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JUL 13 2004

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Subject: LLNL Transportation Safety Document Unreviewed Safety Question Process

References:
1) Letter dated February 14, 2002 (Anastasio/Hooper), "Submittal of Revised LLNL Unreviewed Safety Question (USQ) Procedure (10CFR830)"
2) Letter dated March 4, 2002 (Anastasio/Hooper), "Corrections to Unreviewed Safety Question Procedure Submittal"

Dear Mr. Beach:

NNSA/LSO is aware of the timing for the implementation of the approved LLNL Onsite Nuclear Materials Transportation Safety Document (TSD). To facilitate this implementation, LSO approves LLNL's use of the existing approved procedure for evaluating changes associated with the TSD (references 1 and 2); however, LLNL shall not use Appendix H of the referenced existing procedure.

If you have any questions, please call Sarah E. Spagnolo at 423-3250.

Sincerely,

for Camille Yuan-Soo Hoo
Manager

cc:
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ES and H manual

Environment, Safety, and Health

Volume #V

Part 51: Safety Analysis, Limits, and Authorization

Document 51.3
LLNL Unreviewed Safety Question (USQ) Procedure

Recommended for approval by the ES&H Working Group

Approved by: Glenn L. Mara
Deputy Director for Operations

New document or new requirements

Approval date: August 6, 2004

☐ **New document**
☒ **Major requirement change**

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LLNL Unreviewed Safety Question (USQ) Procedure*

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* Major revision

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LLNL Unreviewed Safety Question (USQ) Procedure

1.0 Introduction

This procedure provides requirements and guidelines for implementing the unreviewed safety question (USQ) process for LLNL nuclear facilities/activities (e.g., on-site transportation. It is intended to be in compliance with 10 CFR 830.203. This procedure establishes the process to determine who has the authority to approve a change: the Department of Energy (DOE) or LLNL.

The USQ process provides the mechanism for keeping a safety basis current by reviewing potential unreviewed safety questions, reporting positive USQ determinations (USQDs) to DOE, and obtaining approval from DOE prior to taking any action that involves a positive USQD. This process allows LLNL to make physical and procedural changes and to conduct tests, experiments, or operations without prior DOE approval if the proposed change is within the existing safety basis. The USQ process is applicable to changes as compared against the safety basis, excluding changes to Technical Safety Requirements (TSRs) and DOE-directed controls. If the change requires a modification to any TSR, DOE approval is required per DOE Order 5480.22 and 10 CFR 830, Subpart B. A change that results in the facility/activity being outside its safety basis involves a positive USQD. A potential inadequacy of the safety analysis (PISA) that may be a result of new information, facility behavior under operational event conditions, or a discrepant as-found condition can be a negative or positive USQD. The USQ process determines if the potential inadequacy places the facility/activity outside its safety basis, if corrective actions are necessary, and the extent to which DOE should be involved.

The revisions to this document shall be implemented within 90 days of DOE-NNSA/LSO (Livermore Site Office) approval.

2.0 Scope

The scope of this procedure applies to the LLNL Category 2 and 3 nuclear facilities and activities. Specific details on the On-site Transportation USQ process are included in Appendix H. The USQ process is required for the following conditions:

- Temporary or permanent change in the facility/activity as described in the existing DSA.

- Temporary or permanent change in the procedures as described in the existing DSA.
- Tests, experiments, or operations not described in the existing DSA.
- Potential inadequacy of the DSA because the analysis potentially may not be bounding or may be otherwise inadequate.

Facility/Activity
B332 Plutonium Facility
B331 Tritium Facility
B334 Hardened Engineering Test Building
B239 High Energy Radiography Facility
B251 Heavy Element Facility
RHWM Facilities
On-site Transportation

In the time period after the issuance of the SER and before start of operation of the new facility or activity, elements of the USQ process may be applied as a best management practice to assure that changes made subsequent to the SER are evaluated to determine whether the change remains within the facility safety basis. Discrepant as-found plant configuration conditions identified in this time frame may be handled using a listing of items requiring corrective action or may be done in accordance with the USQ process**.** Prior to the start of operations of the new facility or activity, known discrepancies of configurations relied upon in the safety basis need to be corrected or documented to be within the safety basis. Changes to the safety basis must be reviewed and approved by DOE prior to the start of that particular operation.

3.0 Terms and Definitions

The brackets [ ] denote the source document for the basis of these definitions.

Accident — An unplanned sequence of events that results in undesirable consequences. [DOE-STD-3009]

Accident analysis	For the purposes of properly implementing the USQ Order, the term "accident analysis" refers to those bounding analyses selected for inclusion in the DSA. These analyses refer to design basis accidents only. [DOE Order 5480.21] Accident analysis typically consists of the formal development of numerical estimates of the expected consequence and probability of potential accidents associated with a facility. Where accident analysis is required, it is a follow-on effort to the hazard analysis, not a fundamentally new examination requiring extensive original work. As such, it is the documentation of the basis for assignment to a given likelihood of occurrence range.
Approved equivalent part	See "Like-in-kind."
Bounding accidents	Representative accidents that bound a number of similar accidents of lesser risk (e.g., the worst fire for a number of similar fires). [DOE-STD-3009]
Change	Any change to procedures or equipment, any new tests or experiments, or any new information, which has the potential to invalidate the safety basis.
Design basis	The set of requirements that bounds the design of equipment important to safety. These design requirements include consideration of safety, availability, efficiency, reliability, and maintainability.
Design basis accidents	Accidents that are considered credible enough to be postulated for the purpose of establishing design and performance requirements for equipment important to safety. [DOE Order 5480.21, Section 6.d]
Documented safety analysis (DSA)	A documented analysis of the extent to which a nuclear facility can be operated safely with respect to workers, the public, and the environment, including a description of the conditions, safe boundaries, and hazard controls that provide the basis for ensuring safety. [10 CFR 830.3(a)] Note: the term Safety Analysis Report (SAR) is superceded by the term documented safety analysis.

Equipment important to safety (EITS)	For the purposes of this procedure, equipment important to safety should be understood to include any equipment whose function can affect safety either directly or indirectly as described in the safety basis. This includes safety class and safety significant structures, systems, and components (SSCs), and other systems that perform an important defense-in-depth function, equipment relied on for safe shutdown, and in some cases, process equipment. These considerations apply to both workers and the public. [modified G 424.1-1]
Evaluation of safety of the situation	A determination of the actual safety of a proposed activity or discovered condition. It is the Facility Manager's qualitative assessment of the relative risk of the situation and provides evidence to DOE for removal of controls. For a positive PISA USQD, the qualitative assessment of the evaluation of safety of the situation could be the basis of a justification for continued operations.
FSP	Facility Safety Plan
Like-for-like	Involves replacing one component with another that is identical (i.e., exact replacement, same manufacturer, same model number, etc.).
Like-in-kind	Involves replacing one component with another that meets the safety function and performance criteria of the item being replaced or has been determined to be equivalent, and documented. Like-in-kind also includes equipment or components on a facility "Approved Equivalent Parts" list or additional items that meet the safety function and performance criteria of the item being replaced, as determined by the system engineer and approved by the Facility Manager or designee for inclusion on the list.

Major modification	A modification to a DOE nuclear facility that is completed on or after April 9, 2001 that substantially changes the existing safety basis for the facility [10 CFR 830.3(a)] (e.g., the replacement of a major safety system, equivalent to the design, construction, and initial operation of a new facility or projects that exceed $5 million). Like-for-like or like-in-kind replacements are not considered major modifications. Experiments or temporary/one-time activities may not be major modifications (even if greater than $5 million) and may be evaluated using the USQ process to determine if the activity is within the existing safety basis.
Margin of safety	That margin built into the safety analysis of the facility as set forth in the acceptance limits for the safety basis. Where a margin of safety is defined in the DSA, the margin of safety is the range between two conditions of (1) the most adverse condition estimated or calculated in safety analyses to occur from an operational upset or family of related upsets, and (2) the worst-case value known to be safe, from an engineering perspective. Sometimes the margin of safety may be implicit. See Appendix E, Section E.3.G for additional details.
Negative USQD	A documented conclusion that a change remains within the safety basis and may be implemented without DOE approval.
Nuclear facility	Those LLNL facilities, activities or operations that involve, or will involve, radioactive and/or fissionable materials in such form and quantity that a nuclear or a nuclear explosive hazard potentially exists to workers, the public, or the environment, but does not include nuclear reactors, accelerators and their operations and does not include activities involving only incidental use and generation of radioactive materials or radiation such as check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines.

OSP	Operational Safety Plan [for this document includes operational safety procedures and Safety Plans (SP)].
Positive USQD	A documented conclusion that (1) the probability of the occurrence or the consequences of an accident or the malfunction of equipment important to safety previously evaluated in the DSA would be increased; (2) the possibility of an accident or malfunction of a different type than any evaluated previously in the DSA would be created; (3) a margin of safety would be reduced; or (4) the DSA is not bounding or is otherwise inadequate. [modified 10 CFR 830.3(a)] When the USQD is positive, DOE approval is required to implement the change.
Potential inadequacy of the safety analysis (PISA)	A condition in which the safety basis may be inadequate or the physical condition may not be accurate because the safety analysis may not match the current physical configuration of the facility or the safety analysis may be inappropriate or contains errors.
Restoration modification	A change that restores the safety function and performance criteria of equipment important to safety to correct a discrepant as-found condition.
Safety analysis	A document that identifies and analyzes the hazards of an operation, the associated potential consequences and risk of accidents, and the adequacy of measures taken to eliminate, minimize, control, or mitigate the hazards. [Analyses is the plural of analysis]
Safety basis	The DSA and hazard controls that provide reasonable assurance that a DOE nuclear facility/activity can be operated safely in a manner that adequately protects workers, the public, and the environment. [10 CFR 830.3(a)] The safety basis includes conditions of approval in Safety Evaluation Reports (SERs) and facility/activity -specific commitments to DOE.

Safety-class structures, systems, and components (SC-SSC)	SSCs whose preventative or mitigative function is necessary to limit radioactive hazardous material exposure to the public, as determined from safety analyses. [10 CFR 830.3(a)]
Safety Evaluation Report (SER)	The report prepared by DOE to document (1) the sufficiency of the DSA for a hazard Category 2 or 3 DOE nuclear facility; (2) the extent to which LLNL has satisfied the requirements of Subpart B of 10 CFR 830; and (3) the basis for approval by DOE of the safety basis for the facility/activity, including any conditions for approval.
Safety-significant structures, systems, and components (SS-SSC)	SSCs that are not designated safety class SSCs, but whose preventative or mitigative function is a major contributor to defense in depth and/or worker safety as determined from safety analyses. [10 CFR 830.3(a)]
Technical Safety Requirements (TSR)	The limits, controls, and related actions that establish the specific parameters and requisite actions for the safe operation of a nuclear facility and include, as appropriate for the work and the hazards identified in the DSA for the facility: safety limits, operating limits, surveillance requirements, administrative and management controls, use and application provisions, and design features, as well as a bases appendix. [10 CFR 830.3(a)]
USQ determination (USQD)	The document required by 10 CFR 830.203 to record the review of a proposed change or existing condition not previously contained in the DSA. This document records a description of the issue and the logic for determining whether a positive or negative USQD exists. The document is used to determine whether DOE must approve the proposed action.
USQ documents	USQ documents include USQ first-level screenings, USQ screenings and USQ determinations, including any attachments.

USQ process	The mechanism for keeping a safety basis current by reviewing potential unreviewed safety questions, reporting positive USQDs to DOE, and obtaining approval from DOE prior to taking any action that involves a positive USQD. [10 CFR 830.3(a)] DOE approval is not required to place the facility in a safe condition.

4.0 Responsibilities

This section specifies the responsibilities related to the USQ process.

4.1 Deputy Director for Operations (DDO)

The Deputy Director for Operations:

- Approves the USQ procedure for LLNL implementation.
- Independently oversees LLNL ES&H activities including ensuring consistent implementation of the USQ process.

4.2 Authorization Basis Section Leader

The Authorization Basis (AB) Section Leader:

- Develops and maintains this LLNL USQ procedure.
- Implements and/or coordinates the USQ process at LLNL related to institutional issues (e.g. aircraft overflights).
- Approves/prepares generic USQ process training for USQ preparers, reviewers, and approvers.
- Maintains a list of the current safety basis documentation for all LLNL nuclear facilities/activities.
- Advises personnel on USQ issues.

4.3 Facility/Activity Manager† (or Designee)

The Facility/Activity Manager:

- Ensures that the USQ process is implemented for the facility/activity in accordance with this procedure.
- Provides LLNL approval for facility/activity -specific USQ documents. Only the Facility Manager, responsible transportation individual, or designees may approve USQ documents.
- Ensures that USQ process is integrated with facility/activity ISM activities, particularly configuration management (Document 41.2, "LLNL Configuration Management Program Description," in the *ES&H Manual*) and work control.
- Maintains a facility/activity -specific list or file of the current safety basis documents and facility/activity procedures that are described in the existing safety analyses.
- Approves USQ preparers and USQ reviewers for his or her facility/activity.
- Approves the facility/activity -specific USQ training.
- Participates in the periodic review of this procedure and concurs with any changes made before submittal to DOE.

4.4 USQ Preparers, Reviewers, and Approvers

USQ preparers, reviewers, and approvers:

- Achieve and maintain proficiency on the USQ process for the designated facility/activity.
- Maintain a thorough knowledge of the safety basis for the facilities/activities for which they are designated as USQ preparers, reviewers or approvers.
- Complete applicable portions of the USQ process as directed by this procedure for preparation, review, and approval of USQ first-level screenings and USQ screenings or USQ determinations.

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† Appendix H defines the responsible transportation individuals who assume the responsibilities comparable to the Facility Manager for transportation activities. When used in this procedure, "Facility Manager" applies to the Facility Manager, responsible transportation individual, or their designees.

5.0 Qualifications and Training

This section specifies the required qualifications and training related to the USQ process.

5.1 Personnel Preparing or Reviewing USQ Documents

Preparers and reviewers of USQ documents shall be qualified to perform or review, as applicable, USQ first-level screenings, USQ screenings and USQ determinations. These personnel shall be designated in writing by the Facility Manager, as described in Section 5.4.

5.1.1 Initial Qualification and Training

Preparers and reviewers of USQ documents shall meet the following education requirements:

- A Bachelor of Science degree in engineering or one of the physical sciences or equivalent experience approved by the Facility Manager consistent with DOE O 5480.20A.

In addition to these education requirements, preparers and reviewers of USQ documents shall also meet the following experience qualifications:

- For preparers, one year experience in a nuclear or radiological facility, or equivalent experience as approved by the Facility Manager consistent with DOE O 5480.20A. This experience can be in either NRC-licensed, military, or DOE facilities.
- For reviewers, two years experience in nuclear or radiological facilities, with at least one year of this time at LLNL, or equivalent experience approved by the Facility Manager consistent with DOE O 5480.20A. This experience can be in either NRC-licensed, military, or DOE facilities.

Training

Preparers and reviewers shall successfully complete the following training on the DOE and LLNL USQ process:

- HS8042, "Unreviewed Safety Questions (USQ) Process". This is a minimum 3-day course covering the USQ process.

Institutional Knowledge

Preparers and reviewers shall be familiar with the requirements of this procedure, i.e., the LLNL USQ process. Training on this procedure is covered in HS8042, "Unreviewed Safety Questions (USQ) Process."

Facility/Activity -Specific Knowledge

Preparers and reviewers shall have a working knowledge of the nuclear facility's characteristics, operations, procedures, and tests or experiments, including SSCs as described in the approved DSA, TSR, FSPs, and selected appropriate OSPs. This knowledge will be based partially on the following:

- Walkthroughs of assigned nuclear facilities/activities, accompanied by a knowledgeable individual.
- Required reading that includes the following documents (training may be completed via individual study):
  - Approved facility/activity Preliminary DSAs, DSAs, TSRs, and other safety basis documents.
  - Approved FSPs for designated nuclear facilities.
  - The activity-specific Appendix H, as applicable.
  - Any applicable Approved Equivalent Parts list.
  - DOE SERs.
  - Other facility/activity -specific safety commitments to DOE.
- Understanding the safety basis of equipment important to safety, including the safety function and performance criteria of safety SSCs.
- With a facility/activity USQ preparer or reviewer, review and discuss four or more previously approved facility/activity USQ determinations, at least two of which are positive USQDs. If the facility/activity does not have four approved USQ determinations, then review USQ determinations approved at another LLNL nuclear facility.

5.1.2 Retraining Requirements

The interval for institutional and facility/activity USQ refresher training, i.e., HS8042-R, "USQ Refresher," and HS8044-xxxx, "USQ Facility/Activity-Specific Refresher" is every 2 years.

5.2 Management Personnel

Management personnel shall meet the qualification requirements specified in ES&H Manual 50.1, Personnel Selection, Qualification, Training, and Staffing at LLNL Nuclear Facilities."

- HS8042, "Unreviewed Safety Questions (USQ) Process," (3-day course to be taken every four years).

The individuals to which this applies are:

- Facility Manager, and designees who approve USQ documents;
- LLNL Program Manager for Packaging and Transportation Safety;
- Materials Management Section Leader in the Mechanical Engineering Department;
- RHWM Division Leader in the Environmental Protection Department;
- AB Section Leader.

The following shall maintain a thorough knowledge of the facility/activity safety basis, as appropriate:

- Facility Manager, and designees who approve USQ documents.
- LLNL Program Manager for Packaging and Transportation Safety.
- Materials Management Section Leader in the Mechanical Engineering Department.
- RHWM Division Leader in the Environmental Protection Department.

5.3 Documentation of Facility/Activity-Specific Training and Education/Experience

The Facility Manager is responsible for the preparation and approval of facility/activity-specific USQ training, and initial education/experience. To accomplish this, the Facility Manager shall ensure completion of a "facility specific checklist" for each individual who prepares, reviews, or approves USQ documents in that manager's facilities/activities. This checklist documents that each individual has completed training as specified in Section 5.1, walkthroughs of the facility/activity and reviews of safety basis documentation, equipment important to safety, and previously completed USQDs. It will also be used to document training completion in LTRAIN and initial education/experience.

5.4 USQ Approved Personnel List

The Facility Manager will ensure that a written list of approved USQ personnel for the facility/activity is maintained. The list identifies who can prepare, review, or approve USQ first-level screenings, USQ screenings, or USQ determinations.

6.0 USQ Process Methodology

As discussed in the scope section, 2.0, the USQ process is applicable to Category 2 and 3 nuclear facilities and activities. The USQ process is required for the following conditions:

- Temporary or permanent change in the facility/activity as described in the existing DSA.
- Temporary or permanent change in the procedures as described in the existing DSA.
- Tests, experiments, or operations not described in the existing DSA.
- Potential inadequacy of the DSA because the analysis potentially may not be bounding or may be otherwise inadequate.

A forward-looking change can enter into the USQ process if changes are proposed, but not yet implemented, in a facility's/activity's hardware, procedures, or operations. These changes may also create new risks (e.g., a new material is introduced). New hardware or new operations may require new procedures; therefore, a single change may feed into the USQ process in multiple ways. The introduction of new technologies in a facility will be evaluated through the USQ process.

Another entry condition to the USQ process is through self-assessments, inspections, new information, operational events or incidents, or identification of a physical condition or configuration that is not accurately described in the DSA and the DSA or facility configuration needs to be changed. The identification of these conditions can result in entering the USQ process through a potential inadequacy of the safety analysis, known as a PISA.

Document 51.3 does not apply to the development of changes to the LLNL Work Smart Standards Set (WSS), applicable to nuclear facilities. However, the application of WSS changes to specific LLNL nuclear facilities are subject to Document 51.3. DOE mandates or direction are outside the scope of Document 51.3.

The process that is described in Sections 6.2 through 6.5 shall be followed for proposed changes. The process that is described in Section 6.6 shall be followed for as-found changes and PISAs. The USQ process in Appendix H shall be followed for

modifications to approved packages and vehicles that affect Department of Transportation (DOT) requirements, and for procedures that implement the provisions of the On-site Transportation Safety Basis (Appendix H). In situations where a change in the Interim On-site Transportation Safety Document (IOTSD) could impact a nuclear facility, representatives of the nuclear facility should be notified to ensure potential impacts to the nuclear facility are considered.

Figure 1 summarizes the USQ process. Exclusions to the USQ process are discussed in Section 6.1. Additionally, Facility Management retains the ability to go directly to DOE for approval of a change without utilizing the USQ process.

6.1 Exclusions to the USQ Process

The USQ process does not apply to the following situations:

- Maintenance activities covered by a procedure that has been subjected to the USQ process.
- Procedures that are specifically reviewed as part of the startup process (e.g., RA or ORR) to assure consistency of a procedure with the safety basis. This exclusion does not apply to subsequent revisions and/or changes to these procedures.
- Administrative procedures (e.g., to purchase office supplies) unrelated to the safety basis of the facility operations.

The following changes to the safety basis can only be approved by DOE and, therefore, need not be evaluated in accordance with this USQ procedure:

- Safety Basis amendment (e.g., DSA or TSR amendment).
- Annual DSA/TSR update.
- A change to TSRs.
- A change that constitutes a major modification.
- Changes as determined by management that will be submitted to DOE for approval.

6.2 Entry Conditions for the USQ Process

The Facility Manager shall be notified of all proposed changes, including changes to hardware or procedures (temporary or permanent), or of any new or modified test, experiment, or operation. When a change is proposed, the Facility Manager will use

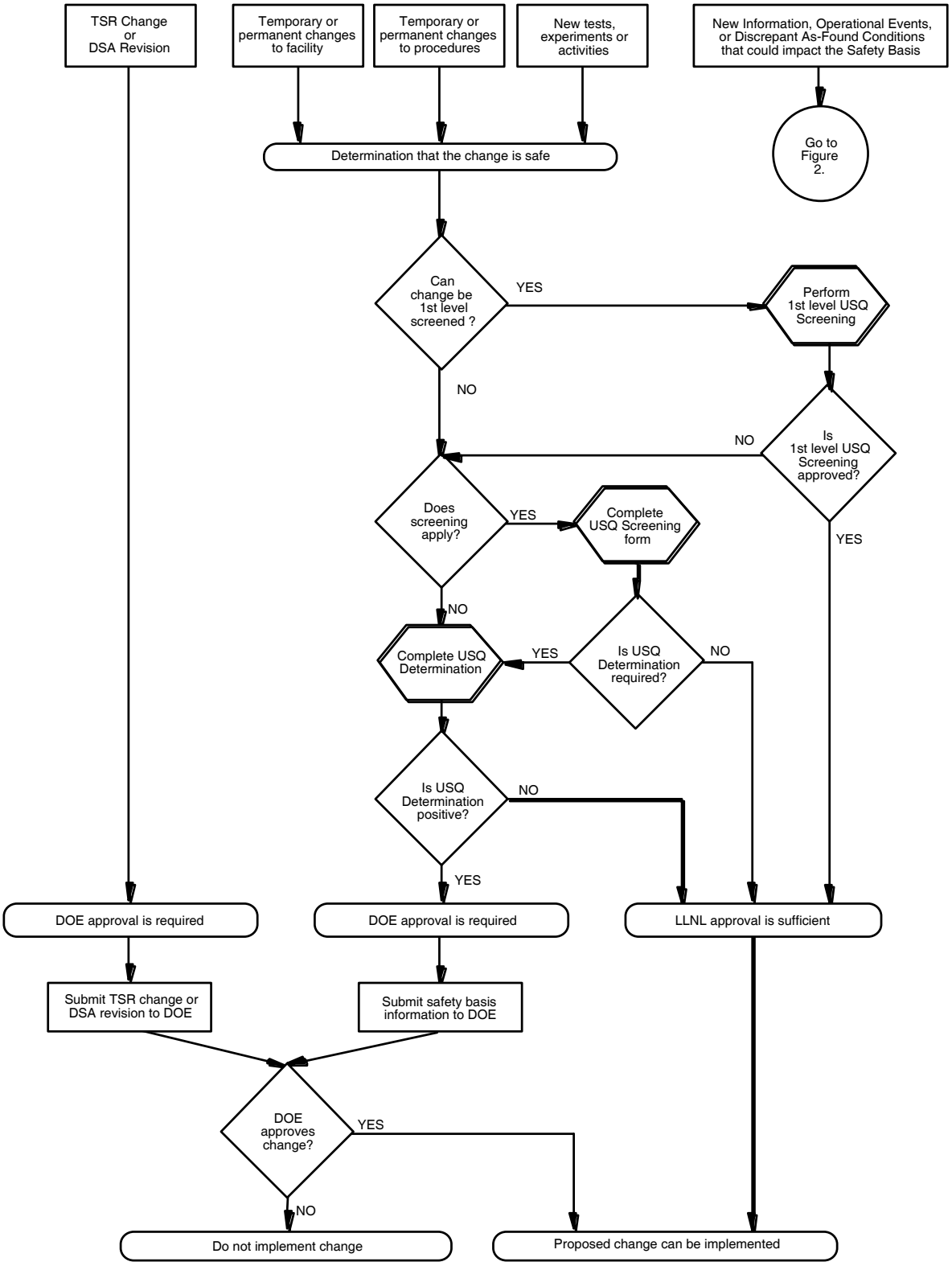

Figure 1. USQ process flowchart. (Exclusions to the USQ process are discussed in Section 6.1. Additionally, Facility Management retains the ability to go directly to DOE for approval of a change.)

qualitative judgment to determine whether the change will affect safety. This does not need to be documented. A proposed change determined to be unsafe shall be canceled, or appropriate modifications shall be made to make it safe. Once the change is judged to be safe, it shall be entered into the USQ process so that the impact on the safety basis can be evaluated and the appropriate approval level can be ascertained. Determination of whether a change is safe or unsafe should be made early in the design phase and prior to procurement.

The USQ process is intended to be implemented along with a configuration management process, which includes change control. The change control process should include generalized steps for (1) identifying and describing the temporary or permanent change, (2) technical reviews of the change, (3) management review and approval of the change, (4) implementation of the change, and (5) documenting the change, including revision of documents. The LLNL Configuration Management Program [see Document 41.2, "Configuration Management Program Description," in the *Environment, Safety, and Health (ES&H) Manual*] describes the change control process and its relationship to the USQ process. As part of the technical reviews of a change, the appropriate type of safety analysis shall be performed to facilitate a determination of whether the change is indeed safe. This is accomplished separately from the USQ process. In the case of a potential facility change resulting from a backfitting process, where a modification of, or addition to, an existing safety SSC would result from implementing a new or revised standard, a separate backfitting analysis is required to determine if the safety benefits of the modification justify the fiscal costs of implementing the modification (see LLNL Backfit Policy, UCRL-MI-201375). The USQ process is used subsequently to determine if final approval of the change by LLNL is sufficient or if DOE approval shall be obtained. For modifications to packaging and modifications to vehicles that affect DOT requirements, and for procedures that implement the provisions of the On-site Transportation Safety Basis, the potential impact on the associated facility's safety basis shall also be considered. If a change involves a positive USQD, DOE approval is required. If a change does not involve a positive USQD, then LLNL approval is adequate.

DOE recognizes that it is possible that some changes can be justified as not requiring USQ determinations as long as screening criteria are documented to ensure that there are no direct or indirect effects of the change and to ensure that the change does not require a USQ determination. The purpose of screening is to ascertain if there is reasonable technical justification for not performing a USQ determination. DOE encourages the use of screening to limit the number of matters for which USQ determinations must be performed, provided that the reasons for exclusion are documented and well supported. Screening will assist in reducing the efforts expended for matters of minor significance and will focus efforts on the more important matters for which the USQ process is intended.

Accordingly, the LLNL USQ process has three levels of review:

1. The first consists of a first-level screening (Section 6.3) of proposed changes to determine if the proposed change requires no further evaluation by the USQ process. First-level screenings cannot be used for PISAs or On-site Transportation activities.
2. The second consists of a USQ screening (Section 6.4) of proposed changes that were not screened out at the first level to determine if a USQ determination is required. USQ screenings cannot be used for PISAs.
3. The third consists of the USQ determination (Section 6.5). This level applies to PISAs and proposed changes that were not screened out in the first two levels of the USQ process.

In accordance with the requirements of this procedure, the proposed change for each level shall be prepared and reviewed by qualified individuals and approved by the Facility Manager.

6.3 First-level Screening

The first-level screening determines and documents whether a proposed change clearly does not require further evaluation. First-level screening is optional, and a proposed change may proceed to USQ screening or directly to USQ determination if desired.

Appendix A provides guidance for preparers and reviewers to use in applying the first-level screening criteria. If the preparer concludes, in accordance with the guidance in Appendix A that a change is clearly not subject to further USQ screening or a USQ determination, the conclusion shall be recorded on the appropriate change document.

The first-level screening Criteria are listed in Appendix B. The USQ First-level Screening Block in Appendix B shall be used to document this decision. The USQ First-level Screening Block can be incorporated into the appropriate change document or can be used as a stand-alone form.

The completed block shall be signed by the preparer, the reviewer and the approving Facility Manager. No reviewer shall review any USQ first-level screening that they have prepared.

See Section 6.7 for follow-up actions to complete the USQ process.

6.4 USQ Screening

USQ screening is optional, and proposed changes may proceed directly to USQ determination if desired. Otherwise, a proposed change is screened using the following questions to determine if a USQ determination is required:

1. Is this a temporary or permanent change in the facility/activity as described in the existing DSA?
2. Is this a temporary or permanent change in the procedures as described in the existing DSA?
3. Is this a new test, experiment, or operation not described in the existing DSA?

Appendix C provides guidance to preparers/reviewers in responding to these screening questions. If all responses to these screening questions are negative, the proposed change does not impact the DSA and may be implemented without DOE approval. Affirmative response to one or more of the screening questions requires the preparation of a USQ determination in accordance with Section 6.5. The documentation shall include a description of the change being evaluated and of its effects on equipment important to safety, operations, or procedures. If the preparer concludes, in accordance with the guidance in Appendix C that a change does not require a USQ determination, the justification shall be recorded on the USQ Screening Form.

The USQ Screening Form in Appendix D shall be used to document this conclusion.

The completed form shall be signed by the preparer, the reviewer and the approving Facility Manager. No reviewer shall review any USQ screening that they have prepared.

See Section 6.7 for follow-up actions to complete the USQ process.

6.5 USQ Determination

The purpose of a USQ determination is to determine if the change requires DOE approval and to document the conclusion. Changes to the safety basis are evaluated by a USQ determination, which uses the following criteria:

- Could the proposed change increase the probability of occurrence of an accident previously evaluated in the facility's/activity's safety basis?
- Could the proposed change increase the consequences (to workers or the public) of an accident previously evaluated in the facility's/activity's safety basis?

- Could the proposed change increase the probability of occurrence of a malfunction of equipment important to safety previously evaluated in the facility's/activity's safety basis?
- Could the proposed change increase the consequence of a malfunction of equipment important to safety previously evaluated in the facility's/activity's safety basis?
- Could the proposed change create the possibility of an accident of a different type than any previously evaluated in the facility's/activity's safety basis?
- Could the proposed change create the possibility of a malfunction of equipment important to safety of a different type than any previously evaluated in the facility's/activity's safety basis?
- Could the proposed change reduce the margin of safety as described in the facility's/activity's safety basis?

Appendix E provides guidance to preparers, reviewers, and approvers in responding to these questions. The documentation shall include a description of the change being evaluated and of its effects on SSCs, operations, or procedures. The USQ determination 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. Appendix E also includes background information to support the completion of the worksheet. While a graded approach cannot be used in performing the USQ determination, where appropriate, a graded approach shall be used when performing an analysis to support the USQ determination. Any analysis that is part of a USQ determination shall employ a level of effort consistent with the importance of the change to safety.

The USQ Determination Worksheet in Appendix F shall be used to document this conclusion.

The completed worksheet shall be signed by the preparer, the reviewer and the approving Facility Manager. No reviewer shall review any USQ determination that they have prepared.

See Section 6.7 for follow-up actions to complete the USQ process.

6.6 Receipt of New Information, Operational Events, or Discrepant As-Found Conditions

Receipt of new information, operational events, or discrepant as-found conditions may lead to a potential inadequacy of the safety analysis as follows:

1. Receipt of new information, including:
   - Notifications regarding potential performance problems with equipment under certain operating conditions.
   - Technological advances.
   - Discovery of inaccuracies or omissions in the analysis.
   - Recognition that a postulated accident would exceed the existing safety analysis.
2. An operational event or incident that may lead to the conclusion that the safety analyses are invalid because the:
   - Event analysis reveals that the safety analysis is invalid or inadequate, e.g., increased source term, failure to recognize existing hazards, assumptions either not realistic or not conservative.
   - Facility response to an event or incident does not occur as expected.
   - Consequences exceeded the bounds of previously analyzed events.
3. Discovery of a discrepant as-found condition, where the actual physical configuration and the physical configuration explicitly or implicitly described in the DSA do not agree. A discrepant as-found condition is a PISA when the discrepant as-found condition reveals an error in the safety analysis or facility configuration. Backward-looking USQ determinations are PISAs.

The above conditions should be evaluated to determine whether the full process depicted in Figure 2 should be followed.

The main consideration with a PISA is that the analysis is inappropriate, contains errors, or does not match the current physical configuration of the facility. Analytical errors might involve using incorrect input values, using invalid assumptions, using an improper model, or calculational errors. The analysis might not match the facility configuration because of a discrepant as-found condition. The USQ process starts when the facility management has information that gives reason to believe that there is the potential that the DSA may not be bounding or may be otherwise inadequate or facility configuration is inconsistent with the safety analysis. The time period from discovery of a condition to the determination of whether a PISA exists should typically be on the order of days, not weeks.

The USQ process does apply when there is reason to believe that the current safety basis might be in error or otherwise inadequate or facility configuration is inconsistent with the safety analysis. However, the USQ process does not apply to the process of upgrading DSAs as it relates to responding to new requirements or to the use of new or different analytical tools during the upgrade process.

Figure 2 is a flowchart of this process. Appendix G is guidance for assessing if there exists a potential inadequacy of the safety analysis.

6.6.1 Discovery of As-Found Change

The Facility Manager shall be notified of any discovery of new information, an operational event or incident, or a discrepant as-found condition that could be considered a PISA, as described above. Upon notification, the Facility Manager shall assign a qualified individual to confirm if the inadequacy has the potential for calling into question information in the safety basis.

Appropriate action shall be taken for each of the USQ process entry conditions described below:

New Information

The discovery of new information that the existing safety analysis is potentially inadequate is expected from several general sources: (1) discovery of errors, inaccuracy or omission in the existing safety analysis, including discovery of a potential failure mechanism which had not been previously known or considered, (2) notification that certain equipment experiences failure under certain conditions, or (3) technological advances revealing that important assumptions in the safety analysis are invalid. The following are exceptions:

- Certain new information received as part of a safety analysis upgrade is excluded from being considered by the USQ process. An example is new safety analysis results stemming from the application of new DOE requirements. For example, DOE may require the addition of Beyond Design Basis Accidents in the DSA. These new results would not invalidate the existing safety analysis since the new requirement is beyond the existing DSA. Also, the USQ process does not apply to the process of upgrading a DSA in response to new requirements or to the use of new or different analytical tools during the upgrade process.
- Another potential source for exclusion is when new information involves the performance capability of TSR related facility hardware. If the performance degradation of the facility hardware could cause noncompliance with a Limiting Condition of Operation in a TSR, the appropriate actions per the

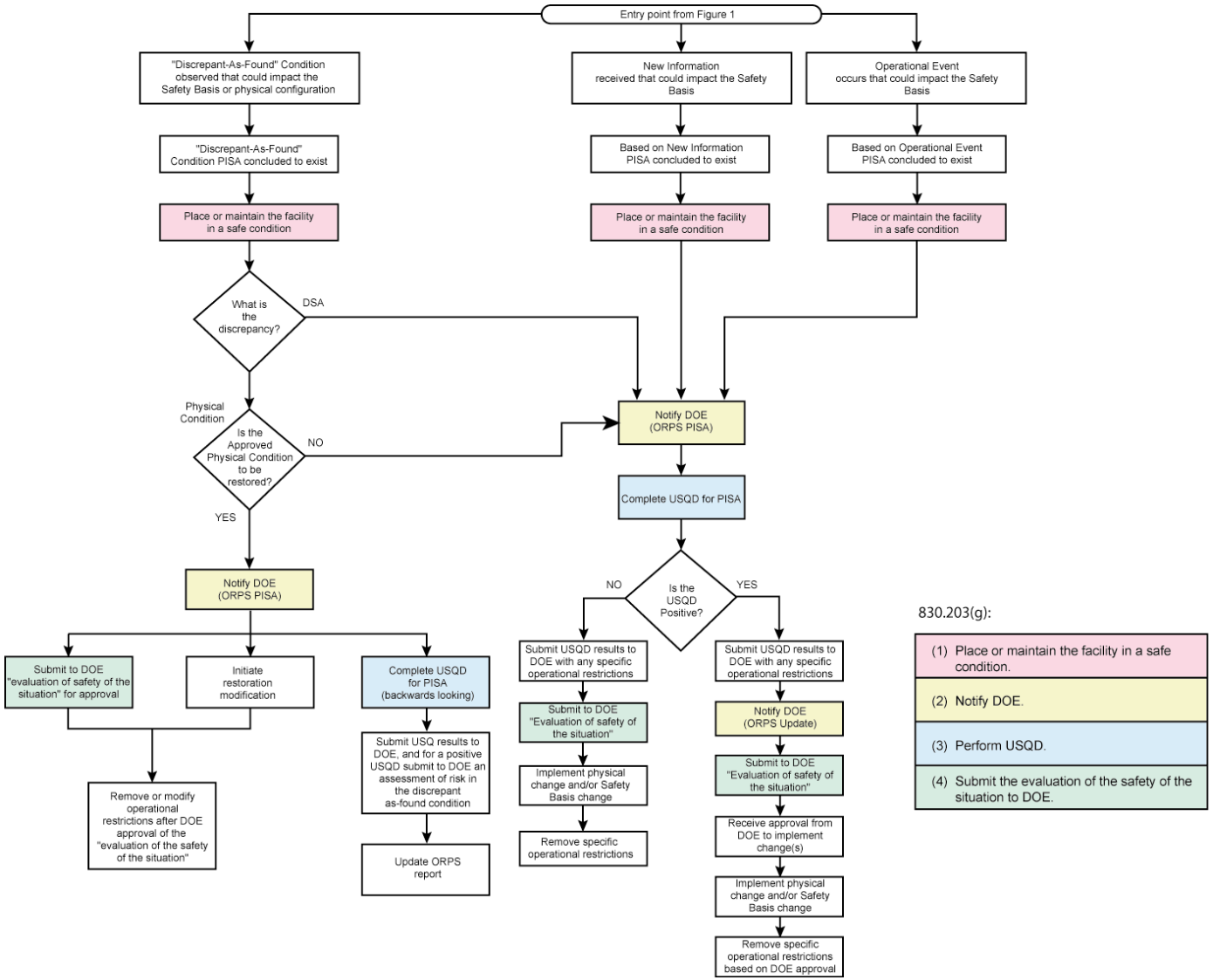

Figure 2. Flowchart of PISA and "Discrepant As-Found" conditions.

facility specific TSRs shall be taken. In this case, the USQ process would not be necessary because actions are taken in accordance with the safety basis to assure the continuing validity of the existing DSA.

If the facility/activity review concludes that the new information could be a PISA, the Facility Manager shall place or maintain the facility/activity in a safe condition, notify DOE, and proceed with the USQ process in accordance with Section 6.6.2.

Operational Event

Operational events that should be included are those that indicate that operator errors occur at a greater rate or probability than is indicated in the safety analysis. Certain operational event may in some cases be excluded. An example is where failure to comply with specific procedures and operational conditions create an event beyond the safety envelope. In this situation the existing analysis remains valid since the cause of exceeding the safety envelope is tied to a programmatic or procedural breakdown not analytical inadequacies.

It is important to distinguish between the concept of a PISA and operating events. Not every event that results in exceeding the boundaries of a safety analysis is a PISA. For example, the occurrence of an operational event that results in exceeding the limits specified in the DSA would not be a PISA (but may be a TSR violation), if the event was caused by failure to follow operating procedures. Of course, certain types of operating events may add New Information that brings into question the validity of risks presented in the safety analysis.

If the facility/activity review concludes that the operational event could be a PISA, the Facility Manager shall place or maintain the facility/activity in a safe condition, notify DOE, and proceed with the USQ process in accordance with Section 6.6.2.

Discrepant As-found Condition

A discrepant as-found condition is a situation where the actual physical configuration of equipment important to safety in the facility does not match the DSA. This may result from an error in the DSA or an error in the facility configuration. If the facility review concludes that a discrepant as-found PISA condition exists, the Facility Manager shall take the following actions:

1. Take action, as appropriate, to place or maintain the facility/activity in a safe condition. If appropriate, additional operating restrictions shall be applied to the facility/activity to ensure a safe condition. The operational restrictions shall remain in effect until an evaluation of the safety of the situation is completed and submitted to DOE and it is determined by this process that the restrictions are no longer required.

2. The Facility Manager shall determine whether the discrepant as-found condition requires correcting the DSA or correcting the facility configuration. If the condition requires correcting the DSA, the Facility Manager will take the actions described in Section 6.6.2. If the condition requires correcting the facility configuration, the Facility Manager will take the actions described in Section 6.6.3.

6.6.2 PISA Requiring a DSA Change

The Facility Manager shall initiate the following actions upon identification of a PISA requiring a DSA change:

1. Notify DOE of the situation as Group 3.B(2) Occurrence.

   The Occurrence Reporting and Processing System (ORPS), implemented at LLNL in accordance with Document 4.3, "LLNL Implementing Procedures for DOE Order 231.1A—Occurrence Reporting and Processing of Operations Information," in the *ES&H Manual* shall be used for this notification, and the report shall explicitly state that the situation involves a "potential inadequacy of the safety analysis."

2. Perform a USQ determination and notify DOE promptly of the results along with any additional operational restrictions. The USQ determination may also be submitted.

   This is intended to mean that the USQ determination should be prepared promptly and the results submitted promptly, whether positive or negative. This is also intended to mean that the time frame after initial notification of DOE to the submittal of the USQ determination results should typically be on the order of days, not months.

   A USQ determination is performed based on the existing, as-found condition. The USQ determination is performed using the rationale, "If we had proposed the as-found condition as a change to the DSA, would it have involved a positive USQD?" For the USQ determination, it is necessary to consider the existing physical configuration of the facility/activity as if the change were a proposed modification. Based on this USQ determination, a positive USQD or negative USQD shall be declared.

Positive USQD for PISA

Following the declaration of a positive USQD, the following actions are required in addition to the actions specified above:

1. The existence of a positive USQD shall be formally reported to DOE using the reporting process outlined in Document 4.3 in the *ES&H Manual*. The Facility Manager shall upgrade the occurrence report to a Group 3.B(1) Occurrence.

2. Submit the evaluation of the safety of the situation to DOE. Also submit suggested corrective actions for closure of the positive USQD and proposed revisions to the safety basis if appropriate.

3. The Facility Manager shall ensure the measures taken previously to put the facility/activity in a safe condition are still sufficient. If they are not, take additional steps based on the evaluation of safety of the situation to put the facility/activity in a safe condition as soon as possible.

   The evaluation of safety of the situation is not the USQ determination. LLNL determines the actual safety of a proposed activity or discovered condition. An evaluation of safety of the situation is the Facility Manager's qualitative assessment of the relative risk of the situation and provides evidence to DOE for removal of controls.

4. Obtain DOE's approval to implement the change, e.g., replacement of equipment, to achieve a compliant condition and/or approval of the revised safety basis.

5. Correct the inadequacy either by document change and/or physical change. If the facility was shut down to allow for the investigation of a PISA, restart shall begin in accordance with Document 51.4, "Startup and Restart of Nuclear Facilities," in the *ES&H Manual*, if applicable.

6. Operating restrictions implemented to place the facility/activity in a safe condition may only be removed after DOE approval.

Negative USQD for PISA

Following the declaration of a negative USQD, the following actions are required:

1. Submit the evaluation of the safety of the situation to DOE.

   The evaluation of safety of the situation is not the USQ determination. LLNL determines actual safety of a proposed activity or discovered condition. An evaluation of safety of the situation is the Facility Manager's qualitative assessment of the relative risk of the situation and provides evidence to DOE for removal of controls.

2. DOE approval is not required prior to removing any operating restrictions implemented to place the facility/activity in a safe condition, once the evaluation of safety of the situation has been submitted.

3. Implement the change, e.g., replacement of equipment and modification of the safety basis if appropriate.

4. Return to normal operations (i.e., remove any restrictions) following appropriate procedures.

6.6.3 Restoration Modification of a Discrepant As-found Condition

The Facility Manager shall initiate the following actions upon determination of a discrepant as-found condition to restore the physical configuration as described in the DSA:

1. Notify DOE of the situation via ORPS as a PISA.
2. Initiate the restoration modification to restore to the approved physical condition. [Note that implementation or construction of the restoration modification requires review under the USQ process.] Initiate the backward looking USQD. Initiate the evaluation of safety of the situation.
3. Complete the evaluation of safety of the current situation and submit the results to DOE for approval. DOE approval is required prior to removing any operational restrictions.
4. Complete the backward looking USQD in accordance with the process described below in "USQD Related to a PISA for Restoration Modification." Submit the results of the USQD to DOE including a qualitative assessment of risk of the discrepant as-found condition for positive USQDs. Update ORPS report as applicable.‡
5. Complete the restoration modification, but do not remove any operational restrictions until DOE approves the evaluation of safety.‡

Note: The evaluation of safety of the situation is not the USQ determination. LLNL determines the actual safety of a proposed activity or discovered condition. An evaluation of safety of the situation is the Facility Manager's qualitative assessment of the relative risk of the situation and provides evidence to DOE for removal of controls.

USQD Related to a PISA for Restoration Modification

The backward looking USQ determination should be prepared promptly and the results submitted promptly, whether positive or negative. This is also intended to mean that the time frame after initial notification of DOE to the submittal of the USQ determination results should typically be on the order of days not weeks.

The USQ determination is performed based on the existing, as-found condition. The USQ determination is performed using the rationale, "If we had proposed the as-found condition as a change to the DSA, would it have involved a positive USQD?" For the USQ determination, it is necessary to consider the existing physical configuration of the facility/activity as if the change were a proposed modification. Based on this USQ determination, a positive USQD or negative USQD shall be declared.

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‡ **Step 4 does not need to be completed before Step 5.**

Positive USQD for PISA

Upon declaration of a positive USQD, the following actions are required in addition to the actions specified above:

1. The existence of a positive USQD shall be formally reported to DOE using the reporting process outlined in Document 4.3 in the *ES&H Manual*. The Facility Manager shall upgrade the occurrence report to a Group 3.B(1) Occurrence.
2. Submit the evaluation of the risk in the discrepant as-found condition for a positive USQD to DOE.

Negative USQD for PISA

Following the declaration of a negative USQD, submit the results of the negative USQ determination to DOE.

6.7 Actions Following Completion of USQ First-Level Screening, USQ Screening, and USQ Determination except PISA(s)

After Facility Manager approval of a USQ first-level screening or a USQ screening the proposed change may be implemented. Any reviewed and concurred/approved USQ determination which results in a negative determination other than PISAs may be implemented without prior approval or without submission to DOE. If the change is implemented it shall be in accordance with the configuration management process, which includes change control. As part of this process, the Facility Manager shall approve each modification, to the facility or to procedures, that relates to the facility safety basis, including proposals for new operations at the facility. This process shall ensure that:

- Design basis and safety basis documents are updated.
- Proposed change is implemented.
- Appropriate documents are controlled in accordance with document control procedures.

If the USQ determination concludes that the proposed change is a positive USQD, complete the following steps:

1. The Facility Manager determines whether to proceed to Step 2.
2. The Facility Manager approves the positive USQD.
3. The Facility Manager prepares the supporting justification for the proposed change which includes as applicable a discussion of the 14 points in the attachment to the DOE letter dated February 18, 2004 (See Appendix I). Submittal of the positive USQD is not required.

4. The AB Section Leader concurs with the positive USQD package.
5. The appropriate Associate Director (or designee) accepts and transmits the package to DOE.
6. DOE approval is required before implementing the change. DOE-approved positive USQDs shall become addenda to the existing safety basis.

The Facility Manager incorporates permanent changes as a result of the USQ determination and any DOE conditions of approval into the existing DSA during the next scheduled update after the change has been approved.

The Facility Manager initiates configuration management steps as appropriate during implementation of the change to ensure that key documents and hardware remain in alignment.

Note: Refer to Document 51.4 in the *ES&H Manual* to determine if any post-change restart requirements apply.

The USQ process does not supersede, nor exclude a change from consideration in, the National Environmental Policy Act or Emergency Preparedness Response Assessment processes. These are separate processes, and appropriate actions should be taken to comply with the necessary requirements.

7.0 USQ Document Preparation and Retention

The results of the USQ process are documented on USQ first-level screenings, USQ screenings and USQ determinations (see Appendix B, D or F) including who prepared, reviewed and approved the conclusion.

7.1 USQ Document Numbering

Each USQ screening and USQ determination shall be identified by a unique number.

Note: First-level screenings are not required to be identified by a unique number (see Appendix B).

The following numbering scheme will be used:

ORG-XX-YYY-Z

where,

- ORG corresponds to facility/activity organization code or building number, e.g., "LLNL", "B239", "B331", etc.
- XX corresponds to the last two digits of the calendar year that the USQ document is prepared.
- YYY corresponds to the numerical order that the USQ document is prepared in that calendar year (use 3 digits).
- Z corresponds to the type of the USQ document where:
  - S stands for USQ screening only.
  - D stands for USQ determination.

For example, B332-01-003-D corresponds to a USQ determination, which was the third USQ document prepared in the 2001 calendar year.

7.2 USQ Document Title

The title of the USQ screening or USQ determination should include a description of the activity for which the USQ screening or USQ determination is being done, and the system, hardware, procedure or requirement to be changed. An example of a title is "Replacement of 50 hp Fan Motor in Increment 1 Room Ventilation Exhaust System."

7.3 USQ Document Forms

USQ first-level screenings shall be performed using the LLNL USQ First-level Screening Block in Appendix B. First-level screenings cannot be used for PISAs or On-site Transportation activities. USQ screenings or USQ determinations shall be performed using the forms in Appendix D and F, respectively, except for On-site Transportation where forms in Appendix H shall be used.

7.4 USQ Document Retention

The Facility Manager shall ensure that USQ documents (including USQ first-level screenings, USQ screenings, and USQ determinations) are:

- Retained for the operational life of the facility/activity until the facility/activity is turned over for decontamination and decommissioning.
- Turned over to any subsequent contractor in charge of the facility/activity.

8.0 Annual Reporting

The Facility Manager shall annually submit to DOE a report summarizing or listing USQ determinations performed since the date of the last report summarizing or listing USQ determinations. A USQ summary report for institutional USQ determinations shall be submitted by the AB Section Leader.

9.0 References

9.1 Work Smart Standards

10 CFR 830, Nuclear Safety Management, including Subpart A, Quality Assurance Requirements (830.120 - 830.122) and Subpart B, Safety Basis Requirements (830.200-830.207).

9.2 Other References

DOE Guide 424.1-1, Implementation Guide for Use in Addressing Unreviewed Safety Question Requirements, October 24, 2001.

DOE-STD-3009-94, Change 1, *Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Safety Analysis Reports*, January 2000.

Document 4.3, "LLNL Implementation Procedures for DOE Order 231.1A —Occurrence Reporting and Processing of Operations Information," in the *ES&H Manual*.

Document 41.2, "LLNL Configuration Management Program Description," in the *ES&H Manual*.

Document 51.4, "Startup and Restart of Nuclear Facilities," in the *ES&H Manual*.

10.0 Resources for More Information

10.1 Contacts

Authorization Basis Section Leader

Directorate Assurance Manager

Facility Manager

Appendix A

Instructions for the USQ First-Level Screening Block

General Instructions

DOE G 424.1-1 and DOE Order 5480.21 acknowledge that screening criteria should be applied to those items that, by broad definition, would enter into the USQ process but for which a detailed evaluation (i.e., USQ determination) is not necessary. For example, an operational procedure that is described in the DSA may be changed to correct a typographical error or to include an additional reference to an equipment list. Such a change is not of any safety significance and clearly does not involve a positive USQD.

Before a change can be first-level screened out of the remaining USQ process, all first-level screening criteria identified in Appendix B shall be reviewed for each use of these criteria. If any criterion is applicable but will not be complied with, then a first-level screening shall not be used and a USQ screening or USQ determination shall be performed. The most applicable criterion is to be selected and documented on the First-Level Screening Block.

First-level screening cannot be applied to:

- Changes/activities affecting equipment important to safety, excepting Criteria 1a and 2c.
- On-site Transportation activities.
- PISAs.

First-level screenings shall be prepared, documented, reviewed and approved as defined in Sections 4.0, 5.0, 6.3, and 7.0.

Appendix B

USQ First-level Screening Block

LLNL USQ First-level Screening Block

Operations	1a ☐	1b ☐	
Physical Changes	2a ☐	2b ☐	2c ☐
Procedure Changes	3a ☐	3b ☐	3c ☐
Prior USQ document	4 ☐	Document #:_____	Date:_____

Justification:

Prepared by:_____ Date: _____

Reviewed by:_____ Date: _____

Approved by:_____ Date: _____

LLNL USQ First-level Screening Criteria

Before a change can be first-level screened out of the remaining USQ process, all First-Level Screening criteria shall be reviewed for each use of these criteria.

If any criterion is applicable but will not be complied with, then First-Level Screening shall not be used, and a USQ screening or USQ determination shall be performed.

The most applicable criterion is to be selected and documented on the First-Level Screening Block.

A brief justification in support of the first level screening shall be provided in "Justification."

OPERATIONS

Criterion #1a: Routinely planned and performed maintenance activities that do not result in modification and that return the facility to its original condition prior to maintenance. The result of such activities should be that the affected system(s) continue to meet or exceed the performance capabilities set forth in the facility safety basis. Examples of such maintenance activities include calibration, refurbishment, and replacement of equipment or a component with like-for-like equipment or component (i.e., exact replacement, same manufacturer, same model number, etc.). They also include like-in-kind equipment or components (i.e., an item on a facility "Approved Equivalent Parts" list or additional items that meet the safety function and performance criteria of the item being replaced as determined by the System Engineer and approved by the Facility Manager or designee for inclusion on the list).

OR

Criterion #1b: Activities/Operations authorized by the facility safety basis; activities/operations described in the facility FSP or an existing OSP that have been subjected to the USQ process and are authorized by the facility safety basis.

PHYSICAL CHANGES

Criterion #2a: Physical changes to components or parts in the facility that clearly are NOT described/relied on implicitly or explicitly in the facility safety basis and physical changes that clearly CANNOT result in new/ increased hazard(s), new accident scenario(s) or increased probability/ consequence of an accident scenario described in the facility safety basis or require new controls for equipment important to safety.

OR

Criterion #2b: Physical changes within areas (e.g., offices, yard areas, and the security perimeter) that clearly CANNOT result in new/increased hazard(s), new accident scenario(s) or increased probability/consequence of an accident scenario described in the facility safety basis or require new controls for equipment important to safety. 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).

OR

Criterion #2c: Installation or removal of like-for-like/like-in-kind equipment on a glovebox or in a glovebox where the hazards/accidents and controls of operation of equipment important to safety are described by the same hazards/accidents and the same controls of equipment important to safety installed on or in other gloveboxes as considered in the facility safety basis. The glovebox safety function, performance criteria, and seismic qualifications remain intact.

PROCEDURE CHANGES

Criterion #3a: Administrative and editorial changes to procedures that are relied upon explicitly or implicitly in the facility safety basis, e.g.:

- Correct typographical, spelling, or grammar errors.
- Provide clarification (additional descriptive language or examples)
- Add reference(s).
- Update reference to incorporate new DOE Orders, Guides, or Standards which are accepted under Appendix G of the DOE/UC Contract (reference updates that are safety basis related shall be made to the facility safety basis before they are made to lower level documents)
- Changes to identified individuals with similar qualifications

OR

Criterion #3b: Changes to portions of existing OSPs/FSPs that are unimportant to safety (i.e., that clearly CANNOT result in new/increased hazards, new accident scenarios, or increased probability/consequence of an accident scenario described in the facility safety basis or require new controls for equipment important to safety).

OR

Criterion #3c: Changes to portions of existing OSPs/FSPs that involve criticality safety controls where an approved Criticality Safety Evaluation maintains the facility safety basis and the margin of safety (e.g., application of double contingency principle).

PRIOR USQ PROCESS

Criterion #4: The change, considering location differences, has been fully evaluated by a previously approved USQ screening, USQ determination, or applicable DOE approval letter. (The applicable document number will be entered in the First-Level Screening Block.)

Appendix C

Instructions for the USQ Screening Form

C.1 Introduction

Many changes in a facility/activity affect equipment important to safety in ways that are not immediately apparent. For example, changes may introduce new failure modes in support and auxiliary systems, place new kinetic energy sources (e.g., compressed gas) near safety systems, and alter seismic response characteristics. These instructions provide guidance for identifying changes that require additional review by a USQ determination. The screening process in these instructions focuses on explicit or implicit changes that affect the facility's DSA, rather than on insignificant changes. Preparers and reviewers shall consider possible direct and indirect effects on the facility's DSA.

C.2 General Instructions

A USQ screening is optional, and proposed changes may proceed directly to USQ determination if desired. Otherwise, a USQ screening shall be performed using the form in Appendix D as follows:

1. The form may be completed electronically, handwritten, typewritten or any combination thereof. Continuation sheet(s) shall be attached if the space provided is not adequate. However, the completed form shall be signed by the preparer, the reviewer and the approving Facility Manager.

2. The preparer shall add the facility/activity title, a USQ screening number (see Section 7.1), revision number (starting at zero), a title (see Section 7.2), and a description of the proposed change.

3. The preparer shall answer "Yes" or "No" to questions A, B, and C of the USQ Screening Form. Section C.3 may be used as guidance.

   If any question A, B, or C of the USQ Screening Form was answered "Yes," then "The issue requires a USQ determination" block shall be checked and a USQ determination shall be performed in accordance with Section 6.5 and Appendix E prior to proceeding with the change.

   If all responses to questions A, B, and C are answered "No," then "The issue does not require a USQ determination" block shall be checked and may be implemented after review and Facility Manager approval.

4. A brief justification in support of this conclusion shall be provided in "Justification." The justification shall include a description of the proposed change's

effects on equipment important to safety, operations, and/or procedures. The justification should include any supporting evidence and amplification of any answers to the form, and identify the use of "engineering judgment," to support any exclusion from further consideration in the USQ process.

5. The references associated with the review shall be documented. Two types of references should be considered. These include biographical details on both the existing DSA and the technical references (e.g., drawings, system descriptions) that may not be part of the safety basis.

6. The preparer shall sign the form and forward it to a reviewer. No reviewer shall review any USQ screening that they have prepared.

7. If the reviewer concurs with the preparer's conclusion, the reviewer indicates agreement by signing and forwards the USQ screening to the preparer who obtains review and approval by the Facility Manager. Whenever the reviewer disagrees with the conclusion of the preparer, the reviewer returns the USQ screening with comments to the preparer for resolution. If these comments cannot be resolved, the preparer so indicates on the form and forwards it to Facility Manager for review and disposition.

C.3 Guidance for Answering USQ Screening Questions A, B, and C

The questions given in the following subsections are provided to help the preparer/reviewer identify when a USQ determination is required for a proposed change. The questions are not meant to be an all-inclusive list but contain an extensive list of situations to consider when evaluating the need for a USQ determination.

Subsection I FACILITY CHANGES

1. Does the temporary or permanent change affect an SSC that is not explicitly described in the existing safety analyses but has the potential for altering the design, function, or method of performing the function of equipment important to safety explicitly or implicitly described in the DSA?

2. Does the change add or delete an automatic or manual feature of any equipment important to safety, or does the change convert an automatic feature of any equipment important to safety to a manual function?

3. Does the change introduce any new system interactions that could potentially lead to the release of hazardous or radioactive material or that could potentially lead to the release of more hazardous or radioactive material than a release scenario already identified in the safety basis?

4. Does the change introduce any new system interactions that could potentially increase the probability of a release scenario already identified in the safety basis?

5. Does the change alter the required seismic performance (including performance category), environmental response, or safety classification of equipment important to safety?
6. Does the change alter the response to external environmental conditions (e.g. missile, flood, wind, lightning, or fire) of equipment important to safety?
7. Does the change replace equipment important to safety that is not "like-for-like" or "like-in-kind"?
8. Is this a nonroutine maintenance activity that (1) may not return the facility to the same condition it was in prior to maintenance, (2) is not enveloped by the safety basis, or (3) might violate a TSR?
9. Is this a maintenance activity that is not covered in a DSA and that requires the operation of certain systems to prevent the release of hazardous or radioactive material (e.g., if a thermal transient could occur during maintenance and could result in a release, then operation of the cooling system would be required)?
10. Is this a maintenance activity that removes from service a system or component in a mode in which TSRs apply, but for which allowed outage times or permitted reduction in redundancy are not defined in the TSRs?
11. If the temporary or permanent change were to a mode of operation of the facility or to a facility process, would the change be outside the safety basis?
12. Although the ultimate modification may not impact the safety basis, would changes made while the modification is in progress (e.g., removing critical equipment from operation) be outside the safety basis?
13. If the modification were to be suspended at any point before completion, would this activity be outside the safety basis?
14. Does the change introduce more, or a different form of, hazardous or radioactive material than was considered in the DSA?
15. Does the change introduce any new hazardous or radioactive materials not considered in the DSA?
16. Could the change increase the likelihood (probability/frequency of occurrence) of a toxic or radiological spill, fire, explosion, or criticality from that considered in the DSA?
17. Could the change introduce new mechanisms by which toxic or radiological spills, fires, explosions, or criticality events could occur?
18. Could the change call into question any assumption made in any part of the DSA?

19. Does the change violate or affect the basis for any TSR such that (1) a new TSR may be required, (2) there would be an associated change to the DSA that involves a USQ; or (3) the way that the associated TSR could be met, applied, or interpreted is affected?

Subsection II PROCEDURE CHANGES

1. Does the change alter a procedure outlined, summarized, or described explicitly or implicitly in the safety basis, which would invalidate the safety basis?
2. Is the change being made to a procedural area that is relied upon in the DSA? (Such modifications qualify as changes to procedures, as described in the DSA.)
3. Does the change to the procedure implement an operational change (e.g., setpoint change)?
4. Does the change to the procedure alter the basic functions to be performed by the original procedure?
5. Does the change to the procedure alter the intent of a procedure or the method of accomplishing that intent?
6. Does the change to the procedure reassign responsibility to a less qualified individual?
7. Does the change to the procedure alter any systems or system interfaces in a way that could potentially affect the operability of equipment important to safety?
8. Does the change to the procedure violate or affect the basis for any TSR such that (1) a new TSR may be required, (2) there would be an associated change to the DSA that involves a USQ, or (3) the way that the associated TSR could be met, applied, or interpreted is affected?
9. Is this a new procedure of the type that would be identified explicitly or implicitly in the safety basis?

Subsection III NEW TEST, EXPERIMENT, OR OPERATION

1. Could the test, experiment, or operation potentially introduce more or a different form of a hazardous or radioactive material, or increase the quantity vulnerable to release, compared to what was considered in DSA?
2. Could the test, experiment, or operation potentially introduce any new hazardous or radioactive material not considered in the DSA?
3. Could the test, experiment, or operation potentially increase the likelihood (i.e., probability/frequency of occurrence) of a toxic or radioactive spill, fire, explosion, or criticality?

4. Could the test, experiment, or operation potentially introduce a new mechanism by which a toxic or radioactive spill, fire, explosion, or criticality could occur?
5. Could the test, experiment, or operation potentially affect safe operations by degrading the margins of safety during normal operations or anticipated transients, or by degrading the performance of equipment important to safety that prevents accidents or mitigates accident conditions?
6. Is the activity a one-of-a-kind test used to measure the effectiveness of new techniques or a new system configuration that might affect equipment important to safety?
7. Is this a post-modification test that was not considered or included in the safety basis?
8. Could the test, experiment, or operation violate or affect the basis for any TSR such that (1) a new TSR may be required, (2) there would be an associated change to the DSA that involves a positive USQD, or (3) the way that the associated TSR could be met, applied, or interpreted is affected?

Appendix D

USQ Screening Form

USQ SCREENING FORM

Facility/Activity: _____ **USQ Number:** _____ **Rev.** _____

Title: _____

Issue:

	Yes	No
A. Is this a temporary or permanent change in the facility/activity as described in the existing documented safety analysis? (Consider the guidance in Appendix C, Section C.3 of the *USQ Procedure*)	☐	☐
B. Is this a temporary or permanent change in the procedures as described in the existing documented safety analysis? (Consider the guidance in Appendix C, Section C.3 of the *USQ Procedure*)	☐	☐
C. Is this a new test, experiment, or operation not described in the existing documented safety analysis? (Consider the guidance in Appendix C, Section C.3 of the *USQ Procedure*)	☐	☐

☐ The issue requires a USQ determination.

☐ The issue does not require a USQ determination.

Prepared:_____

Print name Signature Title Date

Reviewed:_____

Print name Signature Title Date

Approved:_____

Print name Signature Facility Manager Date

Justification: *(Description of supporting evidence for exclusion)*

References:

Appendix E

Instructions for the USQ Determination Worksheet

E.1 Introduction

Many changes in a facility/activity affect equipment important to safety in ways that are not immediately apparent. For example, changes may introduce new failure modes in support and auxiliary systems, place new kinetic energy sources (e.g., compressed gas) near safety systems, and alter seismic response characteristics. These instructions provides guidance for identifying physical and procedural changes and tests, experiments or operations that may be implemented without prior DOE approval if the proposed change is within the existing safety basis. The determination process in these instructions focuses on explicit or implicit changes that affect the facility's DSA. Preparers and reviewers shall consider possible direct and indirect effects on the facility's DSA.

E.2 General Instructions

A USQ determination may be performed without a USQ screening, even if a USQ screening indicates the USQ determination is not required or it is apparent that a USQ screening would require completion of a USQ determination. When a USQ determination is required, the USQ Determination Worksheet (see Appendix F) shall be filled out by a preparer to document the USQ determination as follows:

1. The form may be completed electronically, handwritten, typewritten or any combination thereof. Continuation sheet(s) shall be attached if the space provided is not adequate. However, the completed form shall be signed by the preparer, the reviewer and the approving Facility Manager.

2. The preparer shall add the facility/activity title, a USQ determination number (see Section 7.1), revision number (starting at zero), and a title (see Section 7.2).

3. The Introduction and Parts I, II, and III shall be completed before answering the seven Summary Questions.

   In the Introduction, the preparer shall describe the aspects of the change being evaluated and its expected effects, the parameters and SSCs affected by the change, the SSC failure modes associated with the change, and references used for the USQ determination.

   The preparer shall complete Parts I, II, and III. All discussion questions shall be completed. Section E.3 may be used as guidance in addressing the discussion questions. The preparer shall respond to the questions only to the level of detail consistent with the safety basis. If a question asks for details and the safety basis

does not include such details, determine whether the question is applicable. If applicable, respond; if not, indicate n/a. More elaborate and thorough basis information would be expected for changes to equipment important to safety than for nonsafety equipment. In any case, the justification for the answers to the USQ determination criteria needs to be defensible.

4. Based on the discussion in Parts I, II, and III, the seven Summary Questions shall be answered with either a "Yes" or "No."

   If the preparer answered each of the summary questions as "No," this indicates a positive USQD does not exist for the proposed change and may be implemented after review and Facility Manager approval.

   A "Yes" answer to any summary question indicates that a positive USQD may exist for the proposed change.

5. The preparer shall sign the form and forward it to a reviewer. No reviewer shall review any USQ screening that they have prepared.

6. If the reviewer concurs with the preparer's conclusion, the reviewer indicates agreement by signing and forwards the USQ determination to the preparer who obtains review and approval by the Facility Manager. Whenever the reviewer disagrees with the conclusion of the preparer, the reviewer returns the USQ determination with comments to the preparer for resolution. If these comments cannot be resolved, the preparer so indicates on the form and forwards it to Facility Manager for review and disposition.

7. If the change does not involve a positive USQD, the Facility Manager so indicates and forwards the worksheet back to the preparer for implementation of the change without the need for prior DOE approval.

8. If a positive USQD is involved for the change, the Facility Manager so indicates and forwards a request to the preparer for either cancellation of the proposed change; modification of the proposed change such that it no longer would involve a positive USQD; or preparation of a request to DOE for approval, including the performance of any analysis needed to support such a request. Submittals to DOE supporting positive USQDs shall include as applicable: a scope description, supporting hazards and accident analysis and calculations, assumptions, a list of references, and TSR page changes and controls.

   Note: A determination that a change involves a positive USQD does not mean the change cannot be performed in a safe manner. It means that the safety implications of the change have not been reviewed previously by DOE. Thus, DOE approval is required prior to implementation. Conversely, a determination that a change does not involve a positive USQD does not mean there are no safety implications associated with the change. It means that any

accidents or malfunctions associated with the change are bounded by those previously reviewed by DOE, and thus prior DOE approval is not required.

9. The completed USQ determination documentation shall be sufficient to support the conclusion so that a reviewer can follow the reasoning and arrive at the same conclusion. Items retained with the USQ determination may include:

   - Drawings to illustrate proposed hardware modifications.
   - Markup of proposed procedure changes with additions and changes in **boldface** and deletions as ~~strikethroughs~~.
   - Calculations that support the conclusions reached in the USQ determination.
   - Computer code output that supports the conclusions reached in the USQ determination.

E.3 Guidance for Answering USQ Determination Criteria Questions

The USQ determination is not a substitute for a safety analysis; it merely serves as a benchmark for whether the safety basis is being preserved. A safety analysis may show that a proposed change is safe, yet the USQ determination may find that the change creates a positive USQD and therefore requires DOE approval prior to implementation. This procedure clearly establishes the differences between the concepts supporting safety analyses for the DSA and those used for a USQ determination.

Once it has been determined that a USQ determination is required, it can be approached by providing an answer to each of the seven questions identified using the USQ determination process. If any of these questions is answered "Yes," the change is considered a positive USQD. An appropriate justification for each answer shall be recorded. The examples given in the following subsections are provided to help the reviewer identify positive USQDs. They are not meant to be examples of positive USQDs. That determination requires consideration of the DSA for the nuclear facility/activity or other DOE-approved documentation that provides the safety basis for operations or other activities and the specific details of the activity.

Consistent with the guidance in section 3.3 of DOE G 424.1-1, the phrase "an accident previously evaluated in the facility's/activity's safety basis" is understood to include the hazard analysis as well as the accident analysis. The hazard analysis should always be assessed to verify that the change under consideration does not alter the DSA's accident selection (relative to public consequence), introduce a new accident not covered by the hazard analysis (resulting in the identification of new controls or controls at a higher classification level), or increase the worker or public risk profile of an already covered accident, as determined by qualitative judgment at a level consistent with that originally used to develop the hazard analysis. This activity may be denoted

in USQDs by a statement such as "all the accidents analyzed in the DSA were reviewed for potential impact…" The term "accidents" is understood to include the hazard analysis in such usage. Individual scenarios or line entries from the hazard analysis need be cited only to the degree specific clarification of potential impact is deemed necessary.

Note also that DOE G 424.1-1 only discusses positive USQ determinations relative to ensuring adequate protection of the public and providing worker safety. While the 10 CFR 830 rule discusses hazard controls necessary to protect workers, the public, and the environment, the DOE-STD-3009-94 safe harbor methodology specified in the rule is consistent with the guide's emphasis on public and worker protection. DOE-STD-3009-94 specifically states:

> "The numerical Evaluation Guidelines and legal limits on normal operations (i.e., EPA regulations) inherently place an upper bound on potential environmental releases. Further, issues of environmental contamination are not direct safety issues. Safety SSC designations are not required for issues solely related to environmental protection. In accordance with 10 CFR 830, TSR designations are not required for such issues either. TSR designations associated with prevention of uncontrolled release of hazardous materials would typically be assigned for defense in depth considerations."

Accordingly, the environment is intended to be largely covered by the discussion of defense in depth provided in a DSA, including associated functional capabilities and specific control designations cited in that section. Any residual environmental issues should be evaluated in that context if a change has the potential to significantly degrade some localized capability, such as a containment berm, described in the DSA.

A. Could the proposed change increase the probability of occurrence of an accident previously evaluated in the facility's/activity's safety basis?

To understand how the probability of an accident occurring could be increased, it is important to understand how the term "accident" is applied: the term "accident" refers to the anticipated operational transients and postulated accidents considered in the DSA.

In answering this question, the first step is to determine the accidents, which have been evaluated in the previously approved safety basis that may be affected by the proposed change. By focusing on the initiators of the previously evaluated accidents, a determination is made as to whether there is an increased likelihood that a given accident would occur. The following questions may provide a useful approach in making this determination.

(a) Will the proposed change meet the design, material, and construction standards applicable to the structures, systems, and components (SSCs) being modified? If the answer is "Yes," this aspect of the proposed change is judged not to increase the likelihood of the occurrence of an accident. If the answer is "No" to any of the items, either a justification for saying there is no increase in the likelihood of the occurrence of an accident will need to be developed or it is concluded that the likelihood of the occurrence of an accident is increased.

(b) Could the proposed change affect overall SSC performance in a manner that could increase the probability of a previously analyzed accident? Possible questions to ask are:

(1) Could the proposed change use instrumentation with accuracies or response characteristics that are different from those of existing instrumentation and could make an accident more likely to occur?
(2) Could the proposed change cause SSCs to be operated outside their design or testing limits? Examples include the following: overloading electrical systems, overpressurizing a piping system, or operating a motor outside its rated voltage and amperage.
(3) Could the proposed change cause system vibration, water hammer, fatigue, corrosion, thermal cycling, or degradation of the environment for SSCs that would exceed the design limits?
(4) Could the proposed change cause a change to any SSC interface in a way that could increase the likelihood of an accident?

Accident probability classes may be defined as follows:

Anticipated event. The event may occur during the facility or operation lifetime ($f > 10^{-2}$ per year).

Unlikely event. Occurrence of the event is low; it is not expected to occur but may occur during the life of the facility or operation ($10^{-2} > f > 10^{-4}$ per year).

Extremely unlikely event. Occurrence of the event is very low; it is not expected to occur during the life of the facility or operation ($10^{-4} > f > 10^{-6}$ per year).

Beyond extremely unlikely event. Probability of occurrence is so small that events of this type are not normally considered in the design or DSA accident analyses because the event is expected not to occur during the lifetime of the facility or operation ($f < 10^{-6}$ per year).

For Category 3 facilities, this rating scheme can be used to qualitatively attach a probability rating to an event. The determination of a probability increase for Category 3 facilities is based on a qualitative assessment, which uses engineering

evaluations consistent with the original safety analysis assumptions. For Category 2 facilities, actual numerical values may be associated with event probabilities, and increases in probabilities will be more easily identified. For the purpose of USQ determination, changes result in an increase in the probability an accident only if there is a clearly discernible increasing trend. This may be more obvious if the probability of an event occurring increases such that it changes from one probability class to a higher frequency class. Normally, the determination of a frequency increase at this point is based on a qualitative assessment.

The USQ determination does not necessarily require quantification of probabilities if suitable arguments can be made to support the claim that the probabilities will not change. For example, if a change involves new equipment designed and procured to the same requirements as the components being replaced, and which will be functionally identical to the original components (like-in-kind), a statement to this effect (with supporting references) would be adequate to support the claim that no change in the probability of accidents associated with the equipment would be expected.

If, as a result of a proposed change, additional protective measures (either administrative or hardware-related) are warranted during a postulated accident situation to ensure adequate protection of the public or to provide worker safety, the USQ determination shall conclude that the USQ determination is positive, on the basis that the change will result in either an increase in probability or an increase in consequences of an accident. Additional protective measures that are provided to reduce exposures, e.g., those related to ALARA (as low as reasonably achievable) levels, and not related to potential accidents, are not included. DOE involvement is required for several reasons. First, to verify that the degree of protection is adequate. Second, to ensure that the safety basis is properly revised to include the additional protective measures. Third, to verify that any hardware involved is properly classified (for example, as a safety-class or safety-significant SSC) and hence will receive appropriate surveillance and maintenance.

B. Could the proposed change increase the consequences (to workers or the public) of an accident previously evaluated in the facility's/activity's safety basis?

In answering this question, the first step is to determine which accidents evaluated in the safety basis may have their radiological and hazardous material consequences altered as a direct result of the change. The next step is to determine whether the change could, in fact, increase the consequences of any of the accidents evaluated in the safety basis. When a change in consequence during a USQ determination is such that any of the significant digits of the dose reported in the safety basis increases, the change should be considered an increase in consequence. If however, a dose change is of such a magnitude that there is no change of a significant digit of the reported dose, the change should not be considered an increase in consequence. Thus, when reporting doses in an LLNL DSA, care should be given to reporting doses only to the level of significant digits

for which reasonable justification can be given in light of analytical uncertainties. Consequences to facility and on-site workers and the public shall be considered. Examples of questions that assist in this determination are as follows:

(a) Could the proposed change degrade or prevent safety functions described or assumed in the safety basis?

(b) Could the proposed change alter any assumptions previously made in evaluating the radiological and hazardous material consequences in the safety basis?

(c) Could the proposed change play a direct role in mitigating the radiological or hazardous material consequences assumed in the safety basis?

(d) Could the proposed change affect the integrity or function of any fission product barrier or any radioactive or hazardous material barriers?

C. Could the proposed change increase the probability of occurrence of a malfunction of equipment important to safety previously evaluated in the facility's/activity's safety basis?

The safety basis for the facility assume the proper functioning of equipment important to safety in demonstrating the adequacy of design. The proper functioning of other systems, including support systems, is generally assumed. The scope of the USQ

determination shall include these other systems. For example, a change that does either of the following is a change that increases the probability of a malfunction of equipment important to safety:

- Degrades the performance of equipment important to safety, assumed to function in the accident analysis, to below the performance level assumed in the safety basis; or
- Increases the challenge to equipment important to safety assumed to function in the accident analysis (for example, more rapid pressure rise), degrading performance to a level below that assumed in the safety basis.

In answering this question, the first step is to determine what SSCs could be affected by the proposed change. Then the effects of this change on equipment important to safety are evaluated, including both direct and indirect effects. Direct effects are those in which the change affects the equipment (for example, a motor change on a pump). Indirect effects are those in which the change affects one piece of equipment, which in turn can affect equipment important to safety. An example of indirect effects would be one piece of equipment falling on safety equipment.

After the impact of the change on equipment important to safety is identified, a determination is made whether an increase in the probability of a malfunction of the SSCs has occurred. The following are examples of questions that can be used in making this determination.

(a) Will the proposed change meet the original design specifications for materials and construction practices when the following questions are considered:

(1) Are the seismic specifications met (for example, use of proper supports, proper lugging at terminals, and isolation of lifted leads)?
(2) Are separation criteria met (for example, minimum distance between circuits in separate divisions, channels in the same division, and jumpers run in conduit)?
(3) Are the environmental criteria met (for example, use of materials suitable for the radiation or thermal environment in which they will be used)?

(b) Will the proposed change degrade equipment important to safety reliability by

(1) Imposing additional loads not analyzed in the design?
(2) Deleting or reducing system or equipment protection features?
(3) Downgrading the support system performance necessary for reliable operation of the equipment?
(4) Reducing system or equipment redundancy or independence?
(5) Increasing the frequency of operation of systems/equipment?
(6) Imposing increased or more severe testing requirements on systems or equipment?

If the change adversely affects the equipment important to safety, the likelihood of equipment malfunction may be increased. A "No" answer to any question in paragraph C(a) or a "Yes" answer to any question in paragraph C(b) may not mean that there is a negative impact on safety. It would, however, indicate the existence of a positive USQD and the need for further analyses.

The USQ determination does not necessarily require quantification of probabilities if suitable arguments can be made to support the claim that probabilities will not change. For example, if a change involves new equipment designed and procured to the same requirements as the components being replaced and that will be functionally identical to the original components (like-in-kind), a statement to this effect (with supporting references) would support the claim that no change in the probability of malfunctions associated with the equipment is expected. A qualitative engineering evaluation is used to determine if there is an increase in the probability of a malfunction occurring for Category 3 facilities. A more detailed and quantified analysis may be appropriate for Category 2 facilities.

D. Could the proposed change increase the consequence of a malfunction of equipment important to safety previously evaluated in the facility's/activity's safety basis?

This question asks whether, assuming a malfunction of equipment important to safety, the change would result in increased hazardous material or radiological consequences. For example, consider a change that caused a valve in a safety system to fail in the closed position where previously it was assumed to fail in the open position. If this change results in an increase in consequences of an accident, it indicates the change involves a positive USQD. In some situations, such as a loss of a preferred failure mode, the change might not lead to an increase in the calculated consequences but shall be considered within the context of a possible reduction in a margin of safety.

The discussion associated with Item B above applies here for determining what constitutes an increase in consequences.

E. Could the proposed change create the possibility of an accident of a different type than any previously evaluated in the facility's/activity's safety basis?

An accident or malfunction that involves an initiator or failure not considered in the nuclear facility's/activity's safety basis is potentially an accident or malfunction of a different type. An example would be turbine missiles from a gas turbine added as an alternate power source. Certain accidents or malfunctions are not treated in the nuclear facility's/activity's safety basis because their effects are bounded by similar events that are analyzed.

The possible malfunctions or accidents of a different type are limited to those considered to be as likely to happen as those considered in the safety basis. For example, a seismic- induced failure of a component designed to appropriate seismic criteria will not cause a malfunction of a different type. However, a change that increases the probability of an accident previously thought to be beyond extremely unlikely, so that it is as likely as the accidents considered in the safety basis, creates a possible accident of a different type.

In answering this question, the first step is to determine the types of accidents evaluated in the safety basis. The types of credible accidents that the change could create can then be identified and listed. Evaluating the differences between the two lists will determine the answer to the question. The accidents evaluated in the safety basis are generally chosen to be bounding for a broad class of credible accidents. Thus, comparison of a new accident to the existing analyses may require referral to the underlying hazard analyses.

F. Could the proposed change create the possibility of a malfunction of equipment important to safety of a different type than any previously evaluated in the facility's/activity's safety basis?

To answer this question, the types of failure modes of equipment important to safety that have been previously evaluated in the safety basis and that would be affected by the change are identified. Then the types of failure modes that the change could create need to be identified. Comparing the two lists can provide an answer to the question. An example of a change that might create a malfunction of a different type is the relocation of equipment so that it becomes susceptible to flooding; another example is the replacement of a mechanical control system with a digital control system that could fail in a different mode.

A malfunction that involves an initiator or failure not considered in the facility safety basis is potentially a malfunction of a different type. A possible malfunction of a different type could be created by a change that adds a different type or more likely failure path, than previously identified. Certain malfunctions are not treated in the safety basis because their effects are bounded by other related events that are analyzed. If the proposed activity introduces a malfunction that is bounded by other similar events in the safety basis, that activity shall not be considered a malfunction of a different type.

If additional controls not in the approved safety basis are essential to meet the performance criteria of equipment important to safety or to mitigate/prevent an accident that is in the approved safety basis, then this could constitute a positive USQD.

G. Does the proposed change reduce the margin of safety as described in the facility's/activity's safety basis?

This section deals with margins of safety related to DOE-approved hazard control documents. These controls may be Technical Safety Requirements (TSRs), or they may be in another form, as permitted in 10 CFR 830.205 for certain environmental restoration activities.

For purposes of performing the USQ determination where a margin of safety is defined in the DSA, it is the range between two conditions. The first is the most adverse condition estimated or calculated in safety analyses to occur from an operational upset or family of related upsets. The second condition is the worst-case value known to be safe, from an engineering perspective. This value would be expected to be related to the condition at which some accident prevention or mitigation action shall be taken in response to the upset or accident, as required by a DOE-approved TSR, not the actual predicted failure point of some component.

Hazard control documents set forth the minimum acceptable limits for operation under normal and specified failure conditions; they ensure that the available safety equipment

and operating conditions meet the assumptions in the safety basis. They distill those aspects of the safety analyses that are required to ensure the performance of safety SSCs and personnel as relied on and defined in the safety basis.

The bases for a hazard control should define the margin of safety. If the bases of a hazard control do not specifically identify a margin of safety, the DSA and other appropriate safety basis documents shall be reviewed to determine whether the proposed change, test or experiment, or new information has or would result in a reduction in a margin of safety. The judgment on whether the margin is reduced shall be based on physical parameters or conditions that can be observed or calculated.

The safety margin is sometimes implicitly described. A margin of safety can depend on a parameter other than one of the process variables. Therefore, the precise determination of a numerical value associated with a change is not always possible. Implicit margins are, for example, conditions for acceptance for a computer code, method, or industry-accepted practice. It may be sufficient to determine only the direction of the margin change (that is, increasing or decreasing) due to the proposed change.

Safety margins generally include worst-case assumptions of initial conditions, conservative assumptions in computer modeling and codes, allowance for instrument drift and system response time, redundancy and independence of components in safety trains, and plant response during operating transient and accident conditions. A change that affects initial conditions, a system response time, or some other parameter that can affect the course of an accident analysis supporting the bases of hazard controls shall be evaluated to determine whether the change would reduce the margin of safety.

Whether explicit or implicit, margins of safety can only be evaluated to the level of accuracy originally identified in the safety analysis. For example, assessing impacts on a semi-quantitative or qualitative margin of safety will require some degree of subjective judgment.

Appendix F

USQ Determination Worksheet

USQ DETERMINATION WORKSHEET Page 1 of _____

Facility/Activity: _____ **USQ Number:** _____ **Rev.** _____

Title: _____

Summary Questions
(Consider the guidance in Appendix E, Section E.3 of the *USQ Procedure*)

Yes	No	
☐	☐	1. Based on the answers in Part I, could the proposed change increase the probability of occurrence of an accident previously evaluated in the facility's/activity's safety basis?
☐	☐	2. Based on the answers in Part I, could the proposed change increase the consequences (to workers or the public) of an accident previously evaluated in the facility's/activity's safety basis?
☐	☐	3. Based on the answers in Part I, could the proposed change increase the probability of occurrence of a malfunction of equipment important to safety previously evaluated in the facility's/activity's safety basis?
☐	☐	4. Based on the answers in Part I, could the proposed change increase the consequence of a malfunction of equipment important to safety previously evaluated in the facility's/activity's safety basis?
☐	☐	5. Based on the answers in Part II, could the proposed change create the possibility of an accident of a different type than any previously evaluated in the facility's/activity's safety basis?
☐	☐	6. Based on the answers in Part II, could the proposed change create the possibility of a malfunction of equipment important to safety of a different type than any previously evaluated in the facility's/activity's safety basis?
☐	☐	7. Based on the answers in Part III, does the proposed change reduce the margin of safety as described in the facility's/activity's safety basis?

USQ DETERMINATION CONCLUSION

Based on the answers above the change—

☐ **Does not** constitute an Unreviewed Safety Question (negative USQD).

☐ **Does** constitute an Unreviewed Safety Question (positive USQD).

Prepared:_____
Print name Signature Title Date

Reviewed:_____
Print name Signature Title Date

Approved:_____
Print name Signature Title Date

USQ DETERMINATION WORKSHEET Page 2 of _____

INTRODUCTION

A. Describe the aspects of the change being evaluated and its expected effects.

B. Identify the parameters and/or SSCs affected by the change.

C. Identify the SSC failure modes associated with the change.

D. Identify references used for the USQ determination.

PART I: IMPACT ON THE ACCIDENTS EVALUATED AS THE SAFETY BASIS

1. Identify the design basis or evaluation basis accidents reviewed for potential impact by the change.

2. Discuss how the parameters and SSCs affected by the change impact the consequences of these accidents.

3. Identify the design basis or evaluation basis accidents, if any, for which failure modes associated with the change can be an initiating event.

4. Discuss the impact of the change on the probability of occurrence of the design basis or evaluation basis accidents identified in Item 3 above.

5. Identify the equipment important to safety affected by the change.

6. Discuss the impact of the change, or the failure modes or both associated with the change on the probability of failure of the SSCs identified (from item 5 above).

7. Discuss the impact of the change on the performance of the SSCs identified (from item 5 above).

8. Discuss the impact on accident consequences due to a malfunction of equipment important to safety as a result of the change.

BASED ON THE DISCUSSION ABOVE, ANSWER "YES" OR "NO" TO SUMMARY QUESTIONS 1 THROUGH 4 ON PAGE 1.

USQ DETERMINATION WORKSHEET Page 3 of _____

PART II: POTENTIAL FOR CREATION OF A NEW TYPE OF UNANALYZED EVENT

1. Based on Part I assess the impact of the change or the failure modes or both associated with the change to determine whether the impact has modified the facility response to the point where the change can be considered a new type of event. Discuss the basis for this determination.

2. Determine whether the failure modes of equipment important to safety associated with the change represent a new unanalyzed type of malfunction. Discuss the basis for this determination.

BASED ON THE DISCUSSION ABOVE, ANSWER "YES" OR "NO" TO SUMMARY QUESTIONS 5 AND 6 ON PAGE 1.

PART III: IMPACT ON THE MARGIN OF SAFETY

1. Based on the results identified in Part I, discuss the impact of the consequences on the protective barriers against release.

2. Identify how the protective barriers against release, if any, are directly affected by the change or a failure mode of the change.

3. Discuss the impact of the change on the design limits for the protective barriers against release identified above.

4. Identify the margins of safety that are directly or indirectly related to this change.

BASED ON THE DISCUSSION ABOVE, ANSWER "YES" OR "NO" TO SUMMARY QUESTION 7 ON PAGE 1.

Appendix G

Guidance on PISA Identification

G.1 Introduction

The facility DSA, as part of the safety basis, is important to safety for a number of reasons. Among these, the documented safety analysis defines the safety risks that DOE has accepted when authorizing operation of the facility. Because of this feature, that analysis is the baseline reference for the USQ process. If that reference were to be inadequate, the USQ process would be compromised. Therefore, the USQ process includes special actions to be taken if it appears that the DSA might be inadequate or the facility configuration does not match the DSA.

The DSA or facility configuration may be inadequate for any number of reasons. In general, it is possible for a potentially inadequate analysis to arise from three entry conditions: (1) a discrepant as-found condition, (2) an operational event or incident, or (3) new information, including discovery or an error, sometimes from an external source.

The USQ process does not apply to the process of upgrading DSAs in response to new requirements or to the use of new or different analytical tools during the upgrade process. However, the USQ process does apply when there is reason to believe that the current safety basis or facility configuration might be in error or otherwise inadequate, as discussed in the preceding paragraph.

The traditional application of the USQ process is associated with a proposed (i.e., future) change or activity. However, 10 CFR 830.203 adds a second type of change, an "as-found" change, which can lead to a positive USQD. If the understanding of risks associated with a facility's operation is found to be incomplete or inaccurate, then the facility's safety analyses may be inadequate. The safety analyses supporting the existing safety basis may not be bounding, and the inadequacy may present risks greater than those in the current safety basis. For example, the facility may have a potential unanalyzed event that compromises safety or a condition that is outside the facility's safety basis. In addition, a discovered inadequacy could result in a reduced margin of safety.

Depending on the complexity of a situation, a considerable time lapse can exist between the initial discovery of the as-found change and the final determination of whether a positive USQD exists. The intent of 10 CFR 830.203 is to avoid excessive time between the discovery and notification to DOE of a positive USQD. On the other hand, notifying DOE and taking actions based on unconfirmed information is also not desirable.

In view of the above, the term "potential inadequacy of the safety analysis" (PISA) is designated as an intermediate point in the total information evaluation process that precedes the declaration of a positive USQD and completion of an evaluation of safety of the situation, but, for which sufficient "potential" exists for a positive USQD to warrant taking certain precautionary actions. Before a PISA is declared, a reasonable time period is permitted to confirm the significance of the as-found change and assess the potential for a positive USQD. It is recognized that identifying this point in the process cannot be precisely defined; rather, it is based on the judgment of facility management, considering all of the circumstances and factors involved.

G.2 Guidance for Evaluation of Potential Inadequacy

The following set of questions is designed to help and may be used to determine if the discovery of new information, discrepant as-found conditions, or operational events has the potential to call into question the adequacy of the safety analysis. The questions are not meant to be an all-inclusive list but contain an extensive list of situations to consider when evaluating the need for PISA identification. This appendix is intended to be used for guidance only.

1. If facility personnel are notified that a piece of equipment important to safety or a component affecting the safety function of such equipment has experienced a malfunction or a failure under certain conditions: (1) Is this SSC in service? (2) Do (or could) adverse conditions potentially exist in this particular application? (3) Would the validity or adequacy of existing safety analyses potentially be compromised if such equipment were to fail?
2. Has a technological advance occurred such that (1) information assumed in the safety analyses is less conservative than originally thought, and (2) the validity or adequacy of existing safety analyses is questionable?
3. Does an analytical error, omission, or other discovery result in either (1) there potentially being a greater quantity of hazardous or radioactive material vulnerable to release or (2) energy sources available for dispersion of such material being greater than originally assumed?
4. Has there been a discovery of an inaccurate calculation or incorrect assumption that could impact the analyses in a negative manner and make the validity of the existing safety analyses questionable?
5. Has an important piece of safety information been omitted in previous safety analyses?
6. Has a potential new failure mechanism or new accident initiator been identified?
7. Has it been identified that the performance of a piece of equipment important to safety may not meet requirements in the safety basis?

8. Has an actual facility condition been discovered that is potentially beyond the bounds of existing analyses?
9. During an operational event, did the event progress differently than anticipated, and was it inappropriately documented in existing safety analyses because of an invalid analysis or non-conservative assumptions?
10. During an operational event, were the bounds of existing safety analyses exceeded, or was it determined that the event could have reached consequences that exceeded those documented in the existing safety analyses?
11. During an operational event, did the facility respond differently than expected, and was this response inappropriately assumed in the safety analyses because of an invalid analysis or non-conservative assumptions?
12. Was a physical configuration assumed in the safety analysis incorrect at the time of preparing the safety analysis?
13. Has it been discovered that a physical modification, which may affect safety, has taken place at the facility and that this is not reflected in the safety analyses, or does the safety basis inaccurately reflect the as-built condition of the facility?
14. Is the physical configuration of the facility different than as analyzed in the safety basis?
15. Does an analytical error, omission, or other discovery violate or affect the basis for any TSR such that (1) a new TSR may be required, (2) there would be an associated change to the DSA that involves a positive USQD, or (3) the way that the associated TSR could be met, applied, or interpreted is affected?
16. Does an analytical error, omission, or other discovery require a change to any TSR or the development of new TSRs? [If so, DOE approval is required per 10 CFR 830.205(a)(2).]

Appendix H

On-site Transportation Activities USQ Process

On-site Transportation Safety Basis

For the on-site transportation of nuclear materials, the safety basis is the LLNL Interim On-site Transportation Safety Document (IOTSD) which is comprised of:

1. Letter from Hooper to Mara, Modification to the Interim On-site Transportation Safety Document, dated January 14, 2003.

2. NNSA Oakland Operations Office, Assistant Manager for National Security Nuclear Safety Team, Safety Evaluation Report for Lawrence Livermore National Laboratory (LLNL) Interim On-site Transportation Safety, Revision 0, dated April 5, 2001.

3. AMNS-010083: Letter from Hooper to Fisher, Establishment of Lawrence Livermore National Laboratory (LLNL) Interim On-site Transportation Safety Document, dated April 9, 2001.

4. AMNSNST: 010123, Letter from Hooper to Anastasio, Modification to the Interim On-site Transportation Safety Document, dated October 1, 2001.

As specified in the Executive Summary and Section IV of the DOE Safety Evaluation Report, the USQ process shall be applied against the above cited documents and any associated amendments (or superceding documents). In addition, the USQ process is necessary for modifications to packaging and modifications to vehicles that affect DOT requirements, and for procedures that implement the provisions of the On-site Transportation Safety Basis.

The packages approved by DOE for on-site transportation are listed in Section IV (Item 7) of the Safety Evaluation Report and amendments (i.e., DOE letter dated 10/1/01).

The vehicles to be used for transportation of radionuclides meeting or exceeding Category 3 threshold quantities shall satisfy DOT requirements.

USQ Process Applicability

Modifications to approved packages and to vehicles that affect DOT requirements, and changes to procedures implementing the On-site Transportation Safety Basis are required to be evaluated by the USQ process.

Proposed changes to the specific portions of the documents listed above (from Section IV of the Safety Evaluation Report) beyond those inconsequential changes allowed by

DOE in the letter dated October 1, 2001 cannot be evaluated by the USQ process and require DOE approval prior to implementation. Such changes shall be made as a revision to the IOTSD.

USQ Process Initiation and Responsibilities

The USQ process will normally be initiated by the organization that performs the transportation activity (e.g., Materials Management or RHWM) when modifications to approved packaging or vehicles, or changes to procedures that implement the IOTSD are proposed.

The LLNL Program Manager for Packaging and Transportation Safety serves as the LLNL focal point for transportation related USQ issues and is responsible for:

- Maintaining and implementing this Appendix.
- Oversight of and consistent implementation of the USQ process for transportation activities.
- Assuring that impacts to the transportation program are communicated across LLNL programs.
- Delegating approval authority for USQ screenings and USQ determinations related to material shipments to the Materials Management Section Leader in the Mechanical Engineering Department and for waste shipments to the RHWM Division Leader.
- Ensuring that USQ document preparers and reviewers within the PATS program are appropriately trained and qualified.
- Ensuring that USQ documents (i.e., USQ screenings and USQ determinations) are retained.
- Submitting to DOE an annual report summarizing or listing USQ determinations performed since the date of the last report to DOE.

The Materials Management Section Leader in the Mechanical Engineering Department and/or the RHWM Division Leader are responsible for:

- Implementing the USQ process as specified in this procedure.
- Ensuring that USQ document preparers and reviewers, in their respective organizations, are appropriately trained and qualified.
- Approving USQ screenings and USQ determinations related to on-site transportation associated with their respective facilities and operations.

USQ Screening and USQ Determination

Modifications to packaging or vehicles shall be evaluated to determine whether the modification adversely affects the safety performance of the packaging or vehicle. The potential impact on the associated facility's safety basis shall also be considered and may require implementation of the USQ process. Because DOT requires routine maintenance of vehicles, this maintenance is not considered a change that needs to be considered by the USQ process. Modifications to vehicles that maintain or satisfy DOT requirements are also not considered a change that needs to be considered by the USQ process.

Changes to procedures that implement the On-site Transportation Safety Basis will also be considered by the USQ process. Changes to procedures that are clearly editorial; implement formal DOE directions; or do not affect the IOTSD actions, requirements and controls DO NOT need to be considered by the USQ process. The safety of the change will always be considered.

The following forms (USQ Screening Form for On-site Transportation Activities and USQ Determination Worksheet for On-site Transportation Activities) shall be used to document this evaluation. Guidance is provided in Sections C.3 and E.3 for completion of the USQ Screening and USQ Determination forms for facility DSAs. This guidance can be used as references for completion of the USQ Screening Form and the USQ Determination for On-site Transportation Activities. No USQ first-level screenings may be performed.

The purpose of the USQ screening is to determine whether a proposed packaging or vehicle modification or proposed change to procedures could potentially impact the safety performance of the packaging or impact DOT vehicle requirements, or affect procedures that implement the On-site Transportation Safety Basis. If there is a potential impact, a USQ determination shall be performed. If there is no potential impact, the USQ Screening Form for On-Site Transportation Activities is completed and approved, and the modification or change may be implemented.

The purpose of the USQ determination is to evaluate the potential impact of the proposed packaging or vehicle modification and of proposed change to procedures on accidents and consequences to workers and the public. If there is a potential adverse impact on accidents, probabilities, or consequences, the proposed modification shall be submitted to DOE for approval prior to implementation. If there is no potential adverse impact as documented by the USQ Determination Worksheet for On-Site Transportation Activities, the worksheet is completed and approved, and the modification or change may be implemented.

USQ Document Numbering

The numbering scheme described in Section 7.1 will be used; however, the designation of "ORG" will be as follows:

- ORG will correspond to transportation activity organization code, either "MMT" (Materials Management Transportation) or "HWMT" (RHWM Transportation)

USQ SCREENING FORM FOR ON-SITE TRANSPORTATION ACTIVITIES

USQ Number: _____ **Rev.** _____

Title: _____

Issue:

Yes	No	
☐	☐	Is this a temporary or permanent modification to the transportation packaging as described in the On-site Transportation Safety Basis that could impact the packaging safety performance?
☐	☐	Is this a temporary or permanent modification to a vehicle used to transport Category 3 or greater quantities of radionuclides that could affect DOT requirements as described in the On-site Transportation Safety Basis?
☐	☐	Is this a temporary or permanent change to a procedure that implements the requirements in the On-site Transportation Safety Basis?

☐ The issue requires a USQ determination.

☐ The issue does not require a USQ determination.

Prepared:_____

Print name Signature Title Date

Reviewed:_____

Print name Signature Title Date

Approved:_____

Print name Signature Title Date

Justification: *(Description of supporting evidence for exclusion)*

References:

USQ DETERMINATION WORKSHEET
FOR ON-SITE TRANSPORTATION ACTIVITIES Page 1 of_____

USQ Number: _____ **Rev.** _____

Title: _____

Issue:

Yes	No	**Questions** (Note: The Basis section shall be completed for each question)
☐	☐	1. Could the proposed packaging or vehicle modification or procedure change increase the probability of occurrence of an accident previously identified in the On-site Transportation Safety Basis? Basis
☐	☐	2. Could the proposed packaging or vehicle modification or procedure change increase the consequences (to workers or the public) of an accident previously identified in the On-site Transportation Safety Basis? Basis
☐	☐	3. Could the proposed packaging or vehicle modification or procedure change increase the probability of occurrence of a malfunction of equipment important to safety previously identified in the On-site Transportation Safety Basis? Basis
☐	☐	4. Could the proposed packaging or vehicle modification or procedure change increase the consequence of a malfunction of equipment important to safety previously identified in the On-site Transportation Safety Basis? Basis

USQ DETERMINATION WORKSHEET
FOR ON-SITE TRANSPORTATION ACTIVITIES Page 2 of_____

Yes	No	**Questions** (Note: The Basis section shall be completed for each question)
☐	☐	5. Could the proposed packaging or vehicle modification or procedure change create the possibility of an accident of a different type than any previously identified in the On-site Transportation Safety Basis? Basis
☐	☐	6. Could the proposed packaging or vehicle modification or procedure change create the possibility of a malfunction of equipment important to safety of a different type than any previously identified in the On-site Transportation Safety Basis? Basis
☐	☐	7. Does the proposed packaging or vehicle modification or procedure change reduce the margin of safety where described in the On-site Transportation Safety Basis? Basis?

USQ DETERMINATION CONCLUSION

Based on the answers above the packaging or vehicle modification or procedure change—

☐ Does not constitute an Unreviewed Safety Question (negative USQD).

☐ Does constitute an Unreviewed Safety Question (positive USQD).

Prepared:_____
Print name Signature Title Date

Reviewed:_____
Print name Signature Title Date

Approved:_____
Print name Signature Title Date

Appendix I

Key Criteria for Safety Basis Amendments (using DOE-STD-3009 safe harbor methodology)[§]

1. Identify the scope of work associated with the change (this must include intermediate and end state activities) *(10CFR830.204(b)(1), 830.202(b)(1), 10CFR830.202(c)(1) and DOE-STD-3009)*
2. Identify and describe any site/facility changes (*10CFR830.204(b)(1), 10CFR830.202(c)(1) and DOE-STD-3009 Chapters 1 and 2*)
3. Systematically identify any new hazards or modifications to existing hazards, material/energy sources and quantities/forms (*10CFR830.204(b)(2), 10CFR830.202(b)(2), 10CFR830.202(c)(1) and DOE-STD-3009 Chapter 3*)
4. Determine if hazard categorization has changed and basis (*10CFR830.202(b)(3)*)
5. Identify changes to the hazards analysis for normal, abnormal and accident conditions for key receptors (worker, environment and public), unmitigated and mitigated consequence, unmitigated and mitigated frequency and unmitigated and mitigated risk. Also identify any changes to initiators, preventive and mitigative controls. (*DOE-STD-3009 Chapter 3, AICHE Guidelines for Hazard Evaluation Procedures and 10CFR830.204(b)(3))*
6. Provide any changes to the accident selection and accident analyses. (*10CFR830.204(b)(3), DOE-STD-3009 Chapter 3*)
7. For those accidents that challenge the evaluation guideline identify changes to Safety Class Systems, Structures or Components (SSC). (*DOE-STD-3009 Chapter 3*)
8. For the public, worker and the environment, identify changes to safety-significant SSCs and defense-in-depth controls as appropriate. (*DOE-STD-3009, Chapters 3 and 4 and 10CFR830.204(b)(4))*
9. Identify any modifications to safety management programs as appropriate. (*10CFR830.204(b)(5) and DOE-STD-3009, Chapters 6-17*)
10. Provide changes to safety SSC functional requirements, environmental conditions/stresses, performance criteria, etc. (*10CFR830.204(b)(4) and DOE-STD-3009 Chapter 4*)
11. Identify any changes to passive design features (*DOE-STD-3009, Chapter 5*)

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§ **Note that this listing is the <u>minimum</u> set of topics that must be addressed. The Laboratory is expected to address the associated steps in 3009 and 10CFR830 associated with the topics listed above. This list does not apply to annual updates or major modifications.**

12. Based upon the changes, derive TSRs (DOE-STD-3009 Chapter 5, 10CFR830.204(b)(4) and 10CFR830.205(a)(1))
13. Summarize risks overall relative to the changes (DOE-STD-3009)
14. Prepare TSR page changes (including bases)—no graded approach for TSRs (10CFR830.204(b)(4) and 10CFR830.205(a)(2))