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<b>Unreviewed Safety Question Process Criteria and Review Approach Document</b>		
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## 1.0 PURPOSE

The mission of the U.S. Department of Energy (DOE) Office of Environment, Safety and Health Assessments (EA-30) is to assess the effectiveness of safety and emergency management systems and practices used by line and contractor organizations and to provide clear, concise, rigorous, and independent evaluation reports of performance in protecting workers, the public, and the environment from the hazards associated with DOE activities.

In addition to the general independent oversight requirements and responsibilities specified in DOE Order 227.1A, *Independent Oversight Program*, this criteria and review approach document (CRAD), in part, fulfills the responsibility assigned to EA in DOE Order 226.1B, *Implementation of Department of Energy Oversight Policy*, to conduct independent oversight and appraisals of high consequence activities.

The CRADs are available to DOE line and contractor assessment personnel to aid them in developing effective DOE oversight, contractor self-assessment, and corrective action processes. The current revision of EA's CRADs are available at <https://www.energy.gov/ea/criteria-and-review-approach-documents>.

## 2.0 APPLICABILITY

The following CRAD is approved for use by the EA Office of Nuclear Engineering & Safety Basis Assessments and the Office of Nuclear Safety and Environmental Assessments.

### 3.0 FEEDBACK

Comments and suggestions for improvements on this CRAD can be directed to the Director, Office of Nuclear Engineering & Safety Basis Assessments, at (301) 903-1210.

### 4.0 CRITERIA AND REVIEW APPROACH

This CRAD focuses on the adequacy and implementation of the unreviewed safety question (USQ) process at DOE nuclear facilities that complies with the requirements of 10 CFR 830, *Nuclear Safety Management*, subpart B § 830.203. The CRAD also addresses the adequacy of the Federal review and approval of contractor USQ procedure in addition to subsequent oversight of the USQ process. The USQ process provides a contractor with the flexibility needed to conduct day-to-day operations by requiring that only those changes, tests, and experiments<sup>1</sup> with a potential to impact the safety basis (and therefore the safety of the nuclear facility) be approved by DOE. Changes associated with approved USQ determinations (USQDs) and associated safety analyses, including supporting safety analyses for any DOE-approved changes to a facility, evaluations of the safety of the situation (ESSs), and justifications for continued operations (JCOs) are treated as part of the safety basis until incorporated into the approved DSA. The following criteria and lines of inquiry are independent sections to be used in any combination, based on the need of the specific assessment. Questions that can be answered with a “yes” or “no” should be followed with an open-ended question that would provide insight and details supporting the one-word answer.

#### **OBJECTIVES**

**USQ.1: The contractor’s USQ procedure ensures that any proposed changes or potential inadequacy of the (documented) safety analysis (PISA) against the DOE nuclear facility’s approved and implemented safety basis are effectively evaluated to ensure changes are appropriately recognized, reviewed, and incorporated into the safety basis**

#### **Criteria:**

1. The contractor’s USQ procedure is applicable to any situation where: (1) The probability of the occurrence or the consequences of an accident or the malfunction of equipment important to safety previously evaluated in the documented safety analysis could be increased; (2) The possibility of an accident or malfunction of a different type than any evaluated previously in the documented safety analysis could be created; or (3) The documented safety analysis may not be bounding or may be otherwise inadequate. (10 CFR 830 § 830.3)
2. DOE has approved the contractor’s procedure for carrying out the USQ process. (10 CFR 830 Section 830.203(c))
  - Does the USQ procedure define the purpose of the USQ process?
  - Does the USQ procedure specify the applicability of the USQ process?
  - Does the USQ procedure provide definitions of relevant terms, USQ screening criteria, and the bases for their application?
  - Does the USQ procedure include detailed guidance or directions on what is to be considered and evaluated when performing a USQ review (including USQDs, and USQ screenings and categorical exclusions, if applicable)?

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<sup>1</sup> Tests and experiments should be broadly interpreted to include new activities or operations not described in the safety basis.

- Does the USQ procedure identify site-specific and facility-specific change processes and documents (e.g., non-conformance processes, structures, systems and components (SSC) modification processes, procedural processes, work control processes (including post-modification testing), site-wide manuals, etc.) that are subject to the USQ process?
- Does the USQ procedure address interim conditions that temporarily change how the facility is configured?
- Is the USQ process integrated into the contractor's organization responsible for design, engineering, maintenance, inspection, operations, and assessment of the nuclear facility or activity?
- Does the USQ procedure adequately describe the types of changes (permanent and temporary), tests, and experiments and potential safety basis inadequacies that must be addressed through the USQ process?
- Does the USQ procedure identify the types of changes (permanent and temporary), tests, and experiments that can be screened or excluded from the USQ process?
- Does the USQ procedure identify the scope and boundaries of categorical exclusions? Does the USQ procedure describe steps to screen out the following items: (1) Changes fully covered by a previous USQ document; (2) Changes to documents that are purely editorial and make no technical change; (3) Changes when common commercial practices would suffice?
- Does the USQ procedure require that the rationale for screening, including all categorical exclusions and exclusions in general, be adequately justified and documented?
- Does the USQ procedure provide sufficient information regarding the types of changes (permanent and temporary, including SSCs and their operating environments not explicitly discussed in the SB that have the potential to alter the function of SSCs that are described in the SB), tests, and experiments including documents and procedures that are required to be evaluated by the USQ process to ensure changes affecting the safety basis are not made outside the USQ process?
- Does the USQ procedure address the discovery of a failure or non-conformance that renders an SSC incapable of performing its safety function?
- Does the USQ procedure addresses interim conditions that temporarily change how the facility is configured?
- Does the USQ procedure define clear relationships between the USQ process and other change control processes (e.g., design change procedures, configuration control programs, temporary change procedures, maintenance program, and technical procedures development, review, and approval)?
- Does the USQ procedure address changes to any safety management program procedures that define or affect key elements?
- Does the USQ procedure provide for independent technical review and line management approval of USQD documents?
- Does the USQ procedure clearly identify the evaluation criteria and action steps for USQDs?
- Does the USQ procedure require that a technically defensible explanation be documented for the answers to each of the evaluation criteria?
- Does the USQ procedure specify the expectations for documenting the results of the USQD?
- Does the USQ procedure identify an appropriate time duration for investigation of new information?
- Does the USQ procedure provide information regarding the conditions that may result in a PISA?
- Does the USQ procedure provide sufficient PISA response actions, expected timeframes, and subsequent guidance for development of ESSs and JCOs?
- Does the USQ procedure address the activity where a design or safety basis reconstitution effort is being undertaken, including a clearly defined process for promptly sorting questions and issues

between those that can be addressed as a normal part of the reconstitution project and those that will be handled more promptly as PISAs?

- Does the USQ procedure include a defined mechanism for dispositioning safety basis issues requiring DOE involvement?
- Does the USQ procedure specify the expectations for DOE notification, including the mechanisms to be used?
- Does the USQ procedure mandate that no operational restrictions can be relaxed prior to review by DOE?
- Does the USQ procedure provide for expert-based USQDs?
- Does the USQ procedure identify the situations where an expert-based USQD may be performed?
- Does the contractor's USQ procedure specify the qualification requirements for all personnel performing USQ reviews?
- Does the contractor's USQ procedure identify the review requirements for expert-based USQDs?
- Does the USQ Procedure require expert-based USQDs to be designated as such?
- Does the USQ procedure indicate that formal training and qualification program will be established for all site personnel involved in the USQ process?
- Does the USQ procedure indicate that the list of people certified for USQ determinations (USQD) processes will be kept current?
- Has the current revision of the contractor's USQ procedure been approved by DOE?

**USQ.2: The nuclear facility contractor has effectively implemented the DOE approved USQ procedure.**

**Criteria:**

1. The contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must implement the DOE-approved USQ procedure in situations where there is a (1) temporary or permanent change in the facility as described in the existing DSA; (2) temporary or permanent change in the procedures as described in the existing DSA; (3) test or experiment not described in the existing DSA; or (4) potential inadequacy of the DSA because the analysis potentially may not be bounding or may be otherwise inadequate. (10 CFR 830 § 830.203(d))
  2. The contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must obtain DOE approval prior to taking any action determined to involve a USQ. (10 CFR 830 § 830.203(e))
  3. The contractor responsible for a hazard category 1, 2, or 3 DOE nuclear must annually submit to DOE a summary of the USQ determinations performed since the prior submission. (10 CFR 830 § 830.203(f))
  4. If a contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility discovers or is made aware of a potential inadequacy of the DSA, it must: (1) Take action, as appropriate, to place or maintain the facility in a safe condition until an evaluation of the safety of the situation is completed; (2) Notify DOE of the situation; (3) Perform a USQ determination and notify DOE promptly of the results; and (4) Submit the evaluation of the safety of the situation to DOE prior to removing any operational restrictions initiated to place or maintain the facility in a safe condition. (10 CFR 830 § 830.203(g))
- Is the USQ process and its integration into the facility change control process described by a governing policy?
  - Does the USQ process include a detailed USQ process description document?
  - Based on a review of a representative sample of proposed changes, proposed tests, and occurrence reports involving discrepant as found conditions:
    - Are the changes, tests, and experiments and potential inadequacies appropriately included or excluded from the USQ process?
    - Has the USQ procedure been followed?

- Are there any changes where the contractor has inappropriately eliminated USQ process steps based on a graded approach justification?
- Based on a review of a representative sample of USQ screens, were the screening criteria, specified in the USQ procedure met?
- Based on a review of a representative sample of completed USQD:
  - Has the evaluation process specified in the USQ procedure been fully followed?
  - For the process required by the USQ procedure (i.e., determination is made based on the answers to six questions), are appropriate justifications provided for the questions?
  - Have the appropriate conclusions, from the answers to the six questions, been made regarding the proposed changes, test, or experiment?
  - Are the personnel performing and reviewing USQD trained in accordance with the requirements established in the USQ procedure and DOE-approved training implementation matrix?
  - Have USQD reviewers and approvers met the requirements of the USQ procedure for independence?
- Based on a review of a representative sample of documented positive USQDs, has DOE approval been obtained prior to taking the proposed action?
- Has the contractor submitted an annual summary to DOE of USQDs performed since the prior submission? (10 CFR 830.203(f))
- Based a review of a representative sample of PISA declarations:
  - Were appropriate actions taken to place or maintain the nuclear facility in a safe condition until an ESS was completed?
  - Does the determination reflect the results of a thorough engineering evaluation?
  - Is there adequate description of the degraded or non-conforming condition of the SSC; description of the degraded or non-conforming condition on safe operations and the safety function of the SSC; and description of any operating restrictions that have been imposed and the effect of these restrictions in relation to the degraded SSC and its safety function?
  - Is there adequate evaluation of the operability of the SSC, given its condition, using analysis, tests, operating experience, and/or engineering judgment, and considering conservatism and margins, availability of other equipment, and cumulative effects of other outstanding degraded or non-conforming conditions?
  - Was DOE promptly informed of the situation in writing with clearly identified operational restrictions to ensure the facility is in a safe condition?
  - Was a USQD performed in a timely manner?
  - Was DOE promptly notified of the USQD results?
  - If the USQD was positive, was an occurrence report prepared? (DOE Order 232.2A, Attachment 1)
  - If the USQD was positive and compensatory measures were required to allow continued operation, was a JCO prepared?
  - Does the JCO adequately analyze the hazards and identify compensatory measures, appropriate for the hazards associated with the PISA and the length of time the conditions which resulted in the PISA, are expected to exist?
  - Was an ESS submitted to DOE prior to removing any operational restrictions initiated to place or maintain the facility in a safe condition?
  - Does the ESS adequately document the assessment of the safety of the situation and demonstrate that the immediate controls placed on the facility or activity are not required or provide a basis for how the actions taken and/or planned, ensure safety?
- Based a review of a representative sample of PISA declarations, were the timeframes for implementation of the process actions met?

- Are the records retention requirements specified in the USQ procedure implemented per DOE records schedules?
- Does the contractor organization responsible for the USQ process perform periodic objective management self-assessments?
- Does the nuclear facility contractor assurance systems organization perform effective independent assessments of the USQ process implementation?

## **Federal Review, Approval, and Oversight**

### ***OBJECTIVE***

**USQ.3:** DOE has approved the contractor's USQ procedure. (10 CFR 830 Section 830.203(c)). DOE line management conducts effective oversight of the USQ process. (DOE Order 226.1B)

### **Criteria:**

1. Approval of the contractor's procedure for carrying out the USQ process is documented in a safety evaluation report (SER) or letter with a basis of approval. [DOE-STD-1104-2016, *Review and Approval of Nuclear Facility Safety Basis and Safety Design Basis Documents*, §6.1]
2. The basis for approval of the USQ procedure shall address the expectations from the DOE Guide 424.1-1C, *Implementation Guide for Use in Addressing Unreviewed Safety Question Requirements* (or successor document in the site contract). [DOE-STD-1104-2016§6.1]
3. The DOE basis for approval of the ESS or JCO shall address the expectations for an ESS or JCO as described in DOE Guide 424.1-1C. (DOE-STD-1104-2016, § 6.2.1, 6.2.2)
4. The DOE field element has established and implemented an effective safety system oversight (SSO) program for qualifying staff to apply engineering expertise in its oversight of the assigned safety systems and to monitor performance of the contractor's cognizant system engineer (CSE) and USQ process. (DOE Order 426.1, Appendix D)
5. The DOE Facility Representatives (FRs) and SSOs are sufficiently familiar with the DSA/TSRs, and USQ/PISA process to verify that the contractor is implementing the process effectively. (DOE Order 426.1 Appendix D)
  - Has DOE approved the current revision of the contractor's USQ procedure?
  - Does the SER or letter approving the contractor's USQ procedure address the expectations from the DOE Guide 424.1-1C?
  - Is DOE kept current with respect to all phases of USQ resolution, including notification of discoveries, review of USQDs, and review of corrective actions?
  - Is DOE sufficiently involved in the USQD process to ensure that the adequacy of protection and safety classifications of equipment is justified by safety basis documents?
  - Do the SERs for a representative set of approved ESSs and JCOs meet the expectations from the DOE Guide 424.1-1C?
  - Have the FRs and SSOs been provided training on the current revision of the USQ procedure?
  - Do SSOs or FRs effectively oversee contractor operability determinations initiated as a result of a PISA?
  - Do FRs effectively monitor facility work packages to ensure proper implementation of the USQ process?
  - Are federal self-assessments of the USQ procedure review and approval process performed?
  - Does the federal line management perform periodic assessments of the contractor USQ process?

## ***REVIEW APPROACH***

### Record Review (examples):

- DOE approved USQ Procedure
- USQ process supporting procedures and work instructions
- DOE SER supporting USQ procedure approval
- DOE occurrence reports (PISAs involving positive USQDs)
- Approved DSA and current draft DSA document capturing ongoing changes from negative USQDs
- Technical Safety Requirements (TSR)
- DSA/TSR SER
- Design change/modification and temporary modification procedures
- Temporary modification program procedures and logs
- Test/experiments log
- Maintenance program procedures
- Design change (system/equipment modification) procedure(s)
- Configuration management/control program and operating procedures
- Select USQ screens and determinations
- Last annual summary descriptions of USQDs performed as submitted to DOE
- List of design change packages issued by Engineering
- List of facility work packages as issued by Maintenance and Operations
- Copies of Federal and contractor surveillances and assessments performed on USQ process and related areas
- PISA records (correspondence, compensatory measures, evaluations, etc.)
- Records of ESS and JCO
- A current listing of recent USQ/PISA activity (since last annual report to DOE)
- Closed corrective actions packages relative to the USQ process
- Open corrective action status reports relative to the USQ process
- Procedure for the development, review and approval of technical procedures (including configuration management processes)
- Index of current operations standing orders and periodic management assessments to determine current applicability and technical accuracy
- USQ training course material
- List of qualified personnel
- Qualification cards/records for USQ evaluators, screeners, applicability reviewers as appropriate

### Interviews (examples):

- Nuclear Safety Manager
- Safety Basis Manager
- USQ evaluators
- USQ screeners/applicability reviewers
- Design engineering managers and SMEs
- Maintenance and operations managers
- Configuration management system supervisors and SMEs
- Document control manager
- Technical procedure process managers
- Engineering Manager
- Cognizant system engineers
- Training Manager
- Operations personnel

- Facility Manager
- Nuclear facility CAS program manager
- DOE SSO personnel
- DOE Facility Representatives

Observations (examples):

- Observe Conduct of Nuclear Safety Board/Committee meeting
- Walk down any PISA compensatory measures
- Walk down a selected temporary modification controls