1. INTRODUCTION

1.1 Purpose

This process provides a method for determining the *quality level* (QL; see def.) of *structures, systems, and components* (SSCs; see def.); *software* (see def.); and activities.

This process also provides a method for upgrading the quality level of existing SSCs from QL-4 to QL-3, from QL-3 to QL-2, and—with advance engineering and quality assurance (QA) management involvement—from QL-4 to QL-2.

1.2 Scope and Applicability

The QL is assigned based on whether the SSC, software, or activity is related to a *safety SSC* (see def.) or *safety software* (see def.); and upon its *failure consequence level* (FCL; see def.), *failure potential level* (FPL; see def.) and, if necessary, *mission critical* (see def.) issues. The quality level determination (QLD) is performed for the end use of the SSC, software, or activity; not for the QL at which it will be procured if it is to be dedicated per MCP-3772, "Commercial Grade Dedication."

The QLD is documented on Web-based Form 431.67, "Quality Level Determination," (hereafter referred to the "QLD form") which can then be used to support a *tailored approach* (see def.) to engineering, fabrication, procurement, inspection, construction, acceptance, operations, maintenance, testing, and any other activity that ensures continued safe and efficient use of the SSC or software, or completion of the activity.

The QL process applies to:

A. New and replacement SSCs, including *like-for-like replacement items* (see def.)

B. Software

C. Activities that require QLs, as directed by the governing procedures

D. Existing SSCs that need to be upgraded from QL-4 to QL-3 or, with additional management approvals, from QL-3 to QL-2

E. Existing SSCs that need to be upgraded from QL-4 to QL-2, with advance engineering and QA management involvement.

Quality level upgrades are documented using Form 431.75, "Quality Level Upgrade for Existing SSCs."

QLs are optional for existing SSCs that are not being modified or replaced, including spare parts that were previously purchased for a specific item.

The QL process does **not** apply to SSCs that have been permanently shut down and identified for deactivation, decontamination, and decommissioning.

Activities can either use a QL specifically determined for the activity, or use the highest QL for the associated SSCs. The activity QL will never be higher than the QL of the associated SSCs. If the quality-related attributes of the SSC are not affected by the activity, a separate QLD may be prepared at an appropriate, lesser QL specific to the activity.

Digital instrumentation and control (I&C) software that is integral to the function of a hardware item is evaluated with the hardware as a system under the same QLD. When using the QL of the SSC, the software is considered a component or subcomponent of the SSC, and software failure potentials and failure consequences must be considered in the QLD for the SSC.

Software that is not a component or subcomponent of an SSC (including, but not limited to, safety and hazard analysis software, design software, and safety management and administrative controls software) must have a QLD specific for the software unless exempted in Section 4.1 of this procedure.

Safety software is designated as QL-2 unless it performs a safety class function as part of a safety class SSC, in which case the software will be the same quality level as the SSC (QL-1).

2. RESPONSIBILITIES

NOTE: *The engineering performer designations called out in this procedure are based on function rather than organization. As such, performer responsibilities may be assigned to individuals with titles other than those specified below, with the exception of the quality engineer function. This is acceptable if the competency of assigned personnel is commensurate with responsibility.*

Performer	Responsibilities
Requester/*Design Authority* (see def.) (normally a software owner for software)	Recommend QLs for SSCs, software, or activities in areas of responsibility. Maintain QLs current throughout the lifecycles of assigned SSCs, software, or activities. Review and approve quality level upgrades.
Responsible Engineer	Prepare and process quality level upgrades (see Section 4.5)
Quality Engineer or Inspector	Review and concur with the QL recommendation, and provide as-needed input. Review and perform verification for quality level upgrades.

Performer	Responsibilities
Approver (normally an engineering manager for SSCs, items, or activities; normally a responsible manager for software)	Review and approve QL recommendations.
ICP Personnel	Use the QL in determining the appropriate level of rigor and associated procedures for acquiring, fabricating, using, maintaining, and changing the SSC, software, or activity.
Area/Project Chief Engineer (A/PCE), QA Director, and ICP Chief Engineer	Provide advance input into proposed upgrades from QL-4 to QL-2. Approve upgrades to QL-2.
Design Engineer	Perform analyses on quality level upgrades, as assigned.

3. PREREQUISITES

3.1 Responsible Engineer: Before upgrading an item to QL-2 per Section 4.5, complete qualification QCENGCGD, "Commercial Grade Preparer."

4. INSTRUCTIONS

CAUTION

Proper QL assignment is important to avoid unacceptable expenses and work delays. Otherwise, the SSC, software, or activity may need to be replaced to ensure it performs its intended function.

NOTE: *QLs are established during the design phase or at the earliest possible time consistent with program or project development.*

4.1 Determining if the SSC, Software, or Activity may be Considered QL-4 and Exempt from Further Evaluation

4.1.1 Requester/Design Authority: Determine if the SSC, software, or activity may be considered a QL-4 and exempt from further QL determination using tables 1 and 2 on the following page.

NOTE: *SSCs, software, or activities that would typically be considered QL-4 may not actually be QL-4 if they directly support the function of a QL-1, -2, or -3 SSC, software, or activity. If there is any doubt regarding the QL, Section 4.2 should be used to make the QLD.*

Table 1.

Exempt SSCs or Software
Clothing other than protective personal equipment (PPE) used for radioactive or hazardous material protection
Custodial supplies
Furniture
Film and cameras
Library publications
Medical supplies
Office supplies, including calculators, typewriters, and other office machines
Personal computers and peripherals, such as printers, monitors, hard drives, and memory cards (This exclusion does **not** apply to components that are considered configuration items related to a digital I&C system.)
Underwriters Laboratory (UL)-listed hand-held power tools (such as drills, sawsalls, grinders, and bandsaws)
UL-listed electrical extension cords
Non-safety-related software (see *safety software* definition) that is used ONLY for display purposes (such as static web pages and static files created by word processing and presentation software) or for file compaction purposes (such as WinZip).

Table 2.

Exempt Activities
Custodial services
Clerical services
Financial services
Legal services
Administrative activities
Staff augmentation services where subcontractor staff are required to work to CWI procedures, under CWI direction.
Minor work that does not impact the function of a QL-1, -2, or -3 SSC, item, or activity (see MCP-101, "ICP Integrated Work Control Process," for the process of defining minor work)

NOTE: *Generic QLDs have been established for use with the following specific types of SSCs:*

A. *QLD-4314: QL-3 measuring and testing equipment (M&TE) that is **not** for use as installed facility process and control instrumentation (such as torque wrenches, multimeters, tensile testers, and spectrometers)*

B. *QLD-4315: General tools and equipment to be used in QL-4 applications only (such as hammers, screw drivers, shovels, and sanders)*

C. *QLD-4316: General consumables to be used in QL-4 applications only (such as administrative supplies, cleaning supplies, and other consumables not requiring traceability, special controls, or inspection prior to use)*

D. *QLD-4843: QL-4 flame-resistant clothing, including labeling, that must meet the requirements of standard performance specification ASTM F1506, "Flame Resistant and Arc Rated Textile Materials for Wearing Apparel for Use by Electrical Workers Exposed to Momentary Electric Arc and Related Thermal Hazards."*

4.1.2 Requester/Design Authority: If the SSC, software, or activity is considered to be a QL-4 per step 4.1.1, or a generic QLD may be used (see note above), exit this procedure. Otherwise, go to Section 4.2.

4.2 Designating Quality Levels

NOTE 1: *QLDs that are left in a draft or in-process state for more than 6 months will be canceled.*

NOTE 2: *A change to the mission of a project, program, or facility may necessitate reassignment of QLs per this procedure (see step 4.3.3).*

4.2.1 Requester/Design Authority: Prepare for SSC, software, or activity QLD by reviewing, as needed, applicable facility or activity documents (such as safety analysis documents and hazard assessment documents) to determine relevant factors, such as:

A. Relative importance of the SSC, software, or activity with respect to safety, safeguards, security, waste isolation, and other mission objectives

B. Importance of the data to be generated

C. Magnitude of any hazard or the consequences of failure

D. Lifecycle of the SSC, software, or activity

E. Programmatic mission of the facility or project

F. Particular characteristics of the SSC, software, or activity (such as complexity, uniqueness, history, or the necessity for special controls).

4.2.2 Requester/Design Authority: Determine a QL for the SSC, software, or activity in sufficient detail to understand the scope and boundaries of the identified system by completing the QLD form.

NOTE: *The QL is typically established at the highest level SSC or unit that performs a single, identifiable function (e.g., the entire facility, the overall SSC, the activity, the overall software package).*

4.2.2.1 If a component, subsystem, or part performs a function critical to achieving the purpose of the overall system or unit, use the overall system or unit QLD for the component, subsystem, or part.

4.2.2.2 If a component, subsystem, or part does **not** perform a function critical to achieving the purpose of the overall system or unit, complete separate QLDs, as needed to subdivide the system by QL.

4.2.2.3 Complete applicable fields in the Background Information section.

NOTE: *Each of the QLD sections provides space to include information regarding the SSC, software, or activity being evaluated and reasons for the options selected.*

4.2.2.4 Identify the affected system, components, items, and associated boundaries in sufficient detail to clearly define the scope of the QLD.

NOTE: *If the QLD is associated with a new building or structure that is not listed in the "Building or Structure No. and Description" field of the QLD Background Information screen, a Form 431.17, "Building Structure Number Assignment," can be submitted to have the building or structure added to the database.*

4.2.2.5 Determine which of the following is being evaluated: (1) item or activity, (2) Nuclear Regulatory Commission (NRC)-regulated item or activity, or (3) software.

4.2.2.5.1 If evaluating an SSC or activity, determine if it is credited in a documented safety analysis.

4.2.2.5.2 If evaluating an NRC-regulated item or activity, determine if it is designated as important to safety in a documented safety analysis or design basis document.

4.2.2.5.3 If evaluating software, determine if it is *safety software* (see def.).

4.2.2.5.4 If evaluating a non-NRC-regulated item, activity, or software, determine if it is *waste-acceptance-impacting* (WAI; see def.) per either:

A. PLN-533, "Quality Assurance Program Plan for High Level Waste and Spent Nuclear Fuel"

B. PLN-3393, "Quality Assurance Program Plan for the Calcine Disposition Project."

4.2.2.5.5 If any of the criteria in steps 4.2.2.5.1 through 4.2.2.5.4 apply, go to step 4.2.2.8 to submit the QLD. Otherwise, go to step 4.2.2.6.

4.2.2.6 Complete the *failure consequence level* (FCL; see def.) and *failure potential level* (FPL; see def.) sections of the form. Include any supporting information needed for reviewers and other stakeholders to understand the rationale for FCL and FPL selections.

NOTE: *The completion of the FCL and FPL sections of the form can result in a QL-2 for the SSC, software, or activity. Since this determination was not due to nuclear safety considerations, the item is not considered to be a safety SSC, safety software, or safety activity. The item will be identified as a* QL-2 mission critical *(see def.) SSC, software, or activity.*

4.2.2.7 If prompted by the QLD form, determine if the SSC, software, or activity being evaluated is *mission critical* (see def.); otherwise, go to step 4.2.2.8.

NOTE: *For assistance in selecting the correct mission critical criteria, your environmental, safety, health, or quality assurance representative may be contacted for information (see LST-1, "Responsible Managers, Functional Support Mangers, and Subject Matter Experts").*

4.2.2.8 Submit the form for:

A. Quality engineer review and concurrence

B. Approver review and approval.

4.2.3 Quality Engineer: Review and concur with the QLD form.

4.2.3.1 Advise the requester, as needed, on historical knowledge or lessons learned that may apply to the SSC, software, or activity being evaluated.

4.2.3.2 If necessary, comment on issues that need correction and click "Do Not Concur" to return the form to the requester.

4.2.3.3 Resolve any issues with the requester and concur with the form.

4.2.4 Approver: Review and approve the QLD form.

4.2.4.1 Ensure the recommended QL is appropriate to the ICP, project, and/or facility mission; and to the function of the SSC, software, or activity being evaluated.

4.2.4.2 If necessary, comment on issues that need correction and click "Do Not Approve" to return the form to the requester.

4.2.4.3 Resolve any issues with the requester, provide any needed additional information, and approve the form.

4.2.5 Requester/Design Authority: If the QLD form is returned for correction, work with the quality engineer and/or approver as needed to resolve issues, adjust QL input as needed, and resubmit the form for review.

4.2.6 Requester/Design Authority: When a QLD is issued identifying safety software or a QL-1 or QL-2 SSC that includes software, request LST-430, "Safety Software Inventory List," be updated to include the safety software using the EDMS Suggestion System.

4.3 Using Completed Quality Level Determinations

NOTE 1: *The approved QLD form, which is maintained on a server as a quality record, is used to manage SSCs, software, and activities to the appropriate level of rigor per applicable procedures. For example, procurement personnel use this information to determine the proper level of control to apply during acquisition and receipt inspection, and system engineers use the information to determine the proper level of control applied to managing engineered changes to an SSC.*

NOTE 2: *There may be multiple QLDs against the same SSC, software, or activity. The most recent QLD is the applicable QLD (see Section 4.4 for canceling and replacing outdated QLDs).*

4.3.1 ICP Personnel: Use the QLD form to determine the level of rigor and procedures for acquiring, fabricating, using, maintaining, and changing the SSC, software, or activity.

4.3.2 Requester/Design Authority: If the SSC is a *waste-acceptance-impacting* (WAI; see def.) SSC, update PLN-533, "Quality Assurance Program Plan for High Level Waste and Spent Nuclear Fuel," or PLN-3393, "Quality Assurance Program Plan for the Calcine Disposition Project," as needed.

4.3.3 Requester/Design Authority: If the SSC, software, or activity that will be purchased qualifies as a *commercial grade item* (CGI; see def.) or *commercial grade service* (see def.) and needs to be dedicated for use in a safety application, dedicate the SSC, software, or activity per MCP-3772.

NOTE: *The QLD is performed for the final intended use of the SSC, software, or activity, not for the QL at which it will be procured.*

4.3.4 Requester/Design Authority: If existing SSC, software, or activity has had its scope, mission, or purpose changed, perform one or more of the following steps as needed.

4.3.4.1 Cancel and replace the SSC, software, or activity QLD per Section 4.4.

4.3.4.2 Upgrade the quality level of existing material or item per Section 4.5.

NOTE: *The quality level upgrade (QLU) process is ONLY used for a specific material or item that was previously purchased and is already on hand.*

4.4 Canceling and Replacing Outdated Quality Level Determinations

4.4.1 Requester/Design Authority: Cancel and replace SSC, software, and activity QLs as needed to address changing conditions and situations.

4.4.1.1 Process a new QLD that references QLD(s) it will supersede per Section 4.2.

4.4.1.2 Request the QLD administrator to cancel superseded QLD(s) (such as via email request to EngineeringPrograms@icp.doe.gov).

4.4.2 Requester/Design Authority: Use the new QLD per Section 4.3.

4.5 Upgrading Quality Levels

NOTE 1: *The quality level upgrade (QLU) process is ONLY used for a specific material or item that was previously purchased and is already on hand. The QLU process is **not** used to procure material or items. If a vendor cannot be qualified to furnish a QL-2 item, then the item is dedicated per MCP-3772, "Commercial Grade Dedication."*

NOTE 2: *Before upgrading material or an item to QL-2, the responsible engineer is required to complete qualification QCENGCGD, "Commercial Grade Preparer," per prerequisite 3.1.*

4.5.1 Initiating a Quality Level Upgrade Plan

4.5.1.1 Responsible Engineer: If the material or item that needs to be dedicated to a higher quality level is **not** already on hand, exit this procedure and go to MCP-3772, "Commercial Grade Dedication." Do **not** procure material or items with the intention of using the QLU process to dedicate the material or items.

4.5.1.2 Responsible Engineer: If the QLU is proposed for a QL-4 to QL-2 upgrade, coordinate initial QLU planning with the A/PCE, QA director, and ICP chief engineer to confirm the QLU should proceed.

4.5.1.3 Responsible Engineer: Initiate the QLU plan for existing material or item using Form 431.75, "Quality Level Upgrade for SSCs" (QLU). A quality level upgrade **only** applies to:

A. Previously purchased existing material or component

B. Installed material or component.

NOTE: *In the following step, the QLU number can be obtained from EDMS by clicking the "Numbering" tab, clicking the "Get QLU number" link in the "Get a Quality Level Upgrade Number" area, and completing the requested fields.*

The EDMS QLU numbering system can also be accessed from the Engineering homepage by clicking the "Qual. Level Upgrade" button and then clicking the "Quality Level Upgrade Number" button.

4.5.1.4 Responsible Engineer: Obtain a QLU number and enter the following information in Part 1 of the QLU form**:**

A. QLU number obtained from EDMS

B. Upgrade type (QL-4 to QL-3, QL-3 to QL-2, or QL-4 to QL-2)

C. Item or SSC identification number and name

D. Part number

E. SAR number

F. Safety category

G. Quality level

H. Purchase order (PO) number for the previously purchased material, if known

I. Site area and building identification

J. QLD number and title

K. Item or SSC description

L. Item or SSC manufacturer(s).

4.5.1.5 Responsible Engineer: Identify the SSC safety functions.

4.5.1.6 Responsible Engineer: Identify the technical documents that address technical requirements and safety functions.

4.5.1.7 Responsible Engineer: Identify the following characteristics, acceptance criteria, and verification methods in Part 2 of the QLU form:

A. *Performance characteristics* (see def.) and *physical characteristics* (see def.) required for the material or item to perform its intended function

B. Acceptance criteria to meet required performance and physical characteristics

C. Verification methods, including inspections, tests, or analyses that will be required to demonstrate that the acceptance criteria are met

D. Technical justification and supporting information relevant to the selection of characteristics, acceptance criteria and verification methods.

4.5.1.8 Responsible Engineer: Provide name, signature, and date in QLU Part 3 and send the QLU form to the following personnel for review and approval:

A. Design authority

B. QA engineer

C. A/PCE (for upgrade to QL-2 only)

D. QA director (for upgrade to QL-2 only)

E. ICP chief engineer (for upgrade to QL-2 only).

NOTE: *It may be beneficial to send a draft of the QLU form to the design authority and QA engineer for review prior to this review and approval.*

4.5.2 Review and Approval of the Quality Level Upgrade Plan

4.5.2.1 Design Authority and QA Engineer: Review the QLU form and, if it is acceptable, provide name, signature, and date in Part 3 of the QLU form; otherwise, provide comments back to the responsible engineer.

4.5.2.2 QA Engineer: Indicate whether green tagging will be needed in Part 3 of the QLU form.

4.5.2.3 A/PCE, QA Director, and ICP Chief Engineer: If the QLU plan is to upgrade to a QL-2, review the QLU form and, if it is acceptable, provide, name, signature, and date in Part 3 of the QLU form; otherwise, provide comments back to the responsible engineer.

4.5.2.4 Responsible Engineer: If comments were received on the QLU form, resolve the comments and repeat the review and approval process; otherwise, go to step 4.5.2.5.

NOTE: *In the following step, QLU status can be updated in EDMS by:*

A. Clicking the "Numbering" tab

B. Clicking the "Search/Update QLU Information" link in the "Get a Quality Level Upgrade Number" area

C. Searching for the QLU (such as by QLU number)

D. Selecting "Edit"

E. Selecting the applicable status, clicking "Submit" and then "Confirm."

The EDMS QLU status update function can also be accessed from the Engineering homepage by clicking the "Qual. Level Upgrade" button and then clicking the "Quality Level Upgrade Search and Update" button.

4.5.2.5 Responsible Engineer: When the QLU form is approved, update the QLU system status to "Plan Approved."

4.5.3 Implementing the Quality Level Upgrade Plan

NOTE: *For implementation, it is important that the responsible engineer clearly communicate with the design authority regarding who will perform subsequent steps that are indicated as responsible engineer or design authority.*

4.5.3.1 Responsible Engineer or Design Authority: If inspection or testing is required, initiate a work request per MCP-101, "ICP Integrated Work Control Process."

4.5.3.2 QA Inspector: If inspection or testing is required, perform the inspection or witness the testing as identified in the work order; upon successful completion of inspection or testing, enter verification date and verifier initials in Part 2 of the QLU form.

4.5.3.3 Responsible Engineer or Design Authority: If analysis is required, contact ICP Engineering Analysis to perform the analysis.

4.5.3.4 Design Engineer: If analysis is required, perform the analysis per MCP-2374, "Formal Analysis and Calculations." Provide the approved engineering design file (EDF) for the analysis to the responsible engineer and/or design authority.

4.5.3.5 Responsible Engineer or Design Authority: If analysis was performed and the analysis confirmed the acceptance criteria were met, enter verification date and verifier initials in Part 2 of the QLU form.

4.5.4 Verifying Quality Level Upgrade Implementation

4.5.4.1 QA Inspector and Responsible Engineer: In Part 4 of the QLU form, enter comments, as applicable, and list verification records and attachments; then provide name, signature, and date for completion of implementation verification.

NOTE: *If verification records do not have a unique identifying number (such as WO XXXXXX or EDF-XXXXX) so the records are easily retrievable in EDMS, the records should also be attached to the QLU.*

4.5.4.2 Design Authority: Review the QLU to confirm that the completed upgrade implementation and supporting documentation provide evidence that the acceptance criteria have been met; if so, provide name, signature and date in Part 4 of the QLU form.

4.5.5 Approving the Quality Level Upgrade

4.5.5.1 A/PCE: Provide name, signature, and date in Part 5 of the QLU to approve the quality level upgrade.

4.5.5.2 QA Inspector or Engineer: After A/PCE approval in QLU form Part 5, apply green acceptance tags to the item or SSC, as applicable.

NOTE: *Typically, green tagging applies to equipment that has not been installed, and not to equipment that is already installed.*

4.5.5.3 Responsible Engineer or Design Authority: Submit the final completed and approved QLU (with attachments) to Records Management per MPC-557, "Records Management."

4.5.5.4 Responsible Engineer or Design Authority: Update the QLU status in the QLU system to "Implementation Complete," which is necessary for EDMS to link the completed QLU to the QLU search function (see note preceding step 4.5.2.5 for information on updating QLU status).

4.5.6 Canceling a Quality Level Upgrade

4.5.6.1 Responsible Engineer or Design Authority: If at any time during the QLU process the QLU is determined to be unacceptable or unnecessary, enter the reason for cancellation in Part 6 of the QLU form and provide name, signature, and date.

4.5.6.2 Responsible Engineer or Design Authority: Submit the canceled QLU to Records Management per MPC-557, "Records Management."

4.5.6.3 Responsible Engineer or Design Authority: Update the QLU status in the QLU system to "Cancelled," which is necessary for EDMS to link the canceled QLU to the QLU search function (see note preceding step 4.5.2.5 for information on updating QLU status).

5. RECORDS

Form 431.67, "Quality Level Determination" (QLD form)

Form 431.75, "Quality Level Upgrade for Existing SSCs"

NOTE: *MCP-557, "Records Management", the INL Records Schedule Matrix, and associated record types list(s) provide current information on the storage, turnover, and retention requirements for these records.*

6. DEFINITIONS

commercial grade item. See LST-199, "Quality Assurance Program Requirements Document Definitions."

commercial grade service. See LST-199, "Quality Assurance Program Requirements Document Definitions."

commercial item. See LST-199, "Quality Assurance Program Requirements Document Definitions."

design authority. The organization or personnel having the responsibility and authority for establishing and maintaining the design requirements; ensuring design output documents accurately reflect the design basis; and approving the design bases, configuration, and changes thereto. This function is typically performed by a system engineer, but responsibilities may be assumed by a project engineer, engineering management, or other competent personnel.

engineered item. System, structure, component, or other non-catalog product that does **not** meet the definition of a *commercial item* (see def.); and for which design, manufacture, or fabrication is directly affected or directed by an ICP-produced specification, statement of work, data sheet, or drawing; or by a specification, statement of work, data sheet, or drawing produced for ICP by a subcontractor.

failure consequence level (FCL). An indicator of the degree of adverse effects resulting from the failure of a structure, system, component, software, or activity. The FCL includes the following failure consequence categories, which collectively form the FCL:

A. **Adverse safety impact**—This category is classified based on impact (such as injury or radiological exposure) to the safety of employees and the general public and, as such, addresses both industrial and nuclear safety impacts, including the effect of direct failure of a parent system's nuclear safety function, as documented in the safety analysis report.

B. **Mission interruption**—This category is classified based on adverse impact to the mission of a project, program, or facility. It is recognized that a mission delay, in general, is not perceived to be as severe a risk as personnel injury or environmental damage. However, this category includes the consideration that, should the SSC, software, or activity fail or fail to perform its design function, the success of the project, program, or facility could be significantly impacted. Mission interruption is measured in time and the levels are very approximate. A given delay could vary substantially in significance from one project to another.

C. **Environmental damage**—This category is classified based on the adverse effects to the ecosystem. This category includes the consideration that, should the SSC, software, or activity fail or fail to perform its design function, the ecosystem could be adversely impacted.

D. **Negative government or public perception**—This category is classified based on the adverse impact from the amount of negative public attention about the site. This category is not measured in the number of events, but by the interest in site activities. The amount of interest in site activities is not readily predictable since a primary path of information is through the media, and the type of event that causes interest is dependent on what other information is available at the same time, and on the specific medium used. As such, judgment based on the current political environment is applied.

E. **Adverse cost impact**—This category is classified based on the cost impacts to a project, program, or facility. In general, cost impact is not perceived to be as severe a risk as personnel injury or environmental damage. However, when size of the committed funds is large, more assurance of effective control is required to protect the investment. The basis of cost impact is derived and segregated by monetary considerations.

failure potential level (FPL). An indicator of the degree of possibility that a structure, system, component, software, or activity could fail or fail to perform as designed or planned. Assigning a degree of potential, by its very nature, assumes a level of subjectivity and, hence, requires judgment in the assignment of the FPL and the following failure potential categories that collectively form the FPL:

A. **SSC, software, or activity lifecycle**—This category is classified based on the projected span of time the SSC, software, or activity will be needed. For example, SSCs, software, or activities that will be employed for two weeks or less may not need to be managed to the same level of rigor as those that will be needed for over one year. For existing SSCs, software, and activities, the stage of the lifespan is also a consideration. For example, existing SSCs, software, or activities nearing completion of their lifespan may not need to be managed to the same level of rigor as those in the early stages of their lifespan.

B. **Design or work complexity**—This category is classified based on complexity with the realization that the more complex a design or associated program, project, or activity, the higher the potential for the SSC, software, or activity to fail or fail to perform as designed or planned.

C. **Degree of standardization**—This category is classified based on the maturity of the technology or of the activity. If the SSC, software, or activity has a known performance history, its reliability and, hence, potential for unplanned failure is better understood. If the SSC, software, or activity is an untested state-of-the-art technology or process, the potential for unplanned failure is largely unknown, thus requiring a more conservative approach to design, construction, procurement, operation, performance, and/or maintenance.

D. **Ease of detecting process failure**—This category is classified based on whether failure of the SSC, software, or activity could go undetected while adversely impacting associated equipment, systems, or processes; or if the failure would be readily identifiable at the time of the failure.

E. **Level of personnel qualification and special skills**—This category is classified based on the level and complexity of personnel qualifications and special skills required to operate and maintain the SSC or software or to perform the activity. The other failure potential categories can form a basis for this category. (A more complicated design or work process, less standardized SSC or software, more difficult to detect failure, or history of problems or failures requires more in-depth and specialized training and skill to successfully operate and maintain the SSC or software or perform the activity.)

F. **History of problems or failures**—This category is classified based on the known performance history of the SSC, software, or activity. For example, any of the following types of SSC, software, or activity would receive a higher rating than one with a known history of reliable performance:

- *Suspect/counterfeit item* (see def.) as identified per MCP-9110, "Suspect/Counterfeit Item Identification and Control"
- SSC, software, or activity with a known high rate of failure

- SSC, software, or activity with an unknown history (see degree of standardization failure potential category).

like-for-like replacement item. A replacement item that is typically a spare purchased at the same time from the same vendor as the item it is replacing, or that can be verified to have had no changes in design, materials, or manufacturing process since procurement of the replaced item. A like-for-like-replacement is treated as a routine maintenance or operations function.

mission critical. A structure, system, component, software, or activity that requires a high degree of confidence it will perform its intended function, as determined by the design authority. Considerations include SSCs, software, or activities that:

A. Provide a single barrier to probable serious injury or death. These items may include: pressure relief devices, ASME pressure vessels and over-current protective devices (i.e., breakers and fuses) 480V and above.

B. Provide hazard mitigation or control to protect the public, the workers, or the environment.

C. Perform a defense-in-depth or specific administrative control function.

D. Involves an *engineered item* (see def.).

E. Provide credited protection against regulatory noncompliance or is a requirement of an environmental or other regulatory agreement or permit.

F. Provide for monitoring, surveillance, or data acquisition that is relied upon for regulatory requirement surveillance or reporting.

G. Are permanently installed as active equipment to function as a requirement of PRD-183, "Radiological Control Manual."

H. Perform a load bearing or safety function that is a requirement of Manual 2 "Hoisting and Rigging."

performance characteristic. A property or attribute of an item, process, or service that is determined during testing or operation.

physical characteristic. A property or attribute of an item, process, or service that is primarily material in nature (such as weight, shape, volume, water-proofing, or sturdiness).

quality level (QL). A quantifiable indicator of the failure consequence level, failure potential level, and mission critical status of the structure, system, component, software, or activity. The QL is used to establish the level of rigor applied to process controls intended to protect workers, the public, and the environment; and to protect against mission interruption, negative public perception, and adverse cost impacts.

QL-2 mission critical. SSCs, software, and activities that are not safety significant, but because of the risk level identified using the process for assignment of quality levels directed in this procedure, warrant application of additional quality controls. Risk level is determined from the response to the failure consequence and failure potential levels in the quality level determination.

safety software. The term includes the following:

A. Safety System Software. Software for a nuclear facility that performs a safety function as part of a structure, system, or component and is cited in either (a) a DOE approved documented safety analysis or (b) an approved hazard analysis.

B. Safety and Hazard Analysis Software and Design Software. Software that is used to classify, design, or analyze nuclear facilities. This software is not part of a structure, system, or component (SSC) but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function.

C. Safety Management and Administrative Controls Software. Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirements or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in 10 CFR 830, 10 CFR 835, and the DEAR ISMS clause. *[414.1C]*

safety SSC. A structure, system, or component identified in the documented safety analysis (DSA) for a DOE nuclear facility or activity as safety-class or safety-significant.

software. See LST-199, "Quality Assurance Program Requirements Document Definitions."

structure, system, or component (SSC). See LST-199, "Quality Assurance Program Requirements Document Definitions."

suspect/counterfeit item. See LST-199, "Quality Assurance Program Requirements Document Definitions."

tailored approach. A process by which the level of analysis, documentation, and actions necessary to comply with a requirement are commensurate with the relative importance to safety, safeguards, and security; the magnitude of any hazard involved; the lifecycle stage of the facility; the programmatic mission of a facility; the particular characteristics of the facility; complexity; economic value; and other relevant factors.

waste-acceptance-impacting (WAI). See LST-199, "Quality Assurance Program Requirements Document Definitions."

7. REFERENCES

ASTM F1506, "Flame Resistant and Arc Rated Textile Materials for Wearing Apparel for Use by Electrical Workers Exposed to Momentary Electric Arc and Related Thermal Hazards"

Form 431.17, "Building Structure Number Assignment"

Form 431.67, "Quality Level Determination"

Form 431.75, "Quality Level Upgrade for Existing SSCs"

LST-1, "Responsible Managers, Functional Support Mangers, and Subject Matter Experts"

LST-199, "Quality Assurance Program Requirements Document Definitions"

LST-430, "Safety Software Inventory List"

Manual 2, "Hoisting and Rigging"

MCP-101, "ICP Integrated Work Control Process"

MCP-3772, "Commercial Grade Dedication"

MCP-9110, "Suspect/Counterfeit Item Identification and Control"

PLN-533, "Quality Assurance Program Plan for High Level Waste and Spent Nuclear Fuel"

PLN-3393, "Quality Assurance Program Plan for the Calcine Disposition Project"

PRD-183, "Radiological Control Manual"

8. APPENDIXES

Appendix A, "MCP-540 Procedure Basis"

Appendix A

MCP-540 Procedure Basis

Step	Basis	Source	Citation
All	For hazards identified either in the facility design or during the development of procedures, controls must be incorporated in the appropriate facility design or procedure. Contractors must address hazards when selecting or purchasing equipment, products, and services.	PRD-851, "10 CFR 851 Program Requirements Matrix"	851.22, Hazard prevention and abatement, (a), (1) 851.22, (c)
All	A graded approach based upon risk will be used in categorizing structures, systems, and components and software for applying QA controls…	PRD-5071, "Quality Assurance Program"	4.1.1.9
All	Where appropriate, a graded approach should be used to implement CM. The CM plan should identify how the graded approach will be applied.	PRD-115, "Configuration Management"	3.1, "General Requirements," Graded Approach
All	Many quality assurance programs also have a system for grading quality levels that indicate the importance of the SSCs to safety, mission, operation, or other considerations. Contractors may grade their CM activities consistent with the quality assurance levels.	PRD-115	3.2, "Design Requirements," Quality Level
All	Additional grading may be appropriate. For example, the contractors may want to apply a more stringent CM process to safety SSCs, than to costly SSCs. If so, then the contractor must clearly document the different processes being used and the SSCs to which each process applies.	PRD-115	3.2, "Design Requirements," Documentation of Additional Grading
All	QA controls (grading) will be applied to the degree commensurate necessary to ensure that the level of analysis, documentation, and actions used to comply with requirements are proportioned with…relative importance to safety, safeguards and security; the magnitude of any hazard involved; the life-cycle stage of a facility or item; the programmatic mission of a facility; the peculiar characteristics of a facility or item; the relative importance to radiological and nonradiological hazards; and any other relevant factors.	PRD-5071	4.1.2

Step	Basis	Source	Citation
All	Quality assurance for fire protection systems and equipment shall be provided in accordance with the company's quality assurance program. Fire protection systems and equipment shall be defined as Consumer Grade, QL-4 unless determined otherwise…in accordance with…MCP-540…	PRD-199, "Idaho Cleanup Project Fire Protection Program"	5.2.17, "Quality Assurance, Safety Categorization, and Configuration Control"
4.2.1, 4.2.2, Form 431.67	In applying the graded approach to the CM process, the following factors should be considered: • Relative Importance Factors Situational/Circumstantial Considerations • Facility grade, Facility type, and technical characteristics • SSC grades, Facility remaining lifetime • Facility operational status and life cycle phase • Programmatic and technical issues • Existing programs and procedures	PRD-115	3.2, "Design Requirements," Grading
4.2.1, 4.2.2, Form 431.67	The different expectations for each facility type may be considered to determine what types of implementation actions would be technically appropriate for the facility when the CM process is fully implemented…	PRD-115	3.2, "Design Requirements," Grading Based on Facility Type and Typical Characteristics
4.2.1, 4.2.2, Form 431.67	The facility remaining lifetime is most important in determining the level of effort to expend to develop a new configuration management process for an existing facility…	PRD-115	3.2, "Design Requirements," Grading Based on Remaining Facility Lifetime
4.2.1, 4.2.2, Form 431.67	…For each design, a quality level is assigned to the SSC. The quality level is used as input for application of a graded approach. The graded approach takes into account factors such as (1) level of risk; (2) age, status, and condition of a facility or process; (3) history of problems at a site or facility; (4) adequacy of existing safety documentation; and (5) complexity of products or services.	SAR-100, "ICP Standardized Safety Analysis (SAR) Report Chapters"	Chapter 14, "Quality Assurance, 14.6.2, "Design"

Step	Basis	Source	Citation
4.2.2, Form 431.67	Facility grading for DOE nuclear facilities is performed using DOE STD 1027, "Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports." DOE STD 1027 provides the process for grading DOE nuclear facilities into hazard category 1, 2, and 3 nuclear facilities where: • Hazard category 1 nuclear facilities have the potential for significant off-site consequences. • Hazard category 2 nuclear facilities have the potential for significant on-site consequences beyond localized consequences. • Hazard category 3 nuclear facilities have the potential for only local significant consequences.	PRD-115	3.2, "Design Requirements," Grading Based on Facility Hazard Category
4.2, 4.3, 4.4, 4.5, Form 431.75	The resolution of a programmatic or technical issue can change the importance of a structure, system, or component. For example, a component may be moved from the list of non-safety components to the list of safety components or a system may be determined to be a vital safety system. When such changes occur, contractors will need to review their impact on the list of CM SSCs and revise it accordingly.	PRD-115	3.2, "Design Requirements," Grading Based on Program-matic and Technical Issues
4.2.2, Form 431.67	Items and services may require varying degrees of control and verification to ensure compliance with requirements. Some factors that should be considered in determining appropriate levels of control and verification are: (a) the hazards associated with doing the work or using the results of the work; (b) the consequences of malfunction or failure of the item, or inappropriate use of the results of services provided; (c) the probability of the occurrence of the postulated consequences; (d) the design and fabrication complexity or uniqueness of the item, or difficulty to perform services; (e) the need for special controls and oversight of processes, equipment, and performance; (f) the degree to which functional compliance can be demonstrated by inspection, test, or performance verification; (g) the quality history and degree of standardization of items and services; and (h) the difficulty of repair, replacement, or replication of the items and services.	ASME NQA-1-2008, "Quality Assurance Requirements for Nuclear Facility Applications"	Part III, "Non-mandatory Appendices," 2A-2, "Guidance on Quality Assurance Programs," 502, "Graded Approach"