

**PERFORMANCE DEMONSTRATION PROGRAM
MANAGEMENT PLAN**

DOE/CBFO-01-3107

Revision 11

Effective: March 31, 2022



**U.S. Department of Energy
Carlsbad Field Office
Office of National TRU Program Waste Certification & Disposal**

This document supersedes DOE/CBFO-01-3107, Revision 10.

Performance Demonstration Program Management Plan

DOE/CBFO-01-3107

Revision 11

Effective: March 31, 2022

**U.S. Department of Energy
Carlsbad Field Office
Office of National TRU Program Waste Certification & Disposal**

Approved by: /Signature on File/ 03/31/2022
Kenneth E. Princen
Assistant Manager
Office of the National TRU Program
Waste Certification & Disposal
Date

Concurred by: /Signature on File/ 03/30/2022
Darren Jolley
Director
Quality Assurance Division
Date

Prepared by: /Signature on File/ 03/30/2022
DaBrisha Smith
PDP Appointee
Office of the National TRU Program
Waste Certification & Disposal
Date

TABLE OF CONTENTS

ACRONYMS	4
CHANGE HISTORY SUMMARY	5
1.0 <u>INTRODUCTION TO THE PERFORMANCE DEMONSTRATION PROGRAM</u>	9
2.0 <u>ORGANIZATION AND RESPONSIBILITIES</u>	12
2.1 CBFO	12
2.2 CTAC	12
2.3 PDP Manager	14
2.4 NDA PDP Coordinator	14
2.5 PDP Components Custodian.....	14
3.0 <u>TRAINING AND QUALIFICATION</u>	15
4.0 <u>QA GRADING ACTIVITIES</u>	16
5.0 <u>PROCUREMENT</u>	16
6.0 <u>NONCONFORMANCES AND CORRECTIVE ACTION</u>	18
7.0 <u>PDP QA RECORDS</u>	18
8.0 <u>PDP ASSESSMENTS</u>	18
9.0 <u>PDP SOFTWARE REQUIREMENTS</u>	18
10.0 <u>REFERENCES</u>	20
Attachment I—Example Documentation of Completion of Required Training.....	21

LIST OF FIGURES

Figure 1. Document Hierarchy	11
Figure 2. A Diagram of the Organizations, Lines of Communication, and Coordination for Implementing the PDP Requirements.....	13

ACRONYMS

CBFO	Carlsbad Field Office
CCA	Compliance Certification Application
CFAC	Custodial Facility Assay Coordinator
CRA	Compliance Recertification Application
CTAC	Carlsbad Field Office Technical Assistance Contractor
DOE	U. S. Department of Energy
MP	management procedure
NDA	nondestructive assay
PDP	Performance Demonstration Program
QA	quality assurance
QAPD	Quality Assurance Program Document
SPT	sample preparation team
TRU	transuranic
WAC	Waste Acceptance Criteria
WIPP	Waste Isolation Pilot Plant

CHANGE HISTORY SUMMARY

Revision Number	Description of Changes
1	<p><u>General</u></p> <ol style="list-style-type: none"> 1. The Performance Demonstration Program (PDP) Management Plan, Rev. 0, references contractor-level documents that do not exist. Specifically, the plan references "work instructions." With the change in Carlsbad Field Office Technical Assistance Contractor (CTAC) contractor, the work instructions have been replaced with contractor-level management procedures. The PDP Management Plan was revised to reflect this change. 2. Editorial changes were incorporated as appropriate to improve technical clarity. <p><u>Specific</u> (Section numbers refer to revision 0 unless otherwise noted)</p> <p>Page 6 – Added a description of the three elements of the PDP. Replaced reference to the National Transuranic Waste Certification Team with the National Transuranic Waste Program (NTWP). In first and last bulleted items, provided clarification between Drum NDA PDP Plan and Box NDA PDP Plan.</p> <p>Figure 1 – Changed “Work Instruction” to “Management Procedure” in three boxes under “Contractor documents.”</p> <p>Page 8 – Replaced “work instruction” with “management procedure.” Replaced “NTWCT Waste Characterization/Certification Manager” with “NTWP PDP Appointee” and showed that this individual will review the contractor-level management procedures rather than approve them.</p> <p>Figure 2 – Changed “CBFO-NTWCT Waste Characterization/Certification Manager” in first box with “CBFO NTWP PDP Appointee.” Added a box under NDA PDP Coordinator.</p> <p>Page 10 – Added bulleted item “Contractor MPs for each of the PDP elements” to list of required reading for PDP management personnel.</p> <p>Page 10 – Added complete title for CBFO MP 1.2, Selection of Quality Levels.</p> <p>Page 13 – Text revised to clarify PDP assessment schedules and requirements.</p> <p>Attachment 1 – Replaced PDP Training Requirements form with the revised form currently in use.</p>

CHANGE HISTORY SUMMARY

Revision Number	Description of Changes
2	<p><u>General</u></p> <ol style="list-style-type: none"> 1. The PDP Management Plan, Rev. 1, retained references to contractor-level documents that have been replaced. Specifically, Rev. 1 of the plan referenced "work instructions." With the change in CTAC contractor, the work instructions have been replaced with contractor-level management procedures. Rev. 1 of the PDP Management Plan retained the term "work instruction" in locations where the item referenced was not contained in the contractor-level management procedures to indicate that stand-alone documents of some sort existed for these materials. The PDP Management Plan was revised to clarify that work instructions as they originally existed are no longer used and avoids use of that term. 2. Editorial changes were incorporated as appropriate to improve technical clarity. 3. Throughout the PDP Plans for the various PDP elements (Headspace Gas [HSG], Resource Conservation and Recovery Act [RCRA], and Non-Destructive Assay), the term PDP coordinator is defined as an organization that CBFO designates to manage the PDP. In past revisions of this document, that term "contractor" has been used to define this organization. Because the PDP (or portions thereof) has been managed in the past by entities that were not under a contract to CBFO (e.g., the Idaho National Engineering and Environmental Laboratory), the term "contractor" has been deliberately avoided in the PDP Plans. All documents state that the PDP coordinator designates the PDP manager who, in turn, designates the PDP coordinators for the individual PDP elements. Language has been added to the text in this revision of the PDP Management Plan to make use of terminology consistent between the documents. <p><u>Specific</u> (Section numbers refer to revision 0 unless otherwise noted)</p> <p>Page 6 – Replaced reference to the National Transuranic Waste Program (NTWP) with the Office of Characterization and Transportation.</p> <p>Figure 1 – Changed "Work Instruction" to "Management Procedure" in three boxes under Contractor documents."</p> <p>Page 8 – Replaced "NTWP PDP Appointee" with "Office of Characterization and Transportation PDP Appointee."</p> <p>Figure 2 – Changed "CBFO NTWP PDP Appointee" in first box with "Office of Char. and Trans. PDP Appointee"</p> <p>Page 12 – The section Data Review and Validation has been deleted. In past revisions of this document, it stated that data submitted by participants were entered into spreadsheets that were maintained per Section 6.0 of the Carlsbad Field Office Quality Assurance Program Document (QAPD). The requirements for software used to be validated in accordance with QAPD Section 6.0 is already included in the section titled, PDP SOFTWARE REQUIREMENTS. Therefore, the material in this section was redundant and unnecessary.</p>

CHANGE HISTORY SUMMARY

Revision Number	Description of Changes
3	<p><u>General</u></p> <ol style="list-style-type: none"> 1. The PDP Management Plan was revised to enhance language associated with software verification and validation, supplier selection, and evaluation of supplier performance to ensure Carlsbad Field Office QAPD requirements are met by PDP activities. 2. Editorial changes were incorporated as appropriate to improve technical clarity. <p><u>Specific</u> (Section numbers refer to revision 2 unless otherwise noted)</p> <p>Page 11 – Basis for selection and evaluation of suppliers was revised to ensure conformance with the QAPD.</p> <p>Page 15 – Methods for verification and validation of calculations contained in Excel spreadsheets was added to ensure conformance to QAPD requirements.</p>
4	<p><u>General</u></p> <ol style="list-style-type: none"> 1. The PDP Management Plan was revised to accurately reflect the CBFO organization. 2. Section 3.0, Training and Qualification, was revised to include the routine training records managed by the Program Coordinator training coordinator. 3. Figure 2 was revised to eliminate reference to Argonne National Laboratory-East as the HSG PDP Sample Preparation Contractor.
5	<p><u>General</u></p> <ol style="list-style-type: none"> 1. Section 2 was revised to improve organizational roles and responsibilities. 2. Editorial changes were made for technical clarity. 3. Section 3 was revised to clarify training requirements.
6	<p><u>General</u></p> <ol style="list-style-type: none"> 1. References to the HSG and RCRA PDP Plans were deleted. Because this revision affected the entire Management Plan, no change bars were used. 2. Editorial changes were made for technical clarity.
7	<p><u>General</u></p> <ol style="list-style-type: none"> 1. Updates to the Carlsbad Field Office organizational structure were incorporated. 2. Editorial changes were made for technical clarity.

CHANGE HISTORY SUMMARY

Revision Number	Description of Changes
8	<u>General</u> <ol style="list-style-type: none"><li data-bbox="487 346 1466 388">1. A complete change history was included.<li data-bbox="487 399 1466 472">2. Clarifications to the requirements regarding the Program Coordinator quality assurance program and implementing documents were incorporated.<li data-bbox="487 483 1466 525">3. Editorial changes were made for technical clarity.
9	<u>General</u> <ol style="list-style-type: none"><li data-bbox="487 577 1466 651">1. Updates to the Carlsbad Field Office organizational structure were incorporated.<li data-bbox="487 661 1466 703">2. Editorial changes were made for technical clarity.
10	<u>General</u> <ol style="list-style-type: none"><li data-bbox="487 756 1466 829">1. Updates to the Program Coordinator quality assurance program and implementing documents were incorporated.<li data-bbox="487 840 1466 882">2. Editorial changes were made for technical clarity.
11	<u>General</u> <ol style="list-style-type: none"><li data-bbox="487 934 1466 1008">1. Updates to the Carlsbad Field Office organizational structure were incorporated.<li data-bbox="487 1018 1466 1123">2. References to DOE/CBFO-21-3630, <i>Performance Demonstration Program Plan for Nondestructive Assay of Criticality Control Overpacks for the TRU Waste Characterization Program</i>, were incorporated.<li data-bbox="487 1134 1466 1218">3. Editorial and formatting changes were made for technical clarity and consistency.

1.0 INTRODUCTION TO THE PERFORMANCE DEMONSTRATION PROGRAM

The U.S. Department of Energy (DOE) Waste Isolation Pilot Plant (WIPP) is permitted for the disposal of transuranic (TRU) waste. All TRU waste shipped to WIPP must be characterized by a WIPP-certified program in compliance with WIPP's disposal, packaging, and transportation requirements, as outlined in DOE/WIPP-02-3122, *Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant* (WAC). Prior to achieving WIPP certification, Carlsbad Field Office (CBFO) designated TRU waste programs must develop and implement a quality assurance program that meets all applicable requirements of DOE/CBFO-94-1012, *Quality Assurance Program Document* (QAPD). When implementing the WAC, radiological characterization requirements for TRU waste include the successful participation in the Performance Demonstration Program (PDP). The PDP serves as a measurement comparison program and quality control check for data generated in the characterization of waste destined for the WIPP. Single blind audit samples assembled at each characterization site are used to evaluate analyses of alpha-emitting TRU radionuclides by nondestructive assay (NDA) techniques.

Within the DOE Carlsbad Field Office (CBFO), the Office of National TRU Program Waste Certification & Disposal oversees and is the review and approval authority for all PDP activities. The overall management of the PDP is described in this Management Plan. Separate NDA PDP Plans describe the activities associated with the NDA PDP elements. The PDP includes the following plans:

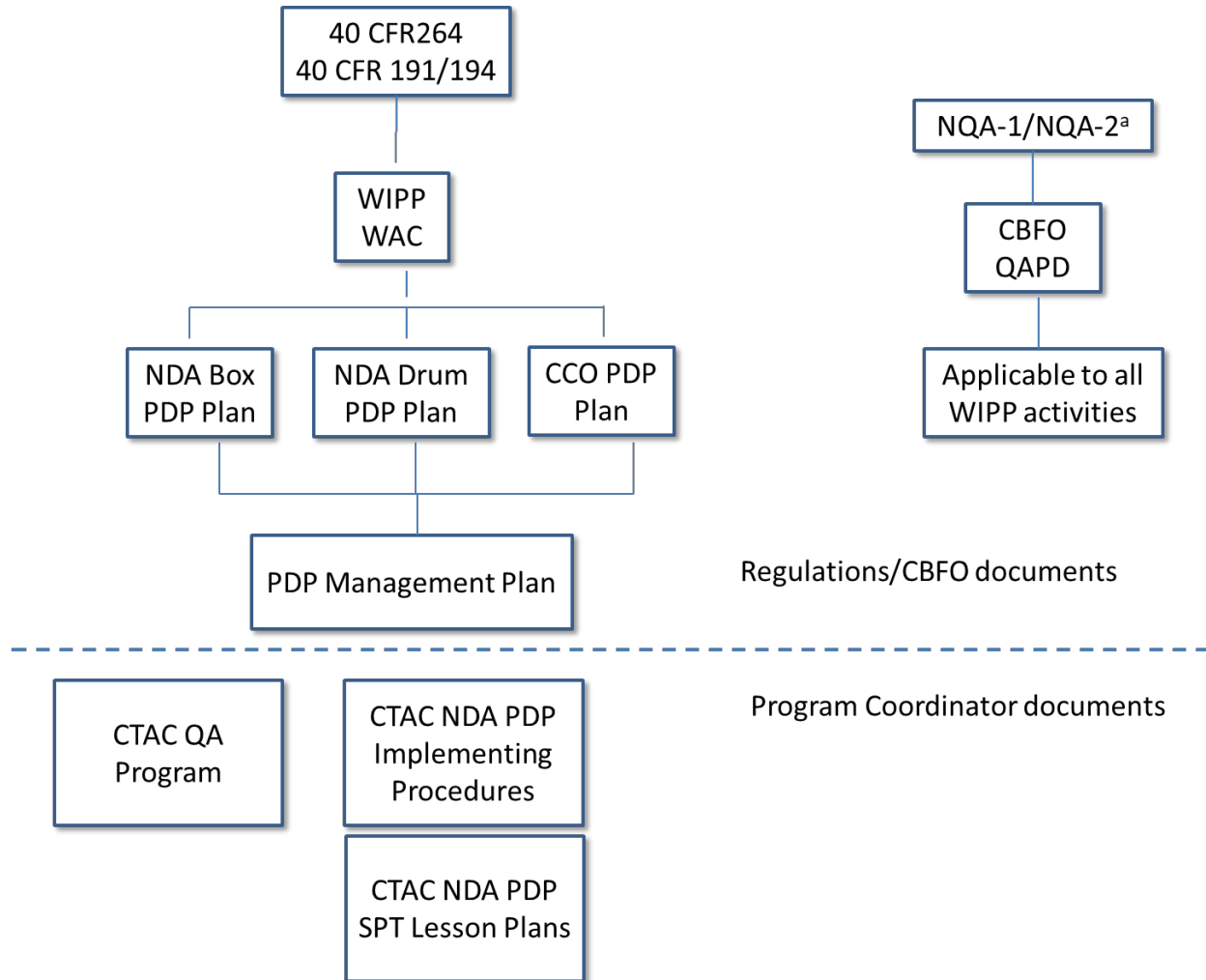
- DOE/CBFO-01-1005, *Performance Demonstration Program Plan for Nondestructive Assay of Drummed Wastes for the TRU Waste Characterization Program* (Drum NDA PDP Plan),
- DOE/CBFO-01-1006, *Performance Demonstration Program Plan for Nondestructive Assay of Boxed Wastes for the TRU Waste Characterization Program* (Box NDA PDP Plan), and
- DOE/CBFO-21-3630, *Performance Demonstration Program Plan for Nondestructive Assay of Criticality Control Overpacks for the TRU Waste Characterization Program*.

The CBFO implements the PDP by designating a Program Coordinator (currently the CBFO Technical Assistance Contractor [CTAC]), and by providing program oversight. The purpose of this Management Plan is to identify how the requirements applicable to the PDP are to be implemented during the management and coordination of PDP activities by the Program Coordinator. The Custodial Facility Assay Coordinator (CFAC), sample preparation team (SPT), and PDP participants (i.e., the measurement organizations conducting NDA at the waste generator sites, the expert analysts, and organizations reporting the final measurement results) are not controlled under this Management Plan. The Management Plan is specifically for use by the CBFO and CTAC. Activities and roles of the CFAC, SPT and the participants for the waste generator sites during the conduct of a PDP cycle are described in the respective PDP Plans listed above and are governed by their respective QA program and procedures, or as otherwise directed by CBFO.

The primary documents governing the conduct of the NDA PDP are:

- DOE/CBFO-94-1012, *Quality Assurance Program Document (QAPD)*
- DOE/CAO-1996-2184, *Compliance Certification Application (CCA)*
- DOE/WIPP-09-3424, *Compliance Recertification Application-2009 (CRA)*
- DOE/WIPP-02-3122, *Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant (WAC)*

These documents require each of the measurement organizations and NDA systems that provide data for the characterization of TRU waste for disposal at WIPP to participate in the applicable PDP element. The three NDA PDP Plans implement the applicable general requirements of the QAPD, CCA, CRA, and WAC. The management and coordination of the PDP are conducted in full compliance with applicable requirements. The relationship of the applicable documents is illustrated in Figure 1. As shown in the figure, the NDA PDP Plans are higher-level documents than the PDP Management Plan. Therefore, in cases where requirements specified in these plans conflict, the element-specific NDA PDP Plan takes precedence.



^aThe complete reference for the applicable documents is: ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7 to ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c) and Section 17.1).

Figure 1. Document Hierarchy

Figure 1 also shows the relationship to the Program Coordinator's QA program and procedures that implement the requirements of the applicable NDA PDP Plan(s) and this Management Plan. The PDP is a quality-affecting activity and work conducted under the Program Coordinator's QA program must comply with the applicable requirements of the CBFO QAPD. At a minimum, the Program Coordinator shall maintain a QA program with implementing procedures for:

- conduct of the Nondestructive Assay Performance Demonstration Programs,
- training,
- procurement,
- corrective actions or issues management,
- nonconformance reporting, disposition and closure, and
- records management.

These procedures shall be reviewed by the CBFO PDP Appointee to ensure adequate implementation of the respective PDP plans.

This Management Plan will be reviewed and revised as necessary to incorporate any changes in CBFO documents that affect the program, including the QAPD, WAC, CBFO management procedures (MPs), or PDP plan(s). The review of and any resultant changes to this Management Plan will be documented.

2.0 ORGANIZATION AND RESPONSIBILITIES

2.1 CBFO

The CBFO is responsible for ensuring the implementation of this Management Plan and assigns a federal individual from the Office of National TRU Program Waste Certification & Disposal as the PDP Appointee to provide technical oversight and coordination for the program. The CBFO PDP Appointee is the reviewing and approving authority for all PDP activities. The CBFO, supported by the Program Coordinator, evaluates and approves an individual waste generator site performance for participation in the WIPP TRU waste disposal characterization program.

2.2 CTAC

The Program Coordinator designates the PDP Manager and administers PDP functions to qualify measurement organizations that are active in waste characterization for the participating TRU waste generator sites.

A diagram of the organizations, lines of communication, and coordination for implementing the PDP requirements is shown in Figure 2, and the responsibilities for implementing and managing the program within the contractor organization are discussed below.

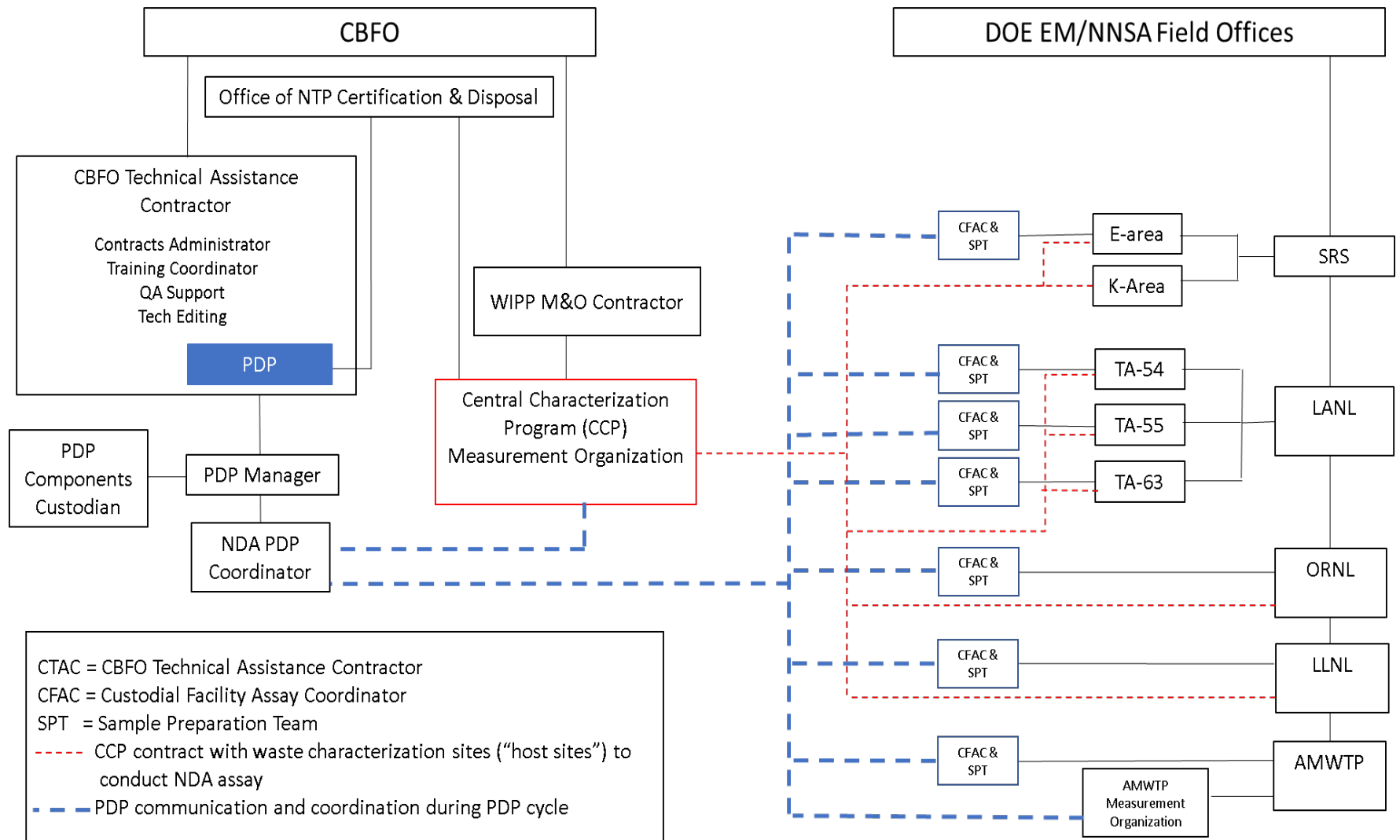


Figure 2. A Diagram of the Organizations, Lines of Communication, and Coordination for Implementing the PDP Requirements

2.3 PDP Manager

The Program Coordinator assigns overall PDP responsibilities to the PDP Manager. The PDP Manager ensures that all PDP responsibilities identified in the NDA PDP Plans, and those implemented through this Management Plan and the applicable CBFO MPs, are met. The PDP Manager:

- Routinely evaluates PDP performance in support of the CBFO and reviews and approves outgoing documentation associated with the PDP.
- Reports to the PDP Appointee and oversees and coordinates PDP activities.
- Serves as the central point-of-contact for technical issues, scheduling, assessment interfaces, quality improvement, and other matters affecting the PDP.
- Designates an NDA PDP Coordinator.
- Designates a PDP Components Custodian.
- Provides prime direction to the NDA PDP Coordinator and PDP Components Custodian, prepares corrective documentation, and coordinates the preparation of PDP budget documents to ensure that adequate resources are available to meet program goals and milestones.

2.4 NDA PDP Coordinator

The NDA PDP Coordinator is responsible for accomplishing the day-to-day tasks associated with the implementation of the PDP Management Plan. Tasks are defined in each of the PDP Plans and are conducted in accordance with the NDA PDP implementing procedure prepared by the NDA PDP Coordinator and approved by the PDP Manager. The NDA PDP Coordinator is responsible for ensuring quality and for promptly reporting all potential conditions adverse to quality to the PDP Manager for evaluation and action as outlined in Section 6 of this plan.

2.5 PDP Components Custodian

The Program Coordinator maintains an inventory of NDA PDP equipment and spare parts in support of CBFO and to ensure efficient programmatic operations. The PDP Manager designates a custodian responsible for maintaining NDA equipment (matrices, internal components, drums and boxes), providing shipping support for PDP equipment, and maintaining accountability of all PDP equipment in the storage unit. Detailed responsibilities for the Components Custodian include the following:

- Assessing the condition of various PDP components to differentiate between conditions warranting refurbishment or components requiring replacement; supporting procurement-related activities such as drafting the statements of work and determining suitable vendors for necessary PDP components; overseeing the refurbishment; and providing support to QA activities such as receipt inspection to ensure the procured components

and the refurbishment activities meet the documented design specifications and that the procurements are conducted in accordance with the QAPD.

- Securing drums or standard waste boxes to pallets, arranging bill of lading for freight carrier service, transporting to and from local establishments for refurbishment, and coordinating exchanges with custodians at each waste generator site.
- Conducting an annual inventory of the storage unit.

The NDA PDP Coordinator may also serve as the PDP Components Custodian.

3.0 TRAINING AND QUALIFICATION

Personnel involved in PDP management activities shall be qualified and trained as follows.

At a minimum, the PDP Manager and NDA PDP Coordinator shall have a bachelor's degree in science or engineering and at least five years of professional experience related to the type of PDP activities that are being coordinated. Qualification and contractor training documentation shall be entered into the CBFO records system. The PDP Manager is responsible for selecting qualified personnel and ensuring the appropriate training is completed.

The minimum required training elements for PDP personnel include reading the current revision of the documents listed below, and any other documents identified as required reading by the PDP Manager. Completion of the reading requirement shall be auditable and may be documented on a form such as shown in Attachment I (or on an equivalent form), via a "read and sign" notice, or in accordance with the Program Coordinator's approved training implementing procedure. The Program Coordinator's Training Coordinator is responsible for notifying PDP personnel of refresher training or training updates as documents are revised and formally issued. The Training Coordinator shall ensure that documentation of completed training is maintained in QA records in accordance with CBFO MP 4.5, *Generating, Receiving, Storing, and Controlling Active CBFO Program Records*, and CBFO MP 4.9, *Quality Assurance Records*.

- CBFO QAPD (DOE/CBFO-94-1012)
- WIPP WAC (DOE/WIPP-02-3122)
- CBFO PDP Management Plan (DOE/CBFO-01-3107)
- CBFO NDA PDP Plan for Boxed Wastes (DOE/CBFO-01-1006)
- CBFO NDA PDP Plan for Drummed Wastes (DOE/CBFO-01-1005)
- CBFO CCO PDP Plan (DOE/CBFO-21-3630)
- CBFO MP 1.2, *Grading Activities and Determination of Quality Levels*
- CBFO MP 3.1, *Corrective Action Reports*
- CBFO MP 4.5, *Generating, Receiving, Storing, and Controlling Active CBFO Program Records*
- CBFO MP 4.9, *Quality Assurance Records*

- Program Coordinator's QA program and implementing procedures for the conduct of the Nondestructive Assay Performance Demonstration Programs, training, procurement, corrective actions or issues management, nonconformance reporting, disposition and closure, and records management.

4.0 QA GRADING ACTIVITIES

The CBFO, assisted by the Program Coordinator, will perform PDP activity grading in accordance with CBFO MP 1.2, *Grading Activities and Determination of Quality Levels*, and will also document and retain the evaluation as required by MP 1.2. The grading applies only to the specific controls placed on the activity and not the requirements. In no case will requirements be graded out of the program.

5.0 PROCUREMENT

CTAC, as the Program Coordinator, implements procurements for continuing operations of the PDP. These may include procurements for:

- Consultant support contracts to obtain the services of an individual with extensive experience in developing and maintaining operations of the PDP, or
- Supplier procurement contracts with commercial suppliers for manufacture of PDP equipment and accessories (e.g., NDA PDP drums, boxes, matrix modules, matrix spacers, and the spare parts associated with these items).

Procurements may involve subcontractors who have previous documented and acceptable performance in support of the PDP. No procurement will exceed the scope of work currently being performed. All applicable procurement requirements of the QAPD shall be met. PDP procurements conducted by the Program Coordinator will be in accordance with procedures written to support the procurement function and will be performed as follows.

Typically, procurement documentation is prepared by the NDA PDP Coordinator or Components Custodian and reviewed and approved by the PDP Manager. The PDP Manager, Program Coordinator's Contracts Administrator, and a QA support individual shall ensure that all applicable elements required by the QAPD are appropriately incorporated in the procurement documents. The PDP Manager is responsible for final review and approval of procurement documentation and for ensuring that the applicable QAPD procurement requirements and the contractor organization's procurement requirements are addressed. The reviews and approvals shall be documented in accordance with the Program Coordinator's procedure for procurement.

The Program Coordinator's Contracts Administrator, in conjunction with the PDP Manager, shall select the procurement source and document the basis for selection.

Suppliers will be selected consistent with the requirements for supplier selection specified in the QAPD. Prospective suppliers shall initially be evaluated and selected on the basis of documented criteria and the PDP Manager and/or applicable PDP Coordinator shall verify that approved suppliers continue to provide acceptable items and services. Supplier selection shall be

based on evaluation of the supplier's capability to provide items or services in accordance with procurement document requirements by performing one or more of the following elements:

1. An evaluation of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use.
2. An evaluation of the supplier's current QA documentation, supported by any documented qualitative and quantitative information.
3. An evaluation of the supplier's technical and QA capability, based on an evaluation of the supplier's facilities, personnel, and quality program implementation.

An evaluation of the supplier's continued performance shall be conducted at least every three years. Evaluations entail review of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use, and examination of the current QA documentation, supported by any documented qualitative and quantitative information, in accordance with approved implementing procedures to determine continued satisfactory performance. These surveillances or evaluations shall be conducted more frequently if performance problems are encountered, or other situations warrant it.

Supplier bids shall be evaluated based upon the following criteria:

- Conformance to the procurement documents (statement of work)
- Technical considerations
- QA requirements
- Prospective supplier's personnel, production capability, past performance, and any exceptions taken. All unacceptable quality conditions shall be resolved prior to order placement.

The NDA PDP Coordinator will perform and document an annual review of each subcontracted supplier or conduct receipt inspections of quality-affecting items to ensure the supplier is performing acceptably. If the results of the review indicate the need, an onsite assessment will be performed.

The NDA PDP Coordinator shall review and document acceptance of the supplier's deliverables to ensure that they meet the procurement requirements. Items that do not conform to specified requirements shall be controlled to prevent inadvertent use or installation. The NDA PDP Coordinator shall also review and approve the disposition of any PDP supplier nonconformance documentation.

Changes to procurement documents require the same degree of control and review as the original procurement documents. Procurement documents and other records generated during the procurement of PDP items and services are QA records. QA records shall be processed in accordance with CBFO MP 4.5 and CBFO MP 4.9. PDP procurement QA records have been determined to be nonpermanent.

6.0 NONCONFORMANCES AND CORRECTIVE ACTION

Conditions adverse to quality identified during the conduct of the PDP and related to the measurement organization's operation are documented and evaluated in accordance with CBFO MP 3.1, *Corrective Action Reports*. Conditions adverse to quality that are specific to the Program Coordinator will be addressed in accordance with the Program Coordinator's QA program documents. Nonconformances associated with procurement of items or services must be addressed by the Program Coordinator's implementing procedures. Whenever significant conditions adverse to quality are identified, the corrective action process must address appropriate remedial actions, investigation, root cause determination, and actions to preclude recurrence.

7.0 PDP QA RECORDS

PDP QA records are designated as nonpermanent. All PDP documents classified as QA records that are prepared by the Program Coordinator in its PDP support capacity shall be transmitted to the CBFO for appropriate management and retention. Documentation in process is maintained with reasonable protection prior to completion. In accordance with the CBFO QAPD, documentation is not considered to be a QA record until it has been completed. CBFO accepts the data, approves the final issuance of results and other documentation, and processes the records in accordance with CBFO MP 4.5 and CBFO MP 4.9.

Records generated by participants that are associated with PDP analyses and measurements are considered QA records and must be maintained by the individual participant in accordance with the CBFO QAPD (section 1.5, Records).

PDP QA records are identified in each of the NDA PDP Plans. The Program Coordinator's procedure for the conduct of the NDA PDP should identify the specific records that are generated during PDP implementation. QA records management, including disposition, when applicable, will be maintained in accordance with CBFO MP 4.5.

8.0 PDP ASSESSMENTS

In addition to the routine reviews of internal activities by the PDP Manager during the conduct of the PDP cycles, the Program Coordinator shall ensure management assessments are conducted periodically. The Contracting Officer shall ensure that applicable aspects of the Program Coordinator's QA program are reviewed and approved by CBFO. CBFO will perform periodic (not to exceed three years) assessments of the PDP, including the Program Coordinator's processes for assuring specified quality objectives are achieved during procurements of PDP related items or services and acceptance and receipt activities. These assessments are performed in accordance with the requirements of the CBFO QAPD.

9.0 PDP SOFTWARE REQUIREMENTS

Any PDP software used for scoring analytical and other measurement results (i.e., spreadsheets developed using commercial software such as Microsoft Excel) shall be in conformance with QAPD requirements. Commercial software is exempt from the software control requirements of

QAPD section 6.0; however, the applications of such commercial software are not exempt from the software control requirements of section 6.0.

Spreadsheet applications produced using the software shall be fully documented and validated according to applicable QAPD requirements. The NDA PDP Coordinator is responsible for ensuring that any spreadsheet development and use is properly documented and validated.

Any spreadsheet developed and used for a PDP activity to obtain final results shall be identified with a revision or version number. Because these spreadsheets will be used only by the NDA PDP Coordinator and possibly a trained backup individual, software distribution and control does not pose a concern. Any newly developed spreadsheets used to obtain final results and any changes to existing spreadsheets used to obtain final results shall be validated by comparing software results with hand calculations or other appropriate means. The hand calculations could be performed by the PDP manager, the NDA PDP Coordinator, or a qualified independent reviewer. Any subsequent revision shall be revalidated by comparing the new results with the values obtained before the change or through some other comparison. The specific validation tests shall be designed to cover the entire range of interest and shall be documented. Records associated with validation of such scoring spreadsheets shall be maintained in the CBFO records system.

If a spreadsheet is used to obtain final results, the calculations performed by the spreadsheet will be verified and validated by verifying that the spreadsheet works correctly over the expected range of the input variables, and documented by issuing a memorandum record containing the following information to the CBFO PDP Appointee:

- Name and version of the software used
- Name and version number (required) of the spreadsheet, and the name of the developer
- Scope of the computation
- Data entry process description
- List and definition of named variables
- Definition of complex formulas (i.e., formulas not easily deduced by inspection of the spreadsheet or macro)
- Documentation of the verification of the software (by hand calculation or other means)
- An electronic disk copy of the spreadsheet set up to run one of the documented verification tests
- Inputs, output results, and ancillary data (if used).

If spreadsheets containing formulas are used to obtain preliminary results, the results of all formulas used in the spreadsheet must be verified and documented prior to using the results as final data.

10.0 REFERENCES

- 40 CFR Part 191, Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-level and Transuranic Radioactive Wastes
- 40 CFR Part 194, Criteria for the Certification and Re-certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations
- 40 CFR Part 264, *Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities*
- DOE/CBFO-94-1012, *Quality Assurance Program Document*, current revision, U.S. Department of Energy Carlsbad Field Office
- DOE/CAO-1996-2184, *Title 40 Part 191, Compliance Certification Application for the Waste Isolation Pilot Plant*, U.S. Department of Energy Carlsbad Field Office
- DOE/CBFO-01-1005, *Performance Demonstration Program Plan for Nondestructive Assay of Drummed Wastes for the TRU Waste Characterization Program*, current revision, U.S. Department of Energy Carlsbad Field Office
- DOE/CBFO-01-1006, *Performance Demonstration Program Plan for Nondestructive Assay of Boxed Wastes for the TRU Waste Characterization Program*, current revision, U.S. Department of Energy Carlsbad Field Office
- DOE/CBFO-21-3630, *Performance Demonstration Program Plan for Nondestructive Assay of Criticality Control Overpacks for the TRU Waste Characterization Program*
- DOE/WIPP-02-3122, *Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant*, current revision, U.S. Department of Energy Carlsbad Field Office
- DOE/WIPP 09-3424, *40 CFR Part 191 and 194, Compliance Recertification Application for the Waste Isolation Pilot Plant*, U.S. Department of Energy Carlsbad, New Mexico
- CBFO MP 1.2, *Grading Activities and Determination of Quality Levels*, current revision, U.S. Department of Energy Carlsbad Field Office
- CBFO MP 3.1, *Corrective Action Reports*, current revision, U.S. Department of Energy Carlsbad Field Office
- CBFO MP 4.5, *Generating, Receiving, Storing, and Controlling Active CBFO Program Records*, current revision, U.S. Department of Energy Carlsbad Field Office
- CBFO MP 4.9, *Quality Assurance Records*, current revision, U.S. Department of Energy Carlsbad Field Office

**Attachment I—Example Documentation of Completion of Required Training
CTAC Training Requirements for Performance Demonstration Program (PDP)
Support to CBFO**

NAME: _____ **POSITION:** _____

1. Prior to performing quality-affecting work, training must be completed and documented.
2. Specific training requirements for your position are identified by an “X” in the “Req.” column.
3. Be sure to document the training for the last revision of the document; list the revision number.
4. List the Training Type(s) used:
C = Classroom
R = Reading
B = Briefing
T = Test Required at Completion
5. For each of the required training elements, acknowledge that you have completed each assigned element by listing the date completed and signing the form.

Training Element	Rev.	Req.	Training Type(s)	Date
CBFO QAPD (DOE/CBFO-94-1012)				
WIPP WAC (DOE/WIPP-02-3122)				
CBFO NDA PDP Plan for Drummed Wastes (DOE/CBFO-01-1005)				
CBFO NDA PDP Plan for Boxed Wastes (DOE/CBFO-01-1006)				
CBFO CCO PDP Plan (DOE/CBFO-21-3630)				
CBFO PDP Management Plan (DOE/CBFO-01-3107)				
CBFO MP 1.2, <i>Grading Activities and Determination of Quality Levels</i>				
CBFO MP 3.1, <i>Corrective Action Reports</i>				
CBFO MP 4.5, <i>Generating, Receiving, Storing, and Controlling Active CBFO Program Records</i>				
CBFO MP 4.9, <i>Quality Assurance Records</i>				
Program Coordinator QA Program and implementing procedure for <ul style="list-style-type: none"> • conduct of the Non-Destructive Assay Performance Demonstration Program, • training, • procurement, • corrective actions or issues management, • nonconformance reporting, disposition and closure, and • records management 				
Other				
Other				

Training Assigned By: _____ Date: _____

Training Completed By: _____ Date: _____