HOLTEC INTERNATIONAL

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BY OVERNIGHT MAIL

July 10, 2001

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

Reference: 1. Holtec Project 5014
2. NRC Quality Assurance Program Approval for Radioactive Material Packages Number 0784, Rev. 2

Dear Sir:

Pursuant to the telecon between SFPO Project Manager Mr. Chris Jackson and Holtec's Licensing Manager Mr. Brian Gutherman, we are pleased to provide a summary of the changes made to Rev. 11 of the Holtec Quality Assurance Manual to upgrade it to Rev. 12. Both Rev. 11 and Rev. 12 are in NRC's possession, the former having been used by the NRC as the basis for the latest SER on our HI-STORM 100 system and by Holtec for our July 3, 2001 response to the RAIs on the proposed amendments to the HI-STORM CoC. Rev. 12 represents an incremental improvement over Rev. 11 and as such, we would like to have it reviewed and approved by the Commission so that all of the company's *Safety Significant* activities are governed by one document that sits at the apex of our QA pyramid.

The changes to Rev. 11 to develop Rev. 12 include both modification of verbiage as well as addition of new material. In the table that follows later in this letter, the *a*dded text (or requirement) is denoted by "A" and *m*odified material is denoted by "M".

As we state in page 3 of Rev. 12 of the HQAM, revisions to the manual have been issued at periodic intervals since 1986 to incorporate the lessons learned from continued operations so as to enhance the reach and effectiveness of the company's QA program. Rev. 12 was principally occasioned by the realization that the dissemination of vital QA information, such as indoctrination of personnel, control of quality records, protocols for internal reviews – indeed, every facet of our corporate activities germane to quality assurance – can be vastly improved through a set of network-based databases and files. This computerization of information, undertaken over two years ago and extensively tested during that period, was finally ready to be formally adopted at the beginning of this year. Other improvements recognized by the company's Quality Initiative Committee since the issuance of Rev. 11 in February 1999, were also incorporated in Rev. 12, issued in January of 2001. Every material change made in Rev.12 can be attributed to one of eight reasons, tabulated below.

1/5

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Table 1 Reason for Change	
1.	Requirement has to be reworded or added to accord with the electronic network medium for storage and dissemination of information.
2.	The verbiage is focused to an implementation activity and, therefore, more appropriately belongs in a lower tier document (Holtec Quality Procedure or Holtec Standard Procedure).
3.	Requirement revised to allow QA personnel to be removed from in-line review role so that they can be truly independent in their policing of the company's QA activities.
4.	Requirement broadened to recognize the increased quality rigor previously introduced through a Holtec quality procedure (HQP).
5.	Error, ambiguity in verbiage, editorial text remedied (i.e., redundant text eliminated or text clarified.)
6.	Verbiage clarified to recognize differences among ITS categories A, B, and C.
7.	Impose additional requirements to address special cases that may be applicable to Holtec operations.
8.	Requirement eliminated- not applicable to Holtec's corporate undertakings.

In addition to the above, Rev. 12 features some generic reformatting and wording change, such as:

i. The pages are sequentially numbered. In Revision 11, each section was numbered separately.

ii. The verb "affect" (such as in "affecting quality") viewed by some as having only a negative connotation, is replaced with the neutral verb "bear upon" (such as "that bear upon quality") throughout the document.

iii. The use of the term " safety significant" replaces "safety related". "Safety significant" is the term defined in the Holtec Q.A. Manual to represent both "safety related" and " important to safety".

In the attached table, all material changes are summarized using the legends from the above table.

We trust that the above information will assist the SFPO in completing the review of Rev. 12 of the QA Manual, which upon your acceptance, will assume its role as single supreme QA document for all QA-related activities carried out by the company.

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We appreciate this opportunity to provide additional information.

Sincerely,

7/10/01

Mark Soler
Quality Assurance Manager

Approval

7/10/01

Dr. K.P. Singh
President and CEO
(Q.A. Program Sponsor)

emcc: - Mr. Christopher Jackson, Project Manager SFPO
- Mr. Robert L. Moscardini, UST&D, Inc.
- Holtec On-Site Q.A. Representative (UST&D)
- Holtec Florida Operations
- Group 1 (Holtec)

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Table of Differences between Rev. 11 and Rev. 12				
No.	Type of Change*	Location in Rev. 11	Description of Change	Reason for Change (Table 1)
1	M	1.0 (4.2(i))	Eliminated " delegation is documented".	2
2	A	NA	Section 1.0; paragraph 5.2 added to address use of electronic capabilities medium	1
3	A	NA	Section 2.0; paragraph 3.4 and 3.5 modified and paragraph 5.3 added to address use of the electronic medium	1
4	M	2.0 (4.1B)	Deleted " Indoctrination sessions must occur at least once a year"	2
5	M	2.0 (4.2)	Added " approximately" before "annually review"	5
6	A	NA	Section 3.0, paragraph 3.10 added to address use of the electronic capabilities medium	1
7	M	3.0 (3.2)	Changed from "..subject to Quality Assurance Review.." to ".. subject to review.."	3,5
8	M,A	3.0 (3.4)	Last sentence changed from, " ..system or component, originator, reviewer, and date; or by other such data such that the analyses are retrievable" to " ... system or component. Design analyses shall be documented in a uniquely numbered document that can be located in hardcopy or in the company's electronic database by project team personnel."	1,2
9	M	3.0 (3.5)	Reworded text from "these activities.." onward.	2
10	A	NA	Section 4.0, paragraph 3.1: Added requirement that at least one independent review occurs on all safety significant purchase requisitions.	4

* A: New material *added* in Rev. 12.
M: Material in Rev. 11 *modified* for Rev. 12.

Table of Differences between Rev. 11 and Rev. 12				
No.	Type of Change*	Location in Rev. 11	Description of Change	Reason for Change (Table 1)
11	M	4.0 (3.1,3.2, 4.2)	Changed last sentence from, " The QA Manager....shall review and approve safety-related purchase orders and invoked requirements to establish conformance to the QA Manual and implementing procedures." To " The Quality Assurance department shall conduct required surveillances to ensure that safety significant purchase orders are being issued in accordance with this QA manual and its implementing procedures". In paragraph 3.2, changed " quality assurance review" to " independent review". Paragraph 4.2 also modified to be consistent with the above changes.	3
12	M	4.0 (4.1)	Changed from " responsible for technical approval of purchase orders" to " responsible for delegating personel to write and review purchase orders on his/her project."	5
13	M	5.0 (4.1)	Deleted " and for Quality Assurance review of all Holtec procedures and drawings."	3
14	M	5.0 (4.2)	Changed from " The President is responsible for approval of Holtec Quality Procedures" to "All Holtec Quality Procedures are subject to approval by the company's executive management".	2,5
15	M	6.0 (3.4)	Deleted " quality assurance records".	2
16	A	NA	In Section 7.0, added paragraph 3.1 and added second sentence to paragraph 3.3.	6
17	M	7.0(3.3A&B)	Deleted the word "technical".	2
18	M	7.0 (3.4)	Added "If required" to the start of the paragraph (paragraph 3.5 of revision 12)	6
19	M	9.0 (5.1)	Deleted "..prior to performing any special processes on materials, parts, or components manufactured by Holtec."	2
20	M	10.0 (3.3)	Changed from, " Inspections shall be performed by qualified individuals other than those who performed or directly supervised the activity being inspected" to " Inspections shall be performed by individuals deemed to be qualified to conduct the specific type of inspection by Holtec's QA Department."	5

Table of Differences between Rev. 11 and Rev. 12				
No.	Type of Change*	Location in Rev. 11	Description of Change	Reason for Change (Table 1)
21	M	10.0 (3.5); 11.0 (3.2)	Changed "as a minimum" to " as appropriate"	5
22	M	10.0 (4.1)	Changed "Quality Assurance Manager" to " Quality Assurance Department".	5
23	M	11.0 (4.2)	Changed from, " The QA manager is responsible for quality assurance review and concurrence with test procedures" to " The QA Department is responsible for conducting periodic surveillance to ensure that the provisions of this section and the associated implementing procedures are followed by the Project teams."	3
24	M	11.0 (5.1)	Added, " Unless the specific testing is a physically trivial activity" to the beginning of the paragraph.	5
25	A	NA	In Section 12.0, added paragraph 3.4 to provide additional mechanism for calibration subject to Project & QA approval.	7
26	A	NA	In Section 16.0, added paragraph 3.2 to categorize nonconformances into levels of severity.	5
27	M	17.0 (3.3)	Removed " results of reviews".	2
28	M	19.0	Section is deleted. Fitness for duty is controlled by the utility.	2,8
29	M	Appendix A	Section is deleted.	2