

EFCOG Best Practice #148

Best Practice Title: *Best Practices in Process Monitoring Reviews and Assessments on Implementation of the USQ Process*

Facility: EFCOG SAWG USQ Subgroup, LLNL, LANL, WRPS, NSTec

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Brief Description of Best Practice: This is a toolbox of best practices developed for process monitoring reviews and assessments on implementation of the Unreviewed Safety Question (USQ) Process. These practices have been found to efficiently and effectively review the USQ process implementation to ensure compliant implementation with 10 CFR 830. This collection spans a variety of techniques and provides a toolbox for reviewers. Techniques include:

- comprehensive assessments,
- focused/targeted reviews,
- vertical/deep slices,
- broad and shallow nets,
- product quality (CatXs, Screens, USQDs, Expert USQDs, ESSs),
- interface with other processes (work control, change control, maintenance, procedures, institutional procedures, and TSR implementation),
- submittal of procedures to the USQ process,
- training/qualification reviews,
- PISA process implementation,
- Effectiveness Reviews, and
- Assists (Tech Assists, Assist Improve Modernize (AIM), and other approaches.

Why the best practice was used: DOE sites need to monitor implementation to ensure a 10 CFR 830 Compliant USQ process. Accordingly, this toolbox provides a variety of reviews and assessment methodologies ranging from broad and shallow to vertical deep slices on a variety of topics. This best practice paper will aid in assessing, verifying and documenting that the USQ process is performed and implemented appropriately.

These tools include both formal assessments and audits as well as process monitoring reviews not intended to be formal audits. Such process monitoring reviews are intended to accomplish two functions: (1) proactively gather data to assist in providing better guidance to USQ preparers and reviewers; and (2) provide real-time feedback to USQ preparers and reviewers to initiate corrective actions before discrepancies become trends. These tools provide a method to ensure that necessary actions are taken to: (1) support the reviews, including providing clear guidance as to expectations; (2) conduct the reviews appropriately; (3) provide recommendations to revise USQ documents as appropriate; and (4) provide feedback of lessons learned to safety analysts and facility management. These tools help the USQ SME assess trends, develops lessons learned, and provides feedback resulting from the reviews.

What are the benefits of the best practice: The USQ Subgroup believes that the proposed recommendations will help ensure Compliance, while streamlining the review process, increasing its efficiency, effectiveness, and timeliness as well as that of the USQ process.

EFCOG Best Practice #148

What problems/issues were associated with the best practice: Many opportunities exist to review the USQ process that some contractors may not be aware of, and thus may be vulnerable for non-Compliant USQ processes. This best practice highlights review topics for consideration.

How the success of the Best Practice was measured: This best practice paper has helped ensure Compliant USQ processes, while streamlining the review process, increasing its efficiency, effectiveness, and timeliness. Improvements have included:

- Developing revised USQ Procedures based upon monitoring of USQ process
 - Proposed Expert USQD
 - Revised existing CatXs to facilitate efficiency, quality improvements, and eliminate confusion
 - Developed new CatXs for physical changes and procedures
- Conducting Safety Basis Technical meeting discussions to facilitate frequent, informal communications as well as formal policy discussions, and to monitor emerging issues in the USQ process.
- Management/USQ Interfaces - Monitored changes in personnel (changeover in facility management) and conducted training accordingly
- Monitoring Integrated USQ Process
 - Monitoring revision of [facility-specific] *Unreviewed Safety Question (USQ) Process*
 - Monitoring revision of [facility-specific] *Approved Equivalent Part/Like-in-Kind Determination for Facilities Replacement/Spare Items, Including Requirements for Procurement and Acceptance*
 - Six sigma data collection for USQ process improvement

Description of process experience using the Best Practice: See attached documentation of best practices.

With regard to sample sizes, best practices indicate that sampling ratios should vary depending on the type of review or assessment. See attached documentation for different sample sizes for different types of reviews (e.g., review of USQDs vs. review of submittal of procedures to the USQ process). For product reviews (e.g., USQD sampling), 25% is typical, although graded approach is merited depending on number USQDs (or other USQ documents) prepared at a facility. A smaller sample % may be representative for a facility that produces 200 USQDs per year, and a higher sample % for a facility with only a few USQDs of a particular type per year. A review on the full range of proposed changes subject to the USQ process may include institutional procedures (e.g., ES&H Manual Documents, SBMS), facility procedures, operational procedures, surveillances, maintenance, administrative procedures, physical changes, new activities/experiment, and D&D. Thus focused reviews may have varying sample statistics.

EFCOG Best Practice #148

Comprehensive USQ Process Assessments

USQ Assessment Report in Preparation for CDNS Review

I. Introduction

10 CFR 830.203, *Unreviewed Safety Question Process*, is implemented by [*site/contractor's DOE-approved USQ procedure*]. In preparation for a NNSA/CDNS comprehensive assessment of the USQ process, [*site/contractor*] first initiated a management assessment focused on [*site/contractor's DOE-approved USQ procedure*] and other institutional implementing issues, such as USQ training records. A detailed assessment of USQ implementation at the facility level followed. This report documents that second assessment. It was directed by the Safety Basis Division Leader and performed by the Safety Basis Deputy Division Leader, the [*site*] USQ SME, and a Safety Basis Division Institutional Reviewer.

They verified the controlled traceability matrix to formally document the flow-down of 10 CFR 830.203 requirements into implementing mechanism(s), including the [*site/contractor's DOE-approved USQ procedure*].

They reviewed facility-specific USQ implementing instructions for independent institutional controls (e.g., required to have prior approval of the USQ SME, or to be submitted for formal approval by DOE).

This report evaluates both facility-specific USQ procedures and other facility-specific procedures that reference or interface with the USQ process for compliance with the provisions of [*site/contractor's DOE-approved USQ procedure*].

Note: Procedural implementation of all requirements in 10 CFR 830 Subpart B, including 10 CFR 830.203, has been demonstrated on multiple occasions, most recently as part of the post-contract transition Integrated Safety Management System verification.

II. Bases for Conclusions

Any items noted in the assessment are classified as a deficiency, a weakness, an opportunity for improvement (OFI), or noteworthy practice. [*Insert definitions per site procedure*]

III. Scope

This assessment focuses on verifying proper field implementation of [*site/contractor's DOE-approved USQ procedure*]. It also assesses potential recurrence of previously identified issues. Six areas of examination are identified:

- (1) Facility-specific command media (based on the field change issue);
- (2) USQD process entry conditions (based on historical issues);
- (3) Application of Categorical Exclusions (CatXs);
- (4) Application of USQ Screening;
- (5) Documentation of Unreviewed Safety Question Determinations (USQDs); and

EFCOG Best Practice #148

(6) Application of the PISA process.

This review assesses implementation of the USQ process for all *[site/contractor]* nuclear facilities/activities, including a sample of relevant USQ documents. The focus of the review is on documents dated after implementation of the latest revision to *[site/contractor's DOE-approved USQ procedure]*. However, documents dated earlier may be examined if issues raised in this assessment point to earlier documents, or additional samples are needed.

IV. Criteria and Review Approach Documents (CRADs)

CRADs are defined for each of the six areas of examination.

EFCOG Best Practice #148

FUNCTIONAL AREA: Nuc. Ops/Safety Basis/ USQ Process	February 2009 REV. 1	CRITERIA MET	
Facility-Specific Command Media (FSCM)	FSCM.1	YES	NO

OBJECTIVE: Scope of facility-specific USQ procedures is limited to providing administrative mechanisms for USQ process assignment and document generation only.

[site/contractor] has historically relied upon a separation of function between [site/contractor's DOE-approved USQ procedure] and facility-specific administrative USQ procedures. [site/contractor's DOE-approved USQ procedure] is the policy procedure approved by DOE that implements 10 CFR 830.203. Facility-specific USQ procedures are not approved by DOE. Therefore, they cannot establish policy. The establishment of policy in a facility-specific procedure would establish an unapproved implementing function for 10 CFR 830.203.

Criteria

1. Facility-specific USQ procedures do not contain policy content or direction implementing the provisions of 10 CFR 830.203.
2. Facility-specific USQ procedures do not otherwise contain instructions in conflict with the provisions of [site/contractor's DOE-approved USQ procedure].
3. Facility-specific USQ procedures reference the current version of [site/contractor's DOE-approved USQ procedure].
4. Facility-specific USQ procedures utilize USQ terminology and definitions (e.g., CatX, Screen, USQD, PISA) consistent with [site/contractor's DOE-approved USQ procedure].
5. Changes to facility-specific USQ procedures are reviewed by USQ qualified personnel for consistency with [site/contractor's DOE-approved USQ procedure].

Review Approach

Records:

1. Review the facility-specific USQ procedures for the [facilities].
2. Review the change control process for facility-specific USQ procedures.

Interviews:

1. Interview lead analysts for each of the three areas.
2. Interview select analysts qualified in each area.
3. Interview facility managers in each area.

EFCOG Best Practice #148

FUNCTIONAL AREA: Nuc. Ops/Safety Basis/ USQ Process	February 2009 REV. 1	CRITERIA MET	
Facility-Specific Command Media (FSCM)	FSCM.2	YES	NO

OBJECTIVE: Facility-specific procedures that reference or interface with the USQ process comply with the provisions of [site/contractor’s DOE-approved USQ procedure].

The field change issue cited in the Chief of Defense Nuclear Safety (CDNS) review originated with direction contrary to [site/contractor’s DOE-approved USQ procedure] ... Work control, configuration management, lesson plans and conduct of operations are examples of areas that may inadvertently establish USQ policy.

Criteria

1. Facility-specific procedures that reference or interface with the USQ process do not contain policy content or direction implementing the provisions of 10 CFR 830.203.
2. Facility-specific procedures that reference or interface with the USQ process do not provide instructions in conflict with the provisions of [site/contractor’s DOE-approved USQ procedure].
3. Facility-specific procedures that reference or interface with the USQ process reference the current version of [site/contractor’s DOE-approved USQ procedure] (quoted extracts are discouraged due to potential configuration management issues).
4. Facility-specific procedures that reference or interface with the USQ process utilize USQ terminology and definitions (e.g., CatX, Screen, USQD, PISA) consistent with [site/contractor’s DOE-approved USQ procedure].
5. Changes to facility-specific procedures that reference or interface with the USQ process are reviewed by USQ qualified personnel for consistency with [site/contractor’s DOE-approved USQ procedure].

Review Approach

Records:

1. Define the facility-specific procedures to be examined for the three areas operating nuclear facilities/activities.
2. Define any institutional procedures to be examined.
3. Review the defined procedures.
4. Review the change control process for facility-specific procedures that reference or interface with the USQ process.

Interviews:

1. Interview appropriate levels of [facility and site] management.

EFCOG Best Practice #148

FUNCTIONAL AREA: Nuc. Ops/Safety Basis/ USQ Process	February 2009 REV. 1	CRITERIA MET	
USQ Process Entry Conditions (UEC)	UEC.1	YES	NO

OBJECTIVE: Temporary or permanent physical changes to the facility enter the USQ process as required by [site/contractor's DOE-approved USQ procedure].

The USQ process is integrated into the facility work control process. Personnel responsible for the work control process must be aware of the USQ process and have mechanisms to identify and document disposition within that process.

Criteria

1. Facility Work Control Processes establish that all required changes enter the USQ process.
2. Facility Work Permits correctly reflect the current requirements of [site/contractor's DOE-approved USQ procedure].
3. Facility Work Permits sampled identify proper USQ process disposition per [site/contractor's DOE-approved USQ procedure].

Review Approach

Records:

1. Review facility Work Control Processes.
2. Review a representative sample of Facility Work Permits to verify (a) the documentation requirements of [site/contractor's DOE-approved USQ procedure] are met, and (b) work permits are properly dispositioned within the USQ process.

Interviews:

1. Interview facility work control personnel.
2. Interview facility managers.
3. Interview facility lead USQ personnel.

EFCOG Best Practice #148

FUNCTIONAL AREA: Nuc. Ops/Safety Basis/ USQ Process	February 2009 REV. 1	CRITERIA MET	
USQ Process Entry Conditions (UEC)	UEC.2	YES	NO

OBJECTIVE: Temporary or permanent procedural changes for the facility enter the USQ process as required by [site/contractor's DOE-approved USQ procedure].

The USQ process is integrated into the document change control process. Personnel responsible for the document and procedure change control process are aware of the USQ process and have mechanisms to identify and document disposition within that process.

Criteria

1. An approved list of procedures/procedure types subject to the USQ process exists for each nuclear facility.
2. All written instructions that would constitute procedures per the USQ process are included on the facility list of procedures/procedure types.
3. Document Control Processes establish that all procedure changes enter the USQ process.
4. Changes to Facility Preventative Maintenance (PM) Task Codes are submitted to the USQ process.

Review Approach

Records:

1. Review approved list of procedures/procedure types.
2. Review other written instructions not on the approved list to ensure they are not procedures subject to the USQ process.
3. Review document change control process governing procedures.
4. Review a representative sampling of procedure changes to verify (a) the documentation requirements of [site/contractor's DOE-approved USQ procedure] are met, and (b) changes are properly dispositioned within the USQ process.
5. Specifically review a representative sampling of PM Task Code changes/baselines to verify (a) the documentation requirements of [site/contractor's DOE-approved USQ procedure] are met, and (b) changes are properly dispositioned within the USQ process.

Interviews:

1. Interview facility document control personnel.
2. Interview facility managers.
3. Interview facility lead USQ personnel.

EFCOG Best Practice #148

Detailed Review

The Review Team examined this CRAD using a three-step approach.

1) The Review Team checked to determine if there is a list of procedure types subject to the USQ process, and the list is maintained in accordance with *[site/contractor's DOE-approved USQ procedure]*.

The Review Team confirmed that the *[facility]* list of documents subject to the USQ process was concurred with by Safety Basis Division Leader in accordance with *[site/contractor's DOE-approved USQ procedure]*. During implementation of each facility's DSA/TSR annual update, the list of documents subject to the USQ process for each facility was compared with the respective TSR implementation checklist for each updated DSA/TSR and with the concurrence of the Safety Basis Division Leader in accordance with *[site/contractor's DOE-approved USQ procedure]*.

A different approach was followed for *[different facility]* as they recently were extensively audited by DOE on this topic. During implementation of the DSA, the list of procedures subject to the USQ process for *[facility]* was compared with DOE letters addressing past issues, as well as the *TSR Implementation Plan of the [facility DSA/TSR]*, reviewed by the Safety Basis Division, and subsequently reviewed by DOE. DOE did not identify any issues.

2) The Review Team sampled the procedures on the list of document types subject to the USQ process for each facility to determine if they had been submitted to the USQ process.

Sampled procedures were found on Enterprise Configuration Management System (ECMS) and checked to confirm that the current revision had been submitted to the USQ process.

Sampled procedures were found on the *[different facility]* server and compared with the USQ log to confirm the current revision had been submitted to the USQ process. Interviews and a sampling of USQ documents confirmed that the list of PM Task Codes continued to be updated and that the results of the previous assessment review valid, i.e., they converted 100% of Plant Engineering Task Codes into *[facility]* Task Codes and submits them to the USQ process

3) The Review Team conducted a review to find if the list of document types was complete by checking for documents potentially subject to the USQ process that were not identified as such. Per DOE concerns and Program and Nuclear Operations management concerns, the Review Team focused this assessment on a review of operational instructions that may potentially be procedures subject to the USQ process per *[site/contractor's DOE-approved USQ procedure]*.

The procedure classes identified in Appendix D were sampled. Sampled approximately 100% of *[facility]* work permits and a significant quantity of *[large facility's]* work permits and Daily Activity Requests.

Interviews Conducted:

- Program Deputy Operations Leader
- Hazard Category 3 Facilities Manager
- Hazard Category 2 Facility Manager

EFCOG Best Practice #148

- Program Safety Basis Manager
- Radiation Safety Section Leader
- Program Compliance Officers
- Safety and Work Control Manager
- Facility Safety Officer
- Safety Coordinator
- Program Manager
- Lead Safety Analyst

EFCOG Best Practice #148

FUNCTIONAL AREA: Nuc. Ops/Safety Basis/ USQ Process	February 2009 REV. 1	CRITERIA MET	
USQ Documents (UD)	UD.1	YES	NO

OBJECTIVE: Categorical Exclusions (CatXs) are utilized consistent with the requirements of [site/contractor’s DOE-approved USQ procedure].

Per the guidance in DOE G 424.1-1A, *Implementation Guide for Addressing Unreviewed Safety Question Requirements*, [site/contractor’s DOE-approved USQ procedure] provides for several CatXs to facilitate efficient application of the USQ process. The applicability of these CatXs is strictly limited to the specific conditions defined in Appendix B of [site/contractor’s DOE-approved USQ procedure]. Exceedance of those conditions represents failure to comply with [site/contractor’s DOE-approved USQ procedure].

Note that application of CatX C.1 requires an Approved Equivalent Part (AEP) process and a DOE approved identification of Equipment Important to Safety (EITS).

Criteria

1. Each facility has an AEP procedure.
2. Each facility has a DOE approved identification of EITS.
3. AEP determinations are properly documented per the requirements of [site/contractor’s DOE-approved USQ procedure].
4. Changes covered by application of a CatX do not require a USQ Screen or a USQD.
5. CatXs are documented properly in accordance with [site/contractor’s DOE-approved USQ procedure].

Review Approach

Records:

1. Review facility AEP procedures.
2. Review DSAs or other facility documentation establishing the DOE approved EITS list.
3. Review a representative sampling of AEP determinations to verify (a) the documentation requirements of [site/contractor’s DOE-approved USQ procedure] are met, and (b) the results are properly integrated with the USQ process.
4. Review a representative sampling of CatX applications to verify (a) the documentation requirements of [site/contractor’s DOE-approved USQ procedure] are met, and (b) CatX is applied properly.

Interviews:

1. Interview facility AEP determination personnel.
2. Interview select USQD preparers.
3. Interview facility managers.

EFCOG Best Practice #148

Interviews Conducted:

- Safety and Work Control Manager
- Facility Safety Officer
- Safety Coordinator
- Facilities Engineering Manager
- Program Manager
- Lead Safety Analyst

EFCOG Best Practice #148

FUNCTIONAL AREA: Nuc. Ops/Safety Basis/ USQ Process	February 2009 REV. 1	CRITERIA MET	
USQ Documents (UD)	UD.2	YES	NO

OBJECTIVE: USQ Screens are utilized consistent with the requirements of ES&H Manual Document 51.3.

Per the guidance in DOE G 424.1-1A, *Implementation Guide for Addressing Unreviewed Safety Question Requirements*, [site/contractor's DOE-approved USQ procedure] provides an allowance for USQ Screening beyond the level of CatXs. [site/contractor's DOE-approved USQ procedure] currently restricts that allowance to procedural changes only.

Criteria

1. Changes covered by application of a USQ Screen do not require a USQD.
2. USQ Screens are documented properly in accordance with [site/contractor's DOE-approved USQ procedure].
3. USQ Screens are non-evaluative in accordance with [site/contractor's DOE-approved USQ procedure].

Review Approach

Records:

1. Review a representative sampling of USQ Screens to verify (a) the documentation requirements of [site/contractor's DOE-approved USQ procedure] are met, and (b) screening is applied properly.

Interviews:

1. Interview select USQD preparers.

EFCOG Best Practice #148

FUNCTIONAL AREA: Nuc. Ops/Safety Basis/ USQ Process	February 2009 REV. 1	CRITERIA MET	
USQ Documents (UD)	UD.3	YES	NO

OBJECTIVE: Unreviewed Safety Question Determinations (USQDs) are prepared consistent with the requirements of [site/contractor's DOE-approved USQ procedure].

USQDs must be prepared at a level of quality such that a qualified independent reviewer can understand the basis for, and concur with, the preparer's conclusions. Relative USQD quality, while potentially subjective, is an enforcement issue that has been seen at most DOE sites. Specific issues of historical concern at [site/contractor] include failure to either properly define or fully evaluate the change, and introduction of new, uncredited controls in evaluation.

Criteria

1. The change under evaluation is fully defined in USQDs.
2. The technical issues associated with a change are fully evaluated in USQDs.
3. Per the guidance in [site/contractor's DOE-approved USQ procedure], no new controls are established to support a negative USQD.
4. An independent technical reviewer can understand and concur with the preparer's conclusion (i.e., other quality issues are not severe).
5. Changes determined by the review team to require DOE approval are not documented to be negative USQDs.

Review Approach

Records:

- Review a representative sampling of USQDs to verify (a) the documentation requirements of [site/contractor's DOE-approved USQ procedure] are met, and (b) the documents are technically complete and support the determination made.

Interviews:

1. Interview select USQD preparers.

EFCOG Best Practice #148

FUNCTIONAL AREA: Nuc. Ops/Safety Basis/ USQ Process	February 2009 REV. 1	CRITERIA MET	
PISA Process (PP)	PP.1	YES	NO

OBJECTIVE: The USQ PISA process is implemented in accordance with [site/contractor’s DOE-approved USQ procedure].

The PISA process is a key aspect of the USQ process in accordance with 10 CFR 830.203. It stipulates specific actions to be followed upon declaration of a PISA, timeliness of reporting, and preparation of a specific type of USQD (“backwards looking”) and an Evaluation of the Safety of the Situation (ESS).

Facility managers must be specifically aware of required actions:

- take appropriate action to place or maintain the facility in a safe condition,
- expeditiously notify DOE when the information is discovered,
- perform a USQD and notify DOE of the results promptly, and
- complete evaluation of the safety of the situation and submit it to DOE.

Facility managers must also be aware of the timeliness goal for PISA declaration and USQD completion (i.e., days, not weeks).

Criteria

1. Facility managers are aware of PISA actions and timelines requirements.
2. Processes exist for identification of potential issues, validation of an issue as a PISA, and subsequent entry into the PISA process.
3. PISA declaration and DOE notification are completed in a timely fashion.
4. USQDs are completed for PISAs and DOE informed of the results in a timely fashion.
5. ESSs are completed for PISAs.
6. PISA USQDs properly define the “backwards looking” change.
7. The USQD quality criteria from UD.3 are met for PISA USQDs.
8. ESSs satisfy the criteria of [site/contractor’s DOE-approved USQ procedure].

Review Approach

Records:

1. Obtain samples to confirm existence of completing DOE notifications, USQDs, and EOSs and number of days to complete each step.

Interviews:

1. Interview facility managers.
2. Interview select USQD preparers.

EFCOG Best Practice #148

The matrix below presents a crosswalk of each ESS to the requirements of [*site/contractor's DOE-approved USQ procedure*].

Requirement from Appendix G	Assessment on Adequacy of ESS for [facility A]	Assessment on Adequacy of ESS for [facility B]
• Title [short, descriptive]		
• Description of occurrence or discovery and immediate compensatory actions taken.		
• Date PISA was discovered and ORPS report number.		
• Results of immediate safety assessment and of USQD (positive/negative). Reference relevant documents.		
• Path forward. Status of compensatory measures.		

EFCOG Best Practice #148

Appendix A

Background: Compliance with 10 CFR 830.203

<i>Requirements from 10 CFR 830.203</i>	<i>Corresponding Requirements from [site/contractor's DOE-approved USQ procedure]</i>
<p>¶ 830.203 (a) The contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must establish, implement, and take actions consistent with a USQ process that meets the requirements of this section.</p>	<p>[site/contractor's DOE-approved USQ procedure] states:</p> <p>...</p>
<p>¶ 830.203 (b) The contractor responsible for a hazard category 1, 2, or 3 DOE existing nuclear facility must submit for DOE approval a procedure for its USQ process by April 10, 2001. Pending DOE approval of the USQ procedure, the contractor must continue to use its existing USQ procedure. If the existing procedure already meets the requirements of this section, the contractor must notify DOE by April 10, 2001 and request that DOE issue an approval of the existing procedure.</p>	<p>This is a dated compliance startup requirement satisfied prior to April 10, 2001 and no longer relevant. Absent DOE direction or concurrence, any procedure originally submitted to DOE for approval must continue to receive DOE approval for subsequent revisions. DOE approval is understood to be required and has been obtained for each revision to [site/contractor's DOE-approved USQ procedure].</p>
<p>¶ 830.203 (c) The contractor responsible for a hazard category 1, 2, or 3 DOE new nuclear facility must submit for DOE approval a procedure for its USQ process on a schedule that allows DOE approval in a safety evaluation report issued pursuant to section 207(d) of this Part.</p>	<p>This is a dated compliance startup requirement satisfied in the past and no longer relevant.</p> <p>Specifically, this requirement is satisfied by the implementing approach agreed upon with DOE. 10 CFR 830.203 is implemented for the overall site by [site/contractor's DOE-approved USQ procedure], which governs all facilities and is approved by DOE.</p>
<p>¶ 830.203 (d) 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:</p> <ul style="list-style-type: none"> (1) Temporary or permanent change in the facility as described in the existing documented safety analysis; (2) Temporary or permanent change in the procedures as described in the existing documented safety analysis; (3) Test or experiment not described in the existing documented safety analysis; or (4) Potential inadequacy of the documented safety analysis because the analysis potentially may not be bounding or may be otherwise inadequate. 	<p>[site/contractor's DOE-approved USQ procedure] states:</p> <p><i>The scope of this procedure applies to the Hazard Category 2 and 3 nuclear facilities and activities at ...</i></p> <p>This statement is repeated in Section 6.0, <i>USQ Process Methodology</i>.</p>
<p>¶ 830.203 (e) A 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.</p>	<p>[site/contractor's DOE-approved USQ procedure] states:</p>
<p>¶ 830.203 (f) The contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must annually</p>	<p>[site/contractor's DOE-approved USQ procedure] states:...</p>

EFCOG Best Practice #148

<p>submit to DOE a summary of the USQ determinations performed since the prior submission.</p>	
<p>¶ 830.203 (g) 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 documented safety analysis, it must:</p> <ol style="list-style-type: none">(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 meet paragraph (g)(1) of this section.	<p>[site/contractor's DOE-approved USQ procedure] states: ...</p>

EFCOG Best Practice #148

See also

Rebaselined USQ Procedure Effectiveness Review Report in Effectiveness Review Section

EFCOG Best Practice #148

USQ Process Annual Assessment

Purpose

The purpose of this specialty assessment is to verify procedural compliance of USQ evaluations with *[site/contractor's DOE-approved USQ procedure]*. *[site/contractor's DOE-approved USQ procedure]* establishes the Contractor USQ process for conducting Hazard Category 2 and 3 nuclear facility USQ evaluations pursuant to the requirements of 10 CFR 830, "Nuclear Safety Management," Section 830.203, "Unreviewed Safety Question Process."

This plan defines the assessment team, the sample population and method of selection for documents reviewed, and provides the assessment schedule.

Scope

The scope of this specialty assessment is the USQ process for *[site/contractor's facilities]*. To verify compliance with *[site/contractor's DOE-approved USQ procedure]*, this assessment will review USQ evaluations performed for changes processed through the USQ process during the review period to verify compliance with *[site/contractor's DOE-approved USQ procedure]*. Also included within the scope of this assessment are document changes that do not receive written USQ evaluations (i.e., outside the scope of the USQ process or "N/A") or that are released prior to USQ evaluation (i.e., Project USQ), but have requirements under the USQ process as described in *[site/contractor's DOE-approved USQ procedure]*. This includes document changes that are determined to be outside the scope of the USQ process (i.e., "N/A"), documents dispositioned under a Project USQ, and documents processed under the GCX-2 categorical exclusion. This assessment also includes a review of Safety Basis bulletins issued during the review period. Additional details are provided below.

USQ Evaluations

USQ Screenings. USQ screenings prepared per Section 4.4 of *[site/contractor's DOE-approved USQ procedure]* during the review period will be included in this assessment. Per *[site/contractor's DOE-approved USQ procedure]*, USQ screenings are used to document use of the GCX-1, and GCX-3 through GCX-5 categorical exclusions (GCX-2 does not require documentation on a USQ screening form).

USQ Determinations. USQ determinations prepared per Section 4.5 of *[site/contractor's DOE-approved USQ procedure]* during the review period will be included in this assessment.

USQ Process Out of Scope ("N/A")

Per Section 4.3.2 of *[site/contractor's DOE-approved USQ procedure]*, documents that are outside the scope of the USQ process do not require a written USQ evaluation. Documents that were determined to be outside the scope of the USQ process ("N/A") during the review period, will be included in this assessment.

Documents Dispositioned under a Project USQ

EFCOG Best Practice #148

Also included in this assessment are documents that were dispositioned as "Project USQ" during the review period. These documents are not outside the scope of the USQ process, but are issued prior to evaluation in the USQ process. USQ evaluation is completed at the end of the project prior to operation of the facility.

Document Changes Applicable to GCX-2

Per Section 4.4.4.b of [site/contractor's DOE-approved USQ procedure] documents that can be excluded from the USQ process under the GCX-2 categorical exclusion do not require a written USQ evaluation. Document changes processed under the GCX-2 categorical exclusion during the review period will be included in this assessment.

Safety Basis Bulletins

A DOE assessment identified a safety basis bulletin that was used to modify the USQ process. This assessment will review all safety basis bulletins issued during the review period to determine if there are additional instances of safety basis bulletins being used to modify the USQ process as described in [site/contractor's DOE-approved USQ procedure].

The review period for this assessment is [date] to [date].

Within the context of ISMS, this assessment evaluates the implementation of the Core Function "Perform work within controls", and the Guiding Principles: "Line Management is responsible for safety", "Each employee knows their roles and responsibilities", and "Competence corresponds with responsibilities."

Specific Lines of Inquiry

Review Area	Criteria	Results
USQ determinations and USQ screenings used to document use of GCX-1, 3, 4, and 5 categorical exclusions.	1. Review a representative sampling of each type of USQ evaluation prepared during the review period.	
	2. Determine if the documents reviewed were properly evaluated in the USQ process based on [site/contractor's DOE-approved USQ procedure]. Appendix A and Appendix B of [site/contractor's DOE-approved USQ procedure] will be used as guidance during review of USQ screenings and determinations, respectively.	
Documents categorically excluded under GCX-2 (without documentation on a USQ screening form).	1. Review a representative sampling of documents categorically excluded under GCX-2 during the review period. Included in the review will be documents changed via ECNs, Calculation Coversheets, ADCAs, DARFs, and work orders.	

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Specific Lines of Inquiry

Review Area	Criteria	Results
	2. Determine if the documents reviewed were properly categorically excluded under GCX-2 per <i>[site/contractor's DOE-approved USQ procedure]</i> .	
Documents determined to be outside the scope of the USQ process (N/A).	1. Review a representative sampling of documents determined to be outside the scope of the USQ process (N/A) during the review period. Included in the review will be documents changed via ECNs, Calculation Coversheets, ADCAs, DARFs, and work orders; and documents released via EDTs.	
	2. Determine if the documents reviewed were properly determined to be outside the scope of the USQ process per <i>[site/contractor's DOE-approved USQ procedure]</i> .	
Documents dispositioned under a Project USQ	1. Review a representative sampling of documents dispositioned under a Project USQ during the review period. Included in the review will be documents changed via ECNs, Calculation Coversheets, and documents released via EDTs.	
	2. Determine if the documents reviewed were properly evaluated in the USQ process per <i>[site/contractor's DOE-approved USQ procedure]</i> prior to operation of the facility.	
Safety Basis bulletins	1. Review all safety basis bulletins issued during the review period.	
	2. Determine if the safety basis bulletins reviewed were used to modify the USQ process as described in <i>[site/contractor's DOE-approved USQ procedure]</i> .	

Assessment Approach and Methodology

Note: Any variances from the assessment approach and methodology must be described in the final assessment report along with a basis for the change.

Document Reviews

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Document reviews will be conducted to verify procedural compliance with [site/contractor's DOE-approved USQ procedure]. The types of documents that will be reviewed and the approach and methodology to be applied for each document type are discussed below.

1. USQ Evaluations.

A representative sampling of each type of USQ evaluation prepared during the review period will be reviewed. The sample population selected for the assessment will be as follows:

A minimum of five (5) USQ evaluations from each USQ evaluator will be selected for review. The evaluations will typically consist of three (3) USQ determinations and two (2) USQ screenings (GCX evaluations). However, any combination of USQ screenings and USQ determinations may be selected to allow 5 evaluations from each USQ evaluator to be reviewed.

2. Documents Categorically Excluded under GCX-2:

A representative sampling of documents categorically excluded under GCX-2 during the review period will be selected for review. Included in the review will be documents changed using ECNs, Calculation Coversheets, ADCAs, DARFs, and work orders. Documents issued on EDTs are not included because GCX-2 cannot be applied for new documents. The sample population will be as follows:

For administrative and technical procedures, a minimum of 10% of documents with GCX-2 applied during the review period will be selected for review. For ECNs, calculations, and work orders, because "GCX-2" is not a searchable field in DMCS or CHAMPS for these documents, document reviews will be performed until a minimum of 15 documents of each type with GCX-2 applied are identified. 100% of the selected documents will be reviewed.

3. Documents Determined to be Outside the Scope of the USQ Process (N/A).

A representative sampling of documents with N/A applied during the review period will be selected for review. Included in the review will be documents changed using Engineering Change Notices (ECNs), Calculation Coversheets, Administration Document Change Authorizations (ADCAs) (i.e., administrative procedures), Document Approval Request Forms (DARFs) (i.e., technical procedures), and work orders; and new documents issued using Engineering Data Transmittals (EDTs). The sample population will be as follows:

For administrative and technical procedures, a minimum of 10% of documents with N/A applied during the review period will be selected for review. For ECNs, EDTs, calculations released on Calculation Cover Sheets, and work orders, because "N/A" is not a searchable field in DMCS or CHAMPS for these documents, document reviews will be performed until a minimum of 15 documents of each type with N/A applied are identified. 100% of the selected documents will be reviewed.

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4. Documents Dispositioned under a Project USQ.

A representative sampling of documents dispositioned under a Project USQ during the review period will be selected for review. Included in the review will be documents changed using ECNs, calculations released on Calculation Coversheets, and new documents issued using EDTs. Procedures and work orders are not included because Project USQs are not applicable to these documents. The sample population will be as follows:

A minimum of 15% of documents dispositioned under a Project USQ that were released during the review period and that have an issued Process Hazard Analysis report will be selected for review.

5. Safety Basis Bulletins.

A 100% review of safety basis bulletins issued during the review period will be conducted. The review will determine if safety basis bulletins are being used to modify the USQ process as described in *[site/contractor's DOE-approved USQ procedure]*.

Interviews

Interviews will be performed in the event that findings are identified. In that case, personnel associated with the findings will be interviewed to confirm factual accuracy of the results.

Problem Evaluation Requests (PERs)

Problem Evaluation Requests (PERs) per TFC-ESHQ-Q_C-C-01, "Problem Evaluation Request," will be initiated to document and track findings and observations identified during the assessment. The PER numbers will be documented in the final report.

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New and/or Revised USQ Procedure

Effectiveness Review Plan

I. Introduction

[fill in historical background] In [date], the [site/contractor's DOE-approved USQ procedure] was revised to be more aligned with the DOE standard USQ process based on DOE G 424.1-1B Admin Change 1 and DOE-accepted USQ training. The purpose of this effectiveness review is to determine if the USQ procedure was correctly implemented and the pre-existing condition may be deemed resolved. The USQ Review Committee, composed of the USQ SME and Safety Basis Manager, will conduct the effectiveness review. The USQ Review Committee has been selected as both knowledgeable of the work scope and independent of the implementation of the corrective action to conduct the effectiveness review. They will assess implementation of the USQ process, including a sample of relevant USQ documents from [date] to [date], following ES&H Manual Document 4.7, *ES&H Analysis Methods*.

II. Background

[Fill in history]

III. Effectiveness Review Actions

This effectiveness review plan assesses the effectiveness of the implementation of the USQ process in [fill in], as reflected below in the six USQ process areas. Note, some topics may influence multiple USQ process areas, but are located for documentation purposes only in one area in this review plan.

A. Selection of the method/extent of the review

The method is observation of assessment of end products, using the results of the USQ Review Committee reviews of USQ documents, as well as interviews as appropriate.

B. Review Criteria

Review criteria were developed as a consensus of the USQ Review Committee and the Safety Basis Manager.

1. Categorical Exclusion

- a. Verify if the facility has established an AEP process.
 - i. If the facility has an AEP procedure, then PASS.
 - ii. If the facility has properly prepared AEP determinations, then PASS.
- b. Verify if the nuclear facilities have a DOE approved EITS list.
 - i. If the facility has a DOE approved EITS list for each nuclear facility, then PASS.
- c. Verify Categorical Exclusion used appropriately.

EFCOG Best Practice #148

- i. If 90% of changes CatX'd did not require a Screen or USQD, then PASS.

2. USQ Screening

- a. Sample USQ Screenings
 - i. If 90% changes Screened did not require a USQD, then PASS.
 - ii. If 90% changes Screened meet these criteria, then PASS.
 1. Description of the proposed activity is factual.
 2. Basis is brief, non-evaluative.
 3. References documented.

Note: The *[site/contractor's DOE-approved USQ procedure]* states, "USQ screening is intended to be a simple decision-making step. Answering any of the seven USQ determination questions is inappropriate for the screening step, since it involves only non-evaluative criteria. Non-evaluative means that the answer to a screening question is obvious from a simple reading of the safety basis document."

The *[site/contractor's DOE-approved USQ procedure]* further states, "The preparer shall provide a brief description of the proposed activity. The description shall be factual only, not evaluative...A brief, non-evaluative basis in support of this conclusion shall be provided in "Basis."...The references associated with the review shall be documented. Two types of references should be considered. These include the existing safety basis and any specific items of interest such as the procedure being revised."

3. USQD

- a. Sample USQDs
 - i. If no changes requiring DOE approval were determined to be negative USQDs, then PASS.
 - ii. If 90% of the USQDs did not have serious quality issues such that an independent technical reviewer could not draw the same conclusion per DOE G 424.1-1A, then PASS.
 - iii. If 90% changes USQDed meet these criteria, then PASS.
 1. Scope of the change is clearly described and appropriately bounded
 - a. USQD includes a description of the change being evaluated and of its effects on the Safety Basis
 - b. USQD answers the 7 USQD questions by providing sufficient detail to allow "independent reviewer could draw the same conclusion" in accordance with DOE G 424.1-1A, per the USQ Procedure.
 - c. USQD Introduction establishes the facts to be evaluated.
 - d. USQD Main Body evaluates the facts established.
 2. Appropriate SSCs and parameters are identified as being potentially affected
 3. Affected EITS is identified consistent with DOE approved facility EITS list

EFCOG Best Practice #148

4. Appropriate process hazards analysis and accident analysis scenarios are identified as being potentially affected
5. Appropriate/sufficient references are provided
6. Interim state hazards are evaluated as appropriate
7. USQDs evaluate impacts to both the workers and the public
8. Responses to the seven USQD questions provide sufficient justification for the conclusions
9. An independent reviewer can reach the same conclusion as the preparer
10. Documentation is consistent with the requirements of the USQ Procedure
11. USQ preparers/reviewers are cognizant of what constitutes the nuclear facility safety basis

5. Training

- a. Verify that the appropriate staff (approved USQ preparers, reviewers, and approvers) have completed the appropriate USQ training
 - i. If all approved USQ preparers, reviewers, and approvers have completed the appropriate training, then PASS.

6. USQ Procedure With Respect to DOE USQ Guide

- a. Verify that the USQ Procedure is consistent with DOE G 424.1-1A and DOE-approved training.
- b. If the USQ Procedure was approved by DOE, then PASS.

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Approach based on Readiness Assessment CRADs

OBJECTIVE

SA.1 Application of the USQ processes and procedures results in the evaluation of as-found conditions and proposed changes using mechanisms that commensurate with significance and complexity.

Criteria

1. USQ processes follow a formal, DOE-approved USQ procedure.
2. The USQ process is effectively integrated into all technical aspects including design, engineering, maintenance, inspection, operations and assessment.
3. The rate of authorization basis issue resolution is commensurate with the projected workload for supporting the reduced scope of operations.
4. Personnel responsible for implementing USQ Processes are knowledgeable of safety basis including changes and limitations based on required compensatory measures for reduced activities.

Approach

Record Review:

- Institutional USQ Procedure
- Facility-level USQ Procedures
- Facility USQ records

Interviews:

- Safety Analysts
- Facility Safety Manager
- Facility Manager and Deputy

Performance:

- The team may try to follow issue(s) through the USQ process if appropriate during the review.

EFCOG Best Practice #148

OBJECTIVE

SA.2 Potential Inadequacies in Safety Analysis (PISA) issues are recognized as such by responsible facility staff and management mechanisms initiate actions (following the DOE-approved USQ Procedure) to maintain facility safety, notify the approval authority and perform USQ evaluation of issues.

Criteria

1. Information and training relevant to operational and facility issues has been provided to and absorbed by personnel responsible for reporting abnormal or inconsistent information that could be source material that trigger PISA issues.
2. A process exists for collecting, confirming, and evaluating operational and facility information necessary to determine if the information constitutes a PISA issue.
3. Determinations of whether a PISA issue triggers the USQ process comply with the formal, DOE-approved USQ Procedure.
4. The rate of authorization basis issue resolution is commensurate with the projected workload for supporting the reduced scope of operations.
5. All known PISA issues have either been resolved or compensatory measures have been approved by DOE.

Approach

Record Review:

- Facility-level USQ procedures
- Facility USQ records

Interviews:

- Safety Analysts
- Facility Safety Manager
- Facility Manager and Deputy
- Facility Engineering Staff
- Facility Operators
- Fissile Material Handlers
- DOE Nuclear Safety Team

Performance:

- The team may try to follow issue(s) through the USQ process if appropriate during the review.

EFCOG Best Practice #148

OBJECTIVE

QA.1 Facility and equipment engineering processes and activities have been reviewed against the criteria of 10 CFR 830, Subpart A and quality assurance implementing documentation has been developed and promulgated for use in day-to-day activities where required.

Criteria

1. Quality critical engineering processes are identified and controlled by polices, and/or procedures that address quality requirements that are applicable to facility engineering.
2. For safety SSC commercially procured equipment, manufacturer technical information needed to maintain, operate and evaluate the reliability of the equipment is retrievable.
3. For laboratory designed and fabricated safety SSC equipment, adequate design basis information is maintained on file.
4. The procurement process for safety SSCs meet requirements with respect to adequate technical specification, vendor qualification, inspection and acceptance.
5. Organizational roles and responsibilities are defined so that facility staff implements quality requirements and quality personnel provide assurances that requirements were correctly implemented.
6. Compensatory measures as defined at the end of the MSA are effectively implemented. (see SA.3)

Approach

Record Review:

- Work Control Manual
- QA Plan
- Engineering records

Interviews:

- QA Manager
- QA Engineer
- Engineering staff
- Work Control Manager
- Facility Manager
- Deputy Facility Manager

Performance: None

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OBJECTIVE

PR.1 Approved and controlled policies, plans and procedures (i.e. “procedures”) exist to ensure the safe operation of the facility and implement the safety management programs in the TSRs.

Criteria

1. Policy exists stating when “procedures” are required.
2. Minimum content standards for “procedures” exist.
2. “Procedures” contain applicable requirements and are appropriately tailored to use in the facility.
3. “Procedure” detail is sufficient that personnel with minimum qualifications would be expected to correctly complete the applicable activities with minimal assistance from more highly qualified personnel.
4. “Procedures” are controlled so that personnel use only current versions. A list of current procedures is maintained.
5. Mechanisms for controlling and processing changes to “procedures” exist.
6. Compensatory measures as defined at the end of the MSA are effectively implemented. (see SA.3)

Approach

Record Review:

- TSR
- [procedures]
- SRPs
- ACPs
- Work Controls and Design Change Control Manual

Interviews:

- Facility Manager
- Deputy Facility Manager
- Facility Safety Manager
- Quality Assurance Manager
- Fissile Material Handlers
- Hazards Control Team Members
- Safety Analysts
- Plant Engineering Support Personnel
- Utilities and Telecommunications Support Personnel

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Performance: Observe procedure control and change practices

OBJECTIVE

CM.1 Baseline information for safety-significant, safety class structures, systems and components (SSCs) and other safety SSCs relied upon by the safety basis is accurate and supports system evaluation. System evaluations support a conclusion of adequate reliability for acceptable risk as defined by the DSA.

Criteria

1. Physical configurations of safety SSCs and documentation of safety SSCs are consistent with DSA stated functions and descriptions.
2. Record keeping of information provides retrievable descriptive information that allows System Engineers to respond to component or system failures.
3. Potential components failures are identified, the effects of component failure on the system are evaluated and approximate failure rates are known.
4. Surveillances and maintenance are appropriate to system function, system configuration and projected failures.
5. Baseline configuration management information is integrated with the maintenance program.

Approach

Record Review:

- DSA, TSRs
- As-built drawings of safety SSCs
- SRPs
- SDDs

Interviews:

- Systems Engineers
- Facility Operators
- Safety Analysts

Performance:

- Sample portions of some safety SSCs will be walked down
- Some SRPs and maintenance procedures will be observed

EFCOG Best Practice #148

Report on the

USQ Sitewide Baseline Surveillance

I. Introduction

The purpose of this sitewide baseline surveillance to determine the initial condition of the USQ program at [site]. The goal is to help facilitate the implementation of the new sitewide USQ procedure, [site/contractor's DOE-approved USQ procedure]. The new USQ procedure was implemented on [date]. Results of this baseline surveillance will be used to identify areas for improvement, improve USQ training, and provide tailored corrective actions to those issues identified.

The USQ Review Committee was composed of the USQ SME (Team Lead), an independent USQ SME, and Safety Analysts. The USQ Review Committee has been selected as both knowledgeable of the work scope and independent of the implementation of the corrective action to conduct the effectiveness review. The review included a sample of relevant USQ Screenings and USQDs from Hazard Category 2 and 3 nuclear facilities and activities (e.g., Onsite Transportation).

II. Root Cause and Corrective Actions

Several primary root causes were identified for the results of the USQ sitewide baseline surveillance:..

III. Surveillance Actions

A. Selection of the method/extent of the review

The method is observation of assessment of end products, using the results of the USQ Review Committee reviews of USQ documents.

B. Topical Area Results Based on Review Criteria

Review sub-criteria were developed as a consensus of the USQ Review Committee and the Nuclear Safety Manager to help facilitate a more comprehensive review. Any additional issues are noted at the end of this report. Each USQ document was rated as follows:

Green – Two or fewer minor mistakes (if more than two minor mistakes, but not more than two of the same types, then count as no more than two)
Yellow – Three or more minor mistakes; only one mistake (if more than one mistake, but mistakes are of the same nature, count as one for the purpose of grading).
Red – more than one mistake; or one or more serious mistakes.

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IV. Definitions:

A. Minor mistakes - mistakes that have no effect on the USQ outcomes. Minor mistakes require no corrective actions. Examples include:

- Wrong USQ number,
- Wrong references,
- Signatures and dates not entered correctly, and
- Boxes on the USQ worksheet incorrectly marked.

B. Mistakes – mistakes that have potential to change the USQ outcome (from negative to positive). Mistakes that require revision of the USQ document to fix the changes. If in fixing the change, the action is discovered to be a positive USQ, the error is elevated to a serious mistake. The revised USQD should reflect the changes to address quality issues. Examples include:

- Approver not on the list,
- Proposed activity not clearly stated,
- Conclusion not detailed enough to reach the conclusion,
- Change package is not available,
- Change package and USQ do not coincide,
- USQ screens out prematurely and USQ is not performed,
- Wrong hazard scenario referenced in the evaluation,
- Incorrect technical basis used to answer the seven USQ questions, and
- Other issues are judged to be neither serious nor minor mistakes.

C. Serious mistake - mistake that could result in a Price-Anderson Amendments Act (PAAA) violation. Examples include:

- USQ is performed by an un-qualified USQ person,
- USQ should be positive but evaluated to be negative or screens out,
- Other issues that are judged to be a serious mistake.

EFCOG Best Practice #148

SAFETY BASIS ASSESSMENT

SCOPE

The scope of this assessment includes the plans, procedures, and processes used by *[site/contractor]* to establish and maintain the safety basis for its nuclear facilities and activities and to establish and implement the unreviewed safety question (USQ) process consistent with the requirements of 10 CFR 830.

OBJECTIVE

The first objective is to verify that the Laboratory has established and implemented plans, procedures, and mechanisms to ensure that hazards associated with nuclear facilities and activities are formally and appropriately analyzed, actions are taken to prevent or eliminate hazards, and controls are developed, implemented, and verified. The second objective is to verify that procedures and processes ensure that a USQ process has been developed, approved by DOE, and adequately implemented.

DISCUSSION of RESULTS

- 1. Procedures and mechanisms address and implement 10 CFR 830 Subpart B requirements, including development and implementation of fully compliant documented safety analyses (DSAs) and technical safety requirements (TSRs) for Hazard Category 2 and 3 nuclear facilities and activities.**
- 2. Laboratory procedures and mechanisms verify the effective implementation of each approved DSA, TSR, and associated controls, including Specific Administrative Controls (SACs). Procedures provide for continued maintenance of all approved DSAs and TSRs for nuclear facilities/activities.**
- 3. The *[site/contractor]* has submitted, and DOE has approved, a compliant USQ process. The *[contractor]* has effectively implemented the USQ program and integrated it with other Laboratory programs, as appropriate.**
- 4. Processes require appropriate competence through education, training, experience, and qualification for those personnel responsible for preparing DSAs, TSRs, and USQ documents.**
- 5. Issues identified during previous reviews [e.g., the most recent Chief, Defense Nuclear Safety (CDNS) Biennial Review and selected DOE readiness assessments and Defense Nuclear Facilities Safety Board Staff Issue Reports] have been appropriately resolved and adequate corrective actions have been completed or a clear path to completion is indicated.**

EFCOG Best Practice #148

Review of USQ Procedures (site and facility)

Summary:

The purpose of this assessment was to review the Facility-specific USQ Procedures for accuracy and consistency with the *[site/contractor's DOE-approved USQ procedure]*.

The facility-specific USQ Procedures are used to describe the individual division administrative process for managing the workflow of the USQ Process. The facility-specific procedures describe the internal steps for submitting a change(s) and process for the workflow for performing a CatX, screening, or determination (i.e., responsibilities, document numbering, and routing). The steps and requirements identified in the individual procedures were found to be consistent with *[site/contractor's DOE-approved USQ procedure]*.

Facility-specific USQ Training associated with this assessment was not covered. Training for the USQ process was covered in a recent internal quarterly USQ Process Monitoring review. The review identified some issues with the facility-specific USQ training documentation, which included confusion with responsibilities and outdated information/documentation. A sampling of completed training records for facility-specific USQ training was verified to be complete and up-to-date.

The conclusion of the assessment is meets expectations. The procedures were found to be consistent with *[site/contractor's DOE-approved USQ procedure]* and a recent USQ review identified some corrective actions and completed training requirements. No other issues or discrepancies were identified in this review.

Details:

The purpose of this assessment was to review the Facility-specific USQ Procedures for accuracy and consistency with the *[site/contractor's DOE-approved USQ procedure]*.

The facility-specific USQ Procedures are used to describe the individual division administrative process for managing the workflow of the USQ Process. The information and steps described in *[site/contractor's DOE-approved USQ procedure]* are not reiterated in detail in the facility-specific procedures. The facility-specific procedures describe the internal steps for submitting a change(s) and process for workflow for performing a CatX, screening, or determination (i.e., responsibilities, document numbering, and routing). The steps and requirements identified in the individual procedures were found to be consistent with *[site/contractor's DOE-approved USQ procedure]*.

Facility-specific USQ Training associated with this assessment was not covered. Training for the USQ process was covered in a recent internal quarterly USQ Process Monitoring review. The review identified some issues with the facility-specific USQ training documentation, which included confusion with responsibilities and outdated information/documentation. A sampling of completed training records for facility-specific USQ training was verified to be complete and up-to-date. The closure of corrective actions may be covered in a future USQ training assessment.

EFCOG Best Practice #148

Focused/targeted reviews, vertical slices, deep slices

Pre-Existing Condition (PEC) Corrective Action Closure

Condition Title: USQ Process Utilization

1. Cancel [bad stuff].
2. Establish an Approved Equivalent Parts (AEP) process.
3. Submit to DOE an EITS list for nuclear facilities for DOE approval.
4. Based on the recent reorganization, evaluate the work control process for appropriate execution of the USQ process.
5. Provide additional Institutional level USQ training and assistance, to include monthly feedback detailing review of USQ documents (closure upon successful completion of #7).
6. Perform Technical Assist and provide a results briefing to the Associate Director of Nuclear Operations.
7. Perform USQ Effectiveness Review

EFCOG Best Practice #148

Contractor and DOE broad and shallow nets

The USQ Review Committee shall meet at periodicities specified by the Authorization Basis Section leader. In these meetings, USQDs and USQs shall be evaluated by the group. Specific topics of interest, which may be used to categorize individual document assessment, include:

- a. Thresholds for opportunities for improvement that do not require further consideration (i.e., reviewer may have done it differently, but the preparer is not incorrect)
- b. Threshold for discrepancies that may create problems in audits
- c. Consistency between directorates
- d. Potential interpretation issues that may require guidance.
- e. Identification of USQDs or USQs that are incorrect or may have clarity problems.

EFCOG Best Practice #148

Product quality (CatXs, Screens, USQDs, Expert USQDs, ESSs), Physical Change USQDs

I. Introduction

The purpose of this quarterly review was to examine a specific issue of the USQ process, “Physical Changes,” in accordance with the *[site/contractor’s DOE-approved USQ procedure]*. The relevant guidance document is AB-0## (Ref. 2). This area has been previously assessed (e.g., Ref. 3, 4) and continues to be monitored by DOE and DOE-HSS (e.g., Ref’s. 5-7). The *[site]* USQ SME, Safety Basis Division Institutional Reviewer, and Safety Basis Deputy Division Leader conducted the review.

II. Monitoring Plan

A sampling of standard USQDs for physical changes in CY12 was reviewed to verify (a) the documentation requirements of *ES&H Manual Document 51.3* are met, and (b) the documents are technically complete and support the determination made. The sample reflected variations in workload across facilities.

OBJECTIVE: Unreviewed Safety Question Determinations (USQDs) are prepared consistent with the requirements of *[site/contractor’s DOE-approved USQ procedure]*. USQDs must be prepared at a level of quality such that a qualified independent reviewer can understand the basis for, and concur with, the preparer’s conclusions. Relative USQD quality, while potentially subjective, is an enforcement issue that has been seen at most DOE sites. Specific issues of historical concern include failure to either properly define or fully evaluate the change.¹

Criteria

1. The change under evaluation is fully defined in USQDs.
2. The technical issues associated with a change are fully evaluated in USQDs.
3. Per the guidance in *[site/contractor’s DOE-approved USQ procedure]*, no new controls are established to support a negative USQD.
4. An independent technical reviewer can understand and concur with the preparer’s conclusion (i.e., other quality issues are not severe).
5. Changes determined by the review team to require DOE approval are not documented to be negative USQDs.

¹ Examples of previous findings (Ref. 3) include:

- DEFICIENCY-UD.# Inadequate Evaluation and Discernible Increase (Criteria 2, 4, and 5)
- WEAKNESS-UD.# Inadequate Information for an Independent Technical Reviewer to Reach the Same Conclusion (Criteria 1, 2, and 4)
- WEAKNESS-UD.# Change Under Evaluation Not Fully Defined Nor Appropriate (Criterion 1)
- OFI-UD.# Clarifying Evaluation of a Hazard in a USQD (Criterion 4)
- OFI-UD.# Quality Issues (Criterion 4)
- OFI-UD.# Inadequate Consideration of Reliability/Operability in a USQD (Criterion 2 and 4)

EFCOG Best Practice #148

USQD (Physical Change) Monitoring

Document	Date	Topic	Compliant ²	Quality/ Comment
USQ-[fac]-YR-0##-D	9/14/11	Installation of HEPA Filters & Gauge	Yes	
USQ-[fac]-YR-0##-D	9/14/11	Storage of LLW Containers in Yard	Yes	
USQ-[fac]-YR-0##-D	9/26/11	Installation of Utilities for Spectrometer and a Storage Cabinet	Yes	
USQ-[fac]-YR-0##-D	9/28/11	Replacement of Feedthrough Plugs and Plate	Yes	
USQ-[fac]-YR-0##-D	10/11/11	Removing Equipment and Modifying Inert Gas Lines to Support Installation of Gas Analyzers	Yes	
USQ-[fac]-YR-0##-D	10/12/11	Installing a Cleanup Cart and Electronics Rack	Yes	
USQ-[fac]-YR-0##-D	10/12/11	Removing Electrical Receptacles in Room 1, and Installing New Speakers in Rooms 1	Yes	
USQ-[fac]-YR-0##-D	10/12/11	Evaluation of Test Machine with Simulated Aliens	Yes	
USQ-[fac]-YR-0##-D	11/32/11	Installation of Enhanced Restraints for Alien Probing Device	Yes	Noteworthy Practice 1

² Compliant with [site/contractor's DOE-approved USQ procedure] (see review criteria for additional information).

EFCOG Best Practice #148

GENERAL USQD REVIEW GUIDELINES

The following general guidelines are based on *[site/contractor]* experience.

1. Are the responses to the different sections in the main body of the USQD consistent with the Introductory description?
 - a. Do they contradict each other?
 - b. If an SSC is brought up in the beginning, is it appropriately reflected in later discussions? Looking at it from the back end, are all the SSCs discussed under the EITS and protective barrier questions also included up front in the beginning of the USQD?
2. Are the responses to the different sections in the main body of the USQD consistent with one another?
3. Is credit taken for controls/SSCs that do not match the DSA (e.g., credit for a glovebox when an item is outside the glovebox)?
4. Can a reviewer who does not have detailed familiarity with the facility determine what the change actually is?
5. Would the facility-specific portions of responses to sections in the main body of the USQD be specific and clear to a reviewer who does not have detailed familiarity with the facility?
6. Would the citation of the relationship between parameters and specific accidents/EITS be specific and clear to a reviewer who does not have detailed familiarity with the facility/DSA? For example is it clear whether the SSC is involved versus affected negatively by the change? Are the parameter citations in responses to Part 1, Question 2 clear?
7. If an answer to a USQD question is based on a conclusion from a supporting document, such as an engineering safety note or assessment by an ES&H technical expert (e.g. Industrial Hygienist), does the USQD state the conclusion and clearly link it to the source document?"
8. Can you determine what the change is?
 - a. Look for track changes/red lines if it's a procedure revision.
 - b. Would a sketch be helpful in documenting the spatial facts?
9. Is there a clearly discernible increase in frequency? Do not argue that no discernible frequency change exists because the frequency bin did not change.
10. Is this part of a bigger change? If so, ensure that a series of individual negative USQDs do not mask an overall change that should have resulted in a positive USQD (i.e., overarching USQD issues).

Is there a clear citation of previous USQDs for other segments of the bigger change, or the overarching USQD on the entire change? Do not parse a change that may involve a USQ into

EFCOG Best Practice #148

small pieces, each of which results in a negative USQD, for the purpose of avoiding the larger positive USQD.

11. Does the change affect a SSC (or control) involved in a recent SER? If so, was the SER reviewed for any commitments that are relevant to the USQD and was the SER cited in the Safety Basis reference section.
12. Is the level of detail (including citations) sufficient for an independent reviewer to reach the same overall conclusion? When in doubt, provide more detail in describing the change. Given that a USQD is being prepared, the time savings by scrimping on detail is minimal.
13. Is the current revision of the USQD form used?
14. Are all the sections in the main body of a USQD included? Some have been inadvertently deleted in the past.
15. Is the right response in the right section of the USQD main body? The computer cut-and-paste function has caused problems in the past.
16. Check that the change is not just described as only part of routine facility operations, but is also as authorized by the Safety Basis, e.g. "<the change> is a normal part of the facility operations and is authorized in the SAR in Section #.#.#, *Operations*."
17. Check to ensure the USQD is following lessons learned, i.e., the USQD is not doing something that a lessons learned indicated not to do. For example,
 - a. Are all the signatures present and appropriate (USQ preparer, reviewer, approver)?
 - b. Is there a clear link (citation) to prior USQDs?
 - c. Is the USQD's documentation of assessment of interim hazards to EITS clear?
18. Check for potentially improper documentation of how minor changes are ruled out from further consideration in the USQD.
19. Has proper editorial QA been applied (e.g., spell check, bullet numbering)?
20. Is a red-lined copy of a procedure change attached to the USQD?

EFCOG Best Practice #148

CatXs

Categorical Exclusion REVIEW GUIDELINES

- 1) Is the signature present and appropriate (USQ approver)?
- 2) Is it an appropriate use of the CatX?
 - a) How does the change correspond to the CatX examples of appropriate and inappropriate CatX use?
 - b) Does the change exceed available CatX definitions and actually require a USQD, especially for EITS changes?
 - c) Where relevant, does an Approved Equivalent Parts List exist? Is the item in question on it?
 - d) Does a prior USQ review cited actually cover the CatX (e.g., for CX E.#)?
 - e) Does the change assigned a CatX actually have PISA implications?
- 3) Is this a revision to something previously covered by a CatX, and is the signature resigned or redated?
- 4) Is the work package level of detail describing the change sufficient to justify the CatX?

EFCOG Best Practice #148

Self Assessment of CatXs

Planned Approach for Self-Assessment:

- Each organization is responsible for maintaining its CatXs per 10CFR830 and [*site/contractor's DOE-approved USQ procedure*] document retention requirements.
- Each organization's AB manager (or their staff) will then temporarily place CatXs in a review location (e.g., movable file cart in a facility office or conference room).
- The AB Section point of contact, AB Manager from the respective organization, and USQ SME will review that organization's CatXs.
- Compile organizational results.
- Institutional CatX report will then be produced by assembling the organizational results.

Criterion:

1. Were CatXs documented properly?
2. Was the CatX properly applied?
3. Is there a DOE approved EITS list?
4. Could the CatXs be collected per 10CFR830 and [*site/contractor's DOE-approved USQ procedure*]?

EFCOG Best Practice #148

Expert USQDs (see also training review below)

EFCOG Best Practice #148

Report on Expert USQD Effectiveness Review

(Note: can also serve for Review of Expert USQD Pilot and ongoing Expert USQD Monitoring)

I. Objective/Purpose

The Expert USQD Process is a new process under the [site/contractor's DOE-approved USQ procedure] implemented by [site] on [date]. The [site] Expert USQD Process was approved by [DOE Field Office] on [date]. [DOE Field Office] approval relied upon NNSA Administrator Thomas D'Agnostino's (NA-1) prior approval of the Expert USQD process as compliant with 10 CFR 830 (Ref. 3). The purpose of this Effectiveness Review (Management Self-Assessment) is to examine Expert USQD Process Implementation as required by NA-1 (Ref. 3), "to conduct an effectiveness review of the Expert-based USQ process within twelve months of implementation to ensure the integrity and quality of the USQ process and the resulting documentation is being preserved." The sample period for the review is the first twelve months of implementing the Expert USQD Process, including the Expert USQD Pilot³. Key requirements of the Expert USQD process are summarized in Attachment 1.

This review uses the terms defined in *PRO-00##* (Ref. 4) and *PRO-00##* (Ref. 5).

Corrective Action: Action taken or measure implemented to rectify an issue. Action taken to address a cause will prevent recurrence or reduce the probability of an issue recurrence.

Deficiency: A condition, event, procedure, or operation that is not in compliance with the requirements of applicable federal, state, and/or local laws and regulations, the Contract, or the -specific implementing procedures/manuals.

Issue: A condition or event that has or may negatively impact [site/contractor's] ability to safely, securely, and effectively perform its mission. These include compliant conditions or events requiring management attention and issues that are or have the potential to be a noncompliance with federal, state, or local law, the Contract, or the specific implementing procedures/manuals.

Observation: A compliant condition, event, operation, or practice that warrants action tracking or is included for trending purposes to identify future potential areas for improvement.

Strength: A compliant condition or process described as a best management practice.

II. Scope

The sample period for the effectiveness review is the first twelve months (Expert USQDs completed between on [date] – [date]) of implementing the Expert USQD Process, including the Expert USQD

³ On a related note, the purpose of the Expert USQD Pilot Review is to conduct reviews of the Expert USQDs completed during the [number of months] trial period, in preparation for a formal briefing to [DOE Field Office] documenting the results at the conclusion. The Expert USQD Pilot is a requirement of [DOE Field Office] (Ref. 2) and NNSA Administrator Thomas D'Agnostino in the NA-1 approval of the Expert USQD process (Ref. 3).

EFCOG Best Practice #148

Pilot and subsequent reviews. All Expert USQDs from all nuclear facilities/activities are within the scope of this review. All Expert USQDs produced in this period will be reviewed.

III. Methodology & Criteria

This is a Management Self-Assessment conducted per *PRO-00##*, Rev. 02. The MSA is included in the Integrated Assessment Program (IAP) and was approved by the Nuclear Operations Functional Area Manager. The methodology is a combination of document review (completed Expert USQDs and past assessments of the Expert USQD process) and interviews as necessary. This MSA will review Expert USQDs for compliance with the *[site/contractor's DOE-approved USQ procedure]*, quality, strengths, as well as tracking utilization of the Expert USQD process with regard to type of changes. This tracking gives an insight into the application of the Expert USQD process. Results from previous reviews (i.e., the Expert USQD Pilot) are considered as part of this review.

The following criteria were selected to “ensure the integrity and quality of the USQ process and the resulting documentation is being preserved” as stated in Ref. 3.

1. Is the Expert USQD process being utilized? If so, is it being utilized properly?
 - a. Have the requirements of *[site/contractor's DOE-approved USQ procedure]* been met?
 - i. Has the Facility Manager (or designee) approved the Expert USQD Preparers and Reviewers for his or her facility?
If the Facility Manager (or designee) approved the Expert USQD Preparers and Reviewers for his or her facility, then PASS.
 - ii. Has the *[institutional]* Safety Basis Division Leader (or *[site]* USQ SME) concurred with the designation of Expert USQD Preparers and Reviewers?
If the Safety Basis Division Leader (or *[site]* USQ SME) concurred with the designation of Expert USQD Preparers and Reviewers, then PASS.
 - iii. Has the *[institutional]* Safety Basis Division Leader (or *[site]* USQ SME) evaluated the performance of the Expert USQD Preparers and Reviewers?
If the Safety Basis Division Leader (or *[site]* USQ SME) evaluated the performance of the Expert USQD Preparers and Reviewers, then PASS.
 - iv. Do the Expert USQD Preparers and Reviewers meet the qualification requirements of Section # of *[site/contractor's DOE-approved USQ procedure]*?
If the Expert USQD Preparers and Reviewers meet the qualification requirements of Section #, then PASS.
 - v. If Expert USQDs were conducted, do they meet the requirements of *[site/contractor's DOE-approved USQ procedure]*?
If Expert USQDs meet the requirements of *[site/contractor's DOE-approved USQ procedure]* (Compliant with *[site/contractor's DOE-approved USQ procedure]*): it was appropriate to prepare an Expert USQD (i.e., did not require a standard USQD) and the Expert USQD was done appropriately, then PASS.
 - vi. Was the official Expert USQD form in *[site/contractor's DOE-approved USQ procedure]* used properly?
If the official Expert USQD form in *[site/contractor's DOE-approved USQ procedure]* used properly, then PASS.

EFCOG Best Practice #148

- vii. Are Expert USQDs being tracked in a manner that facilitates their inclusion on the annual list of USQDs submitted to DOE?
If Expert USQDs are tracked the same as standard USQDs, then PASS.

IV. Schedule

Since this review includes the reviews performed as part of the Pilot Expert USQD process, the sample period for the review is the first twelve months of implementing the Expert USQD Process, including the Expert USQD Pilot and subsequent implementation. The start date is [date]. A draft report will be issued for factual accuracy review by [date]. The review report will be issued by [date].

V. Team

The [site] USQ SME (Assessment Team Leader), Safety Basis Division Institutional Reviewer, and Safety Basis Deputy Division Leader conducted the review. [DOE Field Office] Safety Basis staff has been invited to participate to the degree [DOE Field Office] deems appropriate. The Assessment Team has the skills, knowledge, and abilities (SKAs) necessary to evaluate compliance to the specified requirements. They are technically competent/trained to perform the assessment. The Assessment Leader ([site] USQ SME) developed the [site] USQ training. The Assessment Team conducted the review of the Expert USQD Pilot.

In accordance with PRO-00##, the Management Self Assessment Team Leader completed the required training (CAO###). Team members/ individual assessors meet training and qualification requirements determined by the manager (NucOps FAM) authorizing the MSA.

VI. Assessment Response Owner

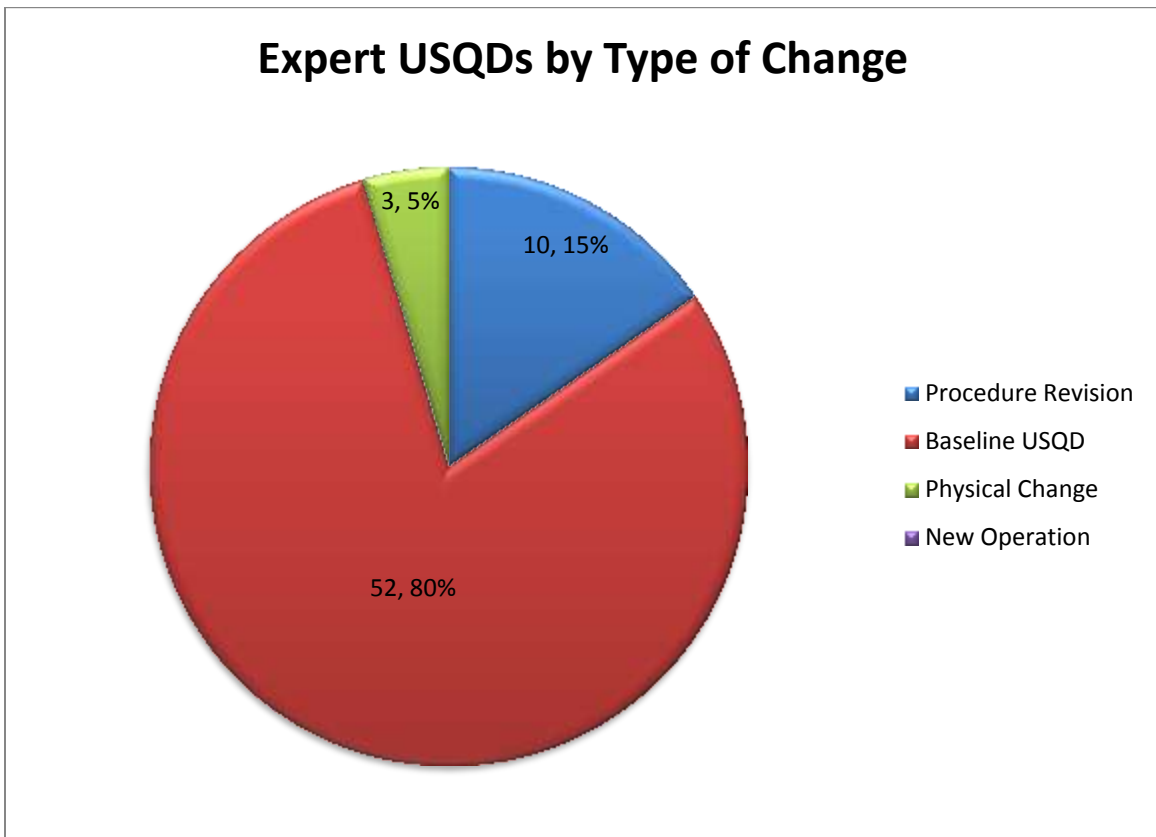
The Assessment Response Owner is the [institutional] Safety Basis Division Leader.

EFCOG Best Practice #148

VII. Data

Table 1 and Figure 1. Type of changes evaluated by Expert USQDs ([date] - [date]).

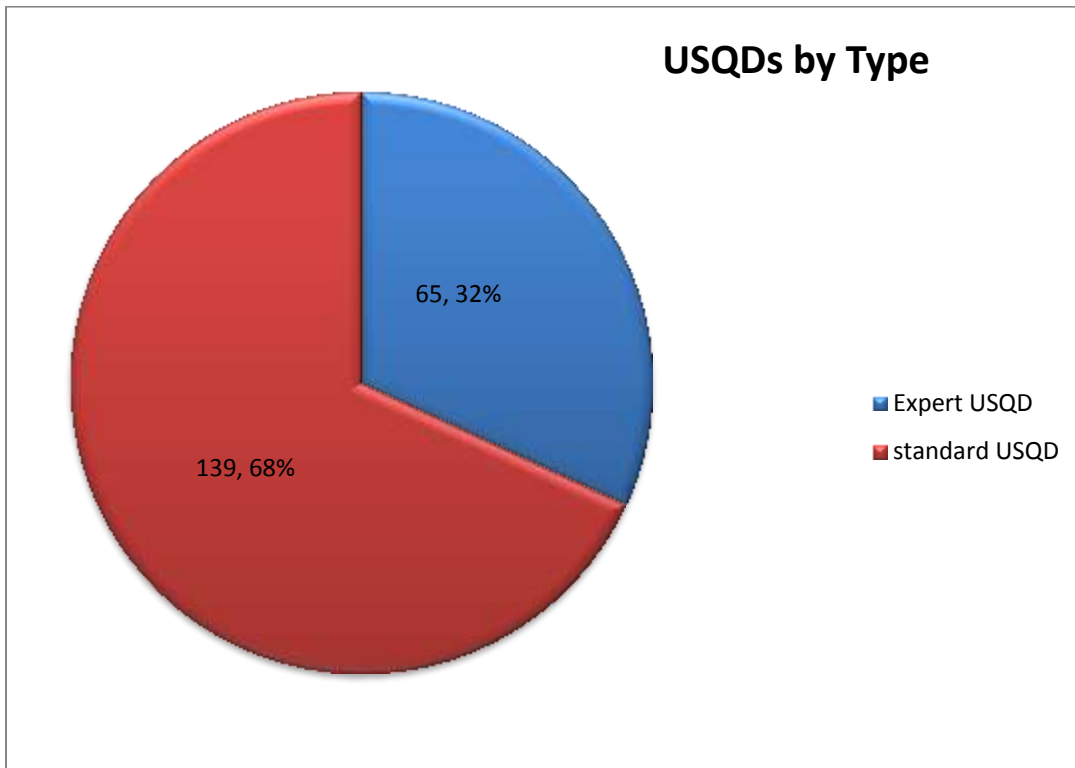
Type of change	Sub-Type	Number	Percent of Total
Procedure		#	#%
	Procedure Revision	#	#%
	Procedure Baseline USQD	#	#%
Physical change		#	#%
New activity/test/operation		#	#%
Total		#	100%



EFCOG Best Practice #148

Table 2 and Figure 2. Utilization of Expert USQDs in comparison to Standard USQDs across [site] ([date]- [date]).

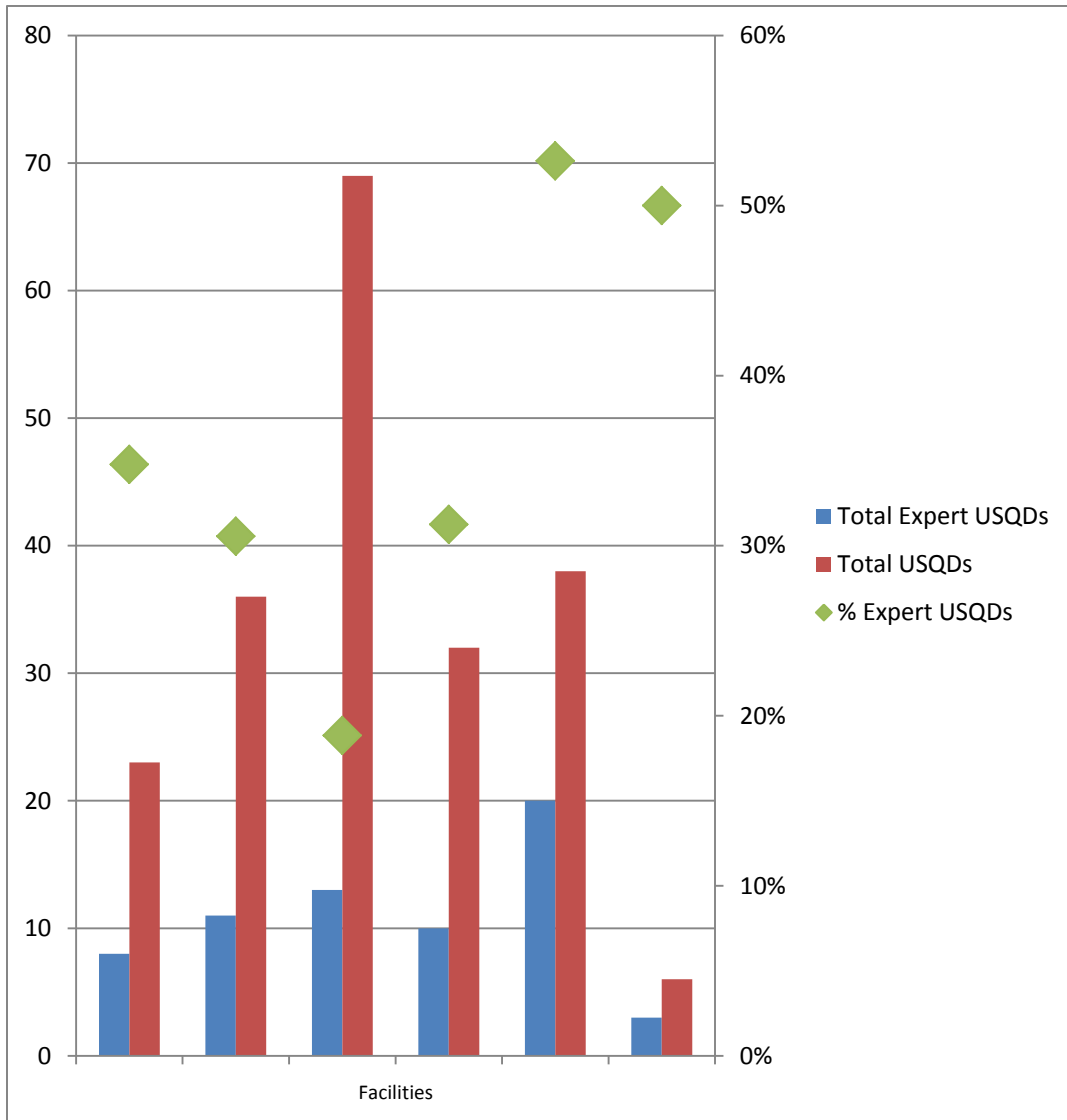
Type of USQD	Number	Percent of Total
Expert USQD	#	32%
Standard USQD	#	68%
Total	200	100%



EFCOG Best Practice #148

Table 3 and Figure 3. Utilization of Expert USQDs in comparison to Standard USQDs for each nuclear facility/activity ([date]- [date]).

	[facility 1]	[facility 2]	[facility 3]	[facility 4]	[facility 5]	[activity 1]
Expert USQD	#	#	#	#	#	#
Total USQDs	#	#	#	#	#	#
% Expert USQDs	35%	31%	19%	31%	53%	50%



EFCOG Best Practice #148

Expert USQD Monitoring – Expert USQD Pilot⁴

Document	Date	Topic	Type of change	Compliant ⁵	Quality/ Comment
USQ-[fac]-YR-0##-D	9/14/11	Field Fingerprint Verification Process	Procedure Baseline USQD	Yes	
USQ-[fac]-YR-0##-D	9/14/11	Certification of TRU Waste Packages	Procedure Revision	Yes	
USQ-[fac]-YR-0##-D	9/28/11	Facility Procedure-###...	Procedure Revision	Yes	
USQ-[fac]-YR-0##-D	10/11/11	<i>[Institutional Procedure], Safety in Design and Major Modification Determination Process</i>	Procedure Baseline USQD	Yes	
USQ-[fac]-YR-0##-D	10/19/11	Installation of a Pressure Gauge and an Isolation Valve in the Compressed Laughing Gas System	Physical (minor change)	Yes	
USQ-[fac]-YR-0##-D	11/32/11	Installation of Enhanced Restraints for Alien Bisector	Physical (minor change)	Yes	Noteworthy Practice 1

⁴ Color code for document table: Procedure Baseline USQD (Purple), Procedure Revision (Pink), Physical Change (Blue), New Activity (not show - none during Pilot).

⁵ Compliant with *[site/contractor's DOE-approved USQ procedure]*: it was appropriate to prepare an Expert USQD (i.e., did not require a standard USQD) and the Expert USQD was done appropriately.

EFCOG Best Practice #148

Interface with other processes (work control, change control, maintenance, procedures, institutional procedures, and TSR implementation)

Work Control

This evaluation included the following lines of inquiry:

- The reviewers attended the facility work permit meetings to observe the work control process and how it triggered, and interacted with, the USQ process.
- The reviewers interviewed the facility safety analyst on the results of the facility's internal corrective action for the work control process.
- The reviewers reviewed work permits for a specified period [dates].
- The reviewers interviewed the Facility Manager with respect to the work permit meetings.
- The reviewers interviewed the Compliance Officers for the respective nuclear facilities, and the other Compliance Officers for the other organizations, as well as the Waste Acceptance Team Lead to verify that all appropriate procedure changes are submitted to the USQ process.
- The reviewers interviewed the Configuration Management Manager to verify appropriate physical changes are submitted to the USQ process.

Report then structure along lines of procedure changes and facility changes

EFCOG Best Practice #148

Application of Prior USQ Process CatXs, including sampling of Work Permits

I. Introduction

The purpose of this quarterly review was to examine a specific issue of the USQ process, Application of Prior USQ Process CatXs, including sampling of Work Permits, in accordance with the [site/contractor's DOE-approved USQ procedure]. This is an issue that DOE specifically requested be examined as part of the RCRs for the revised [site/contractor's DOE-approved USQ procedure]. Specifically, RCR #25 states,

A self-assessment of use of the prior USQ CatX is requested in FY11. This is consistent with the responsibilities assigned to the SB Division Leader by the procedure in Section 4.2.

This issue has been previously assessed by DOE (e.g., Ref. 2 - 9), and continues to be monitored (Ref. 10 and 11). Key requirements are highlighted in the Attachment.

The USQ SME, Safety Basis Division Institutional Reviewer, and Safety Basis Deputy Division Leader conducted the review. Individuals and management in the relevant organizations also supported the review.

II. Monitoring Plan

Examine this specific issue of the USQ process. The last six months of the calendar year 2010 shall be used for the nuclear facilities, although earlier samples from 2010 may also be utilized if insufficient samples are available in the sample period. The sample period was determined in conjunction with the nuclear facilities AB staff as being easily accessible, with a lower probability of requesting open work permits that could interfere with ongoing work. Work permits and CatXs for buildings that went non-nuclear were outside the sample. The following points will be examined:

1. Do the Prior USQ Process CatXs meet the requirements of the [site/contractor's DOE-approved USQ procedure]?
2. Do the sampled work permits appropriately utilize the Prior USQ Process CatXs?
3. Conduct interviews relevant to the above questions.

EFCOG Best Practice #148

Self Assessment Worksheet

(Entry of Changes Associated with Work Permits into USQ Process)

Assessment Criterion:

The purpose of this self-assessment is to review the application of the USQ process to maintenance and physical modifications in the [*specific facilities*]. This assessment is based on a review of 100 work permits covering work performed in the nuclear facilities over a period of 9 months, [*date*] – [*date*]. The intent of this self-assessment is:

- 1) To evaluate the [*specific facilities*] process in light of recent USQ process training which provided clarification regarding the entry of maintenance activities into the USQ process, and
- 2) To identify any issues and recommend corrective actions prior to the implementation of the revised the [*site/contractor DOE-approved USQ procedure*].

Under, all physical changes to nuclear facilities must enter the USQ process and either result in application of a CatX or a USQD. With regards to maintenance this was clarified in the USQ training as follows:...

This assessment reviewed the work activity described on each of the work permits and using the criteria outlined above determined whether the activity constituted a physical change, and hence, required entry into the USQ process. For each work activity that did enter the USQ process, it was then determined whether a USQ document (CatX or USQD) was prepared. In addition, for work activities that involved performance of Preventative Maintenance (PM) Task Codes, the assessment identified whether the PM Task Codes had been evaluated in the USQ process.

EFCOG Best Practice #148

Change Control Pre-Existing Condition Monthly Review

- **Verify process improvement in work permits**
- **Verify AEP process in use**
- **Verify appropriate procedures submitted to USQ process.**
- **PEC CA #4 commented on potential improvements to processes to allow sequential processing the Configuration Control Board Change Review Sheet, then the USQD.**
 - **Processes for collecting information to input to USQ process could be improved to both expedite the USQ process and improve quality of USQDs.**
 - **[facility] has faced issues with the quality of documentation of physical changes.**
- **PEC CA#5 ongoing feedback and review of USQDs**
 - **Continue to assess whether information available for physical changes USQDs is adequate to support compliance.**
 - **Providing additional institutional training on how AEP process can expedite USQ process.**

EFCOG Best Practice #148

Evaluation of Work Control Process for appropriate execution of the USQ process

This evaluation was conducted in response to the Pre-Existing Condition (PEC) Corrective Action Closure for the [facility/contractor] USQ process. PEC #4 states, "Based on the recent reorganization, evaluate the work control process for appropriate execution of the USQ process." This evaluation included the following lines of inquiry:

- The reviewers attended work permit meetings to observe the work control process and how it triggered, and interacted with, the USQ process.
- The reviewers interviewed the safety analyst on the results of internal corrective action for the work control process (safety analyst observed said meetings over the past half-year). His observations of attending work permit meetings over the past year were discussed.
- The reviewers reviewed work permits for a specified period (Dec. 1, 2007 – February 13, 2008) post-dating the DOE approval of the EITS lists which was a necessary pre-condition for appropriate use of several Categorical Exclusions (Ref. 2).
- The reviewers interviewed the Facility Manager with respect to the work permit meetings.
- The reviewers interviewed the Compliance Officers for the respective nuclear facilities and the other Compliance Officers for the other organizations, as well as the Team Lead to verify that all appropriate procedure changes are submitted to the USQ process.
- The reviewers interviewed the Configuration Management Manager to verify appropriate physical changes are submitted to the USQ process.
- The reviewers verified that the [Facility] has a list of procedures subject to the USQ process for each nuclear facility.
- The reviewers verified that Configuration Management is another entry condition into the USQ process. The appropriate System Engineer proposes physical changes to the Configuration Management manager. The configuration management check performed for permit compliance perform double duty by also serving as a check to ensure that physical changes are appropriately submitted to the USQ process.
- The reviewers verified that processes exist such that if a physical change formally enters the Work Permit process, it should be submitted to the USQ process. The Configuration Management manager works on a daily basis with safety analysts and is co-located with them. This facilitates effective communication. Both a safety analyst and the Configuration Management manager attend Work Permit meetings.

EFCOG Best Practice #148

Submittal of procedures to the USQ process

Report on Entry of Documents into USQ Process

(TSR Implementing Procedures) - *Short Version*

I. Introduction

The purpose of this quarterly review was to examine a specific issue of the USQ process, “Entry of Documents into USQ Process (TSR Implementing Procedures),” in accordance with the *[site/contractor’s DOE-approved USQ procedure]*. This area has been previously assessed by DOE (e.g., Ref’s. 3, 4, 5 and 7), continues to be monitored by DOE and DOE-HQ (e.g., Ref’s. 6, 9, 10, 11 and 23).

The [site] USQ SME, Safety Basis Division Institutional Reviewer, and Safety Basis Deputy Division Leader conducted the review.

II. Monitoring Plan

To examine the issue, “Entry of Documents into USQ Process (TSR Implementing Procedures)”, the following review steps were performed:

1. Have the implementation documents on the current TSR Crosswalks been submitted to the USQ process in accordance with the *[site/contractor’s DOE-approved USQ procedure]*?
2. Is the list of institutional implementation documents on the TSR Crosswalks consistent with the *Facility Specific List of Select Institutional Documents Subject to the USQ process* (aka the “*Select List*”)?

EFCOG Best Practice #148

Report on Entry of Documents into USQ Process (TSR Implementing Procedures) - *Long Version*

I. Introduction

The purpose of this quarterly review was to examine a specific issue of the USQ process, Entry of Documents into USQ Process (TSR Implementing Procedures), in accordance with the *[site/contractor's DOE-approved USQ procedure]*. This is an area that has been previously assessed by DOE (e.g., Ref. 3, 4, 5) and continues to be monitored (Ref. 6). Key requirements are highlighted in the Attachment (Ref. 1, 2, and 5).

The *Safety Basis Implementation Procedure for Hazard Category 2 and 3 Nuclear Facilities*, AB-011, states, "Submit new/revised TSR implementing documents (e.g., the aforementioned SRPs, ACPs, OSPs, DAPs) or other changes to the USQ process."

The *[site/contractor's DOE-approved USQ procedure]* states that the Facility Manager, "Maintains a list of facility procedures or procedure types subject to the USQ process. This list of facility procedures or procedure types shall be concurred with by the Safety Basis Division Leader, or designee."

The [site] USQ SME, Safety Basis Division Institutional Reviewer, and Safety Basis Deputy Division Leader conducted the review. Individuals and management in the relevant organizations also supported the review.

II. Monitoring Plan

Examine a specific issue of the USQ process, Entry of Documents into USQ Process (TSR Implementing Procedures), in accordance with the *[site/contractor's DOE-approved USQ procedure]* and the document categories approved by DOE (Ref. 5).

1. Do the facility-specific procedures for administration of the USQ process for each facility meet the requirements of the *[site/contractor's DOE-approved USQ procedure]* in relation to the list of documents/procedures subject to the USQ process for each facility?
2. Are the cited documents/procedures on the TSR implementation checklists/matrices submitted to the USQ process in accordance with the *[site/contractor's DOE-approved USQ procedure]*?
3. Conduct interviews relevant to the above questions.

EFCOG Best Practice #148

Report on Entry into USQ Process of Documents (External Procedures)

I. Introduction

The purpose of this quarterly review was to examine a specific issue of the USQ process, Entry into USQ Process of Documents (External Procedures), in accordance with the *[site/contractor's DOE-approved USQ procedure]*. This review also considers implications of the document categories approved by DOE which were included in the submitted revision of the *[site/contractor's DOE-approved USQ procedure]*. External procedures include Health Physics, SBMS, Contractor Assurance, ES&H Manual Documents, and Emergency Response. This is an area that has been previously assessed by DOE (e.g., Ref. 3, 4, 5) and continues to be monitored (Ref. 6). For smaller facilities, such procedures comprise a significant percentage of the USQDs for CY2010.

The [site] USQ SME conducted the review. Individuals and management in the relevant organizations also supported the review.

II. Monitoring Plan

Examine a specific issue of the USQ process, Entry into USQ Process of Documents (External Procedures), in accordance with the *[site/contractor's DOE-approved USQ procedure]* and the document categories approved by DOE (Ref. 2 and 5).

1. Are external procedures submitted to the USQ process?
 - a. Health Physics procedures
 - b. Select Institutional procedures (ES&H Manual Documents and SBMS documents)
 - c. Emergency response procedures
 - d. MOA with Transportation
2. Conduct interviews relevant to the above questions.

EFCOG Best Practice #148

USQ Process Required Annual Verifications of Documents

I. Introduction

The purpose of this quarterly review was to document the results of the periodic surveillances to verify that procedures are appropriately submitted to the USQ process, as specified in the *[site/contractor's DOE-approved USQ procedure]*, and the annual verifications specified in AB-0## *[Facility Procedures]* and PRO-0### *[Institutional Procedures]*. This area has been previously assessed by DOE (e.g., Ref's. 6, 8, 9, 10, and 13), including a DOE-approved Corrective Action Plan (Ref. 3) and continues to be monitored by *[DOE Site Office]* and DOE-HQ (e.g., Ref's. 7, 12).

The *[site]* USQ SME, Safety Basis Division Institutional Reviewer, and Safety Basis Deputy Division Leader conducted the review.

II. Monitoring Plan

The following 3 review steps were performed:

1. AB-0## *[Facility Procedures]* Annual Verification

- a. Checked if the facilities have a list of procedures/procedure types and whether the *[site]* USQ SME and *[institutional]* Safety Basis Division Leader had concurred (Ref. 1, 2).
- b. Checked if the FM appointed a USQ point-of-contact for their facility (Ref. 2).
- c. Checked if the List of Document Categories (Ref. 3, see also Section IV Requirement Highlights) required updating (Ref. 2) by sampling documents to verify if the criteria in the List of Document Categories were followed. Examined each grouping of Document Categories (*Within the USQ process, Partially within the USQ process, and Outside the USQ process*) as follows:
 - i. *Within the USQ process* (Document Categories 1 - 4)
 - ii. *Partially within the USQ process* (Document Categories 5 - 8)
 - iii. *Outside the USQ process* (Document Categories 9 - 19)
- d. Interviewed the *[institutional]* Safety Basis Division Leader for his verification that the criteria did not require updating.

2. PRO-0### *[Institutional Procedures]* Annual Verification

- a. Checked if the FM appointed a USQ point-of-contact for their facility (Ref. 2).
- b. Checked the application of the SME Document Decision Metric in the List of Document Categories by sampling "select institutional documents" to verify if the criteria were followed.

3. *[site/contractor's DOE-approved USQ procedure]* Periodic Surveillance

- a. Based on the results of Steps 1 & 2, in conjunction with the previous review (Ref. 6), this surveillance determined that procedures were appropriately submitted to the USQ process.

EFCOG Best Practice #148

Training/qualification reviews

Quarterly Issue Specific USQ Process Monitoring:

Report on USQ Training Documentation

I. Introduction

The purpose of this quarterly review was to examine a specific issue of the USQ process, USQ training documentation. This is a review of the training records for the list of qualified USQ personnel⁶ in accordance with *[site/contractor's DOE-approved USQ procedure]* highlights are contained in Attachment A *[copy & paste from USQ procedure]*. This review includes all USQ training, including institutional and facility-specific USQ training. Previously, IVRs and periodic informal reviews⁷ by the *[site]* USQ SME noted that TRAIN records were not always updated in a timely fashion for facility-specific USQ training records. The *[site]* USQ SME previously conducted an extent of condition review and provided the results to the *[facility]* AB Manager. Note: The scope of this review does not include the ongoing efforts related to the systematic approach for training and the Safety Analyst Training Plan. As part of the review, the reviewers identified and corrected potential issues.

The *[site]* USQ SME conducted the review. Individuals and management in the relevant organizations also supported the review.

II. Monitoring Plan

1. Do all qualified USQ personnel meet the requirements of *[site/contractor's DOE-approved USQ procedure]*?
 - a. Does each facility have a list of qualified USQ personnel meeting the training requirements of *[site/contractor's DOE-approved USQ procedure]*?
 - b. Have all qualified USQ personnel completed the training requirements of *[site/contractor's DOE-approved USQ procedure]*?
 - i. Have all qualified USQ personnel completed the initial institutional training requirements of *[site/contractor's DOE-approved USQ procedure]*?
 - ii. Have all qualified USQ personnel completed the refresher institutional training requirements of *[site/contractor's DOE-approved USQ procedure]*?
 - iii. Have all qualified USQ personnel completed the initial facility-specific training requirements of *[site/contractor's DOE-approved USQ procedure]* for the facilities in which they are qualified?

⁶ The scope of this review covers USQ qualified personnel as designated by their facility management; it does not include whether personnel should be USQ qualified due to other reasons in their job description.

⁷ The issues found in the previous informal reviews were found to be corrected. Those reviews and the subsequent confirmation that those issues had been corrected were communicated to the *[facility]* AB Manager.

EFCOG Best Practice #148

- iv. Have all qualified USQ personnel completed the refresher facility-specific training requirements of *[site/contractor's DOE-approved USQ procedure]* for the facilities in which they are qualified?
 - c. Have all qualified Expert USQD personnel completed the training requirements of *[site/contractor's DOE-approved USQ procedure]*?
 - d. Has the Facility Manager (or Designee) approved the USQ preparers and USQ reviewers for his or her facility, including Expert USQD preparers and reviewers?
 - e. Has the Facility Manager designated these personnel in writing?
 - f. Has the *[institutional]* Safety Basis Division Leader concurred with all qualified Expert USQD personnel and evaluated ongoing performance of the Experts?
 - g. Has the qualification requirements of *[site/contractor's DOE-approved USQ procedure]* been documented for all qualified USQ personnel?
2. Training bureaucracy.
- a. Are TRAIN records being updated in a timely manner for USQ training?
 - b. Does the TRAIN Questionnaire result in the qualified USQ personnel taking the appropriate USQ training?

Monitoring Plan Notes: ⁸

- Training completion dates were compared with respect to DSA approval dates.
 - *[DOE Field Office]* approved the following DSAs on the following dates. Thus those dates were used as the dates to check training records for the respective facilities.
 - *[facility]* on *[date]*
 - *[facility]* on *[date]*
 - *[facility]* on *[date]*
 - *[facility]* on *[date]*
 - *[DOE Field Office]* approved the *[facility]* DSA on *[date]*, but that DSA was not implemented. Thus the prior DSA's approval date was used as the date to check training records.
 - *[DOE Field Office]* approved the *[facility]* on *[date]* and subsequently reapproved it without change. Thus *[original approval date]* was used as the date to check training records.
- TRAIN records were queried for all qualified USQ personnel in all nuclear facilities (see Attachment B). Training reviews are conducted by other organizations (e.g., DOE) so for the purposes of this Quarterly Issue Specific USQ Process Monitoring, reviewing TRAIN records was sufficient.

⁸ The *[site]* Nuclear Facilities/Activities Safety Basis Documents Listing was used as a reference.

EFCOG Best Practice #148

USQ Training Documentation

I. Introduction

The purpose of this quarterly review was to examine a specific issue of the USQ process, USQ training documentation. This is the first time a review has been conducted of this documentation relevant to the USQ process. This review includes a broad review of all USQ training, including institutional and facility-specific USQ training. This review also includes efforts before and after the DOE surveillance on systematic approach for training.

The [site] USQ SME conducted the review. Individuals and management in the relevant organizations also supported the review.

II. Monitoring Plan⁹

1. Does USQ Refresher training documentation meet the DOE CRADs?
 - a. Describe how authorization basis training, specifically, the USQ Refresher, has been developed using the Systematic Approach to Training, as required by DOE O 426.2, *Personnel Selection, Training Qualification, and Certification Requirements for DOE Nuclear Facilities*.
 - i. Analysis (determine training needs)
 - ii. Design (learning objectives derived from analysis of job, etc.)
 - iii. Development (training methods, materials, learning activities, test items, etc.)
 - iv. Conduct of Training (schedule, conduct, evaluate trainees, instructor, training)
 - v. Evaluation (self-assess, evaluate exams, courses, feedback for improvement)
2. Examine the USQ initial training (HS8042-06) documentation.
3. Examine the facility-specific USQ training documentation, both initial (HS8040-*facility*) and refresher (HS8044-*facility*) training.
4. Are the USQ training courses current or legacy requiring archival?
5. Are USQ course development documents current?
6. Are the latest versions of USQ training documents in the training files?
7. Is the list of instructors for USQ training current and correct?
8. Is the documentation of instructors for USQ training current and correct?
9. Are the TRAIN questionnaire questions current or do they contain legacy USQ courses?
10. Interface with facility/program staff to determine if facility-specific USQ training documentation needs are met, and if any opportunities for improvement exist.
11. Interface with facility/program staff on other training topics relevant to the USQ process to determine if any opportunities for improvement exist.
12. Determine status of DOE O 426.2 as it relates to the USQ process.
13. Review due dates for USQ Refresher Training and determine optimal path forward.

⁹ Other review considerations from the with [site/contractor's DOE-approved USQ procedure] and DOE-STD-1070 are listed in Attachment A.

EFCOG Best Practice #148

PISA process implementation

Quarterly Issue Specific USQ Process Monitoring: Report on Compliance/Quality of Documentation for PISAs

I. Introduction

The purpose of this quarterly review was to examine a specific issue of the USQ process, Compliance/Quality of Documentation for PISAs, in accordance with the *[site/contractor's DOE-approved USQ procedure]*. This issue has been previously assessed by *[contractor]* and DOE (e.g., Ref. 2 - 5), and continues to be monitored, as recently discussed in the DOE RCR Comments on the revised *[site/contractor's DOE-approved USQ procedure]*. Key requirements are highlighted in the Attachment. The *[site/contractor's DOE-approved USQ procedure]* states,

“The PISA process must be entered when a contractor identifies or is informed of a situation that indicates the safety analysis supporting the DOE -approved safety basis may not be bounding or may be otherwise inadequate.”

The *[site]* USQ SME, Safety Basis Division Institutional Reviewer, and Safety Basis Deputy Division Leader conducted the review.

II. Monitoring Plan

Examine this specific issue of the USQ process. The previous calendar year (*[date]* to *[date]*) shall be used for the nuclear facilities. The following points will be examined:

14. Do the PISA documents meet the requirements of the *[site/contractor's DOE-approved USQ procedure]*?
 - a. PISA USQDs
 - i. Do USQDs properly define the “backwards looking change”?
 - ii. Do USQDs meet the following criteria?
 1. The change under evaluation is fully defined in USQDs.
 2. The technical issues associated with a change are fully evaluated in USQDs.
 3. No new controls are established to support a negative USQD.
 4. An independent technical reviewer can understand and concur with the preparer's conclusion (i.e., other quality issues are not severe).
 5. Changes determined by the review team to require DOE approval are not documented to be negative USQDs.
 - b. Does the Evaluation of the Safety of the Situation (ESS) satisfy the criteria in Appendix G.1 of the *[site/contractor's DOE-approved USQ procedure]*?

EFCOG Best Practice #148

- c. If any Operability Determinations or JCOs were prepared during the time period, do they meet the requirements of the *[site/contractor's DOE-approved USQ procedure]* and AB-0## for JCOs as applicable?
2. Were the PISA Actions conducted in a timely fashion?
 - a. Were PISA declarations and DOE notifications completed in a timely fashion meeting the requirements of the *[site/contractor's DOE-approved USQ procedure]*?
 - b. Were USQDs completed for PISAs and DOE informed of the results in a timely fashion meeting the requirements of the *[site/contractor's DOE-approved USQ procedure]*? Were the associated metrics met? The PEP metrics for timeliness of the PISA process are twofold:
 - 1st Metric - Declaration of a PISA
“Untimely for notification of PISAs is interpreted as > 7 days from the time a Facility Manager becomes aware of the issue.”
 - Note on Dates:
 - PISA Categorized Date is the date the Facility Manager determines that there is a PISA. This is the date given in the ORPS report for categorization of the PISA.
 - DOE Notification Date is the earliest documented date for notification, noted as either by email or given in the ORPS report.
 - 2nd Metric - USQD Completion and Notification
“Untimely completion of USQDs and associated notification is > 21 days after a PISA is declared.”
 - Note on Dates:
 - This is interpreted to be the number of days after the PISA is categorized as a PISA.
 - DOE Notification of USQD Results is the date of the email notifying DOE of the USQD results.
 - ESS Date is the date of DOE Received Date Stamp.

EFCOG Best Practice #148

Assessment of PISAs in Hazard Category 3 Nuclear Facilities

This assessment reviewed PISA USQDs from the Hazard Category 3 nuclear facilities for the time period after the external review (Ref. 2). The USQDs reviewed were:...

Furthermore, ongoing detailed discussions were conducted with program and facility staff during the rebaselining of the *[site/contractor's DOE-approved USQ procedure]*, rebaselining of the USQ training, and the revision of the PISA USQDs.

Acceptance Criteria.

1. Were these issues appropriately processed through the PISA process according to the *[site/contractor's DOE-approved USQ procedure]*?
2. Would increased training have merit in addressing observed problems with the PISA process?

Lines of inquiry. The assessment team addressed the two criteria by lines of inquiry regarding adequate resources and training. Based on responses received, the assessment team was able to come to conclusion for both acceptance criteria. The lines of inquiry used to help evaluate the acceptance criteria included:

1. When issues were identified, did the facilities appropriately recognize that these issues needed to be processed through the PISA process?
2. Are adequate authorization basis resources available to disposition competing DSA, USQ, and PISA issues?
3. Does facility staff interpret directives differently from DOE with respect to PISA process implementation when design, analysis, or functional weaknesses are identified?
4. Is there merit in increased contractor attendance at DOE authorization basis courses?

EFCOG Best Practice #148

Effectiveness Reviews

USQ CAP Effectiveness Review Plan

I. Objective/Purpose

The purpose of this Effectiveness Review is to conduct an effectiveness review in accordance with PRO-0077 (Ref. 1) which states,

The effectiveness review process determines whether corrective actions taken have resulted in the reduced frequency or magnitude of an identified issue to acceptable levels. The validation that an issue is effectively resolved does not always require the absolute elimination of an issue or of similar negative outcomes. A corrective action is effective if it has achieved what was intended.

This review uses the terms defined in PRO-0077 (Ref. 1) and PRO-0042 (Ref. 2).

Corrective Action: Action taken or measure implemented to rectify an issue. Action taken to address a root cause will prevent recurrence or reduce the probability of an issue recurrence. For international consensus standards (ISO 14001 and OHSAS 18001), corrective action equates to the resolution of actual nonconformities, or deficiencies as they are called within the issue management system.

Effectiveness: Effectiveness is a significant improvement indicated by one or more of the following:

- Elimination of the original issue
- Desired reduction in the frequency of the symptoms or issue recurring
- Desired reduction in the number of symptoms or magnitude of the issue
- Desired decrease in probability of the original event recurring

Effectiveness Review: An evaluation to determine whether an issue has been resolved. (PRO-0042)
An evaluation to determine whether the corrective actions taken have resolved the issue. (PRO-0077)

Effective: Corrective actions have resolved and are expected to prevent recurrence of the issue or are have resulted in significant improvement based on the criteria defined in the effectiveness review plan. No new corrective actions are recommended.

Ineffective: Corrective actions have not resolved and/or will not effectively prevent recurrence of the issue.

Partially effective: Corrective actions have partially resolved the issue and/or may not prevent recurrence. Additional or revised corrective actions are recommended to resolve and effectively prevent recurrence of the finding.

EFCOG Best Practice #148

Indeterminate: The reviewer cannot conclusively determine the effectiveness because there has not been adequate opportunity for the actions to be implemented or for their implementation to be challenged, or the issue and its causes could not be adequately recreated in a controlled situation for performance testing. Another effectiveness review will need to be performed at the appropriate time.

Prerequisites for conducting an Effectiveness Review per PRO-0077 are:

- All issues to be reviewed for effectiveness were analyzed for root causes and the corrective actions to correct the issue addressed the root causes.
- All corrective actions that address the issue must be completed, verified, and, if a new process is involved, the process must be implemented prior to conducting the effectiveness review.

Key requirements of the USQ process are summarized in Attachment 1.

II. Background

[site/contractor] performed an internal self-assessment (Ref. 3) of implementation of the USQ process in accordance with *[site/contractor's DOE-approved USQ procedure]*. A number of findings were identified which resulted in a Corrective Action Plan submitted to DOE. Discussion continued (e.g., Ref. 5, 6, 7, 8, 9). DOE approved Document Categories and the process for the applying Document Categories. DOE and DOE-HSS completed a review of the *[site/contractor's]* USQ process (Ref. 10). "The overall conclusion was that implementation of the USQ process was adequate. The current procedure was determined to be compliant with the DOE Rule and Guide." A relevant Weakness stated, "Formal procedures and processes for developing, maintaining, and updating the lists of documents subject to the USQ process have not been developed and approved by DOE."

Final resolution occurred in the DOE approval of the revised *[site/contractor's DOE-approved USQ procedure]* and AB-018 (Ref. 11). Training was revised and conducted accordingly:

- HS8042-06R for currently qualified USQ staff.
- HS8042-06 for new facility management.
- *[site/contractor]* received positive feedback from DOE on the quality and content of the revised training.

III. Issues

Issue A Title: FSCM.1-1: Facility-specific USQ Procedures Contain Instructions in Conflict with the Provisions of *[site/contractor's DOE-approved USQ procedure]*.

Issue symptoms: Facility-specific USQ Procedures inconsistent with *[site/contractor's DOE-approved USQ procedure]*.

Root Causes: As stated in ITS, [fill in]

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Extent of the issue/cause: See ITS.

Corrective actions to address root cause:

- Update Facility-specific USQ Procedures
- Obtain Concurrence from Safety Basis Division Leader and [site] USQ SME on List of Procedure Types

Issue B Title: UEC.2-2 Written Instructions Not on the Approved List Are Procedures Subject to the USQ Process

ITS B

For [facility], the Review Team identified procedures that were not submitted to the USQ process. Appendix D identifies sixty-five procedures that are not currently recognized as subject to the USQ process. The rationale stated for not subjecting these procedures to the USQ process is typically that the governing OSP/IWS identifies the bounding safety controls relevant to the DSA. Not all of these sixty-five procedures have a governing OSP identified.

Summary: [site/contractor] has not demonstrated the capability to verify that all procedures subject to the USQ process are identified. A number of procedures at [facility] are not entered into the USQ process.

Issue symptoms: Programmatic procedures (such as POPs, PSPs, ES&H Support (e.g., HP-FO's)) in [facility] not submitted to the USQ process.

Root Causes: Same as for Issue A.

Extent of the issue/cause: See ITS.

Corrective actions to address root cause:

Proposed Action:

Clarify institutional USQ policy as it specifically applies to programmatic and other procedures identified in the USQ Assessment to ensure that changes to all procedures covered by 10 CFR 830.203 enter the USQ process. A specific determination as to which procedures/procedure types require USQ coverage must be made.

Corrective Actions:

- Identify Documents Requiring USQ Review
- Baseline Identified Procedures Subject to the USQ Process
- Revise list of procedures subject to the USQ process
- Obtain Concurrence from Safety Basis Division Leader on List of Procedure Types

EFCOG Best Practice #148

IV. Review Team

The [site] USQ SME (Assessment Team Leader), Safety Basis Division Institutional Reviewer, and Safety Basis Deputy Division Leader will conduct the review. The Review Team has the skills, knowledge, and abilities (SKAs) necessary to evaluate compliance to the specified requirements. They are technically competent/trained to perform the assessment (they are familiar with the operation). The Review Team Leader (USQ SME) developed the USQ training (HS8042-06 and HS8042-06R). The team members are independent of the corrective actions. They have previously conducted effectiveness reviews.

V. Acceptance Criteria

The following criteria were selected.

1. **Issue A.** Facility-specific USQ Procedures consistent with *[site/contractor's DOE-approved USQ procedure]*.
 - a. If consistent, then EFFECTIVE.
2. **Issue B.** Programmatic procedures in [facility] are submitted to the USQ process.
 - a. If 95% of programmatic procedures in [facility] submitted to the USQ process, then EFFECTIVE.

VI. Method for evaluation

This is an Effectiveness Review conducted per *PRO-0077* and is approved by the Nuclear Operations Functional Area Manager. The methodology is a combination of document review (procedures, USQ logs demonstrating those procedures had been submitted to the USQ process, and past assessments of the USQ process) and interviews as necessary. Interviews may include running verbal test/mock cases through the process as discussed in *PRO-0077*. Document review may include review of equivalent documented evaluation(s) of the original issue, as discussed in *PRO-0077*.

Lines of inquiry:

1. Have the corrective actions resolved **Issue A**?
 - a. In *[facility-specific USQ procedure]*, is the list of documents/procedure types subject to the USQ process for each facility consistent with *[site/contractor's DOE-approved USQ procedure]*?
 - b. Has the SBDL concurred with *[facility-specific USQ procedure]* per *[site/contractor's DOE-approved USQ procedure]*?
 - c. Has *[facility-specific USQ procedure]* been updated to reflect the Document Categories approved by DOE?
2. Have the corrective actions resolved **Issue B**?
 - a. Are programmatic procedures (e.g., POPs, HP-FO's from the Radcon FAM's list of Health Physics procedures) being submitted to the USQ process?

EFCOG Best Practice #148

- b. Does a process for identifying and submitting procedures to the USQ process exist?
 - i. Does [*facility-specific USQ procedure*] contain a list of document/procedure types consistent with [*site/contractor's DOE-approved USQ procedure*]?
 - ii. Has the relevant procedure for submittal of programmatic procedures to the USQ process (AB-018) been implemented per the process approved by DOE?
 - iii. Have USQ Facility Points of Contact been designated for each facility per AB-018?
 - iv. Has the SBD Leader verified that the Document Categories criteria do not require updating? [Note: Related to both Issues A and B]
- c. Have new programmatic procedures been submitted to the USQ process appropriately?
3. Conduct interviews relevant to the above questions. Interviews may include running verbal test/mock cases through the process as discussed in PRO-0077. **Issue B**
4. Conduct document review of relevant equivalent documented evaluation(s) of the original issue, as discussed in PRO-0077. **Issue B**

EFCOG Best Practice #148

Field Change Effectiveness Review Report

I. Introduction

The DOE Monthly Assessment Report (MAR) raised concerns about field changes at nuclear facilities (Ref. 1). *[site/contractor]* submitted a CAP and a revised CAP to address these concerns (Ref. 2 and 3) which was approved by DOE (Ref. 4). The revised CAP states, "Conduct effectiveness review 6 months after completion of the above actions."

The purpose of this effectiveness review is to determine if the corrective actions were correctly implemented and the condition may be deemed resolved. The USQ Review Committee, composed of the *[site/contractor]* USQ SME, Institutional Reviewer, and the Safety Basis Deputy Division, conducted the effectiveness review.

II. Background – Prior Corrective Actions

1. Suspend field change allowance in conflict with *[site/contractor's DOE-approved USQ procedure]*.
2. Red-line procedures to remove field change allowance.
3. Initiate changes to procedures to preclude field change allowance.
4. Per commitment in Causal Analysis letter dated 10/31/08 (Ref. 5), modify Roles, Responsibilities, Accountabilities and Authorities (R2A2s) to ensure that Functional Area Managers have clearly delineated responsibilities and authorities to identify and communicate any compensatory measures necessary to maintain compliance with DOE requirements.
5. Determine which procedures require revision to incorporate the revised R2A2s cited in Action #4.
6. Revise procedures as determined in Action #5.
7. Determine and implement, in consultation with other organizations, a mechanism to insure institutional compliance organizations are represented in MAR dispositions.
8. Determine if sub-tier USQ procedures (facility-specific USQ procedures) are appropriate.
9. Interface with DOE to determine if a more properly defined field change allowance can be consistent with DOE guidance and direction. Modify the *[site/contractor's DOE-approved USQ procedure]* and sub-tier documents as appropriate.

A. Selection of the method/extent of the review

The method is observation of assessment of the relevant implementing documents and interviews of managers on their understanding and involvement with the implemented corrective actions. Procedural compliance with implementing documents is a Conduct of Operations (CONOPs) issue outside of the scope of this review.

B. Review Criteria

Review criteria were developed as a consensus of the USQ Review Committee and the Safety Basis Division Leader, based on input from the CAP.

EFCOG Best Practice #148

1. Implementing Documents

- a. Documentation of [facility and program] management direction
 - i. If documentation of management direction suspending the field change allowance exists, then PASS.
- b. [facility and program] Procedures
 - i. If the Conduct of Operations Manual and the administrative procedure for the USQ process were revised to suspend the field change allowance, then PASS.
- c. R2A2s
 - i. If *[site/contractor's DOE-approved USQ procedure]* was revised to reflect the R2As, then PASS.

EFCOG Best Practice #148

Pre-Existing Condition (PEC) Corrective Action #7, USQ Effectiveness Review for [facility]

I. Introduction

The [facility] USQ Pre-Existing Condition (PEC) Corrective Action (CA) #7 states, “Perform USQ Effectiveness Review for [facility].” As discussed in the 2007 Effectiveness Review Report (Ref. 4), the pre-existing condition was as follows:

- [facility] implementation of USQ process was found “*Ineffective*”
- “Systemic issues call into question [facility] understanding of the [site/contractor’s DOE-approved USQ procedure], and present an unacceptably high potential for recurrence of previously identified problems with the USQ process.”

A PEC Corrective Action Closure was developed to address this issue and was submitted to DOE. The purpose of this effectiveness review is to determine if the PEC corrective actions were correctly implemented and the pre-existing condition may be deemed resolved. The USQ Review Committee, composed of the [site] USQ SME and the Safety Basis Deputy Division Leader, will conduct the effectiveness review. The USQ Review Committee has been selected as both knowledgeable of the work scope and independent of the implementation of the corrective action to conduct the effectiveness review. They will assess implementation of the USQ process at [facility] relevant to the PEC Corrective Actions, including a sample of relevant USQ documents from January to July, following ES&H Manual Document 4.7, *ES&H Analysis Methods*.

II. Background – Prior PEC Corrective Actions

1. Cancel [bad stuff]
2. Establish an Approved Equivalent Parts (AEP) process at [facility].
3. Submit to DOE an EITS list for nuclear facilities for DOE approval.
4. Based on the recent reorganization, evaluate the [facility] work control process for appropriate execution of the USQ process.
5. Provide additional Institutional level USQ training and assistance, to include monthly feedback detailing review of [facility] USQ documents (closure upon successful completion of CA #7).
6. Perform Technical Assist at [facility] and provide a results briefing to the Associate Director of Nuclear Operations.

A. Selection of the method/extent of the review

The method is observation of assessment of end products, using the results of the USQ Review Committee reviews of USQ documents, as well as interviews as appropriate.

EFCOG Best Practice #148

B. Review Criteria

Review criteria were developed as a consensus of the USQ Review Committee and the Safety Basis Division Leader, based on input from the original USQ Effectiveness Review.

1. Entry Conditions for USQ Process

- a. List of procedures subject to the USQ process for each nuclear facility
 - ii. If list of documents subject to the USQ process was updated within the past year per [procedure] and concurred with by SBD Division Leader, then PASS.
 - iii. If 90% of the procedures listed in the list of documents subject to the USQ process sampled were submitted to the USQ process, then PASS.
- b. Preventative Maintenance (PM) Task Codes
 - i. If 90% of the [facility's] Preventative Maintenance (PM) Task Codes sampled were submitted to the USQ process, then PASS.
- c. Work Permits
 - ii. If the [facility] Work Permit form correctly reflects the *[site/contractor's DOE-approved USQ procedure]* current requirements, then PASS.
 - iii. If 90% of work permits are on the new form, then PASS.
 - iv. If 90% of the Work Permits reflect *[site/contractor's DOE-approved USQ procedure]* current requirements for entry to the USQ process, then PASS.¹⁰
 - v. If [facility] can explain how changes now enter the USQ process, then PASS.

2. Categorical Exclusion

- a. Verify if the [bad stuff] are cancelled
 - i. If cancelled, then PASS.
- b. Verify if [facility] established an AEP process.
 - i. If [facility] has an AEP procedure, then PASS.
 - ii. If [facility] has properly prepared AEP determinations, then PASS.
- c. Verify if [facility] has a DOE approved EITS list.
 - i. If [facility] has an DOE approved EITS list, then PASS.
- d. Verify Categorical Exclusion used appropriately.
 - i. If 90% of changes CatX'd did not require a Screen or USQD, then PASS.¹¹

3. USQ Screening

- b. Sample USQ Screenings
 - iii. If 90% changes Screened did not require a USQD, then PASS.

4. USQD

- b. Sample USQDs

¹⁰ For issues corrected as part of PEC Corrective Action (CA) #5, sample starting with the date reflecting implementation of the PEC CA #5 institutional level USQ training (April 4).

¹¹ For issues corrected as part of PEC Corrective Action (CA) #5, sample starting with the date reflecting implementation of the PEC CA #5 institutional level USQ training (April 4).

EFCOG Best Practice #148

- iv. If no changes requiring DOE approval were determined to be negative USQDs, then PASS.
- v. If 90% of the USQDs did not have serious quality issues such that an independent technical reviewer could not draw the same conclusion per DOE G 424.1-1, then PASS.

5. Training

- b. Verify that the appropriate staff (approved USQ preparers, reviewers, and approvers) have completed the revised USQ training (HS8042-06) and PEC CA #5 institutional level USQ training.
 - ii. If all approved USQ preparers, reviewers, and approvers have completed HS8042-06, then PASS.
 - iii. If 90% of approved USQ preparers, reviewers, and approvers have completed PEC CA #5, then PASS.

EFCOG Best Practice #148

Rebaselined USQ Procedure Effectiveness Review Report

The *[site/contractor's DOE-approved USQ procedure]* was revised to be more aligned with the DOE standard USQ process based on DOE G 424.1-1B Admin Change 1 and DOE-accepted USQ training. The revision completed the commitments made in References 1 and 2. The rebaselined USQ procedure was approved by DOE, and was implemented on *[date]*. The purpose of this effectiveness review is to determine if the corrective actions were correctly implemented during the first 6 months after the implementation date. This effectiveness review satisfies the requirements of ES&H Manual Document 4.7. The plan is structured following the ES&H Manual Document's Section 6.7 outline for Effectiveness Reviews.

The action specified in the commitments (ITS) was, "Based on the corrective actions developed for the root cause assessment, assess the effectiveness of the corrective actions to improve the implementation of the USQ process."

The Root Causes assigned were *[Ref. 3]*:

- DOE USQ expectations results from a decentralized management structure that allows different interpretations, and,
- *[site/contractor]* historically developed a philosophy that supported an "expert based system" rather than a strict regulatory compliance model.

The Corrective Action per the Root Cause Assessment *[Ref. 3]* was to "revise the USQ process to more closely match the DOE implementation guide (DOE G 424.1-1B Admin Change 1) and DOE training." The following assessment criteria for that action were assigned:

1. Verify that the rebaselined USQ Procedure is consistent with DOE G 424.1-1B Admin Change 1 and DOE-approved training.
 - b. If the USQ Procedure was approved by DOE, then EFFECTIVE.
2. Sample USQ Screenings completed in the first 6 months after implementation of the rebaselined USQ Procedure.
 - a. If 90% of the USQ Screenings sampled reflect current requirements, then EFFECTIVE.
3. Sample USQDs completed in the first 6 months after implementation of the rebaselined USQ Procedure.
 - a. If 90% of the USQDs sampled reflect current requirements, then EFFECTIVE.
4. Verify that no first level screenings were performed during the review period.
 - a. If no first level screenings were performed during the review period, then EFFECTIVE.
5. Verify that the appropriate staff (approved USQ preparers, reviewers, and approvers) have completed the revised USQ training, HS8042-06.
 - a. If all approved USQ preparers, reviewers, and approvers have completed HS8042-06, then EFFECTIVE.

The Effectiveness Review evaluated the rebaselined USQ Procedure and its implementation. Each area is assessed in terms of review acceptance criteria, review data, and review conclusions. Any additional issues are noted at the end of this report. The effectiveness of each of the five main topical areas, and sub-topics, is rated as EFFECTIVE/INEFFECTIVE, with sub-tier individual program reviews rated as MET/DEFICIENT.

EFCOG Best Practice #148

See above for Effectiveness Review on Expert USQD

EFCOG Best Practice #148

USQ CAP Effectiveness Review Report

The *[site/contractor's DOE-approved USQ procedure]* was revised to address finding 23 of the OA-40 CAP that was approved by DOE. The revised USQ Procedure was also approved by DOE. The purpose of this effectiveness report is to document whether the OA-40 CAP actions were effective in correcting the deficiency identified including implementation during the first quarter (3 months) after the implementation date. In the OA-40 CAP, an action specified was to “Perform an effectiveness review of the USQ process corrective actions related to the USQ procedure changes and issue a report on the results.” That review was broken into five main topical areas, with additional sub-topics and background detail. The resulting effectiveness report satisfies the requirements of ES&H Manual Document 4.7, including its outline for Effectiveness Reviews. ES&H Manual Document 4.7 recommends that at least six months be allowed between the date that the corrective action was completed and the effectiveness reviews. This effectiveness review was done after only three months implementation, as required by the OA-40 CAP, thus having less data upon which to measure effectiveness. In a few cases, there were insufficient actions to measure.

In the OA-40 CA, action 23.5, *[site/contractor]* specified it would “Perform an effectiveness review of the USQ process corrective actions related to the USQ procedure changes and issue a report on the results.” This Effectiveness Review addresses that issue by assessing five relevant topical areas included the revision to *[site/contractor's DOE-approved USQ procedure]* to address (1) “reduction in margin”, (2) “implicit change”, (3) screening criteria, (4) review of technical procedures, and (5) location of operations issues to assure compliance with 10CFR830.” These topics address the OA-40 report’s Finding 23.

The Effectiveness Review Report includes both validation that the changes were made in the USQ Procedure per the OA-40 CAP and a review of the effectiveness of implementation. Each area is assessed in terms of review acceptance criteria, review data, and review conclusions. Additional actions taken are noted at the end of this report. The effectiveness of each of the five main topical areas, and sub-topics, is rated as EFFECTIVE/INEFFECTIVE, with sub-tier individual program reviews rated as MET/DEFICIENT.

2.1 Topical Area 1 – Reduction in Margin

The OA-40 report states, “**Section 6.5 includes an inappropriate criterion for performing USQ determinations.** Section 6.5 lists the seven criteria questions required by 10 CFR 830 in a USQD. According to the rule, the last criterion is “Could the proposed change reduce a margin of safety?” The procedure inappropriately restates this as, “Could the proposed change reduce *the* margin of safety *as described in the facility's/activity's safety basis?*” [emphasis added to words different from the rule]. As worded in the site procedure, the question inappropriately limits the scope of the evaluation. This discrepancy is also reflected in the procedure’s definition of “margin of safety” and in Section E.3, Question G.”

EFCOG Best Practice #148

2.1.1 Margin of Safety Validation

Review USQ Procedure's Section 6.5, definition of "margin of safety" and Section E.3, Question G to determine if requirements are satisfied. If the USQ Procedure correctly states the requirements per the above OA-40 wording, then EFFECTIVE.

EFFECTIVE. The revisions to USQ Procedure's Section 6.5, definition of "margin of safety" and Section E.3, Question G satisfy the CAP requirements. The definition correctly cites the revised Section E.3; thus the CAP requirements are satisfied.

2.1.2 Margin of Safety Implementation – Corrective Action

Sample USQDs completed in the first three months after implementation of the revised USQ Procedure. If 90% of the USQD forms sampled reflect current form requirements, then EFFECTIVE.

2.2 Topical Area 2 – Implicit Change

The OA-40 report states, "The weaknesses in the instructions for evaluating changes that could also result in inappropriate USQ screenings or USQDs include: Sections C.1 and E.1 state that "The screening [determination] process in these instructions focuses on explicit or implicit changes that affect the facility's documented safety analysis..." The use of the term "implicit change" is unclear and could be misleading."

2.2.1 Implicit Change Validation

Review USQ Procedure's Sections C.1 and E.1 to determine if requirements are satisfied. If the USQ Procedure correctly states the requirements per the above OA-40 wording, then EFFECTIVE.

2.2.2 Implicit Change Implementation – Opportunity for Improvement

The effectiveness of implementation was not in the original Effectiveness Review Plan. During the course of the review, management determined it to be an appropriate subject to insure a complete effectiveness review.

2.3 Topical Area 3 – Screening Criteria [First Level Screening]

The OA-40 report states:

Criterion 2a of Appendix B contains an inappropriate condition for screening changes.

Appendix B provides the guidance for *USQ First-Level Screenings* of various types of changes, and includes a criterion (Criterion 2a) that has two conditions for screening physical changes. One of the conditions is inappropriate; it refers to "...physical changes

EFCOG Best Practice #148

that clearly CANNOT result in new/increased hazard(s), new accident scenario(s) or increase probability/consequences of an accident scenario described in the facility safety basis.” This condition is not appropriate for use in screening physical changes because the rule requires such a determination to be made through a USQD, which calls for a higher level of rigor and documentation than required for a screening.

Criterion 2b of Appendix B contains an inappropriate condition for screening changes.

Appendix B, Criterion 2b also contains two criteria for screening out proposed physical changes. The second refers to “Changes that would be considered normal commercial practices if not impacting equipment important to safety (i.e., changing florescent lighting fixtures in an office area).” The use of the word “Changes” in this criterion is not appropriate because, in the context of 10 CFR 830, “changes” are activities that leave the systems, structures, and components in a condition different from the previous condition. The activities addressed here, such as replacing light bulbs, are more appropriately described as routine maintenance activities rather than “changes” according to the rule’s terminology. The incorrect use of the term “change” could lead to misapplication of the rule.

Criterion 3b of Appendix B contains inappropriate conditions for screening changes.

Appendix B, Criterion 3b for procedure changes contains provisions that are not appropriate for screening (e.g., considerations for new/increased hazards and increased probability or consequences). The rule requires that such considerations be made in a USQD; they are not a valid justification for a decision to *not* perform a USQD.

The Effectiveness Review evaluated the revised USQ Procedure’s criterion on screening criteria [first level screening] and its implementation.

2.3.1 Screening Criteria [First Level Screening] Validation

Review USQ Procedure’s Appendix B to determine if requirements are satisfied. If the USQ Procedure correctly states the requirements per the above OA-40 wording, then EFFECTIVE.

2.3.2 Screening Criteria [First Level Screening] Implementation

Determine if any new First Level Screens were conducted during the first three months after implementation of the revised USQ Procedure. If no new First Level Screens were conducted, then EFFECTIVE.

EFCOG Best Practice #148

2.4 Topical Area 4 – Review of Technical Procedures

The OA-40 report states, “Section C.3 provides guidance for answering USQ screening questions. Several questions (Subsection 1 for facility changes, questions 11 through 17, and Subsection II for procedure changes, question 1) contain phrases requiring “determinations” that are tantamount to performing an informal, inadequately documented USQD to justify screening such changes. These phrases could result in an inappropriate screening and could lead [site] not to perform the required formal USQD.”

The Effectiveness Review evaluated the revised USQ Procedure’s criterion on review of technical procedures and its implementation.

2.4.1 Review of Technical Procedures Validation

Review USQ Procedure’s Section C.3 to determine if requirements are satisfied. If the USQ Procedure correctly states the requirements per the above OA-40 wording, then EFFECTIVE.

2.4.2 Review of Technical Procedures Implementation – Opportunity for Improvement

A. Determine if any new Screenings were conducted during the first three months after implementation of the revised USQ Procedure. If no new Screenings were conducted, then EFFECTIVE.

B. Sample technical (operating) procedures completed in the first three months after implementation of the revised USQ Procedure. If 90% of the procedures sampled were submitted to the USQ process, then EFFECTIVE.

B.1 [facility 1]

The AB Section staff initial all USQ documents (e.g. CatXs, USQDs) for [facility 1]. The responsible AB Section staff who reviewed the CatXs verified that they satisfied the requirements and were appropriate.

2.5 Topical Area 5 – Location of Operations Issues

The Effectiveness Review evaluated the revised USQ Procedure’s criterion on location of operations issues and its implementation. The USQ Procedure was effectively revised and effectively implemented, thus the overall topical area is rated as EFFECTIVE.

2.5.1 Location of Operations Issues Validation

The validation of the USQ Procedure revision was not in the Effectiveness Review Plan. Management determined it appropriate to review the USQ Procedure’s discussion of location of operations issues to determine if DOE Guidance is satisfied. If the USQ Procedure correctly reflects the guidance in DOE G 424.1-1, then EFFECTIVE.

2.5.2 Location of Operations Issues Implementation

EFCOG Best Practice #148

Sample Categorical Exclusions completed in the first three months after implementation of the revised USQ Procedure. If 90% of the Categorical Exclusions sampled appropriately considered location differences, then EFFECTIVE.

EFCOG Best Practice #148

Assists (Tech Assists, AIM)

AIM (Assess, Improve, Modernize)

Safety management programs such as the USQ process are to undergo an annual programmatic assessment to verify and monitor the program health. To be effective, the USQ process must be integrated with other safety management programs such as configuration control and work control to ensure that safety basis requirements are not violated by changes to the facility or work associated with implementing such changes. Using corporate subject matter experts to perform this USQ assessment provides the opportunity to self-identify and eliminate weaknesses/failures in the *[site/contractor's]* USQ process. The risk of PAAA enforcement conferences and fines, loss of fees to DOE, and the associated negative publicity may be reduced by completing the assessment.

1.1. Purpose

The purpose of an AIM (Assess, Improve, Modernize) Team is to assist LANS management in assessing and improving critical need areas and deficiencies. AIM Team reviews are performed by representatives from the *[site/contractor's]* parent organizations employed either directly by those organizations or at other DOE sites. The review teams will analyze cross-cutting problems and provide options for solutions to identified issues.

1.2. Scope

The AIM Team assessed work entry into the USQ process at each nuclear facility. The assessment included the interfaces between the USQ process, facility, equipment, and document configuration management, and the work and document change control processes. Other USQ program elements such as training and qualification of the USQ preparers and reviewers, self-assessments, were assessed only to the extent necessary to support the primary objective of the assessment.

A goal of the USQ Process assessment is to identify any weaknesses in the USQ process and identify potential methods to eliminate or minimize these weaknesses. This goal can be accomplished using the corporate USQ expertise gained at other DOE sites. The AIM Team will provide recommendations based on best practices and lessons-learned from the corporate partners and other DOE complex sites to achieve this goal.

1.3 Review Topics:

- Work Package/Change Package
- Equipment/Facility Change Control
- Work Control Process
- Document Change Control
- PISA Process

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Work Package/Change Package

OBJECTIVE: Documentation in the work control/change control package provides the data required to prepare/review a USQ Categorical Exclusion, Screen, or Determination worksheet.

Notes: Given the site's practices, check the relevant procedures and processes for work packages and change packages to see what each includes/has attached.

Criteria

1. The work control/change control package contains the data required by a USQ preparer/reviewer to prepare/review a USQ Categorical Exclusion, Screen, or USQD.
2. Confirm that the work packages/change packages contain sufficient information for USQ preparer to have a cohesive mental picture of the change.
3. There is a mechanism for a USQ preparer or reviewer to return a draft or incomplete work control/change control package to work or change control.

Records:

1. Confirm existence of a mechanism that requires submittal of complete, final work control/change control packages to the USQ process.
2. Confirm existence of a mechanism for a USQ preparer or reviewer to return a draft or incomplete work control/change control package to work or change control.

Interviews:

The following Lines of Inquiry (LOI) will be used to support assessment objectives:

1. Are the work control/change control packages entering the USQ process complete, final packages?
2. What is done with draft or incomplete work control/change control packages submitted to the USQ process? Are the packages returned to work control/change control? Is there a procedure you use for this?
3. If a modification that has been reviewed through the USQ Process requires change in the field, revision, is delayed, or is not completed; does the process require re-evaluation potential hazards that might not have been considered previously in the USQ Process evaluation?
4. Can you think of any examples where this might have been done?

EFCOG Best Practice #148

Equipment/Facility Change Control

OBJECTIVE: The USQ process is integrated into the equipment/facility [configuration] change control process. Personnel responsible for the equipment change control process (including application of the USQ process when appropriate) are familiar with the USQ process for controlling changes to nuclear facilities. USQ process requirements are implemented in procedures and processes for designing, developing, reviewing, approving and implementing changes to equipment. Categorical Exclusions, USQ Screens, and USQDs are completed where appropriate, are retrievable, are traceable to the parent change documentation, and are retained as quality records.

Criteria

1. Configuration Control Procedures includes steps which ensure that facility or programmatic work activities involving interim or temporary equipment configurations resulting from construction, modification, or maintenance activities are submitted to USQ process properly.
2. Interim or temporary configurations involving equipment described (explicitly or implicitly) in the facility safety basis are evaluated and controls specified, as appropriate to ensure that required system performance is not compromised and that such conditions are submitted to USQ process properly.
3. Interim or temporary equipment configurations are submitted to USQ process properly.
4. Categorical Exclusions, USQ Screens, and USQDs, as appropriate, are performed based upon approved procedures and criteria. Consistent with the *[site/contractor's DOE-approved USQ procedure]* completed Categorical Exclusions, USQ Screens and USQDs shall consider all SSCs described (explicitly or implicitly) in the DSA and not limited only to those SSCs specifically credited/described in DSA Chapters 3, 4 and 5.
5. A process exists which ensures that changes to equipment or procedures described (explicitly or implicitly) in the safety basis are evaluated under the USQ process and that the Categorical Exclusions, USQ Screens, and USQDs are performed by appropriately qualified personnel.

Records:

1. Review records of changes to equipment for objective evidence that the change was subjected to review by an appropriately-qualified person to determine if the change must be reviewed through the USQ process.
2. Review the bases for decisions to approve changes to equipment described (explicitly or implicitly) in the facility safety basis that were not reviewed through the USQ process.
3. Review documented assignments of responsibility for personnel to review changes to equipment described (explicitly or implicitly) in the facility safety basis prior to entering the USQ process.
4. Review Categorical Exclusions, USQ Screens and USQDs to verify that the evaluations considered SSCs described (explicitly or implicitly) in the DSA, including Chapters 1 and 2, and are not limited to only those SSCs explicitly credited/described in DSA Chapters 3, 4 and 5.

Interviews:

Interview facility and programmatic personnel involved in the design, preparation, review, approval and implementation of changes to equipment described (explicitly or implicitly) in the facility safety basis to assess their understanding of the USQ and change control processes and procedures as amplified by the [site] Requirements documents. In particular, the integration of the USQ program with the change control program should be explored. Interview personnel to determine their understanding of how interim or temporary equipment configurations resulting from construction, modification, or maintenance activities (as well as post-maintenance testing) are evaluated for potential safety basis impacts. Evaluate their understanding of the Categorical Exclusion process including preparation, approval, and document control.

EFCOG Best Practice #148

Work Control Process

OBJECTIVE: The USQ process is integrated into the facility work control process. Personnel responsible for the work control process are aware of the USQ process. This objective covers work packages for both facility work and programmatic work involving implementation of modifications on structures, systems and components described (explicitly or implicitly) in the documented safety analysis. The Work Control Process and specific work packages that involve implementation of modifications provide evidence that such activities were evaluated through the USQ process as required by *[site/contractor's DOE-approved USQ procedure]*. When new interim configurations or final configurations arise, they are also reviewed through the USQ Process consistent with *[site/contractor's DOE-approved USQ procedure]*.

Criteria

1. Work Control Procedures include steps that ensure that facility or programmatic work activities involving interim or temporary equipment configurations resulting from implementation or modification work activities are submitted to the USQ process properly and do not result in conditions that would violate the TSRs.
2. Interim or temporary configurations involving equipment described (explicitly or implicitly) in the documented safety analysis are submitted to the USQ process properly and, as appropriate, reviewed to ensure that required system performance is not compromised or that conditions are not inadvertently introduced that could violate the TSRs.
3. USQ process has been applied for interim or temporary equipment configurations, which are not covered appropriately by the facility Technical Safety Requirements, as discussed in *[site/contractor's DOE-approved USQ procedure]*.
4. When field changes during installation or modification work activities result in a different interim configuration or in a different final configuration, the WCP ensures that those new configurations are reviewed through the USQ process consistent with *[site/contractor's DOE-approved USQ procedure]*.

Records:

1. Review Work Control Process and documentation to determine whether personnel responsibilities for reviewing changes have been assigned.
2. Review work control process procedures to determine if criteria exist for implementation of the USQ process by responsible individuals.
3. Review Work Packages for evidence that such activities were evaluated through the USQ process.
4. Review Work Package revisions for evidence that such activities were evaluated through the USQ process.
5. Review Work Packages involving interim or temporary equipment configurations for evidence that such activities were evaluated through the USQ process.

Interviews:

The following Lines of Inquiry (LOI) will be used to support assessment objectives:

1. What is your facility's Work Control Process?
2. What is the link to your processes to ensure that change/work is safe prior to submittal to the USQ process? How do you check if work involves more than a standard industrial (SIH) under a safety management program as discussed in DOE G 424.1-1A?
3. How does your facility identify equipment important to safety when performing the USQ process?
4. How do you decide whether the USQ process should be applied to Work Control activities?
5. How are USQ process reviews traceable to design changes in your facility?

EFCOG Best Practice #148

6. How do you apply the USQ process to interim facility configurations that may be required during modification installation?
7. Does the Work Control Process address actions necessary in the event of work interruption?
8. What do you do in the event service outage time is not provided in the TSR?
9. How are Work Package revisions considered/processed for evaluation by the USQ process?
10. How does your facility maintain equipment configuration control when installing modifications, particularly safety significant SSCs?
11. How do you identify equipment/procedures affected by modifications for review by the USQ process?
12. How are maintenance packages submitted to the USQ process?
13. How are approved equivalent part determinations/like-for-like/like-in-kind paperwork prepared and approved? Does the work control process include post-maintenance testing?
14. How is maintenance reviewed for submittal to the USQ process? Is there a minor maintenance process? How is maintenance triaged? Is "expedited maintenance" submitted to the USQ process?

EFCOG Best Practice #148

Document Change Control

OBJECTIVE: The USQ process is integrated into the document change control process. Personnel responsible for the document and procedure change control process are aware of the USQ process. Each facility has a change control process for both temporary and permanent changes to procedures. Document change control records provide evidence that changes to procedures described (explicitly or implicitly) in the documented safety analysis were reviewed through the USQ process.

Criteria

1. Each facility has a change control process for temporary and permanent changes to documents and procedures that are described (explicitly or implicitly) in the documented safety analysis.
2. Personnel responsible for the document and procedure change control are aware of the USQ process.
3. The USQ process is integrated into the document change control process.
4. For work control activities, experiments, safety management program (SMP), maintenance, installations, or modifications, associated procedures were submitted for evaluation by the USQ process.
5. Review processes for other documents to ensure that they are not procedures subject to the USQ process in accordance with DOE G 424.1-1A.

Records:

1. Review procedures for document control to verify that the USQ process is integrated into the document change control process.
2. Review procedure changes identified as a result of work control activities or facility modifications to determine whether they are submitted to the document change control process.
3. Review procedure changes resulting from work control activities or facility modifications to determine whether they are considered for review through the USQ process.
4. Verify that physical modifications potentially affecting Safety Management Programs are reviewed through the USQ process.
5. Determine if there is a DSA/TSR implementing procedure or checklist.

Interviews:

The following Lines of Inquiry (LOI) will be used to support assessment objectives:

1. How does your facility implement the Document Change Control Process?
2. How are document changes subject to the USQ process identified? How do procedure changes get considered for USQ Process review?
3. Does your document control process allow for temporary changes to facility procedures and how are they considered for application of the USQ process?
4. How are potential Safety Management Program impacts as a result of facility modifications identified for review by the USQ process?
5. How are institutional procedures submitted to the USQ process, as appropriate?
6. How are subcontractor/SMP/external organization procedures submitted to the USQ process, as appropriate?

EFCOG Best Practice #148

PISA Process

OBJECTIVE: The PISA process is a key aspect of the USQ process in accordance with 10 CFR 830.203. Personnel responsible for nuclear facilities are aware of the PISA process. This objective covers identification of potential issues, validation of an issue as a PISA and subsequent entry into the PISA process, following the PISA process, and resolution of the PISA process. This objective also covers key points discussed in DOE G 424.1-1A.

NOTE: May alternatively use quote from [site/contractor's DOE-approved USQ procedure] or DOE G 424.1-1B Admin Change 1.

10 CFR 830.203 (g) requires the following actions be taken upon identification of a PISA:

- Place or maintain the facility in a safe condition
- Notify DOE of the situation
- Perform a USQD and notify DOE promptly of the results
- Submit the evaluation of the safety of the situation (ESS) to DOE prior to removing any operational restrictions

PISAs may arise from three entry conditions as discussed in DOE Guide 424.1-1B Admin Change 1,

- a discrepant as-found condition,
- an operational event or incident, or
- new information, including discovery of an error, sometimes from an external source.

The main consideration is that the analysis does not match the current physical configuration, or the analysis is inappropriate or contains errors. The analysis might not match the facility configuration because of a discrepant as-found condition. Analytical errors might involve using incorrect input values, invalid assumptions, improper models, or calculation errors. The USQ process starts when facility management has information that gives reason to believe that there is a potential that the facility DSA might be inadequate.

Upon identification of a PISA, 10 CFR 830.203(g) requires the contractor to place or maintain the facility in a safe condition. The determination of what constitutes a safe condition is the responsibility of the contractor. The contractor should take conservative action to impose operational restrictions to ensure the facility is safe. Operational restrictions may include restrictions on work activities for the affected part of the facility, imposition of additional controls (e.g., fire watches if the adequacy of a fire protection control is in question), or placing the facility into a different TSR mode. In addition, per 10 CFR 830, Subpart B, Appendix A, Section G (3), the contractor must evaluate the operability of impacted safety systems and components and enter any applicable TSR action statements.

Further, the rationale (for the determination that the facility is in a safe condition) should be documented. This should not involve an extensive/detailed analysis as the evaluation of the safety of situation will occur at a later stage of processing the PISA, e.g., after the USQ determination.

EFCOG Best Practice #148

After the potentially inadequate safety analysis has been confirmed, 10 CFR 830.203(g) requires contractors to take four specific actions. One of those actions is to notify DOE of the situation. The current DOE reporting system (DOE O 232.2, Occurrence Reporting and Processing of Operations Information) requires that a potential inadequacy of the documented safety analysis be reported as a Significance Category 3 situation. The Occurrence Reporting and Processing System (ORPS) may be used for this notification if the report explicitly states that the situation involves a “potential USQ involving a potentially inadequate safety analysis.” The ORPS reporting designation used for this notification is Group 3 B (2), “Declaration of a potential inadequacy of the documented safety analysis.” The DOE Facility Representative and/or other DOE management responsible for the facility should be notified immediately. The DOE notification should clearly identify any operational restrictions that were invoked to ensure the facility is in a safe condition. No DOE approval of the operational restrictions is needed; however, DOE should review them and can direct other restrictions be implemented if needed.

Criteria

1. Personnel responsible for nuclear facilities are aware of the PISA process.
2. Processes exist for identification of potential issues, validation of an issue as a PISA and subsequent entry into the PISA process, following the PISA process, and resolution of the PISA process.
3. DOE notifications are completed for PISAs in a timely fashion.
4. USQDs are completed for PISAs in a timely fashion.
5. ESSs are completed for PISAs.

Records:

1. Obtain samples to confirm existence of completing DOE notifications, USQDs, and ESSs and number of days to complete each step.

Interviews:

The following Lines of Inquiry (LOI) will be used to support assessment objectives:

1. Are facility managers, maintenance managers, and other key personnel aware of the PISA process?
2. How are potential issues identified? How are issues validated and the existence of a PISA confirmed? How is the PISA process followed?
3. Are USQDs prepared on proposed changes when the PISA process should instead be followed?
4. Are modifications being conducted on issues that should have been resolved via the PISA process?

EFCOG Best Practice #148

Report on Screening and Expert USQD Process Implementation

I. Introduction

The purpose of this quarterly review was to examine a specific issue of the USQ process, Screening and Expert USQD Process Implementation, in accordance with the *[site/contractor's DOE-approved USQ procedure]*. PEP 8.2.1 Part 2 specifies that, "The monitoring will include evaluation of the use of Screening and/or Expert-based USQ process." Screening has been previously assessed by *[contractor]* and DOE (e.g., Ref. 2 - 5), and continues to be monitored by DOE, as recently discussed in the DOE RCR Comments on the revised *[site/contractor's DOE-approved USQ procedure]*. Key requirements are highlighted in the Attachment. The *[site]* USQ SME, Safety Basis Division Institutional Reviewer, and Safety Basis Deputy Division Leader conducted the review.

II. Monitoring Plan

The following points will be examined:

1. Is USQ Screening being utilized? If so, is it being utilized properly?
 - a. If USQ Screens were conducted, do they meet the requirements of *[site/contractor's DOE-approved USQ procedure]*? Review period is the last 12 months.
 - b. Were any Screens performed where a USQD should have been prepared?
2. Is the Expert USQD process being utilized? If so, is it being utilized properly?
 - a. Have the requirements of *[site/contractor's DOE-approved USQ procedure]* been met?
 - i. Has the Facility Manager (or designee) approved the Expert USQD Preparers and Reviewers for his or her facility?
 - ii. Has the Safety Basis Division Leader (or designee) concurred with the designation of Expert USQD Preparers and Reviewers?
 - iii. Has the Safety Basis Division Leader (or designee) evaluated the performance of the Expert USQD Preparers and Reviewers?
 - iv. Do the Expert USQD Preparers and Reviewers meet the qualification requirements of *[site/contractor's DOE-approved USQ procedure]* Section 5.12?
 - v. If Expert USQDs were conducted, do they meet the requirements of *[site/contractor's DOE-approved USQ procedure]*?
 - vi. Was the official Expert USQD form in *[site/contractor's DOE-approved USQ procedure]* used properly?
 - vii. Are Expert USQDs being tracked in a manner that facilitates their inclusion on the annual list of USQDs submitted to DOE? Note: Section 8.0 states that the Expert USQDs shall be listed on the annual list of USQDs submitted to DOE. That submittal date is outside the scope of this review, thus at this point only the tracking of Expert USQDs can be reviewed. If the Expert USQDs are tracked similar to standard USQDs, that indicates a high probability that this requirement may be satisfied in the future.

EFCOG Best Practice #148

Efficiency Review

Program and Facility Management expressed concerns that some USQDs may be providing far more information on physical changes than is necessary and sufficient under the requirements of *[site/contractor's DOE-approved USQ procedure]*. The USQ Review Committee evaluated 50 USQDs as part of the level of detail assessment. The USQ Review Team identified process inefficiencies as well as quality concerns. Process inefficiencies result from utilization of perceived time saving approaches during preparation of initial USQDs, which resulted in significant downstream process inefficiencies, as subsequent changes to the facility require revisions to USQDs rather than being quickly and efficiently processed by CatX E.1, *Prior USQ Process*. This is due to the scope of the original change being unnecessarily narrow thus making the subsequent change not fully evaluated under the original USQD. The Review Committee identified an additional opportunity to expedite the USQ process for USQDs where extensive changes were described and evaluated instead of simply performing a baseline USQD as allowed by *[site/contractor's DOE-approved USQ procedure]*. For example, USQD # could have been evaluated as a baseline USQD, substantially reducing unnecessary work.

Noteworthy Practice: [facility] prepares crosswalks that demonstrate flow down and consistency with the DSA for key procedures, e.g., safety management programs (ES&H Manual Documents). [facility] prepared a crosswalk during the initial DSA/TSR implementation. Such a practice is an opportunity for improvement for all facilities to consider as part of the DSA/TSR annual update implementation process.

Highlights of Guidance on Documenting Changes for Preparation of USQDs

- ❖ DOE G 424.1-1, Appendix A.2, states: “in performing USQ determination of a proposed change, documented justification for the USQD should be developed. Consistent with the intent of section 830.203, this documentation should be complete in the sense that qualified independent reviewer could draw the same conclusion.”
- ❖ The *[site/contractor's DOE-approved USQ procedure]* states: “The documentation shall include a description of the change being evaluated and of its effects on the Safety Basis. The USQD shall provide sufficient detail to allow an independent reviewer to understand the basis for the preparer's conclusions. The factors considered and assumptions made by the preparer (e.g., experience and engineering knowledge and judgment) shall be clearly stated.”
- ❖ AB-015, Section 5.0, Page 9, “Support statements by providing complete references to supporting documents (e.g., Engineering Safety Notes) or by appending copies of supporting documents to the USQD.”
- ❖ AB-015, Section 5.1, Page 9, “...all details needed to generate a cohesive mental picture of the change should be included in the Introduction. A reviewer should not have to sift through the Main Body of the USQD to arrive at an understanding of the change. It is vital that the USQ preparer provide adequate level of detail on the change itself.”
- ❖ AB-015, Section 5.1, Page 10, “Potentially helpful sources of information for physical changes may include work control process documents, configuration management documents, project descriptions and related safety basis amendments. Memoranda from system engineers, project leaders, and others can serve as useful references to cite.”

EFCOG Best Practice #148

- ❖ AB-015, Section 5.1.1, Page 10, “...ensure detailed technical references are summarized to the degree necessary to understand any implicit assumptions.”
- ❖ AB-015, Section 5.1.1, *Physical Changes*, Item 7, Page 13, “Whenever the physical change involves a significant system where the details are not self-evident, a photo/drawing/sketch is helpful in documenting the spatial facts. Such diagrams may also be attached to the USQD if helpful. This is not formally required, but preparers should always ask whether the written text alone is sufficient to clarify the change. If it is not, picture representations, even those generated at the USQD preparer level, should be provided.”

Review Process

- ❖ Selection Rules for Physical Changes
 - Physical changes related to removal of systems, equipment, or components are not selected for review
 - Activities performed to make physical changes only are not selected for review.

- ❖ Number of USQDs Selected for Review: 50

Review Considerations

- ❖ Are design specifications, drawings, or photos appear to be attached without regard to whether the attachments provide much more information than necessary and sufficient in supporting the USQDs? This may be an effect of requiring less work to add design specifications, drawings, or photos than extracting only pertinent information into sketches. Some of the design specifications in USQDs are much more in detail than those would be described in DSA Ch. 2.
- ❖ Are copies of Seismic Calculations, other types of engineering calculations, or plans attached without regard to attaching a copy of the calculations is necessary and sufficient in supporting USQDs than just referencing them?
- ❖ Are there citations of specific measurable design information such as dimensions, distance, depth, or mass, etc. that may not be of critical from the safety basis perspective?
 - Do they rely upon supporting calculations, references, or reviews/concurrences signed by system engineers without making a clear and explicit safety case from safety basis perspective? For example, is an assessment provided in the USQD about whether placing the transformer on that location has any impact to [facility], such as impact on any underground equipment, etc. (which would not provided in the seismic calculation)?
- ❖ Is there a lack of basic information directly in USQDs? Is the level of detail inadequate to the point where independent review of the USQD cannot not be made to reach the same conclusion? Does it provide references to get more information on physical changes?
 - Is there a description on the distance of the between the [change] and [facility SSC]? Schematics of the areas of changes would facilitate understanding.

EFCOG Best Practice #148

- ❖ Is there a potential appearance of new controls, as some interim/temporary measures are credited without clearly linking to SMPs or enough justification as to why they are not controls? Do USQDs cite interim/temporary compensatory measures to strengthen the argument of the change having no impact on safety basis? For example,
 - *Temporary fire watch* (not tied to Safety Management Program)
 - *Temporary coverage of holes on fire wall with fire retardant cloth*
 - *Restriction on temporary placement of crane for outside work per approved lift plan*
 - *Crane boom will be directed away from SSCs so that unmitigated /mitigated frequency remains*
 - *Erection of temporary tent to contain contamination*
- ❖ Does the USQD make a conclusion in Introduction, Item A of some of USQD revisions by stating “There is no change to the final conclusion of the USQ determination” or “This revision does not change the answers of conclusion of the USQD.”

Side effects of having detailed information in USQDs

- Process inefficiency. Subsequent changes are escalated in USQ workload rather than falling within the scope of the change previously evaluated.
 - Unnecessary information becomes part of safety basis.
 - Accuracy of some of the physical dimensions is not critical in USQD, but would become part of safety basis. Real dimensions may be slightly off from the dimensions cited in the USQD and could be a problem in the future, prohibiting the quick and efficient use of CatX E.1, *Prior USQ Process*.
 - Minor changes on the attached referenced material may need to be reviewed through the USQ process.

NATIONAL SECURITY TECHNOLOGIES ORGANIZATION PROCEDURE			
Title: Review of Completed Unreviewed Safety Question (USQ) Documents		Document Number: OP-NENG.040	
		Revision Number: 4	
Responsible Organization: Nuclear Operations Directorate (NOD)		Effective Date: April 18, 2013	
		Page 1 of 14	
DAR No.: 9671	USQ Exempt: No	USQ Exemption No.: N/A	Quality Affecting: Yes
Revision Control: This organization procedure supersedes OP-NENG.040, "Review of Completed Unreviewed Safety Question (USQ) Documents," Revision 3, effective April 10, 2012.			

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TABLE OF CONTENTS

1.0	Purpose.....	2
2.0	Scope, Applicability, and Implementation	2
2.1	Scope.....	2
2.2	Applicability	2
2.3	Implementation.....	2
3.0	Roles and Responsibilities	2
4.0	Procedure	3
4.1	General	3
4.2	Unreviewed Safety Question Review Preparation	4
4.3	Unreviewed Safety Question Review Checklist Completion	5
4.4	Unreviewed Safety Question Review Completion.....	7
4.5	USQ Mentoring.....	9
4.5.1	USQ Mentoring Sessions	9
4.5.2	USQ Review Results	9
5.0	Definitions	9
6.0	Training	9
7.0	Records Management.....	10
8.0	Forms.....	10
9.0	References.....	10
10.0	Appendices	10

NATIONAL SECURITY TECHNOLOGIES ORGANIZATION PROCEDURE

Document Number: **OP-NENG.040**

Rev. 4

Effective Date: **April 18, 2013**

Document Title: **Review of Completed Unreviewed Safety Question (USQ) Documents**

Page 2 of 14

1.0 PURPOSE

- 1.1 This organization procedure (OP) provides a formal, rigorous, and standardized method for the review of completed Unreviewed Safety Question (USQ) documents in the National Security Technologies, LLC (NSTec)-managed nuclear facilities at the Nevada National Security Site (NNSS). The results of this review will be utilized as follows:

NOTE: An acceptable USQ document is one which contains no mistakes or serious mistakes.

- A. Identify USQ mistakes and serious mistakes.
- B. Identify USQ Opportunities for Improvement (OFIs).
- C. Identify acceptable USQ documents.
- D. Identify areas for additional Safety Analyst mentoring.
- E. Provide data for tracking and trending on the NSTec Dashboard USQ Error metric.

The USQ Error metric will be reviewed to determine areas of weakness requiring additional NSTec management attention and corrective actions.

2.0 SCOPE, APPLICABILITY, AND IMPLEMENTATION

2.1 Scope

NOTE: A nuclear project (e.g., Subcritical Experiment) with its own Documented Safety Analysis is considered a nuclear facility in the context of this procedure.

- 2.1.1 This OP defines the quality review process for completed USQ documents for Hazard Category (HC) -2 and -3 nuclear facilities located within the NNSS.

2.2 Applicability

- 2.2.1 This OP applies to NSTec-managed HC-2 and -3 nuclear facilities located within the NNSS.

2.3 Implementation

- 2.3.1 This document will be fully implemented on the effective date.

3.0 ROLES AND RESPONSIBILITIES

- 3.1 The following organizations or positions are responsible for activities identified in Section 4.0 of this document:

- A. Facility Manager
- B. Nuclear Safety Records Custodian
- C. Safety Basis Program Manager (SBPM)
- D. USQ Coordinator
- E. USQ Functional Area Manager (FAM)
- F. USQ Review Team
- G. USQ Review Team Leader (TL)

NATIONAL SECURITY TECHNOLOGIES ORGANIZATION PROCEDURE

Document Number: **OP-NENG.040**

Rev. **4**

Effective Date: **April 18, 2013**

Document Title: **Review of Completed Unreviewed Safety Question (USQ) Documents**

Page **3** of **14**

4.0 PROCEDURE

4.1 General

4.1.1 Figure 1, "USQ Review Process," graphically depicts the review process. Detailed steps of the USQ review are covered in Section 4.2, "Unreviewed Safety Question Review Preparation," through Section 4.4, "Unreviewed Safety Question Review Completion."

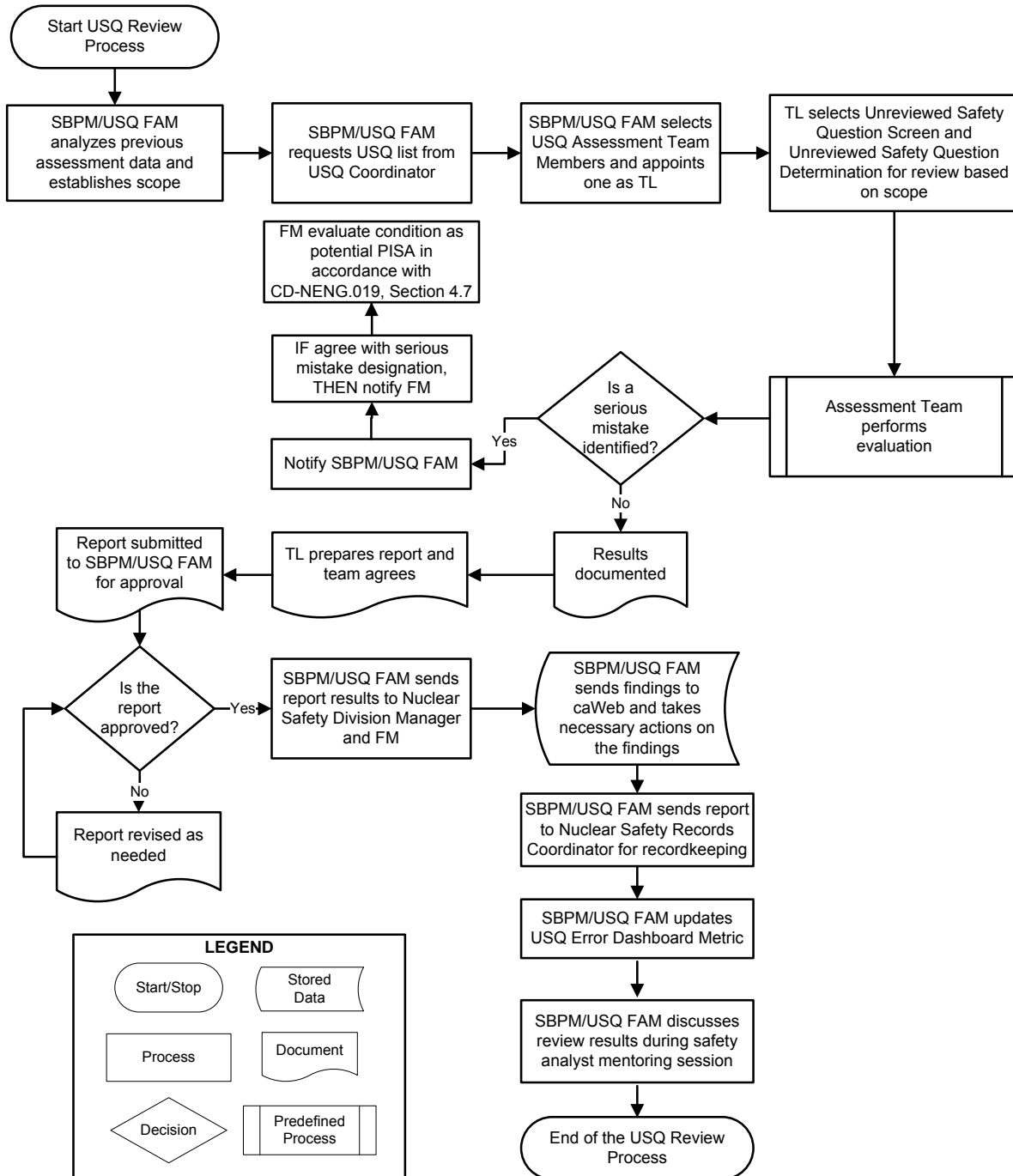


Figure 1. USQ Review Process

NATIONAL SECURITY TECHNOLOGIES ORGANIZATION PROCEDURE

Document Number: **OP-NENG.040**

Rev. 4

Effective Date: **April 18, 2013**

Document Title: **Review of Completed Unreviewed Safety Question (USQ) Documents**

Page 4 of 14

NOTE: It is not the intent of this OP to require that USQ documents from all nuclear facilities be reviewed during the same time period. Reviews of individual facility's USQ documents may be spread over a three-month period.

4.1.2 A sample of USQ documents from each nuclear facility are to be reviewed at least quarterly.

4.1.3 USQ Review Team Members should not review their own work.

4.2 Unreviewed Safety Question Review Preparation

SBPM/USQ FAM [1] Determine the scope of the USQ review as follows:

- A. Identity of the nuclear facility or facilities.
- B. Start date for the review (i.e., when will the review commence).
- C. Time period covered (i.e., what USQ document completion dates will be included in the review).
- D. Minimum percentage of completed USQ documents to be reviewed:
 - 5% of Unreviewed Safety Question Determinations (USQDs) completed during the time period.
 - 10% of Unreviewed Safety Question Screens (USQs) completed during the time period.
 - 10% of Categorical Exclusions (CatXs) completed during the time period.
 - 10% of Institutional Screens completed during the time period.
- E. Review dashboard metrics and working level metrics examination to identify areas of higher or increasing error rates which could benefit from additional oversight. This examination may result in changing the percentages of documents to be reviewed.
- F. Additional special requirements (e.g., lessons learned, other review results, etc.).

[2] Select Review Team members and appoint one member as USQ Review TL.

[2.1] Require each team member to be NSTec USQ qualified (or be USQ qualified at another facility within the DOE complex).

NOTE: Do not include Potentially Inadequate Safety Analysis (PISA)-related USQDs on the list, since they will have been submitted to U.S. Department of Energy, National Nuclear Security Administration Nevada Field Office (NNSA/NFO) for review.

[3] Request that the USQ Coordinator prepare a listing of the numbers and titles of all USQDs, USQs, CatXs associated with the selected facility or facilities, and interval (based on USQ completion date) and all Institutional Screens completed during the USQ review period.

NATIONAL SECURITY TECHNOLOGIES ORGANIZATION PROCEDURE

Document Number: **OP-NENG.040**

Rev. 4

Effective Date: **April 18, 2013**

Document Title: **Review of Completed Unreviewed Safety Question (USQ) Documents**

Page 5 of 14

USQ Coordinator

[4] Prepare the listing as requested by the SBPM/USQ FAM.

[5] Submit the listing to the SBPM/USQ FAM.

USQ Review Team

[6] Read and thoroughly understand this OP and Company Directive CD-NENG.019, "Unreviewed Safety Question Process."

[7] Document completion of the above reading assignment on Form FRM-0491, "Required Reading Review Record."

NOTE: When determining which USQ documents to be reviewed, emphasis is placed on those dealing with physical changes to a facility and technical procedures/work packages, as opposed to those documents related to administrative changes.

[8] Select USQDs, USQSs, CatXs, and Institutional Screens for review based on the percentage determined by the SBPM and the USQ document list provided by the USQ Coordinator.

[8.1] Treat USQDs, USQSs, CatXs, and Institutional Screens separately by obtaining a fractional percentage of each.

[8.2] Round up resulting sampling percentages (e.g., 50% of 23 USQS items would be rounded to 12 items).

4.3 Unreviewed Safety Question Review Checklist Completion

4.3.1 Appendix A, "Unreviewed Safety Question (USQ) Review Checklist," will be used to document the review of each USQ document.

USQ Review Team

[1] Obtain the change packages (the documents that initiated the USQ action, including change request, work package, safety analysis, procedure, or other relevant documents) for the reviewed USQ documents.

[2] **IF** a change package cannot be located, **THEN** document its absence on the checklist as an OFI.

USQ Coordinator

[2.1] **IF** the change package is not available, **THEN** provide the missing documentation in the file.

USQ Review Team

[3] Review the selected USQ documents.

[4] Check "✓" the appropriate "Yes" or "No" column on Appendix A, covering the three categories of errors and their examples, as outlined below:

NATIONAL SECURITY TECHNOLOGIES ORGANIZATION PROCEDURE

Document Number: **OP-NENG.040**

Rev. 4

Effective Date: **April 18, 2013**

Document Title: **Review of Completed Unreviewed Safety Question (USQ) Documents**

Page 6 of 14

NOTE 1: OFI examples include, but are not limited to:

- A. Wrong USQ number
- B. Wrong references
- C. Boxes on the USQ worksheet incorrectly marked

NOTE 2: OFIs generally require no corrective actions, but should be reviewed to ensure they have had no impact on the USQ document results.

**USQ Review Team
(continued)**

[4.1] **IF**, as a result of this review, a potential impact on the USQ document results is discovered, **THEN** elevate the OFI to the mistake category.

NOTE 1: Mistakes generally do not have the potential to change the USQ document results (e.g., from USQS to a positive USQD, or a USQD from negative to positive). All Serious Mistakes will be corrected at the discretion of the USQ FAM, the SBPM, or Safety Basis Division Manager.

NOTE 2: Examples of mistakes include:

- A. Proposed activity not clearly stated.
- B. Appropriate Subject Matter Expert/Cognizant System Engineer (SME/CSE) concurrence is not documented.
- C. For Screens, conclusion is evaluative (i.e., seven USQD questions are answered).
- D. Signature/date missing.
- E. Appropriate technical basis not used to describe requirements or potentially affected areas.
- F. The answers to the seven USQD questions provide insufficient justification/technical basis for the conclusion.

[4.2] **IF**, in correcting the mistake, the USQ document results is changed (e.g., from USQS to a positive USQD, or a USQD from negative to positive), **THEN** elevate the mistake to a serious mistake, **AND** follow the actions of Step 4.3.1[5].

NOTE: An example of a serious mistake includes:

- A. USQD should be positive, but evaluated to be negative.

[4.3] Identify serious mistakes as errors that could result in a PISA.

SBPM/USQ FAM [4.4] Document concurrence with the identified mistakes or serious mistakes, and associated risk ranking/severity level by signing the associated USQ review report.

[4.5] Provide and document formal notification to the affected FM of serious mistakes with associated risk ranking/severity level.

NATIONAL SECURITY TECHNOLOGIES ORGANIZATION PROCEDURE

Document Number: **OP-NENG.040**

Rev. 4

Effective Date: **April 18, 2013**

Document Title: **Review of Completed Unreviewed Safety Question (USQ) Documents**

Page 7 of 14

SBPM/USQ FAM [5] **IF** a serious mistake is discovered, **THEN** perform the following:
(continued)

[5.1] **IF** the change involved in this type of error has been implemented, **THEN** notify affected FM to evaluate as a potential PISA, in accordance with CD-NENG.019, Section 4.7, "Potential Inadequacy of the Safety Analysis (PISA)."

[5.2] **IF** the change has not been implemented, **THEN** notify the FM that the change cannot be implemented until the USQ issues have been resolved.

[6] **IF** there is disagreement as to whether or not a serious mistake has occurred, **THEN** make the final decision on how the issue will be resolved.

USQ Review TL [6.1] **IF** there is disagreement among the Review Team Members, **THEN** document that disagreement in the report.

NOTE: The Review Results apply to the USQ grading for individual USQ documents.

USQ Review Team [7] Indicate the risk ranking/severity level of the USQ review by recording a "✓" in the appropriate box in the "Results" section of Appendix A based on the following criteria:

A. Blue: No OFIs, Mistakes, or Serious Mistakes.

B. Green: One or more OFIs, no Mistakes or Serious Mistakes.

C. Yellow: One or more Mistakes but no Serious Mistakes.

D. Magenta: One or more Serious Mistakes, change not implemented.

E. Red: One or more Serious Mistakes, change has been implemented.

4.4 Unreviewed Safety Question Review Completion

USQ Review TL [1] Collect review results from Review Team Members.

[2] Prepare a USQ Review Report containing the following information, at a minimum:

A. Executive Summary

B. Scope

NOTE: Completed Appendix A checklists are not expected to be included in the USQ Review Report. These are intended to be data collection forms used in the preparation of the Review Report.

C. Review Results, including identification number of USQ documents reviewed, identification of errors noted (i.e., OFIs, mistakes, serious mistakes, or None, as applicable). A table format is acceptable.

D. Analysis of results, including trends regarding improper screening, inadequate technical justification for negative USQDs, etc.

NATIONAL SECURITY TECHNOLOGIES ORGANIZATION PROCEDURE

Document Number: **OP-NENG.040**

Rev. 4

Effective Date: **April 18, 2013**

Document Title: **Review of Completed Unreviewed Safety Question (USQ) Documents**

Page 8 of 14

USQ Review TL (continued)

E. Include the FRM-0491(s) generated in step 4.2[7] as an Appendix to the report.

[3] Submit the draft USQ Review Report to a Derivative Classifier/Reviewing Official (DC/RO) for review.

[4] Sign the USQ Review Report.

[5] Submit the USQ Review Report to the SBPM.

SBPM/USQ FAM

[6] **IF** in disagreement with the USQ Review Report, **THEN** return the report to the USQ Review TL (along with the reason[s] for disagreement) for resolution.

[7] **IF** the USQ Review Report is acceptable, **THEN** determine what corrective actions, if any, are required to correct the identified deficiencies.

[8] **WHEN** sending the USQ Review Report to the NSDM and the affected FMs, **THEN** include a discussion of any identified positive or negative trends with the report and action taken or planned to correct negative trends.

[9] Send the USQ Review Report to the Nuclear Safety Records Custodian for record keeping.

[10] Submit findings (no personnel performance) in the report to caWeb [companywide issues tracking system].

[11] Ensure the review results are applied to the USQ dashboard metric, along with a brief narrative of the issues and trends.

[12] Ensure the review results are discussed with USQ preparers/reviewers during future mentoring sessions. See Section 4.5, "USQ Mentoring Sessions," below.

[13] **IF** the report contains a Serious Mistake, **THEN** notify the Facility Manager of the issue involving the Serious Mistake.

[14] Sign Appendix A, concurring with the results.

Facility Manager

[15] Sign Appendix A acknowledging notification of the Serious Mistake.

USQ Coordinator

[16] Post the completed and approved USQ Review Report on the USQ web site.

NATIONAL SECURITY TECHNOLOGIES ORGANIZATION PROCEDURE

Document Number: **OP-NENG.040**

Rev. 4

Effective Date: **April 18, 2013**

Document Title: **Review of Completed Unreviewed Safety Question (USQ) Documents**

Page 9 of 14

NOTE: The SBPM will utilize the USQ mentoring sessions to reinforce expectations and provide mentoring to Safety Analysts.

4.5 USQ Mentoring

4.5.1 USQ Mentoring Sessions

- SBPM/USQ FAM** [1] Conduct USQ mentoring sessions twice weekly, if possible.
- [2] Conduct round-table discussions to review the following items for continuous improvement:
- A. USQ documents in progress
 - B. Results of reviews of completed USQ documents
 - C. Results of JAS assessments
 - D. Results of external USQ assessments
- [3] Incorporate improvement items from round-table discussions, as well as from internal and external reviews of USQ documents, into USQ program documents, as appropriate.

NOTE: USQ mentoring session minutes will serve as the report to Nuclear Safety management of USQs reviewed and improvement items identified.

- [4] Record and maintain minutes of the USQ mentoring sessions in electronic form in a central location accessible to Safety Analysts and management (e.g., S-drive).

4.5.2 USQ Review Results

- SBPM/USQ FAM** [1] Invite the applicable facility safety analysts to be present during presentations of results of USQ reviews.

5.0 DEFINITIONS

Definitions for commonly used terms can be found in Reference Document REF-GLS.002, "NSTec Glossary of Terms." The following terms are defined for the purposes of this document unless otherwise cited.

- 5.1 **Unsatisfactory USQ.** An Unsatisfactory USQ is a USQ document which contains a Serious Mistake, and has the greatest potential impact on nuclear safety. An Unsatisfactory USQ represents a potential non-compliance to 10 CFR 830.203(e) requiring U.S. Department of Energy approval prior to taking any action determined to involve a USQ.
- 5.2 **Less than Adequate USQ.** It is a USQ document that does not have a mistake but has incorrect application of USQ process quality expectations for implementation.

6.0 TRAINING

- 6.1 None

NATIONAL SECURITY TECHNOLOGIES ORGANIZATION PROCEDURE

Document Number: **OP-NENG.040**

Rev. **4**

Effective Date: **April 18, 2013**

Document Title: **Review of Completed Unreviewed Safety Question (USQ) Documents**

Page **10** of **14**

7.0 RECORDS MANAGEMENT

7.1 Implementation of this document generates the following records:

Record	Disposition Authority	Disposition Instructions	Office of Record
Appendix A, Unreviewed Safety Question (USQ) Review Checklist	ENV 1.b.4.b	EPI – DO NOT DESTROY	Nuclear Safety
FRM-0491, Required Reading Review Record	ADM 23.1.a	Cut off at the end of the fiscal year. Destroy when 2 years old, or when no longer needed.	Nuclear Safety
USQ Review Report	ENV 1.b.4.b	EPI – DO NOT DESTROY	Nuclear Safety

8.0 FORMS

A. FRM-0491, Required Reading Review Record

9.0 REFERENCES

A. CD-NENG.019, Unreviewed Safety Question Process

10.0 APPENDICES

A. Unreviewed Safety Question (USQ) Review Checklist

B. Procedure Basis for OP-NENG.040

NATIONAL SECURITY TECHNOLOGIES ORGANIZATION PROCEDURE

Document Number: **OP-NENG.040**

Rev. 4

Effective Date: **April 18, 2013**

Document Title: **Review of Completed Unreviewed Safety Question (USQ) Documents**

Page 11 of 14

APPENDIX A Unreviewed Safety Question (USQ) Review Checklist

Unreviewed Safety Question (USQ) Number:	
USQ Reviewed by:	Date:
USQ Preparer:	Date:
USQ Reviewer:	Date:
USQ Approver:	Date:

Results (Check "✓" Box)	
<input type="checkbox"/>	Blue
<input type="checkbox"/>	Green
<input type="checkbox"/>	Yellow
<input type="checkbox"/>	Magenta
<input type="checkbox"/>	Red

NOTE 1: A "No" answer to checklist criteria indicates a deficient condition.

NOTE 2: OFIs usually require no corrective actions, but should be reviewed to ensure they have not impacted the USQ document results.

Checklist			
Opportunities for Improvement (OFIs)	Yes	No	Comments
1. USQ number is correct and present on every page.			
2. Boxes on the USQ Worksheet are correctly marked (e.g., Documented Safety Analysis change recommended, if appropriate).			Add this kind of line for A, through H. and the same for 8, and 12
3. Correct/sufficient references.			
4. Other items to check:			
A. Changes to document initialed/dated.			
B. Sections with no text are marked N/A or None.			
C. Correct USQ form revision used.			
D. Other OFIs (e.g., structures, systems, and components identified as equipment important to safety [EITS] or non-EITS).			
E. Page number correct and on all pages.			
F. No classification issues (i.e., missing or incorrect in header/footer or classification stamp incorrect).			
G. Baseline USQD indicated and change evaluated as such.			
H. Change Package cannot be located.			

NOTE: Mistakes require revision of the USQ document. If, in correcting the mistake, the USQ document results is changed (e.g., from USQS to positive USQD, or a USQD from negative to positive), the error is elevated to a serious mistake and the actions of Step 4.3.1[5] are followed.

Mistakes	Yes	No	Comments
5. Name/Signature/Date complete.			
6. Proposed activity clearly stated and appropriately bounded.			

NATIONAL SECURITY TECHNOLOGIES ORGANIZATION PROCEDURE

Document Number: **OP-NENG.040**

Rev. 4

Effective Date: **April 18, 2013**

Document Title: **Review of Completed Unreviewed Safety Question (USQ) Documents**

Page 12 of 14

Checklist

Mistakes	Yes	No	Comments
7. Appropriate Subject Matter Expert/Cognizant System Engineer (SME/CSE) concurrence is documented.			
8. For USQs: A. Conclusion provides clear non evaluative statement why proposed activity doesn't change what is described in the safety basis. B. Not Used. C. Conclusion is not evaluative and does not attempt to answer the seven Unreviewed Safety Question Determination [USQD] questions). D. Categorical Exclusion (CatX) or Institutional Screen is appropriately used to authorize change. Examples include: 1) CatX A.* is used only for types of documents identified in the USQ training. 2) CatX A.* is applied only to changes that do not modify the work process in any way. 3) CatX C.1 is used only when exact replacement part is specified by manufacturer, part number, etc., or the facility's Approved Equivalent Part list use is required. 4) CatX E.1 is used only if the Proposed Activity is completely bounded by the previous USQD, with the exception of 5) CatX A.* administrative changes that do not impact the work process. 6) Other appropriate uses of the Categorical Exclusion or Institutional Screen process.			
9. Change package is available to be filed with the record copy of the USQ document.			
10. Change package and USQ coincide (i.e., the change package is completely covered by the USQ evaluation).			
11. Documentation retained with the USQD record (e.g., drawings or sketches, redlined procedure, calculations, computer code output, SME/CSE concurrence) is sufficient to support the conclusion.			
12. For USQDs: A. Not used. B. Appropriate structures, systems, components, and parameters are identified as being potentially affected. C. Appropriate process hazards analysis and accident analysis scenarios are identified as being potentially affected. D. Statements of fact are introduced in Section 6 which support the answers to the seven questions. E. Interim state hazards are evaluated as appropriate. F. Impacts to both the workers and the public are evaluated.			

NATIONAL SECURITY TECHNOLOGIES ORGANIZATION PROCEDURE

Document Number: **OP-NENG.040**

Rev. 4

Effective Date: **April 18, 2013**

Document Title: **Review of Completed Unreviewed Safety Question (USQ) Documents**

Page 13 of 14

APPENDIX A (continued) Unreviewed Safety Question (USQ) Review Checklist

Mistakes	Yes	No	Comments
G. Responses to the seven questions provide sufficient justification for the conclusions. Responses restate the question as an answer, then provide justification to support the conclusion contained in the final sentence. Potentially affected SSCs, parameters, accidents, etc., identified but not dismissed in Section 6, are addressed in each applicable question.			
H. An independent reviewer can reach the same conclusion as the preparer.			
13. The preparer, reviewer, and approver are qualified.			

.NOTE: If the change involving a serious USQ mistake has been implemented, then treat as a Potentially Inadequate Safety Analysis (PISA) condition. If the change has not been implemented, then notify the Facility Manager (FM) that the change cannot be implemented until the USQ issues have been resolved.

Serious Mistakes	Yes	No	Comments
14. Not used.			
15. The USQ reaches the correct conclusion (i.e., negative determination is supported by the evaluation).			

Additional Comments

Review Results

Blue – No OFIs, Mistakes, or Serious Mistakes.

Green – One or more OFIs, no Mistakes or Serious Mistakes.

Yellow – One or more Mistakes, no Serious Mistakes.

Magenta – One or more Serious Mistakes, change not implemented

Red – One or more Serious Mistakes, change has been implemented.

Concurrence with Mistakes or Serious Mistake conclusion:

SBPM/USQ FAM _____
Name/Signature
Date
Time

Facility Manager (FM) Notified of Serious Mistake:

FM Notified By: _____
Name/Signature
Date
Time

NATIONAL SECURITY TECHNOLOGIES ORGANIZATION PROCEDURE

Document Number: **OP-NENG.040**

Rev. 4

Effective Date: **April 18, 2013**

Document Title: **Review of Completed Unreviewed Safety Question (USQ) Documents**

Page 14 of 14

APPENDIX B Procedure Basis for OP-NENG.040

Row	Source	Citation	Basis	Step
1	CD-NENG.019	1.1	Periodic management review of the performance of the USQ Process.	All