
		ES&H Section Procedures	
Procedure Number/Name ESH-ASD-0001 – Unreviewed Safety Issue (USI) Process Implementation Procedure		Original Date: 12/15/2023	
Written by: <i>Jessica Malo, Accelerator Safety Specialist</i>	Reviewed and Updated By: Jessica Malo	Date: 12/15/2023	

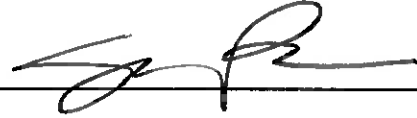
Unreviewed Safety Issue (USI) Process Implementation Procedure

Approvals

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Revision History

Updated by	Description of Change	Revision Number	Revision Date
Jess Malo	Initial Implementation	0	December 15, 2023

Table of Contents

Unreviewed Safety Issue (USI) Process Implementation Procedure 1

Approvals 1

Revision History 2

Table of Contents 3

Procedure 4

 1.0 Purpose 4

 2.0 Scope 4

 3.0 Definitions 4

 4.0 Roles and Responsibilities 5

 5.0 Health and Safety Warnings 8

 6.0 Prerequisites 8

 7.0 Program Requirements 8

 8.0 Data and Records Management 16

 9.0 Quality Assurance/Quality Control 16

 10.0 References 16

 11.0 SOP Signature Sheet 17

Procedure

1.0 Purpose

The purpose of this procedure is to implement the requirements and responsibilities of the Fermi National Accelerator Laboratory Unreviewed Safety Issue (USI) Program. The Fermilab Unreviewed Safety Issue (USI) Program provides a standard approach for accelerators to review Unreviewed Safety Issues (“issues”) to determine if the issue is adequately addressed by the current Safety Assessment Document (SAD) and an approved Accelerator Safety Envelope (ASE).

2.0 Scope

The USI Program is applicable to all Fermilab accelerators that operate above 10 MeV in accordance with DOE O 420.2D Safety of Accelerators (“Order”), once the accelerator has an approved Accelerator Safety Envelope (ASE), to ensure that proposed activities and/or discovered conditions are adequately addressed by the SAD and an approved ASE. The USI Program should be used when there are proposed activities and/or discovered conditions during both operational and non-operational periods to ensure appropriate Configuration Management of the accelerator, and to ensure that accelerator-specific hazards are adequately addressed by the current SAD and approved ASE. The USI Program no longer applies when an accelerator is decommissioned. The USI Process is divided into three (3) main steps: screening, evaluation & determination. The scope of this procedure also includes notifications and records requirements.

3.0 Definitions

The following definitions from the Order are applicable to the USI Process:

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.

Accelerator Safety Envelope (ASE) A documented set of verifiable physical and administrative requirements, bounding conditions, and credited controls that ensure safe operation and address accelerator specific hazards and risks.

Note: *Fermilab has multiple accelerators, each with their own ASE. When going through the USI Process, only the ASE for the accelerator that has the proposed activity and/or discovered condition is used. If the proposed activity and/or discovered condition may require modification to the ASE, this is referred to using language such as “the affected ASE” or as “affects the ASE”.*

Note: Each accelerator’s ASE specifically describes what constitutes an ASE Violation for each Credited Control. In the USI Evaluation phase, specific questions are included in the USI Evaluation Form to determine if the ASE was Violated.

Credited Controls	Controls determined through the Safety Analysis to be essential for safe operation directly related to the protection of workers, the public, and the environment. Note: Credited Controls determined to be impacted and/or modified by proposed activities or discovered conditions will be referred to as “affected Credited Controls” or other such language throughout the Program document.
DOE Field Element Manager	The manager having overall responsibility for a DOE field element including execution of oversight policy implementation. The Field Element Manager directs activities of DOE/NNSA field or site offices and has line accountability for all site program, project execution, and contract management.
Reviewed Safety Issue (RSI)	The outcome of the evaluation and determination phase of the USI Process.
Safety Assessment Document (SAD)	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.
Unreviewed Safety Issue (USI)	An activity or discovered condition with accelerator specific hazards that have yet to be evaluated to determine if the activity or discovered condition introduces accelerator specific hazards that are not adequately addressed by the current SAD and approved ASE.
USI Process	The process or methodology used to evaluate/review USIs to determine if the activity or discovered condition is adequately addressed by the current SAD and approved ASE.

4.0 Roles and Responsibilities

Roles and Responsibilities integral to the USI Process are defined below.

4.1 Screener

The screener is an identified Fermilab employee who has received USI Screening training. These individuals are typically members of the ESH Division, accelerator operators, accelerator Machine Owners and their line management. The ESH Accelerator Safety Department Head is responsible for identifying and providing training to USI Screeners, and maintaining a list of qualified Screeners. The Screener is responsible for:

- completing the USI Screening Form; and
- reviewing/signing the USI Screening Form with the Machine Owner.

4.2 Machine Owner

The Machine Owner is the Fermilab employee identified as the primary point of contact for an accelerator or segment of an accelerator. This individual has knowledge of the accelerator (or segment of the accelerator) and its associated SAD Chapter(s) and ASE. These individuals are identified either by being appointed by their respective Associate Lab Director (ALD) as a Machine Department Head or the author of the SAD Chapter. The Machine Owner is responsible for:

- reviewing and concurring with the determination of the USI Screening Form;
- signing the USI Screening Form with the Screener;
- notifying accelerator operators of proposed activities or discovered conditions that warrant USI Evaluation, requesting that accelerator operations to the affected accelerator, or accelerator segment, be suspended immediately and put in a safe and stable condition;
- submitting completed USI Screening Forms to the ESH Division Accelerator Safety Department;
- completing the USI Evaluation Form, when determined by the USI Screening Form, with the ESH Division Accelerator Safety Department;
- notifying accelerator operations of an ASE violation, requesting that accelerator operations to the affected accelerator, or accelerator segment, be suspended immediately and put in a safe and stable condition; and
- signing the USI Evaluation Form with the ESH Division Accelerator Safety Department Head.

4.3 ESH Division Accelerator Safety Department

The Environment, Safety and Health (ESH) Division Accelerator Safety Department is made up of accelerator safety specialists who have demonstrated familiarity with and ability to interpret DOE O 420.2D, *Safety of Accelerators*, including the USI Process. The ESH Division Accelerator Safety Department is responsible for:

- collecting completed USI Screening Forms;
- completing the USI Evaluation Form with the Machine Owner;
- processing the USI Evaluation Forms, ensuring all required signatures/approvals are received
- providing notification when a USI is identified;
- providing notifications when an ASE violation is identified
- maintains records of USI Screenings and USI Evaluations, including assigning USI Report Numbers; and
- ensuring identified personnel are adequately trained in the USI Program.

4.4 ESH Division Accelerator Safety Department Head

The ESH Division Accelerator Safety Department Head is responsible for:

- maintaining the USI Program
- identifying and providing training to USI Screeners

- maintaining a list of qualified Screeners
- reviewing the USI Program and recommending approval of the USI Program to the Fermilab Director;
- promptly (within one business day) notifying DOE upon discovery of conditions with the credible potential to introduce accelerator specific hazards that are not adequately addressed by the current SAD and approved ASE; and
- reviewing and signing the USI Evaluation Form with the Machine Owner.

4.5 Senior Radiation Safety Officer

The Fermilab Senior Radiation Safety Officer (SRSO) is responsible for:

- reviewing the USI Program and recommending approval of the USI Program to the Fermilab Director;
- approving USI Evaluation Forms with radiological accelerator-specific findings when a USI is identified; and
- determining whether a USI with radiological accelerator-specific findings warrants further reporting, including possible Occurrence Reporting and Processing System (ORPS) and Noncompliance Tracking System (NTS) reporting.

4.6 Chief Safety Officer (CSO)

The Fermilab Chief Safety Officer (CSO) is responsible for:

- reviewing the USI Program and recommending approval of the USI Program to the Fermilab Director;
- approving USI Evaluation Forms with oxygen deficiency hazard (ODH) accelerator-specific findings and/or non-accelerator specific (NASH) findings when a USI is identified; and
- determining whether a USI with ODH findings and/or NASH findings warrants further reporting, including possible Occurrence Reporting and Processing System (ORPS) and Noncompliance Tracking System (NTS) reporting.

4.7 Directorate/Division Leadership

The Directorate Associate Lab Directors and Division Senior Directors who operate accelerators are responsible for:

- reviewing the USI Program and recommending approval of the USI Program to the Fermilab Director.

4.8 Fermilab Director

The Fermilab Director is responsible for:

- Approving the USI Program;
- Approving commencing/resuming operations following a USI that affects the SAD;
- Approving commencing/resuming operations following a USI that affects an ASE; and

- approving resuming operations following an ASE violation.

4.9 Fermilab DOE Site Office Manager

The Fermilab DOE Site Office Manager (i.e., the DOE Field Element Manager) is responsible for:

- Approving the USI Program;
- Approving commencing/resuming operations following a USI that affects an ASE; and
- Approving resuming operations following an ASE violation.

5.0 Health and Safety Warnings

The execution of this procedure is administrative in nature; no additional health and safety warnings are applicable.

6.0 Prerequisites

Material & Equipment

- N/A

Training Required

- General Employee Radiation Training (GERT)
- Applicable ASE(s)
- Read SAD Section 7, Appendix B.2 USI Program

7.0 Program Requirements

The process steps necessary to execute USI program requirements are defined below.

7.1 USI Screening

The USI Process begins with completing the USI Screening Form (R.P. Form 138). The USI Screening Form is completed by the Screener. The Screener may work with other individuals who are proposing an activity or who discovered the unusual condition to understand the details and aid in completion of the USI Screening Form. The purpose of the screening is to review various situations and determine if they should be formally evaluated using the USI Evaluation Process.

The USI screening process is initiated by the acknowledgement of a proposed change or as-found condition and is used to determine if existing Credited Controls specified in the applicable ASE are affected; if there is a potential that the proposed activity or discovered condition introduces new or previously unreviewed accelerator specific hazards; if the proposed activity or discovered condition exceeded, or may exceed, the bounding conditions of the ASE; if there is a potential that the proposed activity or discovered condition introduces new or previously unreviewed non-accelerator specific hazards; or if documentation related to accelerator operations are updated and/or modified.

Based on the USI Screening Questions, the Screener will determine if the proposed activity or discovered condition is not a USI or if it shall be evaluated for a USI. Once complete, the USI Screening Form is reviewed by the Machine Owner who will provide concurrence with the USI Screening Determination.

Possible Outcomes of the USI Screening Process

- If it is determined that a proposed activity is not a USI, the activity may proceed.
- If it is determined that a discovered condition is not a USI, the condition is documented (via the USI Screening Form) but no further action is necessary.
- If it is determined that a proposed activity shall be evaluated for a USI, the accelerator operations with the proposed activity in place may not proceed until approvals are provided at the conclusion of the USI Evaluation.
- If it is determined that a discovered condition shall be evaluated for a USI, ongoing accelerator operations shall be stopped immediately and not resume until approvals are provided at the conclusion of the USI Evaluation.
 - Resumption of affected accelerator operations prior to receiving necessary approvals at the conclusion of the USI Evaluation constitutes an ASE Violation.

7.1.1 USI Screening – Proposed Activity

Initiating event: Work in or on the accelerator and/or adjacent infrastructure is requested or proposed. Proposed changes as described by Fermi National Accelerator Laboratory Unreviewed Safety Issue (USI) Program, Section 1 require USI Screening.

Responsibility	Action Steps
USI Screener	<ol style="list-style-type: none"> 1. Obtains and completes RP Form 138a – USI Screening Form – Proposed Activity <ol style="list-style-type: none"> a. If any “YES” answers, USI Evaluation per 7.2 is required prior to proceeding with the proposed change. b. If all questions were answered “NO”, issue is not a USI. The activity may proceed with machine owner approval per step 3, below. 2. Sign the completed USI Screening form
Machine Owner	<ol style="list-style-type: none"> 3. Review and sign the completed USI Screening form. (Note: the Machine Owner and USI Screener may be the same individual.) <ol style="list-style-type: none"> a. If any “YES” answers were indicated, <ol style="list-style-type: none"> i. Notification to ESH ASD Head is required to request a USI Evaluation. ii. The USI Process must be complete, meaning that any identified actions are

	<p>completed, and the RSI is approved, prior to making the proposed change.</p> <p>b. If all “NO” answers were indicated, no notifications are required.</p>
USI Screener	4. Submit completed form to ESH ASD for records retention
ESH ASD	<p>5. Assign a USI Screening Number to the completed Screening Form.</p> <p>6. Perform quality assurance check of completed USI Screening.</p> <p>7. Completed records of USI Screening Forms are to be filed and retained in ESH DocDB.</p>

7.1.2 USI Screening Process – Discovered Condition

Initiating event: A condition is discovered with the potential to affect credited controls or introduce new accelerator specific hazards outside of the bounds of the approved ASE.

Responsibility	Action Steps
Discoverer	<p>1. Notifies ESH ASD of a discovered condition(s) warranting USI Screening. (Note: If there is a reasonable likelihood that the discovery exceeds the bounding conditions for safe operations in the approved ASE, <u>discoverer should contact the applicable accelerator operations group to request immediate termination of accelerator operations prior to the completion of USI Screening.</u>)</p>
ESH ASD	<p>2. Identify and assign a Screener to perform USI Screening for the Discovered Condition.</p>
USI Screener	<p>3. Obtains and completes RP Form 138b for Discovered Conditions.</p> <p>a. If all questions were answered “NO”, issue is not a USI.</p> <p>b. If any “YES” answers, <u>Accelerator Operations shall be requested to be terminated immediately.</u></p> <p>i. Notify machine owner immediately and proceed to step 4 below. USI</p>

	<p>Evaluation per Section 7.2 is required.</p> <p>4. Sign the completed USI Screening form.</p>
Machine Owner	<p>8. Review and sign the completed USI Screening form. (Note: the Machine Owner and USI Screener may be the same individual)</p> <p>a. If any “YES” answers were indicated,</p> <p>i. <u>Immediate notification to Accelerator Operations is required to terminate accelerator operations.</u></p> <p>ii. Immediate notification to ESH ASD Head is required to request a USI Evaluation.</p> <p>iii. If Accelerator Operations were terminated due to the outcome of the Screening and Evaluation, the Machine Owner shall immediately notify the DOE Facility Representative of the USI.</p> <p>b. If all “NO” answers were indicated, no notifications are required.</p>
USI Screener	<p>9. Submit completed form to ESH ASD for records retention</p>
ESH ASD	<p>10. Assign a USI Report Number to the completed Screening Form.</p> <p>11. Perform quality assurance check of completed USI Screening.</p> <p>12. Completed records of USI Screening Forms are to be filed and retained in ESH DocDB.</p>

7.2 Evaluation & Determination

- 7.2.1 Once it is determined via the USI Screening Process that a proposed activity or discovered condition shall be evaluated for a USI by the Machine Owner and the ESH Accelerator Safety Department complete the USI Evaluation Form (R.P.

Form 139) together. The purpose of the evaluation is to determine if a proposed activity or discovered condition is an Unreviewed Safety Issue (USI) (an “issue”) or not.

Based on the USI Evaluation Questions, the Machine Owner and ESH Division Accelerator Safety Department member will determine if the proposed activity or discovered condition is or is not a USI, and what level of approvals are necessary for USIs. Once complete, the USI Evaluation Form is approved by both the Machine Owner and ESH Accelerator Safety Department Head. All issues determined to be USIs are further approved by either the Senior Radiation Safety Officer (SRSO) or Chief Safety Officer (CSO), based on the type(s) of hazard(s) included in the USI. All issues that affect the SAD (i.e., the SAD needs to be modified based on the outcome of the USI Evaluation Form) are further approved by the Director. All Issues that affect the ASE (i.e., the ASE needs to be modified based on the outcome of the USI Evaluation Form) are further approved by both the Director and Fermilab DOE Site Office Manager. All USIs found to have violated the ASE must follow the ASE Violation response action items specified in the ASE. Fermilab DOE Site Office Manager approval is required prior to resuming operations following an ASE violation. The USI Process must be complete, meaning that any identified actions are completed, and the RSI is approved, prior to beginning operations (for proposed activities) or resuming operations (for discovered conditions).

Possible Outcomes of the USI Evaluation Process

- If it is determined that a proposed activity is not a USI, the activity may proceed.
- If it is determined that a discovered condition is not a USI, the condition is documented (via the USI Evaluation Form) but no further action is necessary.
- If it is determined that a proposed activity or discovered condition is a USI, and is a temporary condition (and the configuration described in the SAD/ASE will be reestablished prior to resuming operations), SRSO/CSO approval is required after confirming that all required Credited Controls are in place. Once SRSO/CSO approval is obtained, operations may resume/proceed.
- If it is determined that a proposed activity or discovered condition is a USI, is a permanent condition and affects only the SAD, SRSO/CSO and Director approval is required after completing necessary actions (i.e., shielding assessment, ODH calculation, SAD Chapter update, etc.). Once SRSO/CSO and Director approval is obtained, operations may resume/proceed.
- If it is determined that a proposed activity or discovered condition is a USI, is a permanent condition, and affects the ASE, SRSO/CSO, Director and DOE FSO Manager approval is required after completing necessary actions (i.e., shielding assessment, ODH calculation, SAD Chapter update, ASE update, review, etc.). Once SRSO/CSO, Director and FSO Manager approval is obtained, operations may resume/proceed.
- If it is determined that a proposed activity or discovered condition is a USI that resulted in an ASE violation, DOE must provide written approval for resumption of impacted/affected operations.

- For activities or discovered conditions that are determined to be a USI, once all appropriate approvals have been received, the issue becomes a Reviewed Safety Issue (RSI) and may be considered an addendum to the SAD.

Completed USI Evaluation Forms are submitted to the ESH Division Accelerator Safety Department for appropriate records retention.

Initiating event: USI Screening form indicated that an issue warrants further USI evaluation. (Note: any “YES” answer on the USI Screening form will necessitate a USI Evaluation).

Responsibility	Action Steps
Machine Owner	<ol style="list-style-type: none"> 1. Obtains and completes RP Form 139 – USI Evaluation Form <ol style="list-style-type: none"> a. Work with ESH ASD to complete USI Evaluation form.

7.2.2 Possible outcome paths state above necessitate distinct action steps for each possible outcome. Steps for each outcome of the Completed RP Form 139 are below.

7.2.2.1 If it is determined that a proposed activity is **not a USI**, the activity may proceed.

Responsibility	Action Steps
Machine Owner	<ol style="list-style-type: none"> 1. Signs completed USI Evaluation form and provides to ESH-ASD. 2. Notifies requestor of proposed activity that activity may proceed with no impact to Accelerator operations.
ESH ASD	<ol style="list-style-type: none"> 3. Completed records of USI Evaluation Forms are to be filed and retained in ESH DocDB.

7.2.2.2 If it is determined that a discovered condition is **not a USI**, the condition is documented (via the USI Evaluation Form) but no further action is necessary.

Responsibility	Action Steps
Machine Owner	<ol style="list-style-type: none"> 1. Signs completed USI Evaluation form and provides to ESH-ASD. 2. Notifies the accelerator operators, informing them the outcome of the USI Evaluation and that operations to the affected accelerator, or accelerator segment, may resume.

ESH ASD	3. Completed records of USI Evaluation Forms are to be filed and retained in ESH DocDB.
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7.2.2.3 If it is determined that a proposed activity or discovered condition is a USI, and is a downtime modification (i.e., the configuration described in the SAD/ASE will be reestablished prior to resuming operations), SRSO/CSO approval is required after confirming that all required Credited Controls are in place. Once SRSO/CSO approval is obtained, operations may resume/proceed.

<u>Responsibility</u>	<u>Action Steps</u>
Machine Owner	<ol style="list-style-type: none"> 1. Signs completed USI Evaluation form and provides to ESH-ASD. 2. Notify the applicable Accelerator ALD.
ESH ASD	<ol style="list-style-type: none"> 3. Notifies the SRSO and the CSO of the USI. 4. Completed records of USI Evaluation Forms are to be filed and retained in ESH DocDB. 5. Configuration Control Log must reflect a restoration of affected credited controls in compliance with the approved SAD and ASE prior to resumption of operation. 6. Completed records of USI Evaluation Forms are to be filed and retained in ESH DocDB.

7.2.2.4 If it is determined that a proposed activity or discovered condition is a USI, is a permanent condition and affects only the SAD, SRSO/CSO and Director approval is required after completing necessary actions (i.e., shielding assessment, ODH calculation, SAD Chapter update, etc.).

<u>Responsibility</u>	<u>Action Steps</u>
Machine Owner	<ol style="list-style-type: none"> 1. Signs completed USI Evaluation form and provides it to ESH-ASD. 2. Immediately notify the applicable Accelerator ALD. 3. Notify the DOE Facility Representative of the USI within one business day.
ESH ASD	<ol style="list-style-type: none"> 4. Immediately notifies SRSO and CSO. 5. Once SRSO/CSO and Director approval is obtained following completion of

	<p>required actions, operations may resume/proceed.</p> <p>6. Completed records of USI Evaluation Forms are to be filed and retained in ESH DocDB.</p>
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7.2.2.5 If it is determined that a proposed activity or discovered condition is a USI, is an operational condition, and affects the ASE, SRSO/CSO, Director and DOE FSO Manager approval is required after completing necessary actions (i.e., shielding assessment, ODH calculation, SAD Chapter update, ASE update, review, etc.). Once SRSO/CSO, Director and FSO Manager approval is obtained, operations may resume/proceed.

Responsibility	Action Steps
Machine Owner	<ol style="list-style-type: none"> 1. Signs completed USI Evaluation form and provides it to ESH-ASD. 2. Immediately notifies affected Associate Lab Director (ALD), Chief Research Officer (CRO) and Fermilab Director of the ASE violation. 3. Immediately notify the DOE Facility Representative of the outcome.
ESH ASD	<ol style="list-style-type: none"> 4. Immediately notifies the SRSO, CSO, and Chief Operating Officer (COO) 5. Once SRSO/CSO and Director approval is obtained following completion of required actions, operations may resume/proceed. 6. Completed records of USI Evaluation Forms are to be filed and retained in ESH DocDB.

7.2.3 For activities or discovered conditions that are determined to be a USI, once all appropriate approvals have been received, the issue becomes a Reviewed Safety Issue (RSI) and may be considered an addendum to the SAD.

Responsibility	Action Steps
ESH ASD Head	<ol style="list-style-type: none"> 1. Send completed USI Evaluation Form to the SRSO, CSO, affected ALD, COO, CSO and FSO Facility Representative. 2. Notifies the Machine Owner, accelerator operators, and the affected ALD that permission has been obtained to resume accelerator operations.

8.0 Data and Records Management

All completed USI Screening Forms and USI Evaluation Forms shall be submitted to the ESH Division Accelerator Safety Department. The ESH Division Accelerator Safety Department will assign USI Report numbers for each screened/evaluated proposed activity or discovered condition. The ESH Division shall maintain the completed forms and ensure appropriate record keeping and archiving.

Electronic copies of completed USI Evaluation Forms shall be submitted to the FSO Facility Representative, regardless of determination.

9.0 Quality Assurance/Quality Control

This procedure is subject to a review frequency requirement of 3 years and is due 12/31/2026.

10.0 References

- DOE O 420.2D, Safety of Accelerators
- Fermi National Accelerator Laboratory Unreviewed Safety Issue (USI) Program
- Fermilab Environment Safety and Health Manual (FESHM), Chapter 2010

11.0 SOP Signature Sheet

This table indicates all qualified personnel, and documents that they have read and understood this procedure and completed necessary Procedure Specific Training listed in Section 7.0. By signing below, the qualified individual agrees to adhere to the requirements and guidelines contained within this procedure along with all other applicable work authorization documents. Only persons who have signed below and have been authorized may perform work covered by this SOP.

Name	Signature	Date	Department Head/Team Leader

*WARNING: Paper copies of this procedure may be obsolete after it is printed.
The current version of this procedure is found at: [ESH DocDB 7576](#)*