:

MPC Type	Peak Cladding Temperature, °F (FSAR Rev. 5 Table 4.5.9)	Peak Cladding Temperature, °F (Holtec’s Fluent 4.5 2-D Analysis Files)
MPC-24	960	980
MPC-24E	942	962
MPC-32	1040	1061
MPC-68	1014	1052

The staff noted the largest deviation between the FSAR and calculation corresponds to MPC-68. The staff also noted that the MPC-32 peak cladding temperature obtained from the analysis is above the allowable limit of 1058°F, as seen in the Table above. The FSAR notes that in order to avoid excessive conservatism in the computed 2-D FLUENT solution, partial recognition for higher axial heat dissipation is adopted in the peak cladding calculations. This approach is described in Appendix I to Holtec FSAR (Report No.: HI-2002407). The team has determined that the approach described in Appendix I is incorrect. This failure to comply with the requirements of 10 CFR 72.146, “Design Control,” is cited in the attached Notice. (Violation 72-01014/2010-201-02)

Further, the staff reviewed Holtec’s FSAR and Technical Specifications to determine if whether the design control processes were properly controlled and performed in accordance with procedures. As a result of the review the team noted the following failures to comply with the requirements of 10 CFR 72.146, “Design Control,” as cited in the attached Notice. (Violation 72-01014/2010-201-02)

- Based on the FSAR documentation Holtec provided for HI-STORM 100, Amendment 5, the staff was able to impose in the Technical Specifications, a 40-hour time limit during vacuum drying for heat loads larger than 23 kW and an MPC shell temperature of 125°F. The team noted failure of the FSAR to provide the supporting documentation in amendments 1-4 to include the same basis for a 40 hour time limit.
- Technical Specifications, Condition B of Limiting Condition for Operation (LCO) 3.1.1, for Amendment 5 for the HI-STORM 100 requires backfilling the MPC cavity with 0.5 atm. of helium when the vacuum drying 40-hour limit is exceeded before achieving dryness

criteria. The staff noted that the FSAR lacks an analysis for restarting vacuum after initial drying attempt has failed. Without the analysis a condition of temperature distribution uncertainties is created for any further attempts at vacuum drying. Consequently vacuum drying time is always dependent on initial fuel temperature distribution at the time drying is to occur.

- The staff noted that FSAR, Chapter 8, Operating Procedures, allows the use of either helium or nitrogen during the MPC blow down operation. The staff noted that even though there is no acceptance criteria described in the FSAR for the nitrogen environment in the MPC cavity, there is assurance that vacuum drying bounds these conditions. Even though operating procedures allows the use of nitrogen, FSAR, Chapter 4, Thermal Evaluation, does not prescribe nor analyze for the use of nitrogen.

3.1.3 Conclusions

Overall, the team assessed that Holtec was effectively implementing procedures governing Project Planning, Design Development, Design Input, Design Verification, and Design Drawing Configuration Control. The issues, though limited to two specific areas, were recognized by the team as weaknesses that could have potentially been avoided by improving the implementation of Holtec's quality assurance program. The team noted that oversight, surveillance and checking are commonly used to ensure that quality products are being provided by staff's efforts. While Holtec design procedures were found to be adequate, the findings included in the attached NOV, leave question in regard to the full control of designs by Holtec. The extent of these conditions should be considered by Holtec Management, as necessary, in their review of Holtec's designs. Any follow-on corrective actions determined should be promptly initiated from the review efforts. Holtec should then determine the effectiveness of any resulting corrective actions and make adjustment for weaknesses still in existence.

4. Exit Meeting

An exit meeting was conducted by the team leader with Holtec personnel on February 10, 2011. The team's preliminary findings and assessments were presented at the meeting. Holtec's management representatives acknowledged the inspection results presented by the team.

NOTICE OF VIOLATION

Holtec International
Marlton, NJ

Docket 72-1014

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted from October 25 through February 10, 2011, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

A. Holtec International is a certificate holder of Certificate of Compliance No. 72-1014

10 CFR 72.48(C)(2) (viii) states in part "...a certificate holder shall obtain a certificate of compliance (CoC) amendment pursuant to 72.244..., prior to implementing a proposed change,...if the change.....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, Holtec failed to obtain a certificate of compliance (CoC) amendment. Specifically, Holtec's change to FSAR, Section 3.5, is a departure from the method of evaluation originally used to establish the safety analysis for cladding integrity during a drop accident event, and therefore, this change requires a CoC amendment request.

This is a Severity Level IV violation (Enforcement Policy 6.2).

B. Holtec International is a certificate holder of Certificate of Compliance No. 72-1014

10 CFR 72.146, "Design Control," states in part "...the certificate holder shall apply design control measures to thermal-hydraulic design."

Contrary to the above, Holtec failed to apply design control measures to thermal-hydraulic design. Specifically, Holtec's design control measures were not adequate for the following four examples:

- 1) Measures did not ensure thermal evaluations during vacuum drying conditions were adequate which resulted in FSAR peak cladding temperature allowable limits potentially exceeded.
- 2) The measures did not specify vacuum drying time and head load limits in Amendments 1 through 4 technical specifications.
- 3) The measures did not provide required actions with supporting thermal-hydraulic analysis in technical specifications when Condition B of LCO 3.1.1 is entered; and,
- 4) The measures did not include either in the FSAR or the technical specifications supporting thermal-hydraulic analysis and acceptance criteria when nitrogen gas is used to blow down the canister.

This is a Severity Level IV violation (Enforcement Policy 6.2).

Pursuant to the provisions of 10 CFR 2.201, Holtec is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to Eric Benner, Chief, Rules, Inspections, and Operations Branch, Division of Spent Fuel Storage and Transportation, Office of Nuclear Material Safety and Safeguards, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 24 day of February, 2011.