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8/9/01

HOLTEC QA MANUAL, REV 12

General

1. Holtec's letter of June 20, 2001, states Revision 12 of the manual is enclosed for review and approval under the provisions of 10 CFR 71.38. Section 71.38 only applies to renewal of an existing QA program approval that is expiring.

2. Contrary to the statement in Holtec's letter of July 10, 2001, stating "all material changes are summarized", some substantial changes were not identified or discussed in the letter's "Table of Differences between Rev. 11 and Rev. 12".

3. In several sections of the manual, responsibilities of the QA Manager were changed to responsibilites of the QA Department. The reason for these changes was not discussed in the Reason for Change in the "Table of Differences between Rev. 11 and Rev. 12."

4. Several requirements in Revision 11 of the manual do not appear in Revision 12 and the Reason for Change was cited as, "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)." This Reason for Change indicates that these commitments in the NRC-approved Revision 11 would be found in implementing procedures under Revision 12.
NO SUBSTANTIAL CHANGES? YES
Is this true for the changes in Revision 12 for Section 1.0, paragraph 4.2(i) [documentation of delegation]; Section 2.0, paragraph 4.1B [indoctrination sessions at least once a year]; Section 3.0, paragraph 3.4 [design analysis identifiable by originator, reviewer, and date]; Section 5.0, paragraph 4.2 [President responsible for approval of quality procedures]; Section 7.0, paragraph 3.4 [evaluation of supplier's technical capability]; and Section 9.0, paragraph 5.1 [submission of special process procedures before performing work]?

Specific

1. Page 3, Preface, first full paragraph. The paragraph states usage of the term "safety-significant" in the manual refers to "safety-related" under 10 CFR 50 and "important-to-safety" under 10 CFR 72. Why is 10 CFR 71 not mentioned?

The paragraph also refers to implementation of a graded approach under the provision of 10 CFR 72. Why is 10 CFR 71 [71.105(b)] not referenced?

2. Page 13, Section 1.0, paragraph 4.2. The Revision 11 requirement for documentation of delegation of quality assurance responsibilities, is removed. The Reason for Change is listed as, "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)." This requirement for documentation of delegation is no less important or more "an implementation activity" than the two items that were left in the paragraph. Is there another reason for the change?

3. Page 13, Section 1.0, paragraph 4.2i. Regarding qualification to perform a delegated quality assurance function, what is the difference and the reason for the change from "qualified" to "determined to be qualified by executive management"? What makes up executive

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management? This change was not identified and discussed in the "Table of Differences between Rev. 11 and Rev. 12".

4. Page 20, Section 4.0. Paragraph 3.1 states all safety-significant purchase requisitions shall be subject to at least one independent review concurrence. Paragraph 4.1 states the Project Manager shall be responsible for delegating appropriate personnel to write and review purchase orders on his project. Paragraph 3.2 states purchase orders shall be subject to approval by the Project Manager. No other reviews or approvals are specified. If the Project Manager selects the writer and the reviewer and only the Project Manager approves the purchase order, how is an independent review achieved? What is the implementing procedure for the independent reivew concurrence?

5. Page 27, Section 7.0, paragraph 3.3. 10 CFR 71.115 states, "The licensee shall have available documentary evidence that material and equipment conform to the procurement specifications before installation or use of the material and equipment." Revision 11 of the Holtec QA Manual states, "Documentary evidence shall be available indicating that material and equipment conform to the procurement documents before installation or use." That paragraph was changed in Revision 12 to state, "Documentary evidence of compliance of the acquisition to the procurement documents shall become part of the quality records of the component system or structure in which it is installed." This change appears to allow installation or use of material and equipment prior to having documentary evidence indicating the material and equipment conform to the procurement documents. This would be contrary to 10 CFR 71.115. This change was not identified and discussed in the "Table of Differences between Rev. 11 and Rev. 12". Why was the change made? What implementing procedures assure that documentation is available prior to use or installation?

6. Page 32, Section 9.0, paragraph 5.1. The Revision 11 requirement for submission of special process procedures prior to performing any special processes, is removed. The Reason for Change is listed as, "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)." This requirement for prior submission is no more "an implementation activity" than some other items that were left in the manual revision. Is there another reason for the change?

7. Page 33, Section 10.0, paragraph 3.3. Regarding internal inspection, 10 CFR 71.121 states, "The inspection must be performed by individuals other than those who performed the activity being inspected." The Revision 11 requirement of, "Inspections shall be performed by qualified individuals other than those who performed or directly supervised the activity being inspected", was changed to, "Inspections shall be performed by individuals deemed to be qualified to conduct the specific type of inspection by Holtec's QA Department." The change deletes the requirement that the inspector not be the individual who performed or directly supervised the activity being inspected. The Reason for Change is listed as, "Error, ambiguity in verbiage, editorial text remedied (i.e., redundant text eliminated or text clarified.)", which does not appear to be appropriate for the change. Is there another reason for the change? "Qualified" is somewhat defined in Revision 11, referring to training and experience. What is meant by "deemed to be qualified"? Is this qualification documented? What procedure controls this activity?

8. Page 37, Section 12, paragraph 3.4. Revision 12 adds, "Subject to Holtec's approval, use of two M&TEs made by two different manufacturers to measure or concurrently test the item is an

acceptable substitute for individually calibrating each M&TE. Approval will be given only if both the Project Team and the QA Department agree that the quality of measurement results will not be adversely affected by two independent M&TEs in lieu of a single calibrated M&TE. If the dual M&TE approach is used, both M&TEs must yield the same result (within the standard bias and uncertainty inherent to the genre of the apparatus) to be acceptable." What is the basis for this approach? How does it comply with 10 CFR 71.125 which requires that measuring devices used in activities affecting quality be calibrated?

9. Page 47, Section 18.0, paragraph 3.4. 10 CFR 71.137 states, "Audited results must be documented and reviewed by management having responsibility in the area audited." Revision 11 of the Holtec QA Manual states, "Audit results, including deficiencies identified, shall be documented and reviewed by management having responsibility in the area audited." That paragraph was changed in Revision 12 to state, "Audit results, including deficiencies identified, shall be documented and reviewed by the company's executive management for consistency and adherence to the company's written procedures." This change removes the specific requirement for review by management having responsibility in the area audited. Failure to review audit results by management having responsibility in the area audited would be contrary to 10 CFR 71.137. This change was not identified and discussed in the "Table of Differences between Rev. 11 and Rev. 12". What is the reason for the change? What makes up executive management?

10. What is the controlling procedure for QA Department surveillances that replace the "in-line reviews"? What is the surveillance frequency?

NO SPECIFIC PROCEDURE EVERY OTHER MONTH

11. What is the controlling procedure for the independent reviews? To what level of management do the reviewers report? How is independence maintained? Who has stop work authority?