HITTMAN

HITTMAN NUCLEAR & DEVELOPMENT CORPORATION

17812

QUALITY ASSURANCE MANUAL

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Hittman Nuclear & Development Corp.

9190 Red Branch Road
Columbia, Maryland 21045

HITTMAN NUCLEAR & DEVELOPMENT CORPORATION	Document Number: HNDC-C-200	Rev: 0	Rev Date: 10/20/80
	Title: Quality Assurance Program for the Use of Radwaste Shipping Packages		

Rev.	Rev Date	Manager, Admin. Services	Vice-Pres. Engineering	Director Trans & Dis Services	Director Marketing & Projects	Quality Assurance Manager	Vice-Pres. & General Manager
0	10/20/80	J. Rawlick	[signature] 10/20/80	[signature]	[signature]	[signature]	B. Kahl

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 10 CFR Part 71.51. This requirement notwithstanding, users may delegate to others, such as Hittman Nuclear & Development Corporation (HNDC), the work of establishing and executing the QA program, or any part thereof, but shall retain responsibility therefore.

HNDC recognizes the practical necessity for users of HNDC owned and certified packages to delegate most, if not all, of the work of establishing and executing the required QA program. HNDC has, therefore, developed this "QA Program for the Use of Radwaste Shipping Packages" in recognition of HNDC's delegated responsibilities for assuring that HNDC 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 HNDC 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 Vice President & General Manager.

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

All HNDC personnel with responsibility for activities related to HNDC package use 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.

Fred Heitner
President

10/1/80
Date

Vice President & General Manager

Date

TABLE OF CONTENTS

SECTION 1

ORGANIZATION

1.1 Scope and Applicability

1.1.1 This section includes a description of the organizational responsibilities normally assumed by HNDC 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 HNDC 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. HNDC 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 71.51

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 HNDC. 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 HNDC has ultimate responsibility for the company's activities related to the use of HNDC packages.

1.2.2.2 The President's day to day responsibilities for company activities, including responsibility for establishing the policies and practices set forth in this QA Program description, have been delegated to the Vice President & General Manager.

1.2.3 Vice President & General Manager

1.2.3.1 The Vice President & General Manager has been designated by the President of HNDC as the responsible corporate officer for all QA matters related to the use of HNDC packages.

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

1.2.3.3 The Vice President & General Manager 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.

1.2.3.4 The Vice President & General Manager 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.

1.2.4 Manager, Administrative Services

1.2.4.1 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.

1.2.4.2 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.

1.2.4.3 The Manager, Administrative Services, has been given the authority by the Vice President & General Manager 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.

1.2.4.4 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 Vice President & General Manager.

1.2.5 QA Manager

1.2.5.1 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.

1.2.5.2 The QA Manager has been given the authority by the Vice President & General Manager 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.

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

1.2.5.4 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 HNDC.

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

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

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

(f) Maintain current status of quality-related activities as they pertain to the use of HNDC packages.

(g) Maintain communication with the QA organizations of the users of HNDC packages.

(h) Inform HNDC management of QA Department activities through distribution of audit reports and other quality-related information.

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

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

1.2.6 Material Control Manager

1.2.6.1 The Material Control Manager reports to the Manager, Administrative Services.

1.2.6.2 The Material Control Manager is responsible for material purchasing, expediting, internal material control and development and implementation of material control procedures and instructions.

1.2.6.3 The Material Control Manager provides supervision to the Expeditor who oversees the HNDC material storeroom, including receipt and disposition of purchased material and items.

1.2.7 Vice President, Engineering

1.2.7.1 The Vice President, Engineering, reports directly to the Vice President & General Manager and is responsible for managing the engineering group within HNDC and for the oversight of internal research and development.

1.2.7.2 The Vice President, Engineering, is responsible for approving proposed modifications to HNDC packages and supervising engineering group activities related to preparation of package license amendments.

1.2.8 Manager, Systems & Equipment Design

1.2.8.1 The Manager, Systems & Equipment Design reports to the Vice President, Engineering.

1.2.8.2 Responsibilities of the Manager, Systems & Equipment Design 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.

1.2.9 Director, Transportation & Disposal Services

1.2.9.1 The Director, Transportation & Disposal Services, reports to the Vice President & General Manager.

1.2.9.2 The Director, Transportation & Disposal Services, has overall responsibility for the coordination and scheduling of HNDC 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 Eastern and Midwest Regional Operations Managers.

1.2.9.3 The Director, Transportation & Disposal Services, also is responsible for the preventive maintenance and repair of packages. Day to day responsibility for package maintenance is delegated to the Maintenance Supervisor.

1.2.10 Regional Operations Managers, Eastern & Midwest

1.2.10.1 The Regional Operations Managers, Eastern & Midwest, report to the Director, Transportation & Disposal Services.

1.2.10.2 Specific duties of the Regional Operations Managers, include the following:

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

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

(c) liaison with package users;

1.2.10.3 The Regional Operations Manager, Eastern, is also responsible for preparation and periodic review of package operation and use procedures and instructions.

1.2.11 Maintenance Supervisor

1.2.11.1 The Maintenance Supervisor reports to the Director, Transportation & Disposal Services.

1.2.11.2 Responsibilities of the Maintenance Supervisor include the following:

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

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

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

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

(e) order spare and replacement parts and materials for HNDC packages;

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

1.3 HNDC-User Interface Control

1.3.1 HNDC 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 HNDC 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 HNDC'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;

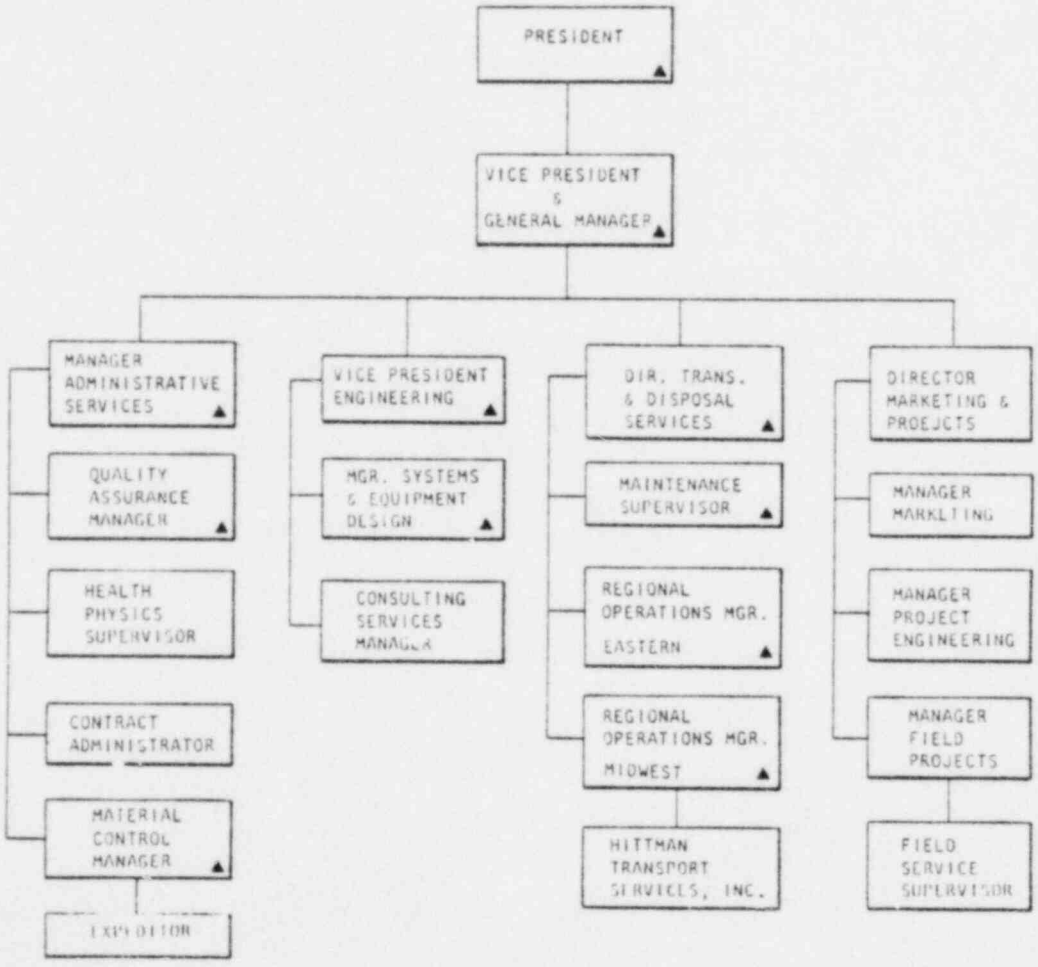
(b) Minimum of two (2) years experience in QA, including testing or inspection (or both) of equivalent materials and structures;

(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 HNDC packages.

Figure 1-1

HNDC Organization



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

SECTION 2

QUALITY ASSURANCE PROGRAM

2.1 Program Objective

2.1.1 The quality objective of this QA Program is to insure that HNDC 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, Appendix E, applicable to the use, including loading and unloading, inspection, maintenance, repair, and modification of HNDC packages. QA requirements set forth in 10 CFR 71, Appendix E for package design, fabrication, assembly and testing are addressed separately in HNDC-C-100, "Quality Assurance Program for the Engineering, Design, Procurement, Fabrication, and Initial Testing of Radwaste Systems and Equipment."

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 HNDC personnel to verify periodically that 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, Appendix E, 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 HNDC'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 HNDC that the application of QA principles and practices whenever practicable to the control of such activities is good policy. To the extent that HNDC 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, Appendix E, to ensure that HNDC 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 HNDC and contractor personnel performing activities within the scope of this QA Program shall adhere to the requirements of the program.

2.2.8 User personnel performing activities within the scope of this QA Program (e.g., package inspection, parts replacement, package handling), will be subject to the requirements set forth herein if the user had adopted this QA Program as the means of meeting its responsibilities under 10 CFR Part 71.51. Responsibility for verifying satisfactory performance of such activities shall rest with the user.

2.3 Policy

2.3.1 This QA Program has been developed by HNDC and establishes the policies and practices for QA related to the use of HNDC 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 HNDC QA Manager. Additions, deletions, or modifications to this document shall require the approvals of the QA Manager, the Manager, Administrative Services, and the Vice President & General Manager 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 Vice President & General Manager.

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

2.3.5 All HNDC 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 HNDC 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 HNDC's organization is described in Section 1.0.

2.5.2 HNDC 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 Manager, Systems & Equipment Design, the Regional Operations Manager, Eastern, and the Maintenance Supervisor. These controls shall include provisions for quality verification appropriate to the activities being performed. The QA Department is primarily responsible for quality assurance reviews, surveillances, and audits, including audits of HNDC contractors and suppliers.

2.5.3 Users of HNDC packages are responsible for establishing, maintaining, and executing a QA program satisfying the requirements of 10 CFR 71, Appendix E, and satisfying the specific provisions established in the NRC's approval for each package used. Users may satisfy this responsibility by either adopting this QA Program or establishing an alternative QA program. In either case, each user is responsible for ensuring that activities performed by user personnel are in compliance with the governing QA program.

2.6 Program Documentation

2.6.1 QA Program policies and practices are contained in various HNDC procedures that comprise the HNDC Procedures Manual. A list of procedures that de-

scribe 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, Appendix E.

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 HNDC packages.

2.7 Personnel

2.7.1 It shall be the responsibility of the QA Manager to insure that HNDC 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 training meetings for HNDC personnel performing activities related to the use of HNDC packages. The frequency of these meetings shall be at the discretion of the QA Manager but shall not be less frequent than 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.

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

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

2.7.4 HNDC departmental managers shall determine what training each individual shall be required to receive in accordance with the individual's job responsibilities and previous training and experience. Training may include a combination of reading assignments, such as portions of the package safety analysis or text material, and special sessions with qualified individuals from, for example, other

functional units within HNDC. Each departmental manager shall document for each individual the training received.

2.7.5 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.

2.7.6 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-1-1979, "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-1-1979.

2.7.7 The QA Manager or his designee shall monitor the performance of quality related activities within the scope of this QA Program to verify that HNDC personnel are adequately qualified. The QA Manager should maintain a written record of these monitoring 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 every 12 months and report the results of that review to the Vice President & General Manager.

2.8.2 The Vice President & General Manager 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 HNDC'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, Appendix E.

TABLE 2-1

DEFINITION 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 N45.2.13-1976, "Quality Assurance Requirements for the Control of Procurement of Items and Services for Nuclear Power Plants"
package	See 10 CFR 71.4
package approval	A license or certificate of compliance issued by the NRC for packaging of type B, large quantity, and fissile radioactive material under 10 CFR Part 71
user	Each person authorized by a specific license issued by the NRC to recieve, possess, use, or transfer licensed materials to a carrier for transport or transports such material ouside 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
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 HNDC Procedures

HNDC PROCEDURES MANUAL	HNDC-C-001 Preparation & Control of HNDC Administrative Procedures	HNDC-C-002 Control of HNDC Manuals	HNDC-C-003 HNDC Forms Index	HNDC-C-004 Preparation & Control of Specifications	HNDC-C-005 Preparation & Control of Purchase Requisitions/Orders	HNDC-C-006 QA Records Management	HNDC-C-100 QA Program (Design)	HNDC-C-200 QA Program (Use)	HNDC-E-001 Engineering Change Requests (ECR's)/ Notices (ECNs)	HNDC-M-001 Cask Maintenance & Repair	HNDC-M-002 Cask Handling & Operation
I. Organization								•			
II. Quality Assurance Program								•			
III. Design Control							•	•	•		
IV. Procurement Document Control				•	•			•			
V. Instructions, Procedures & Drawings								•		•	•
VI. Document Control	•	○	•	•	•	•		•	•		
VII. Control of Purchased Material, Equipment & Services				•				•			
VIII. Identification & Control of Materials, Parts and Components								•			
IX. Control of Special Processes	•							•			
X. Inspection								•			
XI. Test Control	•						•	•			
XII. Control of Measuring & Test Equipment								•			
XIII. Handling, Storage & Shipping				•				•			•
XIV. Inspection, Test & Operating Status								•			
XV. Nonconforming Materials, Parts & components				•				•			
XVI. Corrective Action								•			
XVII. Quality Assurance Records						•		•			
XVIII. Audits								•			

PROCEDURE NUMBER & TITLE	10CFR71 APPENDIX E
Matrix of HNDC Procedures that Implement All or Portions of 10CFR71, Appendix E Requirements for Quality Assurance During Use of Radwaste Shipping Packages.	APPENDIX E CRITERION

SECTION 3

DESIGN CONTROL

3.1 Scope

3.1.1 The requirements of this section shall apply to changes made to HNDC packages that have been designed in accordance with the provisions of HNDC's Quality Assurance Program for the Engineering, Design, Procurement, Fabrication, and Initial Testing of Radwaste Shipping Packages or satisfy the provisions of 10 CFR 71.51(b) or (c).

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, Appendix E.

3.1.4 The requirements of this section do not apply to routine maintenance activities including replacement in kind of 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 HNDC, as owner of the approved package, shall review and approve all proposed modifications to HNDC packages.

3.2.2 Anyone, including user personnel, may propose a modification to HNDC packages. Such proposed modifications must, however, be processed in accordance with the requirements of this section.

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

3.3 Procedure

3.3.1 An Engineering Change Request (ECR) 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 Anyone, including HNDC or user personnel, may initiate an ECR. User personnel should contact the QA Manager who will assume responsibility for initiating an ECR as appropriate.

3.3.4 The engineer performing the evaluation shall study the package license application and 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.

3.3.5 The engineer 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 ECR. Proposed package modifications shall be assumed to require a license amendment unless it can be clearly justified that such an amendment is not required.

3.3.6 The QA Manager and the Manager, Systems & Equipment Design shall review the engineer's conclusion prior to implementation of this change. This review shall be documented on the ECR.

3.3.7 The Vice President, Engineering, shall approve proposed changes primarily for cost and impact on company operations.

3.3.8 Engineering and design activities required in order to implement approved ECRs shall be controlled in accordance with HNDC-C-100, "Quality Assurance Program for the Engineering, Design, Procurement, Fabrication, and Initial Testing of Radwaste Systems and Equipment," so as to ensure that controls

over design activities for package modifications are commensurate with those applied to the original design.

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

3.3.10 Engineering documents that include technical information related to the 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 HNDC 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 HNDC 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, Appendix E, 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 HNDC for information, review or approval;

(e) a statement of HNDC'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, including HNDC or user personnel, 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 HNDC 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. HNDC should, however, be informed of such activities.

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. HNDC 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. These procedures, along with many of the documents controlled by them, are incorporated into several HNDC manuals, as illustrated in Figure 6-1.

6.2.2 The QA Manager shall be responsible for the issuance and control of the manuals illustrated in Figure 6-1.

6.3 HNDC Quality Assurance Manual

6.3.1 The HNDC Quality Assurance Manual illustrated in Figure 6-1, includes controlled copies of the following procedures:

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

(b) HNDC-C-200, "Quality Assurance Program for the Use of Radwaste Shipping Packages." (Note: HNDC-C-200 may be omitted when not applicable to the services being offered or provided to an HNDC client).

(c) other HNDC procedures from the HNDC Procedures Manual determined appropriate for inclusion in the Rad Services Manual - Quality Assurance by the QA Manager for purposes of information for the users of HNDC packages.

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

6.4 HNDC Procedures Manual

6.4.1 The HNDC Procedures Manual contains a variety of technical and administrative procedures governing the operation of HNDC. 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 illustrated in Figure 6-1 include specific information and data for the various HNDC packages.

6.5.2 Each manual 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 the NRC transmittal letter and 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.

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

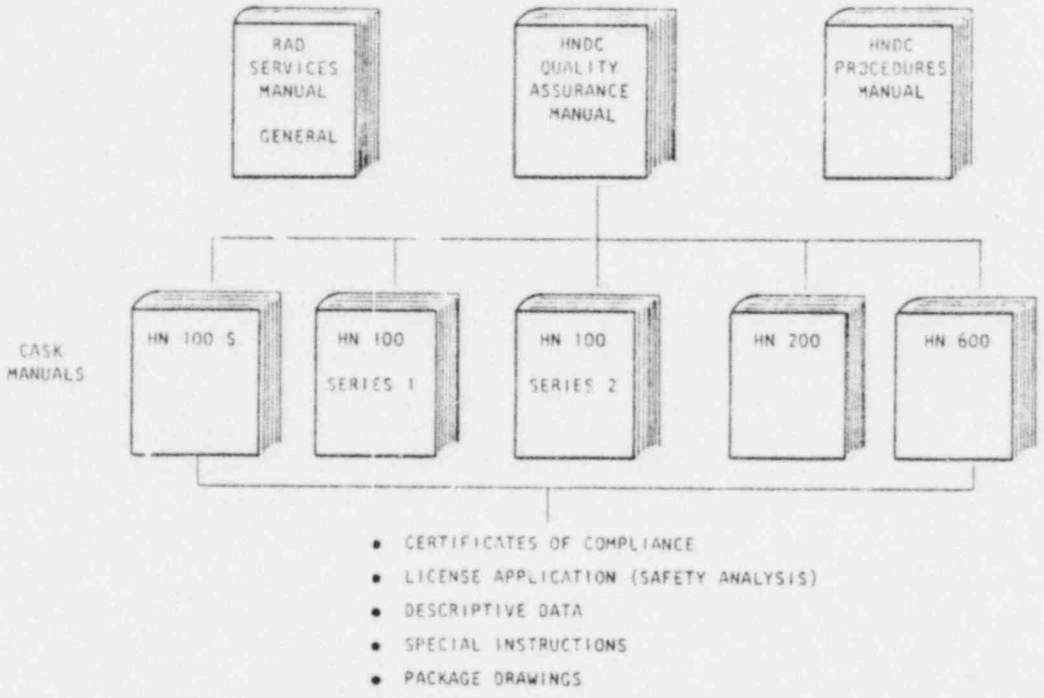
6.5.3 Cask Manuals may also include other information of a general nature regarding package design and use. This information shall be separated from the information described in section 6.5.2 and shall be prefaced with a written statement indicating that such data is for information purposes only and 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 Th Rad Services Manual - General contains information of a general commercial nature not subject to or controlled by this QA Program.

Figure 6-1

HNDC Manuals



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 HNDC packages conform to the procurement documents prepared in accordance with the requirements of Section 4.1.

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 HNDC 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-1-1979, "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-1-1979 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 reevaluate each supplier or remove any supplier from the list. Items may be purchased from suppliers on this list without reevaluation of their certification system.

7.2.12 Receiving inspections shall be the responsibility of the QA Department.

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 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 HNDC, specifically the QA Manager, 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 HNDC. 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 HNDC 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 HNDC packages.

8.2.2 The identification of replacement items for HNDC 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 and 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 or 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 Department shall maintain a segregated and controlled access storage area for replacement items for HNDC packages.

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

8.3.3 Only replacement items issued by QA from the controlled storage area should be used on packages.

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 controlled storage area as well as certain other items stored outside the controlled storage area 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 The tag used to identify replacement items is shown in Figure 8-1. This tag comes in three colors; namely,

Yellow - Pending

Red - Hold/Reject

Green - Acceptance

8.3.7 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.

8.3.8 Replacement items received at the HNDC storeroom and awaiting receipt inspection and acceptance are identified by a yellow tag. This tag must not be removed unless it is replaced with either a green or red tag as appropriate.

8.3.9 Yellow tagged items may be placed in the QA controlled storage area but shall be separated as much as possible from green tagged items.

8.3.10 Receipt inspections shall be performed in accordance with the requirements of section 7. Replacement items found acceptable may be green tagged.

8.3.11 Nonconforming items shall be red tagged and processed in accordance with the requirements of Section 16. Red tagged items may remain in the QA controlled storage area but shall be physically separated from green and yellow tagged items.

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

8.3.13 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.

8.3.14 Green tagged items leaving the QA controlled storage area shall be logged on the Cask Materials Log sheet (form HNDC-08) shown as Figure 8-2. This log shall be controlled by the QA Manager and maintained in the QA controlled storage area.

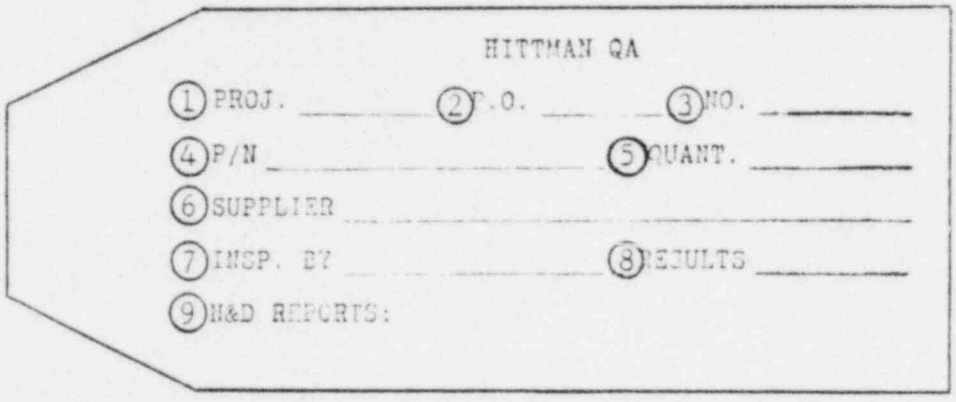
8.3.15 Only green tagged replacement items may be used with HNDC packages. It shall be the responsibility of the Maintenance Supervisor to ensure that the tag number is entered on maintenance work requests orders related to package maintenance and repair.

8.3.16 Unused items returned to the QA controlled storage area shall be yellow tagged and visually reinspected prior to use. A new green tag will be prepared for those items found acceptable for use.

8.3.17 Individuals issued replacement items from the QA controlled storage 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 and yellow tagged.

Figure 8-1

Inspection Status Tag



Each inspection tag will be completed as follows:

(1) Project - Enter cask model number.

(2) P.O. - Enter HNDC purchase order number. Additionally, on items procured for use as part of a certified transportation cask, the purchase order revision must be included (e.g., N34228 (2))

(3) No. - Enter tag number as determined by the log maintained by the QA Manager.

(4) P/N - Enter the purchase order item number.

(5) Quantity - Self Explanatory.

(6) Supplier - As noted on purchase order.

(7) Inspected By - Enter initials of authorized QA representative.

(8) Results - Enter as follows: Green Tag - "ACCEPT," Yellow Tag - "HOLD," Red Tag - "HOLD" or "REJECT."

(9) N&D Reports - List all applicable dispositioned CAM forms applicable to the item.

Figure 8-2

Cask Materials Log

CASK MATERIALS LOG

Materia escription	Tag Number	Quantity Issued/ Returned	Issued to/ Returned by	Checked out by/ Checked in by	Date

HNDC-10(A)

SECTION 9

CONTROL OF SPECIAL PROCESSES

9.1 Requirements

9.1.1 Maintenance and repair of HNDC 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.

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

9.1.3 The Maintenance Supervisor shall be responsible for developing written procedures, when required, for controlling welding operations and nondestructive examination 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.

9.1.4 Welding and NDE procedures 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.

9.1.5 The Maintenance Supervisor 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.

9.1.6 The QA Department shall be responsible for verifying implementation of special process procedures to provide assurance the operators are qualified and that the approved procedures are being followed. 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 HNDC 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 HNDC-C-100, "Quality Assurance Program for the Engineering, Design, Procurement, Fabrication and Initial Testing of Radwaste Systems and Equipment."

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. In general, such tests are not required.

11.2 Requirements

11.2.1 The QA Manager 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 replace-

ments.

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 uder 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.

11.2.6 The QA Manager shall review test procedures prior to use and incorporate hold or writers 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 (HNDC 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 HNDC activities and identifying the measuring and test equipment used by HNDC that must be controlled in accordance with the requirements of this section.

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

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 suitable 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 HNDC packages.

13.1.2 The requirements of this section also apply to the handling, including loading and unloading, of HNDC 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 HNDC 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 HNDC packages are included in Cask Manuals as 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 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 HNDC and received, stored and issued through the HNDC storeroom and QA controlled storage area is maintained by the use of tags as described in Section 8 of this procedure.

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

14.1.3 The tagging system used by HNDC 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 HNDC 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 HNDC purchased replacement parts and materials and/or contractors providing quality related services to HNDC for HNDC packages.

15.1.2 Nonconformances identified by HNDC personnel during receiving inspection of replacement parts and materials for HNDC packages shall be controlled as conditions adverse to quality in accordance with the requirements of Section 16.

15.1.3 Nonconformance of an HNDC package with the requirements of the NRC package approval identified by HNDC personnel shall be controlled as a condition adverse to quality in accordance with the requirements of Section 16. These requirements should also be adhered to by user personnel identifying such package nonconformances.

15.1.4 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

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 responsibilty 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 HNDC using a Supplier Disposition Request (SDR) form (form HNDC-07).

15.2.5 The Supplier Disposition Request (SDR) form shall be processed as follows:

(a) SDR's shall be forwarded initially to the QA Manager for evaluation.

(b) The QA Manager shall assign a control number to the SDR and enter the number and date in an SDR log for followup control purposes.

(c) The QA Manager shall determine if a technical review by the Engineering Department should be required.

(d) When Engineering review is required both Engineering and QA shall approve the SDR disposition action.

(e) Upon completion of the SDR the QA Manager shall enter the close out date in the SDR log and forward the SDR to the Material Control Manager.

(f) The Material Control Manager shall transmit the dispositioned SDR to the supplier or contractor and be responsible for legal/financial negotiations as required.

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

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

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

15.2.9 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.

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

15.2.11 Nonconforming materials, parts and components shall not be used in packages if their use would constitute a nonconformance with the package approval.

SECTION 16

CORRECTIVE ACTION

16.1 Requirements and Responsibilities

16.1.1 This QA Program has been established to provide adequate confidence that HNDC 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 tne 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;

(d) 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 followup 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 Vice President & General Manager.

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 HNDC-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 or 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 responsible for designating one or more individuals within HNDC as an Action Designee. The QA Manager shall sign and date the CAM and forward it to the Action Designee(s) with appropriate instructions.

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 followup action is being taken in a timely manner.

16.2.16 The QA Manager shall be responsible for determining the distribution of completed CAM's. The Vice President & General Manager shall receive a copy of all CAM's that document significant conditions adverse to quality.

Figure 16-1

Form HNDC-Q9
Corrective Action Memo Form

HITTMAN NUCLEAR & DEVELOPMENT CORP.

CORRECTIVE ACTION MEMO

CAM No.

Assigned by HNDC QA Mgr.

Affected Equipment	Reference Documents

Item No.	Date Found	Description of Adverse Condition(s)/Action Recommendations	Action Designee

Initiated By (Name/Company)	Date	QA Manager Review (Sign)	Date

Item No.	Action Description	Date Completed

Action Designee (sign)	Date	QA Manager Review (sign)	Date

HNDC-09(A)

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 replacement parts and materials used in HNDC 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 HNDC packages are controlled in accordance with HNDC-C-100, "Quality Assurance Program for the Engineering, Design, Procurement, Fabrication and Initial Testing of Radwaste Systems and Equipment.

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 HNDC 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., ECRs, 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 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 HNDC 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 pertinant 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 evalute 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 areas, activities, processes, and items and a review of documents and records.

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

18.1.4 Audits shall be performed in accordance with pre-established 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 within a 12-month period or more frequently if appropriate. Documented customer audits may be counted in the implementation of this requirment.

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 or 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 HNDC-10) 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 orgnization management.

18.2.11 When any deficiency is found by an audit further investigation shall be conducted in an effort to identify 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 determind by the audit team leader to represent conditions adverse to quality must be documented on a CAM in accordance with the requirments 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 tenatative 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.

Figure 18-1

Form HNDC-10

Standard Audit Checklist Form

HNDC-11(A)

AUDIT CHECKLIST

Page of

Organization Audited:	Purpose & Scope:	Audit Log No.:
		Audit Date(s):

Reference Codunents:	Personnel Contacted:	Auditors:

Summary Conclusions:

Item	Audit Characteristic	Method of Verification	Results	C&I

PREPARED BY: _____ QA MANAGER APPROVAL: _____

Figure 18-1

17812