
OAR Box 1712

Prepped by Keeia Richards

Document Number:

33) II-A2-24

Docket Number:

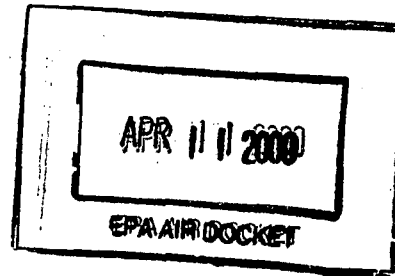
A-98-49

Document ID: PLN-182
Revision ID: 4
Effective Date: 03/13/00

A-98-49
II-A2-24

PLAN

For



INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM

[The following statement is optional:
Prepared for:
U.S. Department of Energy
Idaho Operations Office
Idaho Falls, Idaho]

INEEL

Idaho National Engineering & Environmental Laboratory
BECHTEL BWXT IDAHO, LLC

Form 412.14
10/05/99
Rev. 02

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: i of viii
Radioactive Waste Management Complex		

412.15
10/01/99
Rev. 01

**DOCUMENT MANAGEMENT CONTROL SYSTEM (DMCS)
DOCUMENT APPROVAL SHEET**

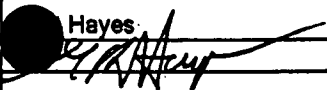
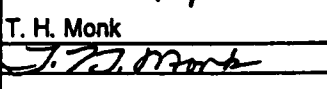
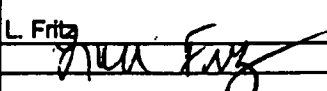
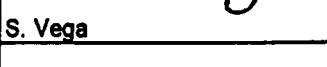
Document Type: Quality Program Plan Document Identifier: PLN-182, R4

Title: INEEL TRU Waste Characterization, Certification, and Transportation Quality Program Plan, Rev. 4

Author: G. R. Hayes Phone: 526-9126

Document Owner: T. H. Monk Phone: 526-3634

REVIEW CONCURRENCE AND APPROVAL SIGNATURES
Denote R for review concurrence, A for approval, as appropriate.

Type or printed name	R/A	Date	Organization Discipline	Mailing Address
Signature				
 Hayes	R/A	3/10/00	SQAO	MS-4201
 T. H. Monk	R/A	3/10/00	Site Project Manager	MS-4201
 L. Fritz	R/A	3-10-00	DOE-ID Field Office	DOE-ID-MS1118
 S. Vega	R/A		DOE-CAO QA Manager	DOE-CAO

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: ii of viii
Radioactive Waste Management Complex		

EXPLANATION OF CHANGES TO INEEL QPP # PLN-182	
Revision 1	
This was the original released version of PLN-182. The Revision 0 version was not released.	
Revision 2	
Section	Description of Change
1.0	Added text in third paragraph to further explain the program document hierarchy.
3.2	Revised Figure 3-1 and Section 3.2.7 to clarify the independence of the QA function. Also deleted ECL and ACL subsections because of ALD reorganization.
4.0	Deleted the "Project Plan for Shipping 3,100m ³ of TRU Waste." This plan addresses work scope, cost and schedule; it is not a QA implementation plan. Section 4.3 – changed title and document revision number.
5.1.1.2	Minor revisions to text throughout section. Deleted most text pertaining to the TWCP Procedures Matrix because it was redundant to Section 6.0. Revised explanation of TWCP procedures matrix.
5.1.1.4	Clarified text to explain that the INEEL QA Program is based on the DOE-CAO QAPD QA Program requirements. Also, deleted the grading strategy text that will be included in MCP-540. Also deleted discussion of quality level designation from this QPP and moved it to MCP-540 to resolve DOE-CAO comment (ref. CAO: QA: ROB: 97-1541).
5.1.3	Added the criteria for "significant conditions adverse to quality."
5.2.2	Added clarification that three facilities (SPO, ACL, ECL) do not perform any design work.
5.2.4	Added clarification that three facilities (SPO, ACL, ECL) do not perform any inspection or testing.
5.4.1 and 5.4.2	Added reference to the INEEL QAPjP for sample control.
5.4.3	Added clarification that SPO does not handle, store or ship samples.
5.4.4	Added clarification regarding the term "Limited Use."
5.6	Added software exemption statement to resolve DOE-CAO comment (ref. CAO: QA: ROB: 97-1541).
5.6.3	Added clarification that three facilities (SPO, ECL, ACL) utilize only commercially available software.
7.0	Revised text to clarify records and added MCP references.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: iii of viii
Radioactive Waste Management Complex		

EXPLANATION OF CHANGES TO INEEL QPP # PLN-182	
Figure 3-1	Revised to show SQAO direct communication to TRU Waste Program Manager.
Table 5-1	Revised TRAMPAC and Certification Program Plan review/approval requirements.
Revision 3	
3.2.8	Revised LMITCO QA&O Branch responsibilities.
Various	Changed "variances" to "PCNs" and added PCN to Acronyms.
5.1.1.4	Revised QA grading discussion to reference LMITCO Form-0414.2.
5.1.1.5	Revised planning elements to be consistent with DOE-CAO QAPD Rev. 2.
Appendix A	Updated references to most recent version of document.
Revision 4	
Various	Editorial clarifications made throughout the document
1.1	Revised purpose and scope to address PRD-198
3.	Renumbered to Section 2.2 and revised to reflect changes in organizational responsibilities
4.	Revised to delete references to PLN-185, PLN-186, PLN-187, PLN-188, and WO96-0481-ES (ANL-W FIP). Added Figure 4-1 to reflect current document hierarchy. Incorporated discussion of various program documents.
5.1.1.3	Section deleted. Deleted Figure 5-1, INEEL TWCP QA Document Hierarchy and added revised Figure to Section 2. Incorporated discussion of various program documents into Section 2.
5.1.2	Section renumbered to Section 3 and revised to clarify applicability of ASNT SNT-TC-1A to helium leak testing of TRUPACT-II only.
References	Revised to add references to WIPP WAP, WIPP WAC, and TRUPACT-II C of C Requirements Matrices.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: iv of viii
Radioactive Waste Management Complex		

CONTENTS

ACRONYMS.....	vi
1. INTRODUCTION.....	1
1.1 Purpose and Scope.....	1
1.2 Background.....	2
2. ORGANIZATION AND QUALITY ASSURANCE PROGRAM.....	3
2.1 Graded Approach.....	4
2.2 Organization and QA Program	5
2.2.1 INEEL TWCP QA Program	5
2.2.2 INEEL TWCP Organization.....	7
2.2.3 Program Responsibilities	7
2.2.4 Associated QA Program Implementation Documents.....	11
3. PERSONNEL QUALIFICATION AND TRAINING.....	14
3.1 Qualification	14
3.2 Training.....	14
3.3 Quality Improvement.....	15
3.3.1 Conditions Adverse To Quality	15
3.3.2 Controlling Conditions Adverse To Quality.....	15
3.3.3 Nonconforming Items	15
3.3.4 Corrective Action Planning and Follow-up	16
3.3.5 Improvement Analysis.....	16
4. DOCUMENTS.....	18
5. RECORDS	19
6. PERFORMANCE REQUIREMENTS.....	20

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: v of viii
Radioactive Waste Management Complex		

6.1	Work Processes.....	20
6.2	Design Control.....	21
6.3	Procurement.....	21
6.3.1	Procurement Document Control	21
6.3.2	Control of Purchased Items and Services	22
6.3.3	Control of Subcontractors.....	22
6.4	Inspection and Testing	22
7.	ASSESSMENT REQUIREMENTS.....	24
7.1	Management Assessments	24
7.2	Independent Assessments	24
7.3	Audits.....	25
7.4	Surveillances.....	25
7.5	Reports to Management.....	25
7.6	Performance Demonstration Program.....	25
8.	SAMPLE CONTROL REQUIREMENTS	26
9.	SCIENTIFIC INVESTIGATION REQUIREMENTS.....	27
10.	SOFTWARE REQUIREMENTS.....	28

FIGURES

2-1.	TWCP organization structure.....	6
2-2.	INEEL TWCP document hierarchy.	13

TABLES

2-1.	Cross-reference of quality assurance requirements.....	3
------	--	---

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: vi of viii
Radioactive Waste Management Complex		

ACRONYMS

ACL	Analytical Chemistry Laboratory
ALD	Analytical Laboratories Department
ANL-W	Argonne National Laboratory-West
ANSI/NCSL	American National Standards Institute/National Conference of Standards Laboratories
ASME	American Society of Mechanical Engineers
CAR	Corrective Action Report
CFR	Code of Federal Regulations
CH-TRU	Contact Handled Transuranic Waste
DMCS	Document Management Control System
DAR	Document Action Request
DOE	Department of Energy
DOE-CAO	Department of Energy-Carlsbad Area Office
DOE-ID	Department of Energy-Idaho Operations Office
DR	Deficiency Report
ECL	Environmental Chemistry Laboratory
FQAO	Facility Quality Assurance Officer
FS	Quality Assurance Field Support Directorate
INEEL	Idaho National Engineering and Environmental Laboratory
MCP	Management Control Procedure
M&O	Maintenance and Operations
NCR	Nonconformance Report
NDA	Nondestructive Assay
NDE	Nondestructive Examination

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: vii of viii
Radioactive Waste Management Complex		

NRC	Nuclear Regulatory Commission
NTP	National TRU Program
NUREG	U.S. Nuclear Regulatory Commission Guidance Report
PDP	Performance Demonstration Program
P&T	Packaging and Transportation
QA	Quality Assurance
QA/QC	Quality Assurance/Quality Control
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Document
QAPjP	Quality Assurance Project Plan
QPP	Quality Program Plan
RWMC	Radioactive Waste Management Complex
SARP	Safety Analysis Report for Packaging
SPM	Site Project Manager
SPO	Site Project Office
SQAO	Site Quality Assurance Officer
SWEPP	Stored Waste Examination Pilot Plant
TCO	Transportation Certification Official
TRAMPAC	TRUPACT-II Authorized Methods for Payload Control
TRUPACT-II	Transuranic Package Transporter
TRU	Transuranic
TWCP	TRU Waste Characterization Program
VE	Visual Examination
WAC	Waste Acceptance Criteria

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: viii of viii
Radioactive Waste Management Complex		

WAP Waste Analysis Plan
WCO Waste Certification Official
WIPP Waste Isolation Pilot Plant
WMPD Waste Management Program Director

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 1 of 28
Radioactive Waste Management Complex		

1. INTRODUCTION

Each Transuranic (TRU) waste site must develop and implement Quality Assurance (QA) plans for TRU waste characterization, certification, packaging, and transportation. The QA plans are submitted to the Department of Energy – Carlsbad Area Office (DOE-CAO) for approval before TRU wastes are characterized, certified, and transported to the Waste Isolation Pilot Plant (WIPP). No waste may be certified unless it is a product of a waste stream evaluated and approved by the CAO. The Transuranic Package Transporter (TRUPACT-II) is not used without DOE-CAO granting authority.

The DOE-CAO Quality Assurance Program Document (QAPD) establishes QA program requirements for all programs, projects, and activities sponsored by CAO. This Quality Program Plan (QPP) implements the QA requirements for certification, packaging, and transportation, established in the DOE-CAO QAPD. The Idaho National Engineering and Environmental Laboratory (INEEL) Quality Assurance Project Plan (QAPjP) (PLN-190) discusses the QA/QC activities and requirements for characterization processes specified in the Waste Analysis Plan (WAP). Activities included in the scope of this QPP are those related to certifying that waste containers and payload assemblies meet the criteria and requirements specified in the WIPP Waste Acceptance Criteria (WIPP-WAC) and TRUPACT-II Safety Analysis Report for Packaging (SARP), operation and maintenance of transport containers, waste transportation services, and the criteria specific to the packaging and transportation of contact handled transuranic (CH-TRU) waste to be shipped to WIPP. The INEEL Certification Plan (PLN-579) addresses the QA/QC requirements for certification specified in the WIPP-WAC. This QPP ensures that all activities that are governed by the *Code of Federal Regulations*, certificates of compliance, or other regulatory requirements are conducted in accordance with written, approved procedures or instructions that incorporate the applicable regulatory requirements. Activities that are important to safety are performed with specified equipment under suitable conditions, and prerequisites are satisfied prior to inspection, testing, or operation. This QPP takes precedence over any other INEEL QPPs related to characterization and certification of TRU wastes destined for WIPP, and packaging and transportation applicable to the TRUPACT-II. This QPP does not apply to the procurement, inspection, or testing of payload containers except as those activities apply to verification that the payload containers meet the requirements of the TRUPACT-II SARP.

1.1 Purpose and Scope

The objective of the TRU Waste Characterization Program (TWCP) is to ensure the effective characterization, certification, and transportation of TRU waste that is shipped to WIPP. The purpose of this QPP is to:

- describe the overall QA program for all INEEL TWCP participants
- identify what requirements are applicable to the INEEL TWCP
- describe the organizational structure, functional roles and responsibilities for compliance with the applicable requirements
- identify related plans and procedures for INEEL TWCP implementation.

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 2 of 28
Radioactive Waste Management Complex		

The scope of this QPP encompasses all INEEL activities related to the characterization, certification, and transportation of INEEL stored TRU waste to be shipped to WIPP. The specific roles and responsibilities for these activities are contained in Section 3. of this QPP.

The implementation of the DOE-CAO-QAPD requirements referenced herein is prescribed in written plans, procedures and instructions, which are identified in the INEEL TRU Waste Program Procedures Matrix for DOE-CAO-QAPD, PRD-198 (INEEL 2000) as described in Section 6. of this QPP.

This QPP addresses the requirements of INEEL MCP-561 and includes all pertinent elements in the DOE-CAO QAPD.

The TWCP activities are assigned Quality Levels in accordance with documented procedures. The assignment of Quality Levels is based on the graded approach and is discussed further in Section 2.1 of this QPP.

1.2 Background

In October 1995, the State of Idaho, DOE, and the U. S. Navy reached a court-approved settlement agreement that included mandated deadlines for the removal of TRU waste from the INEEL Radioactive Waste Management Complex (RWMC). The removal activities will require waste characterization, certification, transportation and disposal which are performed under the direction of the DOE National TRU Program (NTP).

Specifically, the agreement requires shipment of all INEEL TRU waste (estimated at 65,000 cubic meters) to the DOE CAO WIPP, or to another designated facility outside of Idaho by a target date of December 31, 2015, but no later than December 31, 2018. Interim milestones include initial shipment of 3,100 m³ (approximately 14,904 drum-equivalents) out of the State of Idaho by December 31, 2002, and after January 1, 2003, a running average of no fewer than 2,000 m³ per year shall be shipped out of the State of Idaho.

The DOE-CAO was assigned responsibility for the overall implementation of DOE Headquarter programs, policies, and guidance for the National TRU Program. In conjunction with meeting shipment milestones, the INEEL must obtain DOE-CAO authorization prior to each TRU waste shipment to WIPP. The INEEL's ability to obtain shipment authorization will be predicated on meeting the DOE-CAO TRU waste characterization, certification, and transportation prerequisites. These prerequisites are invoked to ensure compliance with applicable Federal, State, and local regulations, DOE Orders and requirements, and the DOE-CAO mission goals. These prerequisites include obtaining DOE-CAO approval of key technical and QA documents that describe the INEEL approach to meeting the DOE-CAO requirements for shipment of TRU waste to WIPP. This QPP is one of the key documents (see Figure 2-2 for others) required by DOE-CAO; it describes the quality program implemented at the INEEL (including ANL-W) specifically for TRU waste characterization, certification, and transportation.

The prime contractor for the INEEL maintains the INEEL TWCP and has responsibility for the performance of these prerequisites and the shipment of TRU waste to the WIPP facility. Argonne National Laboratory - West (ANL-W) supports the INEEL in the performance of these prerequisites.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 3 of 28
Radioactive Waste Management Complex		

2. ORGANIZATION AND QUALITY ASSURANCE PROGRAM

The organization of this QPP is based on the DOE-CAO QAPD elements outlined below. Table 2-1 provides a cross-reference of identical or related QA requirement elements from 10 CFR 830.120 and 10 CFR 71.

- **Organization and QA Program** documents the organizational structure, primary interfaces functional responsibilities, levels of authority, and lines of communication for activities affecting quality, and identifies the activities and items to which the QA program applies.
- **Personnel Qualification and Training** identifies the INEEL TWCP qualification and training programs and plans established to ensure personnel are provided training to perform their assignments and maintain job proficiency.
- **Quality Improvement** describes the processes to detect and prevent conditions adverse to quality, pursue continuous quality improvement, and control and correct nonconforming items.
- **Documents and Records** describes the processes for preparation, review, approval, issue, use, revision, and control of TWCP documents and records.
- **Work Processes** identifies the processes by which work conditions, equipment, and special processes are controlled to ensure quality.
- **Procurement** identifies the technical and QA requirements for procured items and services.
- **Inspection and Testing** identifies the processes for inspection and testing.
- **Assessment Requirements** describes the requirements for conducting management and independent assessments to measure management effectiveness, item quality, and process effectiveness and to promote improvement.
- **Sample Control Requirements** identifies the requirements for the control of waste samples, including identification, handling, storing, shipping, and archiving.
- **Scientific Investigation Requirements** describes the requirements for defining, controlling, verifying, and documenting scientific investigations.
- **Software Requirements** specifies the requirements for developing, procuring, maintaining, and using software.

When the QAPD is revised, TWCP documents and activities will be evaluated for changes to requirements, and revisions will be initiated and implemented, as appropriate.

Table 2-1. Cross-reference of quality assurance requirements.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 4 of 28
Radioactive Waste Management Complex		

QAPD and QPP Section	Equivalent Section in 10 CFR 830.120	Equivalent Section in 10 CFR Part 71, Subpart H
Organization and QA Program	Program	QA Organization QA Program
Personnel Qualification and Training	Personnel Training and Qualification	QA Program
Quality Improvement	Quality Improvement	Corrective Action Nonconforming Materials, Parts, or Components
Documents Records	Documents and Records	Document Control QA Records
Work Processes	Work Processes	Instructions, Procedures, and Drawings Identification and Control of Materials, Parts, and Components Control of Special Processes
Procurement	Procurement	Procurement Document Control Control of Purchased Material, Equipment, and Services
Inspection and Testing	Work Process and Acceptance Testing	Internal Inspection Test Control Control of Measuring and Test Equipment Inspection, Test, and Operating Status Handling, Storage, and Shipping
Assessment Requirements	Management Assessment Independent Assessment	Audits
Sample Control Requirements	Work Processes	Not applicable
Scientific Investigation Requirements	Work Processes Design	Identification and Control of Materials, Parts, and Components
Software Requirements	Not applicable	Not applicable

2.1 Graded Approach

Implementation of the INEEL TWCP QA program is based on the application of the graded approach. The levels of analysis, documentation, verification, and other controls are applied commensurate with an item's risk and importance. The TWCP graded approach process is implemented in accordance with MCP-540, Graded Approach and Quality Level Assignment. Documentation discussing Quality level designations for TWCP activities are maintained by the Site Quality Assurance Officer (SQA). MCP-540 is submitted to the DOE-CAO QA Manager for approval for use in the INEEL TWCP.

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182
Radioactive Waste Management Complex		Revision: 4
		Page: 5 of 28

2.2 Organization and QA Program

2.2.1 INEEL TWCP QA Program

This QPP applies to items and activities affecting TWCP quality. QA activities are integrated into the TWCP through reviews, assessments, inspections and approval and control of records and documents. The INEEL has identified the Site Project Manager (SPM), SQAQ, Waste Certification Official (WCO), and Transportation Certification Official (TCO) as being responsible for ensuring QA within the TWCP. The responsibilities of each of these positions are summarized in Figure 2-1.

All personnel involved with TRU waste certification, packaging, and transportation ensure the quality of their activities and products. If work is delegated, the individual making the delegation retains responsibility for the delegated work. Disputes related to QA program requirements will be resolved by the SQAQ and cognizant TWCP personnel.

The TWCP personnel plan certification activities and document the planning process. Planning documentation is subject to review by TWCP management and/or subject matter experts (SMEs). Project planning documentation consists of the documents discussed in this section, implementing procedures and training plans. These documents establish performance criteria and methods to measure performance relevant to the TWCP. All Project personnel are accountable for ensuring quality within their assigned areas of responsibility; however, the SQAQ is responsible for determining the effectiveness of this QPP, which is accomplished through internal reporting procedures, assessments, and surveillances performed in accordance with MCP-2532, Independent Assessments and MCP-2992, QA Program Surveillances.

The TWCP management at all levels has established communication channels that provide timely and wide dissemination of information related to the TWCP quality performance which includes:

- QA program status
- Lessons learned
- Quality improvement
- Results of trend analysis.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 6 of 28
Radioactive Waste Management Complex		

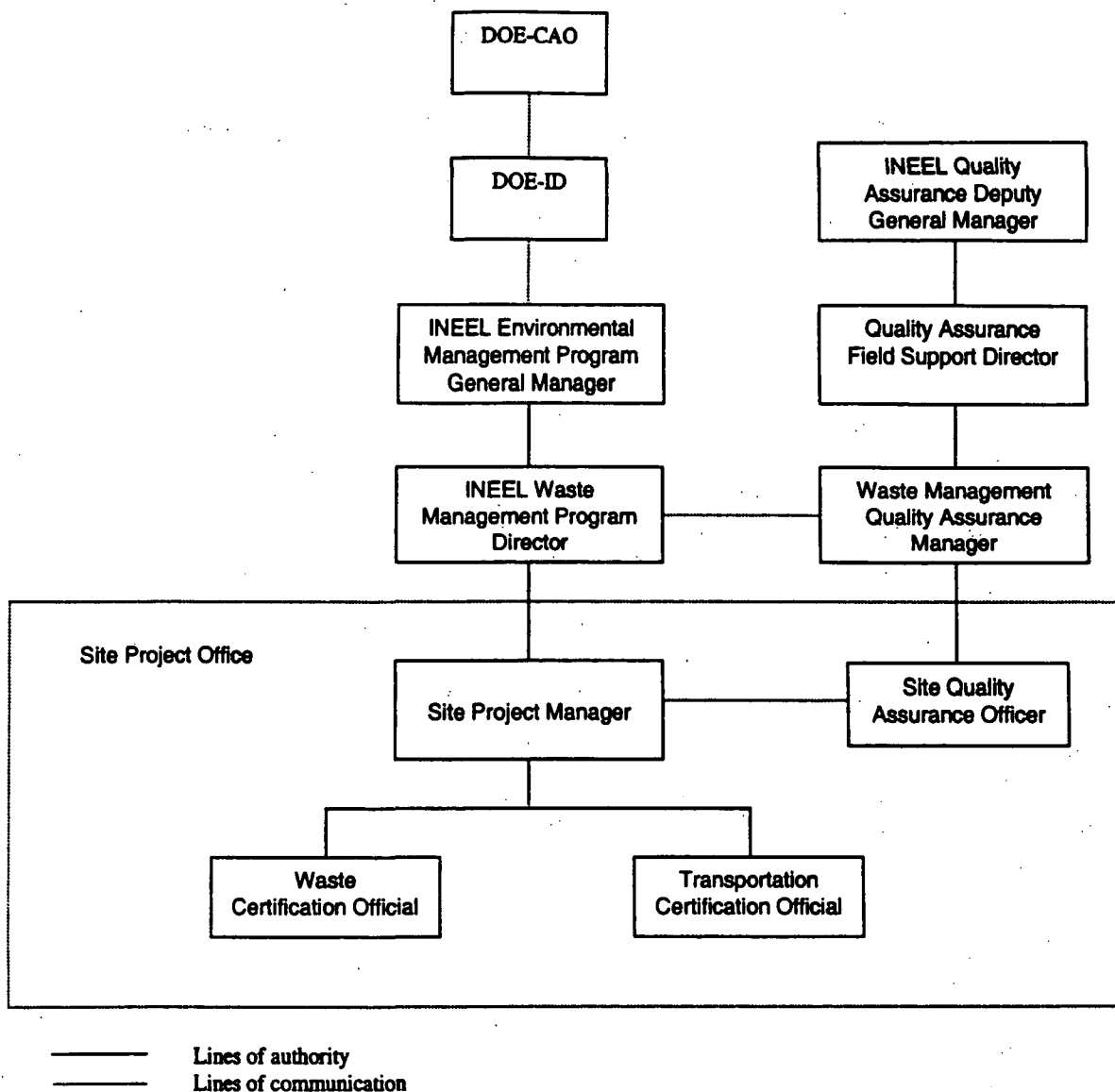


Figure 2-1. TWCP organization structure.

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182
Radioactive Waste Management Complex		Revision: 4
		Page: 7 of 28

INEEL TWCP Organization

The INEEL TWCP includes the following participants:

- Department of Energy Carlsbad Area Office (DOE-CAO)
- Department of Energy Idaho Operations Office (DOE-ID)
- INEEL Environmental Management Program General Manager
- INEEL Waste Management Programs Director
- INEEL TRU Waste Program Site Project Office (SPO), (SPM, SQAQ, WCO, TCO)
- Deputy General Manager (Quality Assurance)
- QA Field Support

2.2.2 Program Responsibilities

2.2.2.1 DOE-Carlsbad Area Office. As defined by the WIPP-WAC (DOE 1999), the DOE-CAO is responsible for the day-to-day management and direction of strategic planning and related activities associated with the characterization, treatment, packaging, transportation and disposal of TRU waste as part of the NTP. The DOE-CAO is responsible for ensuring that all TRU waste accepted for disposal in the WIPP is in compliance with applicable Federal, state, and local laws and regulations, and the WIPP-WAC.

In accordance with the WIPP-WAC, the DOE-CAO is responsible for the review and approval of this QPP, TRU Waste Certification Plans, TRUPACT-II Authorized Methods for Payload Control (TRAMPAC), associated QA Plans, and TRU QAPjPs. After approval of these documents and before waste shipment, the DOE-CAO is responsible for performing certification audits of INEEL activities to assess the implementation of, and compliance with, the approved plans. Additionally, the DOE-CAO is responsible for providing Nuclear Regulatory Commission (NRC)-approved transportation packaging for shipment of TRU waste from the INEEL to the WIPP.

The DOE-CAO Manager is responsible for granting or suspending a site's authority to certify TRU waste to the WIPP-WAC and to use the TRUPACT-II based upon an assessment of their documented TRU waste program and its implementation. Subsequent to the initial audits, the DOE-CAO is responsible to perform annual re-audits and surveillances at the INEEL to confirm continued compliance with the approved plans.

2.2.2.2 DOE-Idaho Operations Office. The Department of Energy-Idaho Operations Office (DOE-ID) is responsible for overseeing the management of the INEEL TWCP for compliance with DOE-CAO requirements, and established NTP policies and guidelines. The DOE-ID serves as a liaison between the INEEL contractors executing this QPP and the DOE-CAO. The DOE-ID will ensure that program documents are prepared and implemented in accordance with the DOE-CAO Requirements, and

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 8 of 28
Radioactive Waste Management Complex		

will approve this QPP, TRU Waste Certification Plans, and TRAMPACs and associated plans, and the INEEL TRU Waste Characterization QAPjP prior to their submittal to DOE-CAO.

2.2.2.3 INEEL Environmental Management Program General Manager. The INEEL Environmental Management Program General Manager is responsible for development and implementation of the overall environmental management policy for the INEEL.

2.2.2.4 Waste Management Program Director. The Waste Management Program Director is responsible for contractor waste operations at the INEEL, and ensures operations are performed in accordance with applicable DOE, Federal, state and local requirements.

2.2.2.5 Site Project Manager. The Site Project Manager has overall responsibility for successfully accomplishing TWCP quality affecting activities in accordance with this QPP. The SPM is the contractor representative responsible for ensuring that the CH stored TRU waste is characterized and certified in accordance with WIPP Hazardous Waste Permit Attachment B, Waste Analysis Plan (NMED, 1999), WIPP-WAC, and TRAMPAC. The SPM is responsible for the implementation and maintenance of the INEEL TRU Waste Characterization Program QAPjP which establishes, documents, and implements DOE-CAO-approved waste characterization methods that meet WAP requirements. The SPM (or designated alternate) is responsible for certifying the WIPP Waste Stream Profile Form(s) data.

The SPM QA (or designated alternate) responsibilities include:

- Review and approval of the INEEL QAPjP and subsequent revisions before submittal to DOE-CAO for review.
- Waste selection and tracking
- Data validation and verification
- Data reconciliation with DQOs
- Assignment of EPA Hazardous Waste Numbers
- QA/QC reports to DOE-ID
- Data transmission to DOE-CAO
- Ensuring that adequate technical and QA training is provided for personnel performing quality affecting activities.
- Ensuring compliance with all applicable regulations, DOE Orders and requirements, and applicable Federal, state, and local laws.
- Ensuring that personnel adhere to procedures for the generation, identification, control, and protection of QA records.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 9 of 28
Radioactive Waste Management Complex		

- Exercising the authority and responsibility to stop unsatisfactory work such that cost and schedule do not override environmental, safety, or health considerations.
- Developing, implementing, and maintaining plans, policies, and procedures that implement TWCP quality requirements.
- Identifying, investigating, reporting, and correcting quality problems.

The SPM is responsible for meeting production CH TRU waste certification goals established by DOE-ID, and for overseeing RWMC CH-TRU waste storage, characterization, certification and transportation activities in accordance with INEEL and CAO requirements. The SPM is responsible for ensuring that methods and control programs have been implemented at the supporting activities, and approved to meet characterization, certification, and transportation program objectives. The SPM is responsible for resolution of identified issues or concerns related to compliance with CAO requirements.

2.2.2.6 Site Quality Assurance Officer. The Site Quality Assurance Officer is the INEEL representative responsible for developing, documenting, and monitoring the implementation of quality assurance documentation specific to activities defined in this QPP. The SQAQO (or designated alternate) is responsible for INEEL approval and implementation of the TWCP characterization, certification, and transportation program quality assurance documentation, and is the QA liaison between all TWCP participants. Additional SQAQO (or designated alternate) responsibilities include:

- Reviewing the INEEL QAPjP and subsequent revisions;
- Verifying that TWCP QA requirements have been implemented;
- Providing day-to-day guidance to the project staff on quality-related matters;
- Stop INEEL TWCP activities if quality is not assured or controlled;
- Laboratory/testing facility assessments;
- Nonconformance tracking;
- Corrective action verification;
- Data validation/verification;
- Data QA documentation verification;
- Evaluating trends in compliance with TWCP objectives;
- QA/QC reports to the SPM;
- Summarize all relevant information on QA/QC activities during the period in a semi-annual report;

412.09
(02/16/2000 - Rev. 05)

Plan Radioactive Waste Management Complex	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 10 of 28
--	---	---

- Scheduling and performance of QA assessments;
- Maintaining liaison with FQAOs and other affected organizations;
- Ensuring preparation, review, and issuance of this QPP and procedures that implement customer and INEEL QA requirements;
- Review and approval of TWCP subcontractor QA plans;
- Tracking and trend analysis of quality problems and reporting of quality problem areas;
- Providing for the administrative processing of documentation concerning conditions adverse to quality;
- Having direct access to responsible management at a level where appropriate action can be effected;
- Being sufficiently independent from cost and schedule considerations;
- Having the organizational freedom to communicate with management;
- Having no assigned responsibilities unrelated to the QA program that would prevent appropriate attention to QA matters;
- Developing, establishing, and interpreting QA policy and ensuring effective implementation;
- Interfacing, as appropriate, with the DOE-CAO staff, TWCP personnel, and other stakeholders on QA matters;
- Assisting subordinate organizations with quality planning, documentation, quality measurement, and problem identification and resolution;
- Providing guidance to all applicable subordinate organizations concerning identification, control, and protection of QA records.

The SQAQO has the authority, access to work, and organizational freedom to identify quality problems, make recommendations for resolution, and verify implementation of corrective actions. In addition, the SQAQO will ensure that unsatisfactory conditions are controlled until proper corrective actions have been completed.

To ensure the independence of the TWCP QA function, the SQAQO reports directly to the SPM.

2.2.2.7 Waste Certification Official. The INEEL TRU Waste Certification Official, and designated alternate, are INEEL contractor representatives responsible for documenting and certifying that all TRU waste payload containers prepared for shipment to the WIPP meet all waste acceptance criteria, and for transmitting the waste certification data to the WIPP Maintenance and Operations (M&O)

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182
Radioactive Waste		Revision: 4
Management Complex		Page: 11 of 28

Contractor. The WCO is responsible for final compilation and INEEL approval of CH-TRU Waste Certification Statements.

2.2.2.8 Transportation Certification Official. The INEEL TRU Waste Transportation Certification Official, and designated alternate, are INEEL contractor representatives responsible for documenting INEEL approval of the authorized contents and certifying TRUPACT-II payloads, ensuring compliance with all packaging and records requirements, assuring that all parameters are met before the package is released to a carrier for transport, and obtaining WIPP authority to ship. The TCO is responsible for final compilation and INEEL approval of TRUPACT-II payload compliance documentation.

2.2.2.9 INEEL Quality Assurance Deputy General Manager. The INEEL Quality Assurance Deputy General Manager is responsible for the overall effectiveness of the INEEL Quality Assurance Program. These responsibilities include QA program policy formulation and promulgation, assessment of effectiveness of QA program implementation, and analysis and correction of INEEL-wide adverse trends.

2.2.2.10 Quality Assurance Field Support (FS) Director. The FS Manager is responsible for providing qualified quality professionals to the TWCP. The FS Manager provides professional training and where applicable certified individuals to perform QA-related activities.

2.2.3 Associated QA Program Implementation Documents

The provisions of the TWCP Quality Program are implemented through the use of numerous INEEL program documents and procedures. The relationships between the various external requirements sources and TWCP programmatic and implementing documents are depicted in Figure 2-2, INEEL TWCP Document Hierarchy. Documents which collectively define TWCP activities are presented below. Implementing procedures are listed within sub-tier program plans, matrices, or other documents.

2.2.3.1 Program Plan for Certification of INEEL Contact-Handled Stored Transuranic Waste, (INEEL), PLN-579. This plan describes the methods and procedures used by the INEEL to certify the contact-handled stored TRU waste as compliant with requirements and criteria defined in the WIPP WAC (DOE 1999). Examples of the parameters addressed by this document include criteria and requirements related to: container and physical properties, nuclear properties, chemical properties, gas generation, and data package(s). Included in this document is a Certification Compliance Methods Implementation Matrix which cross-references the INEEL certification program requirements to the implementing documents.

2.2.3.2 RWMC Compliance Plan for TRUPACT-II Authorized Methods for Payload Control (TRAMPAC), PLN-577. This document describes the methods used at the RWMC to ensure compliance with the TRAMPAC. The TRUPACT-II is used to transport TRU waste from the RWMC to WIPP in Carlsbad, New Mexico. Examples of the parameters addressed by this document include: shipping categories, physical form, chemical properties, chemical compatibility, payload container and contents configuration, etc. Included in this document is a Summary of the Stored Waste Examination Pilot Plant (SWEPP) Documents Used for Waste Certification which cross-references the INEEL TRAMPAC requirements to the INEEL implementing documents.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 12 of 28
Radioactive Waste Management Complex		

2.2.3.3 INEEL Quality Assurance Project Plan for the Transuranic Waste Characterization Program, (INEEL 1999a), PLN-190. The WIPP Waste Analysis Plan delineates the technical and QA/QC requirements for waste characterization activities and requires each generator site to submit a QAPjP to DOE-CAO that describes how the site complies with the WIPP WAP requirements. Waste characterization provides data on the physical and chemical makeup of the waste and these data are important components of the overall waste certification process. The INEEL TRU Waste Characterization QAPjP is the document that describes the INEEL characterization activities. This QAPjP addresses waste characterization and data processing by the following INEEL participants: The Environmental Chemistry Laboratory (ECL), Analytical Chemistry Laboratory (ACL), RWMC, ANL-W and SPO.

2.2.3.4 INEEL TRU Waste Program Procedures Matrix for the DOE-CAO-QAPD, PRD-198 (INEEL 2000). The QAPD matrix identifies all current and applicable documents of each organization or project that serves to implement each applicable requirement of the QAPD. The matrix pertains to all INEEL waste characterization, certification, and transportation activities. This matrix will be updated when/if revisions to implementing procedures are made that impact the matrix.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182
Radioactive Waste Management Complex		Revision: 4
		Page: 13 of 28

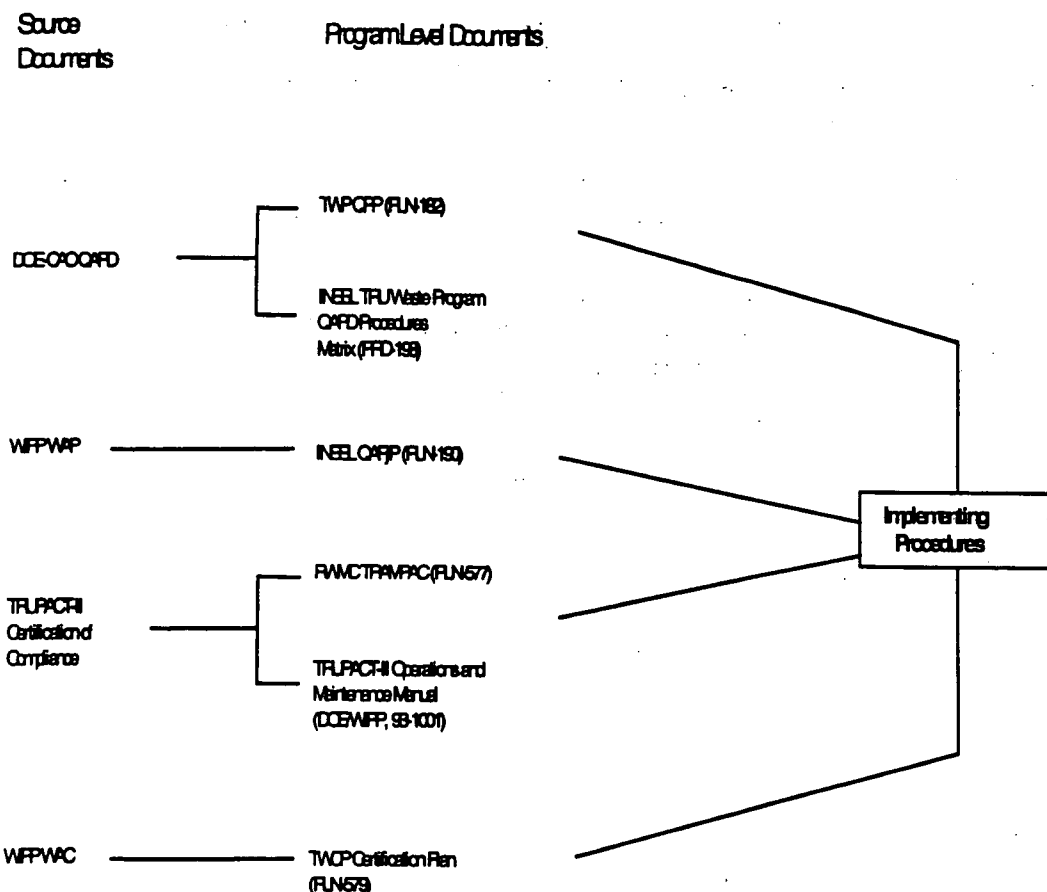


Figure 2-2. INEEL TWCP document hierarchy.

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 14 of 28
Radioactive Waste Management Complex		

3. PERSONNEL QUALIFICATION AND TRAINING

Personnel performing TWCP activities affecting quality receive QA indoctrination and are qualified and trained to ensure that suitable proficiency is achieved and maintained in the performance of their assigned tasks. Records documenting qualifications and completed training programs are maintained and controlled as described in documents referenced in PLN-587, TWCP Training Implementation Plan.

3.1 Qualification

The appropriate managers with support as needed from their respective training organizations determine qualification standards for each job category relevant to the TWCP and ensure that qualifications of TWCP personnel, including minimum education and experience, have been verified. The TWCP personnel maintain minimum qualifications in accordance with PLN-587. The period of effectiveness for qualification associated with special processes and operations that require special skills and the requalification criteria are specified or referenced in these procedures or supporting training program plans. Auditable records documenting personnel qualifications are maintained and retained in the respective facility's TWCP records files.

Nondestructive Assay (NDA), Nondestructive Examination (NDE), and Visual Examination are considered characterization processes, therefore, TWCP personnel performing these activities are exempt from the qualification requirements of the American Society of Nondestructive Testing (ASNT) Recommended Practice No. SNT-TC-1A. TWCP personnel performing helium leak testing of the TRUPACT-II are qualified in accordance with ASNT SNT-TC-1A and its applicable supplements.

3.2 Training

The appropriate managers ensure that all TWCP personnel receive indoctrination and training on the scope, purpose, and objectives of the TWCP and the specific QAOs of the tasks being performed. Personnel performing activities affecting quality are trained according to their respective training plans to ensure they achieve and maintain proficiency prior to performing any tasks subject to these QPP requirements. Personnel receive initial and continuing training requisite with their activities and level of responsibility in accordance with PLN-587.

Training is designed, developed, conducted, and evaluated. Training programs may include classroom instruction, practical hands-on experience, supervised on-the-job training, self-paced individual study, and written, oral, or practical demonstration of worker competence. Job positions are analyzed and task responsibilities for TWCP personnel are analyzed to ensure education, experience, and training is commensurate with minimum requirements specified. Auditable records documenting the required training and qualifications are maintained in accordance with PLN-587.

The TWCP personnel performing activities affecting quality receive indoctrination in the following:

- General criteria, this QPP, and applicable codes, regulations, and standards

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 15 of 28
Radioactive Waste Management Complex		

- Specific criteria, including the INEEL QAPjP and implementing procedures.

3.3 Quality Improvement

The TWCP personnel continually evaluate and improve project activities. The SQAQO ensures that quality improvement in the TWCP is achieved by identifying and reporting conditions adverse to quality, analyzing trends, reporting and tracking nonconformances, and implementing corrective actions. These quality improvement activities detect and prevent unacceptable quality problems and thereby increase accuracy and reliability, and reduce variability.

3.3.1 Conditions Adverse To Quality

A condition adverse to quality is an all-inclusive term used in reference to failures, malfunctions, deficiencies, and nonconforming items, materials, parts, components, data and processes. Significant conditions adverse to quality are those which, if uncorrected, could have a serious effect on safety, operability, waste isolation, TRU waste site certification, regulatory compliance demonstration, or effective implementation of the QA program.

3.3.2 Controlling Conditions Adverse To Quality

Conditions adverse to quality are investigated and documented, including the extent of the condition and the impact on completed work. As appropriate, corrective action plans are developed, documented and implemented as soon as practical.

Significant conditions adverse to quality are reported and evaluated by the responsible QA organization, other relevant regulatory compliance functions (e.g., environmental and safety), and the responsible management, to determine if a work suspension order is necessary. If a work suspension is warranted, the SQAQO, cognizant FQAQO, or the INEEL QA organization verifies and documents the completion of applicable corrective actions prior to any management action releasing the work suspension order. INEEL TWCP work suspensions are processed in accordance with MCP-553, Stop Work Authority. The DOE-CAO is notified of corrective action reports that relate to violations of the WIPP Hazardous Waste Permit. Corrective action plans for significant conditions adverse to quality and all DOE-CAO-issued Corrective Action Reports (CARs) relating to violations of the WIPP Hazardous Waste Permit, address corrective action planning and follow-up. Instructions governing these activities are detailed in procedures referenced in PRD-198, INEEL TRU Waste Program Procedures Matrix for DOE-CAO-QAPD.

3.3.3 Nonconforming Items

The TWCP personnel ensure that nonconforming items (including data), materials, parts, or components are adequately identified and segregated from acceptable items and materials to preclude their inadvertent use. The TWCP nonconformance process is controlled in accordance with MCP-538, Control of Nonconforming Items.

Plan Radioactive Waste Management Complex	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 16 of 28
---	---	--

3.3.4 Corrective Action Planning and Follow-up

Corrective actions are planned and prepared for all significant conditions adverse to quality and for any violation of the WIPP Hazardous Waste Permit. These corrective actions address considerations including:

- The extent and impact of the significant condition adverse to quality
- Actions to resolve the initial problem
- Root cause of the problem
- Actions to be taken to preclude recurrence
- Actionees, responsibilities, and expected completion dates for the required actions.

A follow-up of completion of proposed corrective actions occurs to verify timeliness and effectiveness of implementation. Procedures implementing the TWCP corrective action process are referenced in PRD-198.

3.3.5 Improvement Analysis

1. Performance data are identified, collected, and routinely analyzed to identify opportunities to improve items, activities, and processes. Analysis of quality performance data serves to identify trends adverse to quality. Reports of conditions adverse to quality are evaluated to identify adverse quality trends.
2. When conditions adverse to quality are identified on a recurring basis, actions are taken to evaluate those conditions in order to minimize their impact and to preclude recurrence.

Procedures implementing the TWCP improvement analysis process are referenced in PRD-198.

All personnel have the authority to stop certification, packaging, and transportation activities and/or refuse to accept work products or services (e.g., procured items, documentation, packaging, and waste shipments) that do not conform to TWCP requirements. All INEEL employees have the responsibility to stop work that poses a clear and imminent danger to the safety and health of employees, subcontractors, visitors, or the environment. The TWCP personnel report conditions adverse to quality to their immediate supervision, Facility Quality Assurance Officer (FQAO) and/or the SQAQ, who ensure that the condition adverse to quality is documented, investigated and that corrective action is taken as described in this section.

All violations of the WIPP Hazardous Waste Facility Permit must be managed as a significant condition adverse to quality. The SQAQ notifies DOE-CAO of all conditions adverse to quality affecting waste to be shipped to WIPP and forwards all reports upon issuance and again upon closure related to violations of the WIPP Hazardous Waste Facility Permit to DOE-CAO for tracking. All deficiencies are evaluated for Price-Anderson Amendments Act applicability and reporting.

412.09
(02/16/2000 - Rev. 05)

Plan Radioactive Waste Management Complex	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 17 of 28
---	---	--

Deficiencies are uncontrolled and unapproved deviations from an approved plan, procedure, or expected result. Deficiencies specific to the TWCP also include documentation or management practices that do not meet the requirements related to waste certification, packaging, and transportation which are identified in the WAP, TRAMPAC, WIPP-WAC, QAPD, DOE orders, and applicable federal and state regulations. The TWCP personnel are responsible for identifying any condition that affects the TWCP's compliance with these requirements. Assessments may often identify systems, processes, products, or services that do not meet performance criteria established in planning documents. When deficiencies are found, TWCP personnel take prompt action to rectify the situation.

Any individual who identifies a condition adverse to quality initiates a Nonconformance Report (NCR) or Deficiency Report (DR) in accordance with MCP-538 or MCP-598 respectively. If the safety or quality of TWCP activities could be compromised by continued use of a nonconforming item, the item is taken out of service and tagged or otherwise identified to prevent reuse or acceptance until the nonconformance is corrected. When an NCR is initiated, corrective action is taken to resolve the nonconformance. MCP-538 guides the nonconformance reporting corrective action process. Corrective actions for deficiencies identified on DRs are recorded, evaluated, approved, implemented, verified, and closed in accordance with MCP-598 and MCP-2547.

The NCRs and CARs are forwarded to the responsible quality organization (e.g., SQAQ, FQAQ). The SQAQ or FQAQ is responsible for validating and tracking TWCP-related deficiencies to ensure that corrective action is implemented and that the corrective action resolves the nonconformance. The SQAQ will notify DOE-CAO in writing within five calendar days of identification of any non-administrative nonconformance related to applicable requirements specified in the WIPP Hazardous Waste Facility Permit WAP, which are first identified at the Site Project Manager signature release level. The SQAQ will submit the NCR to CAO within 30 calendar days of identification of the deficiency in accordance with MCP-2933. The SQAQ ensures dissemination of information that may prevent problems or help improve parallel processes in TWCP activities and reevaluates system performance after corrective actions have been implemented. The TWCP management provides or ensures the resources necessary to accomplish corrective actions.

The SQAQ, appropriate managers, and FQAQs are jointly responsible for identifying the following:

- Trends in nonconformances
- Root causes of nonconformances
- Specific, measurable corrective actions to resolve current problems and prevent recurrence
- Personnel responsible for implementing corrective actions
- Schedules for completing corrective actions.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182
Radioactive Waste Management Complex		Revision: 4
		Page: 18 of 28

4. DOCUMENTS

Documents that specify quality requirements or establish activities affecting quality are controlled to ensure that accurate and current documents are used. Document Control ensures that documents have gone through the designated review and approval process and are distributed to the appropriate personnel.

The TWCP personnel prepare and control documents supporting the quality of the TWCP in accordance with procedures referenced in PRD-198. Document Control personnel ensure that documents are developed as prescribed by current procedures, are reviewed for adequacy, correctness, and completeness, and are approved, revised, and distributed to the appropriate personnel. Documents developed specifically for the TWCP are distributed through a document control process. These documents include:

- TRAMPAC
- Certification Plan
- QAPjP
- QAPD Procedures Matrix
- Plans and procedures implementing the TWCP waste characterization, certification, packaging, and transportation requirements.

Other plans and procedures implementing the TRU waste characterization, certification, packaging, and transportation requirements are referenced in PRD-198.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 19 of 28
Radioactive Waste Management Complex		

5. RECORDS

A QA record is an authenticated record that furnishes evidence of the quality of items and/or activities affecting quality. The TWCP QA records are controlled and maintained to certify compliance with requirements and to reflect completed work. The QA records are identified, indexed, classified, controlled, maintained, and dispositioned by records management personnel as described in MCP-2520, TRU Program Records Management.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182
Radioactive Waste Management Complex		Revision: 4
		Page: 20 of 28

6. PERFORMANCE REQUIREMENTS

6.1 Work Processes

The work processes and items supporting and affecting TWCP quality are controlled through plans and procedures identified in PRD-198. Procedures and plans are developed, reviewed, approved, revised, and distributed in accordance with the related PRD-198 procedures. The TWCP technical and QA personnel comply with the applicable technical standards and administrative controls described in procedures, which are reviewed and approved by the SPM (or designee), the SQAQO (or designee), and cognizant management for use in the TWCP. Cognizant managers ensure personnel perform work following established procedures.

The procedures identified in PRD-198 provide the following information:

- organizational and individual responsibilities
- training and qualification requirements
- technical, regulatory, and QA requirements
- step-by-step instructions for the process (prepared by a subject matter expert of the cognizant organization)
- equipment specifications
- methods and criteria for ensuring and verifying the acceptability of equipment and materials used in the process (e.g., calibration)
- prerequisites, precautions, process parameters, and other limiting conditions
- products of the process
- quantitative and/or qualitative criteria for determining that prescribed process activities have been performed satisfactorily
- records generated by the process
- package and design control of equipment and materials.

The SPM and cognizant managers ensure that TWCP activities are controlled and conducted in accordance with process-specific procedures that describe and control work processes applicable to TRU waste characterization, certification, packaging, or transportation. If equipment is designed for TWCP activities, site personnel comply with QAPD design control. Inspection and testing is addressed in Section 6.4.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 21 of 28
Radioactive Waste Management Complex		

Each individual performing the work is responsible for ensuring that work processes are controlled and comply with established criteria. Facility managers are responsible for ensuring that workers have the correct procedures, materials, and training to perform quality work. All instructions and procedures are maintained current with a documented and controlled method of revision (see Section 4). Instructions, procedures, and drawings are readily available to TWCP personnel at locations requiring their use.

Fabrication, installation, and inspection processes that have an effect upon the quality of items or services important to safety are controlled by process procedures. Special processes controlled under this QPP are nondestructive testing [nondestructive assay (NDA), nondestructive examination (NDE) and visual examination (VE)], helium leak testing, and limited maintenance of the TRUPACT-II and associated components. These processes are controlled by the procedures referenced in PRD-198. As discussed in Section 3.1, only those personnel performing helium leak testing of the TRUPACT-II are qualified in accordance with ASNT SNT-TC-1A and its applicable supplements.

Compliance Application Peer Reviews as discussed in the DOE-CAO QAPD, Section 1.1.2.6, are not performed as part of the INEEL TRU Waste Program. Therefore, the requirements of this section are not addressed in this QPP.

6.2 Design Control

The TWCP conducts design control activities for certain items and processes. These design activities are performed in accordance with internal INEEL QA Program design control requirements. The design control requirements of the DOE-CAO QAPD, Section 2.2, apply only to the WIPP. Therefore, these QAO QAPD requirements are not applicable to the INEEL TWCP.

6.3 Procurement

All INEEL TWCP facilities implement procedures to ensure that procurement of items and services important to safety and quality meet requirements and perform as intended. Procurement controls are also applicable to equipment and services that directly affect testing, sampling, and analytical data quality. Project personnel adhere to procurement and recordkeeping practices established in written procedures. The procurement criteria are implemented according to the procedures specified in the following subsections.

6.3.1 Procurement Document Control

The SPM and facility managers ensure that TWCP personnel control procurement documents in accordance with MCP-592, Acquisition of Goods and Services. Procurement documents supporting waste management and packaging and transportation activities must include required specifications and acceptance criteria. Procurement documents are reviewed by appropriate organizations and engineering disciplines to ensure that they contain adequate scope of work, technical requirements, supplier QA program requirements, and provisions for acceptance.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182
Radioactive Waste Management Complex		Revision: 4
		Page: 22 of 28

6.3.2 Control of Purchased Items and Services

The SPM and facility managers ensure that TWCP personnel control items and services purchased (including supplier evaluations and inspections) in accordance with MCP-3491, Acceptance of Procured Items and Services. Documentary evidence that items, material, and equipment conform to the procurement specifications is provided before installation or use of the item, material, and equipment, and is retained in accordance with MCP-3491. Potential suppliers of goods and services to the TWCP will have their own QA program or will comply with applicable TWCP requirements.

Measures are established to ensure that materials, parts, and components used for repair work for maintenance purposes, or packaging and transportation purposes, are adequately identified to preclude the use of incorrect or defective items. Also, where replacement of limited-life items is specified, measures are established to preclude use of items whose shelf life or time in operation has expired.

6.3.3 Control of Subcontractors

Section 6.3.2 also applies to subcontractors who perform work that directly affects the quality of characterization and certification data. MCP-3491 describes how TWCP personnel control subcontractor services. Subcontractors may support TWCP activities under a "staff augmentation" role or for procurement of products and services. The TWCP staff augmentation subcontractors operate under the umbrella of the TWCP QA program and are subject to all applicable requirements for TWCP-related functions they perform. All subcontractors who support the TWCP will be informed of the need to perform operations in compliance with TWCP requirements. Subcontractors are required to establish procurement controls and a QA program to ensure that purchased materials, equipment, and services conform to the TWCP procurement and QA program documents. The controls must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products on delivery. Subcontractors are subject to periodic assessments and audits at intervals consistent with the importance, complexity, and quantity of the product or services provided, to ensure compliance with procurement requirements. Subcontractor personnel must meet applicable TWCP training and qualification requirements. Subcontractors shall submit copies of all TWCP-related, quality-affecting documents to the SPM.

6.4 Inspection and Testing

Equipment is tested, inspected, and identified, in accordance with MCP-2482, Inspection for Conformance. The TWCP personnel identify and control items (e.g., items with limited shelf or operating lives, materials, equipment, samples) and ensure that only correct and accepted items are used. This procedure addresses planning, parameters for evaluation, techniques to be used, qualification of inspection and test personnel, hold points, documentation, acceptance criteria, and organizational responsibilities.

TWCP personnel routinely test and inspect items and processes and control, calibrate, and maintain equipment to ensure proper operation and data quality. The procedure identified above implements an inspection program that establishes criteria for inspection of activities affecting quality by, or for, the organization performing the activity, and to verify conformance with the requirements for accomplishing the activity. The verification is performed in accordance with written procedures, instructions, or

412.09
(02/16/2000 - Rev. 05)

Plan Radioactive Waste Management Complex	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 23 of 28
---	---	--

drawings. Personnel performing the inspections are independent from the individuals performing the activity being inspected. Equipment modifications, repairs, and replacement are inspected in accordance with the original design and inspection requirements, unless an approved alternative exists. The inspection program also provides for identification and documentation of deficiencies discovered during the inspection. Measures are established to indicate, by the use of markings, tags, stamps, labels, routing cards, or other suitable means, the status of inspections and tests performed. These measures provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary, to preclude inadvertent bypassing of the inspections and tests.

Measuring and test equipment with the necessary range and accuracy is provided to qualified personnel for the inspection, test, and acceptance of material, parts, components, and systems. Equipment accuracy is ensured by periodic calibration that is traceable to national standards or a documented equivalent basis for calibration.

The test control program is established for items and services important to safety. No testing requiring a test control program relative to waste payload containers or the TRUPACT-II will be performed under this program. All TRUPACT-II repair parts that may be replaced by the operator are supplied by the CAO or a designated contractor and are tested, inspected, accepted, and tagged in accordance with the CAO *TRUPACT-II Operating and Maintenance Instructions* manual prior to delivery to the user. Leak testing is a special process discussed in Section 6.1.

Specific measures to control packaging, shipping, storage, preservation, handling of components, material, and packaging to prevent damage, loss, deterioration, or substitution are established in MCP-1783, TRUPACT-II Container Maintenance Program. This procedure addresses the following requirements:

- Transport cask handling and operation shall conform to written handling and operating procedures for each licensed cask.
- Prior to shipment of a transport cask, conditions of the NRC's certificate of compliance (e.g., specifications, tests, inspections) shall be satisfied. Required shipping papers shall be prepared and shall accompany the shipment.
- Established safety restrictions concerning handling, storage, and shipping shall be included in the handling and operating procedures for transport casks.

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 24 of 28
Radioactive Waste Management Complex		

7. ASSESSMENT REQUIREMENTS

The INEEL participates in an assessment program to ensure that the TWCP is in compliance with applicable requirements. Management assessments are conducted by the DOE-SPM and independent assessments by SPO personnel independent of the activities being assessed. The CAO and external regulatory agencies also conduct assessments of the TWCP. The SQAQ tracks deficiencies identified during assessments; identifies corrective actions to resolve deficiencies according to MCP-2993, Management of TWCP Deficiencies, and ensures that the resolutions are reported to DOE-CAO as described in Section 7.5.

7.1 Management Assessments

The TWCP managers periodically assess the performance of their organization to determine the effectiveness of QA Program provisions that enable the organization to comply with requirements of the WAP, QAPD, WIPP-WAC, TRAMPAC, and applicable procedures and documents. Managers evaluate QA Program effectiveness by focusing on the identification and resolution of both systemic and management issues and problems, and identifying strengths and weaknesses to facilitate actions to improve quality, efficiency and cost-effectiveness. The management assessment should include an introspective evaluation to determine whether the entire integrated management system effectively focuses on meeting strategic goals. Management assessments are conducted as described in MCP-1757, Management Self-Assessment for the TRU Waste Program. The TWCP managers are responsible for the conduct of these assessments and report at least annually on relevant findings.

7.2 Independent Assessments

Documented independent assessments, also referred to as audits and surveillances, are used to measure item service and quality, process adequacy and effectiveness, and to promote improvement. TWCP personnel and facilities are subject to periodic independent assessments performed by teams assembled by the SQAQ. The SQAQ ensures that characterization facilities and analytical laboratories are assessed and determines whether the independent assessment is an audit or process surveillance (see below). In addition, Facility QA Officers (FQAQs) may perform independent assessments (audits or surveillances) of TWCP activities at their respective facilities. Assessment teams include one or more qualified assessors, one of whom must be a certified lead assessor. Assessment personnel qualifications are addressed in MCP-196, Training Indoctrination and Qualification of Auditors/Lead Auditors.

For independent assessments performed by the SPO, the assessment team is made up of a team leader appointed by the SQAQ and team members and technical specialists selected by the team leader in conjunction with the SQAQ. The team leader provides indoctrination and supervision of the team, organizes and directs the assessment, establishes the scope of the assessment, prepares a plan for conducting the assessment, and prepares and issues an assessment report to the management of the assessed organization and any affected organizations. The assessment team members and technical specialists prepare the assessment checklist, conduct the assessment, brief the management of the assessed organization on a daily basis, and prepare a draft report for presentation at the exit conference for the assessment. Assessments are performed in accordance with MCP-2532, Independent Assessments.

412.09
(02/16/2000 - Rev. 05)

Plan Radioactive Waste Management Complex	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 25 of 28
---	---	--

7.3 Audits

Facilities participating in the TWCP are subject to DOE-CAO audits. A DOE-CAO audit of the TWCP is conducted before waste is shipped to WIPP and annually thereafter. These audits are the responsibility of the DOE-CAO QA manager, who coordinates these audits through the SPM and SQAQ.

7.4 Surveillances

The surveillance program is conducted primarily to monitor work in progress and to follow up on corrective actions. Surveillance results are reported and monitored similarly to other assessment activities. Surveillances are performed in accordance with MCP-2992, QA Program Surveillances.

7.5 Reports to Management

The SQAQ provides the QA interface between facilities and the SPM. The SQAQ oversees the NCR/Document Action Request (DAR) process for TWCP-related deficiencies and coordinates with facility managers to track nonconformances and verify corrective action completion according to MCP-2993. FQAQ, report on the status of QA developments at their facility to the SQAQ. The SQAQ reports these independent assessment results to the SPM in accordance with MCP-2533, Reports to Management. Also, the SQAQ prepares and transmits a semiannual QA report to the SPM and the DOE. The semiannual QA report includes the following information, as appropriate:

- Any QAPjP changes
- Identification of any significant QA/QC problems, recommended solutions, and corrective actions
- An assessment of QC data collected during the period, including the frequency of repeated analyses, reasons they were repeated, and corrective actions
- Discussions of whether QAOs have been met and any resulting impact on decision making
- Limitations on the use of measurement data
- Status of PDP sample results
- Results of audits and surveillances conducted during the period.

7.6 Performance Demonstration Program

INEEL TWCP facilities participate in the Performance Demonstration Program (PDP) as summarized in the QAPjP. The PDP samples are processed according to the facility procedures applicable to the specific testing or analytical characterization activity being assessed.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 26 of 28
Radioactive Waste Management Complex		

8. SAMPLE CONTROL REQUIREMENTS

TWCP personnel use procedures to ensure proper documentation and tracking of sample possession from the time of collection/identification, through handling, preservation, shipment, transfer, analysis, storage, and final disposition. Sample control procedures used by TWCP personnel are described in PLN-190, INEEL Quality Assurance Project Plan for the Transuranic Waste Characterization Program, Section B-4a(3). TWCP personnel ship samples in compliance with DOT regulations and Project QA requirements.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182
Radioactive Waste Management Complex		Revision: 4
		Page: 27 of 28

9. SCIENTIFIC INVESTIGATION REQUIREMENTS

Because the INEEL TWCP does not conduct scientific investigations as defined by the DOE-CAO QAPD, Section 5, this section is not applicable.

412.09
(02/16/2000 - Rev. 05)

Plan	INEEL TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION QUALITY PROGRAM PLAN	Identifier: PLN-182 Revision: 4 Page: 28 of 28
Radioactive Waste Management Complex		

10. SOFTWARE REQUIREMENTS

Computer software and hardware/software configurations used in TWCP activities are developed, documented, verified, validated, tested, and controlled prior to use in compliance with requirements contained in the DOE-CAO QAPD, the INEEL TWCP QAPjP, and NQA-2, Subpart 2.7, "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications" (ASME 1989). MCP-2528, Computer Software Control, and MCP-1803, Configuration Control of SWEPP Hardware/Software, describe the processes for computer software development, validation, verification and control.