

Date: 9/19/01

WEAKNESSES

Problem Identification Sheet

Problem Number: (eg PPN-01): FJ-04

Problem: Title ACTIVITIES AFFECTING QUALITY ARE NOT PRESCRIBED IN DOCUMENTED PROCEDURES.

Problem Description:

ADMINISTRATIVE MEMORANDA AND INTERNAL E-MAILS ARE BEING USED TO PROVIDE PROCEDURES AND INSTRUCTIONS FOR PERFORMING ACTIVITIES AFFECTING QUALITY. THERE IS NO DOCUMENTED PROCEDURE THAT CONTROLS THE USE OF ADMINISTRATIVE MEMORANDA AND E-MAIL FOR ACTIVITIES AFFECTING QUALITY. ADDITIONALLY, RETAINING PROCEDURAL REQUIREMENTS IN VARIOUS FORMATS IN LIEU OF TIMELY REVISION OF THE APPLICABLE QUALITY PROCEDURE IS A POSSIBLE WEAKNESS IN THE QUALITY PROGRAM.

EXAMPLES:

1. AAI-71, "DESIGN/ANALYSIS INTERFACE REQUIREMENTS," PROVIDES PROCEDURAL INSTRUCTION NOT IN THE APPLICABLE HOLTEC QUALITY PROCEDURE 5.1. FOR EXAMPLE, AAI-71 STATES, IN PART, "ACTUAL DRAWING SIGN OFF BY THE TECHNICAL DISCIPLINE(S) CANNOT OCCUR UNTIL THE ANALYSIS IS COMPLETED," THIS IS NOT IN THE APPLICABLE HOP.
2. E-MAIL ~~FROM AT SOLER, 3/13/01~~, SUBJECT: DRY STORAGE DESIGN CHANGES, STATES, "FROM THIS POINT FORWARD, THE FOLLOWING REQUIREMENTS ①

CFR Requirement:

10 CFR 72.150 REQUIRES THAT A CERTIFICATE HOLDER SHALL PRESCRIBE ACTIVITIES AFFECTING QUALITY BY DOCUMENTED INSTRUCTIONS OR PROCEDURES AND REQUIRE THAT THESE INSTRUCTIONS OR PROCEDURES BE FOLLOWED.

Licensee Procedure Requirement:

- ① SHALL APPLY TO ANY DESIGN CHANGE... " SOME OF THE LISTED REQUIREMENTS ARE NOT INCLUDED IN THE APPLICABLE HOLTEC PROCEDURE 5.1.

N-7  
#1116

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To: Everyone@holtec.com  
From: Mark Soler <Mark\_Soler@holtec.com>  
Subject: Dry Storage Design Changes

A concern was recently raised regarding the control of design changes on dry cask storage projects. The specific issue dealt with design changes in the 100S drawings that were made between the old drawings and the new Solid Work system. The following problems were found:

- 1) An ECO was not generated. HQP 5.1, paragraph 6.8.1.3 requires that an ECO be generated whenever the design change affects documents other than drawings ( ie. Licensing Reports, calculation packages) and these documents will not be modified until later. Furthermore, it is not apparent as to whether all documents that will require revision due to design changes have been put on the task database. **The purpose of this requirement is to provide a tracking mechanism so that all required documents are revised. All documents including calculation packages, licensing reports, procedures etc. must be listed. While the ECO process may not be the most efficient process to use, it is the only process at the current time which provides tracking and sorting capabilities for design changes.**
- 2) The specific changes made were not identified in the drawing change summary sheet or the 72.48 database. **Without the specific changes being identified, we rely on the memory of personnel to recall the changes when 72.48s are completed.**
- 3) The 72.48 was not completed including the screening section. **While it was recognized that some 72.48s would require analysis and FSAR markups and that the time to complete these activities could cause significant delays relative to fabrication, it was expected that the majority of 72.48s ( at least the screening) for new ECOs and SMDRs would be generated at the time of issuance of the document. The exception would be the occasional 72.48 that needed to be completed after issuance of the document. Instead, it appears that the majority of ECOs and SMDRs are being generated and no part of the 72.48 is being completed.**

From this point forward, the following requirements shall apply to any design change on the dry storage side that is generated due to a ECO, SMDR, drawing change, procedural change etc.

- 1) At a minimum, the screening section of the 72.48 must be completed.
- 2) If the screening section of the 72.48 determines that a full 72.48 is required and the 72.48 is not immediately completed, then an activity for completing the 72.48 shall be input into the task database.
- 3) Any calculation, FSAR markup, etc. that is not immediately completed to support the design change and/or 72.48 must be input into the task database.
- 4) Task database entrees shall include the ECO, SMDR, 72.48 number as appropriate.
- 5) New drawings for dry storage such as a new MPC design are considered design changes and require completion of the Proposed Design Change Summary Sheet and Evaluation

To: Everyone@holtec.com  
Subject: ECO Revisions  
Cc: Mark Soler <Mark\_Soler@holtec.com>

During a recent surveillance by Entergy at Holtec, the following concern was identified:

*Entergy identified a concern on control of ECO revisions. Specifically Entergy stated that a mechanism for ECO revisions is not defined in the quality procedures and that it is not clear what changed on each revision of the ECO. ECO-1024-8 and 12 were identified as examples.*

As a result of this concern, QPVF 109 was issued.

While there is no violation of the Holtec QA program, there is the potential for a discrepancy to occur if ECO revisions are not handled in a correct manner. Therefore, the following paragraph (see below) has been added to HQP 5.1 (revision 11 which is currently going through review).

"Revisions to ECOs shall be performed in a similar manner (to the original). The revision number shall be identified on the ECO and the ECO shall clearly describe what was revised on the ECO."

Do's and Don'ts for ECO Revisions:

- 1) Make sure that the revision number of the ECO (including revision 0) appears in the appropriate location on the ECO.
- 2) Clearly identify the changes made for a particular revision. A reviewer should be able to read the ECO and easily identify the differences between the new and previous revision. This can be done by providing a summary of changes on the ECO and/or identifying each change by the revision number.
- 3) If an ECO revision will include a design change but fabrication has already incorporated the original ECO requirements without the new design change, then a new ECO must be generated. An ECO revision shall not be made in this case since it will not be possible to track on the database for the various revisions.
- 4) When a design change is made, the original requirement that is being revised shall be removed from the ECO and a note shall be added to explain the reason for the revision. As an example, if the original ECO requirement was to change the bolt circle dimension from 95" to 96" and the revision to the ECO changes the dimension from 96" to 95.5", the 96" dimension shall be removed from the ECO in order to avoid confusion (a note should be added that states "revision ? of this ECO modifies the bolt circle dimension previously identified on the ECO").
- 5) If the ECO revision is for modifications to the justification section only, the ECO revision shall clearly state this.
- 6) Be careful with ECO revisions. While a revision to an ECO may be internally efficient, the ECO revision can be confusing to analysts and fabricators if the ECO revision is not clearly written.