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DOE/WIPP 89 - 012

Quality Assurance (QA) Plan For The Transportation And Receipt Of Transuranic (TRU) Waste

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Waste Isolation Pilot Plant

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**QUALITY ASSURANCE PLAN FOR TRANSPORTATION AND RECEIPT
OF TRANSURANIC (TRU) WASTE**

DOE/WIPP 89-012

DOE/WIPP--89-012

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1.0 INTRODUCTION

1.1 GENERAL DISCUSSION

1.1.1 TRU Waste Program Responsibilities

The Department of Energy (DOE) Albuquerque Operations (AL) Office of Projects and Energy Programs has been assigned the responsibility for administration of the disposal of Contact-Handled (CH) Transuranic (TRU) contaminated material (waste) from generator/storage sites of the United States defense programs that are operated by the DOE. This responsibility encompasses all activities associated with the certification of TRU waste and the transportation, receipt and disposal of that waste at the Waste Isolation Pilot Plant (WIPP).

The WIPP is located near Carlsbad, New Mexico and is being developed under the management of the DOE WIPP Project Office (WPO). The DOE/WPO is a branch of the DOE/AL and has been delegated overall responsibility for all aspects of the WIPP program.

1.1.2 TRU Waste Transportation

All TRU waste that is transported to the WIPP will be enclosed in a Type B packaging design that has been approved by the Nuclear Regulatory Commission (NRC). In compliance with an agreement between the DOE and NRC, the NRC will not license packaging that is procured and used by the DOE, as described in 10 CFR 71. Instead, the NRC has issued a Certificate of Compliance (C of C) attesting to approval of the package design. In this way the DOE is registered as an owner of the TRUPACT-II under the general license provisions of 49 CFR 173.471. However, all the requirements of a licensee (as described in 10 CFR 71) for the procurement, use, maintenance, repair and any subsequent modifications shall apply.

For the TRU waste program the NRC has issued a C of C to the DOE/AL for the design of the Transuranic Package Transporter (TRUPACT-II). The DOE/WPO, as

delegated by the DOE/AL, is procuring a fleet of TRUPACT-IIIs under the requirements of the C of C and 10 CFR 71. In this regard, the DOE/WPO has the overall responsibility to assure that TRUPACT-IIIs are constructed and maintained in compliance with 10 CFR 71, with the guidance of Regulatory Guide 7.10, the TRUPACT-II Safety Analysis Report (SARP)/C of C, DOE Orders 1540.1/1540.2, and the requirements of Department of Transportation (DOT) regulations.

Using the terminology of 10 CFR 71 the generator/storage sites, hereafter called users, will be the shippers of TRU waste and, in conjunction with DOE/WPO, the users of the TRUPACT-IIIs. This responsibility involves waste certification for load management, loading and preparation of the TRUPACT-IIIs for shipment, minor maintenance, and delivery of the TRUPACT-II package to a carrier for transport.

As the holder of the TRUPACT-II C of C, it is the responsibility of the DOE/WPO to assure that the activities of all users of the TRUPACT-II, without exception, comply with the requirements of 10 CFR 71, the TRUPACT-II SARP and C of C, and applicable DOE Orders which reference NRC and DOT regulations for dispositions of non-compliance (see Section 2.15.2).

Duties and activities of the users may be delegated to DOE site contractors but will remain the overall responsibility of the specific DOE field office.

The contract for physical transportation of TRU waste to the WIPP is the responsibility of the DOE/WPO. The carrier under contract to the DOE/WPO must (1) comply with DOT regulations; and (2) meet the Quality Assurance (QA) requirements of DOE Order/AL 5700.6B, as directed by DOE/WPO. Exceptions to DOT requirements (such as overwidth and overload, which require special permits) will not be permitted.

1.2 SCOPE

1.2.1 This QA plan has been prepared by the DOE/WPO to identify the QA requirements imposed for the activities associated with preparations and

delivery of a TRUPACT-II package to a carrier, transportation/receipt of that package, maintenance, and repair or modification to TRUPACT-II(s) and trailer(s). This plan identifies the responsibilities of the QA program at WIPP, the site-specific QA program requirements at user's sites, responsibilities for carriers and subcontractors supporting the program, the interface functions with DOE/WPO, and the DOE/WPO role in assuring compliance with imposed regulations.

The DOE/WPO QA Program complies with DOE Order 5700.6B and AL 5700.6B, and has been structured to comply with 10 CFR 71. The hierarchy of QA documents for DOE/WPO TRU waste certification and transportation is provided in Appendix A. Rather than make the assumption that the users and carriers of TRUPACT-II, while complying with DOE 5700.6B, also comply with 10 CFR 71, this QA Plan will impose the requirements that are applicable to the organization and implementation of a user's 10 CFR 71 QA program. In doing so this plan takes into consideration the structure of the program and the responsibilities of each organization.

1.2.2 The objective of this plan is to define and establish QA requirements that must be implemented for the scope of work in order to comply with DOE 1540.2. DOE 1540.2 requires that DOE users of NRC certified packaging have in place a QA Program equivalent to 10 CFR 71, Part H. This plan also satisfies the requirements of ANSI/ASME NQA-1, as it applies to the user's sites and DOE/WPO.

This QA plan also defines how DOE/WPO QA complies with those requirements, and also identifies the requirements for compliance which are the responsibility of the users and carriers.

1.2.3 The QA requirements of the DOE contractors, users, carriers, and any subcontractors must be defined in their QA programs and implementing procedures. The contractor's QA program shall be approved by their respective DOE Operations or area office(s). QA plans defining responsibilities and activities associated with the use of TRUPACT-II's must subsequently be approved by DOE/WPO. QA programs directing such plans and procedures must be in place in compliance with DOE 5700.6B.

1.2.4 This QA plan does not specifically address the contents of the TRUPACT-II. The SARP requires a user of the TRUPACT-II to prepare site-specific (payload compliance) technical plans and QA plan which shall be submitted to the WIPP Waste Acceptance Criteria Certification Committee (WACCC) for review, comment, and approval. The user shall then prepare on-site procedures for technical implementation and QA verifications. The user's resulting "payload compliance program" shall be audited and approved by the DOE/WPO prior to transporting waste in TRUPACT-II. The requirements for technical plan preparation are found in the Appendix 1.3.7 of the TRUPACT-II SARP--"TRUPACT-II Authorized Methods of Payload Control" (TRAMPAC). DOE guidance for QA plan preparation is found in DOE/WPO 89-007.

1.3 FORMAT

1.3.1 The following generic packaging and transportation responsibilities and QA requirements are taken from 10 CFR 71, Subpart G and Subpart H, and define operating controls and QA requirements for NRC approved packaging. This QA plan encompasses not only packaging, but trailers, carriers, waste certification, traceability, and subcontractors. All these activities will involve the WACCC and WIPP site personnel who work to ANSI/ASME NQA-1 and DOE 5700.6B.

1.3.2 The matrix provided in Appendix B establishes the applicable requirements of each of the 18 criteria established by DOE/WPO at the WIPP. In addition, the matrix also defines the recommended application of the 18 criteria for the users and carriers, based on their scope of work.

1.4 ACRONYMS

ANSI: American National Standard Institute

ASME: American Society of Mechanical Engineers

ASNT: American Society for Nondestructive Testing

C of C: Certificate of Compliance

CFR: Code of Federal Regulations

CH: Contact-Handled

DOE: Department of Energy

DOE/AL: DOE - Albuquerque Operations Office

DOE/HQ: DOE - Headquarters

DOE/WPO: DOE - WIPP Project Office

DOT: Department of Transportation

EPA: Environmental Protection Agency

ICC: Interstate Commerce Commission

MOC: Management and Operating Contractor

NCR: Nonconformance Report (see Section 1.5, "Definitions")

NDE: Nondestructive Examination (or Testing)

NIST: National Institute of Standards and Technology
(Formerly NBS: National Bureau of Standards)

NRC: Nuclear Regulatory Commission

O&MM: Operations and Maintenance Manual

QA: Quality Assurance

SARP: Safety Analysis Report for Packaging

SNT: Standard for Nondestructive Testing

TRT: Technical Review Team

TRU: Transuranic

TRAMPAC: The TRUPACT-II Authorized Methods for Payload Control

WAC: Waste Acceptance Criteria

WACCC: Waste Acceptance Criteria Certification Committee

WID: Westinghouse Electric Corporation, Waste Isolation Division

WIPP: Waste Isolation Pilot Plant

WWIS: WIPP Waste Information System

1.5 DEFINITIONS

NRC Certified Packaging for DOE - Any packaging design that has been approved and issued a C of C to the DOE by the NRC and which is procured, fabricated, delivered to and used by the DOE in accordance with the requirements of 10 CFR 71, associated SARP, and C of C.

Nonconformance Report - A generic name pertaining to a narrative description of a deficiency or problem and requesting disposition. This documentation can describe material, process, operational or procedural related deficiencies or problems that affect items.

Package - Loaded container or cask.

Packaging - Unloaded container or cask.

QA Program - An overall directive for all DOE activities which affects quality defining responsibilities, areas affected, requirements and activities that will take place to assure quality. It must comply with DOE Order 5700.6B and be approved accordingly.

QA Plan - The definition of the responsibilities and activities that will take place in a specific program, with detailed functions listed and explanations of how those functions will comply with the established QA Program and procedures. All functions of the QA plan must comply with the requirements imposed on the program being described.

Item - Hardware, parts, material, equipment, components, etc.

TRUPACT Technical Review Team (TRT) - An ad-hoc committee which convenes to provide technical review whenever there is a need for resolution required regarding the continued use of a TRUPACT-II container.

1.6 APPLICABLE DOCUMENTS

ANSI/ASME NQA-1: Quality Assurance Program Requirements for Nuclear Facilities

DOE Order AL 1540.1: Materials Transportation and Traffic Management

DOE Order AL 5700.6B: General Operations Quality Assurance

DOE Order 1540.1: Materials Transportation and Traffic Management

DOE Order 1540.2: Hazardous Material Packaging for Transport Administrative Procedures

DOE Order 5400.3: Hazardous and Radioactive Mixed Waste Program

DOE Order 5480.3: Safety Requirements for the Packaging and Transportation of Hazardous Materials, Hazardous Substances, and Hazardous Wastes

DOE Order 5700.6B: General Operations Quality Assurance

DOE Order 5820.2A: Radioactive Waste Management

DOE/WIPP 87-007: Operations Quality Assurance Program for the WIPP Project, Carlsbad, NM

DOE/WIPP 88-026: TRUPACT-II Maintenance Program Plan

ASNT SNT-TC-1A: Personnel Qualification and Certification in Nondestructive Testing

DOE/WIPP 89-007: QA Guidance for TRUPACT Payload Control

10 CFR 71, Subpart H: Quality Assurance Requirements and Subpart G, Operating Controls and Procedures

49 CFR: Code Of Federal Regulations, Title 49: Transportation

OM-134: TRUPACT-II Container Operations and Maintenance Manual

Regulatory Guide 7.10, Annex 2: Quality Assurance programs applicable to procurement, use, maintenance, and repair of packaging used in the transport of radioactive material

71-9218: Safety Analysis Report for TRUPACT-II

Certificate of Compliance, TRUPACT-II

2.0 QA PLAN DESCRIPTION

NOTE: All applicable acronyms and definitions are listed in Sections 1.4 and 1.5.

2.1 ORGANIZATIONS AND RESPONSIBILITIES

A formal organization structure shall be established and documented by organization charts identifying each organizational element that functions under a QA program. Measures shall be established to provide adequate control over activities important to safety. Designated individuals, when performing QA and Quality Control (QC) functions, shall have the responsibility and authority to stop unsatisfactory work, and/or delivery or installation of nonconforming material, and will have direct access to management levels to ensure compliance to QA procedures important to safety.

The duties and qualifications required for (1) the individual who has overall authority and responsibility for the QA program; and (2) the other principal personnel performing QA and QC functions shall be established and documented and shall have the written endorsement of top management.

2.1.1 DOE/WPO

The DOE/WPO reports to the DOE/AL and is responsible for approving the WIPP Management and Operating Contractor (MOC) QA Program. DOE/WPO is also responsible for establishing and chairing the WACCC.

Interfaces have been established through the WACCC between DOE/WPO and DOE/AL and other operations offices responsible for operation of generator and storage sites.

DOE/WPO, through the WACCC, is responsible for assuring payload, waste acceptance, and packaging compliance as specified in the SARP, the C of C, and this QA plan through approval of site QA plans and audits of implementation.

The DOE/WPO is also responsible for administration of the waste carrier contract(s).

2.1.2 MOC

The MOC has been delegated the responsibility to procure, maintain, inspect, repair and modify Type B packaging and their trailers for CH waste, as necessary. The MOC will provide NRC certified packaging to the various users (generators/storage sites) for delivery to carriers for transportation to the WIPP.

MOC will procure items (spares) and services to support the program as designated by the DOE/WPO.

MOC is responsible for the WIPP Waste Information System (WWIS) related to transportation and the receipt of waste at WIPP.

MOC Radiation Handling and Surface Operations is responsible for the receipt of packages, monitoring shipment tracking, carrier oversight, and compliance with DOT regulations for return (empty) shipments to the users.

All MOC departments are responsible for complying with the requirements of the MOC DOE approved QA Program Manual and this QA plan. The DOE/WPO/MOC organizational structure is provided for interface activities in Appendix C. The MOC provides support for any activities performed by the WACCC.

2.1.3 Users

The users shall comply with the requirements of the WAC, Packaging C of C, the SARP, DOT regulatory guides, their WACCC approved QA plan and other related documents such as Operation and Maintenance Manuals (O&MMs).

The detailed user's QA plans (see Section 1.5, "Definitions") and implementing procedures for preparation of shipment and delivery of packaging to a carrier (use of TRUPACT-II) and TRUPACT-II maintenance shall be prepared under the

cognizance of the individual sites' QA programs, in accordance with the requirements established by this QA plan. These QA plans and procedures shall adhere to the site specific DOE approved QA program.

The user's QA plan shall be submitted to DOE/WPO for approval prior to any use of TRUPACT-II(s).

The adherence to the user's QA plan and procedures and to the DOE approved site specific QA program will be verified through WACCC review.

2.1.4 Carriers

It is the responsibility of the carriers to be in compliance with applicable DOT, DOE, EPA and ICC requirements, rules, regulations and orders.

The carrier shall submit a QA plan covering the activities required by his DOE contract. This QA plan shall be in accordance with DOE/AL 5700.6B and this QA plan, as applicable.

The transportation activities associated with this QA plan will not require over-dimensional or overweight permits.

The carriers shall perform maintenance and periodic inspections on trailers and related transportation equipment in accordance with the equipment O&MM and as directed by their approved DOE QA plan. The need for repair beyond the O&MM is reported to and directed by DOE/WPO.

2.1.5 Technical Review Team (TRT)

The MOC TRT is a group of individuals who are established as competent authorities in the various technical, regulatory, administrative, operational and QA related aspects of the TRUPACT-II. The group is established and administered by the WID. All basic packaging (see Section 1.5, "Definitions"), including hardware and trailer NCR documentation reviews, shall be performed by the TRT.

2.1.6 Subcontractors

It is the responsibility of all organizations involved in the TRU Waste Transportation Program to assure that any portion of work that is subcontracted includes the applicable requirements imposed on them by the WACCC, DOT, NRC and DOE. Definition of this responsibility shall appear in that organization's QA plans.

QA program plans for the design and manufacture of licensed packagings shall be approved by the NRC in accordance with 10 CFR 71, Subpart H.

2.1.7 Nuclear Regulatory Commission

The NRC is responsible for review and approval of SARP's and providing C of C(s) for Type B packagings used to support this program. The NRC may also perform an oversight function during package fabrication and user/carrier activities.

2.2 QA PROGRAM

2.2.1 Measures shall be established to ensure that (1) activities important to safety are performed with specified equipment and under suitable environmental conditions; and (2) designated QA and QC responsibilities for implementation of activities important to safety are contained in QA plans.

2.2.2 Measures shall be established to ensure that items covered by the QA plans are compatible with and emphasize characteristics identified in the C of C, SARP, O&MM(s), DOE/WIPP 88-026, and TRUPACT-II and trailer design drawings. The rationale used to identify items classified as important to safety and subject to the user's QA plan shall be established.

2.2.3 All DOE operations associated with this program, and their supporting contractors, are required to operate under a QA program as imposed by DOE Order 5700.6B and any additional area office orders supplementing DOE Order 5700.6B. For DOE functions associated with NRC licensed packaging, each DOE Operations office QA organization is required by DOE Order 1540.2 to review

and approve their supporting contractor's QA program as being equivalent to the QA requirements of 10 CFR 71, Subpart H.

2.2.4 This QA plan requires that each user and carrier shall prepare and submit a QA plan to their appropriate DOE Operations Area office for review, after which final approval will be by the WACCC.

2.2.5 The QA program for design and manufacturing of Type B packaging shall meet the requirements of 10 CFR 71, Subpart H, and be so approved by the NRC.

2.2.6 The MOC QA Program for (1) the Procurement of Design and Manufacturing of Type B Packaging; (2) for the assurance that manufacturing meets design requirements; (3) assurance that the fabricator follows a NRC approved QA program; (4) for the operation, maintenance, repair, use and modification; and (5) for control of design subsequent to manufacture, meets the requirements of ANSI/ASME NQA-1 and DOE/AL 5700.6B. The MOC QA program has been approved by DOE/WPO as being equivalent to the requirements of 10 CFR 71 Subpart H, with controlling functions to meet Subpart G.

2.2.7 The QA program requirements applicable to the transportation of TRU waste are defined within this QA plan. Any of the 18 criteria that are not applicable to the user or carrier shall be addressed and justified in their QA plans.

2.2.8 Each user, carrier, and the MOC shall maintain an implementing procedure matrix or comparable document addressing the applicable 18 criteria.

2.2.9 All personnel assigned to activities within the TRU waste program shall be qualified and trained to perform the specific tasks required of them. The requirements for training shall be included in QA plans.

The MOC, users, and carriers shall have the responsibilities for the development, documentation and implementation of the training programs and activities specific to their work or contract scopes.

Annual refresher training shall be given to personnel assigned to activities within the TRU waste program, and this training shall be documented.

2.3 DESIGN CONTROL

2.3.1 The design and manufacturing activities for Type B (TRUPACT-II) packaging shall meet the requirements of a 10 CFR 71, Subpart H. The QA program meeting these requirements has been approved by the NRC.

2.3.2 The C of C for the design of the TRUPACT-II packaging has been provided by the NRC.

2.3.3 Design of certified Type B packaging shall be maintained in accordance with the MOC QA program, supporting procedures, and this QA Plan. The TRT (see 2.1.5) shall disposition repairs, modifications and use-as-is conditions with necessary input by the designer/fabricator.

2.3.4 All design of support and ancillary equipment for the TRU waste program shall adhere to DOE imposed design control criteria.

2.3.5 Users shall adhere to DOE imposed design control criteria, as appropriate to their site specific design activity. However, their design cognizance shall be coordinated with DOE/WPO and limited to support equipment, such as lifting devices, vent tools, etc.

2.4 PROCUREMENT DOCUMENT CONTROL

2.4.1 Procurement actions shall be performed in accordance with written procedures that adhere to the criteria of the DOE approved QA program. These procedures shall describe the actions involved in the preparation, review and QA approval of procurement documents and changes thereto.

2.4.2 Procurement specifications defining supplier QA, document submittal, and records requirements shall be included in all contracts for the procurement of packagings, services, and spare parts. The MOC will provide

spare parts for the packaging and shall be responsible for repair, modification and periodic inspection services for the packaging as necessary.

2.4.3 Items or services provided by the MOC shall be based on the requirements of the Operation and Maintenance Manual(s) (O&MM). The designer has established graded approach QA requirements. Implementation of this graded approach is defined in the MOC QA program. The MOC procurement procedures require QA approval of procurement actions in line with the graded approach. The MOC will not manufacture Type B packaging items.

2.4.4 All MOC approved suppliers are qualified by approved procedures and shall appear on a Qualified Suppliers List. Items and services requiring approved suppliers will not be procured from unapproved suppliers.

2.4.5 The users and carriers scope of work will not include procuring parts or services for packaging, unless specifically directed by DOE/WPO.

2.4.6 Procurement of items and services pertaining to maintenance, inspection, repair and spare parts for trailers and related equipment are the responsibility of the carrier. These procurements shall be performed in accordance with their DOE approved QA plan.

2.4.7 Any procurement of material or support/ancillary equipment by users and carriers for the TRU waste program shall be controlled in accordance with their site specific DOE approved QA program.

2.5 INSTRUCTIONS, PROCEDURES, SPECIFICATIONS, AND DRAWINGS

2.5.1 The MOC, users, carriers and their subcontractor's activities that support the fabrication, transportation, inspection, and maintenance of the packaging shall be described in drawings, specifications, procedures, and instructions appropriate to the activity.

2.5.2 Each document prepared shall include, or reference, appropriate quality acceptance requirements for determining and recording that (1) the prescribed

activity has been satisfactorily accomplished in accordance with the TRUPACT-II, SARP, C of C; and (2) the DOE/WPO QA Plan shall be reviewed by the respective QA Department.

2.5.3 All maintenance, repair, and periodic inspection of Type B packaging is programmed and controlled by DOE/WIPP 88-026, TRUPACT-II Maintenance Program Plan, with input and revisions provided for DOE/WPO by the MOC. The procedures and criteria of DOE/WIPP 88-026 reflect the requirements of the TRUPACT-II Container Operations and Maintenance Manual (No. OM-134), the TRUPACT-II SARP, and C of C Number 9218. Loading, unloading, preparation for shipment, transportation (etc.) activities shall be described by the users/carriers QA plans and be supported by detailed procedures.

2.5.4 All such activities performed by the MOC, users, and carriers shall be performed in accordance with DOE approved QA programs.

2.5.5 All packaging, maintenance, repair, and periodic inspection activities and procedures are administered and controlled by the MOC. Users will perform maintenance only as directed by the MOC.

2.6 DOCUMENT CONTROL

2.6.1 Document control activities by the MOC, users, carriers, and their subcontractors shall be performed in accordance with written procedures that adhere to the criteria of their DOE/WPO approved QA plan and their specific DOE approved QA program.

2.6.2 The procedures shall specify the requirements that are considered necessary to ensure that documents such as procedures, specifications, instructions, records and drawings (including changes thereto) are properly controlled and latest revisions made available to those responsible for their implementation. Revisions shall be approved by the same organizations that approved the originals.

2.6.3 Documents that shall be controlled include (but are not limited to) the following:

- QA/QC Manuals and associated plans and procedures
- Operating Procedures
- Maintenance Procedures
- Inspection and Test Procedures
- Loading and Unloading Procedures
- Packaging for Transport Procedures
- Procurement Documentation
- SARP and Certificate of Compliance
- Operation and Maintenance Manuals
- Configuration Drawings
- NCR Documents, Repair Procedures, and Supporting Documentation
- TRUPACT-II Content Codes (TRUCON)

2.7 CONTROL OF PURCHASED ITEMS AND SERVICES

2.7.1 The extent and nature of controls applied to the procurement of the design, fabrication, inspection, maintenance, repair and modification of the packaging, trailers, spare parts and related transportation equipment shall be defined in written procedures that adhere to the criteria of a specific DOE-approved MOC QA program. These procedures shall include such measures as source surveillance and audits of records and fabrication activities, as appropriate, to ensure that the design and fabrication of packaging is performed under the control of an NRC approved QA program.

At a minimum, these procedures will define the selection, performance evaluation, and acceptance of items/services from suppliers.

Measures shall be established to ensure that packaging, when received at the destination designated by the user, is accompanied by appropriate documentation. Such documents shall (1) be referenced in the C of C; (2) relate to the use and maintenance of the packaging; and (3) identify necessary actions to be taken prior to delivery of the certified material to a carrier for transport.

2.7.2 The users are not responsible for procuring items or services for the packaging, unless otherwise directed by the DOE/WPO. They shall use only those packaging-related items provided through the DOE/WPO.

Carriers will provide items and services for transportation equipment. Details and procedures for this activity shall be identified in their QA plans.

2.7.3 If services are contracted, the requirements for subcontractors, as identified in Section 2.1, "Organizations and Responsibilities," shall apply.

2.8 IDENTIFICATION AND CONTROL OF ITEMS

2.8.1 The required physical identification markings of the packaging and associated items and the maintenance of this marking shall be documented in procedures, drawings, or instructions as required by the SARP, C of C, and O&MM(s).

2.8.2 Procedures shall be prepared that delineate identification requirements or methods, and shall reflect specific DOE approved QA program criteria.

2.8.3 QA plans shall be established to ensure that items used for repair or rework for maintenance purposes are adequately identified to preclude use of incorrect or defective items. Also, where replacement of limited-life items is specified, measures shall be established to preclude use of items whose shelf life or operation times have expired.

2.8.4 Identification and records shall be such that all parts of, and operations performed on, each packaging shall be traceable to that particular packaging serial number.

2.8.5 Waste certification records shall be traceable to waste packages transported to the WIPP through the WWIS.

2.9 CONTROL OF PROCESSES

2.9.1 The responsibilities for processes are identified in Section 2.1, "Organizations and Responsibilities." Processes associated with packaging, such as transportation, waste handling (loading, unloading), welding, heat treating, cleaning, radiological surveys, Nondestructive Examination or Testing (NDE), and leak testing are considered as special processes and shall be controlled and performed by qualified and/or certified personnel, as defined by QA plans.

2.9.2 All processes shall be performed in accordance with written procedures that are reviewed and approved by cognizant technical and QA personnel prior to use.

2.9.3 Special processes that control or verify quality, such as those used in welding, shall be performed using qualified procedures and equipment in accordance with the requirements of the SARP, C of C, O&MM(s) and design drawings.

2.9.4 NDE, including leak testing, shall be performed by personnel certified in accordance with the guidelines of SNT-TC-1A using qualified procedures approved by a Level III individual.

2.9.5 The MOC, users, and carriers shall control their TRU waste transportation processes as described by their QA plan.

2.10 INSPECTION

2.10.1 The inspection, overview or surveillance of packaging quality related and maintenance activities shall be performed by persons independent of the work being verified. All inspection will be performed in accordance with approved procedures or instructions that adhere to the criteria of the DOE approved QA plan. Specific inspection activities for TRUPACT-II are determined by the SARP, C of C, O&MM, DOE/WIPP 88-026, and design drawings.

2.10.2 Personnel performing these activities shall be qualified and/or certified in accordance with written procedures or instructions that adhere to the criteria of the DOE approved QA plan.

2.10.3 Prior to each shipment of TRU waste material, the user shall ensure that the package, with its contents, satisfies the applicable requirements of the C of C, the SARP and the O&MM.

2.11 TEST CONTROL

2.11.1 Acceptance tests for shipment and maintenance performed by the MOC, users, and their subcontractors that are required to verify conformance of packaging to the SARP, C of C and O&MM(s) shall be in accordance with approved procedures that require results to be documented, evaluated, and determined acceptable. These activities shall be described in their DOE approved QA plan.

2.11.2 The procedures shall contain, as a minimum, characteristics to be tested, test methods, and acceptance/rejection criteria as defined by the C of C, SARP, O&MM(s) and DOE/WIPP 88-026.

2.11.3 Personnel performing these activities shall be qualified and/or certified in accordance with written procedures or instructions that adhere to the criteria of the DOE approved QA plan.

2.12 CONTROL OF MEASURING AND TEST EQUIPMENT

2.12.1 Administration of measuring equipment and instrumentation calibration by the MOC, users, and carriers shall be in accordance with procedures that adhere to the criteria of their DOE approved QA program.

2.12.2 The calibration procedures written by the MOC, users, and carriers, as applicable, shall assure that the following occur:

- All Standard Measuring Instruments (SMIs) and test equipment requiring calibration for use in the acceptance of material, equipment, and

assemblies and for all testing are calibrated, properly adjusted, and re-calibrated at specified intervals to maintain accuracy within predetermined limits.

- Calibration accuracy is maintained by utilizing standards traceable to the NIST that have a specified level of accuracy that is greater than the SMI or test equipment being calibrated, unless limited by state-of-the-art. If standards traceable to NIST do not exist, then standards having known relationships to nationally recognized standards may be used. If no nationally recognized standard exists, the bases for calibration shall be documented.
- Calibrated SMIs or test equipment are identified and traceable to applicable calibration test data and have an indication of calibration status.
- Whenever SMIs or test equipment are found to be out of calibration during or after use, all items inspected, or tests performed, during that period with the suspect equipment shall be controlled pending review action for possible re-inspection, re-test, or other appropriate corrective action. These reviews shall be performed in accordance with Section 2.15, "Control of Nonconforming Items," or Section 2.16, "Corrective Action," of this QA plan.

2.13 HANDLING, STORAGE, AND SHIPPING

2.13.1 Handling, storage and shipping activities shall be defined in written procedures. The procedures shall meet the applicable requirements of packaging C of C, SARP, DOE, DOT, and the users, carriers, or MOC QA plan(s). Typical categories that the procedures shall address follow:

- The requirements for and use of special handling and lifting equipment
- Special handling or storage provisions (e.g., shock absorbers, dunnage, tags, or markings) to adequately protect and/or identify critical components

- Proper environmental conditions to preserve components
- Documentation and control of physical and waste characterization related load management activities
- The adherence to all conditions identified in a C of C, SARP, O&MM and DOE/WIPP 88-026 for maintenance of packaging configuration and protection while loading or unloading
- The completion of all preloading conditions, including specified operations, inspections, and tests prior to loading
- The completion of all post loading conditions, including specified operations, inspections, and tests prior to delivery to the carrier
- Verification of compliance with all WAC requirements
- Adherence to all DOE and DOT requirements prior to delivery to a carrier
- Documented verification by qualified personnel that all loading records meet specified requirements.

2.14 INSPECTION, TEST, AND OPERATING STATUS

2.14.1 The identification of inspection, test, and operating status of packaging shall be defined in the implementing QA procedures and required by QA plans. The status identification shall be controlled throughout testing, inspecting, and packaging acceptance for delivery to a carrier for transport and maintenance. DOE/WIPP 88-026 defines requirements for maintenance activities.

2.14.2 Additionally, status identification shall be utilized during certification and preparation of payloads, preparation of packages for shipment, delivery to a carrier, transport, receipt, inspection, and final acceptance.

2.15 CONTROL OF NONCONFORMING ITEMS

2.15.1 Nonconforming items or conditions shall be controlled by procedures that require a formal administrative and disposition process to evaluate and/or correct the condition. These procedures shall adhere to the criteria of the DOE approved QA program plan.

2.15.2 Trailers and packagings which are not in compliance with the WAC, C of C(s), design drawings, and/or SARPs, shall be controlled (identified and segregated) until the nonconforming condition has been resolved.

2.15.3 NCRs for TRUPACT-II parameters shall be submitted to the MOC in accordance with the TRUPACT-II Maintenance Program Plan (DOE/WIPP 88-026). All packaging and associated hardware NCR documentation reviews shall be performed by the TRT, as required. All modification, repair and use-as-is dispositions require approval of the TRT before proceeding. The TRT NCR dispositioning may require interfaces with the designer, fabricator, or the NRC.

2.15.4 Processing of such NCRs resulting from carrier observed nonconformances on trailers, Type B containers, and related tie down equipment shall be submitted to DOE/WPO for disposition.

2.15.5 Acceptability of nonconformance items must be verified by inspection or retesting.

2.15.6 Subcontractors providing packaging and transportation equipment will be responsible for recording and dispositioning NCR documents and performing applicable corrective actions on deliverable product in accordance with their customer's DOE approved QA program plan.

2.15.7 All NCR documentation pertaining to packaging and transportation equipment from all locations and activities shall be submitted to the DOE/WPO to be analyzed for quality trends (TRT responsibility) and for record retention, retrieval, and distribution in accordance with the parameters of Section 2.17, "Quality Records."

2.15.8 Final distribution of NCRs will be established as directed by DOE Order AL 1540.1.

2.16 CORRECTIVE ACTION

2.16.1 Hardware or process control related significant conditions adverse to quality or safety that require corrective action to prevent recurrence shall be processed in accordance with procedures that require data compilation, review, evaluation, and record retention in accordance with the criteria of a DOE approved QA program plan.

2.16.2 The procedures shall require the condition, cause and corrective action taken to prevent recurrence to be documented and reported to cognizant management as delineated in DOE approved, site specific QA programs.

2.16.3 The MOC shall be provided all documentation associated with significant conditions adverse to quality requiring corrective action that directly impact the design and functional integrity of the TRUPACT-II described in the SARP and/or C of C. The WACCC, in conjunction with the TRT, is responsible for evaluating implementation and closing out corrective actions.

2.16.4 After review, evaluation, and approval as discussed in Section 2.15, the MOC shall be responsible for forwarding all corrective action documentation to DOE/WPO for review and approval.

2.17 QUALITY RECORDS

2.17.1 The QA records that are to be retained for the lifetime of packaging include the following:

- Appropriate design and production related records that are programmed by procurement and are generated throughout manufacturing and furnished with packaging

- Records demonstrating evidence of operational capability
- Records verifying repair, rework, and replacement
- Audit plans, audit reports, corrective actions
- Records that are used as a baseline for maintenance

Records for each shipment showing evidence of delivery of packages to a carrier, and proof that all NRC and DOT requirements have been satisfied, in accordance with DOE approved QA plans, shall be provided to DOE/WPO to be retained for a minimum of 2 years. These records include the following:

- Identification of the packaging by model number
- Verification that there are no significant defects in the packaging, as shipped
- Type and quantity of licensed material in each package, and the total quantity of each shipment (WWIS)
- Date of the shipment
- Name and address of the transferee
- Address to which the shipment was made
- Results of the special processes required by Section 2.11, "Test Control," of this QA plan.

2.17.2 Measures shall be established to ensure that documents designated as QA records are legible and completed to reflect the work accomplished, and that these documents are processed quickly to avoid unnecessary delay when the record is needed.

2.17.3 A receipt control system shall be established including identification of the individuals in each organization responsible for receiving records and assessing the current status of records in their possession. Measures shall be established to ensure that records maintained in-house or at other locations are identifiable and retrievable, and are not disposed of until prescribed conditions are satisfied.

2.17.4 Facilities used to store records shall meet the requirements of DOE 1324.2A and shall be constructed to minimize the risk from damage or destruction by severe natural conditions such as wind, flood, or fire; temperature and humidity; and infestation of insects, rodents, or mold. Records shall be firmly attached in binders or placed in folders or envelopes for storage in fire proof cabinets. If dual facilities are used to ensure the integrity of records, they should be sufficiently remote from each other to preclude damage to both facilities from a single event (such as a fire or flood). Measures should be taken to preserve special records (e.g., radiographs and microfilm) from excessive light, electromagnetic fields, and temperature. Measures shall also be taken to preclude the entry of unauthorized personnel into record storage areas. Measures should be established for prompt replacement of a record that is lost or damaged. QA plans shall describe record control.

2.17.5 The MOC shall establish and retain records in order to maintain packaging C of C(s) and QA data related to WIPP-provided packaging, support equipment, and trailers.

All records shall be established and maintained in accordance with applicable portions of the DOE-approved MOC QA Program and associated procedures.

All waste certification data received by WWIS will also be maintained in accordance with the above criteria.

2.17.6 Users shall maintain records of delivery to carriers in accordance with the requirements of the DOT and DOE and applicable portions of their DOE approved QA Plan. Copies of records shall be submitted to the MOC when they are required to meet the criteria of Section 2.17.1.

2.17.7 Carriers shall maintain records of compliance with DOT regulations and all transportation equipment inspection and maintenance activities as required by their DOE approved management plan.

Copies of records shall be submitted to DOE/WPO in accordance with carrier contracts.

2.18 AUDITS

2.18.1 The DOE/WPO approved QA plans shall describe measures that will be established to ensure that (1) audits are performed in accordance with preestablished written procedures or checklists; and (2) audits are conducted by qualified personnel not having direct responsibility in the areas being audited. Qualification requirements for lead auditors shall be included in each user's (generators/storage sites and carrier) QA plan.

2.18.2 A listing of the activities important to safety to be audited and the frequency at which each activity is to be audited shall be established and maintained to reflect current status. The frequency of audits shall be based on the importance of the activity to safety; however, each activity should be audited at least once a year.

2.18.3 The MOC shall establish measures to ensure that audits are made of the manufacturers of packaging, to determine the extent of compliance with the purchase order and to verify that the work is being controlled by their QA program that is approved by NRC.

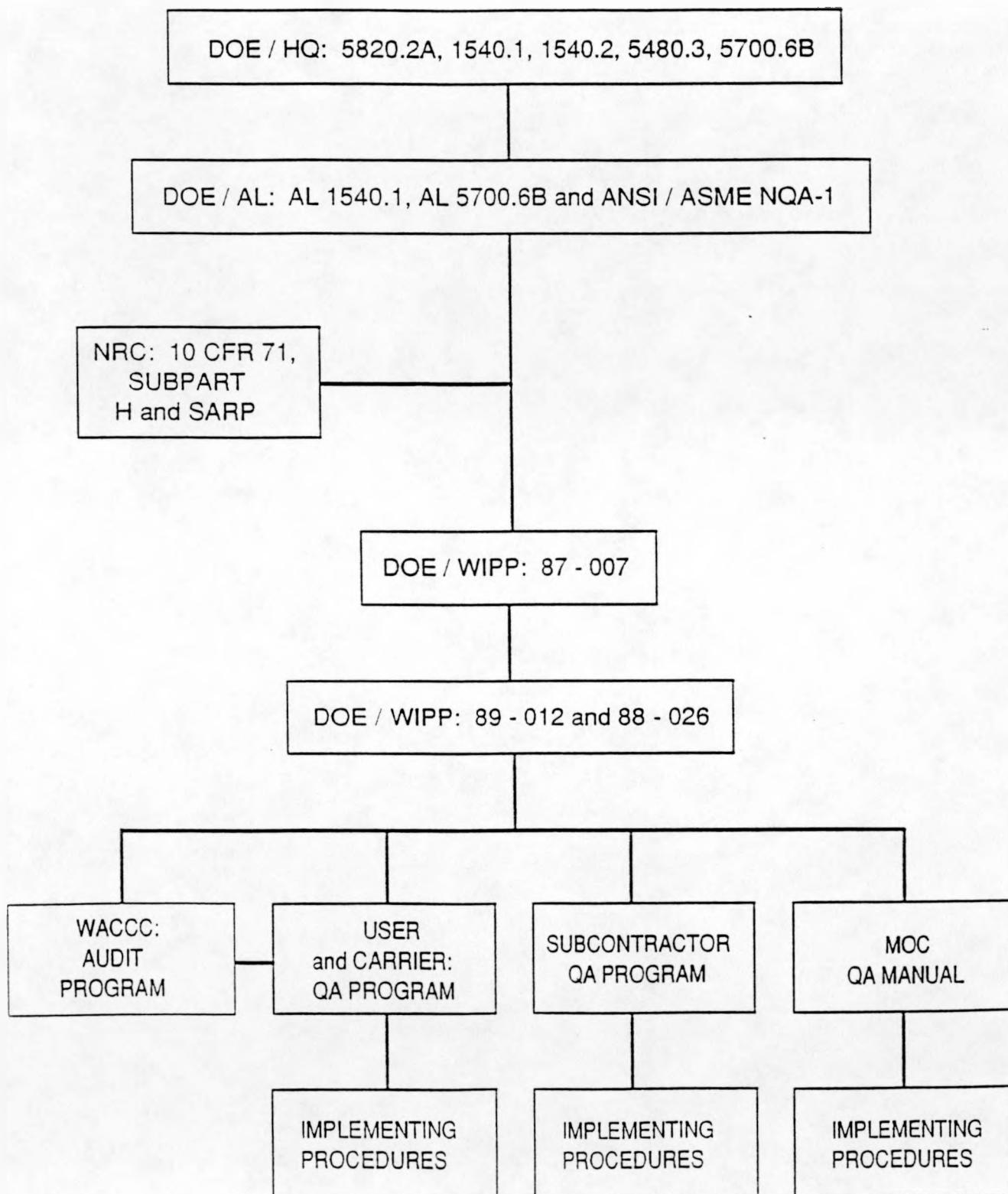
2.18.4 Lead auditors shall have the responsibility and authority for ensuring that corrective actions resulting from findings during audits are accomplished on a timely basis. Deficient areas shall be reaudited on a timely basis to verify implementation of corrective action.

2.18.5 The DOE/WPO shall perform audits of the users in accordance with DOE/WPO procedures, schedules and 2.18.2 above.

2.18.6 Audits of the carriers will be performed as directed by DOE/WPO.

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HIERARCHY OF QA DOCUMENTS



APPLICABILITY OF NQA-1 MATRIX

NOTE: The applicability of NQA-1 for the users and carriers is only recommended. However, the applicability of NQA-1 (Basic and Supplementary Requirements) for the MOC is a mandatory minimum requirement.

NQA-1 CRITERIA AND TITLE	NQA-1 APPLICABILITY (X)		
	USERS	CARRIERS	MOC
1 Organization	X	X	X
2 QA Program	X	X	X
3 Design Control			X
4 Procurement Document Control	X	X	X
5 Procedures, Instructions, and Drawings	X	X	X
6 Document Control	X	X	X
7 Control of Purchased Items and Services	X	X	X
8 Identification and Control of Items	X	X	X
9 Control of Processes	X		X
10 Inspection	X	X	X

NQA-1 CRITERIA AND TITLE	NQA-1 APPLICABILITY (X)		
	USERS	CARRIERS	MOC
11 Test Control	X		X
12 Control of Measuring and Test Equipment	X	X	X
13 Handling, Storage, and Shipping	X	X	X
14 Inspection, Test, and Operating Status	X	X	X
15 Control of Nonconforming Items	X	X	X
16 Corrective Action	X	X	X
17 Records	X	X	X
18 Audits	X	X	X

DOE / WPO / MOC ORGANIZATIONAL STRUCTURE

