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**Safety Basis Upgrade Review
 Criteria Review and Approach Document**

Authorization and Approval

Director, Office of Nuclear Safety
 and Environmental Assessments

Date: August 20, 2014

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Date: August 20, 2014

1.0 PURPOSE

Within the Office of Enterprise Assessments (EA), the Office of Environment, Safety and Health Assessments (EA-30) mission is to assess the effectiveness of those safety and emergency management systems and practices used by line and contractor organizations in implementing Integrated Safety Management; and to provide clear, concise, and independent evaluations of performance in protecting our workers, the public, and the environment from the hazards associated with Department of Energy (DOE) activities and sites.

In addition to the general independent oversight requirements and responsibilities specified in DOE Order 227.1, *Independent Oversight Program*, this criteria review and approach document (CRAD), in part, fulfills the responsibility assigned to EA in DOE Order 420.1C to conduct independent oversight reviews of implementation of the requirements of the Order.

A key to success is the rigor and comprehensiveness of our process; and, as with any process, we continually strive to improve and provide additional value and insight to field operations. Integral to this is our commitment to enhance our program. We continue to make CRADs available for use by DOE line and contractor assessment personnel in developing effective DOE oversight, contractor self-assessment, and corrective action processes; the current revision is available at: <http://energy.gov/iea/listings/criteria-review-and-approach-documents>.

2.0 APPLICABILITY

The following CRAD is approved for use by the Office of Nuclear Safety and Environmental Assessments (EA-31).

3.0 FEEDBACK

Comments and suggestions for improvements on this CRAD can be directed to the Director, Office of Environment, Safety and Health Assessments, at (301) 903-5392.

4.0 CRITERIA REVIEW AND APPROACH

OBJECTIVE

SB.1: The contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must establish and maintain the safety basis for the facility. (10 CFR 830 Section 830.202.a)

SB.2: In maintaining the safety basis for a hazard category 1, 2, or 3 DOE nuclear facility, the contractor responsible for the facility must: (1) Update the safety basis to keep it current and to reflect changes in the facility, the work, and the hazards as they are analyzed in the documented safety analysis (DSA); (2) Annually submit to DOE either the updated DSA for approval or a letter stating that there have been no changes in the DSA since the prior submission; and (3) Incorporate in the safety basis any changes, conditions, or hazard controls directed by DOE. (10 CFR 830 Section 830.202.c)

SB.3: In establishing the safety basis for a hazard category 1, 2, or 3 DOE nuclear facility, the contractor responsible for the facility must: (1) Define the scope of the work to be performed; (2) Identify and analyze the hazards associated with the work; (3) Categorize the facility consistent with DOE-STD-1027-92; (4) Prepare a DSA for the facility; and (5) Establish the hazard controls upon which the contractor will rely to ensure adequate protection of workers, the public, and the environment. (10 CFR 830 Section 830.202.b)

SB.4: Table 2 sets forth acceptable methodologies for preparing a DSA. (10 CFR 830 Appendix A, Section F.4)

SB.5: With respect to a hazard category 1, 2, or 3 new DOE nuclear facility or a major modification to a hazard category 1, 2, or 3 DOE nuclear facility, a contractor may not begin operation of the facility or modification prior to the issuance of a safety evaluation report in which DOE approves the safety basis for the facility or modification. (10 CFR 830 Section 207.d)

SB.6: A contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must: (1) Develop technical safety requirements (TSRs) that are derived from the DSA; and (2) Obtain DOE approval of TSRs and any change to TSRs. (10 CFR 830 Section 205.a.1&2)

SB.7: If construction begins after December 11, 2000, the contractor responsible for a hazard category 1, 2, or 3 new DOE nuclear facility or a major modification¹ to a hazard category 1, 2, or 3 DOE nuclear

¹*Major modification* means a modification to a DOE nuclear facility that is completed on or after April 9, 2001 that substantially changes the existing safety basis for the facility. [10 CFR 830 Section 3]

facility must prepare a preliminary DSA for the facility, and obtain DOE approval of the nuclear safety design criteria to be used in preparing the preliminary DSA (unless the contractor uses the design criteria in DOE Order 420.1, *Facility Safety*) and the preliminary DSA before the contractor can procure materials or components or begin construction. (10 CFR 830 Section 206.a & .b)

CRITERIA

Hazard and Accident Analysis (Chapter 3)

1. The DSA for a hazard category 1, 2, or 3 DOE nuclear facility must, as appropriate for the complexities and hazards associated with the facility, provide a systematic identification of both natural and man-made hazards associated with the facility. (10 CFR 830 Section 830.204.b.2)
2. Defense-in-depth must include using equipment and administrative controls that restrict deviation from normal operations, monitor facility conditions during and after an event, and provide for response to accidents to achieve a safe condition. (DOE O 420.1B Change 1, Chapter I, Section 3.b.2.(f))
 - If a major topic specified in DOE-STD-3009 is not covered due to the application of the graded approach, is it discussed?
 - Is the hazard analysis based on the currently approved scope of work at the facility?
 - Does the hazard analysis include hazard identification that specifies or estimates the hazards relevant for DSA consideration (i.e., both natural and man-made hazards associated with the work and the facility) in terms of type, quantity, and form?
 - Does the hazard analysis present a systematic, comprehensive identification of hazardous materials and energy sources present by type, quantity, form, and location; natural phenomena hazards, including design basis and beyond-design-basis events; and sources of external hazards, such as nearby airports, railroads, or utilities such as natural gas lines?
 - Does the hazards analysis include explicit description or reference to the material at risk (MAR), chemical or radiological, potentially affected in the selected hazard scenarios?
 - Does the hazard analysis include a hazard evaluation that covers the activities for which approval is sought?
 - Is the hazard analysis consistent in approach with safe harbor methodologies?
 - Does the hazard analysis identify preventive and mitigative features for the spectrum of events examined using a proper hierarchy?
 - Does the hazard analysis identify dominant accident scenarios through ranking or an equivalent structure?
 - Do the dominant accident scenarios establish representative, bounding, and unique accidents?
 - Are normal, abnormal, and accident conditions (including consideration of natural and manmade external events, identification of energy sources or processes that might contribute to the generation or uncontrolled release of radioactive and other hazardous materials) evaluated?
 - Are the results of hazards evaluation summarized to identify significant defense-in-depth and worker safety features, hazard controls, including safety-significant structures, systems or components (SSCs), specific administrative controls (SACs), and key elements of safety management programs?
 - Is the Fire Hazards Analysis current and the results integrated into the hazard analysis?
3. The DSA for a hazard category 1, 2, or 3 DOE nuclear facility must, as appropriate for the complexities and hazards associated with the facility, evaluate normal, abnormal, and accident conditions, including consideration of natural and man-made external events, identification of energy sources or processes that might contribute to the generation or uncontrolled release of radioactive and

other hazardous materials, and consideration of the need for analysis of accidents which may be beyond the design basis of the facility. (10 CFR 830 Section 830.204.b.3)

- Does the accident analysis clearly substantiate the findings and delineations of hazard analysis for the subset of events examined and confirm their potential consequences?
 - Are results clearly characterized in terms of public safety, defense-in-depth, worker safety, and environmental protection (i.e., the consequence results represent a significant hazard to safety of workers or the public, or represent a significant uncontrolled release of hazardous material to the environment, or challenge or exceed applicable evaluation guidelines)?
 - Does the accident analysis clearly and completely describe accident progression?
 - Is the accident analysis methodology adequate to conservatively assess dose or exposure at receptor locations representing onsite workers and the public?
 - Are all pertinent assumptions (e.g., hazardous material inventory, airborne release fraction, and damage ratio) established?
 - Are the consequences of postulated accidents appropriately compared with the evaluation guideline and evaluated to classify safety SSCs and SACs?
4. The DSA for a hazard category 1, 2, or 3 DOE nuclear facility must, as appropriate for the complexities and hazards associated with the facility, derive the hazard controls necessary to ensure adequate protection of workers, the public, and the environment, demonstrate the adequacy of these controls to eliminate, limit, or mitigate identified hazards, and define the process for maintaining the hazard controls current at all times and controlling their use. (10 CFR 830 Section 830.204.b.4)
- Are the consequences used appropriately to classify safety SSCs and SACs in accordance with DOE guidance?
 - Is the logic behind assessing the results in terms of safety-significant SSCs, SACs, and designation of TSRs understandable and internally consistent?
 - Have safety-class and safety-significant SSCs, SACs and associated TSRs been identified for preventing and/or mitigating events potentially exceeding evaluation guidelines?
 - Does the selection of hazard controls appropriately follow the principles associated with the hierarchy of controls?
 - Are the selected hazard controls, both individually and collectively, adequate to prevent or mitigate the accidents for which they are credited as a control?
 - Are potential beyond design basis accidents identified and the need for their evaluation considered and evaluated as appropriate?
 - Are mitigated design basis accidents that do not meet the DOE evaluation guideline for the maximally exposed offsite individual evaluated and dispositioned as exigent circumstances (see DOE S-2 Letter: Poneman to Winokur, July 19, 2012)?

Beyond Design Basis Accidents (Chapter 3)

5. The DSA for a hazard category 1, 2, or 3 DOE nuclear facility must, as appropriate for the complexities and hazards associated with the facility, evaluate normal, abnormal, and accident conditions, including consideration of natural and man-made external events, identification of energy sources or processes that might contribute to the generation or uncontrolled release of radioactive and other hazardous materials, and consideration of the need for analysis of accidents which may be beyond the design basis of the facility. (10 CFR 830 Section 830.204.b.3)
6. Program Offices shall direct contractors responsible for hazard category 1 and 2 nuclear facilities that have the potential to exceed DOE's 25 rem public dose evaluation guideline, based on an unmitigated analysis, to conduct an evaluation using the guidance in Attachment 2 in conjunction with the 2015

annual update of their DSAs. [OE-1: 2013-01, Improving Department of Energy Capabilities for Mitigating Beyond Design Basis Events, Action 2]

- Does the facility have the potential to exceed the DOE evaluation guideline (25 rem) for any unmitigated accidents?
- What beyond design basis accidents (DBAs) were identified and considered for evaluation as part of the DSA revision/development? Have these beyond DBAs been identified as bases for additional cost-benefit analysis?
- If beyond DBAs were evaluated, did the types of events include seismic events, fires, explosions, criticality, floods, lightning, wind and tornados, snow and ice, ash fall, airplane crash, electrical blackout, or cascading effects of DBAs?
- Was the rationale for excluding any of the types of events above documented?
- Did the evaluation estimate the consequences associated with failures of SSCs that provide safety functions, such as confinement, energy removal, or prevention of energetic reaction?
- Were any events that could cause an accident with the potential for a release of radioactive material and potentially also impact emergency power supplies identified (i.e., a release of radioactive material from primary confinement barriers with a simultaneous loss of power)?
- What were the results of any analysis (performed as part of the DSA) of capabilities to address beyond DBAs?
- Were SSCs identified as mitigating beyond DBA consequences subjected to a margins assessment (to provide insight into their margin-to-failure)?
- Have descriptions of the performance capabilities of the existing safety SSCs been added or revised to include performance capabilities based on new or relevant information?
- Has the insight from beyond DBA analysis been used to identify additional facility features (such as, non-credited SSCs) that could prevent or reduce severe beyond DBA consequences?
- If so, does the DSA identify these non-credited SSCs as important for providing mitigation of beyond DBAs (for inclusion in the facility configuration management and maintenance programs)?
- Were any additional mitigation strategies identified for beyond DBAs?
- Have the descriptions of the beyond DBA accident scenarios been updated to clarify important assumptions needed to support development of abnormal or emergency operating procedures?
- Have improvements necessary to support emergency management response plans been identified and included in the DSA?

Safety Structures, Systems, and Components (Chapter 4)

7. The DSA for a hazard category 1, 2, or 3 DOE nuclear facility must, as appropriate for the complexities and hazards associated with the facility, derive the hazard controls necessary to ensure adequate protection of workers, the public, and the environment, demonstrate the adequacy of these controls to eliminate, limit, or mitigate identified hazards, and define the process for maintaining the hazard controls current at all times and controlling their use. (10 CFR 830 Section 830.204.b.4)
8. Safety analyses must be used to establish: (a) the identity and functions of safety class and safety significant SSCs, (b) the significance to safety of functions performed by safety class and safety significant SSCs, and (c) the SACs needed to fulfill safety functions. (DOE O 420.1B, Change 1, Chapter I, Section 3.a.1)

- Does the DSA satisfactorily document the basis for determining the safety SSCs and their required functions?
- Are the safety SSCs identified and described in the DSA consistent with the logic presented in the hazard and accident analyses?

- Are safety functions for safety SSCs defined with clarity and consistent with the bases derived in the hazard and accident analyses?
- Is the required functional classification of an SSC (e.g., safety-class or safety-significant) based on a proper assessment of the unmitigated accident consequence?
- Are the boundaries and interface points of safety SSCs (relevant to their safety function), including the support systems, clearly defined?
- Do the functional requirements and system evaluations derive from the safety functions and provide evidence that the safety functions can be performed when called upon?
- Are safety functions and the design and functional requirements for safety SSCs defined with clarity, and are they consistent with the bases derived in the hazard and accident analyses? Specifically, for each safety SSC, does the safety basis document:
 - Identify safety functions to be performed or maintained by safety SSCs, consistent with the hazard and accident analyses, in the normal, abnormal, or accident conditions postulated?
 - Identify functional and design requirements (e.g., to address non-ambient environmental stresses, or to withstand seismic and other natural phenomena)?
 - Identify the performance criteria necessary to provide reasonable assurance that SSC functional requirements will be met (e.g., surveillance, maintenance, specific operational response, requisite operator training and qualifications)?
 - Evaluate the safety SSCs capabilities to ensure that the performance criteria are satisfied?
 - Identify and designate as safety SSC the support systems on which safety SSCs rely to perform or maintain safety functions?
 - Provide for TSR coverage?
- Was a system evaluation performed to assure that the safety functions can be performed when called upon?
- Does the system evaluation identify the performance criteria necessary to ensure that the identified functional requirements will be met?
- Are the general requirements for safety SSCs (e.g., conservative design features, design against single-point failure, environmental qualification, safe failure modes) appropriately specified?
- Are codes and standards appropriately specified and tailored, as necessary, based on functional classification and safety function?
- Is the control of safety SSCs relevant to TSR development clearly defined?
- Are the identified safety SSCs adequate to mitigate or prevent the analyzed accidents with potential to exceed evaluation guidelines?
- Does the suite of safety controls provide multiple layers of protection to prevent or mitigate the unintended release of radioactive materials?

Specific Administrative Controls (Chapter 4)

9. As appropriate for a particular DOE nuclear facility, the section of the TSRs on Administrative Controls Organization and management, procedures, recordkeeping, assessment, and reporting necessary to ensure safe operation of a facility is consistent with the TSR. In general, the administrative controls section addresses (1) the requirements associated with administrative controls (including those for reporting violations of the TSR); (2) the staffing requirements for facility positions important to safe conduct of the facility; and (3) the commitments to the safety management programs identified in the DSA as necessary components of the safety basis for the facility. (10 CFR 830 Appendix A, Table 4)
10. An SAC exists when an administrative control is identified in the DSA as a control needed to prevent or mitigate an accident scenario, and has a safety function that would be SS or SC if the function were provided by an SSC. (DOE-STD-1186, Section 1.2)

- Does the DSA provide the safety requirements and functions of selected SACs and satisfactorily document the basis for determining the assigned functions are appropriately assigned as administrative controls?
- Does the safety analysis establish the functions of SACs and their significance to safety?
- Does the DSA identify the appropriate performance criteria necessary to provide reasonable assurance that selected SAC functional requirements will be met?
- Are the SACs identified and described consistent with the logic presented in the hazard and accident analyses?
- Does the suite of safety controls, including SACs where designated, provide multiple layers of protection to prevent or mitigate the unintended release of radioactive materials?
- Are safety functions for SACs defined with clarity and consistent with the bases derived in the hazard and accident analyses?
- Is there adequate rationale for controlling the identified hazard through an SAC instead of an SSC?
- Is the adequacy of SACs to effectively perform their required safety functions documented in the DSA?
- Are there SSCs whose failure would result in losing the ability to complete the action required by the SAC?
- Where SACs rely on supporting SSCs to perform their intended safety function, have these SSCs been properly identified, classified with respect to safety, and controlled so that they can meet performance requirements consistent with their safety importance?
- Do the functional requirements and evaluations of SAC provisions provide evidence that the required safety functions can be performed when called upon?
- Do the SAC evaluations contain appropriate analysis (i.e. human reliability analysis) of human performance factors that affect task performance and human factors engineering?
- Do the SAC evaluations identify the time interval for re-verification of the SAC(s) and provide the technical basis for these time intervals?
- Are the SAC controls clearly defined to support future TSR development?
- Do the SACs appropriately reflect assumptions of facility configuration and human performance of safety functions, operational parameters, and key programmatic elements?
- Does the formulation of SACs include conservative “design” safety margins?
- Are the SACs classified using the same criteria as used for classifying safety SSCs?

Derivation of TSRs (Chapter 5)

11. A contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must: (1) Develop TSRs that are derived from the DSA; and (2) Obtain DOE approval of TSRs and any change to TSRs. (10 CFR 830 Section 830.205.a.1&2)
 - Are identified TSRs adequate to preserve the functional and administrative requirements necessary to ensure protection of workers, the public, and the environment (as identified in the hazard and accident analyses)?
 - Does Section 1 include a list of defined terms that contain the terms used in the TSR document that require clarification of the intent of their use? Are the definitions clear and consistent with standard usage and the intended use of the terms?
 - Have the facility operational modes (e.g., startup, operation, and shutdown) relevant to derivation of TSRs been adequately defined such that the status of safety SSCs/SACs can be distinctively defined; for example, operation during major outages of facility systems for maintenance or operation of multiple segmented areas of the facility?

- Have the assumptions requiring TSR coverage and the bases for deriving TSRs been identified and described in the safety basis document?
- Is there sufficient information provided to identify the safety limits, limiting control settings, and limiting conditions for operation that will be needed to support the facility TSR documentation?
- Are the bases deriving safety limits, limiting control settings, limiting conditions for operation, surveillance requirements, and administrative controls provided and technically accurate?
- Has each safety-significant or safety-class SSC or SAC identified in Chapter 4 been listed?
- Have passive SSCs been designated as design features and their performance criteria identified when appropriate?
- Is there adequate documented explanation for any safety SSCs/SACs or other safety features that will not be provided TSR controls coverage?
- Have the bases for deriving TSRs been identified and described in the hazard and accident analyses, safety SSC, and SAC chapters?
- Is the logic for the TSR derivation consistent with the logic and assumptions presented in the analyses?
- Is the process for maintaining the TSRs current and controlling their use defined?
- Are the facility design aspects necessary to implement the identified surveillance requirements (e.g., instrumentation, equipment access) adequately identified?
- Does the Design Features section identify the important aspects of the passive design features not specifically required to have TSR Limiting Condition of Operation?
- Are TSRs from other adjacent facilities that can affect this facility's operations identified and summarized?

Safety Management Programs (Chapters 6-17)

12. The DSA for a hazard category 1, 2, or 3 DOE nuclear facility must, as appropriate for the complexities and hazards associated with the facility, define the characteristics of the safety management programs necessary to ensure the safe operation of the facility, including (where applicable) quality assurance, procedures, maintenance, personnel training, conduct of operations, emergency preparedness, fire protection, waste management, and radiation protection. (10 CFR 830 Section 830.204.b.(5))

- Are the major programs needed to provide programmatic safety management identified?
- Are the basic provisions of identified programs noted and references to facility or site program documentation provided?
- Are specific aspects of safety management programs identified in the hazard and accident analysis included in the discussion of the programs in the DSA?
- Do the descriptions of the major program elements include brief abstracts of referenced documentation with enough of the salient facts to provide an understanding of the referenced documentation and its relation to the chapter?
- Do the program descriptions clearly include key elements identified in the Chapter 3 hazard analysis?
- Are cross-references to material in other chapters accurate and is the referenced material adequate to address the subject of the chapter under review?

13. The DSA for a hazard category 1, 2, or 3 DOE nuclear facility must, as appropriate for the complexities and hazards associated with the facility, with respect to a nonreactor nuclear facility with fissionable material in a form and amount sufficient to pose a potential for criticality, define a criticality safety program that: (1) Ensures that operations with fissionable material remain subcritical under all normal and credible abnormal conditions, (2) Identifies applicable nuclear

criticality safety standards, and (3) Describes how the program meets applicable nuclear criticality safety standards. (10 CFR 830 Section 830.204.b.6)

- Are fissile materials and their locations identified? Is the fissile material form (chemical/physical, isotopic content, concentration, densities, etc.) and maximum quantities involved identified? Is this information summarized in the hazard identification discussion in Chapter 3?
- Are the criticality safety evaluations (CSEs) covered by the criticality events identified in the hazard analysis?
- Have controls necessary to prevent or mitigate criticality accidents been considered for inclusion in the DSA and TSR?
- Are the engineered controls and their design basis and limits identified?
- Do the equipment designs and operations ensure criticality safety under normal, abnormal and accident conditions?
- Does the criticality safety program have a mechanism to review all changes or potential changes to nuclear criticality safety controls for capture by the revisions and updates to the DSA and TSRs?

Technical Safety Requirements

14. A contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must: (1) Develop TSRs that are derived from the DSA; and (2) Obtain DOE approval of TSRs and any change to TSRs. (10 CFR 830 Section 205.a.1&2)
15. TSRs establish limits, controls, and related actions necessary for the safe operation of a nuclear facility. (10 CFR 830 Appendix A, Section G.4)
16. TSRs may have sections on (1) safety limits, (2) operating limits, (3) surveillance requirements, (4) administrative controls, (5) use and application, and (6) design features. It may also have an appendix on the bases for the limits and requirements. (10 CFR 830 Appendix A, Section G.4)
17. Table 4 sets forth DOE's expectations concerning acceptable TSRs. (10 CFR 830 Appendix A, Section G.6)
 - Does Section 1 include the standard use and application explanations for TSR devices such as: Logical Connectors, Completion Time, Frequency Notation, Safety Limits, Limiting Control Settings, Limiting Conditions for Operation, and Surveillance Requirements?
 - Do the TSRs accurately reflect the derivation of TSRs in the DSA?
 - Are identified TSRs adequate to preserve the functional and administrative requirements necessary to ensure protection of workers, the public, and the environment (as identified in the hazard and accident analyses)?
 - Have the facility operational modes (e.g., startup, operation, and shutdown) relevant to derivation of TSRs been adequately defined such that the status of safety SSCs/SACs can be distinctively defined; for example, operation during major outages of facility systems for maintenance or operation of multiple segmented areas of the facility?
 - Is there sufficient identification of the safety limits, limiting control settings, and limiting conditions for operation to support safe operation of the facility?
 - Are the requirements relating to test, calibration, or inspection sufficient to assure that the necessary operability and quality of SSCs is maintained, that facility operation is within safety limits, and that limiting control settings and limiting conditions for operation are met?
 - Have passive SSCs been designated as design features, when appropriate, and adequate in-service inspections included?

- Are the important attributes of the design features that are credited in the hazard and accident analyses identified?
- Are the bases deriving safety limits, limiting control settings, limiting conditions for operation, surveillance requirements, and administrative controls provided and technically accurate?
- Are the facility design aspects necessary to implement the identified surveillance requirements (e.g., instrumentation, equipment access) adequately identified?
- Do the TSR bases identify specific information from the DSA used in the derivation of individual TSRs, including operating conditions that limit accident initial conditions, relevant parameters of safety class or safety significant SSCs, instrumentation, operator actions, assumed limits, and design features?
- Do the TSR bases identify the requirements relevant to the safety basis that have been selected by the facility?

Federal DSA/TSR Review and Approval

18. As part of the approval process, DOE will review the content and quality of the safety basis documentation. DOE intends to use the approval process to assess the adequacy of a safety basis developed by a contractor to ensure that workers, the public, and the environment are provided reasonable assurance of adequate protection from identified hazards. (10 CFR 830 Appendix A, section E.2)
19. Because DOE has ultimate responsibility for the safety of its facilities, DOE will review each DSA to determine whether the rigor and detail of the DSA are appropriate for the complexity and hazards expected at the nuclear facility. In particular, DOE will evaluate the DSA by considering the extent to which the DSA (1) satisfies the provisions of the methodology used to prepare the DSA and (2) adequately addresses the criteria set forth in 10 CFR 830.204(b). DOE will prepare a Safety Evaluation Report to document the results of its review of the DSA. A DSA must contain any conditions or changes required by DOE. (10 CFR 830 Appendix A, Section F.3)
20. DOE will examine and approve the TSRs as part of preparing the safety evaluation report and reviewing updates to the safety basis. (10 CFR 830 Appendix A, Section G.5)
21. Approval of documented safety analyses, TSRs, and unreviewed safety question procedures required pursuant to 10 CFR part 830, subpart B, Safety Basis Requirements, must not be further delegated below the most senior-level program officer or deputy at a Field Element office unless concurrence is obtained from the applicable Central Technical Authority (CTA). (DOE Order 450.2, Appendix A, Section 2.a.(1)(a))
22. Delegations must only be made where the candidate's organization possesses, or has access to, sufficient staff (for example, a Service Center) with the necessary qualifications, experience, and expertise to support the candidate for the authorities being delegated. (DOE Order 450.2, Appendix A, Section 2.a.2)
 - Is the safety basis approval authority delegation document current?
 - Does the delegation of safety basis approval authority to the Site Office adequately reflect the conditions and assumptions for the delegation?
 - Is authority for approving base DSAs and major revisions to DSA differentiated from authority for DSA changes, DSA annual updates, and TSR change control?
 - Are DOE personnel assigned responsibility for assessing DSA annual updates and DSA and TSR change control?
 - Are procedures and mechanisms in place to address and implement site office responsibilities for review and approval of DSA updates?
 - Are DOE personnel assigned responsibility to review and approve the updated DSAs prepared by the contractors?

- Are the DOE personnel assigned responsibility to review DSA documents and changes qualified as nuclear safety specialists (i.e. DOE-STD-1183) and qualified for the specific facility represented in the DSA change?
- Have appropriate criteria been developed and implemented for evaluating the classification of nuclear SSCs?
- Have DOE personnel developed and implemented a review plan and evaluation criteria to ensure that the analysis provided by the contractor:
 - Properly covers the hazards associated with the work?
 - Is consistent with the Integrated Safety Management System Description?
 - Adequately traces the hazards identified to the control selected to address the hazard?
 - Identifies adequate safety functions, performance characteristics, and functional requirements to ensure an adequate degree of safety?
- Do Safety Evaluation Reports (SERs) meet the guidance in DOE-STD-1104 and establish an adequate basis for the approval of the DSA update?
- Have issues and comments identified during the review been adequately resolved or included in Conditions of Approval?
- Has DOE verified that the contractor has adequate methods to track and implement Conditions of Approval?
- Have SERs been submitted to the appropriate approval authority (in accordance with a current delegation)?
- Are federal personnel assigned responsibility to verify the adequate development of Preliminary Documented Safety Analyses (PDSAs) for new nuclear facilities or major modifications to nuclear facilities?

Major Modification Applicability Determination

23. With respect to a hazard category 1, 2, or 3 new DOE nuclear facility or a major modification to a hazard category 1, 2, or 3 DOE nuclear facility, a contractor may not begin operation of the facility or modification prior to the issuance of a safety evaluation report in which DOE approves the safety basis for the facility or modification. (10 CFR 830 Section 207.d)
24. The contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must establish, implement, and take actions consistent with an Unreviewed Safety Question (USQ) process that meets the requirements of this section. (10 CFR Section 830 Section 203.a)
25. Safety must be integrated into design early and throughout the design process consistent with DOE-STD-1189, Integration of Safety into the Design Process. (DOE O 420.1B Change 1, Chapter I, Section 3.a.(3))
26. Modification projects that require a new or revised hazards/accident analysis or require new hazard controls must be evaluated using the Major Modification Evaluation Criteria to determine if the modification constitutes a “major modification” and requires a PDSA (see Table 8.1). (DOE-STD-1189, Section 2.3)
 - Do all proposed modifications undergo evaluation under the site or facility USQ process?
 - Does the USQ screening process adequately define the criteria for screening proposed modifications from further evaluation?
 - Do completed USQ screening forms provide evidence that the process is effectively identifying major modifications or document evaluation that the modification is determined to be a simple modification?
 - Does the USQ determination process adequately implement the criteria for determining whether the proposed modification represents an unreviewed safety question?

- Do complete USQ determinations provide evidence that the process for identifying major modifications is being effectively implemented?
- Is the USQ process adequately linked with (or implement) the process for determining whether a modification is a major modification?
- Are procedures and mechanisms in place to address and implement responsibilities for review and approval of modifications to site facilities in order to determine whether the modification represents a major modification (See Section 8.1 of DOE-STD-1189.)?
- Is a screening process and evaluation criteria used to determine whether the proposed modification is a major modification (See DOE-STD-1189, Figure 8.1 and Table 8-1.)?
- Have appropriate criteria been developed and implemented for evaluating the proposed modification?
- Is an integrated evaluation used to determine whether the proposed modification constitutes a major modification?
- Do completed reviews provide evidence that proposed projects are being adequately screened to determine whether they constitute a major modification?
- Are adequate procedures and processes in place to implement major modifications and ensure proper integration with existing facilities that may be affected by the modification, including management of the existing safety basis controls?
- Are personnel assigned responsibility to verify the adequate development of preliminary DSAs and Safety Design Strategy for major modifications to nuclear facilities?

APPROACH

Record Review:

- Revised DSA and associated hazard and accident analysis
- Revised TSRs
- DOE direction and guidance documents
- Technical support documents, including calculations and engineering analyses
- DOE plans and records of reviews for the DSA submittals
- DOE review comment record forms, SERs, and associated documentation
- Procedures and guidance for maintenance and update of the DSA and associated elements
- Procedures and guidance for managing modification projects and conducting USQ evaluations of facility modifications
- Records of reviews of modifications for a sample of modification projects that were determined to be “simple” modifications
- Completed USQ evaluations (USQ screens and USQ determinations) at the site
- Complete major modification evaluation records

Interviews:

- Safety Analysts
- DOE Nuclear Safety personnel
- DOE personnel responsible for coordinating DSA and TSR reviews for nuclear operations
- DOE delegated approval authority, safety basis review managers, Safety Basis Review Team members, system safety oversight personnel, and Facility Representatives involved in the safety basis reviews

- Personnel who conduct and review USQ evaluations, including USQ screens and USQ determinations
- Personnel responsible for implementing or reviewing modification projects

Observations:

- Comment resolution meetings, if applicable
- Field walk-down of new or significantly modified safety controls