EFCOG White Paper:

NRC vs. DOE Safety Classification and the Resultant NQA-1 Acceptance Requirements

By the

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Procurement Engineering Quality Task Team

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Procurement Quality Engineering Task Team Members and Principal Authors of this Document

Daw, Spencer L. – Procurement Engineer P.E.

Idaho National Laboratory

EFCOG Procurement Engineering Task Group Chair

McClung, Brad – Quality Assurance Manager

Idaho National Laboratory

EFCOG Procurement Engineering Task Group Member

Harrison, Lawrnel - Project Engineer P.E. / PMP

Avantech Corporation

EFCOG Procurement Engineering Task Group Member

Fish, Michael – Procurement Engineering Manager PMP

Idaho National Laboratory

EFCOG Procurement Engineering Task Group Member

Hendricks, John - Chief Engineer, Equipment Qualification

Curtiss-Wright

EFCOG Procurement Engineering Task Group Member

Hughes, Thomas – P.E.

Industry Expert

Jantosik, David - Senior Vice President

Sequent Consulting

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1.0 Abstract

This document was developed to provide personnel with information regarding Nuclear Regulatory Commission (NRC) and Department of Energy (DOE) safety classification practices and quality requirements based on that classification.

2.0 Purpose

Compare the NRC and DOE safety classification practices and the quality requirements subsequently applied for the procurement of items performing a nuclear safety function. This comparison will be accomplished by providing a description of the current DOE Quality Program approach for Hazard Category 1, 2, and 3 facilities and contrasting that with the approach employed by the Commercial Nuclear Power Generation Industry for structures, systems and components (SSC) performing a nuclear safety function. The resultant information could inform an approach and method to treat items and services with a risk-based approach. Application of such an approach could reduce the level of effort necessary for DOE to accept items currently designed as safety significant or safety class for Hazard Category 1, 2, and 3 facilities. While the CRD allows the contractor to Select ASME NQA-1 as a consensus standard for Haz Cat 1, 2, and 3 facilities, ASME NQA-1 does not include DOE nuclear safety classifications (Safety Class or Safety Significant) as a basis for applicability of the standard but does require the application of a graded approach.

3.0 Current DOE Methodology

To illustrate the DOE's approach to application of quality requirements for nuclear facilities, this paper will describe how DOE nuclear facility requirements, including the application of the graded approach to quality, can be applied across the DOE Complex. Within the DOE Complex, Quality Programs are based on the application of the contractual requirements established by DOE site specific DOE contract requirements. Most typically, these requirements are a result of combining information from 1) 10CFR830, Nuclear Safety Management, the "Law" governing DOE nuclear facility work; 2) DOE O 414.1D, Quality Assurance, the "Order" establishing the quality assurance program requirements for DOE Facilities and the Contractors that operate them; and 3) ASME NQA-1, Quality Assurance Requirements for Nuclear Facility Applications, the "Standard" as referenced by DOE O 414.1D for nuclear facilities classified as Hazard Category 1, 2 or 3. While most DOE contractors choose NQA-1 as its consensus standard, the Order does allow the contractor to propose a QAP based on an alternate standard. In this case, the contractor must show "how they are equivalent to" the version of NQA-1 noted in the Order.

The typical DOE contractor approach to compliance with the two regulatory drivers is as follows; They utilize the definitions for nuclear safety classifications as written in the Law along with the direction provided in the Order for applicability of the quality standard for the treatment of Structures, Systems and Components (SSCs) classified as Safety Class (SC) and/or Safety Significant (SS). The DOE definitions are found below (see Appendix A for a crosswalk between the DOE and NRC definitions and associated quality requirements):

10CFR830 recognizes and defines 2 basic classifications of SSCs: Safety Class (SC) and Safety Significant (SS).

Safety class (SC) structures, systems, and components means the structures, systems, or components, including portions of process systems, whose preventive or mitigative function is necessary to limit radioactive hazardous material exposure to the public, as determined from safety analyses.

Safety significant (SS) structures, systems, and components means the structures, systems, and components which are not designated as safety class structures, systems, and components, but whose preventive or mitigative function is a major contributor to defense in depth and/or worker safety as determined from safety analyses.

Implementation of the above noted requirements can be accomplished through a process of grading. 10CFR830 addresses application of the "Graded Approach" as follows:

Where appropriate, a contractor must use a graded approach to implement the requirements of this part, document the basis of the graded approach used, and submit that documentation to DOE.

The Law (10CFR830) defines the graded approach as follows:

Graded approach means the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement in this part 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;
- (4) The programmatic mission of a facility;
- (5) The particular characteristics of a facility;
- (6) The relative importance of radiological and non-radiological hazards; and
- (7) Any other relevant factor.

From there DOE O 414.1D establishes the applicability of the overall quality standards in the CRD (Contractor Requirements Document) (DOE O 414.1D, Attachment 1). The following excerpt provides the specific requirements from the Order regarding the applicability of consensus quality standards.

DOE O 414.1D, Attachment 1, Paragraph 1. c: Use appropriate national or international consensus standards consistent with contractual and regulatory requirements, and Secretarial Officer direction. Clearly identify which standards, or parts of the standards, are used. When standards do not fully address the CRD requirements, the gaps must be addressed in the QAP. Select and document the appropriate choice below.

- 1. For Hazard Category 1, 2 and 3 nuclear facilities:
 - a. Existing facilities, or new facilities and major modifications to existing facilities achieving Critical Decision 1 (CD-1) prior to the issuance of the Order containing this CRD, continue to use the consensus standard cited in the DOE-approved QAP consistent with Secretarial Officer direction.
 - b. New facilities and major modifications to existing facilities achieving Critical Decision 1 (CD-1) after the Order containing this CRD has been issued use ASME NQA-1-2008 with the NQA-1a-2009 addenda (or a later edition), Quality Assurance Requirements for Nuclear Facility Applications, Part I and applicable requirements of Part II.

Note: Where NQA-1, Part II language uses the terms "nuclear power plant" or "nuclear reactor", these terms are considered equivalent to the term "nuclear facility" used in this CRD.

c. Consensus standard(s) that provide an equivalent level of quality requirements as required in paragraphs 1.c (1) (b) may be used in lieu of those specified to implement the requirements of this CRD. The QAP must document how this consensus standard is (or a set of consensus standards are) used, as well as how they are equivalent to the consensus standard listed in 1.c (1) (b).

4.0 Compliance with the Quality Standard Requirements

While the CRD allows the contractor to Select ASME NQA-1 as a consensus standard for Haz Cat 1, 2, and 3 facilities, ASME NQA-1 does not include DOE nuclear safety classifications (Safety Class or Safety Significant) as a basis for applicability of the standard but does require the application of a graded approach. It is incumbent on the NRC Licensee or DOE owned facility to define how the standard is applied to the various safety systems. The following excerpt from ASME NQA-1, Part I, Section 200 provides the non-specific language for applicability of the nuclear standard for the industry.

200 Applicability: This Part - Part I - is to be applied using a graded approach to any structure, system, component, activity, or organization that is essential to the safe, reliable, and efficient performance of a nuclear facility. (ASME NQA-1-2017)

ASME NQA-1 does not prescribe applicability of the standard based on SSC classifications nor does it use the same terminology used in the safety bases of DOE nuclear facilities. Incorporation of requirements from the Law and the Order with the chosen consensus standard, inclusive of safety classification treatment and graded approach to quality, into the QAP is the responsibility of the contractor managing the DOE facility.

As such, applicability of quality requirements for SS/SC items within the DOE are defined in DOE O 414.1D, Quality Assurance, Attachment 1, Contractor Requirements Document. (noted above)

Application of grading within the procurement quality acceptance process across the DOE complex is inconsistent. The Law, the Order, and the standard all clearly require the application of the "graded approach" to SSCs. The DOE approach to application of quality processes and requirements does not clearly differentiate between Safety Class and Safety Significant items. This lack of clarity can result in an overapplication or an underapplication of quality requirements thereby impacting the cost and rate at which these missions are conducted without improving the actual safety of DOE facilities, personnel, the public and the environment. Additional guidance based on safety classification would improve DOE contractor's ability to "right size" quality.

5.0 Commercial Nuclear Power Methodology

It is important to understand the nuances in language between the approach of the commercial nuclear power industry to applicability of NQA-1 and DOE's approach. To begin, it is helpful to understand the various safety SSC designation / definitions used by the NRC and the DOE.

10CFR50.2, Definitions:

Safety-related structures, systems and components means those structures, systems and components that are relied upon to remain functional during and following design basis events to assure:

- 1. The integrity of the reactor coolant pressure boundary
- 2. The capability to shut down the reactor and maintain it in a safe shutdown condition; or
- 3. The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in § 50.34(a)(1) or § 100.11 of this chapter, as applicable.

The above definition is aligned with the 10CFR830 definition for Safety Class in that it focuses on providing protection to the public. DOE and NRC are aligned in the quality standard applied when procuring Safety Related (NRC) and Safety Class (DOE) items. For these items, a similar level of quality is required, and commercial grade dedication has been identified as an acceptable method of acceptance for both.

Quality requirements for safety designations related to co-located worker safety is where the NRC and DOE diverge. Where the DOE has the safety classification of "Safety Significant" to address co-located worker safety, the NRC counter parts are defined in 10-CFR50.69 as well as in 10CFR70. Below is a discussion their definition and associated quality requirements.

10CFR50.69 RISC categories 2,3, and 4 as well as Important to Safety (ITS) are items that can provide defense in depth within NRC, but are not required to adhere to 10CFR50

Appendix B. For the mentioned (NRC) items, NRC requires augmented quality to be applied such as what is noted in NUREG 0800, "Standard Review Plan", Section Part 17.5, Part U, "Non-Safety Related SSC Quality Controls". Safety Significant items, as defined by DOE, also require implementation of an NQA-1 program or equivalent utilizing the Graded Approach.

10CFR70, Domestic Licensing of Special Nuclear Material, designates certain items as "Items Relied Upon for Safety (IROFS)". The definition for these items is as follows:

Items relied on for safety mean structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in § 70.61 or to mitigate their potential consequences. This does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety.

This definition more closely approximates with the DOE definition of Safety Significant. NQA-1 can be employed to implement the requirements of 10CFR70 and thereby control the procurement of IROFS via standard NQA-1 controls including Sub-Part 2.14. It is important to note that these requirements are not applied to an operating power plant but are required of facilities controlling special nuclear material, like a fuel manufacturer or a spent fuel storage facility.

Sub-part classification or item re-classification:

In addition, the commercial nuclear power industry is provided further relief through the 10CFR50.69 process which allows further grading of safety related components to limit the treatment of low risk items. The risk determination yields a grading classification which is then used to determine the applicability of requirements. The following definitions provide additional information to clarify options for commercial nuclear power plant:

10CFR50.69, (a) Definitions:

Risk-Informed Safety Class (RISC)–1 structures, systems, and components (SSCs) means safety-related SSCs that perform safety significant functions.

Risk-Informed Safety Class (RISC)–2 structures, systems and components (SSCs) means non-safety-related SSCs that perform safety significant functions.

Risk-Informed Safety Class (RISC)–3 structures, systems and components (SSCs) means safety-related SSCs that perform low safety significant functions.

Risk-Informed Safety Class (RISC)–4 structures, systems and components (SSCs) means non-safety-related SSCs that perform low safety significant functions.

Safety significant function means a function whose degradation or loss could result in a significant adverse effect on defense-in-depth, safety margin, or risk.

While the commercial nuclear power industry does work to different laws, rules and standards than the DOE Complex, both NRC regulators and DOE government oversight provide for the appropriate application of grading to facilitate the best possible outcomes. A factor that differentiates DOE from NRC is that DOE is typically an OWNER/REGULATOR¹ of DOE facilities where NRC only acts in a Regulator role. While the NRC regulatory model's primary focus is to ensure public safety, the DOE has a more direct responsibility to the co-located worker as the Owner. Hence, the additional safety designation of "Safety Significant".

10CFR50.69 allows "alternative treatment" of Safety Significant SSCs based specifically on risk as determined using a documented categorization process. The prescribed alternative treatment allows relief from eleven (11) of the standard program requirements established for the industry including 10CFR50 and 10CFR Part 21.

The approach defined by 10CFR50.69 does require the analysis, including a probabilistic risk analysis (PRA) and categorization of SSCs to assign the RISC categories defined above. The up-front investment to perform this analysis can provide the opportunity to reduce the workload required to maintain low risk SSCs particularly when conservative approaches were used to initially assign the safety significant classification.

The approach used in commercial nuclear power generation is an accepted method and, based on historical performance and safety data, does not have a negative impact on the safety of facilities, personnel, the public or the environment.

6.0 Conclusion

As noted in Appendix A, DOE and NRC differ in their use of terminology applied to safety systems. As such, the application of quality based on those differing definitions also varies. NRC employs a rigorous, well documented, graded approach that instructs licensees on how SSCs can be evaluated and graded based on risk and significance via 10CFR50.69. While the DOE does provide requirements as well as guidance on the application of the graded approach to quality, implementation and application of those requirements and guidance varies across the DOE operated facilities. A contributor to that variance is the absence of the DOE safety designations within the NQA-1 Standard. The net effect of this variation can result in an overapplication of rigor with regards to quality requirements where a properly applied graded approach would result in "right-sizing" needed quality requirements.

A follow on EFCOG task is recommended to provide examples of the graded approach as well as lessons learned and graded approach best practices for safety SSC procurements.

¹ While the term "Regulator" is often used to describe DOE oversight, its role is the not the same as that performed by NRC. See link for additional information: https://www.energy.gov/em/services/program-management/regulatory-compliance

Appendix A

NRC vs. DOE Safety Classification

NRC			DOE		
CFR	Safety Classification	Applicable Codes / Standards / Guides		Safety Classification	CFR / ORDER
10CFR50 Appendix B	Safety Related	NQA-1	ANSI N45.2	Safety Class	10CFR830
10CFR50.69	RISC-1	EPRI 5652			DOE 0 414.1D
10CFR70	IROFS / ITS	NQA-1 or Equiv.	NQA-1 EPRI 5652	Safety Significant (identified as Defense in Depth in 10CFR830)	10CFR830 DOE 0 414.1D
10CFR50.69	RISC-3	NUREG 0800 Section 17.5, Part U			
10CFR50.69	Defense In Depth (RISC-2, RISC-4)	Applicable Codes and Standards			