

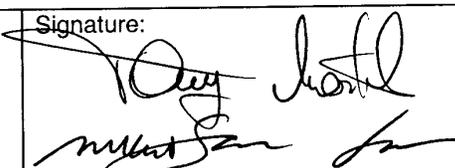
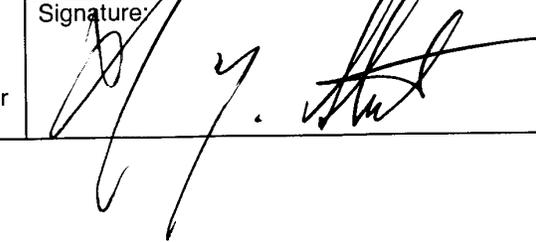
Operational Support Tool 300-00-06C

LANL Unreviewed Safety Question  
Screening and Determination Standard

Los Alamos National Laboratory

Developed by

Facility and Waste Operations Division  
Office of Authorization Basis

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**HISTORY OF REVISIONS**

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1	04/04/01	Updated to incorporate DOE comments and minor editorial comments.
2	12/03/01	Revised requirement for PISA reporting, attached new Attachment G (PISA flowchart), changed training requirements for Applicability Assessments, provided additional guidance for control of hazards during modification implementation process, and incorporated minor editorial changes.

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## 1.0 PURPOSE

This standard specifies the process for conducting Unreviewed Safety Question (USQ) Screens and/or Determinations for changes at Hazard Category 1, 2, and 3 nuclear facilities at the Los Alamos National Laboratory (LANL). The intent of the USQ process is to provide the LANL with the flexibility needed to conduct day-to-day operations and to require that only those changes with a potential impact on the safety basis, and therefore the safety of the facility, be brought to the attention of DOE for approval, prior to making the change.

It also provides for an assessment of the applicability of the USQ process to various situations, for facilities that do not yet have the USQ process integrated into the change control process. The USQ process provides a mechanism for keeping a safety basis current by reviewing potential USQs, reporting USQs to DOE, and obtaining approval from DOE prior to taking any action that involves an USQ.

The intent of the process is to allow the LANL to make physical and procedural changes and to conduct tests and experiments without prior DOE approval provided these activities do not result in an USQ.

This standard implements the requirements of LIR 300-00-06, 10 CFR 830.203 (Nuclear Safety Management Rule), the guidance of the Implementation Guide to 10 CFR 830.203, and DOE Order 5480.21. This standard applies to all nuclear facilities at the LANL.

In order to facilitate the development of consistent USQ procedures at LANL, each nuclear facility at LANL is required to develop a facility-specific USQ procedure based on Operational Support Tool 300-00-06B, LANL Unreviewed Safety Question Screening and Determination Procedure.

## 2.0 SCOPE

The USQ process is intended to be a part of a broader change control process. As such, the USQ process has the same inputs. These inputs include (1) all temporary or permanent physical changes at the facility; (2) all temporary or permanent changes to procedures at the facility; and (3) all activities, operations, tests, or experiments that are new to the facility. As part of the change control process, an assessment of the applicability of the USQ process to the situation is appropriate. The scope of the USQ process includes both safety SSCs and nonsafety SSCs. The USQ process includes USQ screening and the USQ determination (USQD). During the USQ screening, each change is assessed to see if it warrants the performance of a USQD. In addition, the USQ process inputs encompass the possibility that the documented safety analysis for the facility may not be adequate.

The USQ process is facility specific. This is because the baseline reference for the USQ process is the safety basis, which consists of facility-specific documentation. The USQ process applies not only to changes within the boundaries of nuclear facilities but also to changes outside those boundaries when those changes have the potential to affect the safety of the operations within the boundaries.

### 3.0 DEFINITIONS AND ACRONYMS

The acronyms and definitions of terms that are used in a special way in this standard are provided in **Attachment A** to this standard.

### 4.0 PRECAUTIONS AND LIMITATIONS

#### 4.1 DETERMINATION OF FACILITY SAFETY

The title of the process, "Unreviewed Safety Questions", may suggest that the process determines the safety of changes. However, the USQ process is intended to determine the final approval authority for a change. It is not intended to replace or to serve instead of a hazard analysis or safety analysis of the change. A hazard analysis or safety analysis is different from a USQ determination. Hazard and safety analyses are an organized effort to identify and analyze the significance of hazardous situations associated with a process or activity and to develop the appropriate set of controls.

The safety implications of a proposed change should be reviewed, analyzed, understood, addressed, determined to be acceptable, and documented separately from the USQ process. Using the USQ process instead of the hazard analysis or safety analysis complicates the USQ process. Further, such a usage is inappropriate because the seven questions to be answered in the USQD are not geared toward understanding whether the change is safe, but rather if any of the probability or consequence risk factors may have increased beyond what has been accepted previously by DOE, and hence if the existing safety controls remain adequate. The change should already be known to be safe before it enters the USQ process.

The USQ process determines if final approval by the LANL is sufficient or DOE review and approval are required. If the facility wants to implement changes, DOE must review and approve those changes that involve a USQ (that is, the USQD is positive) to verify that the safety controls are adequate to provide an acceptable level of safety to the public, the environment, and workers. The existence of a positive USQD does not mean that the change is unsafe, but only that DOE must take the final approval action.

#### 4.2 CONTROL OF HAZARDS DURING INSTALLATION WORK ACTIVITY

Appropriate safety management programs (such as work planning and control that includes job hazard analysis or a similar process) should address hazards that may be involved during the installation of a modification. For worker protection, DOE relies on the LANL's commitment to various safety management programs to address the hazards involved in the actual installation of a modification, not the USQ process. These programs include radiation protection, hazardous material protection, work planning and control, OSHA, ALARA, and lockout/tagout. One basic tenet of the USQ process is to assess the potential change in probability and consequence risk factors that might be involved when facility operations are resumed after the modification is implemented.

However, sometimes a modification might be only partially implemented because it is interrupted by unforeseen circumstances. In such cases, the USQ documentation would need to be revisited to ensure that it adequately addresses operation with the partially implemented configuration.

During the installation period for construction, modification and routine maintenance activities at nuclear facilities, authorization basis/safety basis (AB/SB) requirements, including controls, may be violated in the absence of proper planning. The TSR/OSR/ITSR Limiting Conditions for Operation are expected to be the primary requirements that could be affected by actions taken or controls not implemented during the construction or maintenance period. TSR design requirements and administrative controls could also be affected. Work packages should include steps to address this issue. When temporary/interim equipment configurations are implemented that are not covered by the existing AB/SB, controls and/or compensatory measures should be included in the work package and reviewed in the USQ process. Removal of controls should be addressed in the planning process and the work package.

### **4.3 GRADED APPROACH**

The Graded Approach is applied to the USQ process only indirectly. During the hazard analysis and safety analysis processes, SSCs are classified as Safety-Class, Safety-Significant, otherwise important to safety, or non-safety. Once these classifications are established, they are used to indicate how much effort should be applied in the hazard analysis and safety analysis processes. However, no steps of the USQ process can be eliminated based on such grading.

The only application of the graded approach to the USQ process is indirect. The graded approach may give a rough indication of how much justification or basis information should be provided when explaining the answers to each of the seven USQD criteria. More elaborate and thorough basis information would be expected for changes to safety SSCs than for non-safety SSCs. In any case, the justification for the answers to the USQD criteria needs to be defensible.

### **4.4 CONSTRAINTS**

The USQ process is an inappropriate vehicle for establishing new constraints on the change. The change should be evaluated the way it is presented, not in some way that would enhance or improve the change from a USQ perspective. The USQ process must not establish or imply any constraints on the change.

## 4.5 DOE DIRECTED CHANGES

The USQ process must be applied to day-to-day changes required to operate the facility including those changes directed by DOE. The notion that a DOE directed course of action requires no further DOE approval is incorrect. All changes require some level of safety evaluation, regardless of any DOE programmatic or operational directive or need. Typically, the parts of DOE that have the funds and authorize programmatic actions have little if any knowledge or involvement in facility safety reviews. Therefore, it is incorrect to assume that if one part of DOE has authorized certain actions, all of DOE has reviewed these actions and that the authorization includes the necessary safety reviews and approvals.

## 5.0 REQUIREMENTS AND GUIDANCE

This section provides a summary of the Nuclear Safety Management Rule requirements, a list of applicable DOE Orders, and guidance on how to implement the Nuclear Safety Management Rule requirements per IG-830.203.

### 5.1 SUMMARY OF 10 CFR 830.203 REQUIREMENTS

§ 830.203 Unreviewed safety question process.

- (a) The contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must establish, implement, and take actions consistent with a USQ process that meets the requirements of this section.
- (b) The contractor responsible for a hazard category 1, 2, or 3 DOE existing nuclear facility must submit for DOE approval a procedure for its USQ process by April 10, 2001. Pending DOE approval of the USQ procedure, the contractor must continue to use its existing USQ procedure. If the existing procedure already meets the requirements of this section, the contractor must notify DOE by April 10, 2001 and request that DOE issue an approval of the existing procedure.
- (c) The contractor responsible for a hazard category 1, 2, or 3 DOE new nuclear facility must submit for DOE approval a procedure for its USQ process on a schedule that allows DOE approval in a safety evaluation report issued pursuant to section 207(d) of this Part.
- (d) The contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must implement the DOE-approved USQ procedure in situations where there is a:
  - (1) Temporary or permanent change in the facility as described in the existing documented safety analysis;
  - (2) Temporary or permanent change in the procedures as described in the existing documented safety analysis;
  - (3) Test or experiment not described in the existing documented safety analysis; or
  - (4) Potential inadequacy of the documented safety analysis because the analysis potentially may not be bounding or may be otherwise inadequate.

- (e) A contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must obtain DOE approval prior to taking any action determined to involve a USQ.
- (f) The contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must annually submit to DOE a summary of the USQ determinations performed since the prior submission.
- (g) If a contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility discovers or is made aware of a potential inadequacy of the documented safety analysis, it must:
  - (1) Take action, as appropriate, to place or maintain the facility in a safe condition until an evaluation of the safety of the situation is completed;
  - (2) Notify DOE of the situation;
  - (3) Perform a USQ determination and notify DOE promptly of the results; and
  - (4) Submit the evaluation of the safety of the situation to DOE prior to removing any operational restrictions initiated to meet paragraph (g)(1) of this section.

## 5.2 DOE ORDERS

DOE retains DOE Orders 5480.21, 5480.22, and 5480.23 during the transition period for the rule. These orders are in the LANL contract requirements and the contract requirements are not changed by the issuance of the Nuclear Safety Management Rule. To the extent there are any conflicts between the rule and the UC contract terms and conditions, the provisions of the rule take precedence. [Federal Register/Vol. 65, No. 196, page 60302: Supplementary Information IV.A and B, October 10, 2000]

## 5.3 GUIDANCE TO IMPLEMENT 10 CFR 830.203 REQUIREMENTS

Each nuclear facility should identify the methods by which facility changes can be made (e.g., whether changes are made under modification processes, non-conformance processes, or maintenance processes). After these methods have been identified, each facility must determine what constitutes an acceptable means to make a change. That is, the facility must clearly control the facility change process and must perform and document changes in accordance with approved procedures. Performing a modification under the guise of maintenance is not acceptable because the proper control processes to analyze the proposed change and document its outcome would probably be absent. Identification of all means for performing a change is necessary because each one provides a direct input into the USQ process and must be integrated accordingly. An example of the Change Control Process is provided in **Attachment C**.

The USQ process is intended to be implemented as part of a change control process that includes 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. As part of the technical reviews of a change, the facility should perform the appropriate type of safety analysis to ascertain if the change is indeed safe. This is accomplished separately

from the USQ process. The USQ process is used subsequently to determine if final approval of the change by the LANL is sufficient or if DOE approval must be obtained.

The USQ process should be integrated into the facility's change control processes. The change processes should ensure that the USQ process is integrated into existing procedures or that new procedures are developed, as necessary, and that the need for completion of a USQD is not overlooked.

Each facility should develop its own change flow process for both temporary and permanent changes to SSCs and documents. This process and its integration should be described by a governing policy, procedure, flow chart, or other description. The purpose of the governing document is to define clear relationships between the USQ process and other change control procedures, including design change procedures, configuration control programs, temporary change procedures, and procedures governing the preparation, review, and approval of procedures. Its purpose is to describe how the USQ processes required by the Nuclear Safety Management rule are integrated into the facility's processes and not to implement the details of the rule independently.

## **6.0 QUALIFICATIONS AND TRAINING**

The LANL realizes that 10 CFR 830.203 does not include explicit requirements for qualification of USQ personnel. However, as explained in the Supplementary Information portion of the Federal Register Notice of October 10, 2000 when 10 CFR 830 was amended, such qualification is required nonetheless (see 65FR60304, paragraph V.A.). The USQ process is important to safety. Therefore, to ensure quality in the performance of that process, the personnel who prepare, review, or approve USQ documents must be qualified to perform their assigned work. This includes both initial qualification and periodic requalification. This requirement for qualification of USQ personnel is consistent with the requirements for quality assurance, such as those codified in 10 CFR 830.122(b). USQ documents include: USQ screens and USQDs. Assessments of applicability of the USQ process are not considered USQ documents for the purposes of the following qualification considerations. USQ qualification includes appropriate consideration of education, experience, specialized technical training, and self-study.

Facility personnel responsible for preparing, reviewing, or approving USQ documents (screens or determinations) must receive initial training on the application of the Nuclear Safety Management rule and facility-specific procedures. In addition, personnel must have the required educational background, work experience, knowledge of the facility, understanding of DOE requirements related to the generic safety basis (including the USQ process) and familiarity with the facility-specific safety basis prior to participating in the USQ process.

Specific types of personnel at a facility may include a “Safety Basis Manager” and a “Training Coordinator”. The Safety Basis Manager with the support of the Training Coordinator will develop and implement a training and qualification program for facility personnel, who implement the USQ process. The Training Coordinator must develop and maintain a list of all personnel currently qualified to perform, review, and/or approve USQ Screens and Determinations. This list must be updated as required to ensure that the list is current and complete. At a minimum, copies of the list of qualified personnel will be provided to the Facility Manager and Safety Basis Manager.

At a minimum, facility personnel preparing, reviewing, and approving USQ documents must have:

1. A BS in engineering or one of the physical sciences or equivalent approved by facility management,
2. Two years of experience at a nuclear facility, at least one year of which is at the facility where the USQs will be processed, or an approved equivalent level of experience,
3. Satisfactory completion of the LANL Site-Specific Initial USQ training course, and
4. Demonstrated knowledge of the facility Safety Basis.

Personnel preparing USQ process applicability assessments must be appropriately qualified in the change control process. Additionally, facility personnel preparing USQ applicability assessments must have:

1. At least one year experience at the facility where the USQs will be processed, or an approved equivalent level of experience,
2. Satisfactory completion of the LANL Site-Specific Initial USQ training course, and
3. Demonstrated knowledge of the facility Safety Basis.

Personnel preparing, reviewing, and approving USQ documents (screens or determinations) must maintain proficiency and be requalified nominally every 2 years. Proficiency is maintained by having performed, reviewed, or approved a minimum of four USQ Determinations over the two-year period. If proficiency is maintained, requalification may be achieved by the completion of the LANL site-specific re-qualification/refresher training class. If proficiency has NOT been maintained, re-qualification is achieved by the completion of the LANL site-specific initial USQ training class. If the individual does not complete requalification within 30 months, the qualification shall be expired.

LANL management personnel who acknowledge USQ documents subsequent to the facility management approval of USQ documents shall complete as a minimum the USQ introductory training course on the USQ process.

## 7.0 RESPONSIBILITIES

In the absence of any individuals identified in the list below, the Facility Manager shall assume these responsibilities.

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**Facility Manager**

- ◆ Establishes and maintains the Authorization Agreement with DOE which identifies the current safety basis documents in accordance with LIR240-01-03.
- ◆ Ensures that USQ processes are integrated with facility activities, particularly change control.
- ◆ Oversees the USQ process at the facility.
- ◆ Approves the knowledge requirements for personnel preparing, reviewing and approving USQ screens and/or determinations at the facility.
- ◆ Approves all USQ determinations per requirements for approvers specified below.
- ◆ Approves requests for amendments to the facility safety basis.
- ◆ Ensures that potential inadequacies in the safety analysis are addressed in a timely manner in accordance with this standard.
- ◆ In the absence of an assigned person, assumes the roles and responsibilities of the Safety Basis Manager.

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**Safety Basis Manager**

- ◆ Implements the USQ process at the facility.
  - ◆ Directs the training and qualification of USQ preparers, reviewers and approvers and USQ process applicability assessment preparers.
  - ◆ Determines the facility specific knowledge requirements for personnel preparing, reviewing, and approving USQ screens and/or determinations.
  - ◆ Maintains a list of the current safety basis documentation for the facility.
  - ◆ Ensures that controlled copies of safety basis documentation are used to perform USQ screens and determinations.
  - ◆ Assigns qualified personnel to prepare and review USQ screens and/or USQ determinations.
  - ◆ Approves USQ screens per requirements for approvers specified below.
  - ◆ Reviews USQ determinations per requirements for reviewers specified below.
  - ◆ Prepares requests for amendments to the facility safety basis.
  - ◆ Implements a system for labeling and tracking USQ screens and determinations.
  - ◆ Ensures that completed USQ documents are properly forwarded to records management for retention.
  - ◆ Prepares the annual summary of USQ determinations for submission to the OAB.
  - ◆ Advises management personnel on USQ issues.
  - ◆ Reviews Tenant and Facility documents for USQ issues.
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<b><i>USQ preparers, reviewers, and approvers</i></b>	<ul style="list-style-type: none"> <li>◆ Qualify and maintain proficiency on the USQ process for the assigned facility (ies).</li> <li>◆ Maintain a thorough knowledge of the safety basis for the facilities to which they are assigned.</li> <li>◆ Complete applicable portions of the USQ process as directed by this standard for preparation, review and approval of USQ applicability assessments and USQ screens and/or determinations.</li> <li>◆ Ensure that only the most current and controlled versions of safety basis documentation and procedures are used in this process.</li> </ul>
<b><i>USQ process applicability assessment preparers</i></b>	<ul style="list-style-type: none"> <li>◆ Qualify and maintain proficiency on the USQ process applicability for the assigned facility (ies).</li> <li>◆ Qualify and maintain proficiency on this aspect of change control.</li> <li>◆ Maintain a thorough knowledge of the safety basis for the facilities to which they are assigned.</li> <li>◆ Prepare assessments of the applicability of the USQ process in accordance with this standard.</li> </ul>
<b><i>Records Management and Document Control</i></b>	<ul style="list-style-type: none"> <li>◆ Maintains all USQ and safety basis documentation as controlled documents.</li> </ul>
<b><i>The Facility Safety Basis Review Committee (Optional)</i></b>	<ul style="list-style-type: none"> <li>◆ If established, meets to discuss USQ screens and/or USQ determinations, as directed by the Facility Manager or designee.</li> </ul>
<b><i>Training Coordinator</i></b>	<ul style="list-style-type: none"> <li>◆ Assists the Safety Basis Manager in establishing and implementing the training and qualification program for USQ preparers, reviewers, and approvers and USQ process applicability assessment preparers, reviewers, and approvers.</li> <li>◆ Maintains a list of qualified USQ preparers, reviewers, and approvers and USQ process applicability assessment preparers.</li> <li>◆ Alerts the Safety Basis Manager and/or Facility Manager and qualified personnel when retraining is required.</li> </ul>
<b><i>FWO Office of Authorization Basis (OAB)</i></b>	<ul style="list-style-type: none"> <li>◆ Coordinates reviews of positive USQDs using a team of qualified reviewers prior to submittal of the change to DOE.</li> <li>◆ Concurs with decision to submit a change to DOE for approval.</li> <li>◆ Oversees the USQ process to ensure a quality process is maintained.</li> <li>◆ Collates the annual facility USQD summaries for the LANL and submits them to DOE.</li> <li>◆ Implements lessons learned.</li> <li>◆ Reviews and approves facility specific USQ procedures.</li> </ul>

## 8.0 USQ PROCESS APPLICABILITY ASSESSMENT, SCREENING, AND DETERMINATION PROCESS

### 8.1 GENERAL OVERVIEW

All proposed activities or changes to activities within the nuclear facility as well as those outside the facility boundary that might affect the safety of the operation of the nuclear facility must be reviewed to determine the applicability of the USQ process. The USQ process is part of a broader process known as change control and hence they share common inputs. The inputs to change control, which was discussed in Section 5.3, include:

- (1) All activities, operations, tests, or experiments that are new<sup>1</sup> to the facility;
- (2) All temporary or permanent changes at the facility; and
- (3) All temporary or permanent changes to documents at the facility.
- (4) A potentially inadequate safety analysis (PISA). [In addition to inputs 1-3 from the change control process, the USQ process also has an input related to potentially inadequate safety analysis (PISA), which is addressed in Section 9.0]

These generic inputs are shown on the left side of the figures in **Attachments B and D**.

Activities that lead to these USQ process inputs include:

- a. Modifications, both temporary or permanent, to facility SSCs;
- b. Revisions, both temporary or permanent, to facility procedures;
- c. Changes, both temporary or permanent, to programmatic or experimental operations (either hardware, software, or procedures);
- d. Discrepant as-found conditions;
- e. Dispositioning of non-conformance reports, and
- f. Maintenance activities.

As these various situations are being processed within change control, the question arises of who has the approval authority for the change. Or, said another way, is it necessary to enter the USQ process for this situation? Is the USQ process applicable to the current situation? To address this question, use a USQ process applicability assessment, which is explained in Section 8.2 below. The USQ process applicability assessment could be viewed as the gateway into the USQ process. It could be argued that the applicability assessment is part of change control and not a part of the USQ process. Nonetheless, the USQ process applicability assessment is included in this

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<sup>1</sup> Programmatic operations that have been previously performed in the facility but are not described in the current DSA are new activities and require USQ screening.

LANL USQ standard for use by facilities that do not have a robust change control process.

The general USQ process consists of two key steps:

- USQ Screening
- USQ Determination

NOTE: Previously, the USQ process included three key steps because the need for a change to the TSR requirements was considered within the USQ process as well as within the TSR program. 10 CFR 830.203, 01/10/01, deleted this repetitious consideration from the USQ process. Changes to TSRs are discussed in section 8.2.2 below.

The USQ process is illustrated in **Attachments B, C, D and E**. Attachment B illustrates the fundamental USQ process in its context of being part of a change control process. As shown in this figure, changes enter the USQ process from the Facility Change Control process. Attachment C illustrates the Change Control process. Attachment D provides a detailed outline of the process of assessing if the USQ process applies. Attachment E illustrates the logic of the USQ Screening steps.

The facility safety basis is the baseline point of reference for the USQ process. The Safety Basis Manager maintains a list of the specific documents that are currently designated to be part of the facility safety basis. Personnel involved in the USQ process should have ready access to copies of all safety basis documentation. Those copies must be verified to ensure that only the versions that are currently part of the safety basis are used in the USQ process, such as through a controlled document process.

## 8.2 USQ PROCESS APPLICABILITY

As outlined by 10 CFR 830.203 Implementation Guide section III.A, the USQ process should be integrated into the facility's change control processes. Although the USQ process applicability assessment is not a part of the USQ process itself, the LANL nuclear facilities are responsible to ensure that the steps outlined below are clearly defined in the existing change control procedure to ensure that all changes requiring USQ screening and/or USQ determination enter the USQ process.

The USQ process applicability assessment is the method for determining whether or not it is necessary to apply the USQ process. Screening of items from entering the USQ process is an accepted and necessary part of the process to reduce the number of USQ screens and determinations to those that could potentially impact the safety of the facility operations. The USQ process applicability assessment process is a time and labor saving effort, but it must be properly documented in order to ensure that the USQ process has not been bypassed and that the safety basis has been maintained. In some situations, the applicability assessment might determine that the matter does not require any further USQ consideration. In other situations, the assessment may determine that the matter should proceed directly to a USQD without any further screening consideration.

Personnel preparing USQ process applicability assessments must be appropriately qualified.

### 8.2.1 Changes that do not enter the USQ process and do not require DOE approval

It is not necessary to enter the USQ process for every situation. In some of those situations, the change does NOT require DOE approval. These include:

- a) Maintenance actions that involve the replacement of SSCs with an exact replacement (that is, same make, manufacturer, model number, etc.),
- b) Maintenance actions that involve the replacement of SSCs with an Approved Equivalent Part (for which a facility engineer has determined and documented that the replacement part meets all the requirements relevant to the specific facility application),
- c) Changes to programmatic operations (including experimental and research activities, hardware, software, and procedures) that remain within the safety envelope already approved for the operation or activity. This provision presumes that an appropriate safety envelope has been established, reviewed, and approved, and that the safety envelopes for all such programmatic activities are enveloped by the facility's documented safety analysis. This approach assures that as long as the safety envelope for a particular programmatic operation remains valid, the documented safety analysis for the facility cannot be in jeopardy. This approach provides the maximum programmatic flexibility while providing adequate safety protection. In order to be considered covered by the established safety envelope, the facility must demonstrate in a documented fashion that:
  - a hazard analysis (safety envelope) has been established for each programmatic operation, and
  - the change to an existing programmatic operation will not adversely impact the hazard analysis (safety envelope) for that operation.

These steps provide maximum programmatic flexibility to avoid curbing creativity and still provide adequate safety protection,

- d) The non-conforming part is restored to become compliant with the requirements. In a typical QA program, there is a set of standard dispositions for non-conformances. These may include: a "reject" disposition in which the non-conforming part is replaced with a conforming part, a "Use-As-Is" disposition in which the non-conforming part is justified as not meeting all functional requirements but is nonetheless an acceptable part, a "repair" disposition in which the part is made to agree better with the requirements for the part (but it remains not fully compliant with the requirements), and a "rework" disposition in which the part is restored to the point that it becomes fully compliant with the requirements, (NOTE: Discovery of a nonconforming part in an operating system, requires that the facility evaluate the operability

of the system and take appropriate steps to report the condition and place the facility in the required operating mode.)

- e) Modifications to return to the original condition as corrective action to resolve discrepant as-found conditions (i.e. exact restoration), [If the disposition of the discrepant as-found condition is a “restoration modification”, then this corrective action hardware modification will exit the USQ process. If not, the as-found condition must be considered further within the USQ process],
- f) Purely editorial changes that do not affect the technical content.

### **8.2.2 Changes that do not enter the USQ process but do require DOE approval**

The USQ process is not applicable to situations that are beyond the scope of day-to-day operations, and hence the LANL is required to submit those changes to DOE for approval. Such situations include:

- a) Changes that introduce a technology that is new to the facility,
- b) Changes that are major modifications, in that they go beyond those necessary for day-to-day operations,
- c) Changes that management has predetermined to submit to DOE for safety review and approval, and
- d) Changes to the TSRs.

If the change introduces a technology that is new to the facility (for example, a high energy x-ray machine at a facility that has not previously had similar equipment), the change is beyond the intended scope of the USQ process (as envisioned by DOE 5480.21) and hence requires approval by DOE prior to implementation.

The USQ process is not applicable to major modifications. Because they have a major impact on the existing safety basis of the facility, DOE must approve them. In most cases the safety document associated with such a change is a preliminary documented safety analysis. [10 CFR 830.206(b)]

The Nuclear Safety Management rule requires that changes to the TSRs be submitted to DOE for review and approval. A change to the TSRs could involve the need either to modify an existing TSR or to add a new TSR. If the entirety of the change is merely a change to the requirement of the TSRs, then that change should be submitted to DOE for review and approval without having to perform a USQ screen or USQD. However, most real-world changes involve something more, such as a procedure change, a physical change, or a new activity. In those situations, it is necessary to point out that the whole change must be submitted, not simply the word change for the TSR without the underlying change. The basis for not having to go through the USQ steps is that the entire change is already going to DOE. If the whole change were not already going to DOE, it would become necessary to complete the USQ steps.

Until further clarified, the LANL requires that any change to the bases of the TSRs, even those considered editorial, shall be submitted to DOE for review and approval.

The scenarios above require the facility to request an amendment to the facility safety basis. The preparation of such a request is discussed in Section 8.6 below.

**Attachment F** to this standard provides the worksheets to be used for the USQ process applicability assessment, screening, and determination, and addresses the USQ process applicability steps in more detail. Except where specifically instructed otherwise, all the steps of the USQ process applicability assessment are to be completed. The questions included in the USQ process applicability assessment section are intended to provide a method for documenting those changes that do not require entry into the USQ process.

### 8.2.3 Changes that must enter the USQ Process

Section 830.203, "Unreviewed Safety Question Process," applies to all Hazard Category 1, 2 and 3 nuclear facilities. However, the previous two sections indicate that not all changes require application of a USQ process.

The applicability of Section 830.203 is broad. Non-safety-related systems are not excluded by the scope of Section 830.203 if they could affect the proper operation of safety SSCs relied on in the safety basis. For example, losses of certain non-safety-related systems may represent critical operational occurrences identified as initiators in the accident analysis. Therefore, changes to non-safety-related systems must be evaluated and may be determined to involve an Unreviewed Safety Question (USQ).

Physical interactions may also fall under the purview of Section 830.203. For example, the installation of a non-seismically supported piece of equipment above a seismically qualified component designed to perform a safety function explicitly described or implicitly assumed in the existing safety analyses may constitute a USQ and must be evaluated.

The following sections discuss the types of changes, tests, and experiments, as well as potential inadequacies in the documented safety analysis that the USQ process needs to address to comply with the Nuclear Safety Management rule.

- a) A temporary or permanent hardware and/or software change in the facility as described in the existing documented safety,
- b) A temporary or permanent change in the procedures as described in the existing documented safety analysis,
- c) A test or experiment not described in the existing documented safety analysis,
- d) A potential inadequacy of the documented safety analysis (PISA) based on:
  - a discrepant as-found condition, including a discrepancy with the requirements of the TSRs,
  - the receipt of new information, or an operational event, or

- the discovery of a potentially inadequate documented safety analysis.

The example Change Control Process in **Attachment C** illustrates the interrelationships between the facility change control process and the USQ process.

The change control process should provide a documented hazard analysis or safety analysis for the change, if applicable. If a hazard analysis or safety analysis has not been provided, the change should be returned to the change control process to develop such an analysis.

### 8.3 USQ SCREENING

Although some changes must enter the USQ process, they may not need a detailed USQ determination. USQ screening is intended to be a simple Go/No-Go decision-making step.

Changes that are not eliminated during the USQ process applicability assessment need to go through a formal USQ screening. The use of “Commercial Practices” for implementing a change is not definitive in determining as to whether or not the change is within the safety basis. Therefore, although not required by DOE, the LANL requires that changes for which normal commercial practices may be sufficient and a nuclear-grade formal change control process seems unwarranted, must enter the USQ process. This allows the facility to determine if the proposed change could affect the ability of safety SSCs to perform their intended functions (due to the introduction of new interactions and hazards).

The necessity to distinguish between changes and routine maintenance activities is an important consideration. Routine maintenance activities (except those that are not enveloped by current analyses or that might violate a TSR) do not require review under the rule. Examples of routine maintenance activities include calibration, refurbishment, exact replacement, and replacement with an equivalent component as discussed in section 8.2.1. Refer to section 4.2 for control of hazards during the installation process.

Systems or components removed from service for maintenance should be covered by the TSR for allowable outage times, permissible mode conditions, and permitted reduction in redundancy. A USQD, therefore, need not be performed for these activities. However, for safety systems or components that are included in the safety basis for the nuclear facility, and for which allowed outage times are not included in the TSRs, a USQD should be completed.

The conservative approach is to provide a written USQD for any change to the nuclear facility, whether discussed in the existing safety basis or not. However, it is possible that some changes can be justified as not requiring determinations under Section 830.203, as long as screening criteria are developed that will ensure that there are no indirect or secondary effects of the change. In this case, the screening criteria are relied on to ensure that the change does not introduce a USQ.

The screening process is outlined in the process flow chart in **Attachment E**.

A USQ qualified person must perform the USQ screening. It is important that the screening process does not inappropriately screen out conditions requiring a USQD. A basis for each of the questions must be provided.

If the USQ process was entered because of a PISA, screening is not applicable. Proceed directly to the USQD section 8.4.

### 8.3.1. Screening Part I

The responses to the following questions will determine if a USQ Determination is required:

***a. Is this a purely editorial change that does not affect the technical content?***

If the answer is YES, this change will screen out.

***b. Is this change covered by a DOE approved Categorical Exclusion?***

A different manner in which screening criteria may be applied is through categorical exclusions approved by DOE (for example, different procedure types). However, it should be understood that, whenever screening criteria are applied in this manner, the facility must provide DOE with justification of why a categorical exclusion (for example, of maintenance procedures) from the USQ process is acceptable.

If the answer is YES, this change will screen out.

**DISCUSSION:**

For example, a basic premise of performing maintenance is that the SSC and the facility will be restored to the exact functional condition it was in prior to the maintenance action. That is, the functional capability will continue to meet or exceed those performance requirements set forth in the safety basis. Under these circumstances, a change to a maintenance procedure would not result in a change to the facility and would therefore result in a negative USQ screen or determination, if performed. Rather than perform a USQ determination for each change to a maintenance procedure, the facility may choose to prepare a categorical exclusion and submit it to DOE for approval.

***c. Is this change covered by a previous USQD?***

Another possible screening consideration is the possibility that the matter being considered is fully covered by a previous USQD, even when location differences are considered.

If the answer is YES, this change will screen out.

### 8.3.2. Impacts

Once it has been determined that the change cannot be screened out as discussed in section 8.3.1 above, all areas impacted by the change shall be identified. The responses to the following questions will provide the basis for properly responding to the questions in section 8.3.3:

- a. *Identify all Safety Basis documents, procedures, tests and experiments that may be impacted by this change (e.g. FSAR, TSRs, Procedures, etc.):***

Include all applicable Safety Basis documentation. Each document listed here should also be listed in the Reference section. Consider both direct and indirect impacts on each document, procedure, test, experiment, and programmatic operation. If no documents, tests, experiments, or programmatic operations are impacted, state that.

- b. *Identify all accidents evaluated in the facility Safety Basis that may be impacted by this change:***

Identify the accidents that may be affected by any of the failure modes associated with the change.

- c. *Identify all safety SSCs described in the current Documented Safety Analysis that may be impacted by this change:***

Include all applicable safety-significant and safety-class SSCs. Consider both direct and indirect effects. If no SSCs are impacted, state that.

- d. *Identify all equipment important to safety other than safety SSCs that may be impacted by this change:***

Include all applicable equipment important to safety other than safety SSCs. Consider both direct and indirect effects. If no equipment important to safety other than safety SSCs is impacted, state that.

- e. *Identify credible dominant failure modes, process parameters, and malfunctions associated with this change:***

Reference appropriate Hazards Analyses and/or Failure Modes and Effects Analyses, and summarize the results of these analyses (related to failure modes) in this section.

### 8.3.3 Screening Part II

- a. *Is this a temporary or permanent change in the facility as described in the existing documented safety analysis?***

Does this change involve a physical change, i.e. hardware or software modification (or a revision to a design document), that affects either directly or indirectly any structures, systems, or components (SSCs) identified in the existing documented safety analysis?

If the answer is YES, it will be necessary to prepare a USQD.

DISCUSSION:

This item encompasses physical changes, changes to software, and changes to design documents. Changes to design documents are treated as design changes and hence addressed under this screening item, and not as changes to documents that are addressed in item "8.3.3.b" below.

This item also encompasses changes anywhere within the boundaries of the nuclear facility as defined by the safety basis, including programmatic, experimental, and research equipment. Additionally this item addresses changes outside that boundary that might affect the safety of the operation of the nuclear facility.

Screening to determine whether an SSC is described in the safety analyses (safety basis) should consider only whether the SSC is identified anywhere in the safety basis. Screening criteria should not be based on whether the SSC is formally classified as a safety SSC (that is safety class or safety significant), is taken credit for in the safety analysis (or accident analysis) chapter of the safety basis document, nor whether the particular characteristic(s) of the SSC to be changed are taken credit for.

If the hardware or software to be changed is identified in the facility's safety basis, the change must have a USQ Determination performed. New hardware or software systems, which are not yet identified in the safety basis, must be evaluated when the nature of the change is such that the change would be identified in the updated safety basis after the new hardware/software has been installed.

The Nuclear Safety Management rule requires USQ determinations (USQDs) for changes to a nuclear facility that alter an SSCs design, function, or method of performance as described in the existing safety analyses by text, drawing, or other information relied on as the safety basis. The safety analyses include descriptions of many SSCs, but a nuclear facility also contains many SSCs that are not explicitly described in the safety analyses. These can be components, subcomponents of larger components, or even entire systems.

Changes to SSCs that are not explicitly discussed in the safety basis should not be excluded from the USQ process, since changes to these SSCs may affect the ability of a safety SSC to perform its intended function. The recommended approach for deciding whether a modification involves a change to the nuclear facility, as described in the safety basis, is to consider the effect of the change on the safety SSCs of which the SSC being modified may be a part or which the SSC being modified may support. If the change alters the design, function, or method of performing the function of the safety

SSC, as described in the safety basis, a USQD is required. Also, a change to a SSC that is not a safety SSC may affect the potential initiation of an accident or the course of an accident, so virtually no change can be ignored.

Understanding the term "change" as it applies to modes of operation or facility processes is also important. For example, when a facility is designed to accommodate several nuclear processes (but must modify the equipment lineup to accommodate another process), this operational change does not constitute a change under the rule provided that it is performed in accordance with approved procedures and was considered within the safety basis of the facility.

Temporary changes to the nuclear facility should be evaluated to determine whether a USQ exists. Examples of temporary modifications include jumpers and lifted leads, temporary lead shielding on pipes and equipment, temporary blocks and bypasses, temporary supports, and equipment used on a temporary basis.

***b. Is this a temporary or permanent change in the procedures described in the existing documented safety analysis?***

Does this change involve a documentation change, e.g. a revision to a procedure that is identified in the facility's safety basis? Procedures are not limited to those items specifically identified as procedure types (e.g., operating, chemistry, system, test, surveillance, and emergency plan) but could include anything described in the facility safety basis that defines or describes activities or controls over the conduct of work.

Changes to these activities or controls qualify as changes to procedures "described in the documented safety analysis," and therefore must be evaluated as a potential USQ.

Does the change involve either of the following two types of implicit procedures?

- A procedure that is implicitly included in the documented safety analysis because it is an operational, surveillance, or maintenance procedure for a safety SSC that is identified in the safety basis?
- A procedure that is implicitly included in the facility's safety basis, because it is one of the top-level procedures that implement a Safety Management Program that is committed to in the safety basis?

Is this a NEW Procedure? Changes to procedures include both revising an existing procedure and creating a new procedure. A new procedure can be prepared from scratch or from combining two or more existing procedures. Most often changes to procedures involve revisions to existing procedures. However, in some cases the change might involve a new procedure. In the case of a new procedure, which could not be described already, the question becomes, if the documented safety analysis

were to be prepared (or updated) after the new procedure had been approved, is the new procedure of a type that would be identified in the documented safety analysis. If so, the new procedure should have a USQD prepared.

If the answer to any of these questions is YES, it will be necessary to prepare a USQD.

#### DISCUSSION:

The identification of procedures may be explicit or implicit in the facility documented safety analysis. If the procedure is implied directly by the nature of a topic in the safety basis (including the OSRs/TSRs), that change should be considered to be to a procedure described in the documented safety analysis, so that a USQD is done when appropriate. Such implicitly described procedures include: (1) the upper level procedures that implement a Safety Management Program (SMP) described in the safety basis, and (2) operating, maintenance, and surveillance procedures for safety equipment (when that equipment is identified in the documented safety analysis). If the characteristics of the SMP described in the safety basis remain correct, complete, and valid, then the result of the USQD would be expected to be negative, signifying that DOE approval is not required.

If a system, structure, or component has been classified as a safety SSC, procedures for operations, surveillance, and maintenance for that system are implicitly included in the documented safety analysis. The term “surveillance” as used here means those activities that are required by a surveillance requirement of the facility TSRs and does not necessarily include all inspections, tests, or calibrations. Procedures for operations, surveillance, and maintenance of non-safety systems in the facility are not considered to be implied procedures.

The need for implementation procedures is obvious for Safety Management Programs that are committed to in the safety basis. For example, a SAR may state that a nuclear criticality safety program will be implemented that conforms to a particular ANSI standard. Then, those top-level procedures necessary to meet this commitment are included implicitly in the safety basis. This criterion does not affect lower tier implementation procedures, so long as the effects of changes that are rolled up do not result in a change to the top-level procedures.

Changes to procedures that implement the administrative control requirements in the TSRs will need to have USQ determinations performed in order to ensure that the change does not adversely affect the administrative control.

#### ***c. Is this a test or experiment that is not described in the existing documented safety analysis?***

The term “test or experiment” should not be taken so literally as to become restrictive in nature. The emphasis should be placed on the term “not

described.” Although not explicitly required by DOE, the LANL requires that this item include all programmatic operations within the facility safety basis. This includes experimental and research activities, hardware, and procedures associated with these operations. The result is that this screening criterion encompasses any activity, operation, test, or experiment that is beyond those already described in the documented safety analysis for the facility.

Does the change involve a new activity, i.e. a test, experiment, or programmatic operation (including experimental and research activities, hardware, and procedures) that is not bounded by the facility safety basis?

If the answer to this question is YES, it will be necessary to prepare a USQD.

**DISCUSSION:**

Written USQ determinations are required for tests or experiments not described in the existing safety analyses. The intent of the criteria of Section 830.203 is to require that safety evaluations be conducted for tests and experiments that are not described in the existing safety basis that might affect safe operations of the facility. By definition, these are tests and experiments that could degrade the margins of safety during normal operations or anticipated transients or degrade the ability of safety SSCs to prevent accidents or mitigate accident conditions.

Previously evaluated tests or experiments do not require written USQ screens and determinations. For example, pre-operational tests, surveillance tests, and functional tests that are described in the documented safety analysis and/or the Technical Safety Requirements do not require the performance of a USQ screen and/or determination every time a test is performed. However, one-of-a-kind tests or experiments used to measure the effectiveness of new techniques or a new system configuration that might affect safety SSCs will require screens and/or determinations before they can be conducted. Post modification testing should be considered and included in the USQ screen and/or determination for the modification.

**Attachment F** to this standard provides the worksheets to be used for the USQ process applicability assessment, screening, and determination, and addresses the USQ screening steps in more detail. Except where specifically instructed otherwise, all the steps of this form are to be completed.

## 8.4 UNREVIEWED SAFETY QUESTION DETERMINATION

Changes that are not eliminated during the USQ screening process require a USQD.

The USQD serves two primary functions:

- It determines the approval authority of the change.
- It documents the technical basis for the conclusion reached.

Once it has been determined that a USQ determination is required, the USQ determination is made by providing an answer to each of the seven questions. If any of these questions is answered "Yes," the determination is said to be positive, the change is said to involve a USQ, and, if implementation of the change is desired, DOE must approve the change prior to implementation. The USQ determination requires consideration of the documented safety analysis for the nuclear facility (or other DOE approved documentation that provides the safety basis for operations or other activities) and the specific details of the activity.

A defensible explanation must be documented for the answers to each of the USQ criteria. The explanation is to capture the technical basis for each of the answers. It is inappropriate to set a numerical margin for increases in the probability or consequences within which a positive USQD would not be triggered.

If additional protective measures (either administrative or hardware-related) are necessary to ensure adequate protection of the public or to provide worker safety during a postulated accident situation, the USQD preparer should conclude that the USQD is positive (on the basis that either an increase in probability or an increase in consequences of an accident has occurred).

One could view this situation as a change that has two distinct parts. The first part causes some increase in the probability or consequences of an accident. The second part provides additional protective measures that offset the increase(s) in probability or consequences. Consolidating these two offsetting parts of a change may be effective in reducing the net risk to an acceptable value, but does not eliminate the need for DOE review and approval action on the change. DOE must be involved 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 SSC) and hence will receive appropriate surveillance and maintenance.

When evaluating for "increases in consequences" of an accident, if the previously bounding case for that family of accidents remains the bounding case, then generally there is no increase in the consequences within the USQ process. In this regard, it is important not only that the family of accidents be related, in addition to being of the same type (e.g., fires), but also that the accident being considered utilizes the same set of preventative and mitigative measures. While this is appropriate for public safety, adequate protection of workers requires further evaluation. Each change must be evaluated for increases in the consequences to workers. Any increase in consequences will result in a positive USQ determination.

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 is a USQ and hence requires DOE approval prior to implementation.

The following seven questions are based on the definition of USQ provided in the rule and are therefore not consistent with the implementation guide.

1. **Could the Proposed Change<sup>2</sup> Increase the Probability of Occurrence of an Accident Previously Evaluated in the Documented Safety Analysis?**

To understand how the probability of occurrence of an accident 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 Documented Safety Analysis.

In answering this question, the first step is to determine the accidents, which have been evaluated in the previously approved safety basis, which 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 SSC 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 such that an accident is 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, over pressurizing a piping system, and operating a motor outside its rated voltage and amperage.

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<sup>2</sup>For the purposes of this standard, "change" will mean any change to procedures or equipment (including prior undocumented changes), any new tests or experiments, or any new information which has the potential to invalidate the safety basis.

- (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?

**2. Could the Proposed Change Increase the Consequences of an Accident Previously Evaluated in the Documented Safety Analysis?**

In answering this question, the first step is to determine which accidents evaluated in the safety analyses 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 existing safety analyses. It is important to note that consequences to workers (in-facility and outside, or collocated) as well as to the public must 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 existing safety analyses?
- (b) Could the proposed change alter any assumptions previously made in evaluating the radiological and hazardous material consequences in the existing safety analyses?
- (c) Could the proposed change play a direct role in mitigating the radiological or hazardous material consequences assumed in the existing safety analyses?
- (d) Could the proposed change affect the integrity or function of any fission product barrier or any radioactive or hazardous material barriers?

**3. Could the Proposed Change Increase the Probability of Occurrence of a Malfunction of Equipment Important to Safety Previously Evaluated in the Documented Safety Analysis?**

The safety analyses for the facility assume the proper functioning of safety SSCs in demonstrating the adequacy of design. The proper functioning of other systems, including support systems, is generally assumed. The scope of the USQ determination should include these other systems. For example, a change that does either of the following is a change that increases the probability of occurrence of a malfunction of safety SSCs:

- Degrades the performance of a safety SSC, assumed to function in the accident analysis, to below the performance level assumed in the existing safety analyses
- Increases the challenge to safety SSCs assumed to function in the accident analysis (e.g., more rapid pressure rise) such that safety SSC

performance is degraded below that assumed in the existing safety analyses

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

After the impact of the change on safety SSCs is identified, a determination is made whether an increase in the probability of a malfunction of the safety 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 (e.g., use of proper supports, proper lugging at terminals, and isolation of lifted leads)?
  - (2) Are separation criteria met (e.g., minimum distance between circuits in separate divisions, channels in the same division, and jumpers run in conduit)?
  - (3) Are the environmental criteria met (e.g., use of materials suitable for the radiation or thermal environment in which they will be used)?
- (b) Will the proposed change degrade safety SSC reliability by:
  - (1) Imposing additional loads not analyzed in the design?
  - (2) Deleting or reducing system/equipment protection features?
  - (3) Downgrading the support system performance necessary for reliable operation of the safety equipment?
  - (4) Reducing safety system/equipment redundancy or independence?
  - (5) Increasing the frequency of operation of safety systems/equipment?
  - (6) Imposing increased or more severe testing requirements on safety systems/equipment?

If the change adversely impacts the safety equipment, the likelihood of equipment malfunction may be increased. A “no” answer to any question in (a) above or a “yes” answer to any question in (b) above may not mean that there is a negative impact on safety. It would, however, indicate the existence of a USQ and the need for further analyses.

**4. Could the Proposed Change Increase the Consequence of a Malfunction of Equipment Important to Safety Previously Evaluated in the Documented Safety Analysis?**

This question asks whether, assuming a malfunction of safety equipment, the change would result in increased hazardous-material or radiological consequences. For example, consider a change such that a valve in a safety system fails 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 USQ.

**5. Could the Proposed Change Create the Possibility of an Accident of a Different Type than any Previously Evaluated in the Documented Safety Analysis?**

An accident or malfunction that involves an initiator or failure not considered in the nuclear facility’s existing safety analyses 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 existing safety analyses 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 existing safety analyses. 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 existing safety analyses, 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 existing safety analyses. 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 existing safety analyses 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.

**6. 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 Documented Safety Analysis?**

To answer this question, the types of failure modes of safety SSCs that have been previously evaluated in the existing safety analyses 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. A change that might create a malfunction of a different type could be the relocation of safety equipment so that it becomes susceptible to flooding. Another might be replacement of a mechanical control system for a safety SSC with a digital control system that could potentially fail in a different mode.

**7. Does the Proposed Change Reduce the Margin of Safety?**

TSRs 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 existing safety analyses. TSRs provide a distillation of those aspects of the safety analyses that are required in order to ensure the performance of safety SSCs and personnel as relied on and defined in the safety analyses. The bases for TSRs define the operating limits from which margins of safety may be determined.

The bases for a TSR should define the margin of safety. If the bases do not address a specific margin of safety, the documented safety analysis and other appropriate safety basis documents should 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 safety margin may be implicitly described in the TSRs rather than explicitly described. A margin of safety defined in the Bases section of a TSR document may 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 required to comply with Section 830.203. 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 (i.e., increasing or decreasing).

For purposes of performing the USQ determination, the margin of safety is the range between the TSR limits and the acceptance limit reviewed and approved by DOE as part of the authorization process. In making the judgment on whether the margin is reduced, the judgment should be based on physical parameters or conditions that can be observed or calculated. Where a change in margin is so small or the uncertainties in determining whether a change in margin has occurred are such that it cannot be concluded reasonably that the margin actually has changed (i.e., there is no clear trend toward reducing the margin), the change need not be considered a reduction in margin.

With regard to the margin of safety, the change, test or experiment, or new information should be evaluated with respect to safety limits, limiting control settings (LCSs), and limiting conditions of operation (LCOs), as well as design parameters for safety systems or components. These safety margins are based

on, for example, 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. However, a change in the margin of safety above the acceptance limit is the focus of Section 830.203. A change in initial conditions, in a system response time, or in some other parameters affecting the course of an accident analysis supporting the bases of TSRs must be evaluated to determine whether the change causes the acceptance limit to be exceeded for that analysis. If the limit were exceeded, the change would involve a reduction in the margin of safety pursuant to Section 830.203.

There are "margins" associated with existing safety analyses to account for uncertainties in the design, construction, and operation of a nuclear facility (e.g., conservatisms in computer modeling and codes and allowances for instrument drift and system response time). These "margins" may be reduced by LANL, provided specific acceptance conditions, criteria, and limits (e.g., models, tests, uncertainties, and methodology) are not invalidated.

To develop the definition of "margin of safety," it is first necessary to define the relationship of operating points, acceptance limits, and actual failure points. To do this, one must determine the original safety analyses of the parameter in question. A margin of safety defined in the Bases section of the TSR may depend on a parameter other than one of the process variables. However, a change in the margin will depend only on an increase in the result beyond an established acceptance limit.

To answer this question, it is first necessary to determine whether a margin of safety for any Technical Safety Requirement (TSR) is involved. To do this, the basis for each TSR related to the proposed change should be identified. If a margin of safety is defined in the TSR, or if the safety basis or basis for interim operation defines a margin of safety that TSRs were derived from, a margin of safety is involved and the effects of the change on it should be assessed.

**Attachment F** to this standard provides the worksheets to be used for the USQ process applicability assessment, screening, and determination, and addresses the USQ Determination steps in more detail. Except where specifically instructed otherwise, all the steps of this form are to be completed.

## 8.5 USQ REVIEWS AND APPROVALS

### 8.5.1 Technical Review

USQ procedures shall provide that the USQ screen and/or determination documents are prepared by one individual and then reviewed technically by a second person. The reviewer must be independent in the sense that he/she has not been involved in the preparation of the USQ documents. The reviewer does not need to be organizationally independent.

When the preparer has completed the USQ screen and/or determination, he/she forwards the USQ screen and/or determination to the technical reviewer. The

technical reviewer conducts an independent assessment of the USQ screen and/or determination. Review comments shall be provided to the preparer and resolved prior to sign off of the review. The USQ determination shall be provided to the sponsoring organization for review prior to final approval.

### **8.5.2. Coordination Review**

The sponsoring organization for a change might be a programmatic group or might be the facility management team. To ensure appropriate coordination between the sponsoring organization and the USQ processing organization, a subject matter expert in the sponsoring organization shall review the USQ screen and/or determination when the organization preparing the USQ documents is different from the organization sponsoring the change. This review should ensure the accuracy of the description and understanding of the change, the accuracy of the hazard and risk factors associated with the change, and ensure that the risk control measures (preventive and mitigative measures) are appropriate and consistent with those that are already part of the change. This review also establishes agreement between the sponsoring organization and the preparer on the change as it is described and evaluated in the USQ documents.

The review by the sponsoring organization shall be performed prior to final approval.

### **8.5.3. Facility Management Approval**

The facility USQ procedure should provide also that facility management takes approval action on the USQ documents. This ensures that management is informed of the results of the USQ process and hence can take whatever follow-up actions are appropriate, such as submitting the change to DOE for safety review and approval or canceling the proposed change. The use of a facility safety review committee or other safety committee, or a configuration control board, or the Office of Authorization Basis to review the complete USQ documents may be beneficial, but such reviews are advisory and may not serve in lieu of direct approval action by line management. Care should be used to avoid excessive levels of approval.

### **8.5.4. Acknowledgement Signature**

LANL management personnel who only desire to acknowledge that they were informed of USQ documents subsequent to the facility's approval of USQ documents, but who do not desire to comply with the training requirements of an "approver", may sign as acknowledging manager.

## **8.6 REQUESTS FOR AMENDMENTS TO THE FACILITY SAFETY BASIS**

In the event that the result of the USQ process is positive (a positive USQD) or the situation is beyond the scope of day-to-day operations as discussed in section 8.2.2, and Facility or Division Management wants to implement the change as it is currently envisioned, Facility Management will generate a request for an amendment to the facility safety basis. The following format will be used for submitting unreviewed safety questions to the DOE.

The Safety Basis Manager will prepare a memorandum from the Facility Manager addressed to the Senior Authorization Basis Manager of DOE/LAAO requesting approval of the proposed change.

To the maximum extent practical and appropriate, the memorandum should address the following topics, as applicable:

1. An introductory summary of the purpose of the memorandum and its contents,
2. A description of the proposed change that generated the need for action,
3. A summary of the applicable safety analyses, such as:
  - Failure modes and effects analysis,
  - Calculations of affected accident probabilities and/or consequences,
  - Engineering and/or technical considerations,
  - Alternative actions and associated safety implications and
  - The selected action and supporting reasoning,
4. A summary of the results of the USQ determination,
5. Programmatic, budgetary, and schedule considerations,
6. Conclusion of the safety analysis upon which DOE is requested to approve the proposed change.
7. A clear presentation of the required controls.

Although not required by DOE, the LANL requires that completed USQ documents should be enclosed with the memorandum. The safety analysis documentation and supporting analyses, calculations, etc. that are necessary to establish the safety of the proposed change (and for DOE to evaluate the request) should also be enclosed.

The request memorandum should then be forwarded to the OAB for concurrence and transmittal to DOE.

## **8.7 USQ DOCUMENT TRACKING**

The Safety Basis Manager will implement a system for tracking the status of the USQ documents (screens and determinations). The system must provide the capability to track the status of the screen and/or determination from initiation through approval and closeout. Potential items to include in the database are: the change number, the process applicability assessment number, the unreviewed safety question screen and/or determination number, document title, brief description of change, date approved, date implemented, date cancelled, date incorporated into documented safety analysis, screened out at applicability, screen, negative USQD, positive USQD.

## **9.0 POTENTIAL INADEQUACY OF THE DOCUMENTED SAFETY ANALYSIS**

A PISA may arise from any of three generic types of entry conditions: 1) a discrepant as-found condition, 2) an operational event or incident, and 3) new information. New information includes: New information sent by a vendor, technology advances, or the discovery of errors and omissions in an analysis. Analytical errors include: Use of an improper model, inappropriate assumptions associated with that model, incorrect input values, incorrect calculations, or inappropriate interpretation of results.

Any time an individual has reason to believe that the facility's safety basis might be inadequate, the situation must be reported to management immediately. The Facility Manager is then allowed a "reasonable time" to confirm the existence of the potential for an inadequate documented safety analysis prior to entering the PISA part of the USQ process. This "reasonable period" is typically a few hours up to a day or so. It is not days, weeks, or months.

In the event the facility discovers a condition that is contrary to the documented safety analysis, the condition must be evaluated to determine if a PISA exists. This involves evaluating a hardware discrepancy as if it were a proposed change ("backward-looking USQ") or evaluating an analytical error with the error as corrected. If a PISA is identified, follow the steps outlined below.

After the Facility Manager has confirmed the potential for an inadequate documented safety analysis, the following actions are required:

1. Take action, as may be necessary and appropriate, to ensure the safety of personnel and to place or maintain the facility in a safe condition, at least until an evaluation of the safety of the situation is completed.
2. Notify the DOE (normally the Facility Representative) of the situation. Declare as Off-Normal only if "Significant Compensatory Measures" are required per Laboratory Occurrence Reporting Requirements/ Guidance, OST 402-130-01.
3. Perform a USQD on the situation. The time period for the performance of a USQ determination related to a PISA should be on the order of days, not weeks or months. [10 CFR 830; final rule; 01/10/01; response to comment "Q"]
4. Promptly notify DOE of the results of the USQD. Although not required by DOE, the LANL requires submittal of the USQD to the DOE through the OAB.
  - If the USQD is negative, an actual inadequacy of the documented safety analysis does not exist.
  - If the outcome of the USQD is positive, an actual inadequacy of the documented safety analysis exists. Report this situation to the DOE as an Unusual Occurrence per Laboratory Occurrence Reporting Requirements/ Guidance, OST 402-130-01.. This report must explicitly identify the occurrence as a PISA.
5. Submit the evaluation of the safety of the situation to DOE through the OAB in accordance with section 8.6.
6. Operational restrictions initiated to meet item 1 above must be maintained until the evaluation of the safety of the situation has been submitted to DOE, and:
  - the USQD is negative, or
  - the USQD is positive and DOE has approved removal of the operational restriction(s).

The PISA process is outlined in the process flow chart in **Attachment G**.

## **10.0 DOCUMENTATION AND REPORTING**

### **10.1 DOCUMENT RETENTION**

The USQ documents are maintained for the full operational life of the facility.

### **10.2 RECORDS TURNOVER**

In the event that the operating contractor of the LANL or the owning LANL division for the facility should change, the exiting contractor or LANL division is required to turn over all USQ documents to the new contractor or LANL division.

Although not required by the Nuclear Safety Management rule, when a LANL nuclear facility has completed its operational life and transitions to decontamination and decommissioning (D&D), the USQ records must be turned over to the transition team.

### **10.3 ANNUAL USQ SUMMARY**

The LANL is required to provide DOE with an annual summary description of USQ determinations performed since the prior submission. This report should be submitted on a schedule commensurate with the annual update of the documented safety analysis. For the LANL, the OAB serves a central coordinating role in this matter.

Annually in January, the Safety Basis Manager will prepare a summary of all the USQ determinations that have been completed since the last submission. This summary will provide the following information for each change that involved a USQD: The number and title of the matter, and a brief summary of the matter (a few sentences).

The summary will be forwarded to the OAB by January 31<sup>st</sup> for subsequent submission to DOE. The OAB will collate the summaries for the LANL and submit them to DOE.

## 11.0 DEVELOPMENTAL REFERENCES

The references below were used in the creation of this document.

Number	Title
10 CFR 830.203	Nuclear Safety Management
IG-830.203 (Draft) dated 7/16/01	Implementation Guide for Use in Addressing USQ Requirements
29 CFR 1910.119	Process Safety Management (chemical hazards)
DOE Order 5480.21	Unreviewed Safety Questions
DOE Order 5480.22	Technical Safety Requirements
DOE Order 5480.23	Nuclear Safety Analysis Report
DOE Order 420.2 Chg 2	Safety of Accelerator Facilities
DOE-STD-3009-94	Preparation Guide for U.S. Department Of Energy Nonreactor Nuclear Facility Safety Analysis Reports
DOE-STD-3011-94	Guidance for Preparation of DOE 5480.22 (TSR) and DOE 5480.23 (SAR) Implementation Plans
DOE Manual 440.1-1	DOE Explosives Safety Manual
NUREG-1606 (Draft)	Proposed Regulatory Guidance Related to Implementation of 10CFR50.59 (Changes, Tests, or Experiments)
LIR 240-01-03	Authorization Agreement
LIR 300-00-06	Nuclear Facility Safety Authorization Basis
LIG 302-100-03	Guide for Developing Laboratory Operations Implementation Requirements and Guidance Documents

**APPENDICES**

**AND**

**ATTACHMENTS**

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## ATTACHMENT A - DEFINITIONS AND ACRONYMS

### Definitions:

**Accident.** An unplanned sequence of events that results in undesirable consequences.

**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 SAR. These analyses refer to design basis accidents only. [DOE 5480.21] Accident analysis has historically consisted of the formal development of numerical estimates of the expected consequence and probability of potential accidents associated with a facility. For the purposes of implementing this Standard, accident analysis is a follow-on effort to the hazard analysis, not a fundamentally new examination requiring extensive original work. As such, it requires documentation of the basis for assignment to a given likelihood of occurrence range (e.g., 1/yr to  $10^{-2}$ /yr,  $10^{-2}$ /yr to  $10^{-4}$ /yr,  $10^{-4}$ /yr to  $10^{-6}$ /yr) in hazard analysis and performance of a formally documented consequence analysis. Consequences are compared with offsite Evaluation Guidelines to identify safety-class structures, systems, and components.

**Activity.** SEE "Programmatic Operation"

**Administrative Controls.** The provisions relating to organization and management, procedures, record keeping, assessment, and reporting necessary to ensure safe operation of a facility. [Part 830.3(a)]

**Approved equivalent replacement.** A change that involves replacing one component with another that is identical, meets all design specifications, or has been demonstrated and documented to be equivalent.

**As Described.** An item is described in the documented safety analysis if:

- an explicit description of the item is contained in the documented safety analysis,
- the item is implicitly included in documented safety analysis descriptions, or
- the item may affect the functions of any other item that is implicitly or explicitly described in the documented safety analysis.

**Authorization Agreement.** The criterion and agreements for the operation of specified facilities at the LANL that when signed by the LANL and DOE constitutes a contractual requirement under provisions of the University of California Contract. [LIR 240-01-03]

**Authorization Basis.** The safety documentation that supports the decision to allow a process or facility to operate. Included are corporate operational and environmental requirements as found in regulations and specific permits, and, for specific activities, work packages or job safety analyses. The safety basis as defined below is a subset of the authorization basis. [10 CFR 830; final rule; 01/10/01; response to comment "M"]

**Backward-looking USQ.** A USQD performed on an existing, as-found condition, as an inadequate documented safety analysis finding. The USQD is performed using the rationale, "If we had proposed such a change under our previous conditions, would it have involved a USQ?" [See Sec. 1.4 of Attachment 2 of the "Supplemental Guidance for DOE Order 5480.21.]

**Bases appendix.** An appendix that describes the basis of the limits and other requirements in technical safety requirements. [Part 830.3(a)]

**Basis for Interim Operation.** A document, developed according to DOE Orders 5480.22 and 5480.23 and DOE Standard 3009-94 and negotiated with DOE, that establishes the interim safety basis for the facility until SAR and TSR documents have been approved. [DOE-STD-3011]

**Categorical Exclusion.** The basis for screening of a change that poses insignificant hazards because it is bounded by similar operations that have been previously analyzed and determined to pose insignificant hazards. An approved list of these with guidance is maintained by the facility. A USQ is developed to cover repeated activities/operations and must be approved by DOE. An example of what may be included is the installation of white boards in offices.

**Change.** Any alternation or addition, temporary or permanent, to the facility configuration, facility documentation, design requirements, specification, facility software, procedures or processes, or introduction of new technology or the conduct of tests or experiments not described in the hazard analysis. Identical replacements or approved equivalents are not changes.

**Design Basis Accidents.** Those accidents that are considered credible enough to be postulated for the purpose of establishing design and performance requirements for systems, structures, and components important to safety. [DOE Order 5480.21, Section 6.d]

**Design Features.** The features of a nuclear facility specified in the technical safety requirements that, if altered or modified, would have a significant effect on safe operation. [Part 830.3(a)]

**Document.** Recorded information that describes, specifies, reports, certifies, requires, or provides data or results. [Part 830.3(a)]

**Documented Safety Analysis.** 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. [Part 830.3(a)]

**Equipment Important to Safety.** Structures, systems, and components determined through the facility documented safety analysis to be either safety class, safety significant, or otherwise important to safety as defined in DOE-STD-3009-94, and identified in the facility SAR.

**Experiment.** See Test or Experiment

**Graded Approach.** The process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement are commensurate with (1) the relative importance to safety, safeguards, and security; (2) the magnitude of any hazard involved; (3) the life cycle stage of a facility; (4) the programmatic mission of a facility; (5) the particular characteristics of a facility; (6) the relative importance of radiological and nonradiological hazards; and (7) any other relevant factor. [Part 830.3(a)]

**Hazard.** A source of danger (i.e. material, energy source, or operation) with the potential to cause illness, injury, or death to a person or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation). [Part 830.3(a)]

**Hazard Analysis.** The determination of material, system, process, and plant characteristics that can produce undesirable consequences, followed by the assessment of hazardous situations associated with a process or programmatic operation. Largely qualitative techniques are used to pinpoint weaknesses in design or operation of the facility that could lead to accidents. The DSA hazard analysis examines the complete spectrum of potential accidents that could expose members of the public, onsite workers, facility workers, and the environment to hazardous materials.

**Hazard Classification.** Evaluation of the consequences of unmitigated release classify facilities or operations into the following hazard categories:

1. Hazard Category 1: The hazard analysis shows the potential for significant offsite consequences.
2. Hazard Category 2: The hazard analysis shows the potential for significant onsite consequences.
3. Hazard Category 3: The hazard analysis shows the potential for only significant localized consequences. [DOE 5480.23]

DOE-STD-1027-92 provides guidance and radiological threshold values for determining the hazard category of a facility. DOE-STD-1027-92 interprets Hazard Category 1 facilities as Category A reactors and other facilities designated as such by the Program Secretarial Officer.

**Hazard Controls.** Measures to eliminate, limit, or mitigate hazards to workers, the public, or the environment, including (1) physical, design, structural, and engineering features, (2) safety structures, systems, and components, (3) safety management programs, (4) technical safety requirements, and (5) other controls necessary to provide adequate protection from hazards. [Part 830.3(a)]

**Important to Safety.** Equipment whose function can impact safety either directly or indirectly. This includes safety-related equipment, equipment relied upon for safe shutdown, and, in some instances, balance-of-plant (nonsafety-related) equipment. [DOE Order 5480.21, Section 6.f]

**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. [Part 830.3(a)]

**Malfunction:** Failure to perform as expected.

**Modification:** A change to an existing SSC, document, or activity.

**Margin of Safety:** That margin built into the safety analyses of the facility as set forth in the authorization basis acceptance limits. [DOE Order 5480.21, Section 6.h]

**Must.** Indicates a requirement mandated by law. In this standard “Must” is used wherever the criterion for conformance with the specific recommendation requires that there be no deviation. [ANSI, Eighth Edition, Version 1.0]

**New DOE nuclear facility.** A DOE nuclear facility that begins operation on or after April 9, 2001. [Part 830.3(a)]

**Non-Safety-Related.** SSCs that are not necessary to maintain structural integrity, the capability to shut down safely, and the capability to prevent or mitigate the consequences of accidents [10CFR50.59].

**Nuclear Facility.** A reactor or a nonreactor nuclear facility where an activity is conducted for or on behalf of DOE and includes any related area, structure, facility, or activity to the extent necessary to ensure proper implementation of the requirements established by this Part. [Part 830.3(a)]

**Operability.** A system, subsystem, train, component, or device capable of performing its specified function. Also, all necessary attendant instrumentation, controls, electrical power, cooling or seal water, lubrication, or other auxiliary equipment required for the system, subsystem, train, component, or device to perform its function(s) are capable of performing their related support function(s).

**Operational Safety Requirements.** Those requirements that define the conditions, safe boundaries, and their bases, and management control required to assure safe operation of a DOE facility.

**Potentially Inadequate Safety Analysis.** A safety analysis that may be inadequate because of the receipt of new information, the discovery of a discrepant-as-found state, or the occurrence of an event. Note that development of improved or alternative analysis methodology does not render the existing safety analysis as “inadequate” and does not require a USQD.

**Preliminary Documented Safety Analysis.** Documentation prepared in connection with the design and construction of a new DOE nuclear facility or a major modification to a DOE nuclear facility that provides a reasonable basis for the preliminary conclusion that the nuclear facility can be operated safely through the consideration of factors such as

- (1) The nuclear safety design criteria to be satisfied;
- (2) A safety analysis that derives aspects of design that are necessary to satisfy the nuclear safety design criteria; and
- (3) An initial listing of the safety management programs that must be developed to address operational safety considerations. [Part 830.3(a)]

**Procedure.** A document that describes a process (a sequence of actions) to be performed to achieve a desired outcome. [DOE G 450.4-1A; ISM Guide]

**Programmatic Operation.** Any operational process, system, structure, equipment, or group that fulfills a programmatic purpose (including experimental activities, hardware, and procedures). Examples include, but are not limited to, storage areas, radioactive waste disposal and processing systems, environmental restoration projects, tank farms, characterization and decontamination projects, transportation, and analytical laboratories. (DOE-EM-STD-5505-96)

**Safety Analysis Report.** A report that documents the adequacy of safety analysis to ensure that a facility can be constructed, operated, maintained, shut down, and decommissioned safely and in compliance with applicable laws and regulations. [DOE 5480.23]

**Safety Basis.** The documented safety analysis and hazard controls that provide reasonable assurance that a DOE nuclear facility can be operated safely in a manner that adequately protects workers, the public, and the environment [Part 830.3(a)]. For the purposes of the Unreviewed Safety Question (USQ) process, the safety basis includes the Documented Safety Analysis (DSA), the Technical Safety Requirements (TSRs), DOE-issued safety evaluation reports (SERs), and facility-specific commitments made in compliance with DOE rules, Orders, or policies. [IG-830.203, section I, paragraph 2]

NOTE: The safety basis may also include supporting documents that were relied upon in developing and approving the safety analysis.

**Safety Class Structures, Systems, and Components.** The structures, systems, or (and) components, including portions of process systems, whose preventive or mitigative function is necessary to limit radioactive hazardous material exposure to the public, as determined from safety analyses. [Part 830.3(a)]

**Safety Management Program.** A program designed to ensure a facility is operated in a manner that adequately protects workers, the public, and the environment by covering a topic such as: quality assurance; maintenance of safety systems; personnel training; conduct of operations; inadvertent criticality protection; emergency preparedness; fire protection; waste management; or radiological protection of workers, the public, and the environment. [Part 830.3(a)]

**Safety Significant Structures, Systems, and Components.** The structures, systems, and components which are not designated as safety class structures, systems, and components, but whose preventive or mitigative function is a major contributor to defense in depth and/or worker safety as determined from safety analyses. [Part 830.3(a)]

**Safety Structures, Systems, and Components.** Both safety class structures, systems, and components and safety significant structures, systems, and components. [Part 830.3(a)]

**Shall.** Indicates a requirement mandated by the LANL. In this standard “Shall” is used wherever the criterion for conformance with the specific recommendation requires that there be no deviation. [ANSI, Eighth Edition, Version 1.0]

**Should.** Nonmandatory guidance and recommendation. [LIG 302-100-03] In this standard “Should” is used wherever noncompliance with the specific recommendation is permissible.

**Technical Safety Requirements (TSRs).** 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 documented safety analysis 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. [Part 830.3(a)]

**Test or Experiment.** A special procedure for a particular purpose or an evolution performed to gather data. [Draft NRC NUREG-1606]

**Unreviewed Safety Question.** A situation where

- (1) The probability of the occurrence or the consequences of an accident or the malfunction of equipment important to safety previously evaluated in the documented safety analysis could be increased;
  - (2) The possibility of an accident or malfunction of a different type than any evaluated previously in the documented safety analysis could be created;
  - (3) A margin of safety could be reduced; or
  - (4) The documented safety analysis may not be bounding or may be otherwise inadequate.
- [Part 830.3(a)]

**Unreviewed Safety Question Determination:** That record required by 10 CFR Part 830 and this standard to document the review of a proposed change or existing condition not previously contained in the documented safety analysis.

**USQ Documents.** USQ documents include USQ screens and USQDs, but do not include USQ applicability assessments.

**USQ Process applicability assessment:** The method for determining whether or not the USQ process should be applied to a particular situation.

**Unreviewed Safety Question Evaluation.** That record required by DOE Order 5480.21 to document the review of a “change”. This document records the scope of the evaluation and the logic for determining whether or not an Unreviewed Safety Question exists. [DOE Order 5480.21] (For the purpose of this standard, LANL considers a USQ evaluation equivalent to a USQ Screen and/or USQ Determination)

**Unreviewed Safety Question Process.** The mechanism for keeping a safety basis current by reviewing potential unreviewed safety questions, reporting unreviewed safety questions to DOE, and obtaining approval from DOE prior to taking any action that involves an unreviewed safety question. [Part 830.3(a)]

**Unreviewed Safety Question Screening:** An initial examination or analysis of the proposed change to determine if the change is of technical significance and requires a USQD.

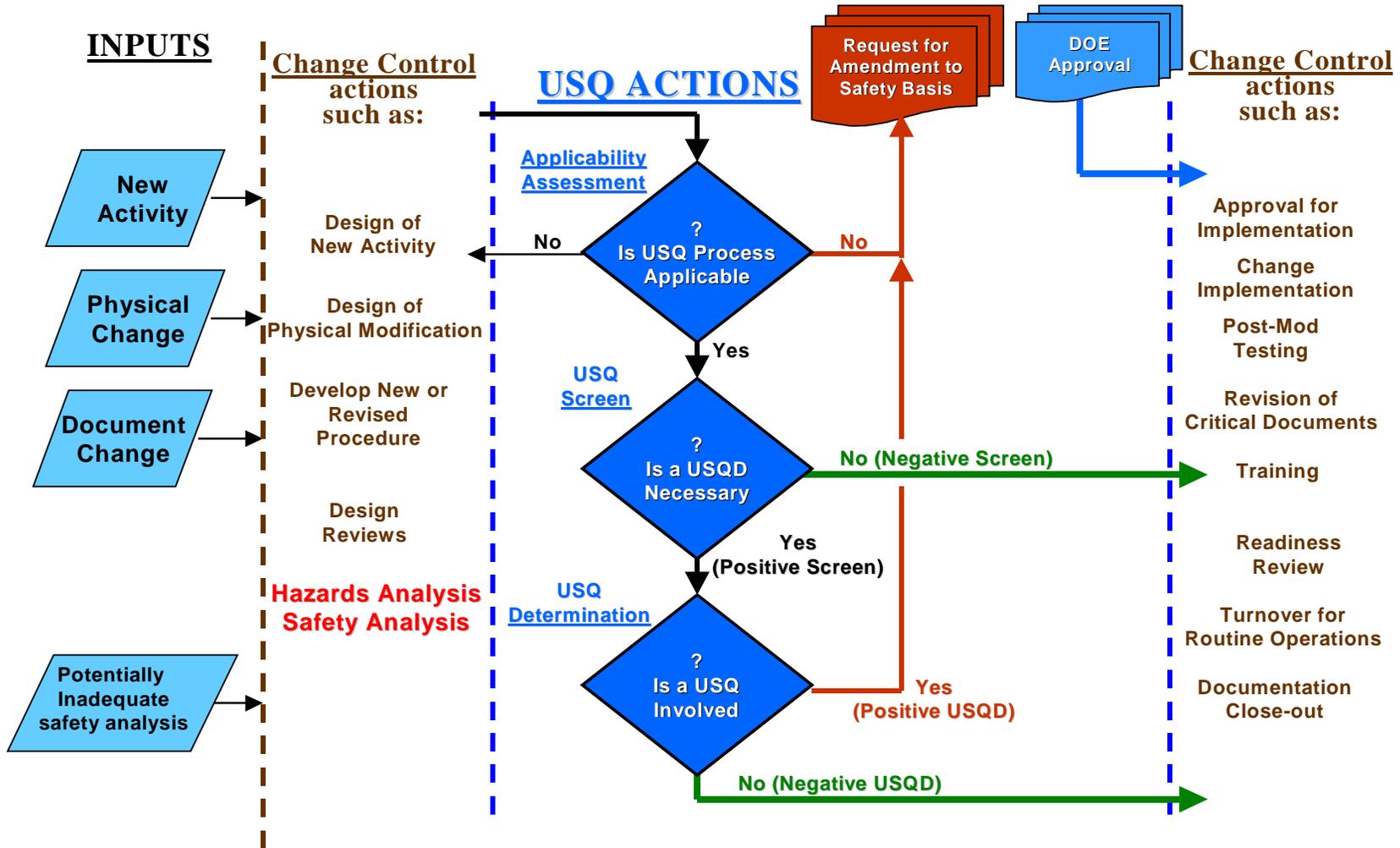
## Abbreviations and Acronyms:

AB	Authorization Basis
AC	Administrative Control
AL	Albuquerque
ALARA	As Low As Reasonably Achievable
BIO	Basis for Interim Operation
BS	Bachelor of Science
CFR	Code of Federal Regulations
DID	Defense In Depth
DOE	Department of Energy
DOE-STD	Department of Energy Standard
D&D	Decontamination and Decommissioning
DSA	Documented Safety Analysis
FM	Facility Manager
FMEA	Failure Modes and Effects Analysis
FSAR	Final Safety Analysis Report
FWO	Facility and Waste Operations Division
ITSR	Interim Technical Safety Requirement
LAO	Los Alamos Area Office
LANL	Los Alamos National Laboratory
MER	Management Evaluation Report
MOI	Maximum-exposed Off-site Individual
OAB	Office of Authorization Basis
OSHA	Occupational Safety and Health Administration
OSR	Operational Safety Requirement
PISA	Potentially inadequate safety analysis
RMDC	Records Management and Document Control
SAR	Safety Analysis Report
SBM	Safety Basis Manager
SC	Safety Class
SER	Safety Evaluation Report
SME	Subject Matter Expert
SMP	Safety Management Program
SS	Safety Significant
SSC	Structure, System, or Component
TSR	Technical Safety Requirement
USQ	Unreviewed Safety Question
USQD	Unreviewed Safety Question Determination

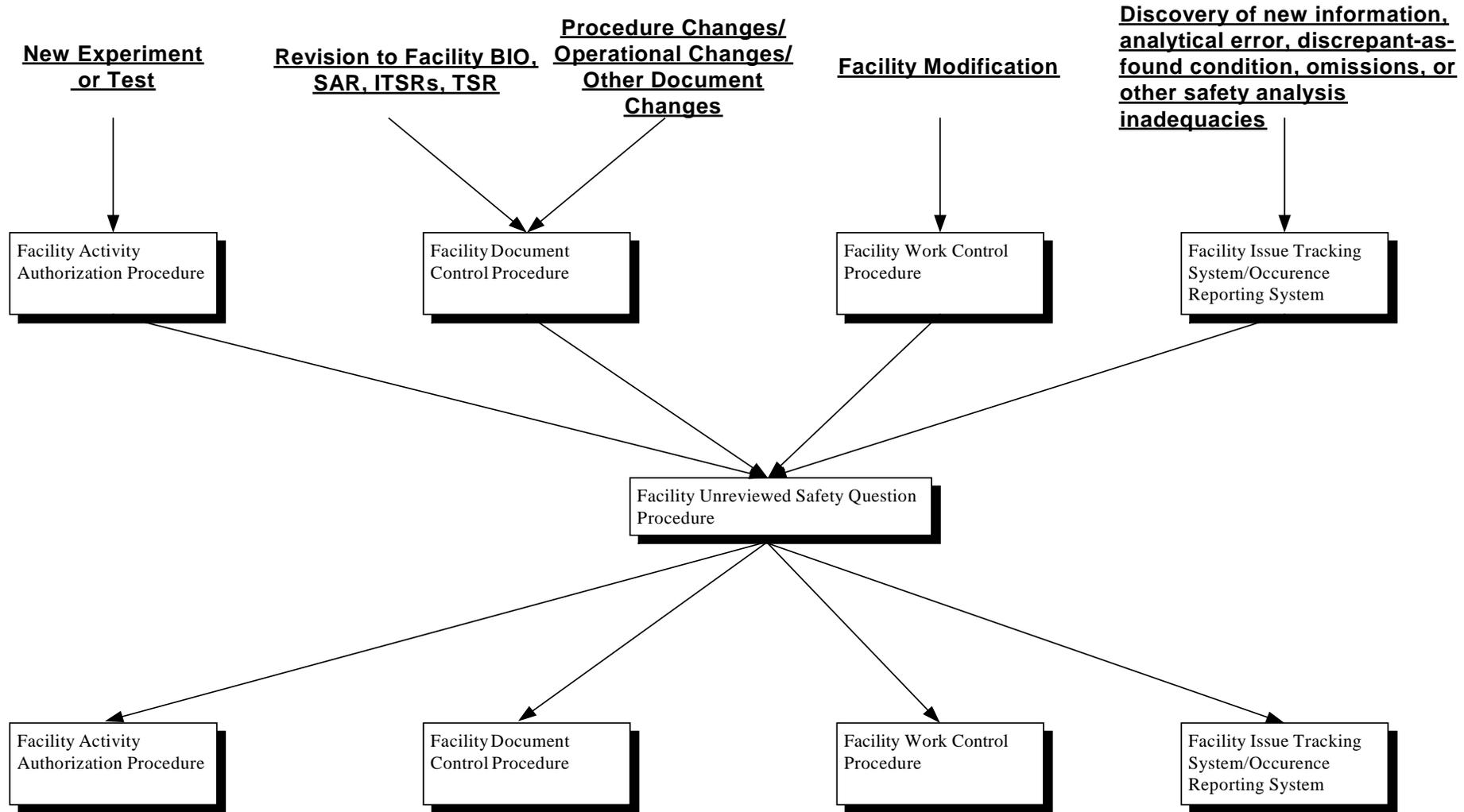
ATTACHMENT B. USQ PROCESS FLOW CHART

# USQ Process Flow Chart

*(including relationships with change control)*

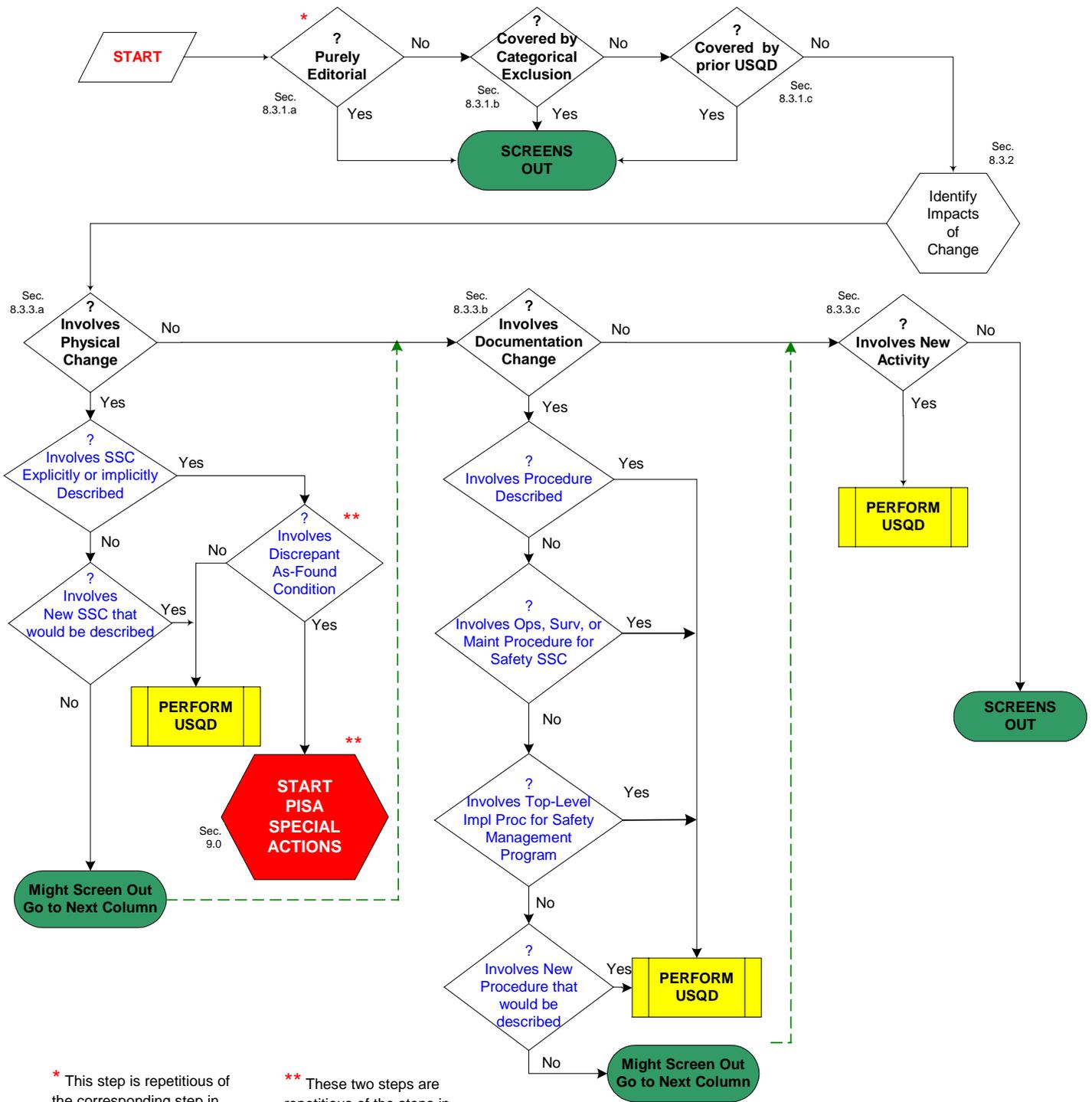


# ATTACHMENT C. EXAMPLE CHANGE CONTROL PROCESS





# ATTACHMENT E. USQ SCREENING FLOW CHART



\* This step is repetitious of the corresponding step in the Applicability Assessment.

\*\* These two steps are repetitious of the steps in the Applicability Assessment. Go to the PISA actions if a previous step has not already directed this move.

## ATTACHMENT F. USQ WORKSHEETS

	<b>USQ PROCESS APPLICABILITY ASSESSMENT WORKSHEET</b>
Change number:	Date:
Facility-Specific Unreviewed Safety Question Process Applicability Assessment Number:	
Facility Identification:	
Change description:	
Based on the evaluation presented in this worksheet:	
<input type="checkbox"/> The USQ process IS APPLICABLE, and USQ Screening will be performed (NOTE: A hazard/safety analysis must be provided as appropriate)	
<input type="checkbox"/> The USQ process is NOT APPLICABLE to this situation, and	
<input type="checkbox"/> DOE review and approval is NOT REQUIRED, or	
<input type="checkbox"/> DOE review and approval IS REQUIRED, and a Request for Amendment to the Facility Safety Basis should be prepared.	

### SIGNATURES

Assessment Preparer's Signature	Date
Typed or printed name of assessor	
Acknowledging Manager's Signature	Date
Typed or printed name of acknowledging manager	

***Retain original copy per facility records management procedures.***

This document was reviewed to ensure proper classification:	
<input type="checkbox"/> Unclassified <input type="checkbox"/> UCNI <input type="checkbox"/> Classified	
ADC Signature	Date
Typed or printed name of ADC	
UCNI Reviewing Official Signature	Date
Typed or printed name of UCNI reviewing official	

# ATTACHMENT F. USQ WORKSHEETS

## APPLICABILITY ASSESSMENT

In assessing the applicability of the USQ process to various situations, it is realized that: (1) some changes do NOT require USQ processing and do NOT require DOE approval, (2) some changes do NOT require USQ processing but DO REQUIRE DOE approval, and (3) if not covered by the first two cases, become mandatory inputs to the USQ process.

**NOTE: The number in brackets following the questions below is a reference to the corresponding section of the standard.**

1. If the answer to any of the questions in Section 1 is "Yes," the change does NOT require entering the USQ process and does NOT require DOE approval
  - a. Is this a maintenance action that involves the replacement of equipment with an exact replacement? [8.2.1.a]  Yes  No
  - b. Is this a maintenance action that involves the replacement of equipment with an approved equivalent part? [8.2.1.b]  Yes  No
  - c. Is this a change to programmatic operations and/or programmatic hardware that remains within the safety envelope of the approved hazard analysis for those operations? [8.2.1.c and 8.2.3]  Yes  No
  - d. Is the non-conforming part restored to become compliant with the requirements (i.e. the non-conformance report is dispositioned "reject" or "rework")? [8.2.1.d]  Yes  No
  - e. Is this change part of a corrective action for a discrepant as-found condition, and is the action a restoration modification (return to the original condition)? [8.2.1.e]  Yes  No
  - f. Is it an editorial change to a procedure or document? [8.2.1.f]  Yes  No
2. If the answer to any of the questions in Section 2 is "Yes," the change does not require entering the USQ process; however, does require DOE review and approval. Therefore, if there is a "Yes" answer, a Request for Amendment of the Safety Analysis should be prepared (See section 8.6 of the USQ Standard).
  - a. Is this a change that introduces a new technology to the facility? [8.2.2.a]  Yes  No
  - b. Is this a change that is a major modification, in that it goes beyond that necessary for day-to-day operations? [8.2.2.b]  Yes  No
  - c. Has management decided to submit the proposed change to DOE for review and approval? [8.2.2.c]  Yes  No
  - d. Is this a change to the TSRs? [8.2.2.d]  Yes  No

The USQ process IS APPLICABLE, and USQ Screening will be performed (NOTE: A hazard/safety analysis must be provided as appropriate)

- The USQ process is NOT APPLICABLE to this situation, and
- DOE review and approval is NOT REQUIRED, or
  - DOE review and approval IS REQUIRED, and a Request for Amendment to the Facility Safety Basis should be prepared.

Complete the cover sheet summary.

## ATTACHMENT F. USQ WORKSHEETS

	<b>UNREVIEWED SAFETY QUESTION SCREENING AND DETERMINATION WORKSHEET</b>
Change number:	Date:
Facility-Specific Unreviewed Safety Question Number:	
Facility Identification:	
Change description:	
Based on the evaluation presented in this report, the change:	
<input type="checkbox"/> entered this process as a PISA <input type="checkbox"/> has been screened out of the USQ process and does not constitute an Unreviewed Safety Question <input type="checkbox"/> does not constitute an Unreviewed Safety Question based on a full USQD <input type="checkbox"/> constitutes an Unreviewed Safety Question and <b>DOE approval is required</b> prior to implementation	

### SIGNATURES

Preparer's Signature	Date
Typed or printed name of preparer	
Reviewer's Signature	Date
Typed or printed name of reviewer	
Sponsoring Organization Reviewer's Signature	Date
Typed or printed name of sponsoring organization reviewer	
Approver's Signature	Date
Typed or printed name of approver	
Acknowledging Manager's Signature	Date
Typed or printed name of acknowledging manager	

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This document was reviewed to ensure proper classification:	
<input type="checkbox"/> Unclassified <input type="checkbox"/> UCNi <input type="checkbox"/> Classified	
ADC Signature	Date
Typed or printed name of ADC	
UCNI Reviewing Official Signature	Date
Typed or printed name of UCNI reviewing official	

# ATTACHMENT F. USQ WORKSHEETS

## SECTION 1: INTRODUCTION

### 1.1 DETAILED DESCRIPTION OF CHANGE

Provide a concise but detailed description of the proposed change. Include references to specific FSAR/BIO process descriptions where applicable. This section should clearly explain the relationship of the change to the process. (e.g. is this a component no longer required for the existing process [i.e. a legacy issue], or is this change in preparation for a new process to be approved in a separate USQD), discuss phases of the project including construction, start-up, normal operation, and provide one-line drawings, logic diagrams, and other reference drawings, as appropriate. Cite MAR and significant chemicals (amount, form, confinement, controls), energy sources and other significant hazards.

**NOTE: The number in brackets following the questions below is a reference to the corresponding section of the standard.**

### 1.2 REFERENCES

- a) List documents and analyses that constitute the current safety basis for the facility/process
- b) List other references used to support the evaluation
- c) List hazard analyses/safety analyses that support the conclusions reached in this worksheet

**NOTE: If applicable and if a hazard or safety analysis has not been provided, the change should be returned to change control to develop such an analysis.**

## SECTION 2: USQ SCREENING

### 2.1 Screening – Part I

If a USQD must be performed because USQ screening is not applicable (PISA), complete Section 2.2 and continue to Section 3 to complete the USQD.

- a. Is this a purely editorial change that does not affect the technical content? [8.3.1.a]  Yes  No
- b. Is the change covered by a DOE approved categorical exclusion? [8.3.1.b]  Yes  No
- c. Is this change completely enveloped by a previous USQD? [8.3.1.c]  Yes  No

If any answer to any question in Section 2.1 above is "Yes", the change does not require a USQ Determination. Continue to the Summary of Section 2. Otherwise continue below.

### 2.2 Impacts [8.3.2]

- a. Identify all Safety Basis documents, procedures, tests and experiments that may be impacted by this change (e.g. FSAR, TSRs, Procedures, etc.) [8.3.2.a]:
- b. Identify all accidents evaluated in the facility Safety Basis that may be impacted by this change [8.3.2.b]:
- c. Identify all safety SSCs described in the current Documented Safety Analysis that may be impacted by this change [8.3.2.c]:

## ATTACHMENT F. USQ WORKSHEETS

d. Identify all equipment important to safety other than safety SSCs that may be impacted by this change [8.3.2.d]:

e. Identify credible dominant failure modes, process parameters, and malfunctions associated with this change [8.3.2.e]:

### **2.3 Screening – Part II**

a. Is this a temporary or permanent change in the facility as described in the existing documented safety analysis? [8.3.3.a]  Yes  No

b. Is this a temporary or permanent change in the procedures as described in the existing documented safety analysis? [8.3.3.b]  Yes  No

c. Is this a test or experiment not described in the existing documented safety analysis? [8.3.3.c]  Yes  No

Basis for your answers (reference documents reviewed):

If the answer to any question in Section 2.3 above is "Yes", a USQ Determination must be performed. Continue to Section 3 after completing the Summary section below.

### **USQ Screening Summary:**

Based on answers to the screening questions above:

this change does not require a USQ Determination. Complete the cover sheet summary.

this change requires a USQ Determination. Complete Section 3.

## ATTACHMENT F. USQ WORKSHEETS

<b><u>SECTION 3: Unreviewed Safety Question Determination (USQD)</u></b>	
1. Could the proposed change increase the probability of occurrence of an accident previously evaluated in the documented safety analysis? Explain your answer below.	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Could the proposed change increase the consequences of an accident previously evaluated in the documented safety analysis? Explain your answer below.	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Could the proposed change increase the probability of occurrence of a malfunction of equipment important to safety previously evaluated in the documented safety analysis? Explain your answer below.	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Could the proposed change increase the consequence of a malfunction of equipment important to safety previously evaluated in the documented safety analysis? Explain your answer below.	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Could the proposed change create the possibility of an accident of a different type than any previously evaluated in the documented safety analysis? Explain your answer below.	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. 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 documented safety analysis? Explain your answer below.	<input type="checkbox"/> Yes <input type="checkbox"/> No
7. Does the proposed change reduce the margin of safety? Explain your answer below.	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b><u>USQ Determination Summary:</u></b>	
<p>If the answer to any question in Section 3 above is "Yes", the proposed change involves an Unreviewed Safety Question. Based on the evaluation above:</p> <p><input type="checkbox"/> this change does not constitute an Unreviewed Safety Question.</p> <p><input type="checkbox"/> this change does constitute an Unreviewed Safety Question (and DOE approval is required prior to implementation).</p> <p>Complete the cover sheet summary.</p>	

# ATTACHMENT G. PISA PROCESS FLOW CHART

## PISA PROCESS FLOW CHART

Including some related activities

