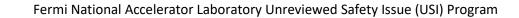
FERMI NATIONAL ACCELERATOR LABORATORY

FERMI NATIONAL ACCELERATOR LABORATORY UNREVIEWED SAFETY ISSUE (USI) PROGRAM

Revision 0 December 21, 2023

Appendix B of the Safety Assessment Document



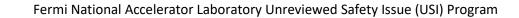




Unreviewed Safety Issue (USI) Program

Approval Page

The following individuals have reviewed the Unreviewed Safety Issue (USI) Program and recommend its approval. School ESH Division Accelerator Safety Department Head Chief Safety Officer Accelerator Directorate (AD) Associate Lab Director Director & Fermi Site Office Final Approval Final approval of the Unreviewed Safety Issue (USI) Program is granted by the Fermilab Director and the DOE Field Element Manager. Director, Fermi National Accelerator Laboratory DOE Field Element Manager, Fermi Site Office

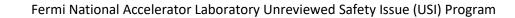






Revision History

Author	Rev. No.	Date	Description of Change
Angela Aparicio Nino Chelidze Jess Malo Maddie Schoell	0	December 21, 2023	Initial issue of the Unreviewed Safety Issue (USI) Program within Appendix B of the SAD. Updating process to align with DOE O 420.2D. Removed the term "significant" from evaluation questions, replaced with Risk Categorization determinations from DOE-HDBK-1163-2020 Split the USID Form into two parts: (1) Screening and (2) Evaluation Clarified Roles & Responsibilities Incorporation of Reviewed Safety Issue (RSI) at the end of the USI Process





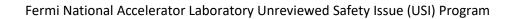




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Unreviewed Safety Issue (USI) Program

1. Program Overview

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). The USI Program is applicable to all Fermilab accelerators that operate above 10 MeV (see R.P. Form 135 List of Accelerators). The USI Program does not apply to accelerators that operate below 10 MeV that are managed as Radiation Generating Devices (RGDs) (see R.P. Form 108 List of Radiation Generating Devices).

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 following elements of the USI Program are explicitly required per the Order's Contractor Requirements Document (CRD) §2.f:

- The USI Process must 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, and new activities.
- The USI Process must evaluate USIs to determine if accelerator specific hazards associated with a proposed activity or discovered condition are adequately addressed by the current SAD and approved ASE. Any activity expected to exceed the bounding conditions of the ASE must be evaluated using the USI process. Once an USI has been appropriately reviewed, the issue becomes a Reviewed Safety Issue (RSI) and may be considered as an addendum to the SAD.
- DOE approval is required if the USI Process determines that a Reviewed Safety Issue introduces accelerator specific hazards that are not adequately addressed by the current SAD and approved ASE prior to implementation of the proposed activity.
- DOE must be promptly notified 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.
- If conditions are discovered that introduce accelerator specific hazards that are not adequately
 addressed by the current SAD and approved ASE, impacted/affected operations must be
 suspended immediately and put in a safe and stable configuration. Discovered conditions must



be addressed using DOE approved measures, as appropriate. DOE must provide written approval for resumption of impacted/affected operations.

The Fermilab SAD evaluates accelerator specific hazards to ensure they're maintained within acceptable levels. For Prompt Ionizing Radiation, acceptable levels are described in Table 1 below. For Oxygen Deficiency Hazards (ODH), acceptable levels are risk categories of III or IV, per DOE-HDBK-1163-2020 methodology as described in SAD Section I Chapter 4.

Table 1. Acceptable Dose Levels (from SAD Section I Chapter 4)

Dose	Location	Potentially Exposed Individual
5 Rem	Inside service buildings	A Facility Worker and/or Co-
		Located Worker
500 mrem	Outside of enclosures/facilities	A Facility Worker and/or Co-
	and surrounding shielding, in	Located Worker
	non-publicly accessible areas	
100 mrem	Outside of enclosure, in location	Maximally-exposed Off-Site
	where public is invited	Individual (a.k.a. a member of
		the public

If a proposed activity or discovered condition changes the hazard to an unacceptable level (i.e., beyond the acceptable levels in Table 1 for Prompt Ionizing Radiation, or risk category of I or II for ODH), that is a condition that was not previously evaluated and/or adequately addressed in the SAD. As such, the USI Process shall be utilized; when there is a reasonable chance that an issue could affect the probability or consequence (a.k.a., the "risk") of an accident from that evaluated in the Fermilab SAD, or when the issue could introduce an accident or malfunction of a different type than any evaluated in the SAD.

Unreviewed Safety Issues ("issues") fall into two categories: (1) proposed activities, or (2) discovered conditions. Issues that warrant review using the USI Process include, but are not limited to:

Proposed Activities

- New accelerators, accelerator segments, or experimental areas
- Modifications¹ to existing accelerators, accelerator segments, or experimental areas
- Modifications¹ to existing operating modes and/or parameters
- Modifications¹ to Credited Controls beyond the bounds of the ASE

¹ Modifications is a general term used throughout the USI Process, and encompasses both proposed activities and discovered conditions. "Downtime modifications" are modifications made during accelerator/segment downtime, in which the configuration will be back in place as described in the SAD prior to resuming operations, and do not require updates to the SAD and/or ASE. "Operational modifications" are activities or conditions that will remain in place when accelerator/segment operations resume, and can be both temporary modifications or permanent modifications. Operational modifications to Credited Controls will require updates to the applicable SAD Chapter and ASE prior to resuming operations. Operational modifications to other aspects of the accelerator will require an approved Reviewed Safety Issue (RSI) prior to resuming operations.



- Planned excavation or construction within the Excavation Waiver Prohibited Zone
- Non-editorial modifications to a procedure whose implementation is associated with a Credited Control
- Decommissioning activities
- Discovered Conditions
 - Discovery of modifications to existing accelerators, accelerator segments or experimental areas that include hazards beyond those evaluated in the SAD or ASE
 - Discovery of modifications to existing operating modes and/or parameters that have the potential to introduce new accelerator specific hazards or increase the consequence of a previously evaluated accelerator specific hazard
 - Discovery of failed or missing Credited Controls
 - Discovery of non-editorial modifications to a procedure whose implementation is associated with a Credited Control

The USI Process is divided into three (3) main steps: screening, evaluation & determination, and also includes notifications and records requirements. The USI Process is described in Section 3.

1.1. Program Approvals

The USI Program is approved in the following order/manner:

- 1. Program updated and maintained by the ESH Accelerator Safety Department.
- 2. Program reviewed and recommended by:
 - a. Accelerator Safety Department (ASD) Head
 - b. Senior Radiation Safety Officer (SRSO)
 - c. Chief Safety Officer (CSO)
 - d. Accelerator Directorate (AD) Director
 - e. Applied Physics and Superconducting Technology Directorate (APS-TD) Director
- 3. Program approved by Lab Director
- 4. Program submitted to Fermi Site Office (FSO) with request for approval
- 5. Program approved by FSO Manager

1.2. Definitions

Definitions from the Order applicable to the USI Process are defined in ESH-ASD-0001 – *Unreviewed Safety Issue (USI) Process Implementation Procedure*.



2. Roles and Responsibilities

Machine owners, qualified screeners, and ESH ASD will work together to meet the requirements of the USI Program, including the required notifications through the execution of the ESH-ASD-0001 – *Unreviewed Safety Issue (USI) Process Implementation Procedure.*

Detailed description of roles and responsibilities is defined in ESH-ASD-0001 – *Unreviewed Safety Issue (USI) Process Implementation Procedure*. The ESH Division Accelerator Safety Department Head is further responsible for maintaining the USI Program. 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. The Fermilab Chief Safety Officer (CSO) is responsible for reviewing the USI Program and recommending approval of the USI Program to the Fermilab Director. 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. The Fermilab Director is responsible for approving the USI Program. The Fermilab DOE Site Office Manager (i.e., the DOE Field Element Manager) is responsible for approving the USI Program.



3. The USI Process

The USI Process is divided into three (3) main steps: screening, evaluation & determination, and records. The process is summarized in the flowchart shown in Appendix 1.

The USI Process is described in the implementation procedure (Doc # ESH-ASD-0001), describing how proposed activities and discovered conditions are screened, evaluated, and the final determination is documented.

3.1. 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 Form asks a series of questions 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.

Accelerator operations must be terminated when the USI Screening indicates that an issue shall be evaluated for a USI, however operations may be terminated at any point during the USI Screening portion.

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.

3.2. USI Evaluation & Determination

Once it is determined via the USI Screening Process that a proposed activity or discovered condition shall be evaluated for a USI, 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.

The USI Evaluation Form asks a series of questions to determine: if Credited Controls are affected; if the ASE was violated; if new accelerator specific hazards are introduced that were not previously evaluated in the SAD, or change the risk categorization of a previously evaluated hazard to a Category I or II; if new non-accelerator specific hazards are introduced that were not previously evaluated in the SAD, or change the risk categorization of a previously evaluated hazard to a Category I or II; if documents related



to accelerator operation remain within the bounds of the SAD; and if there are additional aspects to the proposed activity or discovered condition that would necessitate an update to the SAD or ASE.

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).

Prior to approving USIs, the SRSO and/or CSO evaluate the Issue to determine if further reporting via ORPS and/or NTS is warranted.

3.3. Notifications

Various notifications occur throughout the USI Process. The following notifications are required when the specified conditions are identified throughout the USI Process.



Table 2. Notification Requirements for USI Process

Condition	Required Action (who notifies who)	Completion Time
It is determined via the USI Screening Process that a discovered condition shall be evaluated for a USI.	The Machine Owner notifies the accelerator operators, and requests that accelerator operations to the affected accelerator, or accelerator segment, be suspended immediately and put in a safe and stable condition. AND The Machine Owner notifies the ESH Division Accelerator Safety Department Head that a USI Evaluation needs to be	Immediately
It is determined via the USI Evaluation Process that a discovered condition is not a USI.	performed. The ESH Accelerator Safety Department Head notifies the accelerator operators, informing them the outcome of the USI Evaluation and that operations to the affected accelerator, or accelerator segment, may resume.	At the completion of the USI Evaluation Form (once the Machine Owner and ESH Accelerator Safety Department Head sign)
It is determined via the USI Evaluation Process that the proposed activity or discovered condition is a USI.	The ESH Accelerator Safety Department Head notifies the SRSO and the CSO of the USI.	Immediately
It is determined via the USI Evaluation Process that a USI has a credible potential to introduce accelerator specific hazards that are not adequately addressed by the current SAD and approved ASE.	The ESH Accelerator Safety Department Head notifies the SRSO and the CSO of the USI. AND The ESH Accelerator Safety	Immediately
	Department Head notifies the DOE Facility Representative of the USI.	Within one business day



Condition	Required Action (who notifies who)	Completion Time
If it is determined that a USI warrants further reporting, including ORPS and/or NTS.	The SRSO and/or CSO notifies the Office of Contractor Assurance Director and the Event Response & Analysis Program Director. AND Event Review & Analysis Program Manager notifies the Lab Management, the DOE Fermi Site Office, and the FRA Board.	Notifications follow the reporting timelines defined within FESHM 3010: Occurrence Reporting, and FESHM 3030: Noncompliance Tracking System
If it is determined that there has been an ASE violation.	The Machine Owner notifies the accelerator operators of the ASE violation, and requests that accelerator operations to the affected accelerator, or accelerator segment, be suspended immediately and put in a safe and stable condition. AND The ESH Accelerator Safety Department Head notifies the SRSO, CSO, affected Associate Lab Director (ALD), Chief	Immediately
	Operating Officer (COO), Chief Research Officer (CRO) and Fermilab Director of the ASE violation. AND The ESH Accelerator Safety Department Head notifies the FSO Facility Representative and FSO Site Office Manager of the ASE violation.	Immediately



Condition	Required Action (who notifies who)	Completion Time
The USI Evaluation is complete, and an issue has become a Reviewed Safety Issue (RSI).	The ESH Accelerator Safety Department Head send completed USI Evaluation Form to the SRSO, CSO, affected ALD, COO, CSO and FSO Facility Representative.	Within one business day of the completion of the USI Evaluation Form
If additional approval is required prior to proceeding/resuming operations.	The ESH Accelerator Safety Department Head notifies the Machine Owner, accelerator operators, and the affected ALD that permission has been obtained to resume accelerator operations.	At the completion of receiving all required approval

4. Records

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 once they have been submitted. USI report number will be in the format of: xxx-yyyymmdd where "xxx" is an abbreviation for the segment/accelerator as indicated below.

Table 3. Accelerator/Segment Abbreviations for USI Report Numbers

Accelerator/Segment	Abbreviation
Linac	LIN
400 MeV Test Area	MTA
Booster	ВОО
8 GeV	8GV
Booster Neutrino Beam	BNB
Main Injector	MI
Recycler	RR
NuMI	NuMI
Muon Campus	MUON
Switchyard	SY
Meson	M
Neutrino Muon	NM
Fermilab Accelerator	FAST
Science & Technology	
(FAST)	
Proton Improvement	PIP2IT
Plan II Integration Test	
(PIP2IT)	



Cryomodule Test Stand	CMTS1
1 (CMTS1)	
Vertical Test Stand (VTS)	VTS

The ESH Division shall maintain the completed forms and ensure appropriate record keeping and archiving is performed in accordance with

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



Appendix 1 – USI Process Flowchart

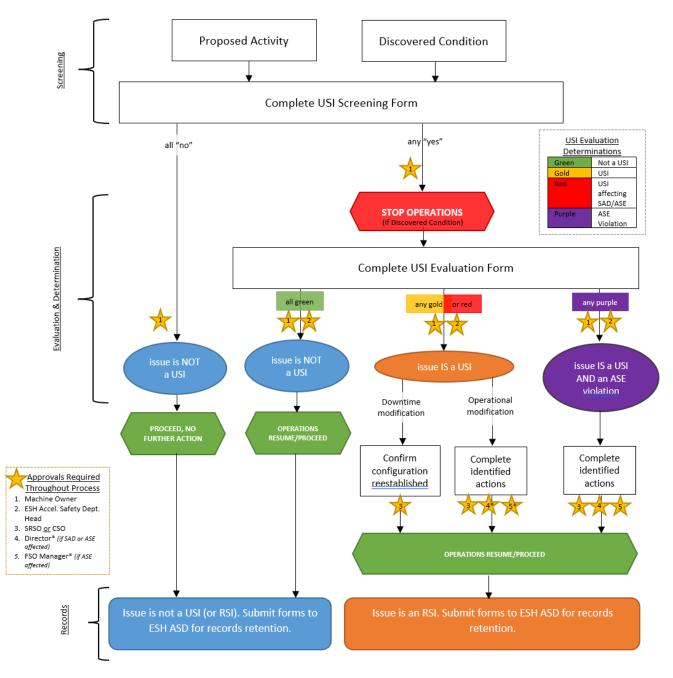


Figure 1. Flowchart of the USI Process.