

Administrative Procedure, Level 1 - Company Wide

CPCC-PRO-QA-259

Graded Approach

Revision 0, Change 1

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Program: Contractor Assurance

Topic: Quality Assurance

Technical Authority: Armstrong, William C

Functional Manager: Gillespie, Danial J

Use Type: Administrative



USQ Facility	USQ Review	Screeners
Solid Waste Operations Complex	Exclusion Reason: <i>N/A per CPCC-PRO-NS-53097 Table 1</i>	
Canister Storage Building/Interim Storage Area	Exclusion Reason: <i>N/A per CPCC-PRO-NS-53097 Table 1</i>	
Central Plateau Surveillance and Maintenance	Exclusion Reason: <i>N/A per CPCC-PRO-NS-53097 Table 1</i>	
Waste Encapsulation Storage Facility	Exclusion Reason: <i>N/A per CPCC-PRO-NS-53097 Table 1</i>	
Plutonium Finishing Plant	Exclusion Reason: <i>N/A per CPCC-PRO-NS-53097 Table 1</i>	
Transportation	Exclusion Reason: <i>N/A per CPCC-PRO-NS-53097 Table 1</i>	
Capsule Storage Area	Exclusion Reason: <i>N/A per CPCC-PRO-NS-53097 Table 1</i>	
105 KW Facility	Exclusion Reason: <i>N/A per CPCC-PRO-NS-53097 Table 1</i>	
324 Building	Exclusion Reason: <i>N/A per CPCC-PRO-NS-53097 Table 1</i>	

JHA: Administrative

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Change Summary

Description of Change

Added for clarification "For additional details on the graded approach as it applies to software and its implementation, see CPCC-MP-QA-54798, Graded Approach Management Plan, and CPCC-PRO-IRM-309, Controlled Software Management."

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1.0 INTRODUCTION

1.1 Purpose

The scope, depth and rigor of the Central Plateau Cleanup Company (CPCCo) Quality Assurance (QA) Program application of requirements to a specific activity are determined by using a grading process. The purpose of grading is to select the controls and verifications to be applied to various items and activities consistent with their importance to safety, environmental protection, cost, schedule and success of the program. It applies to items, services, and processes regardless of safety classification, and is to be used in conjunction with CPCC-PRO-MS-589, *Central Plateau Cleanup Company Procedures*, for the development of processes that implement the requirements of CPCC-MP-QA-599, *Quality Assurance Program (QAP)*.

1.2 Scope

This procedure applies to items, services, and processes regardless of safety classification, and is to be used in conjunction with CPCC-PRO-MS-589 for the development of processes that implement the requirements of CPCC-MP-QA-599. The graded approach is primarily implemented at a programmatic level during the development of procedures and processes. Additionally, this process provides support in determining the appropriate quality level for procurement and transportation packaging activities. The issuance and use of approved procedures control application of the graded approach.

Since there are significant variations among items, services, and processes, as well as differences in project scopes of work and responsibilities, this procedure does not attempt to provide a precise definition of how each section of the QAP is applied in a graded manner. Some possible grading applications are provided in [Table 1](#).

Limitations on use of the graded approach include:

- The grading process shall not be used to circumvent applicable quality assurance, legal, or contractual requirements. Rather, grading determines the extent to which controls within the quality assurance criteria are applied.
- The graded approach may not be used in implementing the un-reviewed safety question (USQ) process or in implementing technical safety requirements.

For additional details on the graded approach as it applies to software and its implementation, see CPCC-MP-QA-54798, *Graded Approach Management Plan*, and CPCC-PRO-IRM-309, *Controlled Software Management*.

1.3 Applicability

This procedure is applicable to CPCCo employees who conduct activities requiring the use of a graded approach.

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1.4 Implementation

This procedure is effective upon publication.

2.0 RESPONSIBILITIES

See Section 3.0 for responsibilities.

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3.0 PROCESS

See [Figure 1](#) for Graded Quality Assurance Flow Chart.

Grading is a management process for determining the degree of rigor, or effort (resources), which needs to be applied to the QA program implementation. The factors of cost, schedule, environmental, health and safety, mission, public perception and security must all be taken into account when grading quality requirements.

3.1 Incorporation of Grading into Applicable Process Procedures and Other Documents

Actionee	Step	Action
Process Owner Subject Matter Expert (SME), Functional Area Manager, Cognizant QA Representative	1.	Using the guidance provided in Table 1 of this procedure, and considering the risk, importance to safety, and quality requirements associated with the activity, ENSURE the graded approach is incorporated in applicable process procedures, plans, manuals and other documents.
	2.	REVIEW the implementing procedures, plans, manuals and other documents to ENSURE the requirements of CPCC-MP-QA-599 are not being negated but rather are being implemented on a graded approach commensurate with the importance to safety and risk associated with the process.

3.2 Risk Determination

Actionee	Step	Action
Process Owner SME, Functional Area Manager	1.	<p>DETERMINE the probability and consequence of failure, considering both safety and project risk. Assessment of risk shall consider, as applicable:</p> <ul style="list-style-type: none"> • Nuclear safety classification or hazard category of the item or activity • Relative importance to safety, safeguards, and security • Magnitude of any hazard or risk involved • Adequacy of existing safety documentation • Particular characteristics of a facility or activity • Programmatic mission of a facility • Life cycle stage of a facility • Complexity of items, services, or processes involved • History of problems at a facility, or with an item, service, or process • Application of required codes, standards, laws, regulations, or imposed requirements.

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Actionee	Step	Action
Process Owner SME, Functional Area Manager	2.	Based on the risk determination, ESTABLISH documented controls for the activity for implementation of the services and/or processes commensurate with the safety classification designation of the associated structures, systems, and components (SSC), taking into account the impact the item, service, or process could have on the functionality of the SSCs. (See Table 1 for guidance)

3.3 Quality Level Determination

The following process is used for establishing a graded approach for procurement of items and services for all CPCCo activities, with the exception of Transportation and Packaging. The graded approach to be utilized relative to Transportation and Packaging activities shall be in accordance with requirements specified in [Appendix A](#) and B of this procedure.

The quality determination utilizes a risk-based methodology predicated on the end use of the items or services to categorize the appropriate Quality Level. The Quality level of an item or service establishes the range of suitable methods for acceptance of the delivered item or services. The basis of acceptance is a function of the Quality Level and the type and nature of the supplier for the items or service. A given item or service for a given end use can have only one Quality Level assigned: therefore, the more conservative determination of Quality Level is to be used.

A simple way of thinking about quality levels is that if there is any need (requirement or desire for documentation, evidence of compliance, qualifications, inspections, etc.) on the part of CPCCo to have a documented basis that the item or service provided will meet its intended function, then an assignment of Quality Level - 0 (QL-0) would be inappropriate. On the other hand, if the advertised attributes provide sufficient basis for establishing confidence, then QL-0 may be sufficient. Examples where a need for a documented basis would influence the designation as being QL-3 or above include, but are not necessarily limited to:

- Certified Material Test Reports
- Certificates of Conformance
- Inspection Reports
- Test Reports
- Qualified Processes (Welding, Inspection, assembly, testing, etc.)
- Training/Certification documents
- Inspection for Suspect/Counterfeit, S/CI
- Inspection for Nationally Recognized Testing Lab, NRTL

When an item or service is designated as QL-3 or above, then the specific items being requested are usually itemized on a Quality Assurance Inspection Plan for items or in a submittal register for services (or a combination of both). These two methods provide the upfront description of acceptance (documents or attributes) by which a reasonable assurance that the item or service will meet its intended need is attained.

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Actionee	Step	Action
Design Authority (DA)/ Technical Authority (TA) or Cognizant Personnel	1.	<p data-bbox="526 363 1386 499"><u>IF</u> not already done, <u>THEN IDENTIFY</u> scope of work and specific actions to be taken to ensure the item or service under consideration meets its intended purpose, function and requirements.</p> <p data-bbox="526 527 1386 762">While application of a safety class designator is not always applicable to environmental activities, the graded approach for environmental activities is normally based on specific needs and objectives for the activity. The environmental graded approach is documented in project documents such as Sampling and Analysis Plans (SAP) as appropriate and as required by the governing standard(s) (e.g., EPA QA/R-5).</p> <p data-bbox="480 789 1386 856">2. IDENTIFY the potential consequences of failure, considering both safety and project impact.</p> <p data-bbox="480 884 1409 951">3. ASSIGN a Procurement Quality Level, if applicable (e.g., part of the procurement process) in accordance with the following criteria:</p> <p data-bbox="526 978 1422 1419">a. Quality Level-1 is assigned to items and services that are high risk, and the quality assurance program employed by the vendor is important to the acceptability and suitability of the item or service to perform as specified. These suppliers are required to have their quality assurance program evaluated as part of the Bid Evaluation process, unless the item or service is to be dedicated utilizing the Commercial Grade Dedication process. Acceptance methods shall be specified including acceptance and other applicable performance criteria documented and verified before use of the item or service. Examples where this level would be applied include Safety Class (SC) items or services, environmental laboratory analytical services and other items/services classified as high risk.</p> <p data-bbox="526 1446 1422 1812">b. Quality Level-2 is assigned to Safety Significant (SS) items and associated services not designated as QL-1 and items and associated services posing a moderate project risk. These suppliers are required to have their quality assurance program evaluated as part of the Bid Evaluation process, unless the item or service is to be dedicated utilizing the Commercial Grade Dedication process. Acceptance methods shall be specified including acceptance and other applicable performance criteria documented and verified before use of the item or service. Some of the required characteristics may be examined less rigorously than for QL-1.</p>

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Actionee	Step	Action
DA/TA or Cognizant Personnel	c.	<p>Quality Level-3 is assigned to items and services that are important to project mission and represent sufficient risk that controls beyond standard commercial practices are considered necessary to ensure the item or service is suitable for its intended purpose. Suppliers for such items or services typically have commercial quality assurance programs that need not be evaluated as part of the Bid Evaluation process. However, procurement documents shall describe the method/s of acceptance to establish confidence that the item/service is suitable for its intended purpose. If post installation testing is specified as acceptance criteria the verification activity is the post installation test. Examples where this Level would be assigned include:</p> <ol style="list-style-type: none"> 1) General Service (GS) items and associated services posing a low project risk, but, based on engineering evaluation, require additional controls beyond standard commercial practices. 2) Any item or service with the potential to cause radiological harm (in the present or future) by: <ol style="list-style-type: none"> a) Affecting the integrity of a radiological barrier b) Increasing the extent, level, or duration of radiological exposure during routine operations and/or reasonably anticipated off-normal events c) Affecting the effectivity of radiological detection, monitoring, or alarm capability (except for properly functioning, calibrated detection instrumentation). 3) Items, work activities and services where special processes, or regulatory code (welding, special coatings, and special permitting), are called out and/or when independent verification/review/examination/inspection is required by a national consensus standard (e.g., American Welding Society, AWS, D1.1; American Society of Mechanical Engineers, ASME, B31.3; ASME Section VIII) which have not been designated as QL-1 or 2.

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Actionee	Step	Action
NOTE:		<p><i>If it is necessary for CPCCo to have/maintain documents or records that provide evidence of an item or service meeting a standard or technical requirement or in cases where a receipt inspection for specific attributes is desired, then designation of QL-3 would be the minimum QL designation. Examples of items that would preclude designation of QL-0 would include, but are not necessarily limited to:</i></p> <ul style="list-style-type: none"> • <i>Certified Material Test Reports</i> • <i>Certificates of Conformance</i> • <i>Inspection Reports</i> • <i>Test Reports</i> • <i>Qualified Processes (Welding, Inspection, assembly, testing, etc.)</i> • <i>Training/Certification documents</i> • <i>Inspection for Suspect/Counterfeit</i> • <i>Inspection for NRTL</i>
DATA or Cognizant Personnel	4)	<p>The following are examples of GS items and services which may be graded as QL-3, based on an engineering evaluation:</p> <ul style="list-style-type: none"> • Item or service performs a safety function (defense-in-depth), but does not meet the criteria for SC or SS. • Item or service performs a function to minimize impact to the environment. • Item or service performs a function to minimize damage to the facility or its critical equipment. <p>d. Quality Level-0 is assigned to items and services that are low risk and the controls inherent in standard commercial practices are acceptable. Items procured as QL-0 are purchased solely on the information advertised by the supplier in the vendor/suppliers item catalog. For these low risk items and services, end-users will ensure the item/service is acceptable for its intended purpose. These suppliers may or may not have a commercial quality assurance program and it is likely that limited, if any, pedigree will come with the item or service.</p> <p>4. DETERMINE the depth, extent, and degree of rigor necessary in the application of the appropriate quality assurance controls for the item, service or process. Through the evaluation of project risk, it may be determined that although the items/services are categorized as GS, the projects risks may warrant an incremental increase in the risk designation (low, moderate, high) commensurate with the identified risks. That is, a risk category of high may result from the evaluation causing the Quality Level to be re-designated to QL-1.</p>

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Actionee	Step	Action
NOTE:		<i>Determination of the depth, extent and degree of rigor, including evaluation of project risk, applies to new work/activities where quality levels have not been previously established.</i>
DATA or Cognizant Personnel	5.	<p>Control variables may include, but are not limited to:</p> <ul style="list-style-type: none"> • Number and specificity of procedures, instructions, drawings, specifications, or work control documents that define the processes or work methods involved • Extent of preparatory analysis and planning for the work • Frequency and scope of assessments, verifications, reviews, inspections, and other oversight activities • Extent of documentation generated as a result of work completion that is reviewed to verify that work has been accomplished in accordance with the applicable requirements • Degree of review and level of approval of procedures, plans, and other documentation • Extent of training and qualification/certification of personnel • Degree of control over procurement activities • Extent of in-process controls for design, fabrication, installation, testing, and operation • Procurement quality level designated in the Safety Equipment List for items associated with safety class or safety significant SSCs.
NOTE:		<i>Communicate and implement the requirements, and degree of rigor by means of appropriate documents.</i>

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4.0 FORMS

None

5.0 RECORD IDENTIFICATION

None

6.0 SOURCES

6.1 Requirements

CPCC-MP-QA-599, *Quality Assurance Program*

6.2 References

American Welding Society, AWS, D1.1

American Society of Mechanical Engineers, ASME, B31.3; ASME Boiler and Pressure Vessel Code Section VIII

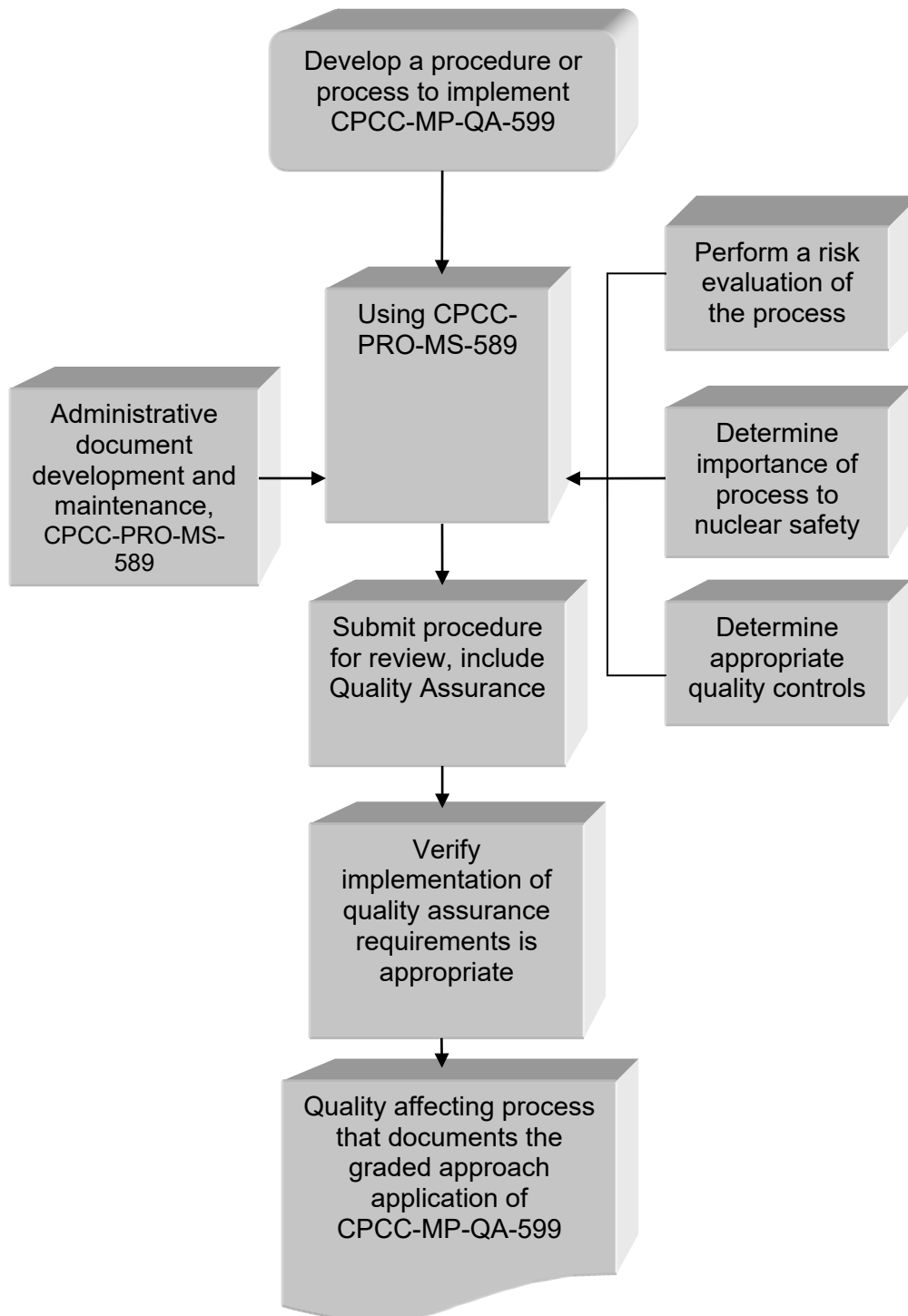
CPCC-MP-QA-54798, *Graded Approach Management Plan*

CPCC-PRO-IRM-309, *Controlled Software Management*

CPCC-PRO-MS-589, *Central Plateau Cleanup Company Procedures*

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Figure 1 - Graded Quality Assurance Flowchart



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Table 1 - Examples of Graded Application of Quality Assurance Controls Applied to Processes

This table provides examples of grading that process owners might take into consideration when establishing controls for their work processes based on risk and/or quality assurance level designations. This table is for illustration purposes only and can be referenced for use by process owners to develop their own required graded controls in accordance with this procedure.

Quality Assurance Criteria	Quality Level 1 or 2 Critical-Near Critical Risk	Quality Level 3 Significant Risk	Quality Level 3 Marginal Risk	Quality Level 0 Negligible Risk
Program	CPCC-MP-QA-599, QAP	CPCC-MP-QA-599, QAP	CPCC-MP-QA- 599, QAP	CPCC-MP-QA- 599, QAP
Personnel Training and Qualification	Routine training requirements (e.g., HGET) Qualification and certification in accordance with applicable standards Extensive pre-job training Dry run of critical services or processes	Routine training requirements (e.g., HGET) Qualification and certification in accordance with applicable standards Extensive pre-job training	Routine training requirements (e.g., HGET) Qualification and certification in accordance with applicable standards	Routine training requirements (e.g., HGET)
Quality Improvement	Issues Management, assessment and Lessons Learned processes, including those documented and tracked in the Integrated Contractor Assurance System (iCAS) and OPEXShare system.	Issues Management, assessment and Lessons Learned processes, including those documented and tracked in the iCAS and OPEXShare system.	Issues Management, assessment and Lessons Learned processes, including those documented and tracked in the iCAS and OPEXShare system.	Issues Management, assessment and Lessons Learned processes, including those documented and tracked in the iCAS and OPEXShare system.
Documents and Records	Quality records.	Quality records.	Quality records.	No quality records unless specified by procedure
Work Processes	Extensive pre-job planning. High level of detail in procedures based on the complexity of the task and the associated risk	Pre-job planning, with focus on most critical services or processes. Procedures provide general direction unless the process is performed infrequently	Pre-job planning, with focus on most critical services or processes. Procedures provide general direction unless the process is performed infrequently	Routine planning. Standard work practices or manufacturer's instructions

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Table 1 – Cont.

Quality Assurance Criteria	Quality Level 1 or 2 Critical-Near Critical Risk	Quality Level 3 Significant Risk	Quality Level 3 Marginal Risk	Quality Level 0 Negligible Risk
Program	CPCC-MP-QA-599, QAP	CPCC-MP-QA-599, QAP	CPCC-MP-QA-599, QAP	CPCC-MP-QA-599, QAP
	M&TE calibrated by a supplier on the Evaluated Supplier List Hold and witness points Pre-job walk-through and critiques	M&TE calibrated by a supplier on the Evaluated Supplier List Hold and witness points	M&TE calibrated by a supplier on the Evaluated Supplier List	
Design	Independent design review Inspection/test requirements and methods in design documents Team review Use of mock-ups Engineering walkdowns	Independent design review Inspection/test requirements and methods in design documents Team review	Design review by design organization Inspection/test requirements and methods in design documents	Design review by design organization
Procurement	Use of Material Request/Contract Requisition Quality Assurance review and approval of procurement documents Approved supplier from Evaluated Supplier List if not procured as commercial grade item Development of Subcontractor Oversight Plans	Use of Material Request/Contract Requisition Quality Assurance review and approval of procurement documents	Use of Material Request/Contract Requisition Quality Assurance review and approval of procurement documents	Use of Material Request/Contract Requisition/ PCard/Ebom

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Table 1 – Cont.

Quality Assurance Criteria	Quality Level 1 or 2 Critical-Near Critical Risk	Quality Level 3 Significant Risk	Quality Level 3 Marginal Risk	Quality Level 0 Negligible Risk
Program	CPCC-MP-QA-599, QAP	CPCC-MP-QA-599, QAP	CPCC-MP-QA-599, QAP	CPCC-MP-QA-599, QAP
Inspection and Acceptance Testing	Inspection/test performed by technically qualified personnel Inspection/test requirements defined in design and procurement documents Quality Assurance Inspection Plan. Source inspection	Inspection/test performed by technically qualified personnel Inspection/test requirements defined in design and procurement documents Quality Assurance Inspection Plan. Source inspection	Inspection/test performed by technically qualified personnel Inspection/test requirements defined in design and procurement documents Quality Assurance Inspection Plan	Inspection and acceptance by procurer, warehouse personnel, or material controller per applicable procedure End user inspect for suspect/ counterfeit items
	Quality control receiving inspection. Final inspection. Inspection/test results documented. Inspect for suspect/ counterfeit items.	Quality control receiving inspection. Final inspection. Inspection/test results documented. Inspect for suspect/ counterfeit items.	Quality control receiving inspection. Final inspection. Inspection/test results documented. Inspect for suspect/ counterfeit items.	Need not be inspected by certified inspection personnel.
Management Assessment	High focus.	Medium focus.	Medium focus.	Low focus.
Independent Assessment	Assessment performed by independent person or group. Scheduled	Assessment performed by independent person or group. Scheduled	Assessment performed by independent person or group. Scheduled	Spot checks performed during surveillances conducted by Projects group

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Appendix A - Special Grading Considerations for Transportation and Packaging Activities

For Transportation and Packaging activities, as required by DOE/RL-2001-36 *Hanford Onsite Transportation Safety Document (OTSD)*. That guidance establishes Quality Assurance categories for transportation and packaging systems, structures, and components as follows:

Quality Assurance Category A: Structures, systems, and components for which a failure or malfunction could directly result in a condition that would adversely affect public health and safety. This would include such conditions as loss of primary containment with subsequent release of radioactive material, loss of shielding, or an unsafe geometry compromising criticality control.

Quality Assurance Category B: Structures, systems, and components for which a failure or malfunction could indirectly result in a condition that would adversely affect public health and safety. However, an unsafe condition could result only if the primary event occurs in conjunction with a secondary event or other failure or environmental occurrence. (e.g., an adverse effect to onsite workers and to a lesser extent public health can only occur when a secondary event or other failure or environmental occurrence happens in conjunction with a primary event.)

Quality Assurance Category C: Structures, systems, and components for which a failure or malfunction would not significantly reduce packaging effectiveness and would be unlikely to create a condition that would adversely affect public health and safety. (i.e., any adverse conditions resulting from a failure or malfunction would be limited to facility workers only.) These categories would fall into the graded approach as defined in the rest of this procedure as shown in Table 1.

QA Category (NRC RG 7.10)	CPCCo Quality Level	Risk	Examples
QA Category A	QL-1 or QL-2	QL-1 for Critical Risk and QL-2 for Near Critical Risk	Type B Casks
QA Category B	* QL-3 (Enhanced)	Significant Risk	Type A packaging used for Type B quantity, Risk Based Shipments, etc.
QA Category C	QL-3 (Standard)	Marginal Risk	IP Type and Type A packaging for DOT compliant shipments
Non-Quality	QL-0	Negligible Risk	Not used for packaging

The DA, in coordination with the QA representative, determines transportation and packaging grading for systems, structures, and components including packaging.

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Appendix B - QL-3 Quality clause Selection for Transportation and Packaging Activities

In accordance with CPCC-PRO-QA-259 a risk based approach will be used to determine specific quality clauses for each transportation and packaging procurement. The table below provides a comparison and general guidance for QA Clause selection for QL-3 Standard and Enhanced procurements. To start with, as a QL-3 procurement we cannot invoke B01, *Quality Assurance Program Submittal and Pre-award Survey*; B04, *Supplier Quality Program Evaluation*; or B07, *Certified Quality Program*; and it is unlikely that B10, *Quality System for Materials Specifying Testing per ASME*, would be invoked.

General QA Clauses for Standard QL-3 Procurement	*General QA Clauses for Enhanced QL-3 Procurement
B32 <i>Identification of Items with Part Number/Model Number</i>	B13 <i>Fabrication/Inspection/Test Plan</i>
B33 <i>Identification of Items with Catalog Cut</i>	B16 <i>Source Inspection</i>
B34 <i>Identification of Items</i>	B19 <i>First Article Inspection-Source</i>
B43 <i>Identification of Age Control Items</i>	B22 <i>Nonconformance Documentation and Reporting</i>
B76 <i>Procurement of Potentially Suspect or Counterfeit Items</i>	B25 <i>Certified Weld Inspector (CWI)</i>
B79 <i>Certificate of Conformance</i>	B28 <i>Welding Procedures and Qualifications</i>
	B31 <i>Nondestructive Examination Process</i>
	B37 <i>Identification and Traceability of Items</i>
	B43 <i>Identification of Age Control Items</i>
	B52 <i>Inspection and Test Report</i>
	B73 <i>Control of Graded Fasteners</i>
	B76 <i>Procurement of Potentially Suspect or Counterfeit Items</i>
	B79 <i>Certificate of Conformance</i>
	B82 <i>Recommended Spare Parts Listing</i>
	B85 <i>Packaging/Shipping Procedures</i>

NOTE: Other QA Clauses may be invoked depending on the specific item being procured and its planned use.