



Holtec Center, 555 Lincoln Drive West, Marlton, NJ 08053

Telephone (856) 797-0900

Fax (856) 797-0909

November 21, 2001

United States Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Subject: Reply to a Notice of Violation
NRC Inspection Report 72-1014/01-201

Dear Sir:

We acknowledge receipt of the NRC's letter from Dr. Charles Miller, Deputy Director, Licensing and Inspection Directorate, Spent Fuel Project Office along with its enclosures, dated October 22, 2001. Pursuant to the provisions of 10 CFR 2.201, we herewith submit a written response to the violations and weaknesses cited in the above-referenced "Notice of Violation."

Based on our interaction with the NRC's Inspection Team during the inspection and feedback received during the exit meeting, we were able to initiate Quality Program Violation Forms (QPVFs) and Corrective Action Requests (CARs) for the issues identified, immediately after the NRC's team departed from our headquarters. As a result, the investigation of causes and extent of conditions, as well as implementation of corrective actions has been in progress virtually since the day the inspection was completed.

In addressing the issues, Holtec has focused broadly on identifying and correcting the underlying causes of any programmatic weaknesses in our processes or human performance. As a result, we have established comprehensive corrective actions and other initiatives to enhance our performance and assure regulatory compliance. These broad actions include a comprehensive procedure review effort to upgrade our procedures, revisions to our corrective action program to improve root cause identification and trending, and intensive training of nuclear department personnel to emphasize management's expectations for strict compliance with procedures.

In the attached reply, our response to each violation is organized as follows:

- I. A "violation response summary" table to provide an overview of the violation response.
- II. Reason for the violation, in which we address both the specific violation examples and the root cause of any programmatic or fundamental issue (e.g., failure to follow procedure), as appropriate.
- III. Corrective action and results achieved, wherein actions taken or planned to restore compliance are described.
- IV. Corrective actions to avoid recurrence, wherein actions taken or planned to address the root cause(s) are described.
- V. Date when full compliance will be achieved, representing the date when all corrective actions associated with a violation will be complete.

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While the responses to the first four violations are self-contained, Violation E, as stated in the enclosure, requires NRC's review and concurrence to enable us to proceed with the submittal of the proper type and number of additional Code exception requests on each of our two dry storage docket. We look forward to a brief telephone discussion of our response to Violation E after the SFPO has had the opportunity to review it.

Finally, while the amount of information provided may be more than is typical for an inspection response (e.g., each weakness is addressed as well as the violations), we have decided to err on the side of thoroughness. In keeping with our policy of securing maximum client participation in regulatory matters, this submittal has been subject to review and comment by the Holtec Users' Group membership. We trust that the NRC will find this response in keeping with the Commission's expectations.

Should the NRC require any additional information concerning this response, please contact our Licensing Manager, Brian Gutherman at (856) 797-0900, extension 668.

Sincerely,

Mark Soler
QA Manager

Concurrence:

Brian Gutherman, P.E.
Licensing Manager

Approval:

K.P. Singh, Ph.D., P.E.
President and CEO

Enclosure: Responses to the Notice of Violation and Weaknesses

Document I.D.: 5014443

Emcc: Mr. Paul Narbut, USNRC (w/encl.)
Mr. Timothy Kobetz, USNRC (w/encl.)
Holtec Group 1 (w/encl.)
HUG Group N (w/encl.)



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RESPONSES TO VIOLATIONS

Violation 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.

Response To Violation A

I. Violation Response Summary

QUESTION	RESPONSE
Does Holtec agree with the violation?	Yes
Have prompt immediate corrective actions been implemented to restore compliance?	Yes
Was a Corrective Action Report (CAR) issued, requiring a full root cause, extent of condition review, and corrective actions to prevent recurrence?	Yes
Do the corrective actions include revisions to procedures or the creation of new procedures?	Yes
Are all of the new or revised procedures implemented?	No
Is training of personnel to preclude recurrence of the violation necessary?	No
Have all corrective actions to prevent recurrence been taken? If no, when will they be completed?	December 21, 2001
Was the consequence of the violation evaluated and reconciled for previously completed work?	Yes
When will full compliance be achieved?	December 21, 2001



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II. Reason for Violation

The direct cause of this violation was a failure to translate a regulatory requirement into Holtec procedures. Holtec personnel overlooked the regulatory requirement to request and receive prior NRC approval before implementing changes to a QA program manual previously approved by the NRC under 10 CFR 71. An indirect cause of the failure to recognize this regulatory requirement was the pre-disposition on the part of Holtec personnel responsible for instituting compliance with the Part 71 and 72 regulations to rely on their Part 50 experience. This indirect cause is discussed in more detail below.

When Holtec requested and received NRC approval of its QA program manual under 10 CFR 71 in 1994, we did not subsequently establish appropriate administrative controls to obtain NRC review and approval prior to implementing revisions to the QA program manual thereafter. Further, at the time Revision 12 to the QA program manual was implemented in January 2001, Holtec personnel mistakenly believed that changes could be made to the Part 71 NRC-approved QA program without prior NRC approval, provided those changes did not reduce the level of commitment in the program (as is permitted under 10 CFR 50.54(a)(3)). The proposed changes were not considered a reduction in commitment at the time.

III. Corrective Actions Taken and Results Achieved

NRC approval of Revision 12 to Holtec QA program manual was requested by letter dated June 20, 2001. Shortly thereafter, Holtec was informed by the SFPO project manager of a potential problem with implementation of Revision 12 to the QA program manual without prior NRC approval. Quality Program Violation Form (QPVF) No. 117 was initiated on June 26, 2001 to track the issue, as required by the Holtec corrective action program. Because of the regulatory significance of the issue, QPVF 117 was escalated to a Corrective Action Request (CAR No. 63), indicating a significant condition adverse to quality. The corrective actions listed below include those immediate actions executed to restore compliance with the regulations as well as those taken to address the extent of condition and prevent recurrence of similar violations. The corrective actions to restore compliance were taken in an expedited manner in recognition of the regulatory significance of the issue.

- a. Important-to-safety (ITS) activities associated with 10 CFR 71 and 72-certified cask systems were required to be performed to the last NRC-approved revision of the Holtec QA program manual (Revision 11) beginning on July 3, 2001. Revision 11 was to be used until a later revision was approved by the NRC and declared ready for implementation by Holtec. Revision 13 of the QA program



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manual was approved by the NRC on September 25, 2001 and implemented at Holtec on November 1, 2001.

- b. An evaluation was performed to determine those important-to-safety activities conducted pursuant to Revision 12 of the QA program manual up until July 3, 2001. No activities related to cask fabrication were affected by this QA program manual change. A reconciliation was performed for those ITS activities performed under Revision 12 of the QA program manual to ensure all provisions of Revision 11 of the QA program manual were complied with.
- c. Component Completion Records (CCRs) for certified dry storage components are being reviewed and revised as necessary to indicate that certifications performed under Revision 12 of the QA program manual are reconciled and certified under Revision 11 of the Holtec QA program manual.

IV. Corrective Actions to Avoid Further Violations

- a. The Holtec Quality Procedure (HQP) governing changes to the QA program manual has been revised to require prior NRC approval of revisions to the QA program manual before implementation.
- b. The 10 CFR 71 and 72 regulations were reviewed in their entirety by the QA Manager and the Licensing Manager.
- c. Using the information culled under item (b) above, procedural controls are being created or strengthened to ensure that regulatory requirements are adequately captured in procedural guidance.
- d. In order to assure ongoing compliance with the new and revised procedures, a QA checklist will be developed to periodically assess implementation under Holtec's internal surveillance program (HQP 18.5).

V. Date Full Compliance Will Be Achieved

December 21, 2001.



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Violation 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.

Response To Violation B

I. Violation Response Summary

QUESTION	RESPONSE
Does Holtec agree with the violation?	Yes
Have prompt immediate corrective actions been implemented to restore compliance?	Yes
Was a Corrective Action Report (CAR) issued, requiring a full root cause, extent of condition review, and corrective actions to prevent recurrence?	Yes
Do the corrective actions include revisions to procedures or the creation of new procedures?	Yes
Are all of the new or revised procedures implemented?	No
Is training of personnel to preclude recurrence of the violation necessary?	No
Have all corrective actions to prevent recurrence been taken? If no, when will they be completed?	January 15, 2002
Was the consequence of the violation evaluated and reconciled for previously completed work?	Not required
When will full compliance be achieved?	January 15, 2002



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II. Reason for Violation

The direct cause of this violation was that when in-line QA reviews were proposed to be replaced with QA surveillance, it was not recognized that this created a different QA activity that would require procedural guidance. A contributing cause was that the specific details of the previous practice of performing in-line QA reviews were never proceduralized.

An indirect cause of this violation was that the QA Manager has historically provided a level of instruction for internal surveillances that was specific to the processes being evaluated under the premise that he would be in control of all internal surveillances. He did not recognize the possibility of another individual controlling the internal surveillance program in the future and therefore did not provide general instructions via a Holtec Quality Procedure to govern the performance of internal surveillances.

III. Corrective Actions Taken and Results Achieved

Internal surveillances were previously performed and documented by the QA Manager. A new Holtec Quality Procedure (HQP 18.5) was developed and issued on September 5, 2001 to provide procedural guidance on internal QA surveillances.

IV. Corrective Actions to Avoid Further Violations

The implementation of HQP 18.5 will prevent recurrence of the specific violation identified. Other Holtec activities that bear on quality are being reviewed to determine if new or revised procedural guidance is required. Procedures will be revised or created as appropriate to address previously unproceduralized quality activities.

V. Date Full Compliance Will Be Achieved

January 15, 2002



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Violation 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.

Response To Violation C

I. Violation Response Summary

QUESTION	RESPONSE
Does Holtec agree with the violation?	Yes
Have prompt immediate corrective actions been implemented to restore compliance?	Yes
Was a Corrective Action Report (CAR) issued, requiring a full root cause, extent of condition review, and corrective actions to prevent recurrence?	Yes
Do the corrective actions include revisions to procedures or the creation of new procedures?	Yes
Are all of the new or revised procedures implemented?	No
Is training of personnel to preclude recurrence of the violation necessary?	Yes
Have all corrective actions to prevent recurrence been taken? If no, when will they be completed?	January 31, 2002
Was the consequence of the violation evaluated and reconciled for previously completed work?	Yes
When will full compliance be achieved?	January 31, 2002



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II. Reason for Violation

Corrective Action Request (CAR) 59 was written to address several physical equipment interface problems and was not written as a direct result of discrepant or absent ECO markings on drawings. ECO control was investigated as part of the root cause evaluation for CAR 59, but the scope of that root cause evaluation did not specifically address the issue of repeated errors in marking ECOs on drawings.

The direct cause for the failure of Holtec's corrective action process to stem repetitive errors in correctly marking ECOs into drawings is attributed to weaknesses in the company's corrective action program. Specifically, this direct cause can be broken down into three major contributing causes: i) weaknesses in the area of failure to identify repetitive quality infractions that individually did not rise to significant conditions adverse to quality; ii) the inability to effectively evaluate trends in QPVFs and CARs; and iii) a limited and informal follow-up review of the effectiveness of corrective actions.

III. Corrective Actions Taken and Results Achieved

The QPVFs issued for the ECO problems were escalated into a CAR and a root cause evaluation was performed as discussed in the response to Violation D.

IV. Corrective Actions to Avoid Further Violations

- a. The checklist used to determine whether a QPVF is a significant condition adverse to quality (SCAQ) is being modified to lower the threshold for escalating a QPVF to CAR status if multiple QPVFs have been initiated for the same class of discrepancies. In addition, the time frame for reviewing the aggregate of QPVFs to determine trends is being increased from one year to two years.
- b. The trending capability of the Holtec electronic QPVF database is being improved to enable a focused sorting of QA program violations to serve as an effective trending tool, and as a means to sharpen the diagnosis by the QA organization of the underlying causes of discrepancies.
- c. HQP 16.0, "Conditions Adverse to Quality and Corrective Action" and HQP 16.1, "Root Cause Evaluations" are being revised to improve the root cause evaluation process and trending of procedure compliance, definition of actions required to



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address adverse trends, and actions to determine the effectiveness of corrective actions.

- d. The semi-annual frequency for the analysis of the QPVF database will be added to the applicable procedure.

V. Date Full Compliance Will Be Achieved

January 31, 2002

Violation 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.



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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 canister (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.



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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.

Response To Violation D

I. Violation Response Summary

QUESTION	RESPONSE
Does Holtec agree with the violation?	Yes
Have prompt immediate corrective actions been implemented to restore compliance?	Yes
Was a Corrective Action Report (CAR) issued, requiring a full root cause, extent of condition review, and corrective actions to prevent recurrence?	Yes
Do the corrective actions include revisions to procedures or the creation of new procedures?	Yes
Are all of the new or revised procedures implemented?	No
Is training of personnel to preclude recurrence of the violation necessary?	Yes
Have all corrective actions to prevent recurrence been taken? If no, when will they be completed?	January 15, 2002
Was the consequence of the violation evaluated and reconciled for previously completed work?	Yes
When will full compliance be achieved?	January 15, 2002



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II. Reason for Violation

The issues related to the effectiveness of Holtec's QA program in identifying problems, determining root causes, and establishing effective corrective actions are addressed in the response to Violation C. Based on the number of violation examples, a root cause evaluation was performed on the fundamental issue of failure to follow procedures. The apparent cause for each violation example is listed in this subsection in the sequential order in which they are cited in the inspection report. The root cause of this violation is described at the end of this section.

1. The specific responsibility and ownership for the function of marking drawings with the ECO number was not clearly delineated in the procedure. The intent of the procedure was that the project manager responsible for the affected drawing would ensure proper marking of the drawing with the ECO number.
2. This violation example was caused by inadequate attention to detail and inadequate self-checking by the individuals responsible for preparing, reviewing and approving drawing revisions.
 - 3a. The governing procedure only requires that the ECO number be marked near the area of the change on the drawing. Personnel were adding more information to the drawing mark-up as an aid to others who may need to know what the specific change was from the ECO. The procedure and associated training lacked sufficient detail to prevent additional information from being marked on the drawing.
 - 3b. This violation example was caused by inadequate attention to detail and inadequate self-checking by the individuals responsible for preparing, reviewing and approving the ECO.
 - 3c. This violation example was caused by a lack of adequate procedural guidance on how to control voiding of ECOs.
4. This violation example was caused by a lack of adequate clarity in the governing procedure. Calculation Package HI-951322 was initiated in 1995, before the procedural requirement to list all computer input files in the calculation was in place. Since that time, and after the subject procedural requirement was in place, the calculation package was revised several times, including Revision 12 as cited in the violation example. The requirement to list all computer input files is



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located in the "Format" subsection of the current version of HQP 3.2. However, in Subsection 6.4.5 of HQP 3.2, it states:

"Original issue or revised design analysis/calculation package reports authored or initiated prior to the approval date of this HQP revision do not require upgrading to the above-referenced format."

This provision is included in HQP 3.2 to recognize the fact that the format of a calculation is not a significant enough element of the procedure that would justify the revision of all previously existing calculation packages solely to comport with the new format requirements. The intent of this procedure step was to include those calculation packages initiated or revised before the procedural requirements were in place as well as those initiated *before* the procedural requirements were in place and revised thereafter. However, the language in the procedure step is not clear in this regard.

5. The cause of this violation example was a lack of adequate clarity in the governing procedure and the lack of adequate attention to detail by the individuals responsible for preparing, reviewing and approving the ECO. The intent of the procedural step is to ensure that documents *under Holtec's authority to change* are listed in the ECO's "affected documents" field. This is to ensure that all affected Holtec calculations and other documents, including the FSARs, that are not revised at the time the ECO is issued are revised in the future to include the effects of the change. The CoC cannot be changed by Holtec and should not have been listed as an affected document. However, the procedure is not clear in this regard.
6. The causes of this violation example were a lack of adequate clarity in the governing procedure, inadequate training, and a misinterpretation of the procedure by the individuals responsible for preparing, reviewing, and approving the drawing. The procedure states:

"An ECO shall be generated for ... any design change that affects a dry storage FSAR or drawing included in the FSAR... (this includes new drawings that will be added to the FSAR)."

The intent of this procedural step was to ensure that any drawing change requiring a corresponding change to the FSAR be made via ECO to ensure tracking of the



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FSAR change. The responsible individuals thought that since the drawing itself was not being added to the FSAR, no ECO was required. In fact, the new drawing affected text in the FSAR regarding how certain ancillary equipment is used with the HI-STORM 100 System and an ECO should have been generated to track those FSAR text changes.

7. The cause of this violation example is inattention to detail on the part of the 72.48 preparer. The intention of the preparer signing off the 10 CFR 72.48 evaluation before preparation was complete was to provide information to other interested parties as to whom was assigned responsibility for preparing this 10 CFR 72.48 evaluation while preparation was still in progress. This intent is not recognized in the procedure.

Root Cause Identification

To investigate the root cause and extent of condition for this problem, the Holtec Root Cause Investigation Board (ROCAIB) reviewed all QPVFs issued in 2001. A total of 19, including five issued as a result of NRC's inspection, were found to be attributable to a failure to follow procedure. In addition, the ROCAIB interviewed 18 Holtec nuclear department personnel to investigate whether there are any specific cultural or other programmatic problems at Holtec that would explain the number of noncompliances related to failure to follow procedures. Carefully crafted questions regarding procedure use, procedure adequacy, procedure comprehension, and training were posed to each person. Aided by these interviews and additional evaluations, the ROCAIB has identified the following root causes:

- a. Certain Holtec Quality Procedures (HQPs) require enhancement to add detail and clarity.
- b. The wording in certain procedures resulted in an attitude of *interpretive* rather than *literal* compliance with the HQPs among some personnel.
- c. Certain HQPs contain processes that are intrinsically cumbersome to implement. In other words, the processes described by the procedures are, in certain cases, not well-developed from a human factors perspective such that they are conducive to compliance by those who implement the processes. This is particularly true of HQPs that govern ECO implementation.



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- d. Certain personnel did not feel accountable for ownership of the procedures governing the processes they use in performing quality-related activities.
- e. Human performance in executing procedural requirements is not meeting expectations as evidenced by an inadequate level of attention to detail. The contributing causes of this inadequate attention to detail are:
 - i. Inadequate self-checking of work by certain personnel.
 - ii. A significant temporary increase in the number of documents processed through the Holtec QA program strained the available resources and led to reduced attention to detail and human error. This increase was due to the first-time manufacturing of HI-STORM overpacks, HI-TRAC transfer casks, and several ancillary components starting simultaneously.
- f. The training program at Holtec failed to adequately emphasize the importance of verbatim procedure compliance, attention to detail, and self-checking.
- g. The management control and oversight structure for design control in the corporate engineering division was not adequately organized to meet the changing demands on the organization as the company moved to support increased volume of SMDRs, ECOs, etc.

III. Corrective Actions Taken and Results Achieved

Using the same format as that used for presenting the reasons for the specific examples of violations, the corrective actions to restore compliance are described below for each violation example. Section IV contains the corrective actions taken to prevent recurrence for the specific violation examples as well as for the over-arching causes underlying the failure to follow procedure issue.

- 1. Dry storage drawings with outstanding ECOs have been marked with the ECO numbers as required by HQP 5.1 or the drawings are being revised to incorporate all outstanding ECOs. Holtec is using the ECO database to ensure that all applicable ECOs are captured for drawing revisions and drawing markups.



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2. Drawing number 2602, Sheet 1, is being revised to reference the incorporation of ECOs 1027-5, 7, 10, and 19 in Revision 3. We are evaluating the extent of this violation to determine its impact on configuration control.
- 3a. Dry storage drawings are being revised to incorporate all outstanding ECOs.
- 3b. Drawing 3471 has been revised to incorporate the changes from ECO 1022-21 (in lieu of revising the ECO).
- 3c. Procedure HQP 5.1 has been revised to provide appropriate guidance for voiding ECOs.
4. HQP 3.2 will be revised to clarify this procedural step to reflect the intent.
5. The "affected documents" sections of ECOs 1021-30, 1022-18, and 1023-5 have been updated to include the FSARs and transportation SAR as affected documents. We are performing a comprehensive ECO review to ensure the affected documents field is completed correctly.
6. An ECO has been issued for Drawing 3437. A review is being performed for other drawings that may require a change to the FSAR description, and which may have been issued without an ECO. ECOs will be generated as necessary.
7. A review of all open, Holtec-prepared 72.48 screenings and evaluations will be performed. For those in which the activities of the preparer were not complete, the preparer's electronic signature will be deleted. This problem did not apply to the reviewers' signatures since they only signed the 72.48 evaluations when they were complete.

IV. Corrective Actions to Avoid Further Violations

- a. HQP 5.1 and the associated design control databases have been overhauled to streamline and automate required activities with electronic barriers to prevent common human errors. In particular, HQP 5.1 has been revised to require the immediate revision of drawings at the time an ECO is issued, eliminating the need to mark ECO numbers on the affected drawings. The ECO process (configuration control) is being enhanced to enable comprehensive tracking of required changes to other documents affected by the change and for cask component certification.



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- b. HQP 5.1's revisions include clarifying the instructions for listing affected documents on ECOs to include only those documents under Holtec's authority to change. Changes made under ECOs that potentially affect non-Holtec controlled documents such as the CoCs are controlled through the ECO database, where checklist questions are used to navigate the engineer towards determining the potential for impact on the Holtec CoCs and provide guidance to the sponsor of the change if such an impact is indicated.
- c. To address the procedure/process adequacy and personnel ownership issues, a comprehensive review of all Holtec Quality procedures has been undertaken by the *procedure users* and key management personnel. Each procedure is being reviewed for content, clarity, regulatory compliance, and consistency with how activities are actually performed. Processes are being re-vamped and procedures revised accordingly to improve ease of compliance by procedure users.
- d. An intensive training campaign is being carried out to train all nuclear department personnel on the changes to the processes and procedures and to emphasize verbatim procedure and licensing basis compliance, attention to detail, and self-checking.
- e. A formal training program for new nuclear department employees is being developed. This training will include an indoctrination to nuclear work, nuclear licensing, information on Holtec's products, and an overview of the Holtec database systems. This training is in addition to the QA indoctrination training and other specialized training and qualification programs already required for nuclear department personnel.
- f. All nuclear department personnel are being required to re-read the quality assurance manual and all quality procedures applicable to their activities as the procedures are revised from the enhancement effort.
- g. To heighten the need to follow quality procedures literally, an "all-hands" meeting was held by Holtec's president. In the meeting, he re-emphasized his expectations regarding procedure compliance. He encouraged communication and feedback on procedures and processes as an important aspect of Holtec's program of continuous improvement.



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- h. The availability of the Holtec Quality Procedures Manual will be improved by: i) the addition of a direct link to *read-only* electronic copies of the current procedures from the Holtec network database main menu, and ii) the placement of an additional controlled hard copy set of procedures in the corporate engineering office.
- i. The design and engineering interface has been strengthened through the identification of a Design Manager responsible for overseeing the design/drafting department. This manager is the single point of accountability for design/drafting performance and communication with engineering.
- j. The practice of processing ECOs, SMDRs, etc. by a large number of personnel is being discontinued in favor of a core group dedicated to manufacturing and design support functions. For this purpose, a new engineering services group has been established and staffed commensurate with the expected future workload. The Engineering Services Manager is accountable for enforcing management expectations for procedure compliance on a day-to-day basis through direct oversight of the completion of assigned tasks.
- k. The effectiveness of the above-mentioned corrective actions will be evaluated by the QA department through tracking and trending of QPVFs and internal surveillances.

V. Date Full Compliance Will Be Achieved

January 15, 2002 (except item k, which is an ongoing activity)



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Violation 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.

Response To Violation E

I. Violation Response Summary

QUESTION	RESPONSE
Does Holtec agree with the violation?	Yes
Have prompt immediate corrective actions been implemented to restore compliance?	Yes
Was a Corrective Action Report (CAR) issued, requiring a full root cause, extent of condition review, and corrective actions to prevent recurrence?	Yes
Do the corrective actions include revisions to procedures or the creation of new procedures?	Yes
Are all of the new or revised procedures implemented?	No
Is training of personnel to preclude recurrence of the violation necessary?	Yes
Have all corrective actions to prevent recurrence been taken? If no, when will they be completed?	January 31, 2002
Was the consequence of the violation evaluated and reconciled for previously completed work?	In progress
When will full compliance be achieved?	January 31, 2002



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II. Reason for Violation

The direct cause attributable to this cited violation is the failure of Holtec personnel to obtain necessary clarification of the regulatory guidance governing the Code exception tables in the CoCs. ISG-10, Revision 1 addresses the issue of ASME Code compliance relative to spent fuel storage casks. The Code exception tables in the HI-STAR and HI-STORM CoCs, first created during HI-STAR licensing (which pre-dated ISG-10), are not all-inclusive of every single potential deviation from the ASME Code. As explained below, however, Holtec believes that this practice is reasonable and was consistent with the NRC's expectations at the time the tables were developed. As part of our follow-up actions, Holtec is planning to identify necessary additional Code exceptions based on the approach described below.

A review of the Code indicates that the original note in Drawing 1401 itself does not comply with Code Article NG-4427(a). This note was already on the approved drawings in the HI-STAR and HI-STORM FSARs and its provisions have been used to evaluate welds in MPCs currently loaded with spent fuel. We have evaluated the note as applied to previous fabrication work and determined that there is no safety significance and no impact on the operability of any Holtec MPCs currently loaded with spent fuel.

Our extent of condition review conducted thus far has also revealed that similar omissions from the Code exception table exist in both HI-STAR and HI-STORM FSARs. The underlying reason for these omissions, as stated above, is the failure on our part to pro-actively pursue clarification of the existing guidance. The following discussion provides an in-depth assessment of the Code exception issue.

The most obvious Code exception is the matter of the Design Specification. The Design Specification is the central governing document for all "NB" components: The Code mandates (NCA-3251) that the Owner of the component prepare a certified Design Specification, as we quote below:

"NCA-3250 PROVISION OF DESIGN SPECIFICATIONS

NCA-3251 Provision and Correlation

It is the responsibility of the Owner to provide, or cause to be provided, Design Specifications for components, supports, and appurtenances. The



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Owner, either directly or through his designee, shall be responsible for the proper correlation of all Design Specifications.”

The Design Specification, among other things, is required to specify the unique service conditions for the component, delineating all loadings into the four categories (Level A, B, C and D) and specifying material and failure mode analysis requirements germane to the operation of the components. For dry storage casks, such as our HI-STAR and HI-STORM systems, the FSAR serves the role of the Design Specification. Inasmuch as the Owners are not required to provide a Design Specification for these dry storage components, the role served by the FSAR to fulfill the mandate of NCA-3251 ought to be the first item in the Code exception table. Therefore, this Code exception will be submitted for NRC approval.

With the FSAR explicitly recognized as the Design Specification, the required content of the Code exception tables can be defined using the table below as the guidance.

	Case	Action
1.	Exception from a direct Code requirement or prohibition.	Include in Code exception table(s).
2.	There is no applicable Code requirement.	Defer to FSAR as Design Specification.
3.	Code requirement is ambiguous with respect to dry storage casks, and compliance is subject to interpretation.	Defer to FSAR as Design Specification; inclusion in the Code exception table is not mandatory but may be requested at Holtec’s discretion.
4.	Exception from a Code requirement is implicit due to an existing, NRC-approved exception to a higher level requirement in another Code paragraph.	Listing in Code exception table is not mandatory.

An example for each of the four cases is provided below to illustrate the logic behind the above table.

Example for Case 1

The weld-related note on our MPC drawings and the FSAR-as-design specification issue are direct exceptions to specific paragraphs in the Code. They, therefore, must be listed in the exception table (presently, they are not).



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Example for Case 2

The cases of non-mechanistic tipover and handling loads defined in the FSAR are illustrative of the many examples where the Code provides no criteria as to the applicable load combinations, stress limits, etc. for dry storage cask systems. In such cases, the FSAR's provisions constitute the sole basis for design.

Example for Case 3

The MPC baseplate-to-shell (MBS) weld typifies Case 3. The MBS weld, labeled Category C by virtue of its location in the MPC enclosure vessel, is a weld joint subject to extensive stress analysis in the FSAR. This weld, because of its service requirement, is a full penetration weld, but without a covering fillet shown in Figure NB-4243-1, under the heading "Acceptable Full Penetration Weld Details for Category C Joints."

Because the ASME Code allows the weld joint geometries to be modified to accord with the component's service need under NB-3350 (quoted below), a full penetration joint that meets all applicable NB stress intensity limits should be considered to meet the intent of the ASME Code.

"NB-3350 DESIGN OF WELDED CONSTRUCTION

NB-3351 Welded Joint Category

The term *Category* defines the location of a joint in a vessel, but not the type of joint. The categories established are for use in specifying special requirements regarding joint type and degree of examination for certain welded joints. Since these special requirements, which are based on *service*, material, and thickness, do not apply to every welded joint, only those joints to which special requirements apply are included in the categories. *The special requirements apply to joints of a given category only when specifically stated*" [emphasis added].

The weld detail shown in the FSAR design drawing recognizes the special operational imperatives of the MPC. The fact that the weld detail in the component's Design Specification (in this case, the FSAR) is different from the standard detail shown in NB-4243-1 is readily understood by recognizing the *special requirements* (the term used in NB-3251) germane to the MPC.



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The fillet weld, as Figure NB-4243-1 would suggest that we provide on the inside of the MPC cavity space, is considered operationally unacceptable because the toe of a continuous fillet weld would provide a hard blockage to the differential thermal expansion of the fuel basket. Avoiding a dimensional interference between the fuel basket and the MPC shell under all scenarios of operation is a cardinal objective in MPC design and operation.

To summarize, it is Holtec's assertion that the MBS weld detail in our FSARs is sanctioned by Subsection NB of the Code and therefore does not need to be cited as a specific exception to the Code, even though the verbiage in several paragraphs of the Code on this matter is rather ambiguous. It is, therefore, not mandatory to list the deviation from the standard weld detail in the case of the NB joint in the Code exception table.

There is currently some disagreement among the Holtec Users' Group (HUG) membership regarding whether this confinement boundary weld meets ASME Code requirements for Subsection NB, Category C weld locations. The NRC's 10 CFR 72 Safety Evaluation Report for HI-STAR 100, Section 3.1.4.4 states: "The staff reviewed [the MPC] confinement boundary weld designs for compliance with the design code used and found them acceptable." This SER statement may lead one to believe that the NRC staff concurs with the assessment of Code compliance for the configuration of this weld, as articulated in the preceding paragraphs. Case 3 would allow items of ambiguous status regarding Code compliance to be conservatively submitted to the NRC as a proposed Code exception at Holtec's reasonable discretion.

Example for Case 4

The ASME Code contains a multitude of requirements that, if tabulated, would likely run into the hundreds. Of these, certain requirements are "parent", or upper tier, while others are derivative or lower tier requirements. An exception to a parent or upper tier requirement listed in the Code exception table provides a clear direction as to the manner in which a derivative requirement should be treated. Such derivative requirements, therefore, generally do not need to be listed individually in the Code exception tables.

As a specific example, NF-2000 requires all raw materials to be procured from an ASME approved supplier. An exception to this requirement, with appropriate justification, is provided in the HI-STAR and HI-STORM Code exception tables. The ASME-approved supplier predicate, however, runs throughout the Code: For example, NF-4121 provides requirements on the means of material supplier certification. To avoid excessive clutter in the Code exception table, and tedious parsing of each Code paragraph, it would be preferable to treat approval of the upper tier exception as the governing exception over all applicable lower tier requirements in the Code.



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The group of Holtec's Code experts working on this issue believe that the above framework for creating the Code exception table would result in a well-articulated, uncluttered set of exceptions, while preserving implementation of the Code "to the extent practicable" as stated in ISG-10 and our FSARs.

III. Corrective Actions Taken and Results Achieved

- a. We have confirmed that the fabricator has not incorporated the use of the revised note in their fabrication documents. Since this addition to the note was never incorporated into the fabrication process; none of the previously manufactured equipment was affected by the revision to the note.
- b. An ECO has been initiated to remove the portion of the drawing note cited in the violation.

IV. Corrective Actions to Avoid Further Violations

- a. We are performing a review of the HI-STAR and HI-STORM FSARs and drawings to compile a list of necessary additional Code exceptions in both docket (Docket 72-1008 and 72-1004) consistent with the above classification table. Additional Code exceptions identified will be evaluated for safety significance and our cask users will be informed of additional Code noncompliances in a timely manner.
- b. Procedural guidance currently exists to identify changes that require prior NRC review and approval before implementation. This procedural guidance will be updated to include the Code exception classification process described above and required actions. Training will be provided to appropriate personnel to ensure changes that create the need for a revised or additional Code exception are processed appropriately.
- c. Exception requests to augment the Code exception tables for the two Holtec Part 72 CoCs will be submitted based on the results of corrective action IV.a above. At a minimum, the Code exceptions requested will include the subject drawing note (Case 1 example) and the MBS weld configuration (Case 3 example).



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V. Date Full Compliance Will Be Achieved

January 31, 2002

RESPONSES TO WEAKNESSES

In addition to addressing the above violations, we also herein address the eight weaknesses noted in the inspection report. These weaknesses are addressed individually below and are numbered sequentially as they appear in the inspection report.

Weakness 1

From Inspection Report Section 2.1.2.2:

Administrative memoranda and internal e-mails were being used to supplement procedures and instructions in lieu of revising the procedures. 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.

Response to Weakness 1

As explained in the Violations section, Holtec is undertaking a comprehensive procedure review effort. As part of this effort, Holtec is reviewing all administrative memoranda email instructions and re-locating procedural guidance to the appropriate procedures.

Weakness 2

From Inspection Report Section 2.3.2:

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 QPVFs issued in 2001 as compared to the year 2000 QPVFs. 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 QPVFs and CARs, root causes were attributed to inattention to detail or an employee's failure to follow procedures; however, there was no evidence that



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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.

Response to Weakness 2

The Holtec corrective action process is being reviewed and strengthened to address these issues. Please also see our responses to Violations C and D.

Weakness 3

From Inspection Report Section 3.2.1:

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.

Response to Weakness 3

The calculation reviewed by the inspector was generated over six years ago, before the current format requirements for calculation packages were in place. Since that time, more restrictive format requirements for calculation packages have been proceduralized. HQP 3.1 requires design input to be taken from "robust sources" and lists a hierarchy of acceptable sources. The FSARs are considered robust sources since they contain the detailed cask design criteria and design basis information. We will revise our process for citing and controlling references, as necessary, to ensure configuration control of information cross-referenced among the various design and licensing documents.



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Weakness 4

From Inspection Report Section 3.2.2, 6th paragraph:

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.

Response to Weakness 4

The intent of the procedure is to require ECOs for changes affecting transportation as well as dry storage cask designs. The term “dry storage” in the Holtec vernacular means any work associated with the cask program (as opposed to “wet storage” work). We failed to define the term “dry storage” in the HQP to reflect its definition. We recognize the confusion this may create for those not fully indoctrinated in the Holtec product line. We have, therefore, revised the procedure to distinctly identify dry storage and transportation cask work, where appropriate.

The ECO database is used to identify whether the *particular change* in the ECO requires a Part 71 CoC amendment or SAR change. However, it is not the sole source of identifying changes needed for the Part 71 CoC or SAR. The ECO database is one tool used to collect future CoC amendment needs. Other sources of change input include the dry storage amendment requests, customer requests, and internally identified needs. Since the coordination of changes for future certificate amendment requests is not a quality-related activity, it is not controlled by a procedure; rather, it is controlled by the Licensing Manager using both the ECO database and other organizational tools.

Weakness 5

From Inspection Report Section 3.2.2, 7th paragraph:

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 Holtec decided on a case-by-case basis whether NRC should be notified of a needed change. The team



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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.

Response to Weakness 5

As we committed during the inspection, on October 24, 2001 Holtec submitted the criteria used to determine whether a design change affecting an item currently under NRC review needs to be submitted to the NRC. We have requested a meeting with SFPO management to discuss these criteria. We are also revising our procedure to assure proper identification and submittal of changes to the NRC in accordance with these criteria.

Weakness 6

From Inspection Report Section 3.2.2, 8th paragraph:

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.

Response to Weakness 6

We are revising our procedures to control interim changes to items under NRC review. If the change is not required to be submitted to the NRC under the criteria referenced in the response to Weakness 5 above, the new process controls the deferral of the 10 CFR 72.48 screening/evaluation approval until after the NRC has approved the design change under review. After NRC approval, the "deferred" 10 CFR 72.48 screening/evaluation approval may be completed after verifying that the change is consistent with the NRC-approved information.



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Weakness 7

From Inspection report Section 3.2.2, 9th paragraph:

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.

Response to Weakness 7

Drawings cannot be issued under the Holtec QA program until the database assigns a randomly generated Verification Identification Record (VIR) number, indicating final approval of the drawing. At the time of the inspection, the Holtec database would assign a VIR number after the project manager approved the document to ensure a complete document was presented for final, in-line QA approval. In some cases, the QA review date could have been after the VIR number was assigned. The logic in the database has since been modified to assign the VIR after the last required approval is obtained.

Weakness 8

From Inspection report Section 3.2.3.2:

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.



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Response to Weakness 8

A SAR control procedure is being developed to provide additional procedural guidance on the living FSAR that complements the existing guidance that is in place for changes approved under 10 CFR 72.48. The new SAR control procedure will include instructions for changes involving pending or completed NRC approval.