

Holtec Inspection Debrief 10/17/01

1. Inspection started 9/10 and terminated 9/11, restart 9/17
2. Identified five violations and 4 weakness and one NCV
 - a. One violation for **failure to use an NRC approved QA program**
 - b. A second violation for **lack of procedure** (for QA surveillances). Also Six examples of a weakness regarding inadequate procedures
 - c. A third violation for **Ineffective Corrective Action** (re incorporating ECOs on Drawings). Also 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.
 - d. A fourth violation for **failure to follow procedure** with 7 examples. Also the NCV involved a failure to implement the requirements of the QA manual in a quality procedure.
 - e. A fifth violation for **inadequate design control** regarding a drawing note that allowed weld defects in excess of the applicable industry code.
Also, in the area of design controls for calculations, 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 calculations: the calculations sampled did not specify the assumptions made nor the results obtained.

As a general conclusion we found more problem areas than we expected to especially in the area of the adequacy and compliance to procedures. We told Holtec to take a step back and examine the reasons for the problem and find a solution that will lead to an improving trend

The areas of design control and the 72.48 process were overall adequate with room for improvement

The areas involved in QA controls were overall adequate but indicated a need to strengthen the resolution of problem areas

F-12

Inspection Findings
HOLTEC Inspection 9/10-11, 9/17-21/01

October 18, 2001

Find- ing Cat.	Num ber	Finding	Type	Hi conc Y/N	Notes
Vlo 1 QAP	FJ-01	Failure to use an NRC approved QA program. QA manual Rev 12 was put into use before Rev 12 was approved by NRC	NOV	Y	
Vlo 2 LP	FJ-03	Activities affecting quality are not prescribed by a procedure. The QA surveillances substituted for in-line QA approval of drawings and procedures was implemented by an administrative memorandum rather than a formal procedure. (AM-56 dated 10/17/00 removed in line QA reviews of certain work products required by Holtec QA Manual Revision 11 Section 5 paragraph 4.1 and substituted surveillances of the activities.)	NOV	No	<i>Holtec doesn't consider a procedure was necessary. They had a schedule and a checklist. Note they issued a procedure in Aug 01 when this issue was discussed with NRC in relation to the QA Manual question</i>
Weak 1 Ex 1 LP	FJ-04	Administrative memoranda and E-mails are being used to supplement procedures vice formally changing the procedure. E.g. AM-71 added a requirement beyond those in HQP-5.1 (it required that drawing sign offs only be done after analysis is completed.) Also Email 3/13/01 added requirements to HQP 5.1 for drawings.	Weakness	Y	None of these examples violated procedure requirements
Weak 1 Ex 2 LP	CJ-02	Inadequate procedure. HQP 5.1 does not clearly require an ECO to be prepared for Part 71 design changes . The ECO provides a process to determine what associated documents must be changed also.	Weakness	Y	No improper examples noted.
Weak 1 Ex 3,4 LP	CJ-01	Lack of a procedure. 1) There is no procedural guidance for determining if emerging changes to a design feature under active NRC review should be submitted to NRC for review. What changes need to be submitted, when they should be submitted, and how NRC should be kept informed need clarification and proceduralization. 2) Also, Holtec needs a procedure to clearly identify how to handle changes being made at-risk- for fabrication when 72.48 doesn't apply (since NRC has not approved the change under NRC review)..	Weakness	Y	Suggest that Holtec develop a policy and meet with SFPO management to discuss it. Holtec agrees and is developing guidance.
Weak 1 Ex 5 LP	CJ-04	Procedure weakness. Procedure allows QA Manager approval of a drawing after the drawing is issued. Two examples of QA manager approval after drawing issued. No examples of a change to the dwg as a result of QA review but there was an additional review added for the structural analyst .	Weakness	Y	This needs to be corrected even after Rev 13 of the QAM is approved. QA Manager in line approval of purchase specs will be retained.
Weak 1 Ex 6 LP	CJ-03	Lack of a procedure. Holtec has a living SAR concept where all approved and not-yet-approved changes are incorporated in a copy of the SAR. The changes to be incorporated, when they are to be incorporated, and how (and when) the living SAR vice the official SAR are to be used, are not described in a procedure	Weakness	Y	<i>Holtec has guidance for moving 72.48 changes into the living SAR but not for ammendments</i>

Vio 3 ICA	RRT-03	Ineffective Corrective Action. Several recent QPVs cited problems with the updating of drawings with ECO information as required by QPM 5.1. A sample of about 30 ECOs by NRC found that about 1/3 had similar problems.	NOV	?	QPVF-136
Weak 2 ICA	RRT-01	Corrective Action Weakness. NRC trending of two years of QPVs indicates that attention-to-detail and failure-to-follow procedure issues continue with no apparent improvement. Configuration management issues appear to be increasing. The trend was identified in the QA mid-year assessment but corrective actions are not exploring cultural or programmatic issues behind the trend	Weakness	Y	
Vio 4 Ex 1,2,3 FTFP	RRT-04	Failure to follow procedure QPM 5.1 requires marking drawings with an ECO number near the affected area on a drawing. However Holtec personnel are marking up the drawing in a variety of ways which do not meet procedure and are subject to errors. (E.g. some drawings are "bubbled" and the ECO change drawn in ...but this can lead to erroneous unchecked drawing changes.	NOV	Y	QPVF-136
Vio4 Ex 4 FTFP	AG-01	Failure to Follow Procedures. Calculation Package HI-951322, "HI-STAR 100 Shielding Design and Analysis for Transport and Storage" was reviewed for compliance with Holtec Quality Procedure 3.2, "Design Analysis." HQP 3.2, Section 6.2.1(h) requires that each calculation provide a list of all input files and the residence in the electronic network. Appendices 24 and 25 (BWR and PWR Source Terms, respectively) do not list the input files as required by procedure .	NOV	y	
Vio 4 Ex 5 FTFP	CJ-05	Failure to follow procedure. The ECO and license amendment request 1014-1 Rev 2 dated July 3 (for a design change making the aluminum heat conduction elements optional) missed the fact that the CoC also needed to be changed and missed identifying two areas in the SAR which needed to be changed.	NOV	Y	The missed SAR areas were describing calc models and one can infer that the model includes the heat conduction elements
Vio 4 Ex 6 FTFP	CJ-06	Failure to follow procedure. A drawing change that affected the HIStorm FSAR (an extensive change to the HITRAC/HISTORM transition device) was approved without an ECO being issued as required by HQP-5.1. The ECO process assures that other affected documents are identified and tracked for change	NOV	Y	QPVF 135
Vio 4 Ex 7 FTFP	CJ-07	Failure to follow procedure: Contrary to HQP 19.2, a 72.48 evaluation was signed off electronically by the preparer without completing the 72.48 evaluation.	NOV example	Y	
NCV 1 FTFP	FJ-02	Failed to follow procedure. Procedure HQP 5.1 for drawing controls does not agree with the QA Manual. The procedure no longer requires QA Manager approval of dwgs, but the QA Manual does). Licensee identified	NCV	Y	

Vio 5 IDC	PPN- 01	Inadequate design control. ECO 1021-1 changes a drawing note and adds an allowance for weld defects in excess of Code. It adds "and other weld imperfections" to an N the Code exception is not listed in the CoC.	NOV	Y	UST&D procedure did not implement the change, but the SAR Code exception does not include the expanded scope.
Weak 3 Calcs	AG- 02	Weakness in Calculations. For shielding calculation sampled the team noted that the calculations do not list the assumptions and input data (or results?). The calculation refers to the SAR for this information but the SAR is an ever changing document. No specific Revision or date of the SAR is referenced. The calculation of record is should be clear on assumptions and inputs. (And results?)	Weakness	Y	

SFPO Management Discussion Item

NA	PPN -03	We (NRC and industry) need to resolve the question of when ISFSI licensees should obtain certificate holder concurrence to their 72.48s. Our example is: Hatch did a 72.48 to move a loaded HISTORM cask from the reactor building to outside the reactor building without a lid. Hatch did not solicit Holtec input other than a dose rate calc at the site boundary. Possible issues involve accident analysis for the tipping accident and tornado missile analysis.	NA	NA	NRC Team to pursue at SFPO
----	------------	---	----	----	----------------------------