

October 22, 2001

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

SUBJECT: NRC INSPECTION REPORT NO. 72-1014/01-201 AND  
NOTICE OF VIOLATION

Dear Dr. Singh:

This refers to the inspection conducted September 10-11, and 17-21, 2001, at the Holtec offices in Marlton, NJ. The purpose of the inspection was to examine design and quality assurance activities to determine if they were performed in accordance with the requirements of 10 CFR Parts 21 and 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 examination 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 has determined that five Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/OE>. 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.

Based on the results of this inspection, the NRC has also determined that one additional Severity Level IV violation of NRC requirements occurred. This violation is being treated as a Non-Cited Violation (NCV), consistent with Section VI.A of the Enforcement Policy. The NCV is described in the subject inspection report.

If you contest the violations, the NCV, or their significance, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to the Deputy Director, Licensing and Inspection Directorate, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards, and the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," is enclosed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

K. Singh

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In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room).

Sincerely,  
**/RA/ original signed by /s/**  
Charles L. Miller, Deputy Director  
Licensing and Inspection Directorate  
Spent Fuel Project Office  
Office of Nuclear Material Safety  
and Safeguards

Docket No. 72-1014

Enclosures:   1. Inspection Report No. 72-1014/01-201  
                  2. Notice of Violation  
                  3. NRC Information Notice 96-28, "Suggested Guidance Relating to  
                      Development and Implementation of Corrective Action,"

cc:     Mr. Kenneth A. Phy  
          HUG Chairman  
          Entergy Nuclear NE  
          268 Lake Road  
          P.O. Box 41  
          Lycoming, NY 13093

K. Singh

-2 -

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HUG Chairman  
Entergy Nuclear NE  
268 Lake Road  
P.O. Box 41  
Lycoming, NY 13093

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

**Inspection Report**

Docket No.: 72-1014

Report No.: 72-1014/01-201

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

Dates: September 10 -11and 17 -21, 2001

Inspection Location: Holtec International, Marlton, NJ

Inspection Team: Paul Narbut, SFPO, Team Leader  
Robert Temps, SFPO, Safety Inspector  
Frank Jacobs, Safety Inspector  
Christopher Jackson, Project Manager  
Makuteswara "Sriini" Srinivasan, Technical Analyst  
(9/10 - 11/01)  
Adelaide Giantelli, Technical Analyst (9/17 -21/01)

Approved by: Charles L. Miller, Deputy Director  
Licensing and Inspection Directorate  
Spent Fuel Project Office, NMSS

## EXECUTIVE SUMMARY

Holtec International  
NRC Inspection Report No. 72-1014/01-201

The U.S. Nuclear Regulatory Commission (NRC) performed a team inspection at Holtec International in Marlton, New Jersey, to examine design and quality assurance (QA) activities associated with the design of spent fuel storage system components. The objective of the inspection was to verify that activities were performed in accordance with 10 CFR Part 72 and Holtec's NRC-approved QA program.

The team concluded that management controls and implementation of the QA program met regulatory requirements. The exceptions are identified in five cited violations and one non-cited violation (NCV). One of the cited violations concerns a failure to use an NRC-approved QA program. A second violation concerns the lack of a procedure for QA surveillances. A third violation concerns an ineffective corrective action regarding incorporating design changes on drawings. A fourth violation, for which there were seven examples, concerns the failure to follow procedures. A fifth violation was cited for inadequate design control regarding a drawing note that allowed weld defects in excess of the applicable industry code. The NCV involved a failure to implement the requirements of the QA manual in a quality procedure.

The team noted weaknesses that were not violations of the regulations but which demonstrated that the procedural issues identified in the violations were fairly broad in scope. The team identified six examples of a weakness regarding inadequate procedures.

In addition to the third violation mentioned above, for ineffective corrective action, the team identified a weakness regarding corrective actions for configuration management problems caused by inattention to detail, and failure to follow procedure. Trending done by the NRC team showed steady or increasing numbers for these problems.

In the area of calculation controls, one of the examples in the fourth violation mentioned above, for failure to follow procedure, involved the failure to list the input file data as required by the applicable quality procedure. In addition, the team identified a weakness in the execution of the sampled calculations: the calculations sampled did not specify the assumptions made nor the results obtained.

Overall, the team considered design control and quality assurance activities to be adequate, but the team found more problem areas than expected, particularly in the area of the adequacy of and compliance to procedures.

Table 1 provides information about the violations.

**Table 1**  
Summary of Inspection Findings

Regulatory Requirement 10 CFR Section	Subject of Finding	Number of Violation Examples/ Weakness Examples	Type of Finding	Violation described in Report Section
72.140	Quality assurance requirements	1/0	Violation 01	2.1.2.1
72.150	Instructions, procedures, and drawings (lack of or inadequate procedure)	1/6	Violation 02	2.1.2.2
72.172	Corrective action	1/1	Violation 03	2.3.2
72.150	Instructions, procedures, and drawings (failure to follow procedure)	7/0	Violation 04	Ex. 1,2,3 2.4.2 Ex. 4 3.2.1 Ex. 5,6 3.2.2 Ex. 7 3.2.3.2
72.146	Design control	1/1	Violation 05	3.2.2
72.150	Instructions, procedures, and drawings (failure to follow procedure)	1	Non-cited Violation	2.1.2.3

**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**

AM	Administrative Memorandum
ASME	American Society of Mechanical Engineers
CAR	corrective action report
CFR	Code of Federal Regulations
CoC	certificate of compliance
DDR	design document request
ECO	engineering change order
FSAR	final safety analysis report
HQP	Holtec Quality Procedure
MPC	multi-purpose cannister
NCR	nonconformance report
NCV	non-cited violation
NRC	Nuclear Regulatory Commission
QA	quality assurance
QPV	quality problem violation
QPVF	quality problem violation form
SAR	safety analysis report
SMDR	supplier manufacturing deviation report
TSAR	topical safety analysis report

## PERSONS CONTACTED

The team held an entrance meeting on September 10, 2001, to present the scope and objectives of the NRC inspection. On September 21, 2001, the team held an exit meeting at the Holtec offices to present the preliminary findings of the inspection. The people present at the meetings are listed in Table 2.

**Table 2**  
Entrance/Exit Meeting Attendees

Name	Title	Organization	Entrance 9/10/01	Exit 9/21/01
Bill Farmer	QA oversight, UST&D	Portland General Electric		x
Adelaide Giantelli	Technical Analyst	USNRC		x
Bernard Gilligan	Program Manager	Holtec International	x	x
Brian Gutherman	Licensing Manager	Holtec International	x	x
Christopher Jackson	Project Manager	USNRC	x	
Frank Jacobs	Inspector	USNRC	x	x
Ray Kellar	Director Dry Storage Projects	Holtec International	x	x
Philip Lang	Senior Quality Engineer	Pacific Gas and Electric	x	x
Michael McNamara	Vice President, Nuclear	Holtec International	x	x
Paul Narbut	Senior Inspector	USNRC	x	x
Indresh Rampall	Thermal Lead	Holtec International	x	x
Everett Redmond	Principle Engineer, Nuclear	Holtec International	x	x
Joy Russell	Dry Storage Marketing Manager	Holtec International		x
Kris Singh	President	Holtec International		x
Alan Soler	Executive Vice President	Holtec International	x	
Mark Soler	QA Manager	Holtec International	x	x
Makuteswara Srinivassan	Technical Analyst	USNRC	x	
Rob Temps	Inspector	USNRC	x	x
Daryll William*	Project Manager for Dry Fuel Storage ANO	Entergy South		x*
Randy Durtch*	Supplier QA Engineer	Entergy South		x*
David Eichenberger*	Fabrication Project Manager	Entergy South		x*

\* Attended by telephone

## REPORT DETAILS

### 1. Inspection Scope

The NRC team inspected design and quality assurance activities associated with spent fuel transportation and dry storage components to determine if they were performed in accordance with the requirements of 10 CFR Parts 21 and 72, the certificate of compliance (CoC), the applicable safety analysis report (SAR), and the NRC-approved QA program.

The team determined the acceptability of dry storage activities by reviewing procedures and instructions, inspecting selected documents, records, and drawings, verifying personnel training and qualifications, and interviewing personnel responsible for various activities.

### 2. Management Controls

#### 2.1 Quality Assurance Program

##### 2.1.1 Scope

The team reviewed Holtec's QA manual and implementing procedures and assessed the effectiveness of the QA program implementation. The team reviewed QA authorities and responsibilities, organizational independence, cost and schedule independence, identification of components covered by the QA program; and the application of a graded-approach for components important to safety.

##### 2.1.2 Findings and Observations

The team determined that overall, implementation of the QA program met regulatory requirements except for the five violations described below.

###### 2.1.2.1 Use of a QA Program Revision That Had Not Been Approved by the NRC

Prior to the inspection, the NRC learned that Holtec had implemented Revision 12 of its QA manual, before it had obtained NRC approval of the revision. Holtec implemented Revision 12 of the QA manual on January 2, 2001. Holtec submitted Revision 12 to the NRC for approval on June 20, 2001. After discussions with the NRC, Holtec submitted a letter dated July 13, 2001, stating that the previous (NRC-approved) Revision 11 had been reinstated for dry storage activities. The Holtec letter further stated that all manufacturing activities had complied with Revision 11, and that engineering design and analysis activities performed since the adoption of Revision 12 in January had been assessed for conformance with Revision 11 and differences were being reconciled under Holtec's corrective action process.

During telephone discussions with NRC staff on August 9, 2001, Holtec determined that additional changes to the manual were necessary, and on August 17, 2001, Holtec submitted Revision 13, superseding Revision 12, for NRC approval.

The failure to obtain NRC approval of a change to the QA program prior to its use is considered a violation of 10 CFR 72.140(c)(3), which requires each certificate holder to obtain Commission

approval of its quality assurance program before commencing fabrication or testing of a spent fuel storage cask.

(Violation 72-1014/01-201-01)

#### 2.1.2.2 QA Surveillance Activities Not Prescribed by Procedure

The team identified a violation of 10 CFR 72.150 involving performing activities affecting quality without the controls of a documented procedure. Holtec Administrative Memorandum (AM)-56, dated October 17, 2000, countermanded the requirement to perform in-line quality assurance reviews of drawings, engineering change orders (ECOs), reports, and supplier manufacturing deviation reports (SMDRs). The reviews were required by the established quality assurance program and procedures. In lieu of the in-line reviews, AM-56 required that QA surveillances be performed on a random basis. Fourteen surveillances were performed between February 14, 2001, and August 20, 2001. The surveillances were not controlled by a documented procedure describing controls for scheduling, performing, evaluating, and reporting the surveillances. After the issue was identified by the NRC, but prior to the inspection, Holtec issued a letter to the NRC, dated August 17, 2001, stating that it was developing a procedure "in order to provide a formal set of requirements for the performance of internal surveillances." Subsequently, Holtec Quality Procedure (HQP) -18.5, "Internal Surveillance," was issued on September 5, 2001, containing formal controls for the performance of surveillances.

The failure to have a procedure for the performance of surveillances was considered to be a violation of 10 CFR 72.150, "Instructions, procedures, and drawings."

(Violation 72-1014/01-201-02)

Additionally, the team identified a weakness related to procedure use. The team noted that administrative memoranda and internal e-mails were being used to supplement procedures and instructions in lieu of revising the procedures. For example, AM-71, "Design/Analysis Interface Requirements," provided additional instructions not found in the applicable procedure, HQP-5.1, "Engineering Drawings." AM-71 states: "Actual drawing sign off by the technical discipline(s) cannot occur until the analysis is completed." Another example is e-mail from the QA manager, dated March 13, 2001, which stated: "From this point forward, the following requirements shall apply to any design change..." Some of the requirements listed in the e-mail were not included in the applicable Holtec Quality Procedure 5.1. Although these supplemental e-mail instructions did not conflict with the applicable procedures, and therefore were not violations, the team considered the use of informal supplements to procedures controlling quality-related activities to be a weakness.

#### 2.1.2.3 QA Manual Requirements Not Implemented in the QA Procedure

Prior to the inspection Holtec had identified that one of its quality procedures did not agree with the requirement of its QA manual. Paragraph 4.1 of Section 5.0 of the Holtec International Quality Assurance Manual states that the QA manager is responsible for QA review of all Holtec drawings. QA procedure HQP-5.1, "Engineering Drawings," was revised on January 29, 2001, to require the performance of random surveillances for drawings, in lieu of the in-line review by the QA manager required by the QA manual. Holtec identified and addressed this issue in Corrective Action Report (CAR) 63 dated July 2, 2001. As a corrective action, Holtec reinstated in-line QA reviews. The failure to follow the QA manual requirements in procedure HQP-5.1, "Engineering Drawings," is considered a violation of 10 CFR 72.150, "Instructions,

procedures, and drawings.” This non-repetitive, licensee-identified and corrected violation is being treated as a non-cited violation, consistent with Section VI.A.8 of the NRC Enforcement Policy.

## 2.2 Audit Program and Controls

### 2.2.1 Scope

The team reviewed the audit program to determine whether audit plans, procedures, and records were available and properly implemented. The team examined the audit program to determine if (1) internal audits and vendor audits were scheduled and performed in accordance with approved procedures or checklists; (2) the audits were performed by qualified personnel independent of the area audited; (3) the audit results were documented and reviewed by management; and (4) appropriate followup actions were taken in areas found to be deficient.

### 2.2.2 Findings and Observations

The team determined that, overall, implementation of the audit program met regulatory requirements.

## 2.3 Nonconformance Controls

### 2.3.1 Scope

The team reviewed Holtec’s program for identifying and resolving problems. The review included administrative procedures governing the program, the various types of problem reporting mechanisms, and the adequacy of Holtec’s resolution of problems.

### 2.3.2 Findings and Observations

The team reviewed procedure HQP-16.0, “Conditions Adverse to Quality and Corrective Action,” and HQP-16.1, “Root Cause Evaluation.” HQP-16.0 describes the process for documenting quality program violations (QPVs). QPVs are defined as “any condition potentially adverse to quality, any departure from a Holtec quality program commitment, or any departure from a project-specific document, excluding items where nonconformance reports (NCRs), design deviation requests (DDR) or SMDRs have been issued.” NCRs, SMDRs, and DDRs are used to document Holtec vendor and project specification deviations and nonconformances.

QPVs are entered into the corrective action system through completion of a quality program violation form (QPVF). A checklist attached to the QPVF is reviewed to determine whether the issue is considered a significant issue adverse to quality in which case the QPVF is closed and a CAR is generated. CARs require formal root cause evaluation through the process described in HQP-16.1.

The team reviewed all QPVFs and CARs generated since January 2001. In reviewing the corrective actions taken for the QPVs and CARs, the team noted that the corrective actions were generally narrow in scope and usually involved fixing the immediate problem (e.g., a calculation or drawing error), issuing a lesson-learned training summary (often via e-mail to all

Holtec employees with no response required). Less frequently, procedures were revised and classroom training was required.

The team identified a violation of NRC requirements involving ineffective corrective actions. Specifically, a number of recent Holtec QPVs and CARs documented various configuration control problems involving the incorporation of engineering change orders (ECOs) onto controlled drawings. As detailed in Section 2.4.2, the team also found a large number of examples of continuing problems with incorporating ECOs onto controlled drawings. The team concluded that the corrective actions implemented by Holtec to address these ECO problems had been ineffective.

The failure to take effective corrective action for a significant condition adverse to quality was considered to be a violation of the requirements of 10 CFR 72.172, "Corrective Action." (Violation 72-1014/2001-201-03)

Additionally, the team reviewed a two year period in the QPVF database to identify any adverse trends. The team noted an adverse trend in the area of configuration control problems. The number of configuration control problems appeared to be increasing as a percentage of total QPVs issued in 2001 as compared to the year 2000 QPVs. Although the trend was identified in the QA manager's mid-year assessment report, the team considered that the response to this trend was weak. Specifically, in many of the QPVs and CARs, root causes were attributed to inattention to detail or an employee's failure to follow procedures; however, there was no evidence that Holtec's root cause evaluations had systematically looked at the problems from a cultural or programmatic perspective, or assessed why personnel did not follow procedures or were inattentive to detail. The failure to take sufficient actions to correct the adverse trend was considered a weakness. The problem was not considered a violation of NRC requirements since there is no regulatory requirement for trending.

## 2.4. Documentation Controls

### 2.4.1 Scope

The team reviewed a sample of ECOs that affected controlled drawings to verify that they were controlled and implemented in accordance with Holtec's quality procedures.

### 2.4.2 Findings and Observations

The team identified examples of a violation regarding the failure to follow procedure. The team reviewed a sample of about 30 engineering change orders (ECOs) that affected controlled drawings. The team identified that approximately one-third had discrepancies that were in violation of procedure HQP-5.1, "Engineering Drawings," Revision 11, dated August 8, 2001. Specific deficiencies included the following:

- a. Paragraph 6.8.2.8 of HQP-5.1, states that if drawings are not going to be immediately revised, the ECO number must be written on the drawing(s) being modified near the area of the design change. Further, earlier revisions (prior to Revision 10) of HQP-5.1 stated that a copy of the ECO and any attachments had to be stapled to the affected drawing and the ECO number written on the drawing being modified. However, contrary to the present and past requirements to HQP-5.1, on September 19 and 20, 2001, the

team identified that three drawings affected by ECOs 1025-26 and 1021-27 did not have the ECO number written on them.

- b. Paragraph 6.7.3 of HQP-5.1, states that the revision block on the drawing must summarize changes made to the specific drawing. When the drawing revision incorporates an ECO, the ECO number must be listed on the revision block. However, contrary to this requirement, the revision blocks on Drawing 2602, Sheet 1, Revision 3, dated July 19, 2001, did not list the ECO number for ECOs 1027-5, 7, 10, and 19, which were incorporated in Revision 1 of the drawing.

The instances of failure to follow procedure described above are considered to be examples of a violation of 10 CFR 72.150, "Instructions, procedures, and drawings."

(Violation 72-1014/01-201-04, Examples 1 and 2)

The team also identified examples of a violation involving performing activities affecting quality without the controls of a documented procedure. The following deficiencies were noted during the review of the 30 ECOs sampled by the team:

- a. Several drawings, besides having ECO numbers written on them in various places, were marked up using red pen line-outs and write-ins to reflect the ECO information. In several cases, the ECO changes were only partially transferred to the affected drawings. However, this drawing markup practice was not described or controlled by HQP-5.1. Further, this markup practice avoided the usual independent checks associated with engineered drawing changes.
- b. ECO 1022-21 referred to Drawing 3471, Revision 1; however, Revision 0 was the current revision of the drawing when the ECO was issued. A draft marked-up copy of Revision 1 to Drawing 3471 was attached to the ECO cover sheet. However, HQP-5.1 does not contain instructions on attaching marked-up drawings to the ECO cover sheet. Further, even without such instructions, a draft copy of the drawing should not have been attached to the ECO as the draft drawing was not yet an officially approved document.
- c. Drawing BM-1575, Sheet 1, Revision 10, dated April 5, 2000, the bill of materials for Drawings 1495 and 1561, was marked up to reflect a change made by ECO 1024-17. Next to the markup, someone had written in red pencil "NO CHG." The team identified that ECO 1024-17 had been voided. However, HQP-5.1 provides no instructions on actions to take for drawings that have been marked up to reflect ECO changes when the ECO is subsequently voided. It was not clear that "NO CHG." meant that the ECO had been voided.

The discrepancies described above are considered to be further examples of a failure to follow procedures for activities affecting safety, a violation of 10 CFR 72.150, "Instructions, procedures, and drawings."

(Violation 72-1014/01-201-04, Example 3)

### 3. Design Controls

#### 3.1 Scope

The team examined Holtec's design controls to determine whether the design control processes were properly controlled and performed in accordance with procedures. The team's review focused on design development, modifications, and the 10 CFR 72.48 change approval process. The team inspected design activities associated with the HI-STORM 100 and HI-STAR 100 spent fuel storage and transportation cask models .

#### 3.2 Findings and Observations

Overall the team found design controls to be adequate with the exceptions identified below:

##### 3.2.1 Calculation Reviews

The team reviewed calculation package HI-951322, "HI-STAR 100 Shielding Design and Analysis for Transport and Storage." It was noted that Appendices 24, "BWR Source Terms," and 25, "PWR Source Terms," did not list the computer input files. Computer input files detail the assumptions and input data, such as dimensions, used in the calculation.

Section 6.2.1(h) of procedure HQP 3.2, "Design Analysis," requires that each calculation list all computer input files.

The failure to follow procedure for listing computer input files is considered an example of a violation of 10 CFR 72.150, "Instructions, procedures, and drawings."  
(Violation 72-1014/01-201-04, Example 4)

In addition, the team identified a weakness in the adequacy of the procedure controlling calculations. The weakness was not considered a violation of NRC requirements. The team reviewed calculation packages HI-951322, "HI-STAR 100 Shielding Design and Analysis for Transport and Storage"; HI-971608, "HI-STORM Shielding Design and Analysis for Storage"; HI-971620, "Criticality Analyses of the HI-STORM 100 System"; HI-981928, "Structural Calculation Package for HI-STORM 100"; and HI-2012702, "HI-STORM 100 System Additional Shielding Calculations."

The team noted that the calculation records referred to the most recent revision of either the SAR, the topical safety analysis report (TSAR), or the final safety analysis report (FSAR) for a description of the calculation inputs, assumptions and methodology, rather than listing the calculation inputs, assumptions, and methodology specifically. In one case (HI-951322), the calculation record also referred the reader to the most recent revision of the TSAR and SAR for a summary of the calculation results. The staff noted that SARs, FSARs, and TSARs were living documents and were frequently revised. Therefore, the referral to information in the SARs, FSARs, and TSARs for a calculation record could be inaccurate with the passage of time. The team considered this issue to be a procedure weakness, not a violation of NRC regulations, since no adverse examples of incorrectly referenced data were found.

### 3.2.2 Design Change Control

The team noted several examples of a failure to follow procedure in the design control area. Procedure HQP-5.1, "Engineering Drawings," requires that all affected documents be identified when preparing an ECO. ECO 1022-18 made aluminum heat conduction elements optional in the multi-purpose cannister (MPC) 24; however the HI-STORM CoC, an affected document, was not identified as an affected document. Additionally, the ECO did not identify two locations in the FSAR that were affected and required revision. The failure to list all affected documents on ECO 1022-18 was considered to be an example of a violation of 10 CFR 72.150, "Instructions, procedures, and drawings," for failure to follow procedures. (Violation 72-1014/01-201-04, Example 5)

Another example of a violation involved procedure HQP-5.1 which requires that an ECO be prepared when the FSAR is affected. The team noted that Holtec Drawing 3437, Revision 3, revised the dimensions and tolerances described in the FSAR for the HI-STORM/HI-TRAC mating device, but that the required ECO had not been issued. The failure to issue an ECO for a change affecting the FSAR was considered an example of a violation of 10 CFR 72.150, "Instructions, procedures, and drawings," for failure to follow procedure. (Violation 72-1014/01-201-04, Example 6)

The team also observed that the design drawing for the fabrication of the MPC implemented exceptions to the American Society for Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (Code) which were not listed in the CoC list of Code exceptions. Appendix B of the CoC contains a list of authorized exceptions to the Code. The team noted that Holtec Drawing 1401, "HI-STAR 100 MPC-68 Construction," Sheet 2, Note 2, Revision 9, dated November 2, 1999, authorized weld imperfections for the MPC basket assembly which were in excess of those allowed by the Code. The CoC for the HI STAR 100, Amendment 2, approved May 25, 2001, did not list the weld defect exception to the Code.

The failure to comply with the provisions of the ASME Code was considered a violation of NRC requirements of 10 CFR 72.146, "Design control." (Violation 72-1014/01-201-05)

Responsible Holtec personnel said that the weld imperfection latitude authorized in the note had not been translated into the manufacturer's fabrication procedures which are approved by Holtec. Therefore, they did not consider that the latitude had been implemented in fabrication. They also noted that the drawing and note had been submitted to the NRC as part of the proposed CoC change on August 4, 2000, but, they acknowledged that they had not specifically identified the change as a Code exception or updated the Code exception list in the CoC.

Additionally, the team noted weaknesses in design control procedures that were not violations of NRC requirements. The team noted that HQP-5.1 does not require an ECO to be initiated for drawing changes that affect descriptions in the SAR for 10 CFR Part 71 transportation designs. The team noted further that Holtec uses the ECO database to identify any SAR amendments that may be required. The team concluded that the ECO database may not be a complete database for all changes requiring a 10 CFR Part 71 SAR amendment. Having procedural requirements that establish an incomplete ECO database for identifying SAR changes was considered a design control weakness. No adverse examples of incomplete SAR changes were identified.

The team identified other design control procedure weaknesses that were not violations of NRC requirements. First, the team noted that procedure HQP-5.1 did not provide guidance regarding if and when newly arising design changes to a design actively under NRC review should be submitted to the NRC. The team noted that the Holtec decided on a case-by-case basis whether NRC should be notified of a needed change. The team noted that in some cases the change could fundamentally affect the validity of the ongoing NRC review, and that NRC should be notified for the sake of efficiency.

Second, Holtec's methods of tracking "interim" changes to not-yet-NRC-approved designs to ensure that they did not conflict with the design eventually approved by the NRC were not documented and were not clear to the team. The regulations allow Holtec to make changes to an NRC-approved design under certain conditions described in 10CFR 72.48. The team noted that in some instances Holtec initiated and implemented the changes in fabrication but deferred performing a 10 CFR 72.48 evaluation since NRC approval had not been obtained. The lack of procedure guidance for tracking and controlling interim changes to designs under active NRC review was considered a weakness in design controls. The team did not identify any examples where the interim changes were mishandled.

Third, procedure HQP 5.1 allows drawings to be issued after the project manager makes the "final approval." However, the procedure also allows drawings to be issued before the QA approvals have been obtained. The team identified two examples where the QA approval actually occurred after the drawing was issued: Drawings 1135-3668 and 1024-3669. The team considered the lack of clarity as to when the final approval occurs to be a weakness in the design control procedure. The team did not identify any changes required by the QA review after the final project manager review. The team noted that Holtec is proposing to remove in-line QA reviews for most procedures, but intends to retain them for purchase specifications. Therefore, this NRC-identified weakness will remain valid.

### 3.2.3 10 CFR 72.48 Controls

#### 3.2.3.1 Scope

The team reviewed a sample of design changes, 10 CFR 72.48 evaluations, and screenings for conformance with NRC regulations and Holtec Quality Procedure (HQP) 19.2, "Screening and Evaluation of Changes, Tests, and Experiments."

#### 3.2.3.2 Findings and Observations

The team identified an example of a violation for failure to follow procedure. Procedure HQP 19.2, requires that the preparer complete a 72.48 evaluation before signing to certify the evaluation as complete. The team observed that 10 CFR 72.48 evaluation no. 1024-29, Revision 1, had been signed as complete but the 10 CFR 72.48 evaluation had not been performed. The team noted that the independent reviewer had not signed the evaluation and the 72.48 design change had not been implemented. Involved Holtec personnel explained that the preparer signed to show the task had been assigned to him. They stated that the approval form did not have a space for the name of the person assigned to perform the evaluation. The

failure to complete the 10 CFR 72.48 evaluation before signing to certify its completion is considered an example of a violation of 10 CFR 72.150, "Instructions, procedures, and drawings," for a failure to follow procedure.  
(Violation 72-1014/01-201-04, Example 7)

Additionally, the team identified a weakness in adequacy of procedures that was not a violation of NRC requirements. The team noted that there was no procedure guidance for a process that Holtec uses to keep configuration status, including the status of pending design changes. Holtec maintains a "living FSAR" to facilitate configuration status for use in performing 10 CFR 72.48 evaluations. The living FSAR is intended to ensure that all changes are considered in a 10 CFR 72.48 evaluation. The team noted that, to be effective, the living FSAR needed to contain both (1) changes submitted to, pending, and approved by NRC and (2) changes approved by Holtec through the 10 CFR 72.48 process. The team observed that the 72.48 procedure only contained instructions for updating the living SAR for 72.48 generated changes. The team observed that there were no procedure instructions for changes involving pending or completed NRC approval. The team considered the absence of procedure requirements for controlling the living FSAR to be a weakness in design control.

### 3.3 Material Procurement, Test and Inspection Controls, and Tool and Equipment Control

#### 3.3.1 Scope

The team followed up on a weakness previously identified in NRC Inspection Report 71-0784/00-201 regarding neutron shielding material and the identification and reporting of conditions adverse to quality.

#### 3.3.2 Findings and Observations

The inspection report stated that Holtec had failed to identify the need to apply its corrective action process on three separate occasions.

As required by procedure HQP-15.2, "Nonconformances," Holtec issued QPVF 45 on May 22, 2000, and subsequently specified corrective actions. The team considered the corrective actions specified and taken to be adequate.

## **4. Exit Meeting**

On September 21, 2001, at the conclusion of the inspection, the team held an exit meeting with Holtec International management representatives to present the preliminary inspection findings. Holtec management acknowledged the inspection findings presented by the team.

## NOTICE OF VIOLATION

Holtec International Incorporated  
Marlton New Jersey

Docket No. 72-1014

During an NRC inspection conducted at the Holtec International offices in Marlton, New Jersey, on September 10 -11 and 17 -21, 2001, 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. 10 CFR 72.140, "Quality Assurance Requirements," requires, in part, that each certificate holder obtain Commission approval of its quality assurance program before commencing fabrication or testing of a spent fuel storage cask.

Contrary to the above, Holtec adopted Revision 12 of the Holtec International Quality Assurance Manual on January 2, 2001, and performed fabrication activities prior to receiving NRC approval of the revised program. Holtec submitted Revision 12 to the NRC for approval on June 20, 2001.

This is a Severity Level IV violation (Supplement VI).

- B. 10 CFR 72.150, "Instructions, procedures, and drawings," requires, in part, that a certificate holder prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances.

Contrary to the above, Holtec procedures were not of a type appropriate to the circumstances in that quality assurance personnel performed activities affecting quality, internal quality assurance surveillances, which were not prescribed by a documented procedure. Fourteen surveillances were performed between February 14, and August 20, 2001, before an appropriate procedure, HQP-18.5, "Internal Surveillance," was issued on September 5, 2001.

This is a Severity Level IV violation (Supplement VI).

- C. 10 CFR 72.172, "Corrective action," requires, in part, that the certificate holder shall establish measures to ensure that conditions adverse to quality are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must ensure that corrective action is taken to preclude repetition.

Contrary to the above, corrective actions for a significant condition adverse to quality did not preclude repetition. In 2000 and 2001, Holtec's corrective action program had documented numerous examples of problems involving the incorporation of engineering change orders (ECOs) onto controlled drawings. For example, Corrective Action Report (CAR) 59 and Quality Procedure Violation Form (QPVF) 98, document the significant condition adverse to quality. As detailed in NRC Inspection Report 72-1014/01-201, the NRC identified numerous ongoing repetitive errors regarding the incorporation of ECOs onto controlled drawings.

This is a Severity Level IV violation (Supplement VI).

D. 10 CFR 72.150, "Instructions, procedures, and drawings," requires, in part, that a certificate holder prescribe activities affecting quality by documented instructions, procedures, or drawings and that these instructions, procedures, or drawings be followed.

1. Holtec procedure HQP-5.1, "Engineering Drawings," Revision 11, dated August 8, 2001, paragraph 6.8.2.8, states that if drawings are not going to be immediately revised, the ECO number be written on the drawing near the area of the design change.

Contrary to the above, on September 17 through 19, 2001, NRC inspectors observed that the Holtec library controlled drawings, number 3438, "125 Ton HI-TRAC Assembly," Sheet 2, Revision 3, number 1402, "HI-STAR 100 MPC-68 Construction," Sheet 4, Revision 12, and number BM 1479, Revision 13, were affected by ECOs 1025-26 or 1021-27 but did not have the applicable ECO number written on them.

2. Holtec Procedure HQP-5.1, "Engineering Drawings," Revision 11, dated August 8, 2001, paragraph 6.7.3, states that when a drawing revision incorporates an ECO, the ECO number shall be listed in the revision block.

Contrary to the above, on September 17 through 19, 2001, in the Holtec library, NRC inspectors observed that, the revision block for controlled drawing number 2602, Sheet 1, Revision 3, dated July 19, 2001, did not reference the incorporation of ECOs 1027-5, 7, 10, and 19.

3. Holtec Procedure HQP-5.1, "Engineering Drawings," Revision 11, dated August 8, 2001, describes the allowed methods for marking and attaching temporary material to controlled drawings pending a drawing change.

Contrary to the above, on September 17 through 19, 2001, in the Holtec library, NRC inspectors observed the following controlled drawings that had been changed by methods not described in HQP-5.1.

- a. Numerous drawings had been marked up using red pen line-outs and write-ins to reflect some or all of the ECO information. One example was drawing BM 1575, Sheet 1, Revision 10, dated April 5, 2000.

- b. ECO 1022-21, Revision 0, had a marked-up draft copy of Revision 1 to Drawing 3471 attached to it. The ECO referred to Drawing 3471, Revision 1; however, Revision 0 was the active revision of the drawing when the ECO was issued.

- c. Drawing BM-1575, Sheet 1, Revision 10, dated April 5, 2000, the bill of material for Drawings 1495 and 1561, was marked up to reflect a change made by ECO 1024-17. However, ECO 1024-17 had been voided. Next to the markup, "NO CHG" had been written in red pencil.

4. Holtec Quality Assurance Procedure (HQP) 3.2, "Design Analysis," requires that each calculation provide a list of all input files.

Contrary to the above, Holtec Calculation Package HI-951322, Revision 12, dated October 12, 2000, Appendices 24 "BWR Source Terms," and 25 "PWR Source Terms," do not list the computer input files.

5. Holtec Quality Procedure 5.1, "Engineering Drawings," requires that all documents that require revision be identified when preparing ECOs.

Contrary to the above, all documents requiring revision were not identified in ECO 1022-18, Revision 0, regarding aluminum heat conduction elements in the multi-purpose cannister (MPC) 24. Specifically, the HI-STORM Certificate of Compliance and two locations in the Final Safety Analysis Report were not identified as requiring revision.

6. Holtec Quality Procedure 5.1, "Engineering Drawings," requires that an ECO be prepared when a drawing change requires a change to the FSAR description.

Contrary to the above, an ECO was not prepared for Drawing 3437, Revision 3, which revised dimensions and tolerances of a HI-STORM mating device described in the FSAR.

7. Holtec Quality Procedure 19.2, "Screening and Evaluation of Changes, Tests, and Experiments Under 10 CFR 72.48," requires that the preparer of the 10 CFR 72.48 evaluation electronically "sign" a particular electronic record when a 10 CFR 72.48 evaluation has been completed.

Contrary to the above, the preparer of 10 CFR 72.48 evaluation no.1024-29, Revision 1, electronically signed the electronic record without having completed the 10 CFR 72.48 evaluation.

This is a Severity Level IV violation (Supplement VI).

- E. 10 CFR 72.146, "Design control," states, in part, that the certificate holder shall establish measures to ensure that the design basis as specified in the Certificate of Compliance is correctly translated into specifications, drawings, procedures, and instructions.

Certificate of Compliance (CoC) 72-1008, Amendment 2, dated May 29, 2001, specifies that the American Society of Mechanical Engineers Boiler and Pressure Vessel Code (Code), 1995 Edition with Addenda through 1997, is the governing Code for the HI-STAR 100 Cask System, subject to specific exceptions to the Code listed in the CoC.

Contrary to the above, Holtec Drawing 1401, "HI STAR 100 MPC-68 Construction," Sheet 2, Note 2, Revision 9, dated November 2, 1999, authorizes weld imperfections for the MPC basket assembly which are in excess of those allowed by the Code, and are not listed in the CoC as exceptions to the Code.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Holtec International 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 the Director, Licensing and Inspection Directorate, Spent Fuel Project Office, 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. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. 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 Publicly Available Records (PARS) component of NRC's document system (ADAMS), 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. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room). 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 2.790(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 22 day of October 2001

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 nor written response is required.

Background

On June 30, 1995, NRC revised its Enforcement Policy (NUREG-1600) 60 FR 34381, 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 VII.B.1 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:
  - p 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.

- p 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.
- p 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 an auditable record and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

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

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

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

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

1. Has management been informed of the violation(s)?
2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?
3. Have precursor events been considered and factored into the corrective actions?
4. In the event of loss of radioactive material, should security of radioactive material be enhanced?
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?

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

signed by

Elizabeth Q. Ten Eyck, Director  
Division of Fuel Cycle Safety  
and Safeguards  
Office of Nuclear Material Safety  
and Safeguards

signed by

Donald A. Cool, Director  
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