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February 1, 2024

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Subject: Berkeley Site Office (BSO) Review and Approval of Lawrence Berkeley National Laboratory (LBNL) Unreviewed Safety Issue (USI) Process Document

Reference: (1) RP24006, David Kestell to Paul Golan, "Request for Review and Approval of Lawrence Berkeley National Laboratory's Unreviewed Safety Issue (USI) Process Document," November 9, 2023
(2) EHS Procedure: 703.4 Revision: 0, "Unreviewed Safety Issue (USI) Process," November 8, 2023

Dear Mr. Kestell:

The BSO has completed its review of the subject Institutional Unreviewed Safety Issue (USI) Process. BSO participated in a series of meetings held throughout October-November 2023 during which RPG staff, representatives of the LBNL accelerator facilities and BSO reviewed and provided comments on various drafts of the USI process. BSO is satisfied that all comments were appropriately resolved and approves the USI Process (Reference 2) for immediate implementation.

If you have any questions, please contact Salma El-Safwany of my staff at salma.el-safwany@science.doe.gov.

Sincerely,

PAUL GOLAN Digitally signed by PAUL GOLAN
Date: 2024.02.01 11:51:20 -08'00'

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Unreviewed Safety Issue (USI) Process

EHS Procedure: 703.4 Revision: 0
Effective Date: February 1, 2024

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1 OVERVIEW

1.1 Purpose

The purpose of this procedure is to define the institutional-level Unreviewed Safety Issue (USI) Process for Lawrence Berkeley National Laboratory (LBNL), ensuring compliance with U.S. Department of Energy (DOE) Order 420.2D, *Safety of Accelerators* (hereafter "Accelerator Safety Order," or "ASO").

1.2 Scope

This procedure applies to accelerators at LBNL that operate above 10 MeV and works in conjunction with an accelerator facility's current Safety Assessment Document (SAD), DOE-approved Accelerator Safety Envelope (ASE), and facility-specific implementing procedures.

Accelerators that operate at 10 MeV or below, or have a DOE-approved exemption from ASO's Contractor Requirements Document Section 2(b).3, are not subject to the USI Process but may choose to apply the process nonetheless.

1.3 Discussion

This USI Process provides guidance for the uniform review of proposed activities; changes to systems, equipment, or operations; and discovered conditions at accelerators or accelerator facilities to determine whether they introduce new or previously unreviewed accelerator-specific hazards. This process does not determine the safety of a given situation but rather identifies and evaluates changes and categorizes them as within or exceeding the established and approved authorization basis. The USI Process supports configuration management efforts to maintain facility and supporting safety documentation.

The USI Process:

- focuses on proposed changes to system/equipment and/or operations/activities as well as discovered changes or conditions not matching the description of the facility, its operations, or the reviewed hazards in the SAD;
- allows accelerator facility line management to make changes to the facility, activities, and procedures without DOE Berkeley Site Office (BSO) approval only if the changes introduce accelerator-specific hazards that are adequately bounded and addressed by the current SAD and approved ASE;
- determines who has the final approval authority for the proposed change (accelerator facility line management or BSO); and
- documents or references the technical basis for the conclusions that are reached by the screener/evaluator.

In general, the USI Process contains two steps:

1. Screening: Through completion of this step, the accelerator facility line management determines whether a more detailed evaluation of a condition is needed regarding the

potential for introducing new accelerator-specific hazards not adequately addressed by the SAD and ASE.

2. Evaluation: A formal safety evaluation of the USI is conducted by the facility. When a USI evaluation is completed, it becomes a Reviewed Safety Issue (RSI).

2 DEFINITIONS

Accelerator: "A device and its components employing electrostatic or electromagnetic fields to impart kinetic energy to molecular, atomic, or sub-atomic particles and capable of creating a radiological area as defined by 10 CFR Part 835, *Occupational Radiation Protection*. Accelerator components include injectors, targets, beam dumps, detectors, experimental enclosures, accelerator enclosures, experimental areas, and experimental apparatus utilizing the accelerator. The accelerator also includes associated support and test facilities, equipment, systems, and utilities necessary to operate the accelerator or utilize the accelerated beam" (DOE O 420.2D).

Accelerator facility: The accelerator, plant, buildings, structures, and equipment supporting the accelerator and its operation that are under the direct control of LBNL.

Accelerator Safety Envelope: "A documented set of verifiable physical and administrative requirements, bounding conditions, and credited controls that ensure safe operation and address specific hazards and risks" (DOE O 420.2D).

Authorization basis: The set of documents or requirements upon which a decision is made by DOE as to whether to authorize the start or continuation of activities. For LBNL accelerators, the authorization basis is contained in the SAD, DOE-approved ASE, and in BSO's review and approval report.

Reviewed Safety Issue: "The outcome of the evaluation and determination phase of the USI Process" (DOE O 420.2D).

Safety Assessment Document: "A document containing the results of a safety analysis for an accelerator or accelerator facility pertinent to understanding the risks to workers, the public, and the environment of operating the accelerator" (DOE O 420.2D).

Unreviewed Safety Issue: "An activity or discovered condition with accelerator-specific hazards that have yet to be evaluated to determine whether the activity or discovered condition introduces accelerator-specific hazards that are not adequately addressed by the current SAD and approved ASE" (DOE O 420.2D).

USI Process: "The process or methodology used to evaluate/review USIs to determine whether the activity or discovered condition is adequately addressed by the current SAD and approved ASE" (DOE O 420.2D).

3 RESPONSIBILITIES

3.1 Radiological Control Manager

- Establishes LBNL ASO policy

- Provides compliance oversight for each accelerator facility to ensure that the USI processes meet the requirements of the ASO
- Notifies BSO upon discovery of accelerator conditions that are not adequately addressed in an accelerator facility's current SAD and approved ASE
- Oversees periodic USI assurance activities
- Provides compliance oversight of RSIs

3.2 Accelerator Division Director

- Provides leadership and resources to ensure that the division complies with the requirements of the ASO, including adherence to the USI Process

3.3 Accelerator Program Head

- Establishes and maintains an implementing USI procedure that recognizes changes to the facility and process conditions affecting an existing SAD or ASE
- Ensures that personnel conducting USI screenings and evaluations are properly qualified
- Notifies the Radiation Protection Group (RPG) upon discovery of conditions that introduce accelerator-specific hazards that are not adequately addressed by the current SAD and approved ASE

4 PROCEDURE

4.1 Unreviewed Safety Issue Implementation

Each accelerator program subject to this USI Process must write and maintain a USI implementation procedure that satisfies the accelerator facility requirements listed within this document.

The USI Process at each accelerator facility shall evaluate proposed activities or discovered conditions that introduce new or previously unreviewed accelerator-specific hazards to ensure controls are in place to prevent or mitigate hazards as appropriate. The term "activities" includes modifications, temporary changes, permanent changes, affected procedures, and new activities that potentially compromise the bounding conditions of the ASE. A flowchart guide of the USI Process for proposed work or discovered conditions is provided as Attachment A.

The procedures describing implementation of the USI Process for each accelerator must detail how and when proposed activities or discovered conditions are evaluated. Each facility must describe how the USI Process is integrated into facility-specific configuration management, work planning, and incident reporting processes.

Any activity expected to exceed the bounding conditions of the ASE must be formally evaluated as a USI.

4.2 Training and Qualifications

Each facility must ensure that personnel conducting the USI screenings and evaluations are adequately trained and qualified.

At a minimum, accelerator facility personnel who perform USI screenings or USI evaluations must be knowledgeable in the ASE requirements, assumptions in the SAD, reporting requirements of this document, and the design of the accelerator facility and processes being screened or evaluated.

Each facility must stipulate in its implementing USI procedure the qualifications and how they are documented.

4.3 USI Screening

Screening questions are used to help determine whether a proposed change or discovered condition requires the formal evaluation of a USI.

Accelerator facilities must identify how their USI screening process, including the specific screening questions in this section and Sections 4.3.1 and 4.3.2, is built into facility-specific processes through their implementing procedures. Each facility may develop additional screening questions, as appropriate, specific to the accelerator's SAD and ASE.

If a discovered condition represents a noncompliance with a DOE-approved safety program (e.g., the Radiation Protection Plan, including the Radiological Work Authorization [RWA] process) but the noncompliance does not introduce a precursor to an accelerator hazard or affect an already analyzed accelerator hazard, the issue is not considered a USI.

> *Example*: A worker enters a posted radiological area and they do not have the minimum required training required by the RWA.

Additionally, if the hazards associated with changes in the facility are completely mitigated by DOE-approved safety management systems and processes, then use of the USI evaluation is not invoked for those changes. This represents the primary screening question applicable to both proposed changes or discovered conditions.

> *Primary screening question*: Are the hazards related to the proposed change or discovered condition completely mitigated by DOE-approved safety management systems and processes separate from the SAD and approved ASE?
>
> If the answer is "yes," then the issue is not a USI. No USI evaluation is required and no RSI needs to be generated.

Accelerator facilities should track proposed changes or discovered conditions that were screened and found not to be a USI. If implemented, this tracking process should be described in their implementing USI procedure.

4.3.1 Screening for Proposed Changes

The following screening questions are used to determine whether a proposed change, including a temporary change, requires a USI evaluation and development of an RSI:

Screening Question 1 for Proposed Changes: If the proposed change is related to an administrative or physical control discussed in the SAD, will the change decrease the effectiveness of the controls managing accelerator hazards (including those stated in the approved ASE)?

If "yes," then an evaluation must be performed and documented as an RSI.

SADs discuss the effects of mitigated and unmitigated risks. Therefore, changes to administrative controls discussed in the SAD have the potential to affect the integrity of the ASE. Accelerator Program Heads must ensure that changes made to administrative controls, facility procedures, and the physical infrastructure do not adversely affect the approved ASE.

Physical changes considered to be "equivalent changes" (i.e., like-for-like) do not constitute a "change" and are not subject to a USI evaluation or RSI documentation, provided the following applicable screening questions yield a "yes" response:

If the change is implemented, will the physical equipment:

- continue to meet the identified design and hardware interface requirements for the equipment as described in the SAD?
- continue to fall within the identified assumptions of the SAD?
- not affect the safety or design basis?

Each facility must describe how equivalent changes are identified and determined to be like-for-like. The above questions must be addressed and the results documented as part of the accelerator facility's configuration management process.

Changes to facility-specific procedures, including revisions that affect controls discussed in the SAD or the approved ASE, are subject to USI screening.

Screening Question 2 for Proposed Changes: Does the proposed change introduce a new accelerator hazard or change an existing accelerator hazard?

If "yes," then an evaluation must be performed and documented as an RSI.

4.3.2 Screening for Discovered Conditions

Discovered conditions are unexpected, as-found conditions or events that may introduce unreviewed accelerator-specific hazards or compromise a mitigating control required by the approved ASE. If the screening outcome shows that the discovered condition does not affect or implicate accelerator hazards or the controls that mitigate them as discussed in the SAD, no USI evaluation is required.

Screening Question 1 for Discovered Conditions: Does the discovered condition involve a physical control, administrative control, or critical assumptions (e.g., beam parameters) included in the SAD or approved ASE and used to mitigate an accelerator hazard?

If "yes," then an evaluation must be performed and documented as an RSI.

Example 1: Upon a facility walk-through, it is found that an unexpected penetration has been made in the permanent accelerator shielding. This shielding is required to be in place per the ASE controls.

This condition involves a physical control included in the SAD and approved ASE and is used to mitigate an accelerator hazard. Therefore, an evaluation must be performed and documented as an RSI.

Example 2: During movement of an overhead crane that requires head protection, it was found that a worker was not wearing protective headgear while walking under the crane.

This condition does not involve a physical or administrative control in the SAD or approved ASE that is used to mitigate an accelerator hazard. Therefore, no USI evaluation is required.

Screening Question 2 for Discovered Conditions: Does the discovered condition indicate that existing or new accelerator-specific hazards are not adequately addressed by the current SAD and approved ASE?

If "yes," then an evaluation must be performed and documented as an RSI.

For discovered discrepant conditions that have the credible potential to introduce accelerator-specific hazards that are not adequately addressed by the current SAD and approved ASE, the accelerator facility must do the following pending completion of an RSI:

1. Immediately suspend the impacted or affected operations.
2. Place the facility in a safe and stable configuration.
3. Promptly notify the Accelerator Division Head and Radiological Control Manager (RCM).
4. Identify necessary measures to safeguard against recurrence.

4.4 Development of the RSI

If a proposed activity or discovered condition bypasses USI screening or does not pass the USI screening questions, it must be formally evaluated to determine whether accelerator-specific hazards are adequately addressed by the current SAD and approved ASE. Once a USI has been evaluated, it becomes an RSI, may be considered as an addendum to the accelerator's SAD, and must be managed by line management accordingly.

Accelerator facilities must describe how their RSI process discusses and evaluates the USI, which determines whether changes and conditions in the facility are bound by the provisions of the SAD and the approved ASE.

Accelerator facilities must describe how RSIs are documented.

All completed RSI evaluations must be documented and provided to RPG for oversight.

4.5 RSIs for Proposed Activities

4.5.1 RSI Result: New Hazard(s) Introduced

If the RSI determines that proposed work will introduce accelerator-specific hazards that are not adequately addressed by the current SAD and approved ASE, then further action is needed before the proposed work is implemented (e.g., changes needed to the SAD and ASE).

BSO must approve the implementation or start of activities associated with the RSI. This approval may come in the form of other required BSO approvals (e.g., updates or amendments to an approved ASE or the start of commissioning or routine activities after an Accelerator Readiness Review).

For all RSIs that determine further action is needed, RPG must be contacted to determine the approvals needed before the proposed work starts or is implemented.

4.5.2 RSI Result: No New Hazards Introduced

If the RSI determines that no new hazards will be introduced and the proposed changes are adequately addressed and mitigated by the current SAD and approved ASE, no further action is necessary.

4.6 RSIs for Discovered Conditions

If a physical or administrative control is implicated in a discovered condition, then the RSI evaluation must demonstrate that the safety envelope is being maintained with reasonable assurance through the aggregate of controls discussed in the SAD. The standard for reasonable assurance is higher for DOE-approved credited controls since there are specific design requirements that are intended for those controls. In general, if the effectiveness of a credited control has been diminished beyond its design specifications, then reasonable assurance has been lost.

4.6.1 RSI Result: New Hazard(s) Introduced

If the RSI determines that discovered conditions introduce accelerator-specific hazards that are not adequately addressed by the current SAD and approved ASE, the accelerator facility must do the following:

1. Immediately suspend the impacted or affected operations.
2. Place the facility in a safe and stable configuration.
3. Promptly notify the Accelerator Division Head and RCM.
4. Identify necessary measures to safeguard against recurrence.

BSO must approve any measures implemented to address the discovered condition and any updates or amendments to the approved ASE. Additionally, BSO must provide written approval for the resumption of impacted/affected operations.

4.6.2 RSI Result: No New Hazards Introduced

If the RSI determines that no new accelerator hazards have been introduced and the discovered condition is adequately addressed by the current SAD and approved ASE, no further action is necessary.

4.7 Notification Requirements

Accelerator Program Heads or their designees must promptly notify the RCM upon discovery of conditions that introduce, or have credible potential to introduce, accelerator-specific hazards that are not adequately addressed by the current SAD and approved ASE.

The RCM must promptly notify BSO upon discovery of conditions that introduce, or have credible potential to introduce, accelerator-specific hazards that are not adequately addressed by an accelerator facility's current SAD and approved ASE.

4.8 Control of This Document

The initial version of this procedure and any future changes require BSO approval. Editorial revisions (e.g., correcting typographical errors) may be made to this procedure without DOE approval. However, the revised document must be provided to BSO when changed.

5 RECORDS

5.1 Records Created

- Accelerator-specific procedures implementing the USI Process
- USI screening documentation
- RSI determination documentation

5.2 Who Retains Records

The accelerator facility retains the documentation of all USI screenings, RSI determinations, and the facility-specific USI implementing procedure in accordance with standards and methods established and overseen by RPG.

6 REFERENCES

DOE G 420.2-1A, *Accelerator Facility Safety Implementation Guide for DOE O 420.2C, Safety of Accelerator Facilities*, Washington, DC: Office of Science, U.S. Department of Energy.

DOE O 420.2D, *Safety of Accelerators*, Washington, DC: Office of Science, U.S. Department of Energy.

EHS Procedure 703, *Institutional Assurance of Accelerator Safety Order Compliance*, Radiation Protection Group, Environment, Health & Safety, Lawrence Berkeley National Laboratory.

EHS Procedure 780, *Records Management/Document Control*, Radiation Protection Group, Environment, Health & Safety, Lawrence Berkeley National Laboratory.

Radiation Protection Program for Lawrence Berkeley National Laboratory, Environment, Waste & Radiation Protection Department, Lawrence Berkeley National Laboratory.

7 REVISION LOG

Date, Revision #	Brief Description of Revision / Changes	Pg. #, Sec. #, Parag.
February 1, 2024 Revision 0	New document describing Berkeley Lab's site-wide procedure for implementing the Unreviewed Safety Issue (USI) Process, in compliance with DOE Order 420.2D, *Safety of Accelerators.*	All

8 ATTACHMENTS

Attachment A – USI Process Flowchart

Attachment A – USI Process Flowchart