

CCP-QP-001

Revision 5

CCP Graded Approach

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PRINTED NAME

APPROVED FOR USE

RECORD OF REVISION

Revision Number	Date Approved	Description of Revision
2	04/09/2002	Revised Scope; Modified Attachment 1-QA Grading Level Determination Checklist; Added a Table of Contents; Added the functions and responsibilities of a CCP Qual Level Database Administrator, Paragraph; Added Attachment 3 - Standard Quality Assurance Clauses and User Guide; Added notes between 4.1.1 and 4.1.2, 4.1.5 and 4.1.6, and 4.1.11 and 4.1.12; Modified wording in step 4.1.7 and 4.1.8.
3	03/29/2005	Revised to modify Attachment 1 form and update references in procedure. Added step 4.1.11 and 4.1.12. Added new Section 4.2. Deleted Attachment 3. Added ID# to Attachment 1.
4	11/16/2006	Revised to implement the Waste Isolation Pilot Plant Hazardous Waste Facility Permit requirements resulting from the Section 311/Remote-Handled (RH) Permit Modification Request (PMR).
5	09/18/2008	Revised to better define Graded Approach per DOE/CBFO-94-1012, <i>U.S. Department of Energy Carlsbad Field Office Quality Assurance Program Document</i> . Also revised to assign technical expertise to select grading requirements and provide for Department of Energy (DOE)/Carlsbad Field Office (CBFO) Quality Assurance (QA) Manager's approval.

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1.0 PURPOSE

This procedure provides instructions for implementing a graded approach to applying management and Quality Assurance (QA) controls to Central Characterization Project (CCP) items, services, and activities associated with transuranic (TRU) waste characterization, certification, packaging, and transportation to the Waste Isolation Pilot Plant (WIPP) for disposal.

1.1 Scope

This procedure defines the method for determining the appropriate level of quality controls necessary to manage the items, services, and activities, including software, necessary to ship TRU waste to the WIPP. This procedure is to be used by CCP personnel and subcontractors responsible for procurement, waste characterization, waste certification, waste packaging, and waste transportation, including Measuring and Test Equipment (M&TE), and Monitoring and Data Collection (M&DC) which takes a quantitative measurement with limits established by procedure or requirement.

The extent of management and QA controls applied to an item or activity will vary as a function of the degree of confidence needed to achieve the desired quality of the item or activity. The grading process provides the flexibility to design and implement controls that best suit the facility or activity. Each organization should develop their own method to determine that the defined grading process is effective. The use of the graded approach shall determine the appropriate level of controls necessary to manage the items, systems, and activities necessary to ship TRU waste to the WIPP.

Items such as office supplies and maintenance tools that do not require calibration, and activities that are administrative in nature or do not directly affect activities, or data associated with those described in the previous paragraph, are exempted from the requirements of this procedure.

QA levels are described in Attachment 2, Detailed Descriptions of the Management and QA Control Provisions Corresponding to Quality Levels (QL), of this procedure, and the criteria used in selecting the appropriate QA level for a particular item, service or activity is detailed in Attachment 1, QA Grading Level Determination Checklist.

The use of the graded approach will determine the appropriate level of controls necessary to manage the items, services, and activities necessary to ship TRU waste to the WIPP.

Grading methods will provide for:

- The assignment of management and QA control levels
- The definitive criteria used in selecting those levels
- Detailed descriptions of the management and QA controls which correspond to those levels based on the definitive criteria.

2.0 REQUIREMENTS

Baseline Documents

- DOE/CBFO-94-1012, *U.S. Department of Energy Carlsbad Field Office Quality Assurance Program Document*
- DOE/WIPP-02-3214, *Remote-Handled TRU Waste Characterization Program Implementation Plan*

Referenced Documents

- CCP-QP-008, *CCP Records Management*
- CCP-QP-015, *CCP Procurement*
- CCP-QP-022, *CCP Software Quality Assurance Plan*
- CCP-PO-001, *CCP Transuranic Waste Characterization and Quality Assurance Project Plan*
- CCP-PO-002, *CCP Transuranic Waste Certification Plan*
- CCP-PO-003, *CCP Transuranic Authorized Methods for Payload Control (CCP CH-TRAMPAC)*
- WP13-QA-3012, *Supplier Evaluation/Qualification*

2.1 Graded Approach Factors

The graded approach is the process by which the level of analysis, documentation, verification, and other controls necessary to comply with QA program requirements are developed commensurate with the following factors:

- The importance of an item or activity with respect to safety, waste isolation, and regulatory compliance
- The importance of the data to be generated
- The need to demonstrate compliance with specific regulatory design and QA requirements
- The impact on the results of performance assessments and engineering analyses
- The magnitude of any hazard or the consequences of failure
- The life-cycle stage of a facility or item
- The programmatic mission of a facility
- The particular characteristics of a facility, item, or activity (e.g., complexity, uniqueness, history, or the necessity for special controls or processes)
- The relative importance of radiological and non-radiological hazards

3.0 RESPONSIBILITIES

3.1 Initiator (CCP requesting personnel)

3.1.1 Reviews the items, services, or activities, related to CCP TRU waste characterization, certification, packaging, and transportation, and works with the Cognizant Manager (CM)/Technical Specialist and CCP QA to determine the appropriate quality requirements.

3.1.2 Documents on Attachment 1 the QA controls determined to be needed.

3.1.3 Applies the QA controls determined to be needed and ensures the identified QA controls are current.

3.2 Cognizant Manager (CM)/Technical Specialist

3.2.1 Provides technical input to the initiator and QA and delineates the requirements based on the elements identified in Section 2.1.

3.3 CCP Quality Assurance (QA)

3.3.1 Develops and maintains the Graded Approach Program (GAP) for the CCP including administering the Graded Approach Database.

3.3.2 Ensures proper application of the CCP QA Program.

3.3.3 Ensures coordination, implementation, and oversight of the GAP.

3.3.4 Ensures the establishment of QA controls appropriate to the work activities to be performed.

3.3.5 Ensures information from Attachment 1 is entered into the Graded Approach Database.

3.3.6 Submits Attachment 1 to CCP Records.

4.0 PROCEDURE

4.1 Grading Items, Services, and Activities for Application of QA Controls

NOTE

See descriptions of quality levels in Attachment 2.

Initiator

NOTE

The CCP Graded Approach Database is located on the WIPP Intranet by accessing <http://bellview/> and clicking on Business Management then on Procurement then on CCP Graded Approach Database. The CCP Graded Approach Database may also be accessed through the CCP Data Center on the QA Data page.

- 4.1.1 Check the CCP Graded Approach Database prior to initiating the graded approach process for items, services, or activities to determine if QA applicability has previously been determined.
- 4.1.2 **IF** there have been **NO** changes that would affect the previously determined QA applicability for the item, services, or activity, **THEN STOP AND** apply the QA controls as listed in the CCP Graded Approach Database, otherwise, proceed with step 4.1.3.
- 4.1.3 **IF** QA applicability has **NOT** previously been determined, **OR** there have been changes to the item, services, or activity, **THEN** determine QA applicability in accordance with Attachment 1.
- 4.1.4 Identify facility location and describe the item in the spaces provided on Attachment 1.
- 4.1.5 Complete Attachment 1 per instructions on the attachment.
- 4.1.6 Print name, sign, and date as Initiator on Attachment 1.
- 4.1.7 Forward to CM or Technical Specialist for review, **AND** obtain approval signature on Attachment 1.
- 4.1.8 Forward completed Attachment 1 to CCP QA for review, approval, and signature.

CCP QA

4.1.9 Review, approve, sign, and date completed Attachment 1, **AND** return to the Initiator.

4.1.10 **IF** concurrence is **NOT** given,
THEN return Attachment 1 to Initiator for resolution.

Initiator

4.1.11 **IF** CCP QA did **NOT** concur with completed Attachment 1,
THEN resubmit to CCP QA upon resolution.

4.1.12 Forward the original Attachment 1 to the CCP QA.

CCP QA

4.1.13 Enter data from Attachment 1 into the CCP Graded Approach Database.

NOTE

The quality level, item description, and quality requirements, are entered into the CCP Graded Approach Database. Data is password protected and can only be entered (authenticated) by authorized personnel. Authorized personnel include the CCP QA and CCP Graded Approach Database Administrator.

4.1.14 Submit Attachment 1 to CCP Records.

4.2 Qualified Supplier List (QSL) Determination

NOTE

Not all items, services, or activities that will be performed under the WTS CCP QA Program require the use of a QSL vendor.

Initiator

4.2.1 **IF** the desired item, service, or activity is graded as QL1 or QL2,
AND is commercially available,
THEN GO TO CCP-QP-015, *CCP Procurement*, to initiate the procurement process.

- 4.2.2 **IF** the desired item, service, or activity is graded QL1 or QL2, **AND** is **NOT** commercially available, **THEN GO TO** WP 13-QA3012, *Supplier Evaluation/Qualification*, to initiate the QSL process.

5.0 RECORDS

Records generated during the performance of this procedure are maintained as QA records in accordance with CCP-QP-008, *CCP Records Management*. The records are the following:

5.1 QA/Nonpermanent

5.1.1 Attachment 1 – QA Grading Level Determination Checklist

5.2 Non-QA

5.2.1 CCP Graded Approach Database (Electronic)

Attachment 1 – QA Grading Level Determination Checklist

ID# _____

Facility Location:					
Description of Item, Service or Activity:					
System: (Check All that Apply)		<input type="checkbox"/> HSG	<input type="checkbox"/> NDA	<input type="checkbox"/> NDE	<input type="checkbox"/> Other:
Section A - Nuclear Processes and Regulatory Compliance Issues					
		Criterion	Yes	No	Quality Requirements
Quality Level 1	A.1	Does the item, service or activity affect the potential to breach (drop, crash, puncture, etc.) of any waste container?			
	A.2	Does the item, service or activity affect the confinement or shielding of radioactive material?			
	A.3	Does the item, system or activity affect characterization, certification, packaging or transportation requirements as delineated in CCP-PO-001, <i>CCP Transuranic Waste Characterization and Quality Assurance Project Plan</i> , CCP-PO-002, <i>CCP Transuranic Waste Certification Plan</i> , or CCP-PO-003, <i>Contact Handled Transuranic Waste Authorized Methods for Payload Control (CCP CH-TRAMPAC)</i> ?			
	A.4	Does the item, service or activity require a quantitative measurement? (If yes, the item must be calibrated in-house or by a QSL vendor, and controlled by the CCP calibration program).			
	A.5	Does the item, service or activity affect computations, computer codes, or methods used to demonstrate compliance with CCP-PO-001 or CCP-PO-002? (If yes, the software must be controlled through CCP-QP-022, <i>CCP Software Quality Assurance Plan</i>).			
Instructions: Check Yes or No for each criteria. If any of the above blocks are checked "Yes" the Quality Level is 1 and all applicable QA requirements apply. Proceed with Section B.					

Attachment 1 – QA Grading Level Determination Checklist (continued)

ID# _____

Section B - Special Provisions					
Criterion			Yes	No	Quality Requirements
Quality Level 2	B.1	Is the item, service, or activity addressed by a recognized industry code or standard, which requires certification?			
	B.2	Does the item, service, or activity require material certification or testing that are either difficult or impossible to verify at a later point or tests which must be performed at some intermediate stage during fabrication?			
	B.3	Are there additional certifications or verifications warranted by unique conditions for the item, service or activity, as determined by the cognizant individual?			
	B.4	Does the item, service or activity require welding on pressure vessels, structural steel or load bearing components of hoisting, lifting, and rigging equipment (i.e., forklift tines)? (Welding on miscellaneous steel, such as ladders, platforms, stairs, handrails, bulkheads, and non-load bearing components does not require additional QA involvement or a welding program.)			
	B.5	Does the item require NDT/NDE (SNT-TC-1A)? (If yes, NDT/NDE must be performed by WTS Fabrication Oversight or a QSL Vendor).			
Instructions:		Check Yes or No for each criteria. If any criteria under Section A was answered Yes, the item, service or activity graded will default to the higher quality level. If any of the blocks in Section B above are checked Yes, the Quality Level is 2. List any required industry code, standards, certification or tests that need to be obtained, performed or not. Also, list any specific QA requirements that need to be met as determined by cognizant individual and CCP QA. Proceed with Section C, as applicable. If all blocks in Section B above are checked No, the Quality Level is 0. Enter QL0 as the Quality Level designation. Print name, sign, and date and forward this form to the CCP QA for review and approval.			

Attachment 1 – QA Grading Level Determination Checklist (continued)

ID# _____

Instructions: Check ALL of the blocks below either Yes or No. (See Attachment 3, Procurement of Commercially Available Items For Use in Quality Level 1 or 2 Assemblies, for further guidance.)

Section C - Commercial Grade Determination (As Applicable)	Yes	No
Does the proposed item(s) meet all of the following requirements:		
a) Not Subject to design or specification requirements that are unique to nuclear facilities		
b) Used in applications other than nuclear facilities		
c) Is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., catalog)		
d) Identified in an approved design output document (i.e., drawing, specification, or other document from a design input document).		

Instructions: Check Yes or No for each criteria. If **ALL FOUR** of the questions are answered Yes, then the item may be procured as a commercial grade item for use in Quality Level 1 or 2 items, services, or activities (Refer to qualifying statement in the first paragraph of Attachment 3).

Enter the quality level designation in the space below as QL1, QL2, or QL0 as determined in Section A and B above. Check the Commercial Grade Determination box below as determined in Section C. Print name, sign, and date, obtain Cognizant Manager or Technical Specialist signature and forward to the CCP QA for review and approval.

Quality Level Designation:	Commercial Grade: <input type="checkbox"/> Yes <input type="checkbox"/> No
Initiator Printed Name:	Signature: _____ Date: _____
CM or Technical Specialist Printed Name:	Signature: _____ Date: _____
CCP QA Printed Name:	Signature: _____ Date: _____

Attachment 2 – Detailed Descriptions of the Management and QA Control Provisions Corresponding to Quality Levels (QL)

QL0

QL0 items, services, and activities are those not classified as QL1 or QL2. QL0 items, services and activities are those which **DO NOT** require active QA Program controls above and beyond standard commercial practices.

QL1

QL1 items, services, and activities are those required to directly demonstrate that the QA Program has been established and executed.

QL1 items, services, and activities are controlled through the implementation of CCP Site Project Office (PO) documents, CCP Quality Assurance Procedures (QP), and Technical Procedures (TP) which implement the overall CCP.

QL1 items, services, and activities are governed by CBFO-94-1012, *U.S. Department of Energy Carlsbad Field Office Quality Assurance Program Document (CBFO QAPD)*, State or Federal regulations, CCP-PO-001, CCP-PO-002, and nuclear health and safety requirements.

QL1 items, services, and activities must comply with applicable programmatic documents and procedures.

QL2

QL2 items, services, and activities are those not classified as QL1. QL2 items, services, and activities require good management and engineering practices.

QL2 items, services, and activities may require controls governed by recognized industry codes, standards, or certifications. Required industry codes, standards, certifications, or tests that need to be obtained, performed, or met are listed under “quality requirements”.

QA program elements for QL2 items, services, and activities apply at the discretion of the Initiator and CCP QA and are listed under Quality Requirements.

Attachment 3 – Procurement of Commercially Available Items For Use in Quality Level 1 or 2 Assemblies

NOTE

Structures, Systems, and Components (SSCs) determined to be Quality Level 1 or 2 assemblies may be composite assemblies that include numerous standard components, which are commercially available, such as light bulbs, switches, fuses, fasteners, bearings, etc.

Individual parts and components in Quality Level 1 and 2 SSCs with items that are commercially procured from suppliers not on the QSL are acceptable if the individual part or component meets **ALL FOUR** of the requirements stated in Section C of Attachment 1. If **ALL FOUR** of the requirements are not met, the items may be commercially procured but may not be used in any Quality Level 1 or 2 SSCs.

If the consequence of failure or malfunction of the commercially available item or services is such that nuclear safety, radiological safety, Hazardous Waste Facility Permit requirements, etc. are jeopardized, a Qualified Supplier may still be utilized.