WESTINGHOUSE HITTMAN NUCLEAR INCORPORATED	Document Number: C-200	Rev: 3	Rev Date: 3-1-85
	Title: Quality Assurance Program for the Use of Radwaste Shipping Packages		

Rev.	Rev Date	President	Manager Administrative Services	Quality Assurance Manager			
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FOREWORD

In order to use a U.S. Nuclear Regulatory Commission (NRC) certified package (hereafter simply referred to as package) for shipments of greater than Type A quantities of radioactive material in accordance with the general license provided in 10 CFR Part 71.12, the user of the package must have a quality assurance (QA) program whose description has been submitted to and approved by the NRC as satisfying the provisions of Subpart H of 10 CFR Part 71. This requirement notwithstanding, users may delegate to others, such as Westinghouse Hittman Nuclear Incorporated (Hittman), the work of establishing and executing the QA program, or any part thereof, but shall retain responsibility therefore. Westinghouse Hittman Nuclear Incorporated is a subsidiary of the Westinghouse Electric Corporation.

Hittman recognizes the practical necessity for users of Hittman owned and certified packages to delegate most, if not all, of the work of establishing and executing the required QA program. Hittman has, therefore, developed this "QA Program for the Use of Radwaste Shipping Packages" in recognition of our delegated responsibilities for assuring that Hittman packages are used in such a manner as to provide for the safety of the public. The importance of QA in contributing to this safety is also recognized.

In accordance with this philosphy this QA Program description has been prepared and by its issuance establishes the policies and practices for QA for the use of Hittman packages.

The approval, issuance, and control of this QA Program description shall be the responsibility of the Manager, Administrative Services, who has been assigned overall responsibility for its development and implementation. Day-to-day responsibilities for QA, including preparation and review of additions, deletions, or modifications to this QA Program description shall rest with the QA Manager who reports directly to the Manager, Administrative Services.

Disagreements or differences of opinion on QA matters which originate with or are brought to the attention of the QA Manager are expected to be resolved by him and the affected department manager or group supervisor. Where such resolution is not achieved within a reasonable period of time, unresolved differences shall first be referred to the Manager, Administrative Services, who shall then refer still unresolved matters to the President.

As directed by the President through the issuance of this QA Program description, the Manager, Administrative Services, is hereby assigned the responsibility for all matters related to quality with authority as established in this QA Program.

All Hittman personnel with responsibility for activities related to the use of Hittman packages have the additional responsibility for being fully knowledgeable of policies and procedures described in this QA Program description that are pertinent to their particular duties.

Conformance to the policies and practices described herein shall be required as of the date of approval and issue of this procedure.

President

3-1-85
Date

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SECTION 1

ORGANIZATION

1.1 Scope and Applicability

1.1.1 This section includes a description of the organizational responsibilities normally assumed by Hittman for package handling, inspection, transportation, maintenance, repair, and modification. These responsibilities include both the performing functions involved in attaining quality objectives and the QA functions. The QA functions are those of (a) assuring that an appropriate QA program is established and effectively executed and (b) verifying, such as by checking, auditing, and inspecting, that activities affecting safety-related functions have been correctly performed.

1.1.2 Users of Hittman packages may assume responsibility for performing certain activities falling within the scope of this QA Program. Examples include package inspection and handling and, in some cases, package maintenance and repair, including parts replacement. Hittman has no authority over user organizations and, therefore, no direct control over the activities that may be carried out by user personnel not in compliance with the requirements of this QA Program. It is important, therefore, that users adopting this QA Program as the means of meeting the requirements of 10 CFR Part 71, Subpart H recognize that they have a responsibility to carry out safety-related activities in accordance with the requirements and procedures described herein.

1.2 Organization and Responsibilities

1.2.1 Figure 1-1 shows the organizational structure for Westinghouse Hittman Nuclear Incorporated. Those individuals and groups having responsibility for activities falling within the scope of this QA Program are clearly identified in the figure. The authority and specific responsibilities of these individuals and groups for such quality related activities are described in the following sections.

1.2.2 President

1.2.2.1 The President of Hittman has ultimate responsibility for the company's activities related to the use of Hittman packages.

1.2.2.2 The President's day-to-day responsibilities for implementing the QA Program are delegated to the QA Manager through the Manager, Administrative Services.

1.2.2.3 The President shall retain responsibility for assuring the independence of the QA Manager from schedules and costs and for providing the QA Manager, through the Manager, Administrative Services, the authority to direct and control the QA Program and to ensure conformance to quality requirements.

1.2.2.4 The President reserves the right to conduct, or order, the auditing of any activity at any time to determine the effectiveness of the policies and requirements set forth in this QA Program description and to determine compliance with the provisions of the QA Program and implementing procedures.

1.2.3 Manager, Administrative Services

1.2.3.1 The Manager, Administrative Services, is responsible for establishing QA policies and for managing the implementation of the QA Program. This is accomplished primarily through supervision of the QA Manager and assessments of the performance and effectiveness of QA Department personnel and the effectiveness of this QA Program.

1.2.3.2 The Manager, Administrative Services, is responsible for ensuring that the individual assigned the position of QA Manager satisfies the qualification and experience requirements discussed in Section 1.4 of this procedure.

1.2.3.3 The Manager, Administrative Services, has been given the authority by the President to stop unsatisfactory work or further processing of

unsatisfactory material that is not in conformance with specified quality requirements and/or the provisions of the QA Program.

1.2.3.4 The Manager, Administrative Services, is responsible for conducting a formal review of the QA Program on an annual basis and reporting the results to the President.

1.2.4 QA Manager

1.2.4.1 The QA Manager reports to the Manager, Administrative Services, and is responsible for ensuring the implementation of the QA Program and for advising the Manager, Administrative Services, regarding its effectiveness.

1.2.4.2 The QA Manager has been given the authority by the President to identify quality problems and to initiate, recommend, or provide solutions to responsible individuals and groups through the Manager, Administrative Services. The QA Manager verifies implementation of these solutions.

1.2.4.3 The QA Manager is responsible for advising the Manager, Administrative Services, of the need to stop unsatisfactory work or further processing of unsatisfactory materials.

1.2.4.4. Specific duties of the QA Manager include the following:

(a) Prepare and control the QA Program description including revisions and its distribution.

(b) Formulate QA policies for use by Hittman.

(c) Review the QA programs of suppliers and contractors as appropriate.

(d) Review specifications, drawings, and procedures for conformance to Hittman quality requirements, applicable industry standards, and regulatory requirements.

(e) Manage the QA staff in the performance of their activities.

(f) Maintain communication with the QA organizations of the users of Hittman packages.

(g) Inform Hittman management of QA Department activities through distribution of reports, e.g., monthly operations, audit, and other quality-related information.

(h) Monitor the performance of quality related activities and conduct periodic audits of the QA Program.

(i) Provide assistance as appropriate with the preparation of quality related procedures controlling the activities of Hittman personnel.

1.2.5 Purchasing Manager

1.2.5.1 The Purchasing Manager reports to the Manager, Administrative Services.

1.2.5.2 The Purchasing Manager is responsible for material purchasing, expediting, internal material control and development and implementation of material control procedures and instructions.

1.2.5.3 The Purchasing Manager provides supervision to the Expeditor who oversees the Hittman material storeroom, including the receipt and disposition of purchased material and items.

1.2.6 Director, Engineering

1.2.6.1 The Director, Engineering, reports directly to the President and is responsible for managing

the engineering group within Hittman and for the oversight of internal research and development.

1.2.6.2 The Director, Engineering, is responsible for approving proposed modifications to Hittman packages and supervising engineering group activities related to the preparation of package license amendments.

1.2.7 Manager, Design Engineering

1.2.7.1 The Manager, Design Engineering reports to the Director, Engineering.

1.2.7.2 Responsibilities of the Manager, Design Engineering include the following:

(a) supervision of engineering, design and design drafting personnel;

(b) preparation and review of drawings, specifications, calculations, and test procedures;

(c) preparation of license documents including safety analysis reports, topical reports and amendments thereto;

(d) coordination of engineering reviews and approvals of reports of nonconforming materials and items, including the disposition of those materials and items;

(e) reviews of special test results;

(f) development and implementation of engineering procedures and instructions.

1.2.8 Director, Operations

1.2.8.1 The Director, Operations, reports to the President.

1.2.8.2 The Director, Operations, has overall responsibility for the coordination and scheduling of

Hittman package shipments including liaison with package users and the burial sites and transportation companies. Day-to-day responsibility for these activities is delegated to the Managers, Eastern and Western Operations and to the Manager, Transportation.

1.2.8.3 The Director, Operations, is also responsible for the preventive maintenance and repair of packages. Day-to-day responsibility for package maintenance is delegated to the Manager, Maintenance through the Manager, Eastern Operations.

1.2.9 Managers, Eastern and Western Operations

1.2.9.1 The Managers, Eastern and Western Operations report to the Director, Operations.

1.2.9.2 Specific duties of the Operations Managers, include the following:

(a) coordination and scheduling of Hittman package shipments from the eastern and western regions of the U.S.;

(b) scheduling, in coordination with the Manager, Maintenance, package preventive maintenance and repairs;

(c) liaison with package users;

1.2.9.3 The Manager, Eastern Operations, also serves as the Project Manager for Hittman package activities and is responsible for preparation and periodic review of package operation and use procedures and instructions. These activities may be delegated to the Manager, Maintenance.

1.2.10 Manager, Transportation

1.2.10.1 The Manager, Transportation is responsible for the operation of the Hittman Transport Services, Inc. (HTS). These activities include the scheduling and maintenance of the HTS fleet of vehicles to transport many of Hittman's packages.

1.2.10.2 The Manager, Transportation reports to the Director, Operations.

1.2.11 Manager, Maintenance

1.2.11.1 The Manager, Maintenance reports to the Manager, Eastern Operations.

1.2.11.2 Responsibilities of the Manager, Maintenance includes the following:

(a) establishment of preventive maintenance plans, procedures, and schedules for Hittman packages;

(b) implementation of the preventive maintenance program including coordination and supervision of Hittman maintenance personnel at both headquarters and field locations;

(c) preparation of repair procedures and supervision of repair activities for Hittman packages;

(d) notification of and coordination with the Managers, Eastern and Western Operations, when package maintenance must be scheduled;

(e) ordering, maintenance, and distribution of spare and replacement parts and materials for Hittman packages;

(f) training of maintenance personnel in the performance of maintenance activities.

1.3 Hittman-User Interface Control

1.3.1 Hittman and the user share responsibility for establishing and maintaining effective lines of communication between them. In this regard the primary communication line between the user and Hittman for matters related to the establishment and/or execution of this QA Program shall be between the user's designated representative for such matters and Hittman's QA Manager.

1.4 QA Manager Position Qualifications

1.4.1 The QA Manager is responsible for ensuring implementation of the QA Program. The QA Manager shall satisfy the following minimum qualification requirements:

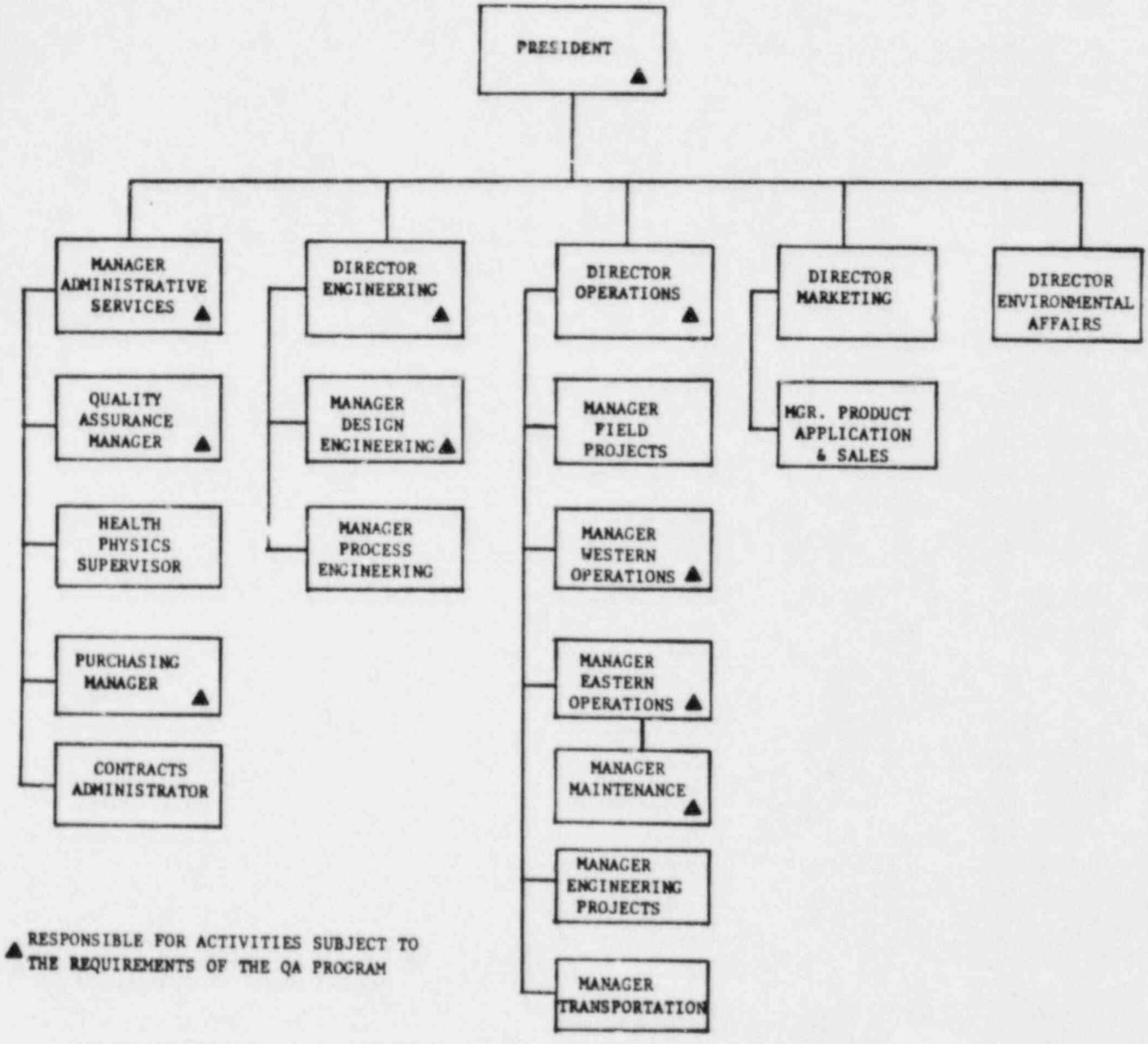
(a) Graduate of a four-year accredited college or university program in engineering or science;

(b) Minimum of two (2) years experience in QA, including testing or inspection (or both) of equivalent materials and structures;

(c) In lieu of a degree, a high school graduate plus five (5) years of experience in general QA or engineering of equivalent materials and structures;

(d) Individuals without any prior experience with radwaste shipping packages shall have training sufficient to acquaint them with the safety aspects of Hittman packages.

Figure 1-1



▲ RESPONSIBLE FOR ACTIVITIES SUBJECT TO THE REQUIREMENTS OF THE QA PROGRAM

SECTION 2

QUALITY ASSURANCE PROGRAM

2.1 Program Objective

2.1.1 The objective of this QA Program is to insure that Hittman packages used for the shipment of radioactive materials conform to the NRC approved design and are used in accordance with the terms and conditions set forth in each package approval.

2.2 Scope and Applicability

2.2.1 This QA Program satisfies the requirements of 10 CFR 71, Subpart H, applicable to the use, including loading and unloading, inspection, maintenance, repair, and modification of Hittman packages. QA requirements set forth in 10 CFR 71, Subpart H, for package design, fabrication, assembly and testing are addressed separately in document C-100, "Quality Assurance Program for the Engineering, Design, Procurement, Fabrication, and Initial Testing of Radwaste Shipping Packages."

2.2.2 The structures, including appurtenances, components, parts, and design characteristics, controlled by this QA Program are those described in the NRC package approval and safety evaluation.

2.2.3 Activities that shall be controlled by this QA Program include the following:

(a) Activities specifically required to be performed as a condition of the package approval (e.g., certain inspections);

(b) Activities that if performed improperly could cause the package to be used under conditions not in compliance with the conditions of the package approval;

(c) Activities in addition to those covered under (a) above that are determined necessary by the QA Manager and/or other qualified Hittman personnel to verify periodically that a package complies with the conditions of the package approval.

2.2.4 Activities not included within the scope of this QA Program established to implement the specific requirements of 10 CFR 71, Subpart H, are:

(a) Activities specifically authorized and/or required under a license to receive, possess, and transfer to authorized land burial facilities packages containing solid waste by-product, source, and special nuclear materials. These activities include, for example, radiation surveys and decontamination operations, and other activities prescribed and controlled generally in accordance with 10 CFR Parts 30, 40, and 70, and Hittman's RadSafe Program;

(b) Operations at a radioactive material burial site including receipt, transfer, storage, repackaging, and disposal or burial. These activities are licensed in accordance with NRC and State regulations;

(c) Carrier activities regulated in accordance with the requirements of 49 CFR dealing with transportation of hazardous materials. Such activities include vehicle maintenance and inspection, driver qualifications and training, and motor carrier recordkeeping and reporting.

2.2.5 The exclusions described in Article 2.2.4 notwithstanding, it is recognized by Hittman that the application of QA principles and practices whenever practicable to the control of such activities is good policy. To the extent that Hittman is involved in such activities, this will be the case. It is emphasized, however, that the provisions of this QA Program are directed towards satisfying the specific requirements of 10 CFR 71, Subpart H, to ensure that Hittman packages conform to the NRC approved design and specifications for each individual package.

2.2.6 The QA Manager shall be responsible for determining the specific activities to be controlled in accordance with the requirements of this QA Program and informing individuals and groups responsible for those activities.

2.2.7 Hittman and contractor personnel performing activities within the scope of this QA Program shall adhere to the requirements of the program.

2.3 Policy

2.3.1 This QA Program has been developed by Hittman and establishes the policies and practices for QA related to the use of Hittman packages. These policies and practices are set forth in written procedures and instructions and shall be carried out in accordance with those procedures and instructions throughout the period during which the package is used.

2.3.2 The issuance and control of this QA Program description shall be the responsibility of the Hittman QA Manager. Additions, deletions, or modifications to this document shall require the approvals of the QA Manager, the Manager, Administrative Services, and the President before such changes may be incorporated.

2.3.3 Disagreements or differences of opinion on QA matters which originate with or are brought to the attention of the QA Manager are expected to be resolved jointly by him and the affected group or individual. Where such resolution is not achieved within a reasonable period of time, unresolved differences shall be referred first to the Manager, Administrative Services, and, if necessary, to the President.

2.3.4 All Hittman QA/QC personnel are responsible for being fully knowledgeable of all policies and practices described in this QA Program description.

2.3.5 All Hittman personnel responsible for and/or performing activities covered under this QA Program are responsible for knowing and implementing the portions of this program description pertinent to their respective responsibilities.

2.3.6 Conformance to the policies and practices described herein shall be required as of the date of approval and issue shown on the title page.

2.3.7 Terms, abbreviations, and definitions used in this QA Program description are included in Table 2-1.

2.4 Program Description

2.4.1 This QA Program consists of (1) a formal, documented system of administrative controls over activities affecting quality, and (2) quality verification through independent review, surveillance, and audit of those activities.

2.4.2 Administrative Controls

The QA Program requires the preparation of appropriate documents, including procedures, drawings, and specifications, which prescribe the measures which have been established to control activities affecting quality. Compliance with this requirement is the responsibility of each and every organization or group with responsibility for activities related to the use of Hittman packages. The measures which are established to control work must be detailed to the extent necessary to ensure that adequate controls have been incorporated.

2.4.3 Quality Verification

Quality is verified and assured through a system of planned reviews, surveillances, and audits of quality affecting activities by the QA Department which is independent of other organizations responsible for performing such activities.

2.4.4 The QA Program provides for control over activities affecting the quality of identified materials and components to an extent consistent with their importance to safety and as necessary to assure conformance to the approved design of each package used for the shipment of radioactive materials.

2.5 Responsibilities

2.5.1 Hittman's organization is described in Section 1.0.

2.5.2 Hittman has overall responsibility for this QA Program. Primary responsibility for establishing and implementing an integrated system of administrative controls over quality affecting activities rests with the QA Manager, the Director, Engineering, the Manager, Eastern Operations, and the

Manager, Maintenance. These controls shall include provisions for quality verification appropriate to the activities being performed. The QA Department is primarly responsible for quality assurance reviews, surveillances, and audits, including audits of Hittman contractors and suppliers.

2.5.3 Users of Hittman packages are responsible for establishing, maintaining, and executing a QA program satisfying the requirements of 10 CFR 71, Subpart H, and satisfying the specific provisions established in the NRC's approval for each package used. Each user is responsible for ensuring that activities performed by user personnel are in compliance with his governing QA program.

2.6 Program Documentation

2.6.1 QA Program policies and practices are contained in various Hittman procedures that comprise the Hittman Procedures Manual. A list of procedures that describe and implement this QA Program is included in Table 2.2. This list includes a cross-reference of these procedures to the requirements of 10 CFR 71, Subpart H.

2.6.2 Various other documents, including instructions, NRC certificates of compliance, and drawings that identify package requirements and delineate controls over activities are contained in separate Rad Services Manuals for each package model.

2.6.3 The QA Manager has the right to review and comment on all documents, including manuals, procedures, instructions, drawings, specifications, analyses, computations, and procurement documents that prescribe requirements for and controls over activities related to the use of Hittman packages.

2.7 Personnel

2.7.1 It shall be the responsibility of the QA Manager to insure that Hittman personnel responsible for performing quality related activities are instructed as to the purpose, scope, and implementation of this QA Program and implementing procedures.

2.7.2 The QA Manager or his designee shall periodically hold indoctrination and training meetings for new or newly reassigned Hittman personnel performing activities related to the use of Hittman packages. Such personnel will usually be members of the Quality Assurance, Engineering, Operations, Purchasing, and Field Services Departments. The frequency of these meetings shall be at the discretion of the QA Manager, but shall not be less frequent than once every twelve (12) months. The scope of these meetings should include the following:

(a) Review of sources of Quality Assurance requirements.

(b) Review of Hittman QA program descriptions and associated manuals.

(c) Review of Hittman operating procedures, e.g., procurement document control, engineering design control, highlighting as appropriate to the responsibilities of the personnel being trained.

The indoctrination and training meetings may be held with or by the appropriate departmental managers. The written record of such meetings shall be forwarded to the QA Manager for his records.

2.7.3 In addition, the QA Manager or his designee shall periodically hold training meetings for Hittman personnel performing activities related to the use of Hittman packages. The frequency of these meetings shall be at the discretion of the QA Manager but shall not be less frequent that once every 12 months. The scope of these meetings should include the following:

(a) Review of audit results including any significant deficiencies or nonconformances.

(b) Review of significant changes to the following documents:

(1) Package certificates of compliance.

(2) QA Program policies and practices contained in procedures listed in Table 2.2.

(3) Rules and regulations related to package use.

2.7.4 The QA Manager shall maintain a written record of all training meetings including the date held, subjects discussed, and attendance.

2.7.5 It shall be the responsibility of individual Hittman departmental managers to ensure that Hittman personnel responsible for performing quality related activities in each department are knowledgeable in the principles and techniques of the activity being performed.

2.7.6 The QA Manager shall be responsible for the selection and assignment of qualified auditors. The QA Manager, whose minimum qualification requirements are described in Section 1.4, shall establish the audit personnel qualifications appropriate to the nature and scope of the work to be performed and the importance of the activities being audited. Personnel shall be selected for QA auditing assignments based on experience or training which establishes that their qualifications are commensurate with the complexity or special nature of the activities to be audited.

2.7.7 The supplementary and nonmandatory guidance on the qualification, education, and experience of audit personnel set forth in Supplement 2S-3 and Appendix 2A-3 respectively of ANSI/ASME NQA-1-1983, "Quality Assurance Program Requirements for Nuclear Power Plants," will be followed. The QA Manager will maintain auditor qualification records as recommended in ANSI/ASME NQA-1-1983.

2.7.8 The QA Manager shall also establish requirements for the qualification, maintenance, and certification of inspection and test personnel. Personnel shall be selected for inspection and test assignments based upon experience or training which establishes that their qualifications are commensurate with the complexity or special nature of the activities to be performed.

2.7.9 The QA Manager will maintain the qualification records of personnel performing inspection and test activities.

2.8 Management Reviews

2.8.1 The Manager, Administrative Services, shall review the status and adequacy of the QA Program at least once annually and report the results of that review to the President.

2.8.2 The President may require the QA Manager and other departmental managers to make formal recommendations with regard to the adequacy of QA Program policies and practices and Hittman's compliance with these policies and practices. These recommendations shall become part of the formal record of review of program effectiveness which shall be maintained by the Manager, Administrative Services.

2.8.3 The purpose of the management review is to assess the scope, implementation, and effectiveness of the QA Program to assure that the program is adequate and complies with the applicable requirements of 10 CFR 71, Subpart H.

2.9 Hittman Generated Certifications

2.9.1 Primary responsibility for the preparation and sign-off of certificates of conformance and/or compliance, issued by Hittman, shall rest with the Quality Assurance Manager. In his absence, the Manager, Administrative Services or the President may assume this responsibility.

2.9.2 Other delegation of this responsibility may be made in writing by the QA Manager.

TABLE 2-1

DEFINITIONS OF TERMS

certificate of compliance	Form NRC-618 issued by the NRC for radioactive materials packages under 10 CFR Part 71
certificate of conformance	See ANSI/ASME-NQA-1-1983 "Quality Assurance Program Requirements for Nuclear Facilities"
package	See 10 CFR 71.4
package approval	A license or certificate of compliance issued by the NRC for packaging of Type B, highway route controlled quantity, and fissile radioactive material under 10 CFR Part 71
user	Each person or organization authorized by a specific license issued by the NRC to receive, possess, use, or transfer licensed materials to a carrier for transport or transports such material outside the confines of his plant or other place of use
should	A recommendation
shall	A requirement that must be complied with as part of the QA program
10 CFR 71 Subpart H	A subpart that describes QA requirements applying to the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair and modification of components of packaging which are important to safety
will	An indication of an intention to carry out a particular action even though that action is not a requirement of the QA Program

Table 2-2

MATRIX OF HITTMAN PROCEDURES

Matrix of Procedures that Implement All or Portions of 10 CFR 71 Subpart H Requirements for Quality Assurance During Use of Radwaste Shipping Packages

SUBPART H REQUIREMENTS	PROCEDURE NUMBER & TITLE: A-003 Training & Certification of Inspection, Test, and Audit Personnel	C-001 Preparation & Control of HNDC Operating Procedures	C-002 Control of HNDC Manuals	C-003 Forms Index	C-004 Preparation & Control of Technical Specifications	C-005 Preparation and Control of Purchase Requisitions (PRs), Requests for Quotation (RFQs) and Purchase Orders (POs)	C-016 Control of HNDC Quality Assurance Program Description Documents	C-019 HNDC Review of Radwaste Shipping Package Certificate of Compliance Revisions	C-100 QA Program (Design)	C-200 QA Program (Use)	E-001 Engineering Work Requests (EWRs), Technical Support Requests (TSRs) and Engineering Change Notices (ECNs)	O-001 Cask Maintenance and Repair
71.101 Organization		•								•		
71.105 Quality Assurance Program	•						•		•	•		
71.107 Design Control									•	•	•	
71.109 Procurement Document Control					•	•				•		
71.111 Instructions, Procedures & Drawings						•		•		•	•	•
71.113 Document Control		•	•	•	•	•	•			•		
71.115 Control of Purchased Material, Equipment & Services					•					•		
71.117 Identification & Control of Materials, Parts & Components										•		
71.119 Control of Special Processes		•								•		
71.121 Inspection	•									•		
71.123 Test Control	•	•							•	•		
71.125 Control of Measuring & Test Equipment										•		
71.127 Handling, Storage & Shipping					•			•		•		
71.129 Inspection, Test & Operating Status								•		•		
71.131 Nonconforming Materials, Parts & Components					•					•		
71.133 Corrective Action										•		
71.135 Quality Assurance Records										•		
71.137 Audits										•		

SECTION 3

DESIGN CONTROL

3.1 Scope

3.1.1 The requirements of this section shall apply to changes made to Hittman packages that have been designed in accordance with the provisions of Hittman's Quality Assurance Program for the Engineering, Design, Procurement, Fabrication, and Initial Testing of Radwaste Shipping Packages or satisfy the provisions of 10 CFR 71.101(d) or (e).

3.1.2 This section establishes measures to insure that proposed changes to package structures, components, parts and/or design characteristics are reviewed by qualified individuals, including QA personnel, prior to implementation to insure that the proposed change does not violate the conditions of the package approval.

3.1.3 This section also establishes measures to insure that proposed changes or amendments to the package approval are prepared, reviewed and approved in accordance with the applicable requirements of 10 CFR 71, Subpart H.

3.1.4 The requirements of this section do not apply to routine maintenance activities including replacement of in-kind components and parts.

3.1.5 Regardless of the type of package, component or part, or its function or the extent of the design change, every proposed package modification must be reviewed to determine whether the modification or the results of the modification will constitute a change to the package approval.

3.2 Responsibilities

3.2.1 Hittman, as owner of the approved package, shall review and approve all proposed modifications to Hittman packages.

3.2.2 Proposed package modifications shall be reviewed by the QA Manager or his designee prior to implementation.

3.3 Procedure

3.3.1 An Engineering Work Request (EWR) form shall be used in accordance with the applicable requirements of Engineering Department procedures to document and control the processing of all package modifications.

3.3.2 Any Hittman employee may request approval of a modification to a package by initiating an EWR.

3.3.3 After acceptance of the EWR by the Project Manager and by the Director, Engineering, the Manager, Design Engineering or his designee, shall perform an evaluation by studying the package license application, safety analysis and the NRC package approval to determine if implementation will require a change to the package approval; in other words, the modification will change the package as designed and/or analyzed in the license application and described in the package approval.

3.3.4 If it is determined that a change to the package approval is not required, the Manager, Design Engineering or his designee shall prepare a written justification, including a list of factors he considered in his evaluation and any calculations, supporting his conclusion as to whether or not a license amendment is required. This conclusion shall be indicated on the EWR or on an attachment referenced on the EWR. Proposed package modifications shall be assumed to require a license amendment unless it can be clearly justified that such an amendment is not required.

3.3.5 The QA Manager, the Director, Engineering, and the Manager, Eastern Operations shall review the conclusion of the evaluation performed in 3.3.4 above prior to implementation of a change. This review shall be documented, preferably on the EWR form. The QA Manager's review will be for information and to assure adherence to appropriate modification procedures.

3.3.6 Engineering and design activities required in order to implement approved EWRs, evaluated solely by step 3.3.3 or by steps 3.3.3-3.3.5, shall be controlled in accordance with C-100, "Quality Assurance Program for the Engineering, Design, Procurement, Fabrication, and Initial Testing of Radwaste Shipping Packages," so as to ensure that controls over design activities for package modifications are commensurate with those applied to the original design.

3.3.7 The QA Manager shall be responsible for verifying that documents, including drawings, procedures, manuals, etc., affected by a package modification are change in accordance with document control requirements described in Section 6.0 of this procedure.

3.3.8 Engineering documents that include technical information related to a design change shall be maintained as a quality record in accordance with the requirements described in Section 17.0 of this procedure.

SECTION 4

PROCUREMENT DOCUMENT CONTROL

4.1 Scope and Applicability

4.1.1 This section delineates the sequence of actions to be accomplished in the preparation, review, approval and control of procurement documents used for the purchase of items and services for Hittman packages. Purchased items consist principally of replacement parts, for example, studs, nuts, and gaskets. Services may include, for example, repair welding or certain nondestructive examinations.

4.2 Procedure

4.2.1 Items and services shall be purchased in accordance with the requirements of this section and the applicable requirements of Hittman procurement procedures.

4.2.2 The requisitioner shall be responsible for reviewing the requirements of the package approval, including drawings and specifications, and identifying the specific requirements for the items and services to be procured.

4.2.3 The requisitioner shall be responsible for incorporating and/or referencing the following in a purchase requisition;

(a) a statement of work to be performed by the supplier;

(b) technical requirements including applicable regulatory requirements, material and component identification requirements, drawings, specifications, codes and industrial standards, test and inspection requirements, and special process instruction;

(c) QA requirements, specifically the requirements of 10 CFR 71, Subpart H, appropriate to the items or services being procured;

(d) the documentation (e g., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedure qualifications, material certifications, etc.) to be available for review or submitted to Hittman for information, review or approval;

(e) a statement of Hittman's requirements for access to the supplier's facilities and records for source inspection and audit.

4.2.4 When the item's conformance to technical requirements can be verified upon receipt by inspection, test or other suitable means, the requirements of 4.2.3(c), (d), and (e) may be waived by the QA Manager after reviewing the procedures to be used for such verification activities.

4.2.5 When a Certificate of Conformance is used to accept an item or service, the requirements of 4.2.3(c), (d), and (e) may be waived by the QA Manager after verifying and documenting that the supplier's certification system is acceptable. The purchase requisition shall include the requirement that a Certificate of Conformance be submitted by the supplier.

4.2.6 The QA Manager or his designee shall approve purchase requisitions for items and services subject to the requirements of this QA Program.

4.2.7 Purchase requisitions, including attachments, and purchase orders requiring QA approval are quality records and shall be controlled in accordance with the requirements of Section 17 of this procedure.

SECTION 5

INSTRUCTIONS, PROCEDURES AND DRAWINGS

5.1 Policy

5.1.1 Activities subject to the requirements of this QA Program shall be prescribed by documented instructions, procedures, or drawings of a type appropriate to the circumstances and accomplished in accordance with such documents.

5.1.2 These documents shall include, when necessary to ensure quality, appropriate quantitative and/or qualitative criteria for determining whether or not an activity has been satisfactorily accomplished.

5.2 Responsibilities

5.2.1 Individuals or groups responsible for performing quality related activities shall insure that written and approved instructions, procedures, and drawings appropriate to the circumstance are available prior to undertaking the activity.

5.2.2 The QA Manager shall verify by audit that activities controlled by this QA Program are prescribed by documented instructions, procedures, and drawings, as required by this section.

5.2.3 Hittman instructions, procedures, and drawings prescribing activities subject to the requirements of this QA Program shall be reviewed and approved in accordance with requirements described in Section 6.0 of this procedure.

5.2.4 Instructions, procedures, and drawings prepared by and prescribing user activities should be reviewed by the user's QA organization.

5.2.5 A contractor or supplier responsible for an activity subject to the requirements of this QA Program shall be required in procurement documents to provide the instructions, procedures and drawings appropriate to the activity being accomplished. Hittman may require the submittal of such documents for review and acceptance prior to undertaking the activity. Such a requirement will be identified in procurement documents.

SECTION 6

DOCUMENT CONTROL

6.1 Policy

6.1.1 The review, approval and issue of documents, including changes thereto, which prescribe activities subject to the requirements of this QA Program shall be controlled in accordance with written procedures or instructions.

6.1.2 Changes to documents subject to the requirements of this section shall be reviewed and approved by the same organizations that performed the original review and approval. This requirement may be waived in writing by the QA Manager. The written waiver shall be maintained as part of the record of document revision.

6.1.3 Documents subject to the requirements of this section will be available for use at the location where the prescribed activities are performed.

6.2 General

6.2.1 Quality related documents, including instructions, procedures, drawings, and specifications are controlled by written procedures to insure that such documents have been properly prepared and that appropriate revisions are at or available to personnel at the location where the work is to be performed. These procedures, along with many of the documents controlled by them, are incorporated into several Hittman manuals.

6.2.2 Controlled lists (tables of contents, etc.) or master lists shall be accessible to all personnel to verify the latest approved revision of the document. Where such lists are not appropriate, other written notice should be provided to document users to indicate the implementation date of a document revision, specific disposal or isolation requirements, or other appropriate instructions.

6.2.3 For documents on controlled distribution, instructions for the disposal of superseded documents shall be identified on the document transmittal/ receipt acknowledgement form.

6.2.4 The QA Manager shall be responsible for the issuance and control of the following manuals.

6.3 Hittman Quality Assurance Manual

6.3.1 The Hittman Quality Assurance Manual includes controlled copies of the one or more of the following documents:

(a) C-100, "Quality Assurance Program for the Engineering, Design, Procurement, Fabrication, and Initial Testing of Radwaste Shipping Packages."

(b) C-200, "Quality Assurance Program for the Use of Radwaste Shipping Packages."

(c) Other Hittman procedures from the Procedures Manual determined appropriate for inclusion in the Quality Assurance Manual by the QA Manager for purposes of information for the users of Hittman packages.

6.3.2 The Hittman Quality Assurance Manual is intended to ensure that both Hittman and user personnel have ready access to a description of the QA policies and practices related to the design and use of Hittman packages.

6.4 Hittman Procedures Manual

6.4.1 The Hittman Procedures Manual contains a variety of technical and administrative procedures governing the operation of Hittman. A number of these procedures describe measures for control over activities subject to the requirements of this QA Program, including activities related to document control. These procedures are identified in Section 2.0.

6.4.2 The QA Manager has the right to review and comment on any procedures that include measures for the

control of quality related activities subject to the requirements of this QA Program.

6.5 Cask Manuals

6.5.1 Cask Manuals include specific information and data for the various Hittman package models.

6.5.2 Each manual volume will include, as a minimum, the following:

(a) A copy of the latest revision of the NRC Certificate of Compliance for the particular model shipping package including a copy of all enclosures thereto, a copy of all drawings referenced in the Certificate of Compliance, and a copy of all other references identified in the Certificate with the exception of rules, regulations, and standards. A copy of the NRC Certificate of Compliance transmittal letter should also be included.

(b) Copies of procedures and/or checklists describing requirements and methods for certain specific activities, e.g., inspection, repair handling, loading, and unloading.

6.5.3 Cask Manuals may also include other information of a general nature regarding package design and use. This information shall be separated from the information described in Section 6.5.2 and shall be prefaced with a written statement indicating that such data is for information purposes only and that it shall not be used as the basis for control over any quality related activities.

6.6 Rad Services Manual - General

6.6.1 The Rad Services Manual - General contains information of a general commercial nature not subject to the requirements of or controlled by this QA Program.

SECTION 7

CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

7.1 Scope

7.1.1 This section describes the measures that have been established to ensure that replacement items purchased for Hittman packages conform to the procurement documents prepared in accordance with the requirements of Section 4.0.

7.1.2 The measures described in this section shall also apply to the acceptance of services, such as third party inspection, engineering and consulting services, and installation, repair, and overhaul or maintenance work associated with packages in use to the extent that such services involve activities subject to the requirements of this QA Program.

7.2 Requirements

7.2.1 The measures established by Hittman to ensure that purchased items and services for packages in use conform to procurement documents place reliance on examination of products upon delivery and verification that documentary evidence exists and is available prior to use showing that items conform to specific requirements. These measures are considered appropriate, sufficient, and consistent with the importance, complexity, quantity, and cost impact of the replacement items and services that may be purchased for packages in use.

7.2.2 The policy stated in Section 7.2.1 notwithstanding, the QA Manager shall be responsible for evaluating on a case-by-case basis the need for supplementary measures to control purchased items and services, including evaluation and selection of procurement sources prior to award of contract and evaluation and verification of suppliers performance, including source surveillance and inspection. These measures may be required when the quality of the item cannot be adequately verified through documentary evidence or inspections upon receipt.

7.2.3 The supplementary requirements and nonmandatory guidance for control of purchased items and services set forth in supplement 7S-1 and Appendix 7A-1 respectively of ANSI/ASME NQA-1-1983, "Quality Assurance Program Requirements for Nuclear Power Plants," will be followed.

7.2.4 The QA Manager shall perform the evaluation described in Section 7.2.2 prior to approving quality related purchase requisition for further processing.

7.2.5 Item conformance to procurement requirements may be determined in accordance with Section 7.2.1 by receiving inspection only or by a combination of receiving inspection and a supplier's Certificate of Conformance that specified requirements have been met.

7.2.6 Verification of item or service conformance to procurement requirements solely by receiving inspection will only be considered when the items or services:

(a) are relatively simple or standard in design, manufacture, and test;

(b) are adaptable to standard and easily verifiable inspections and/or tests of the end product to verify quality characteristics after delivery; and

(c) are such that receiving inspection does not require operations which could affect the integrity, function, or cleanliness of the item.

7.2.7 Verification of item or service conformance to procurement requirements by a combination of receiving inspection and a supplier's Certificate of Conformance shall be satisfactory when the item or service is of simple design and involves standard materials, processes, and tests. However, specific supplemental documentation such as material certificates or test reports shall be required as appropriate by procurement documents. The QA Manager shall be responsible for specifying requirements for supplier Certificates of Conformance and supplementary documentation in purchase requisitions.

7.2.8 When a supplier's Certificate of Conformance is required by the purchase requisition, the requirements set forth in Section 8.2.1 (a) through 8.2.1 (e) of Supplement 7S-1 of ANSI/ASME NQA-1-1983 shall be communicated in writing to the supplier.

7.2.9 Certificates of Conformance attesting to the acceptance of items or services shall be available prior to installation or use of the item or equipment.

7.2.10 The QA Manager shall be responsible for verifying the validity of supplier Certificates of Conformance and evaluating the effectiveness of the supplier's certifications system. Such verifications shall be conducted (e.g., during performance of audits of the supplier) at intervals commensurate with the supplier's past quality performance and the importance and complexity of the purchased items. Verification activities and results shall be documented, e.g., by written memoranda, and maintained in a file for the supplier.

7.2.11 The QA Manager shall maintain a list of suppliers whose certification systems have been evaluated and determined to be effective. This list will be reviewed at least annually by the QA Manager and determinations made regarding the need to re-evaluate each supplier or remove any supplier from the list. Items may be purchased from suppliers on this list without re-evaluation of their certification system.

7.2.13 Receiving inspections shall be coordinated with the review of supplier documentation when procurement documents require such documentation to be furnished.

7.2.14 Most replacement items purchased for packages in use are simple and standard in design (e.g., studs, nuts, washers, gaskets, etc.) and can be adequately inspected by QA Department personnel without formal written inspection checklists. The need for written inspection checklists, however, shall be determined on a case-by-case basis as part of the QA Manager's review of purchase requisitions. When it is determined that special inspection checklists are necessary to ensure the quality of inspection activities the QA Manager shall be responsible for having

written checklists prepared, for reviewing and approving those checklists, and for having those checklists available at the inspection location.

7.2.15 In certain cases involving procurement of services only, service may be accepted by any or all of the following methods:

(a) technical verification of the work performed and results;

(b) surveillance and/or audit of the activity;

(c) review of objective evidence for conformance to the procurement document requirements.

7.2.16 Procurement documents include statements requiring suppliers to notify Hittman of any deviations from the requirements of the procurement documents that the supplier intends to incorporate in the item or service to be offered for acceptance by Hittman. The documentation and disposition of such deviations shall be controlled in accordance with the requirements of Section 15.0 of this procedure.

SECTION 8

IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

8.1 Applicability

8.1.1 The requirements of this section apply to the identification and control of replacement items (e.g., studs, nuts, and gaskets) used in Hittman packages.

8.2 Policy

8.2.1 Replacement items shall be identified through all phases of receipt, storage, issue, and use or installation to ensure that only correct and accepted items are used in Hittman packages.

8.2.2 The identification of replacement items for Hittman packages shall be traceable to appropriate documentation such as drawings, specifications, purchase requisitions/orders, and manufacturing and inspection documents that establish requirements for the item and document how those requirements were satisfied.

8.2.3 The identification of replacement items shall be maintained either on the item or on records traceable to the item to preclude use of incorrect or defective items.

8.2.4 When parts marking is used, it must be clear, unambiguous, indelible and it must not affect the fit, function or quality of the item.

8.2.5 The correct identification of replacement items shall be verified during receiving inspection and/or prior to installation or use.

8.2.6 Control and identification of replacement items shall be the responsibility of primarily the QA Manager and the Maintenance Supervisor.

8.3 Procedure

8.3.1 The QA and Maintenance Departments shall maintain segregated and controlled access storage areas for replacement items for Hittman packages.

8.3.2 The QA Manager shall maintain a list of persons authorized access to the QA controlled storage area and the Maintenance Supervisor shall maintain a list of persons authorized access to the maintenance controlled storage area. Access will be controlled by key lock.

8.3.3 Only replacement items issued by QA from the QA controlled storage areas should be used on packages. Such items may be issued to the Maintenance Supervisor or his designee for storage in the maintenance controlled storage area.

8.3.4 Use of replacement items other than those issued by QA must be approved by the QA Manager. The requirements of Section 8.2 must be satisfied prior to use of such items.

8.3.5 Identification of replacement items entered into, maintained in, and issued from the QA and Maintenance controlled storage areas as well as certain other items stored outside the controlled storage areas with the approval of the QA Manager is through the use of tags attached to each item or lot. In addition, markings may appear on an item as required by purchase specifications which serve to identify certain characteristics (e.g., material) of the item. These markings are verified during receiving inspection.

8.3.6 Replacement items received at the Hittman storeroom and awaiting receipt inspection and acceptance shall be secured in the QA controlled area.

8.3.7 Receipt inspections of replacement items received at the Hittman storeroom shall be performed in accordance with the requirements of Section 7. Replacement items found acceptable shall be identified by a green tag.

8.3.8 Items found to be nonconforming shall be identified by the attachment of a Quality Inspection Document (QID) form (Form-38). The QID shall be processed in accordance with the requirements of Section 15.

8.3.9 Rejected items may remain in the QA controlled storage area but shall be physically separated from green tagged items.

8.3.10 Only green tagged replacement items shall be issued for use from the QA controlled storage area.

8.3.11 The QA Manager shall maintain a log of all tags used. Tags may be applied and removed only by the QA Manager and other individuals designated by the QA Manager and identified in the Tag Log. Following the issuance of a green tagged item from the QA or maintenance storage area, the individual performing cask maintenance may remove the tag prior to installation.

8.3.12 When one or more items are issued from a lot that has been green tagged the item or group of items shall be green tagged with a tag identical to the original lot tag with the following change: under "QUANT," identify the quantity of the items issued. The quantity of items remaining should be marked on the original green tag.

8.3.13 Green tagged items leaving the QA controlled storage area shall be logged on the Cask Materials Log Sheet (Form-10) shown as Figure 8-1. This log shall be controlled by the QA Manager and shall be maintained in the QA controlled storage area.

8.3.14 Green tagged items leaving the maintenance controlled storage area shall be logged on the Maintenance Controlled Cask Attachment Disposition Log (Form-93) shown as Figure 8-2.

8.3.15 Only green tagged replacement items may be used with Hittman packages. It shall be the responsibility of the Maintenance Supervisor to ensure that the tag number is entered on the maintenance checklist related to package maintenance and repair, on the stud and gasket inspection and report form, or on a similar document approved by the Maintenance Supervisor.

8.3.16 Replacement items issued, but not used shall be returned to the QA controlled storage area and visually reinspected by Hittman QA prior to use. If necessary, a new green tag will be prepared for those items found acceptable for use.

8.3.17 Individuals issued replacement items from the QA and Maintenance controlled storage areas shall be responsible for ensuring that tags attached to the items are not lost, misplaced and/or damaged. Items not properly tagged shall be returned to the QA controlled storage area for reinspection and identification.

Figure 8-1

CASK MATERIALS LOG

CASK MATERIALS LOG

Material Description	Tag Number	Quantity Issued/ Returned	Issued to/ Returned by	Checked out by/ Checked in by	Date

FORM-10(B)

Figure 8-2

FORM-93
MAINTENANCE CONTROLLED CASK ATTACHMENT DISPOSITION LOG

MAINTENANCE CONTROLLED CASK ATTACHMENT DISPOSITION LOG

Material Description	Date	Tag No.	Issued To	Location	Cask/ Date Installed	Form Received

HNDC-93(A)

SECTION 9

CONTROL OF SPECIAL PROCESSES

9.1 Applicability

9.1.1 The requirements of this Section apply to the use of special processes performed by Hittman personnel.

9.1.2 The procurement of services for the performance of special processes or the performance of special processes during the repair or modification of a package or the fabrication of a replacement subassembly shall be controlled in accordance with the requirements of Sections 4 and 7.

9.2 General

9.2.1 Maintenance and repair of Hittman packages shall be controlled in accordance with documented instructions, procedures or drawings of a type appropriate to the circumstances in accordance with the requirements of Section 5.

9.2.2 Maintenance and repair activities may involve special processes, specifically welding, heat treating and/or nondestructive examinations.

9.3 Requirements

9.3.1 The Manager, Maintenance shall be responsible for the development of written procedures, when required for controlling welding operations and nondestructive examination, or other special processes and for qualifying such procedures as well as equipment and personnel used in those activities in accordance with applicable codes or standards as specified in the package Certificate of Compliance.

9.3.2 Welding and NDE procedures, the most commonly used special processes, shall be reviewed by knowledgeable individuals within the Engineering Departments prior to use. The QA Manager shall verify that these reviews have been accomplished prior to authorizing use of special process procedures. Changes to welding and NDE procedures used for package maintenance and repair must be signed-off

by the QA Manager prior to use. Additional Engineering Department reviews may be required by the QA Manager.

9.3.3 The Manager, Maintenance shall maintain control over welding procedures as well as qualification records of procedures, equipment, and personnel associated with those processes. The Maintenance Supervisor shall ensure that those records are established, filed and kept current.

9.3.4 The QA Department shall be responsible for verifying implementation of special process procedures to provide assurance that operators are qualified and that the approved procedures are being followed.

9.3.5 The QA Manager may define hold or witness points in special process procedures as appropriate.

SECTION 10

INSPECTION

10.1 Scope

10.1.1 Inspection activities related to package use fall into the following three categories:

(a) inspections, including visual inspections and measurements, performed as part of normal periodic maintenance and as required by package Certificates of Compliance (e.g., seal inspection prior to each shipment.)

(b) receiving inspections of replacement parts or materials prior to acceptance and use.

(c) independent verifications performed by QA Department personnel, including inspections and surveillance or monitoring of package use operations (e.g., maintenance, repair, package loading and unloading, etc.).

10.1.2 Inspections performed as a normal part of periodic maintenance and package shipment are controlled through the maintenance program and by package handling procedures. Such inspections are not subject to the requirements of this section.

10.1.3 Receiving inspections are performed by QA Department personnel in accordance with the requirements of Section 7 or this procedure.

10.1.4 The requirements of this section shall apply to verification of the quality of important activities related to the use of Hittman packages.

10.2 Requirements

10.2.1 Quality verification may include, as appropriate, measurements and inspections, surveillance or monitoring, and reviews of the records or performance of activities.

10.2.2 Responsibility for quality verification activities rests with the QA Manager.

10.2.3 The QA Manager shall determine when quality verification is required, the requirements for the verification, the method (s) to be used, the schedule, and the personnel to be assigned.

10.2.4 Personnel assigned to perform quality verification activities shall be other than those who are performing or directly supervising the activity being verified. These individuals shall not report directly to the immediate supervisors who are responsible for the activity being inspected. In general, individuals performing quality verification activities will be part of the QA Department.

10.2.5 The QA Manager shall, by written memo, assign responsibility for performance of specific quality verifications. The memo should include, to the extent necessary, the following information:

(a) identification of characteristics and activities to be verified;

(b) a description of the method of verification;

(c) identification of the individual(s) responsible for performing the verification;

(d) acceptance and rejection criteria as appropriate;

(e) identification of required procedures, drawings, and specifications and revision;

(f) description of necessary measuring and test equipment including accuracy requirements.

10.2.6 Individuals assigned quality verification duties shall document the results of the verification on the memo and return it to the QA Manager.

10.2.7 The QA Manager shall maintain a file of all quality verification memos as a record of implementation of the quality verification program.

10.2.8 Provisions shall be established in special process and repair procedures for mandatory inspection hold points for witness by QA Department personnel.

These provisions provide for the review of such procedures by QA prior to use.

10.2.9 When quality verification activities are initiated by mandatory inspection hold points, a copy of the completed procedure with signoffs shall be placed in the quality verification file by the QA Manager.

10.2.10 QA hold and witness points in procedures shall be clearly marked in writing or by use of suitable stamps.

10.2.11 The QA Manager shall ensure that individuals assigned quality verification duties are knowledgeable in the activities to be verified and clearly understand the requirements of the quality verification memo. The QA Manager may satisfy this responsibility by discussing the planned verification with the individual(s) to be assigned.

SECTION 11

TEST CONTROL

11.1 Scope and Applicability

11.1.1 Preoperational tests conducted during or upon completion of package fabrication will be controlled in accordance with the requirements of document C-100, "Quality Assurance Program for the Engineering, Design, Procurement, Fabrication and Initial Testing of Radwaste Shipping Packages."

11.1.2 Tests conducted during package use other than nondestructive examinations controlled in accordance with Section 9 of this procedure shall be subject to the requirements of this section if those tests are required by the package approval to demonstrate that the package or part thereof will perform satisfactorily in service.

11.2 Requirements

11.2.1 The Manager, Eastern Operations, or his designee shall be responsible for reviewing package approvals and identifying the need for tests of packages and/or items used in packages. Such testing may be required, for example, following package modifications, repairs, and/or part replacements.

11.2.2 Testing required to demonstrate that items will perform satisfactorily in service shall be performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design and licensing documents.

11.2.3 Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation and equipment is available and used, and that the test is monitored and is performed under suitable environmental conditions by competent personnel.

11.2.4 Test results shall be documented and evaluated to assure that test requirements have been satisfied.

11.2.5 The Engineering Department is responsible for preparation of test procedures and the review of test results if acceptance criteria is not delineated in test procedures or referenced documents and/or standards (e.g., drawings, codes).

11.2.6 The QA Manager shall review test procedures prior to use and incorporate hold or witness points as appropriate.

11.2.7 The Maintenance or Engineering Departments will generally be responsible for performance of testing, when required, in accordance with documented and approved procedures.

SECTION 12

CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 Policy

12.1.1 Tools, gages, instruments, and other measuring and testing devices used in activities affecting quality shall be properly controlled and calibrated and adjusted to maintain accuracy within necessary limits.

12.1.2 Controlled measuring and test equipment may be calibrated either at specified intervals or on a prior-to-use basis.

12.2 Responsibilities

12.2.1 The organization (Hittman or package users) responsible for performing quality affecting activities requiring the use of measuring and test equipment shall be responsible for establishing and documenting the measures that ensure that the requirements of this section are satisfied.

12.2.2 The QA Manager shall be responsible for reviewing Hittman activities and identifying the measuring and test equipment used by Hittman that must be controlled in accordance with the requirements of this section.

12.2.3 The Maintenance Department shall be responsible for the control of measuring and test equipment used by Hittman personnel and subject to the requirements of this section.

12.2.4 The Maintenance Supervisor shall maintain a log of measuring and test equipment controlled under this section. The log shall include the following information:

(a) A description of the measuring and test device, including serial number if necessary to identify the item.

(b) The date of last calibration check.

(c) The date of next scheduled calibration check.

12.2.5 The Maintenance Supervisor shall review this log at least annually and revise it as necessary to assure that it is current.

12.3 Requirements

12.3.1 The method and interval of calibration of controlled measuring and test equipment should be based on the type of equipment, its stability characteristics, the required accuracy and other conditions affecting measurement control.

12.3.2 Controlled measuring and test equipment shall be calibrated, adjusted and maintained against certified equipment having known valid relationships to nationally recognized standards. If no national standard exists, the basis for calibration shall be documented. If normal commercial practices provide adequate accuracy, special calibration and control measures are not required.

12.3.3 When controlled measuring and test equipment calibrated at specified intervals are found to be out of calibration, the QA Manager may require that an evaluation be made and documented of the validity of previous measurements or tests performed with that equipment. Such evaluations shall be required when the verification of the acceptability of items previously measured, inspected or tested with that equipment is required to ensure that the package conforms to its approval requirements.

12.3.4 Special calibrations shall be performed when accuracy of controlled measuring and test equipment is suspect. Measuring and test equipment consistently found to be out of calibration will be repaired or replaced.

12.3.5 Records shall be maintained and equipment suitably marked to indicate the calibration status for controlled measuring and test equipment.

SECTION 13

HANDLING, STORAGE AND SHIPPING

13.1 Applicability

13.1.1 The requirements of this section apply to purchased material and parts used as replacement items for Hittman packages.

13.1.2 The requirements of this section also apply to the handling, including loading and unloading, of Hittman packages.

13.2 Requirements and Responsibilities

13.2.1 Procurement documents shall include, as appropriate, requirements for handling, storage, shipping, cleaning, and preservation of purchased replacement parts and materials for Hittman packages.

13.2.2 The QA Manager shall be responsible for reviewing the adequacy of handling, storage and shipping requirements specified in procurement documents for replacement items.

13.2.3 Written instructions for the handling, including loading, unloading and inspection prior to shipment of Hittman packages shall be included in Cask Manuals described in Section 6 of this procedure. Use of these instructions ensures that conditions of the NRC package approval are satisfied prior to shipment.

13.2.4 The Manager, Eastern Operations, shall be responsible for the preparation and issue of package handling instructions and for the periodic review of these instructions to assure that they are kept current.

13.2.5 Written package handling instructions may be generic in nature or specific to a particular package, as appropriate. However, as a minimum, package handling instructions shall address the following aspects of package handling and use for each package:

(a) Responsibility of users of Hittman packages for handling and use in conformance with the package approval.

(b) Prerequisites that must be satisfied prior to package use (e.g., radwaste activity levels, package certification requirements, etc.).

(c) Surveys and inspections of packages prior to use (e.g., inspections of cask tiedowns including lugs, shackles, cables, ratchets, and turnbuckles; lid removal and inspections of lid holddown nuts, studs, gaskets, and cask interior; shield plug removal, etc.).

(d) Package handling instructions, including removal of lid, removal of cask from trailer, loading, replacement on trailer, closure, stud torquing, etc.

(e) Final verification prior to shipment (e.g., a pre-release checklist).

13.2.6 Responsibility for implementation of package handling instructions included in each Cask Manual rests with the package user.

SECTION 14

INSPECTION, TEST AND OPERATING STATUS

14.1 Requirements

14.1.1 The inspection status of replacement items purchased by Hittman and received, stored and issued through the Hittman storeroom and QA and maintenance controlled storage areas is maintained by the use of tags as described in Section 8 of this procedure.

14.1.2 The applications and removal of tags used by Hittman is procedurally controlled in accordance with Section 8.

14.1.3 The tagging system used by Hittman for replacement items provides for the identification of nonconforming items to prevent their inadvertent use.

14.1.4 The use of signs, labels, stamps, and other markings with packages shall adhere to the requirements of the package approval. Provisions have been established for signs indicating the operating status of Hittman packages.

SECTION 15

NONCONFORMING MATERIAL, PARTS OR COMPONENTS

15.1 Scope and Applicability

15.1.1 The requirements of this section apply to nonconformances identified by suppliers of Hittman purchased replacement parts and materials and/or contractors providing quality related services to Hittman for its packages.

15.1.2 Nonconformances identified by Hittman personnel during receiving inspection of replacement parts and materials for Hittman packages shall also be controlled in accordance with the requirements of this section.

15.1.3 Procedural and equipment noncompliances that occur during testing, repair and/or modification activities that are directly related to package material, parts, and components shall also be controlled in accordance with this Section.

15.1.4 Nonconformance of a Hittman package with the requirements of the NRC package approval identified by Hittman and user personnel shall be controlled as a condition adverse to quality in accordance wth the requirements of Section 16.

15.1.5 Procedural nonconformances and other conditions adverse to quality that are not directly related to package materials, parts or components shall also be controlled in accordance with the requirements of Section 16 of this procedure.

15.2 Requirements and Responsibilities - (Supplier Identified)

15.2.1 Suppliers furnishing replacement parts or materials for use in packages and contractors fabricating, erecting or installing materials or parts for packages may be required in procurement documents to establish procedures for the control of nonconforming items.

15.2.2 The responsibility for specifying requirements in procurement documents for the control of nonconforming items by the supplier/contractor shall rest with the QA Manager.

15.2.3 When required by procurement documents, the supplier, upon identification of a nonconformance, shall be required to suspend the affected work until the nonconformance has been evaluated if:

(a) the continuance of the work would conceal the nonconformance and make corrective action difficult or impossible, or

(b) the nonconformance is due to the work procedure and continuing its use would increase the extent or severity of the nonconformance.

15.2.4 Suppliers and contractors may be required in procurement documents to submit a description of nonconforming conditions to Hittman using a Deviation Disposition Request (DDR) form (Form-07).

15.2.5 The Deviation Disposition Request (DDR) form shall be processed as follows:

(a) DDR's shall be forwarded initially to the QA Manager or his designee to assign a control number to the DDR and to enter the number and date in the DDR log for control purposes.

(b) The DDR shall then be forwarded to the Engineering Department for disposition. This will usually be accomplished through the initiation of an Engineering Work Request (EWR).

(c) The DDR disposition shall be approved by Engineering and QA.

(d) Upon completion of the DDR the QA Manager shall enter the close-out date in the DDR log and forward the DDR to the Purchasing Manager. (Note: The Hittman Engineering follow-up is not necessarily required for this close-out as it is primarily for internal Engineering Department usage).

(e) The Purchasing Manager shall transmit the dispositioned DDR to the supplier or contractor and be responsible for legal/financial negotiations as required.

15.2.6 The DDR form may be generated for a vendor by Hittman personnel.

15.3 Requirements and Responsibilities - (Receipt Inspections)

15.3.1 When replacement parts or materials for use in packages are found, during receipt inspections, to be nonconforming, the nonconforming item shall be identified by a partically dispositioned Quality Inspection Document (QID) form (Form-38), as described in Section 8 (Figure 15-2).

15.3.2 The QID form, attached to the item, shall identify the item, provide a description of the nonconformance, and shall be stamped "Rejected" in bold red letters.

15.3.3 Following repair, rework, or replacement of an item, the corrective action verification shall be described on the QID and the form shall be closed out.

15.3.4 Engineering approval shall be required prior to repair of nonconforming materials, parts or components and prior to acceptance-as-is. This approval will generally be obtained by processing a DDR as discussed in Section 15.2.

15.4 Requirements and Responsibilities - Package Material and Procedures

15.4.1 When material and procedural nonconformances are identified during or as a result of test, repair, or modification activities, these conditions shall be identified and dispositioned using a Deviation Disposition Request (DDR) form (Form-07).

15.4.2 The DDR form shall identify the package unit number and shall be processed as follows:

(a) The DDR shall be forwarded initially to the QA Manager or his designee to assign a control number to the DDR and to enter the number and date in the DDR log for control purposes.

(b) The DDR shall then be forwarded to the Engineering Department for disposition. This will be accomplished through the initiation of an Engineering Work Request (EWR). The EWR shall be processed as a modification in accordance with the requirements of Section 3.

(c) The DDR disposition shall be approved by Engineering and QA.

(d) Upon completion of the DDR the QA Manager shall enter the close-out date in the DDR log. (Note: The Hittman Engineering follow-up is not necessarily required for this close-out as it is preimarily for internal Engineering Department usage).

15.4.2 If an accept-as-is disposition results in the package not being in compliance with the package approval, a Corrective Action Memo shall be initiated in accordance with the requirements of Section 16.

15.5 General

15.5.1 Nonconforming materials, parts and components shall be accepted, rejected, repaired or reworked as appropriate.

15.5.2 Repaired and reworked items shall be reinspected to determine acceptability.

15.5.3 Engineering approval shall be required prior to repair of nonconforming materials, parts or components and prior to acceptance-as-is dispositions.

15.5.4 A description of the change, waiver, or deviation that has been accepted must be documented as a record of the change and to denote the as-built condition.

15.5.5 Control of nonconforming materials, parts and components shall include tagging, marking, or other means of identification acceptable where physical segregation is not practical.

15.5.6 Nonconforming materials, parts and components shall not be used in packages if their use would constitute a nonconformance with the package approval unless a CAM has also been initiated as described in Paragraph 15.4.2 above.

Figure 15-1

FORM-07
DEVIATION DISPOSITION REQUEST

Westinghouse
Hittman Nuclear
Incorporated

DEVIATION DISPOSITION REQUEST
(DDR)

Westinghouse Hittman DDR #_____
Date Received_____

Date Deviation Determined_____

SUPPLIER (Name & Address)

Westinghouse Hittman Purchase Order #	Supplier Job/DDR#	Westinghouse Hittman Notification Date

SUPPLIER COMPLETE

DEVIATION DESCRIPTION | Quantity

PROPOSED CORRECTIVE ACTION AND TECHNICAL JUSTIFICATION

Supplier's Authorized Representative

Signature:_____ Title:_____
Name:_____ Date:_____

WESTINGHOUSE HITTMAN DISPOSITION

- ☐ APPROVED
- ☐ DISAPPROVED
- ☐ CONDITIONALLY APPROVED

WESTINGHOUSE HITTMAN APPROVAL:

ENGINEERING SUPERVISOR_____ Date:_____
PROJECT ENGINEER_____ Date:_____
QUALITY ASSURANCE_____ Date:_____

WESTINGHOUSE HITTMAN DISPOSITION STATEMENT INCLUDING JUSTIFICATION/COMMENTS

Westinghouse Hittman Quality Assurance Verification of DDR Corrective Action

Verified by:_____ Date:_____

Westinghouse Hittman Engineering Follow-up:

- ☐ Drawing Change
- ☐ Spec./Req. Change
- ☐ Other

FORM-07(B)

SECTION 16

CORRECTIVE ACTION

16.1 Requirements and Responsibilities

16.1.1 This QA Program has been established to provide adequate confidence that Hittman packages will perform satisfactorily in service. Notwithstanding the program as instituted, conditions will occasionally occur which could cause a degradation of quality. Such conditions as failures, malfunctions, deficiencies (including design deficiencies and procedural deficiencies), deviations, defective material and equipment and nonconformances should be promptly identified and corrected.

16.1.2 In the case of significant conditions adverse to quality the cause of the condition will be determined if possible and species corrective action taken to preclude repetition. In general, such special corrective action will be required where:

(a) nonconformance reports indicate trends due to inadequate procedural controls;

(b) existing procedures controlling important activities related to package use are not being properly implemented;

(c) recurring problems with nonconforming materials, parts or components are encountered;

(d) conditions adverse to quality identified during audits or surveillance are not resolved to a satisfactory conclusion within a reasonable time.

16.1.3 The QA Manager shall be responsible for the control of conditions adverse to quality including performance of follow-up reviews to verify proper implementation of corrective actions.

16.1.4 Significant conditions adverse to quality shall be reported to the Manager, Administrative Services, and the President.

16.1.5 Package users should document and report conditions adverse to quality including nonconforming materials, parts and components, in accordance with the procedure described in this section.

16.2 Procedure

16.2.1 Any individual encountering conditions adverse to quality shall notify the QA Manager by initiating or causing to be initiated a Corrective Action Memo (CAM) form (Form-09) shown in Figure 16-1.

16.2.2 CAM control numbers shall be assigned by the QA Manager or his designee. The QA Manager shall maintain a log of all CAM's.

16.2.3 The CAM initiator shall identify the specific materials, parts of components involved and/or procedures, drawings, purchase orders, etc. that contain requirements related to the adverse condition.

16.2.4 The CAM initiator shall list and describe the condition(s) adverse to quality and may provide recommendations as appropriate for resolution of the condition(s).

16.2.5 CAM's may be forwarded to the QA Manager directly or by mail, telex, or any other suitable means.

16.2.6 The CAM initiator shall sign and date the CAM.

16.2.7 The individual receiving the CAM for the QA Manager shall forward it as soon as possible to the QA Manager or his designee.

16.2.8 The CAM initiator should retain a copy of the CAM transmitted to the QA Manager.

16.2.9 The QA Manager or his designee shall be resporsible for designating one or more individuals within Hittman as an Action Designee. The QA Manager shall sign and date the CAM and forward it to the Action Designee(s) with appropriate instructions, if necessary.

16.2.10 When more than one Action Designee is assigned separate copies of the CAM shall be forwarded to

each Action Designee. A suffix letter (i.e., A, B, C) shall be added to each CAM for identification purposes. A notation shall be made in the CAM log.

16.2.11 The Action Designee shall be responsible for coordinating the resolution of the CAM including determining cause and special corrective action to preclude repetition for significant conditions adverse to quality. This responsibility includes obtaining the assistance as appropriate of other individuals or groups technically knowledgeable in the problem area.

16.2.12 The Action Designee shall describe the action taken or to be taken to resolve each condition adverse to quality. Actual and planned close out dates shall be included.

16.2.13 The Action Designee shall sign and date the CAM when completed and return it to the QA Manager for review and acceptance.

16.2.14 A copy of the CAM shall be transmitted to the CAM initiator for review by him or his management as appropriate.

16.2.15 The QA Manager shall maintain a file of all CAM's and shall regularly review the log of CAM's to ensure that follow-up action is being taken in a timely manner.

16.2.16 The QA Manager shall be responsible for determining the distribution of CAM's that have been closed out. The President shall receive a copy of all CAM's that document significant conditions adverse to quality.

Figure 16-1

FORM-09
CORRECTIVE ACTION MEMO

WESTINGHOUSE HITTMAN NUCLEAR INCORPORATED	CORRECTIVE ACTION MEMO	CAN NO.

Affected Equipment

Reference Documents

Description of Adverse Condition(s)/Action Recommendations

Date Found:_____

Action Designee:_____ Initiated By:_____ Date:_____

Respond By:_____ QA Manager Review:_____ Date:_____

Action Description

Cause of Adverse Condition(s):

Corrective Action Plan (Including Action to Prevent Recurrence):

Corrective Action Will Be Completed By:_____ (Date) Action Designee:_____ (Signature/Date)

Evaluation of Proposed Corrective Action:

QA Manager_____ (Signature/Date)

Follow-up Action Date

1)_____ Comments:_____

2)_____ Comments:_____

3)_____ Comments:_____

Final Close-out: _____ Date _____ QA Manager

FORM-09(B)

SECTION 17

QUALITY ASSURANCE RECORDS

17.1 Scope

17.1.1 The requirements of this section apply to records that furnish evidence of the quality of replacment parts and materials used in Hittman packages and of the quality of activities that fall within the scope of this QA Program.

17.1.2 Records related to the original design and fabrication of Hittman packages are controlled in accordance with document C-100, "Quality Assurance Program for the Engineering, Design, Procurement, Fabrication and Initial Testing of Radwaste Shipping Packages."

17.1.3 Records subject to the requirements of this section include at least the following:

(a) NRC Certificate of Compliance and all changes thereto including applications for license ammendments.

(b) Copies of drawings, specifications, procedures, safety analyses and other documents referenced in each package license.

(c) Procurement records including purchase requisitions, purchase orders and specifications.

(d) Supplier documentation including certificates of conformance, material certifications, test reports, etc.

(e) Personnel training and qualification records, as required, for Hittman personnel performing activities within the scope of this QA Program.

(f) Records of management reviews of QA Program effectiveness.

(g) Package design change records including completed ECRs and supporting documentation.

(h) Records of control of purchased items and material including receiving inspection reports, tag logs, and material issue logs.

(i) Special process procedures and personnel certification records.

(j) Records of reviews of procedures, instructions and other documents as required by this QA Program.

(k) Records of quality verification activities performed by QA Department personnel, including witness and hold point inspections or waivers thereof.

(l) Measuring and test equipment calibration records.

(m) Records of package inspections required to be performed by the package license.

(n) Records of the identification and processing of nonconformances and other conditions adverse to quality including completed CAM's and supporting documentation.

(o) Records of QA Department audits.

17.2 Requirements and Responsibilities

17.2.1 The QA Manager shall be responsible for preparation and maintenance of a Records System Index.

17.2.2 The Records System Index shall consist of a listing of document or record types (e.g., EWRs, CAM's purchase orders, certificates of conformance, etc.) that contain information related to the quality of items and activities controlled by this QA Program.

17.2.3 The Records System Index shall include the following information:

(a) Record name and/or designation

(b) filing or storage location (s)

(c) retention time requirements

(d) records custodian, i.e., the name of the individual responsible for the file

(e) description of access control provisions, if any

(f) file verification frequency

17.2.4 When access control provisions (see 17.2.3(e)) are identified on the Records System Index, removal of records from files and from the immediate storage area shall be documented with record OUT cards. These cards shall be placed in the storage location of the removed record and shall contain the following:

(a) identification of the record

(b) name of individual removing the record

(c) date of removal

17.2.5 Records pertaining to a particular Hittman package shall be retained for at least the lifetime of the package with the following exception: only current records of certain maintenance, inspection, and parts replacement activities performed on a repetitive basis are required to be maintained. Records of the previous performance of such activities may be disposed of by the QA Manager after determination that they do not contain information pertinent to the current condition of the package.

SECTION 18

AUDITS

18.1 Policy

18.1.1 Audits of this QA Program shall be performed:

(a) To evaluate compliance with the QA Program requirements, methods, and procedures

(b) To assess progress in assigned tasks

(c) To determine adequacy of performance

(d) To verify implementation of recommended corrective action.

18.1.2 Audits shall include evaluation of work area, activities, processes, and items and a review of documents and records.

18.1.3 Audits shall be performed by competent individuals having no direct responsibility in the area being audited.

18.1.4 Audits shall be performed in accordance with preestablished written procedures or checklists.

18.1.5 Audit results shall be documented and reviewed with management having responsibility in the area audited.

18.1.6 Conditions adverse to quality revealed by the audit shall be documented and resolved in accordance with the requirements of Section 16 of this procedure.

18.1.7 Deficient areas will be reaudited on a timely basis to verify implementation of correction actions.

18.1.8 All quality related functions are to be audited annually or more frequently if appropriate. Documented customer and interdivisional Westinghouse audits may be counted in the implementation of this requirement.

18.2 Procedure

18.2.1 The QA Manager is responsible for planning, scheduling, conducting, evaluating, and documenting audits.

18.2.2 QA and non-QA Department personnel may assist the QA Manager with planning and implementing the audit program. These functions will be performed, however, under the direction of the QA Manager.

18.2.3 The QA Manager shall prepare and maintain an audit schedule. The schedule shall include the following information:

(a) A description or listing of the major elements of the QA Program that must be audited at least annually

(b) The date and audit log number for the last audit conducted for each element

(c) The planned date for the next audit for each program element.

18.2.4 The audit schedule shall be periodically reviewed and revised by the QA Manager as necessary to assure that coverage and schedule reflect current activities.

18.2.5 Unscheduled audits may be conducted by QA for one or more of the following conditions:

(a) When it is necessary to determine the capability of a supplier's QA program prior to awarding of a contract or purchase order

(b) When significant changes are made in functional areas of the QA Program such as a significant reorganization or procedure change

(c) When there is evidence that the performance or reliability of package materials or parts is in jeopardy due to deficiencies in this QA Program

(d) When a systematic, independent assessment of program effectiveness or item quality, or both, is necessary

(e) When it is necessary to verify implementation of required corrective actions.

18.2.6 Scheduled or unscheduled audits shall be conducted by using appropriately prepared audit checklists. The standard Audit Checklist form (Form-11) shown in Figure 18-1 may be used to prepare audit checklists.

18.2.7 The auditor should review applicable portions of the QA Program description and other documents such as the package license, CAM's, previous audit checklists, procedures, specifications, codes, and standards to develop an audit checklist. The checklist is intended for use as a guide and should not restrict the audit investigation when findings raise further questions that are not specifically included in the checklist.

18.2.8 One or more individuals comprise an audit team. The QA Manager shall select a leader for each audit team. The team leader shall assure that the audit team is prepared prior to initiation of the audit.

18.2.9 Involved organizations shall be notified by the QA Manager of a scheduled audit reasonably in advance of the audit date. This notification should be in writing and should include general information on the scope of the audit, schedule of meetings and method of audit. Unannounced audits may be performed.

18.2.10 A brief pre-audit conference should be scheduled with the cognizant organization management.

18.2.11 When any deficiency is found by an audit, further investigation shall be conducted in an effort to indentify the basic cause of the deficiency. Elements found to be deficient should be acknowledged by a member of the audited organization.

18.2.12 Deficiencies determined by the audit team leader to represent conditions adverse to quality must be documented on a CAM in accordance with the requirements of Section 16.

18.2.13 At the conclusion of the audit an exit interview should be held with management of the audited organization. An effort should be made to clarify misunderstandings and reach agreement on findings that constitute QA program deficiencies. An effort should also be made to establish a tentative course schedule for corrective action for each deficiency.

18.2.14 The audit team leader shall prepare an audit report listing the audit findings, items of understanding, and dates when corrective action is to be accomplished and when response to the audit report is required. The audit report shall be transmitted to the audited organization with a cover letter or memo signed by the QA Manager.

18.2.15 The Manager, Administrative Services shall receive a copy of all audit reports.

18.2.16 The QA Manager shall maintain an audit log to record entries of audits that were conducted. The audit log number shall be assigned to audit checklists used during the audit.

QA2C

Figure 18-1
FORM-11
STANDARD AUDIT CHECKLIST FORM