

Joseph LiVecchi

From: Bernard [Bernard_Gilligan@holtec.com]
Sent: Wednesday, February 06, 2002 12:41 PM
To: joseph_LiVecchi@holtec.com
Subject: Response to Mr. Narbut's Question for Mark Soler



paul_narbut_questi
on_response.... Mark,

The attached .pdf file contains letters and e-mails in chronological order. These documents demonstrate that the HUG membership had been notified in a timely manner and have been working with Holtec throughout this process.

Shortly after the NRC completed their inspection at Holtec, Mike McNamara issued a summary of the inspection findings to all the HUG members. This is the first document in the attached file. We developed an action plan to address each of the items cited by the NRC. This action plan (2nd document) was distributed to the HUG membership and included a listing (Item #10) for the drawing note not in compliance with ASME Code. The actions to be performed included a review of the design for other Code exceptions/clarifications. At least every other week, there have been telecons in the various HUG committees (HUG Fabrication Committee and Licensing Committee) to address ASME Code exceptions. Next, the NRC issued the official inspection findings, which was forwarded to all HUG members (3rd document). The response from Holtec was developed in conjunction with the HUG membership and is included as the 4th document. After an exhaustive review of the design, a draft of the changes to the Code exception table was distributed to the HUG membership for review (see e-mail). A Telecon was held to discuss the comments and the draft was revised and was re-distributed to the HUG membership (see e-mails). Then, the final letters for HI-STAR and HI-STORM were submitted to the SFPO and copied to the HUG membership.

Each of the utilities has been notified of the ASME Code exception issue and they have each separately placed the issue in their corrective action program. Safety assessments have been performed for casks in-service to confirm that their is not a significant reduction in safety.

If there are any further questions, do not hesitate to contact me.

Bernard Gilligan
Holtec Program Manager

m-3
#20



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E-MAIL MEMORANDUM

To: HUG Membership

From: Michael McNamara
Vice President, Nuclear Projects
Holtec International

Date: September 26, 2001

As you know, the USNRC began a routine inspection at Holtec International in Marlton, New Jersey on Monday, September 10, 2001. Their last inspection at Holtec was in 1996. The scope of the inspection was anticipated to include a follow-up of QA issues related to the issuance of our QA Manual, Revision 12, prior to NRC approval, and design control activities, including the implementation of the 10CFR72.48 process. This was a very detailed, in-depth inspection conducted by a team of five inspectors over a one-week period.

The NRC inspection actually began on Monday, September 10, 2001; however, it was interrupted by the terrorist attack in New York. The inspection team left Holtec on Tuesday September 11, 2001 and then returned on Monday, September 17, 2001. The NRC inspection team consisted of five NRC personnel, which included Mr. Christopher Jackson, a PM from the NRC Licensing Section; Mr. Paul Narbut, the Lead and also the Section Chief of the Transportation and Storage Safety and Inspection Section; Mr. Robert Temps; and Frank Jacobs, also from the Inspection Section; and Ms. Adelaid Giantelli from the Technical Review Section.

In an effort to keep our clients informed we have summarized the Exit Meeting below. **It must be noted that this information is considered preliminary.** The NRC report is due within forty-five days and may contain some changes from what was discussed at the Exit Meeting.

In general the NRC found our QA Program and processes adequate and did not discover any issues of safety significance or that would affect delivered hardware. They did, however, find several issues that they believe will become low level violations and where improvements are warranted. These are summarized below. Note that after NRC management review and discussion with the inspection team, some of the findings may be reorganized, grouped or changed to a different violation. Except as noted, Holtec concurred with all findings at the Exit Meeting.

1) An NOV was proposed for failure to use an NRC-approved QA program due to Revision 12 being used prior to NRC approval.

2) An NOV was proposed for performing activities (internal surveillances) affecting quality without a procedure. This issue relates to #1 above as surveillances replaced the in-line QA reviews. We did not concur with this finding.

3) An NOV was proposed for failure to follow procedures. Examples included not marking ECO's on drawings, not identifying that a COC change was needed, signing a 72.48 evaluation before completing all procedurally required steps, not listing all input files in a calculation, and performing a drawing revision without using the ECO process for a dry storage design change.

4) An NOV was proposed for inadequate design control due to a drawing change that appeared to be made without NRC approval. Note: we have subsequently informed NRC that the drawing change had received NRC approval under a LAR in 1999 and this is under further NRC review.

Memorandum to HUG Membership
September 26, 2001
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- 5) An NOV was proposed for ineffective corrective action because several examples of QPVF's involving failure to follow procedure and inattention to detail did not prompt an increase in corrective actions.
- 6) An NCV was proposed for failure to follow a procedure that was changed when the QA manual revision was implemented.
- 7) Several weaknesses were proposed, including those discussed under item #3 and for issues involving proposed design changes made while LAR's are under NRC review, use of Email for training, inadequate procedures, and lack of a procedure for the living FSAR.

Holtec's response during the inspection and at the exit included an acknowledgement that the inspection team had performed a very thorough and detailed review and had discovered several issues that would be corrected immediately. We also explained that many corrective actions were ongoing prior to the team's arrival and that some of the initiatives were of a design to completely eliminate a repeated error. This includes an electronic Approved Vendor List (AVL) that would be automatically scanned for each Purchase Order and thereby eliminate the problem of use of an unapproved vendor and the creation of an electronic ITS classification of hardware which eliminates errors in specification of the wrong ITS classification. Other improvements in procedures and electronic infrastructure were cited as examples of our continuing enhancement to the QA program.

We further explained that all Holtec employees are committed to QA program and procedural compliance; that we did not suffer from systemic procedural non-compliance due to lackadaisical employees or programmatic deficiencies. Our QA program is strong and is being tested by fire. We have gone through numerous first time designs, calculations, drawings and manufacture of first-time hardware. New designs, additional design demands on our standard design, coupled with implementation of the new 10CFR72.48 process are all occurring simultaneously and we have made some mistakes. We have also learned a great deal, and have and will continue to self-correct.

Implementation of the 10CFR72.48 process was challenging due to the complexities introduced by the relationship among the licensee, the COC holder (Holtec), and the NRC. Christopher Jackson, the NRC Project Manager, who has significant experience in Part 50 work, expressed his opinion of the Part 72 work in this area as immensely complicated. We were pleased that the NRC team felt that Holtec was somewhat of a pioneer in this area, since we have accommodated the industry demand for the many design changes. That we did not process all of this work through our QA program and procedures without error is our challenge; however, we have captured the lessons learned, will benefit from the NRC's findings, and will emerge from the shadow of all these first-time designs a stronger organization. We take responsibility for these issues and will respond fully, comprehensively, and without delay.

We have already held internal meetings with QA, licensing, and senior management to formulate a plan of action to respond to these issues. A preliminary action plan will be issued by the end of this week. We will not await the NRC report to begin making changes. In fact we made several before they left our facility. An "All Hands" meeting will be held to reinforce Holtec's management's expectations for all employees working in the Nuclear Division.

As our clients and HUG members, we welcome your input to our action plan. We also welcome your comments on the QA program, corrective action process, procedures, and to our response to these findings. We value your opinions and would appreciate your thoughts on how we can further improve. We believe that the NRC now knows us better than ever, and confident that they will continue to repose their confidence in Holtec International as a COC Holder in the dry storage of spent nuclear fuel.

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From: Brian <Brian_Gutherman@holtec.com>
Subject: NRC Inspection Report
Cc: stengerd@ballardspahr.com,group1

Attached is the final NRC inspection report from our September inspection. This electronic version does not include the Information Noticed referred to as being enclosed with the report. The number and severity level of the violations, and the weaknesses are essentially the same as they explained in the exit meeting. I will be working on the response with a draft complete by 11/12 for client review. Client comments will be due on 11/16. I will resolve comments and issue the response by 11/21 to meet the 30-day clock.

Brian



9 01inspection report.doc

Brian Gutherman, P.E.

Licensing Manager

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Brian, 06:33 PM 10/25/01, Action Plan Update

Delivered-To: <group1@holtec.com>
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jfurr@entergy.com
From: Brian <Brian_Gutherman@holtec.com>
Subject: Action Plan Update
Cc: group1

Attached is an updated corrective action plan for the NRC inspection.

Brian

 NRC INSPECTION ACTION PLAN.doc

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HOLTEC INTERNATIONAL

NRC INSPECTION ACTION PLAN

| **Updated:** February 6, 2002

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NRC INSPECTION ACTION PLAN

BACKGROUND

Holtec International holds three Certificates of Compliance (CoC) under Parts 71 and 72 of the Code of Federal Regulations. As a CoC holder, Holtec is subject to periodic inspections by the Nuclear Regulatory Commission (NRC). The NRC conducted a routine inspection of Holtec International from September 17 through 21, 2001. The focus of the inspection was to verify the implementation of regulatory requirements and Holtec's own QA program requirements through the review of documents. In particular, the design control (including 10 CFR 72.48 implementation) and corrective action processes were reviewed in depth. No programmatic breakdowns or design deficiencies were identified during the inspections. However, a number of findings were identified in the areas of process/procedural adequacy, failure to follow procedures, and implementation of the corrective action program. These findings were preliminarily classified as either potential violations, non-cited violations, or weaknesses. These findings will be formally classified and documented in an NRC inspection report to be issued within 45 days of the close of the inspection.

PURPOSE

The purpose of this action plan is to provide an overview of the actions to be taken to address the findings from the NRC inspection, and other related issues (see Approach below). It also is used as a management tool to communicate the status of corrective actions to internal and external parties. This action plan does not replace the function of Holtec's formal corrective action program. For example, detailed root cause discussions are not included here, but are found in the Corrective Action Request (CAR) documentation packages. Rather, this document serves to summarize the individual corrective action items (sorted by NRC finding), in one location for ease of management tracking and communication.

APPROACH

The approach to responding to the issues identified in the NRC inspection is to look deeply into the extent of condition and root causes so that any actions proposed will result in processes that are in compliance with the regulations, comprehensive, effective in preventing recurrence, and clear to the user. The corrective actions related to revising processes and associated personnel training are the lynchpins to preventing future errors. To ensure a broad-based approach, three key elements will be used to develop the corrective actions:

1. In addition to the specific inspection findings, other related issues identified during the inspection, or found through any extent-of-condition evaluations performed by Holtec will be addressed.
2. User feedback from Holtec personnel will be specifically requested and considered to root out flaws in processes (including guidance that is missing or not clear) or training that contribute to errors.

NRC INSPECTION ACTION PLAN

3. Feedback from utility clients will be solicited and considered for incorporation into corrective actions. This feedback will be incorporated to the extent that it addresses issues identified here and is appropriate for an organization of Holtec's size.

The intent of the approach for developing actions to prevent recurrence is to look deeper than just the findings identified in the inspection so that the full extent of the problems are identified. Then, root causes will be identified and effective corrective actions taken in the areas of organizational structure, process improvement and personnel training, as required. This action plan includes two main areas of focus, based on the nature of the inspection findings: 1) design control/licensing interface and 2) corrective action program improvements.

RESPONSIBILITIES

President, Holtec International

- Provides senior management vision and expectations for developing root causes and corrective actions.
- Approves all revisions to Holtec Quality Procedures and organizational structure and responsibilities.

Vice President, Nuclear Projects

- Provides day-to-day senior management oversight of the determination of extent of condition and development of root causes and corrective actions.
- Prioritizes resources to ensure timely implementation of corrective actions.
- Ensures periodic communication of action plan status to the President, Holtec International, other Holtec personnel, and utility clients (through the Holtec Users Group).
- Recommends and implements changes in organizational structure and responsibilities.

Quality Assurance Manager

- Manages the corrective action program documents associated with these actions. Specific corrective actions may be delegated to others in the line organization.
- Ensures all necessary revisions to quality procedures are made in accordance with the QA Program.
- Coordinates development of corrective action program improvements and associated training.
- Ensures overall execution of this action plan in accordance with the schedule.

NRC INSPECTION ACTION PLAN

Licensing Manager

- Prepares the formal response to the inspection report.
- Ensures regulatory compliance of design control/licensing interface (e.g., 72.48 process, SAR control).
- Coordinates development of design control/licensing interface improvements and associated training.

ACTION PLAN

The specific actions are listed by NRC violation or weakness in the attached table. This table will be modified periodically to reflect the completion of actions and the revision to or addition of actions.

INSPECTION ACTION PLAN* (Attachment)

ITEM	ISSUE	INSPECTION REFERENCE	ACTIONS	RESPONSIBLE	DUE DATE	STATUS
1	Failure to use an NRC-approved QA program. QA program Rev. 12 was implemented before NRC approval was received.	Violation 1 FJ-01	a. Submit QA program manual Rev. 12 for NRC approval b. Revert to previously approved revision of QA manual to govern work until later revision is approved. c. Revise HQP governing control of QA program manual revisions to recognize this requirement. d. Recognize this requirement in licensing procedure. e. Review Part 71 and 72 regulations for other potential compliance issues. f. Revise QA procedures per item e above g. Revise licensing procedures per item e above	a. Gutherman b. M. Soler c. M. Soler d. Gutherman e. M. Soler and B. Gutherman f. M. Soler g. Gutherman	a. Complete b. Complete c. Complete d. 11/16/01 e. Complete f. Complete g. 11/16/01	d. HQP 19.6 in peer review g. HQPs 19.4, 19.5, and 19.6 in peer review

* Root cause and extent of condition evaluations may add to, or modify these corrective actions.

INSPECTION ACTION PLAN* (Attachment)

ITEM	ISSUE	INSPECTION REFERENCE	ACTIONS	RESPONSIBLE	DUE DATE	STATUS
2	Activities affecting quality not prescribed in a procedure. QA surveillance activities not prescribed by a procedure	Violation 2, Ex. 1 FJ-03	Develop QA surveillance procedure	M. Soler	Complete	
3	No procedural guidance for determining whether changes to designs under NRC review need to be submitted to NRC.	Weakness 1, Ex. 2 CJ-01	a. Establish criteria and submit to NRC b. Add licensing checklist for review of ECOs/SMDRs/drawings. c. Recognize these types of changes in ECO/72.48 process d. Meet with NRC to discuss criteria	a. Gutherman b. Gutherman, Chaudhary c. Gutherman d. Gutherman	a. 10/19/01 b. 10/12/01 c. 10/31/01 d. 12/21/01	a. Complete b. Complete c. Criteria to be added to ECO checklist questions in IIQP 5.1 d. Meeting has been requested and proposed agenda submitted to NRC

* Root cause and extent of condition evaluations may add to, or modify these corrective actions.

INSPECTION ACTION PLAN* (Attachment)

ITEM	ISSUE	INSPECTION REFERENCE	ACTIONS	RESPONSIBLE	DUE DATE	STATUS
4.	Failure to follow procedure. ECOs not marked on controlled stick file drawings per procedure.	Violation 3 Ex. 4 RRT-04	a. Ensure all ECOs are properly marked on stick file drawings b. Ensure single point accountability for future drawing mark-ups c. Update HI-STORM drawings to incorporate ECOs d. Update HI-TRAC drawings to incorporate ECOs e. Update MPC drawings to incorporate ECOs f. Update HI-STAR drawings to incorporate ECOs g. Conduct all hands meeting to reinforce senior management expectations regarding procedure compliance	a. Butler b. M. Soler c. Butler d. Butler e. Butler f. Butler g.	a. 10/5/01 b. 10/5/01 (interim) 10/31/01 (procedure change) c. 10/12/01 d. 10/26/01 e. 11/9/01 f. 1/31/02 g. Complete	a. Complete b1. Complete. c. Complete d. In progress

* Root cause and extent of condition evaluations may add to, or modify these corrective actions.

INSPECTION ACTION PLAN* (Attachment)

ITEM	ISSUE	INSPECTION REFERENCE	ACTIONS	RESPONSIBLE	DUE DATE	STATUS
5	Failure to follow procedure. ECOs 1021-30, 1022-18, and 1023-5 did not indicate the HI-STORM CoC as an affected document, nor were the proposed CoC changes in LAR 1014-1 revised to indicate the ACHes are optional.	Violation 3, Ex. 1 CJ-05	a. Revise procedure to clarify "affected documents" to only include those Holtec has the authority to change. b. Supplement LAR 1014-1 to revise CoC c. Develop amendment request preparation procedure	a. M. Soler b. Gutherman c. Gutherman	a. 10/31/01 b. 10/5/01 c. 11/30/01	b. Complete c. HQP 19.5 in peer review.
6	Failure to follow procedure. A drawing change affecting the HI-STORM FSAR (HI-TRAC mating device) was made without an ECO	Violation 3 Ex. 2 CJ-06	a. Issue ECO for mating device drawing. b. Clarify procedure and train	a. Goodrich b. M. Soler	a. 10/7/01 b. 10/31/01	a. Complete (1027-46)
7	Failure to follow procedure. 72.48 # 29, Rev. 1 was signed off by preparer before work was complete	Violation 3, Ex. 3 CJ-07	a. Look at all unfinished 72.48s and "undo" preparer's signature b. Provide reminder to personnel that signatures are only to be added to 72.48 database after work is done (ready for review). c. Add "assigned to" block in 72.48 database. And revise procedure accordingly	a. Complete b. Complete c. Chaudhary and Gutherman	c. 10/31/01	

* Root cause and extent of condition evaluations may add to, or modify these corrective actions.

INSPECTION ACTION PLAN* (Attachment)

ITEM	ISSUE	INSPECTION REFERENCE	ACTIONS	RESPONSIBLE	DUE DATE	STATUS
8	Failure to follow procedure. Shielding calculation HI-951322 does not list all electronic address of all input files.	Violation 3, Ex. 5 AG-01	None			After further review, it was determined that, per IIQP 3.2, Step 6.4.5, reports issued prior to this procedural requirement do not need to be updated to meet new format requirements.
9	Failure to follow procedure. QA procedure does not require QA manager approval of drawings, but QA manual does	Non-cited Violation FJ-02	a. Provide interim guidance to ensure QA manager approval of drawings b Revise procedure to address QA approval of drawings.	a. M. Soler b. M. Soler	a. Complete b.10/31/01	

* Root cause and extent of condition evaluations may add to, or modify these corrective actions.

INSPECTION ACTION PLAN* (Attachment)

ITEM	ISSUE	INSPECTION REFERENCE	ACTIONS	RESPONSIBLE	DUE DATE	STATUS
10	Inadequate design control. ECO 1021-1 added a note to the MPC drawings with an open-ended allowance for weld defects on the basket welds. This appears to be a Code exception not approved by the NRC ¹	Violation 4 PPN-01	a. Issue ECO(s) to correct the note or request NRC approval of a Code exception. b. Evaluate any other design details on drawings for Code compliance c. Request deviations as necessary.	a. Rosenbaum b. Gilligan c. Gutherman	a. 11/2/01 b. 11/30/01 c. Two weeks after completion of Item b.	a. ECOs in prep.
11	Ineffective corrective action. Several recent QPVFs cited problems with updating rack drawings with ECO information. Additional problems in this area were found during the inspection.	Violation 5 RRT-03	a. Evaluate corrective action program effectiveness, including root cause evaluation process, corrective actions to prevent recurrence, and personnel training. b. Evaluate and make necessary revisions to drawing revision process to reduce likelihood of errors.	a. M. Soler b. M. Soler	a. 12/31/01 b. 10/31/01	

¹ UST&D has not incorporated this flexibility in their procedures.

* Root cause and extent of condition evaluations may add to, or modify these corrective actions.

INSPECTION ACTION PLAN* (Attachment)

ITEM	ISSUE	INSPECTION REFERENCE	ACTIONS	RESPONSIBLE	DUE DATE	STATUS
12	Administrative memos and emails are being used to supplement procedures versus revising the procedures	Weakness 1 Ex. 1 FJ-04	a. Evaluate use of emails and AMs to govern quality activities (e.g., for interim guidance only) and develop policy for AM/email use re: quality activities.	a. M. Soler	10/31/01	
13	Lack of a procedure. Living SAR concept not adequately proceduralized. Need to address where working version of SAR changes are kept until approved and then added to living FSAR. Address how users are to consult work in progress (72.48 database vs. living SAR)	Weakness 1, Ex. 2 CJ-03	a. Brainstorm with users for input to living SAR process b. Address living SAR in procedure. c. Provide training	a. Gutherman b. Gutherman c. Gutherman	a. 10/12/01 b. 11/16/01 c. 11/16/01	a. Complete b. HQP 19.2 revision and new HQP 19.4 in peer review
14	Procedure weakness. Procedure allows QA manager approval and issue of drawing after VIR number is assigned.	Weakness 2 Ex. 2 CJ-04	Revise procedure and database to address VIR timing vs. signatures	M. Soler and P. Chaudhary	10/31/01	
15	Inadequate procedure. Procedure does not clearly require use of an ECO for Part 71 drawing changes	Weakness 2, Ex. 1	a. Revise procedure to require ECO for all cask design changes, including new drawings for cask product line (including ancillaries) whose design function may be discussed in the SAR documents.	a. M. Soler	10/31/01	

* Root cause and extent of condition evaluations may add to, or modify these corrective actions.

INSPECTION ACTION PLAN* (Attachment)

ITEM	ISSUE	INSPECTION REFERENCE	ACTIONS	RESPONSIBLE	DUE DATE	STATUS
16	Corrective action weakness. Attention to detail and procedure compliance trends appear flat. Configuration management issues appear to be increasing. Corrective actions don't appear to explore cultural or programmatic issues	Weakness 3 RRT-01	a. Perform root cause of procedural compliance and attention to detail issues (address culture and organizational structure issues). b. Revise processes and programs as necessary to include barriers to prevent errors c. Revise organizational structure as necessary. d. Provide training	a. M. Soler b. M. Soler c. M. McNamara d. M. Soler	a. 10/12/01 b. 10/31/01 c. 10/31/01 d. 11/9/01	a. Complete c. Complete. Dedicated Engineering Services group created.
17	Weakness in calculations. Shielding calculation reviewed do not list assumptions and input data (or results?). Calculation refers to SAR for information but the SAR is an ever-changing document. No specific revision or date of the SAR is referenced. The calculation of record should be clear on assumptions and inputs.	Weakness 4 AG-02	Review calculation/design input procedure and factor this weakness into revision. SAR should only be used as a source of input if no other source document is available. If used, ensure the specific revision of the SAR is listed	M. Soler	10/31/01	

* Root cause and extent of condition evaluations may add to, or modify these corrective actions.