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REVISION/CHANGE LOG

Revision/Change Letter	Description of Changes	Pages Affected	Date of Revision/Change
FR0	Blue Sheeted Version	All	10/20/2017
FR1	Changes from FPDP to FRNP throughout document; Sections 1.1, 5.2 and Table 1 Appendix B revised. New 1.3 Section added to address safety analysis and safety related items in nuclear criticality safety evaluations. Table 3 - Unmitigated probability of failure revised.	All	11/29/2017
FR2	Changes for performance of graded approach analysis and documentation.	All	01/16/19

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1.0 PURPOSE AND SCOPE

1.1 Purpose

The purpose of graded approach is to select the controls and verifications to be applied to various items and activities consistent with their importance to safety, cost, schedule, and success of the quality program. The selection of controls to be applied to activities that pose the greatest risk for significant negative impact on quality focuses management attention on activities which require the most control and oversight, reducing costs by minimizing the application of controls in areas of low risk.

The graded approach process is intended to:

- Identify activities which present significant quality risk
- Determine the risks and necessary controls
- Document the determination

Project-wide requirements described in the Quality Assurance Program Description (QAPD) specifies a minimum level of quality controls that all activities must satisfy. This prevents any activity from being "graded to zero".

1.2 Scope

This procedure applies to Four Rivers Nuclear Partnership (FRNP), LLC Paducah Gaseous Diffusion Plant (PGDP) Deactivation and Remediation (D&R) contractor employees and subcontractor employees who are directly responsible for activities that have a probable risk of failure. It is intended to be implemented at all levels throughout FRNP.

The Directorate will review the activities associated with the goals defined in the prime contract, while Engineering will review the activities associated with design or plant operational controls.

Formalized processes exist for most applications to consistently and continually address the graded approach (for example, records management, assessment and surveillance planning, work control, hazard analysis, training determination, etc.). For quality level graded approach controls, refer to CP3-EN-0400, *Quality Level Determination (QLD)* and CP3-QA-0307, *Engineering Procurement Specification,* and CP3-QA-1002, *Software Quality Assurance,* for implementation of the graded approach for these processes.

1.3 Safety Function

Items with a specified "safety function" (for example, safety significant items documented within the documented safety analysis, safety related items in nuclear criticality safety evaluations) and associated activities affecting quality are subject to NQA-1 requirements on a graded approach to support the specified "safety function," and in accordance with the definition of commercial grade with respect to initial dedication or acceptance. Similarly, items/activities required by other drivers that specify compliance with NQA-1a, 2009 and all Safety Software are subject to NQA-1 requirements on a graded approach. The term "**NOT** grade to zero" applies to all items and activities including those that are **NOT** nuclear safety related. Quality Level (QL)-4 is the lowest quality level and is subject to the "**NOT** grade to zero" philosophy. The application of QL-4 includes activities subject to Department of Energy (DOE) O 414.1D, Admin. Chg. 1, Criteria 1-10, such as on-site use of the issues management process; use of standard work practices, or manufacturer's instructions within a controlled program (for example,

Integrated Safety Management System effectively covered); suspect counterfeit item controls; and all software.

2.0 REFERENCES

2.1 Use References

- CP3-EN-0307, *Engineering Procurement Specification*
- CP3-EN-0400, *Quality Level Determinations*
- CP3-QA-1002, *Software Quality Assurance*
- DOE-STD-1073-2016, *Configuration Management*

2.2 Source References

- 10 CFR 830, Subpart A, *Quality Assurance Requirements*
- CP2-QA-1000, *Quality Assurance Program Description*
- DOE O 414.1D, *Quality Assurance*
- EM-QA-001, *EM Quality Assurance Program (QAP)*

3.0 COMMITMENTS

None

4.0 RESPONSIBILITIES

Functional Area Manager

- Responsible for applying the graded approach to activities under their control.
- Provides the necessary resources to implement and maintain the graded approach process.
- Ensure compliance with this procedure.
- Ensures processes defined as utilizing graded approach include methods and grading criteria that apply to the activity.

5.0 GENERAL INFORMATION

5.1 The graded approach process is part of Four Rivers Nuclear Partnership (FRNP), LLC Paducah Gaseous Diffusion Plant (PGDP) Deactivation and Remediation (D&R) Quality Assurance Program Description (QAPD). The QAPD is based on the principle that the people best suited to understand risks are the ones who plan and perform the work.

5.2 The graded approach process is an evaluation of activities that describe an incremental process, which guides the user in determining the quality assurance (QA) controls suitable for managing an activity, and applies the methodology described in DOE-STD-1073-2016, *Configuration Management*, with respect to the assignment of graded levels to facilities and programs.

5.3 The graded approach is based on changes in lifecycle considerations, changes related to programmatic and technical concerns, and changes based on remaining lifetime.

NOTE:

Per Contract DE-EM0004895: Non-Category 2 facilities that are: 1) shutdown, 2) do **NOT** have routine personnel access, 3) have utilities isolated, and 4) do **NOT** have authorization basis requirements associated with facility safety should be evaluated on a graded approach . This exemption does **NOT** apply to facilities with structural membrane systems (C-310, C-310-A, C-331, C-333, C-335, and C-337). The roof structural membrane must be maintained according to warranty requirements.

5.4 This procedure describes an incremental process which guides the user in determining the level of controls suitable for managing the risks posed by an activity.

5.5 The graded approach may **NOT** be used in implementing the unreviewed safety question process or in implementing technical safety requirements.

5.6 The application of this process depends on the mission of the organization performing the evaluation.

5.7 While each department and project has the freedom to tailor a grading scale that will fit their specific needs, factors (such as cost, schedule, environment, health & safety, mission, public perception, and security,) shall be considered when grading quality requirements.

6.0 INSTRUCTIONS

NOTE:

When using a graded approach, it should be noted that some activities identified are unique to each organization or project and shall be evaluated by the functional area manager, while other programmatic activities will cut across organizational lines.

Graded Approach is established within formal FRNP processes and this procedure may be exited and those processes used, as applicable.

Examples of existing FRNP processes, where Graded Approach is formalized are listed in Appendix C, *Examples of Programs with Documented Graded Approach*.

6.1 Identification of Hazards, Consequences, and Probability of Failure

<u>Functional Area Manager</u>

6.1.1 When performing a graded approach analysis, go to the governing document for the activity or documentation, for example, plan (such as the QAPD), procedure, directive etc.

6.1.2 **When** other programmatic activities will cut across organizational lines, include the head (or designated representative) of each affected organization or project in the review and selection of controls applied in cross-functional cases.

6.1.3 Identify activities presenting a significant risk if proper controls are **NOT** in place including, but **NOT** limited to, the following examples:

- Processes identified as critical
- Control failures that result in program downtime or a delay to the project schedule
- Single point failures of equipment that may jeopardize project capabilities, budgets, or schedules

- Control failures that may compromise data quality or result in complete or partial loss of data
- Submission of documentation or quality records to ensure an accurate file is compiled
- Activities that can cause injuries, environmental hazards, liabilities, or risks greater than those generally accepted in a deactivation and remediation environment
- Occurrences that could cause a significant reduction in the public trust or project reputation

6.1.4 Identify the activities that present a significant risk and all the steps involved in those activities that have been chosen.

6.1.5 Ensure these activities are documented appropriately according to procedural requirements.

6.1.6 **When** understanding the chosen activities, consider the following:

- Goals of the activities, inputs, outputs, operating constraints, and interactions
- Utilizing subject matter experts
- Consulting with individuals from other organizations if an activity involves that organization

6.2 Determination of Risk Management Strategies & Additional Controls

Functional Area Manager

NOTE:

For example, the Software Quality Assurance Program ensures proper controls are put in place depending on the software classification level assigned to software applications.

The output of this step shall be that adequate controls are chosen and risk management strategies identified to mitigate the risk of impact on quality regardless of the method or tools employed. Results are documented in accordance with program guidance.

6.2.1 Choose the risk management strategy that best fits the activity being evaluated and the risk level associated with that activity.

6.2.2 Utilize available established methods to assist in determining appropriate controls and risk management strategies to implement including, but limited **NOT** to the following:

- Project risk plans for deactivation and remediation project teams – tools used include Welcome Risk, Primavera Risk Analysis, and Risk Registers
- Risk plans used for Information Technology Infrastructure implementation and other computing sector projects
- Activity Level Work Planning and Control Program
- Readiness Review Program

6.3 Determination of Depth, Extent, and Degree of Rigor for Requirements/Controls

Functional Area Manager

6.3.1 Determine the known risks associated with each activity, adequacy and effectiveness of controls for each risk, **and** identify any remaining risks.

6.3.2 **When** evaluating risks, consider factors such as cost, schedule, environment, health & safety, mission, public perception, and security.

NOTE:

Process owners may utilize and/or adapt all or part of Appendix B, *Risk Management Strategies*, within their processes or procedures, as appropriate. The process procedure governs. The appendices are methods or tools to aid in the development and refinement of the graded approach for associated existing or new procedures.

6.3.3 Determine a graded risk level to each activity based on the potential impact for the risks identified.

NOTE:

Activities rated as higher risk/high impact will require a higher degree of control and risk management as opposed to activities rated as low risk/low impact.

6.3.4 Determine risk levels, for example:

- High Risk – Consequences such as injury or death, environmental hazards, release of Department of Energy (DOE) sensitive information could occur.
- Moderate Risk – Consequences such as program downtime, or minor disruptions in laboratory operations could occur.
- Low Risk – Consequences such as reduction in data quality could occur.

6.3.5 Identify risks associated with the process or program being evaluated **and** develop appropriate risk charts to apply to the tasks.

NOTE:

Applications or operations considered as high risk would require more controls than those considered as low risk.

Appendix B may be used in part or whole with processes utilizing graded approach.

6.3.6 Refer to CP3-EN-0307, *Engineering Procurement Specification*, **and** refer to CP3-EN-0400, *Quality Level Deterimination*, for QLD processes.

6.3.7 Evaluate the current state of the identified activity and controls that are already in place.

6.3.8 Determine where controls are missing.

6.3.9 Identify the controls that are necessary to close the gaps, **and** mitigate risk based on the quality level and risk management strategy selected.

6.3.10 Review results from the graded approach processes.

6.3.11 Incorporate the results through established methods such as the following:

- Performance documents,
- Practices,
- Requirements documents,
- Policy statements,
- Standing orders, or
- Other written and controlled means as deemed appropriate by facility/activity management.

6.3.12 **When** graded approach is cited as a process in performance documents or other established methods, describe how the graded approach is applied and captured.

NOTE:

This approval may be conducted through other established processes and is **NOT** standalone from this procedure (for example, procedures, work orders, quality level determinations, etc.)

Level of approval is also based upon the hazards, complexity, and/or relative risk.

Dual documentation is **NOT** required if other processes are utilized (for example, quality level determination, activity level work processes). This also recognizes that the use of graded approach is a routine and regular process through the other established processes.

Approved methods of implementation are maintained as controlled documents and as documentary evidence of the application of the graded approach.

6.3.13 Approve the method for incorporation of the graded approach results.

6.4 Communicate and Implement Requirements and Controls

Functional Area Manager

6.4.1 Determine the method of communication and implementation to affected personnel.

6.4.2 Communicate the documented results to facility/activity personnel to ensure appropriate application using, but **NOT** limited to the following, as applicable:

- Training
- Required Reading
- Crew Briefing

7.0 RECORDS

7.1 Records Generated

The following record may be generated by this procedure:

None

Records of graded approach applications are generated through their respective performance documents.

Appendix A – Acronyms/Definitions

ACRONYMS

D&R – Deactivation and Remediation

DOE – Department of Energy

FRNP – Four Rivers Nuclear Partnership, LLC

PGDP - Paducah Gaseous Diffusion Plant

QA – Quality Assurance

QAPD – Quality Assurance Program Description

QL – Quality Level

QLD – Quality Level Determination

DEFINITIONS

Activities Affecting Quality – The actions that affect the quality of an item or service to meet or demonstrate compliance to requirements. Examples of activities affecting quality include siting, designing, procuring, calibrating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, refueling, modifying, and decommissioning.

Functional Area Manager – A manager responsible to manage the development and implementation of performance strategies, controls, work processes, and flow-down of requirements for a specific functional area. FAMs may also serve as SMEs. Refer to Section 4.0.

Graded Approach – The process of ensuring that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with:

(1) the relative importance to safety, safeguards, and security;

(2) the magnitude of any hazard involved;

(3) the life-cycle stage of a facility or item;

(4) the programmatic mission of a facility;

(5) the particular characteristics of a facility or item;

(6) the relative importance to radiological and nonradiological hazards; and,

(7) any other relevant factors. (10 C.F.R. § 830.3)

Appendix A – Acronyms/Definitions (Continued)

Grading Process - Grading is a management process for determining the degree of rigor, or effort (resources), which needs to be applied to QA program implementation. Multiple factors such as cost, schedule, environment, health and safety, mission, public perception, and security should be considered and taken into account when grading quality requirements. The process includes identifying risk; identifying specific requirements to be applied; determining depth, extent, and degree of rigor in the application of requirements; assigning probability of failure levels; specifying the applicable controls, and documenting the basis for the graded approach.

Risk - A quantitative or qualitative measure of the likelihood and unfavorable consequence of an action. Consequences may be related to public or employee safety, the environment, programmatic impact, cost, schedule, or public perception.

Appendix B - Risk Management Strategies

Consequence: Or impact to the process, is an element of the evaluation of risk and is selected as a designated consequence category, or in some cases is given a numerical consequence level ranking, to determine the overall risk. Consequences can be defined very simply (such as low, medium, high) or have multiple complexity levels depending on the process.

Probability: Probability of failure is the chance or possibility that an error, failure, or unintended outcome will occur over a specific duration. This can apply to individual errors, random failures, or a failure of item(s) within a group.

Risk: Regarding events that, when triggered, cause problems. Usually once risks have been identified, they are evaluated as to their potential severity of impact and to the probability of occurrence. When these quantities are not simple to determine, it is important to make the best estimate possible. In ideal risk management, a prioritization process is followed whereby the risks with the greatest impact and the greatest probability of occurring are handled first, and risks with lower probability of occurrence and lower impact are handled in descending order.

Risk is also dependent upon the probability of failure occurring over a period of time. For a short duration activity the probability of an error may be low but increase with multiple performances of the process or activity.

In practice the process can be very difficult, and balancing between risks with a high probability of occurrence but lower loss versus a risk with high loss but lower probability of occurrence can often be mishandled. The objective of risk management is to eliminate or reduce different risks related to a preselected domain to an acceptable level.

Tolerate: Risk retention (or toleration) means accepting the possible consequences of **NOT** applying controls. This may be a viable strategy for small risks where the cost of mitigating the risk would be greater over time than the total losses sustained or where the likelihood of the negative outcome is considered sufficiently low. This may also apply to high risks where there is **NO** feasible way of mitigation due to cost, technology or other consideration. Risks that are **NOT** terminated or treated are tolerated by default.

Terminate: Risk avoidance (or termination) includes either eliminate the risk by modifying the activity or **NOT** performing an activity that could carry risk. An example would be **NOT** flying to avoid the risk of being in an airplane that is hijacked.

Treat: Risk reduction (or treatment) involves methods that reduce the impact or likelihood of a negative outcome by applying additional controls. Examples include sprinklers or more expensive fire suppression systems designed to reduce the risk of loss in the event of a fire. Additional controls require a method to ensure that the chosen controls work as expected. Administrative checks, monitors or alarms may be used or, in the case of sprinklers, periodic functional tests may be required to ensure that they perform as expected.

Treatment options may include:

- Engineer a physical control or barrier

- Change the design of an activity, process or system to reduce dependence on human performance

Appendix B - Risk Management Strategies (Continued)

- Add to an existing set of controls (An example might be adding a situation to an existing response plan)
- Change a procedure
- Use a new or different technology
- Add an administrative control (create a procedure, add an audit, etc.)
- Transfer the risk to another party (for example, outsource the activity to others)

Some ways of managing risk with high impact or high likelihood (or both) involve the concept of employing multiple barriers to provide defense in depth. Therefore more than one strategy and treatment may be utilized to provide sufficient assurance against the risk.

Grading involves determining the extent, depth, and degree of rigor necessary in the application of quality assurance controls for the items or activities. Such controls may include:

- 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

Appendix C – Examples of Programs with Documented Graded Approach

CP3-EN-0400, *Quality Level Determination*, applies to items and activities for FRNP, and is established based on graded approach consistent with the QAPD. This procedure effectively considers consequence, risk, compliance, and efficiency in its' establishment.

CP3-SM-1101, *Work Package Development*, covers multi-discplines within different areas. This procedure utilizes a formalized graded approach (for example, Type 1, Type 2, Type 3 work packages), includes quality levels, and considers risks, consequences, complexities, and etc.

CP3-OP-0002, *Developing and Maintaining Performance Documents*, covers the performance document development process which includes policies, programs, plans and procedures. This process includes a graded approach to include intent, non-intent, administrative, technical, and additional controls for highly hazardous chemicals (as well as others), all of which have consideration for risk, consequence, etc.

CP3-QA-1007, *Procurement Quality Assurance*, effectively correlates with the quality level determination, procurement, and supplier evaluation procedures to deploy quality on a graded approach to all FRNP items and activity procurements, effectively considering complexity, risk, efficiency, etc. in its' deployment.

CP3-QA-3001, *Issues Management,* applies to the identification, reporting, and resolution of problems, deficiencies, findings, observations, concerns, alerts, occurrences, potential noncompliance, and other events or conditions requiring evaluation for corrective action. This process includes grading levels for the rigor applied to resolution of the issue.

CP3-TR-0100, *Training Program,* ensures levels of analysis, documentation, and activities are commensurate with the importance to safety and security, the hazard(s) involved, facility lifecycle, programmatic mission, and relative importance of hazards.