



FERMI NATIONAL ACCELERATOR LABORATORY

FERMI NATIONAL ACCELERATOR LABORATORY UNREVIEWED SAFETY ISSUE (USI) PROGRAM

Revision 0 November 20, 2023

Appendix B of the Safety Assessment Document

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Unreviewed Safety Issue (USI) Program

Approval Page

Recommendations for Approval

The following individuals have reviewed the Unreviewed Safety Issue (USI) Program and recommend its approval.

ESH Division Accelerator Safety Department
Head

Senior Radiation Safety Officer

Chief Safety Officer

Accelerator Directorate (AD) Associate Lab
Director

Applied Physics & Superconducting Technology
Directorate (APS-TD) 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

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Revision History

Author	Rev. No.	Date	Description of Change
Maddie Schoell	0	November 20, 2023	Initial issue of the Unreviewed Safety Issue (USI) Program within Appendix B of the SAD. <ul style="list-style-type: none"> • 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 implemented for all Fermilab accelerators in accordance with DOE O 420.2D *Safety of Accelerators* (“Order”) to ensure that proposed activities and/or discovered conditions are adequately addressed by the SAD and an approved ASE. 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 hazard to ensure they’re maintained at an acceptable risk category of III or IV. If a proposed activity or discovered condition changes the level of risk to an unacceptable risk category of I or II, 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
 - Credited Controls include: shielding, fencing, the Radiation Safety Interlock System (RSIS) including interlocked radiation monitors, ODH Safety System components, operation authorization documents, operator staffing, search and secure process, and operational parameters (as described in SAD Section I Chapter 4, Section I-4.3.3.4)
 - Planned excavation or construction within the Excavation Waiver Prohibited Zone
 - Non-editorial modifications to a procedure whose implementation is associated with a Credited Control
 - Use of a Compensatory Measure as allowed in the ASE
 - 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
 - Including compromise of soil berms (to determine if the required Credited Control shielding was impacted)
 - Including compromise of fencing (to determine if the required configuration of the Credited Control fencing was impacted)
 - 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 notifications & records. The USI Process is described in Section 3.

¹ Modifications is a general term used throughout the USI Process, and encompasses both proposed activities and discovered conditions. Temporary modifications are activities or conditions that are in place for a short duration of time, and 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. Permanent modifications are activities or conditions that will remain in place moving forward, and will require updates to the applicable SAD Chapter and/or ASE.

1.1. 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.

2. Roles and Responsibilities

2.1. 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 Screener is responsible for:

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

2.2. 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.

2.3. 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.

2.4. ESH Division Accelerator Safety Department Head

The ESH Division Accelerator Safety Department Head is further responsible for:

- maintaining the USI Program;
- 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.

2.5. Senior Radiation Safety Officer (SRSO)

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.

2.6. 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.

2.7. 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.

2.8. Fermilab Director

The Fermilab Director is responsible for:

- approving the USI Program (*note: concurrent approval of DOE-FSO is also required*);
- approving commencing/resuming operations following a USI that affects the SAD;
- approving commencing/resuming operations following a USI that affects an ASE (*note: concurrent approval of DOE-FSO is also required*); and
- approving resuming operations following an ASE violation (*note: concurrent approval of DOE-FSO is also required*).

2.9. 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 (*note: concurrent approval of the Fermilab Director is also required*);
- Approving commencing/resuming operations following a USI that affects an ASE (*note: concurrent approval of the Fermilab Director is also required*); and
- Approving resuming operations following an ASE violation (*note: concurrent approval of the Fermilab Director is also required*).

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.

3.1. USI Screening

The USI Process begins with completing the USI Screening Form (R.P. Form 139.) 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.

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.

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

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 140) 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 (i.e., accelerator operations were permitted to resume after the USI Screening Processes determined that a USI Evaluation was needed and prior to obtaining all required approvals at the conclusion of the USI Evaluation process) are approved by the Fermilab DOE Site Office Manager.

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.

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 or NTS is warranted.

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

3.3. Notifications

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

Table 1. 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.	Immediately
	<u>AND</u> The Machine Owner notifies the ESH Division Accelerator Safety Department Head that a USI Evaluation needs to be performed.	Immediately
It is determined via the USI Evaluation Process that a discovered condition is not a USI.	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 <i>(once the Machine Owner and ESH Accelerator Safety Department Head sign)</i>
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.	Immediately
	<u>AND</u> The ESH Accelerator Safety Department Head notifies the DOE Facility Representative of the USI.	Within one business day
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.	Immediately
	<u>AND</u> Event Response & Analysis Program Director notifies the Lab Management, the DOE Fermi Site Office, and the FRA Board.	Within two hours of ORPS categorization

Condition	Required Action (who notifies who)	Completion Time
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.	Immediately
	<u>AND</u>	
	The ESH Accelerator Safety Department Head notifies the SRSO, CSO, affected Associate Lab Director (ALD), Chief Operating Officer (COO), Chief Research Officer (CRO) and Fermilab Director of the ASE violation.	Immediately
	<u>AND</u>	
	The ESH Accelerator Safety Department Head notifies the FSO Facility Representative and FSO Site Office Manager of the ASE violation.	Immediately
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. 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.

Appendix 1 – USI Process Flowchart

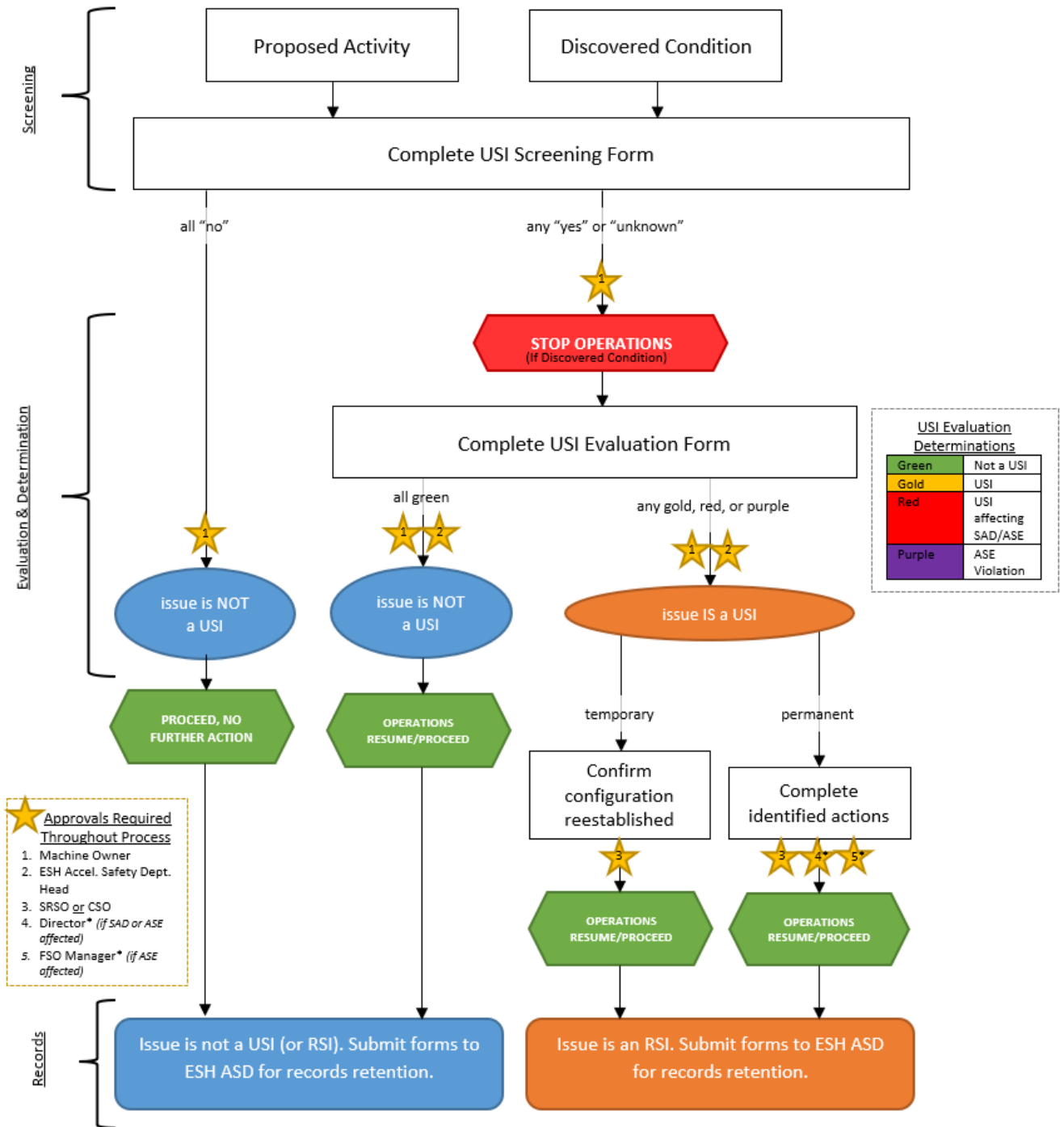


Figure 1. Flowchart of the USI Process.