STAFF REVIEW OF DOE'S APPROACH TO THE RISK-SIGNIFICANCE CATEGORIZATION OF STRUCTURES, SYSTEMS, AND COMPONENTS IMPORTANT TO SAFETY

1. 0 PURPOSE

The purposes of this paper are to: (1) identify attributes of an acceptable approach to risk-significance categorization of structures, systems, and components (SSCs), consistent with their importance to safety; (2) evaluate the U.S. Department of Energy's (DOE's) proposed approach for the risk-significance categorization of structures, systems and components important to safety (SSCIS) for the proposed geologic repository operations area (GROA) at the Yucca Mountain site; and (3) summarize the staff's position on DOE's proposed approach.

To this end, this paper discusses the governing regulation and applicable policy and guidance and develops general acceptance criteria based on this information. Further, it discusses DOE's proposed approach to risk-significance categorization and evaluates its approach against the general acceptance criteria, governing regulation, and applicable policy and guidance. This paper also summarizes the staff's position regarding DOE's proposed approach to risk-significance categorization and identifies potential concerns resulting from this review.

2.0 APPLICABLE NRC REGULATION

Draft Final 10 CFR Part 63 (Ref. 1) allows the risk-significance categorization of SSCs to an extent consistent with their importance to safety (Draft Final 10 CFR 63.142) and identifies the performance objectives governing preclosure operations (Draft Final 10 CFR 63.111). It also requires DOE to conduct a preclosure safety analysis (PCSA) for the GROA (Draft Final 10 CFR 63.112). However, the Part 63 does not identify or designate any specific process or methodology for risk categorization. Therefore, to ensure regulatory consistency it is essential for the reader to have a clear understanding of the regulations governing the design, construction, and operations of a potential GROA at the Yucca Mountain site and other similar U.S. Nuclear Regulatory Commission (NRC) -regulated facilities. With this in mind, relevant portions of applicable regulatory requirements and preclosure performance objectives for the GROA are provided in Appendix A.

3.0 APPLICABLE NRC POLICY AND GUIDANCE

There are no regulatory guidance documents or policies specifically relating to the risk-significance categorization of SSCs consistent with their importance to safety for a potential GROA. However, NRC has developed extensive direction (in the form of regulatory policy and guidance) on risk-informed decision-making that is directly related to risk categorization and the issues being considered by this paper. A summary of relevant information from such documents is provided in Appendix B.

4.0 ATTRIBUTES OF AN ACCEPTABLE RISK-SIGNIFICANCE CATEGORIZATION PROCESS FOR GROA SSCS

The following discussion identifies acceptable attributes for an approach to risk-significance categorization of SSCIS, consistent with their relative importance to safety. These attributes are based on the governing regulation and applicable policy and guidance discussed in the appendices. The following attributes represent the minimum characteristics necessary for an acceptable approach to risk-significance categorization of SSCIS.

4.1 The risk-significance categorization of SSCIS shall be consistent with the existing regulatory framework:

- The identification of SSCIS shall be done using a PCSA methodology that is consistent with and fulfills the requirements in Draft Final 10 CFR 63.112;
- The categorization methodology shall consider the frequency of Category 1 and 2 event sequences as defined in the Draft Final 10 CFR 63.2;
- The categorization methodology shall consider the dose limits in the Draft Final 10 CFR 63.111 [including Draft Final 10 CFR 20(Ref. 2)]; and
- The categorization methodology shall provide due consideration of uncertainty and variability in the event sequence frequencies and their sensitivity analyses in a manner that is consistent with applicable portions of existing NRC policy and guidance, including: "Use of Probabilistic Risk Assessment in Nuclear Regulatory Activities: Final Policy Statement" (Ref. 3); Regulatory Guide (RG) 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis" (Ref. 4); RG 1.176, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance"(Ref. 5); SECY-98-144, "White Paper on Risk-Informed and Performance-Based Regulation"(Ref. 6); SECY-99-100, "Framework for Risk-Informed Regulation in the Office of NMSS"(Ref. 7); and NUREG-0800, Chapter 19, "Use of PRA in Plant-Specific Risk-Informed Decision-Making: General Guidance"(Ref. 8).

4.2 The risk-significance categorization of SSCIS shall be consistent with their relative importance to safety:

- The categorization methodology shall ensure that SSCIS are categorized consistent with their risk-significance and relative importance to safety (Draft Final 10 CFR 63.142);
- The distinctions between quality levels (QLs) shall have a well-defined and well-documented technical basis;
- The frequencies and consequences of failures of SSCIS at the various QLs shall be well-defined and consistent with applicable portions of existing NRC policy and guidance; and
- The categorization methodology for SSCIS shall be supported by appropriate qualitative descriptions of the different QLs and quantitative or semi-quantitative methods for determining the SSC's importance to safety.

4.3 The risk-significance categorization of SSCIS shall demonstrate flexibility:

- The categorization methodology should demonstrate flexibility to accommodate the iterative nature of the design process;
- The categorization methodology should permit the revision of the QL of individual and groups of SSCIS as a result of the introduction of new data and/or design changes; and
- The categorization methodology should be flexible enough to accommodate multiple iterations of the PCSA and subsequent evaluation of risk-significance.

4.4 The documentation and analysis for the risk-significance categorization of SSCIS shall be transparent and traceable:

- The risk-significance categorization methodology shall be developed and presented in such a manner that the reviewer can gain a clear understanding of every step of what has been done, what the results are, and the technical bases for the results; and
- The categorization methodology shall include an unambiguous and complete record of the decisions and assumptions made, and the process used in arriving at a given conclusion or result.

The previous discussion outlines the staff's expectations for an acceptable categorization methodology and is based on an extensive review of existing regulatory requirements, policy, and guidance. These attributes are expected to be developed into acceptance criteria and introduced into the appropriate sections of the Yucca Mountain Review Plan (YMRP) that is currently under development.

5.0 DOES'S PROPOSED APPROACH TO THE RISK-SIGNIFICANCE CATEGORIZATION OF SSCIS

The DOE's proposed approach to the risk-significance categorization of SSCIS is still evolving. It is described in the Preliminary Preclosure Safety Assessment (PPSA) (Ref. 8) and in the Repository Safety Strategy (RSS)(Ref. 10), and an updated version of the approach was presented to the staff during the most recent technical exchange (Ref. 11). This approach involves performing a Preclosure Safety Analysis (PCSA) that identifies those SSCs that will be relied upon to protect the health and safety of the public and onsite workers, as required in Draft Final 10 CFR 63.112.

The PPSA and the RSS and material presented in a recent technical exchange provide descriptions of the individual elements of the PCSA process, as well as a graphical representation of this process. The DOE's PCSA is comprised of the following elements:

- Internal and External Hazard Identification;
- Event Sequence Identification;
- Quantitative Frequency Assessment;
- Design Basis Event (DBE) Categorization <u>or</u> Beyond Design Basis Event (BDBE) Determination;
- Consequence Analysis of DBEs;
- Evaluation of Specific DBE Consequences Against Regulatory Performance Objectives for DBE Category;
- Identification of SSCIS and development of the Safety Basis <u>or</u> Determination of the Need for Preventive or Mitigative Features and Assessment of Impact on the Design.

DOE's categorization process uses a combination of risk-informed and deterministic screening criteria. Quality assurance (QA) procedure QAP-2-3, "Classification of Permanent Items" (Ref. 12), contains all of these screening criteria and is summarized in Appendix C (Note: this procedure is in the process of being revised). SSCs are categorized in a graded fashion to assure QA controls are commensurate with the item's importance to safety. This categorization process screens the SSCs into one of the following categories or QLs:

- QL-1: Permanent items (SSCIS) whose failure could *directly* result in a condition adversely affecting public safety. These permanent items are determined to have a high safety or waste isolation significance.

- QL-2: Permanent items (SSCIS) whose failure or malfunction could *indirectly* result in a condition adversely affecting public safety, or whose direct failure would result in consequences in excess of normal operational limits. These permanent items are determined to have low public safety or waste isolation significance.

- QL-3: Permanent items (SSCIS) whose failure or malfunction would not significantly impact public or worker safety, including those defense-in-depth design features intended to keep doses As Low As Reasonably Achievable (ALARA). These permanent items are determined to have minor impact on public or worker safety or waste isolation.

- Conventional Quality(CQ): Permanent items not meeting any of the criteria for QLs 1, 2, or 3.

The risk-informed screening criteria are very closely linked to the PCSA, and several of the elements identified above play an integral role in DOE's risk-significance determination and categorization process. The PCSA identifies the credible event sequences, initiating events, event sequences, and the associated frequencies and consequences. The categorization process individually considers each event sequence frequency and consequences to determine a step-wise risk measure (in terms of dose). These risk measures are compared to the screening criteria identified in QAP-2-3 (illustrated in Appendix D) which are based on the performance objectives identified in Draft Final 10 CFR 63.111. In addition, a "take-away" analysis (Ref. 11) will also be performed on each of the SSCs identified in each of the event sequences to establish a measure of risk associated with each of the individual SSCs. Each of these SSCs will be conservatively categorized consistent with the event sequences frequency reduction and dose mitigation importance, again as compared to the screening criteria identified in QAP-2-3 (illustrated in Appendix D). DOE is developing a revised procedure and desktop reference that will document and provide a clear description of the categorization process, screening criteria, and "take-away" analysis (Ref. 11).

The remaining screening criteria are deterministic in nature and are intended to address waste package containment and criticality control, fire suppression and protection [consistent with Regulatory Guide 1.189, Fire Protection for Operating Nuclear Power Plants (Ref. 13)], and seismic [consistent with Regulatory Guide1.29, Seismic Design Classification (Ref. 14)] issues and concerns.

DOE's categorization process is based on, and is considered by DOE to be consistent with the classification process outlined in NUREG/CR-6407 (Ref. 15). A detailed summary of the QL screening criteria is included in Appendix C. Finally, this iteration of the categorization process is completed when the appropriate SSCs are added to the Q-List as described in the procedure YAP-2.7Q (Ref. 16).

6.0 STAFF'S POSITION ON DOE'S APPROACH TO RISK-SIGNIFICANCE CATEGORIZATION OF SSCIS

Draft Final 10 CFR Part 63, and Part 20 and 10 CFR Parts 50 (Ref. 18), and 70 (Ref. 19) do not identify or require any specific process or methodology for the risk-significance categorization of SSCIS. Further, there is no regulatory guidance or policy specifically addressing risk categorization of SSCIS for a potential GROA. However, NRC has developed extensive direction (in the form of regulatory policy and guidance) on risk-informed decision-making that is directly related to risk categorization and the issues being considered by this paper. To adequately review DOE's proposed risk-categorization methodology, it is necessary to consider the applicable policy and guidance governing the design, construction, and operations of a potential GROA at the Yucca Mountain site and other similar NRC-regulated facilities.

DOE's proposed risk-categorization methodology is based on the QLs defined in procedure QAP-2-3 and its associated screening criteria, as discussed earlier in this paper. DOE has stated that the QL or "important-to-safety classification" is "consistent" (Ref. 11) with the three tier approach and classification categories described in NUREG/CR-6407 (Ref. 14). It is important to note that the approach identified in NUREG/CR-6407 [and its predecessor RG 7.10 (Ref. 19)] predates all of the risk-informed policy and guidance developed by the NRC since the Commission's "Use of Probabilistic Risk Assessment in Nuclear Regulatory Activities: Final Policy Statement" (Ref. 3) was issued in 1995. Further, the approach to classification identified in NUREG/CR-6407 does not require the consideration of risk insights or significance, nor does it consider probability. It only assesses consequences in terms of the maximum activity of radioactive material permitted in the transportation package. It assigns classification categories using a strictly deterministic approach. The staff has several concerns regarding DOE's use of the classification categories described in NUREG/CR-6407 for the risk-significance categorization of SSCIS of a potential GROA. Many of these concerns were discussed with DOE during a recent technical exchange (Ref. 11).

DOE has agreed to address these NRC concerns raised at the last Preclosure Technical Exchange, including the need to:

- Provide a definition of the term "indirect impact" that is based on, and consistent with, RGs 1.29 and 1.189;
- Perform and document sensitivity and uncertainty analyses;
- Use a multi-disciplinary review group similar to the "expert panel" described in Regulatory Guide 1.176; and
- Consider the occurrence of multiple category 1 event sequences within a given year.

DOE will need to show compliance with all the requirements contained in Draft Final 10 CFR Part 63. Although NRC requires compliance with all its requirements, NRC does not expect that the same level of QA is necessary for demonstrating compliance for each requirement. The NRC regulations provide flexibility to DOE in the development of its QA program, subject to review and approval by the NRC staff. The objective of a graded QA program is to provide a level of confidence that each structure, system, or component will perform its safety function, commensurate with its importance to safety or waste isolation. Therefore, DOE's demonstration of compliance with NRC requirements may include graded QA and other appropriate measures to provide a level of confidence that is consistent with the safety significance of the SSCs that affect compliance. However, the NRC has the authority to make certain exceptions and specify additional requirements for certain attributes of the DOE QA plan.

Draft Final 10 CFR Part 63 allows DOE to categorize or assign different levels of QA to SSCs whose failure to function has different risk or dose implications. In approving such an approach, the NRC staff will take into account such things as the regulatory basis for the specific requirements, regulatory precedence, and risk-significance. For example, DOE has suggested a level of QL-1 for SSCs related to meeting the overall public dose limit of 1.0-millisievert per year (mSv/yr) [100-millirem per year (mrem/yr)] and a level QL-2 for SSCs necessary for meeting the preclosure dose limit of 0.15-mSv/yr (15-mrem/yr). Subject to further staff review of the quality provisions associated with QL-1 and QL-2, this appears to be appropriate. Rationale for such grading may include: (1) the 0.15-mSv/yr (15-mrem/yr) limit is a constraint on this potential source of radiation exposure to ensure that the overall public dose limit of 1.0-mSv (100-mrem) is not exceeded from all sources [i.e., if the 0.15-mSv (15-mrem) limit were to be exceeded but remain below 1.0-mSv (100-mrem), the overall dose limit of 1.0-mSv (100-mrem) would be exceeded only if the individual received additional exposure(s) from other sources in the area]; (2) the risk associated with a 0.15-mSv (15-mrem) annual dose is significantly below the risk associated with a 1.0-mSv (100-mrem) annual dose; and (3) compliance will be monitored during any repository operations [i.e., practices that produce doses in excess of the 0.15-mSv (15-mrem) limit may be subject to corrective actions, including the cessation of operations until corrective actions are implemented].

7.0 SUMMARY

This paper has: (1) identified attributes of an acceptable approach to risk-significance categorization of SSCs, consistent with their importance to safety; (2) evaluated DOE's proposed approach for the risk-significance categorization of SSCIS for the proposed GROA; and (3) summarized the staff position on DOE's proposed approach to categorization. The staff consider the issue of QL categorization to be an integral component of preclosure safety. The staff fully expect to continue discussing issues associated with this important matter and provide feedback as necessary during DOE's implementation of their QL categorization.

8.0 REFERENCES

1. *U.S. Nuclear Regulatory Commission*, "Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada," Part 63, Title 10, "Energy."
2. U.S. Nuclear Regulatory Commission, "Use of Probabilistic Risk Assessment in Nuclear Regulatory Activities: Final Policy Statement," *Federal Register*, Vol. 60, No. 158, August 16, 1995, pp. 42622-42629.
3. *U.S. Code of Federal Regulations*, "Standards for Protection Against Radiation," Part 20, Title 10, "Energy."
4. U.S. Nuclear Regulatory Commission, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," Regulatory Guide 1.174.
5. U.S. Nuclear Regulatory Commission, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance," Regulatory Guide 1.176.
6. U.S. Nuclear Regulatory Commission, "White Paper on Risk-Informed and Performance-Based Regulation," SECY-98-144, June 22, 1998.
7. U.S. Nuclear Regulatory Commission, "Framework for Risk-Informed Regulation in the Office of NMSS," SECY-99-100, March 31, 1999.
8. U.S. Nuclear Regulatory Commission, "United States Nuclear Regulatory Commission Standard Review Plan, Office of Nuclear Reactor Regulation," NUREG-0800, April 10, 2000.
9. U.S. Department of Energy, Office of Civilian Radioactive Waste Management, "Preliminary Preclosure Safety Assessment," BC0000000-01717-0210-00001, REV 00, ICN 01, August, 2000.
10. U.S. Department of Energy, Office of Civilian Radioactive Waste Management, "Repository Safety Strategy," TDR-WIS-RL-000001, Rev. 04, ICN 01, November 2000.
11. U.S. Nuclear Regulatory Commission, "U.S. Nuclear Regulatory Commission/ U.S. Department of Energy Technical Exchange and Management Meeting on Preclosure Safety (July 24-26, 2001)," August 14, 2001.
12. U.S. Department of Energy, Office of Civilian Radioactive Waste Management, "Classification of Permanent Items," QAP-2-3, Revision 10, May 26, 1999.
13. U.S. Nuclear Regulatory Commission, "Fire Protection for Operating Nuclear Power Plants," Regulatory Guide 1.189, April 2001.
14. U.S. Nuclear Regulatory Commission, "Seismic Design Classification," Regulatory Guide 1.29, Revision 3, September 1978.
15. U.S. Nuclear Regulatory Commission, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety," NUREG/CR-6407 (INEL-95/0551), February 1996.

16. U.S. Department of Energy, Office of Civilian Radioactive Waste Management, "Item classification an Maintenance of the Q-List procedure," YAP-2.7Q, Revision 1, ICN2, December 24, 1999.
17. *U.S. Code of Federal Regulations*, "Domestic Licensing of Production and Utilization Facilities," Part 50, Title 10, "Energy."
18. *U.S. Code of Federal Regulations*, "Domestic Licensing of Special Nuclear Material," Part 70, Title 10, "Energy."
19. U.S. Nuclear Regulatory Commission, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," Regulatory Guide 7.10, Revision 1, June, 1986.

APPENDIX A

APPLICABLE NRC REGULATIONS

Draft Final 10 CFR Part 63 (Ref. 1) provides regulations governing the licensing and operation of the U.S. Department of Energy to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area (GROA) sited, constructed, or operated at Yucca Mountain, Nevada, in accordance with the Nuclear Waste Policy Act of 1982, as amended, and the Energy Policy Act of 1992.

To have a clear understanding of the requirements governing the categorization of structures, systems, and components (SSCs), it is first necessary to review several key sections of the rule, including: Draft Final 10 CFR 63.2, Definitions; Draft Final 10 CFR 63.111, "Performance Objective for the Geologic Repository Operations Area through Permanent Closure;" Draft Final 10 CFR 63.112, "Requirements for Preclosure Safety Analysis of the Geologic Repository Operations Area;" and Draft Final 10 CFR 63.142, "Quality Assurance Criteria."

Draft Final 10 CFR 63.2 provides a definition of "event sequences":

> "Event sequence means a series of actions and/or occurrences within the natural and engineered components of a geologic repository operations area that could potentially lead to exposure of individuals to radiation. An event sequence includes one or more initiating events and associated combinations of repository system component failures, including those produced by the action or inaction of operating personnel. Those event sequences that are expected to occur one or more times before permanent closure of the geologic repository operations area are referred to as Category 1 event sequences. Other event sequences that have at least one chance in 10,000 of occurring before permanent closure are referred to as Category 2 event sequences."

Draft Final 10 CFR 63.2 provides a definition of "important to safety" (ITS):

> "... those engineered features of the geologic repository operations area whose function is: (1) To provide reasonable assurance that high-level waste can be received, handled, packaged, stored, emplaced, and retrieved without exceeding the requirements of § 63.111(b)(1) for Category 1 event sequences; or (2) To prevent or mitigate Category 2 event sequences that could result in doses exceeding the values specified at § 63.111 (b)(2) to any individual located on or beyond any point on the boundary of the site."

Draft Final 10 CFR 63.2 provides a definition of "Preclosure Safety Analysis" (PCSA):

> "... a systematic examination of the site; the design; and the potential hazards, initiating events and event sequences and their dose consequences to workers and the public. The analysis identifies structures, systems, and components important to safety."

Draft Final 10 CFR 63.111 specifies performance objectives governing each of the following areas: protection against radiation exposures and releases of radioactive material; numerical guides for design objectives; preclosure safety analysis; performance confirmation; and retrievability of waste. A summary of these performance objectives has been included in the following discussion:

Draft Final 10 CFR 63.111, "Performance Objectives for the Geologic Repository Operations Area through Permanent Closure."

(a) *Protection against radiation exposures and releases of radioactive materia*l.

(1) The GROA must meet the requirements of Part 20 of this chapter.

(2) During normal operations, and for Category 1 event sequences, the annual dose to any real member of the public, located beyond the boundary of the site may not exceed the preclosure standard specified at 10 CFR 63.204.

(b) *Numerical guides for design objective*s.

(1) The GROA must be designed so that taking into consideration Category 1 event sequences and until permanent closure has been completed, the aggregate radiation exposures and the aggregate radiation levels in both restricted and unrestricted areas, and the aggregate releases of radioactive materials to unrestricted areas, will be maintained within the limits specified in paragraph (a) of this section.

(2) The GROA must be designed so that taking into consideration any single Category 2 event sequence and until permanent closure has been completed, no individual located on, or beyond, any point on the boundary of the site, will receive, as a result of the single Category 2 event sequence, the more limiting of a total effective dose equivalent of 0.05 sieverts (Sv) [5 rem], or the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 0.5 Sv (50 rem). The lens dose equivalent may not exceed 0.15 Sv (15 rem), and the shallow dose equivalent to skin may not exceed 0.5 Sv (50 rem).

(c) *Preclosure safety analysi*s. A preclosure safety analysis of the GROA that meets the requirements specified at 10 CFR 63.112 must be performed. This analysis must demonstrate that:

(1) The requirements of 10 CFR 63.111(a) will be met; and

(2) The design meets the requirements of 10 CFR 63.111(b).

(d) *Performance confirmatio*n. The GROA must be designed so as to permit implementation of a performance confirmation program that meets the requirements of Subpart F.

(e) *Retrievability of wast*e.

(1) The geologic repository operations area must be designed to preserve the option of waste retrieval throughout the period during which wastes are being emplaced and thereafter, until the completion of a performance confirmation program and Commission review of the information obtained from such a program. To satisfy this objective, the GROA must be designed so that any or all of the emplaced waste could be retrieved on a reasonable schedule starting at any time up to 50 years after waste emplacement operations are initiated, unless a different time period is approved or specified by the Commission. This different time period may be established on a case-by-case basis consistent with the emplacement schedule and the planned performance confirmation program.

(2) This requirement may not preclude decisions by the Commission to allow backfilling part, or all of, or permanent closure of the GROA before the end of the period of design for retrievability.

(3) For purposes of paragraph (e) of this section, a reasonable schedule for retrieval is one that would permit retrieval in about the same time as that required to construct the GROA and emplace waste.

The rule specifies the use of a PCSA of the GROA to, in part, provide a comprehensive identification of hazards. Specifically, 10 CFR 63.112(b) requires:

> "An identification and systematic analysis of naturally occurring and human-induced hazards at the geologic repository operations area, including a comprehensive identification of potential event sequences.

The rule specifies the use of an PCSA of the GROA to, in part, identify those SSCs that are important to safety. Specifically, and 10 CFR 63.112(e) requires:

> "An analysis of the performance of the structures, systems, and components to identify those that are important to safety. This analysis identifies and describes the controls that are relied on to limit or prevent potential event sequences or mitigate their consequences. This analysis also identifies measures taken to ensure the availability of safety systems...."

Subpart G of the rule outlines the scope, applicability, and implementation of the Quality Assurance Program. Specifically, 10 CFR 63.142(a) states:

> "DOE is required by §63.21(c)(20) to include a description of the quality assurance program to be applied to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to related activities in its safety analysis report."

10 CFR 63.142(c)(1) states:

> "... The quality assurance program must control activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety."

These sections of the rule form the regulatory basis for the risk-informed categorization of ITS SSCs for the GROA.

The use of integrated safety analysis (ISA) and risk categorization as required in the revised 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material: Possession of a Critical Mass of Special Nuclear Material" (Ref. 2), provides another U.S. Nuclear Regulatory Commission staff approved approach to risk-informed decision-making. The new 10 CFR 70.61(a) requires an applicant or licensee to perform an ISA to demonstrate compliance with the performance requirements stated in 10 CFR 70.61(b), (c), and (d). These performance requirements outline the interaction between consequences, likelihood, and ultimately, risk, as it is defined in this rule; and are summarized in the following discussion:

- 10 CFR 70.61(b) requires that the risk of each credible high-consequence event must be limited. It further states that engineered and/or administrative controls shall be applied to the extent needed to reduce the likelihood of occurrence of the event such that, implementation of the controls, the event is highly unlikely or its consequences are less severe than those identified in 10 CFR 70.61(b)(1)-(4).

- 10 CFR 70.61(c) requires that the risk of each credible intermediate-consequence event must be limited. It further states that engineered and/or administrative controls shall be applied to the extent needed to reduce the likelihood of occurrence of the event such that, implementation of the controls, the event is unlikely or its consequences are less severe than those identified in 10 CFR 70.61(c)(1)-(4).

- 10 CFR 70.61(d) requires that the risk of nuclear criticality must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality.

The rule prescribes consequence categories and acceptable levels of risk, while allowing the applicant or licensee to determine and justify the gradation of likelihood categories.

Revised 10 CFR 70.4 defines items relied on for safety as SSCs and activities of personnel that are relied on to prevent potential accidents, at a facility, that exceed the performance requirements in 10 CFR 70.61 above or to mitigate their potential consequences.

The new 10 CFR 70.62(d) requires that each applicant or licensee establish management measures to ensure compliance with the performance requirements of Sec. 70.61. It states that the measures applied to a particular engineered or administrative control or control system may be graded commensurate with the reduction of the risk attributable to that control or control system. These management measures shall ensure that engineered and/or administrative controls and control systems, that are identified as IROFS, are implemented and maintained, as necessary, to ensure they are available and reliable to perform their function when needed, in compliance with the performance requirements in 10 CFR 70.61.

REFERENCES

1. *U.S. Nuclear Regulatory Commission*, "Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada," Part 63, Title 10, "Energy."
2. *U.S. Code of Federal Regulations*, "Domestic Licensing of Special Nuclear Material," Part 70, Title 10, "Energy."

APPENDIX B

APPLICABLE NRC POLICY AND GUIDANCE

The U.S. Nuclear Regulatory Commission (NRC) has also developed extensive direction (in the form of policy and guidance) on the use and application of risk insights in the regulatory decision-making process. The following discussion captures the portions of the policy and guidance that provide insight into the risk-informed categorization process identified in the Draft Final 10 CFR Part 63 (Ref. 1), as discussed above.

NRC's "Use of Probabilistic Risk Assessment in Nuclear Regulatory Activities: Final Policy Statement," (Ref. 2) encourages greater use of probabilistic risk assessment (PRA) and risk insights to improve safety decision-making and regulatory efficiency. This policy statement sets forth the Commission's intention to encourage the use of PRA, and to expand the scope of PRA applications in all nuclear regulatory matters to the extent supported by the state-of-the-art in terms of methods and data. The probabilistic approach to regulation is considered an extension and enhancement of traditional (deterministic) regulation, by considering risk in a more coherent and complete manner ultimately focusing regulations on those items most important to safety.

Several Regulatory Guides (RGs) discuss the application of risk insights and risk-importance measures to categorize structures, systems, and components (SSCs) with respect to safety significance, including: RG 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis" (Ref. 3), and RG 1.176, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance" (Ref. 4).

RG 1.174 provides general guidance concerning an approach that NRC has determined to be acceptable for analyzing issues associated with proposed changes to a plant's licensing basis (LB) and for assessing the impact of such proposed changes on the risk associated with plant design and operation. This RG forms the basis for the approach to graded Quality Assurance (QA) as discussed in RG 1.176, and referenced by the U.S. Department of Energy (DOE). One of the major considerations (or decision criteria) for incorporating risk insights into the risk-informed decision-making process is an estimate of the change in risk as a result of the proposed change. This approach supports NRC's desire to base its decisions on the results of traditional engineering evaluations, supported by insights (derived from the use of PRA methods) about the risk-significance of the proposed changes. This RG is intended to improve the consistency in regulatory decisions in the areas in which the results of risk analyses are used to help justify regulatory action.

Regulatory Guide 1.174 establishes a set of key safety principles and expectations which the risk-informed decision-making approach is based and describes a four-element process for evaluating risk-informed regulatory changes, consistent with those safety principles. The key principles of integrated risk-informed regulatory decision-making are identified as: consistency with current regulation; consistency with defense-in-depth philosophy; maintaining sufficient safety margins; requiring increases in risk to be small and within the intent of the NRC's "Safety Goals for the Operation of Nuclear Power Plants" (Ref. 5); and lastly, monitoring the impact of the of the proposed changes using performance measurement strategies. The four-element approach for evaluating risk-informed regulatory changes is identified as: defining the change; performing engineering analyses (traditional and PRA); defining the implementation and monitoring program; and submitting the proposed change.

Regulatory Guide 1.174 focuses on the use of PRA findings and risk insights as they relate to the regulatory decision-making process associated with proposed changes to a plant's LB. RG 1.174 indicates that some proposed licensing basis changes can be characterized as involving the categorization of SSCs according to their safety significance. An example is grading the application of QA controls commensurate with the safety significance of equipment. Licensing Basis change requests for applications involving safety categorization will be evaluated according to the acceptance guidelines associated with each of the key principle and expectations presented in this RG, unless equivalent guidelines are proposed by the licensee. Since risk-importance measures are often used in such categorizations, guidance on their use is provided in Appendix A of this RG. Other application-specific guidance documents address guidelines associated with the adequacy of programs (in this example, quality controls) implemented for different safety-significant categories (e.g., more safety-significant and less safety-significant).

Guidance on the use of risk-importance measures, which are often used to support the categorization of SSCs, is provided in RG 1.174, Appendix A, "Use of Risk-Importance Measures to Categorize Structures, Systems, and Components with respect to Safety Significance." Specific guidance on the categorization of SSCs according to safety significance is provided in RG 1.176. Of particular interest, it discusses grading the application of QA controls commensurate with the safety significance of the equipment.

Regulatory Guide 1.176 describes an acceptable method for the categorization of SSCs at nuclear power plants in a manner commensurate with their safety significance (using an integration of insights from traditional engineering analyses, applicable qualitative considerations, and probabilistic analyses) and for applying appropriate QA programs to each category of SSC. RG 1.176 focuses the risk-informed decision-making process discussed in RG 1.174 on proposed changes to the QA categorizations of certain SSCs. This RG provides considerable guidance relating to the categorization of safety-significant SSCs, including:

- Identification of system functions;
- System function safety-significant categorization;
- Quantitative (importance measures) and qualitative safety categorization insights;
- Identification and categorization of support systems;
- The use of an expert panel to perform an integrated assessment; and
- Performance monitoring, operational feedback, and corrective actions.

Regulatory Guide 1.176 presents a categorization process that uses quantitative PRA results, supplemented by traditional qualitative engineering evaluations, to develop an initial categorization level based on the safety-significance of the respective SSC. Such a combined, integrated approach is necessary to use the strengths and avoid the inherent limitations in both probabilistic and traditional engineering analysis methodologies.

NUREG-0800, "Standard Review Plan", Chapter 19, "Use of Probabilistic Risk Assessment in Plant-Specific, Risk-Informed Decisionmaking: General Guidance" (Ref. 6), identifies the roles and responsibilities of NRC organizations in the NRC that participate in risk-informed reviews of licensees' proposals for changes to the LB of nuclear power plants. This chapter provides additional insights on the use and review of PRA in risk-informed regulatory decision-making and is directly applicable to the risk-informed categorization of SSCs consistent with their contribution to risk. Specifically, this chapter has a substantial discussion of the adequacy and use of PRA, risk insights, and importance measures used in the risk-informed decision-making process. It also provides expanded discussion on the key principles, expectations, and elements discussed in RG 1.174. Further, Appendix C, "Categorization of Plant Specific Elements with Respect to Safety Significance", provides detailed guidance on the use, review, and expectations regarding the use of PRA and importance measures as they relate or contribute to the risk-informed decision-making. The guidance provided in this document is a logical extension of current NRC policy, on the use of PRA in regulatory activities, that is documented in the U.S. NRC's, "Use of Probabilistic Risk Assessment in Nuclear Regulatory Activities: Final Policy Statement" (Ref. 7). It also notes that the decision-making process should use the results of the risk analyses in a manner that complements traditional engineering approaches, supports the defense-in-depth philosophy, and preserves safety margins; however, it should not be the sole basis for regulatory decisions.

Draft NUREG-1520, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility”, Chapter 3, “Integrated Safety Analysis” (Ref. 8), provides guidance on integrated safety analysis (ISA) methodology (including acceptance criteria for the quantitative and qualitative definitions of likelihood); hazard and accident analysis, items relied on for safety (IROFS), and an example procedure for risk evaluation.

The ISA is initially used to identify credible uncontrolled and unmitigated accidents that exceed intermediate and high consequence. After this determination, the ISA is also used to determine the IROFS that are needed to ensure that the probability of occurrence of those accidents that exceed intermediate and high consequence are unlikely and highly-unlikely, respectively. Draft NUREG-1520, Chapter 3, Appendix A, “Example Procedure for Risk Evaluation”, provides an approved methodology that could be used to categorize risk and demonstrate compliance with the performance requirements identified in 10 CFR 70.61. In this example a risk matrix is used to quantify risk in terms of risk index numbers (refer to Table A-3). These risk index numbers then provide a mechanism for the categorization of risk for the credible accident scenarios identified in the ISA. These risk index numbers are used to determine if the level of risk associated with an accident is acceptable or unacceptable (based on the performance requirements in 10 CFR 70.61). Further, these risk index numbers can be used to categorize IROFS commensurate with the reduction of risk attributable to the IROFS, as required in 10 CFR 70.62(d).

NUREG/CR-6407, “Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety” (Ref. 9), is included in this discussion because DOE has incorporated several aspects of the described classification methodology into the DOE-proposed approach to risk-informed categorization for the geologic repository operations area (GROA). The methodology described in NUREG/CR-6407 presents an approach to the classification of components according to their importance to safety and was based on RG 7.10, “Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material”(Ref. 10). NUREG/CR-6407 and RG 7.10 present a method of classification of various components in transportation packaging. Each component of a transportation package is first identified as either important to safety (ITS) or not ITS. The components that are considered ITS are further categorized into one of the following three classification categories (depending on that component’s importance to safety):

- Critical to Safe Operation - These items include structures, components, and systems whose failure could directly result in a condition adversely affecting public health and safety. The failure of a single item could cause loss of primary containment, leading to release of radioactive material, loss of shielding, or unsafe geometry compromising criticality control.
- Major Impact on Safety - These items include structures, components, and systems whose failure or malfunction could indirectly result in a condition adversely affecting public health and safety. The failure of this type of item, in conjunction with the failure of an additional SSC, could result in an unsafe condition.
- Minor Impact on Safety - These items include structures, components, and systems whose failure or malfunction would not significantly reduce the packaging effectiveness and would not be likely to create a situation adversely affecting public health and safety.

NUREG/CR-6407 provides a well-defined list of typical components for each container type and assigns a primary safety function (containment, criticality control, shielding, heat transfer, structural integrity, and operations support) to each of these components. It then assigns an ITS classification category to each of the components based on the component’s, safety-function and container type.

REFERENCES

1. *U.S. Nuclear Regulatory Commission*, “Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada,” Part 63, Title 10, “Energy.”
2. U.S. Nuclear Regulatory Commission, “Use of Probabilistic Risk Assessment in Nuclear Regulatory Activities: Final Policy Statement,” *Federal Register*, Vol. 60, No. 158, August 16, 1995, pp. 42622-42629.
3. U.S. Nuclear Regulatory Commission, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” Regulatory Guide 1.174.
4. U.S. Nuclear Regulatory Commission, “An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance,” Regulatory Guide 1.176.
5. U.S. Nuclear Regulatory Commission, “Safety Goals for the Operation of Nuclear Power Plants, Policy Statement,” *Federal Register*, Vol. 51, August 4, 1985, p. 30028.
6. U.S. Nuclear Regulatory Commission, “United States Nuclear Regulatory Commission Standard Review Plan, Office of Nuclear Reactor Regulation,” NUREG-0800, April 10, 2000.
7. U.S. Nuclear Regulatory Commission, “White Paper on Risk-Informed and Performance-Based Regulation,” SECY-98-144, June 22, 1998.
8. U.S. Nuclear Regulatory Commission, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,” (Draft Report) NUREG-1520, September 20, 2001.
9. U.S. Nuclear Regulatory Commission, “Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety,” NUREG/CR-6407 (INEL-95/0551), February 1996.
10. U.S. Nuclear Regulatory Commission, “Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material,” Regulatory Guide 7.10, Revision 1, June, 1986.

APPENDIX C

SUMMARY OF PROPOSED SCREENING CRITERIA IDENTIFIED IN PROCEDURE QUALITY ASSURANCE PROCEDURE, QAP-2-3, Rev. 10 (Ref. 1)

All the systems, structures, and components (SSCs) are pre-screened for importance to safety or waste isolation, using the following criteria:

- Is the item directly or indirectly relied upon to provide an important-to-safety (ITS) function (confinement/containment, criticality control, shielding, heat transfer, structural integrity; or operations necessary for waste-handling safety) for radioactive wastes received or handled?

Preclosure screening criteria for quality level 1 (QL-1) SSCs are summarized as:

- Can failure of the item *directly result* in loss of waste package containment or criticality control for the spent nuclear fuel, high-level wastes, or other radioactive materials received for emplacement at the monitored geologic repository (MGR)?
- Is the item required to *prevent or mitigate* a Category 1 event sequence that could result in offsite doses of greater than or equal to performance objectives identified in 10 CFR 63.111(a)(1), 10 CFR 63(b)(1), and 10 CFR 20.1301(a)(1) [1.0-millisievert (100-mrem)] (Ref.2)?
- Is the item required to *prevent or mitigate* a Category 2 event sequence that could result in offsite doses of greater than or equal to performance objective identified in 10 CFR 63.111(b)(2) [0.05-sievert (Sv) [5 rem]]?

Preclosure screening criteria for QL-2 SSCs are summarized as:

- Does the item function to provide control or management (i.e., collection and/or confinement) of site-generated liquid, gaseous, or solid low-level or mixed waste?
- Does the item provide fire protection, fire suppression, or otherwise protect important-to-radiological-safety or waste isolation functions of QL-1 SSCs from the hazards of a fire?
- As a result of design basis event (DBE), could consequential failure of the item, which is not intended to perform a QL-1 radiological safety function, prevent QL-1 SSCs from performing their intended radiological safety function?
- Is the item required to *prevent or mitigate* a Category 1 event sequence that could result in offsite doses of greater than, or equal to, performance objectives identified in 10 CFR 63.111(a)(2)?
- Is the item *in conjunction with an additional item or administrative control* (i.e., indirect impact), required to *prevent or mitigate* a Category 1 event sequence that could result in offsite doses of greater than, or equal to, performance objectives identified in 10 CFR 63.111(a)(1), 10 CFR 63(b)(1), and 10 CFR 20.1301(a)(1)?
- Is the item *in conjunction with an additional item or administrative control* (i.e., indirect impact), required to *prevent or mitigate* a Category 2 event sequence that could result in offsite doses of greater than, or equal to, performance objectives identified in 10 CFR 63.111(b)(2)?

Preclosure screening criteria for QL-3 SSCs are summarized as [occupational/monitoring/as low as is reasonably achievable (ALARA)]:

- Does the item function to provide an alarm to warn of significant increases in radiation levels or concentrations of radioactive materials?
- Does the item function to monitor variables to verify that operating conditions are within technical specification limits?
- Is the item used in MGR emergency response to provide prompt evacuation of personnel, or to monitor variables used in helping to determine the cause or consequence of DBEs (during post-accident investigations)?
- Does the item function as a part of the radiological, meteorological, or environmental monitoring systems required to assess radionuclide release or dispersion after a DBE?

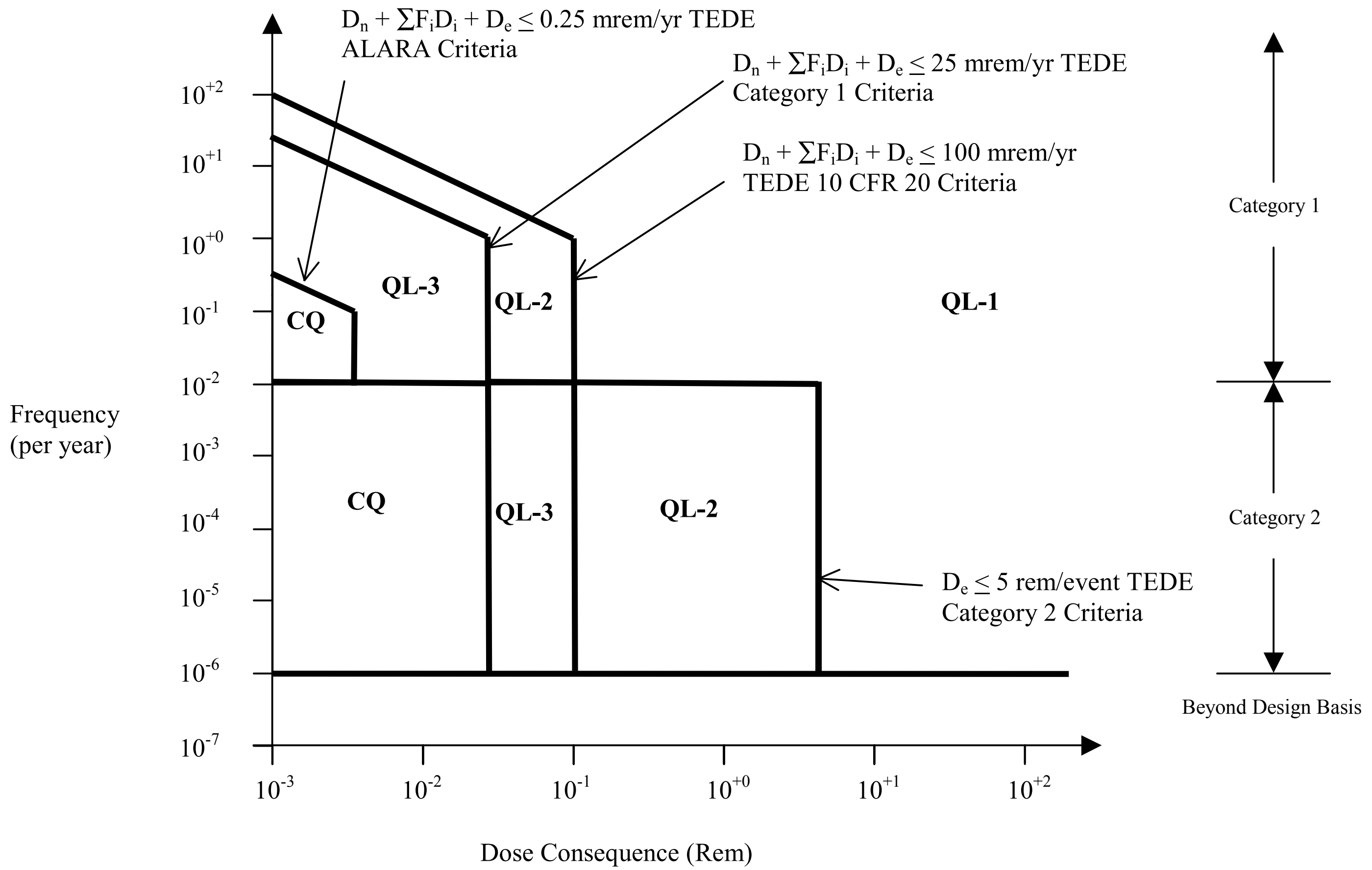
- Is the item part of the design or design objectives for keeping levels of radioactive material in effluent to unrestricted areas as low as practicable during normal operations?
- Is the item required to limit onsite worker doses from normal operations and during Category 1 DBEs, including planned recovery operations; to less than 0.05-Sv (5-rem) per year total effective dose equivalent (TEDE); 0.5-Sv (50-rem) per year combined deep dose equivalent and committed dose equivalent to any individual organ or tissue (other than the eye); 0.15-millisievert (mSv) 15-millirem (mrem) per year dose equivalent to the lens of the eye; or 0.5-Sv (50-rem) per year shallow dose equivalent to the skin or any extremity?

REFERENCES

1. U.S. Department of Energy, Office of Civilian Radioactive Waste Management, "Classification of Permanent Items," QAP-2-3, Revision 10, May 26, 1999.
2. *U.S. Nuclear Regulatory Commission*, "Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada," Part 63, Title 10, "Energy."

APPENDIX D

DOE's Proposed Criteria for Risk-Informed Classification Analysis



(Presented at the NRC/DOE Technical Exchange July 24-26, 2001)