

ES&H manual

Environment, Safety, and Health

Volume I

Part 4: Feedback and Improvement

Document 4.2 ES&H Issues and Deficiencies Management

Recommended for approval by the ES&H Working Group

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New document or new requirements

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- New document
 Major requirement change

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4.2

ES&H Issues and Deficiencies Management*

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4.2

ES&H Issues and Deficiencies Management

1.0 Introduction

The Lawrence Livermore National Laboratory's (LLNL) Environment, Safety, and Health (ES&H) Issues Tracking System is an improved management system for addressing LLNL's ES&H issues and deficiencies. The ES&H Issues Tracking System (ITS) expands on previous system functions by organizing issues and deficiencies in a centralized and structured way. By doing so, it ensures timely and consistent identification and resolution of safety and health issues and deficiencies at the directorate, cross-directorate, and institutional levels, and provides status information across all directorates. The ITS provides a consistent, standardized approach for documenting assessments, assigning priorities, and tracking issues and deficiencies. This *ES&H Manual* document describes the ITS and the tools used to track the status of issues and deficiencies.

2.0 Overview

This document gives an overview of issue and deficiency management using the electronic Issues Tracking System, the sequence involved in processing issues and deficiencies, and roles and responsibilities. The *ITS Users Manual* provides detailed information on using the ITS.

2.1 Issue and Deficiency Management

Issues and deficiencies can be identified in many settings but are primarily identified during external reviews and internal assessments or event-based reviews, such as Occurrence Reports. Issues and deficiencies may also arise as a result of evaluations of reports and other documents. Document 4.1, "Directorate Environment, Safety, and Health Self Assessment Program" in the *ES&H Manual* contains information describing the overall ES&H self-assessment program at LLNL and identifies assessment reports, event reports, and other documents which might describe deficiencies and issues. Figure 1 shows the fundamental processes used in the identification, tracking, and resolution of issues and deficiencies. (See Appendix A for definitions of terms used in this document.)

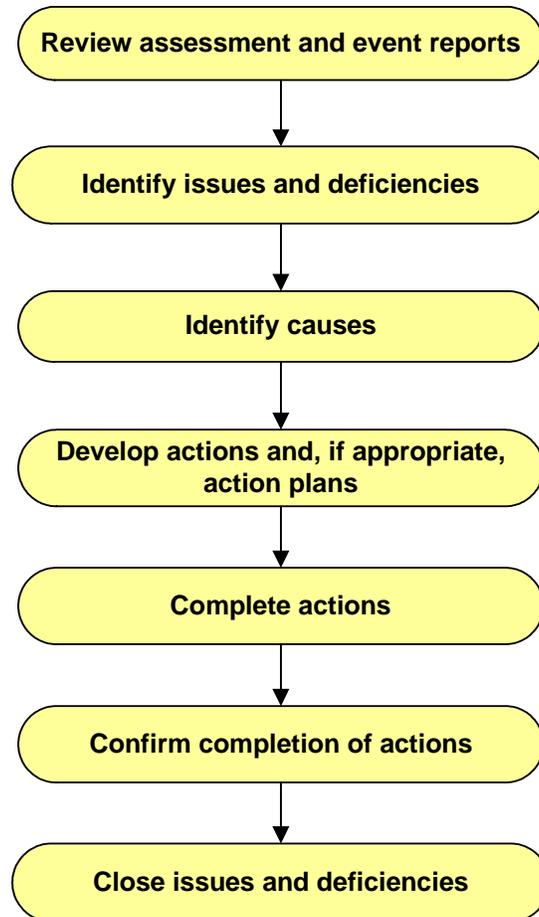


Figure 1. ES&H Issue and Deficiency Management Process.

Issue and deficiency management involves identifying, analyzing, and addressing issues and deficiencies as they occur, while the people of the Laboratory carry out work to meet its mission. As part of this process, management shall use a graded approach based on significance, severity, or risk in:

- Reviewing reports of audits, inspections, investigations, surveillances, and other assessment information to identify issues and deficiencies.
- Developing actions and, if appropriate, action plans.
- Correcting observed deficiencies.
- Determining the underlying cause(s) of deficiencies.
- Taking action to minimize the opportunity for repetition.
- Confirming completion of actions.

Documented action plans may be needed to address some issues and deficiencies, depending on their nature and the extent of their effect upon the organization. Corrective action plans shall be created in response to issues or deficiencies identified in assessments conducted by the Department of Energy (DOE) and the Director's office (e.g., the Assurance Review office and the Audits and Oversight office) as described in Section 3.0. To ensure that the planned actions have taken place, a confirmation that actions are complete is performed prior to closure of the issues and deficiencies and as appropriate for the nature and extent of the item.

2.2 The Issues Tracking System

ITS is a web-based application that provides a centralized database for managing assessment information and tracking issues and deficiencies Laboratory-wide.

By using a web interface and centralizing data storage, ITS provides a wide group of individuals and departments access to information. The system supports management of items that affect one or more directorates. It also allows local (i.e., directorate level) items to be marked as being institutionally important and to be monitored at the institutional level. Both ownership transfer and delegation of authority are allowed.

The ITS uses a common structure across LLNL for describing Directorate- and Institutional-Level items. The information is related by using assessment, a single term used to describe the source of an issue or deficiency, such as an assessment report; event-based report (such as an Occurrence Report, Supervisor Accident Analysis Report; issues; deficiencies; and actions as shown in Figure 2. Each assessment may contain zero, one or more than one issue and deficiency, and each issue or deficiency may contain one or more action.

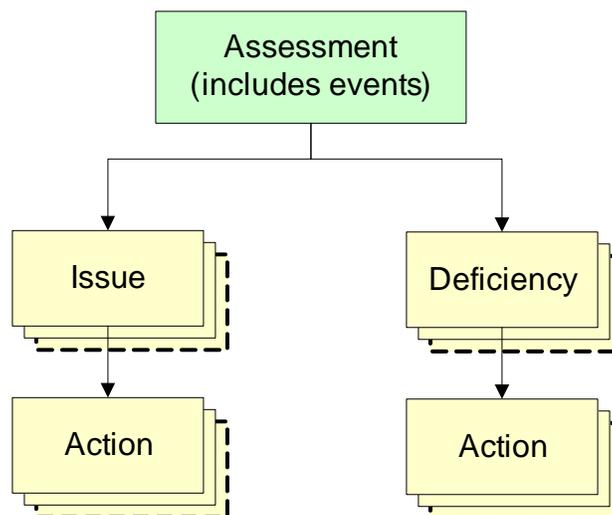


Figure 2. Three-level ITS Information Structure.

2.2.1 Overview of Levels

In the ITS, information items (i.e., assessments, issues, deficiencies, and actions) are entered and stored in one of two database levels: the Directorate Level or the Institutional Level. The system also contains a Laboratory View that is a “window” where the status of issues and deficiencies can be viewed by Associate Directors, the Deputy Director for Operations (DDO), the Director, specific organizations such as the Assurance Review Office (ARO), and designated individuals. Issues and deficiencies are made available for viewing in the Laboratory View from the Directorate Level or the Institutional Level. Issues and deficiencies seen in the Laboratory View constitute the official set of ES&H issues and deficiencies. The relationship of the two levels and the Laboratory View is shown conceptually in Figure 3. An in-depth description of each of these levels and the criteria for entering, releasing to the Laboratory View, and managing issues and deficiencies within ITS is discussed in Section 3 of this document.

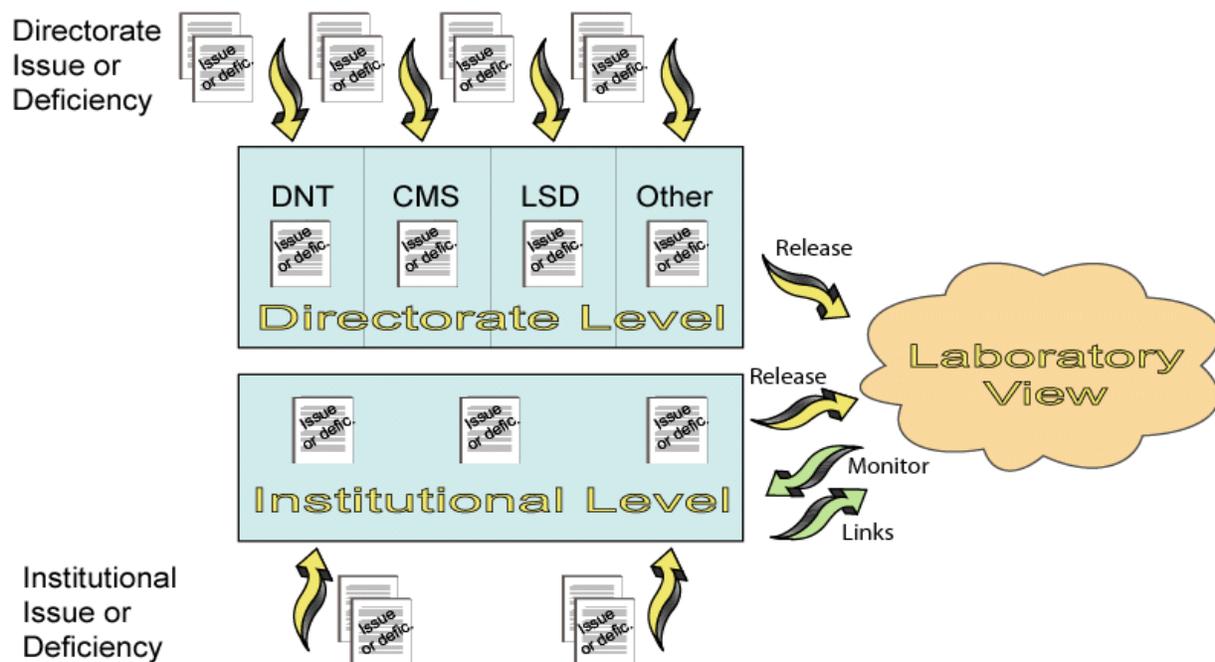


Figure 3. Relationship between Directorate and Institutional Levels and the Laboratory View.

Directorates enter issues or deficiencies into the Directorate Level where they are available for viewing by the originating directorates and designated individuals. Each information item is entered with accompanying identifying information. An item is assigned a unique number by the database and users enter associated information. Documents can also be electronically attached. Similar type information may be entered for issues, deficiencies, and actions. In a process similar to the Directorate Level, issues and deficiencies deemed to be of institutional importance may be entered into the database directly at the Institutional Level. There, they may also be released to the

Laboratory View for viewing by authorized individuals. Some of these may need to have a restricted viewing capability.

Other issues and deficiencies, originally entered at the Directorate Level and later entered into the Laboratory View, may be identified as affecting more than one directorate. They may be entered into the Institutional Level as crosscutting items and then be linked within the ITS from the Institutional Level to the Laboratory View items. The links created are only pointers and the status of an item does not change. A resolution at the Institutional Level does not close the Directorate-Level item.

Senior management will be able to monitor certain issues and deficiencies of an institutional nature by electronically marking the Laboratory View item.

3.0 Institutional ES&H Corrective Action Plans

A formal Corrective Action Plan (CAP) shall be developed for DOE assessment reports and ARO institutional assessments. Figure 4 shows the flow of actions to prepare and close a CAP. The SEP directorate shall coordinate the development of the CAP in conjunction with the affected directorates and submit it to the DDO for approval. Upon receipt of the draft CAP, the DDO will ask the affected directorates and the ARO to review and comment on the plan with respect to its responsiveness to the issues. Following resolution of comments, the DDO will approve the CAP for implementation (ARO assessments) or submittal to the Livermore Site Office (LSO) for approval (DOE assessments).

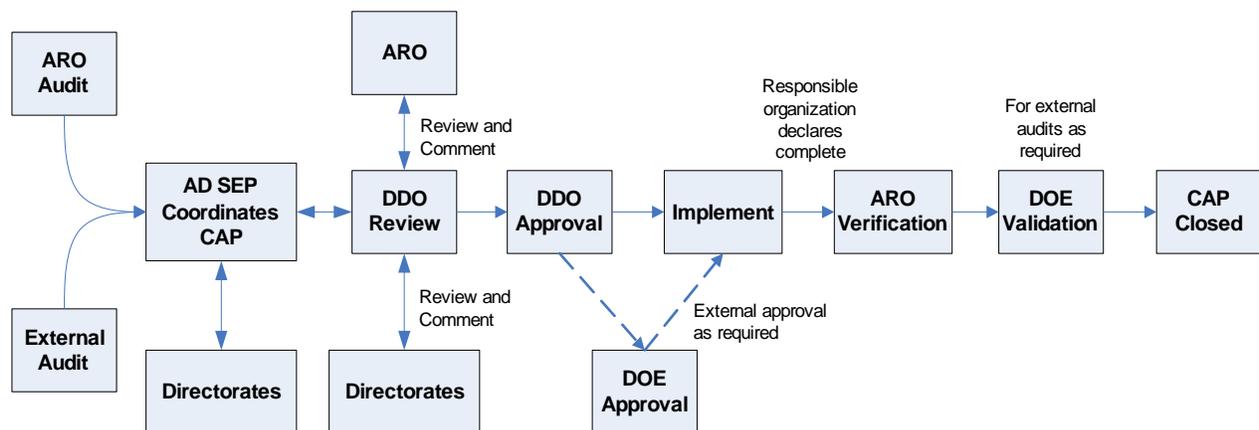


Figure 4. Development of Corrective Action Plans.

Once CAPs are approved, the corrective actions shall be entered into ITS by the responsible directorate and carried out. Any anticipated slippage in delivery dates shall be reported to the ARO in advance of the milestone so that impacts can be assessed and new milestones negotiated. Proposed changes to DOE-approved CAPs must be approved by the DDO prior to submittal to LSO.

The ARO will track progress and the closure of CAP commitments and will issue a quarterly status report. The ARO will provide status reports to the LSO as required.

When completion of an item is declared by the responsible organization, the ARO will confirm that the agreed upon actions have been completed and the item will be considered closed by LLNL. The ARO will coordinate validation of CAP item closure with LSO for DOE assessments.

4.0 Issues Tracking System Process

This section discusses the criteria for entering assessments issues and deficiencies into ITS and describes the Directorate Level, Institutional Level, and Laboratory View of the ITS.

The ITS shall be used to report and document assessments by organizations external to the directorate (e.g., DOE, University of California, ARO, Price-Anderson Amendments Act office, Audits and Oversight office, regulatory agencies) and assessments performed by the directorate (or at the directorate's request) that are scheduled in its self assessment plan, whether or not these assessments resulted in deficiencies. ITS shall be used to document and track commitments to external organizations and to the Director's Office.

4.1 Directorate Level

Most information items will enter the ITS database at the Directorate Level. The Directorate Level allows individual organizations to manage assessments, issues, deficiencies, and actions in a consistent Laboratory-wide manner. Unless released, items entered in the Directorate Level are only available for viewing by the originating directorate, facility management, the associated ES&H Team, and by those as permitted on a need-to-know basis by the originating directorate. For example, Responsible Individuals (RIs) may need to know facility deficiencies that could affect program work occurring in the facility.

Figure 5 gives an overview of the Directorate Level process flow and Table 1 describes the responsibilities and sequence of actions at each phase of the process.

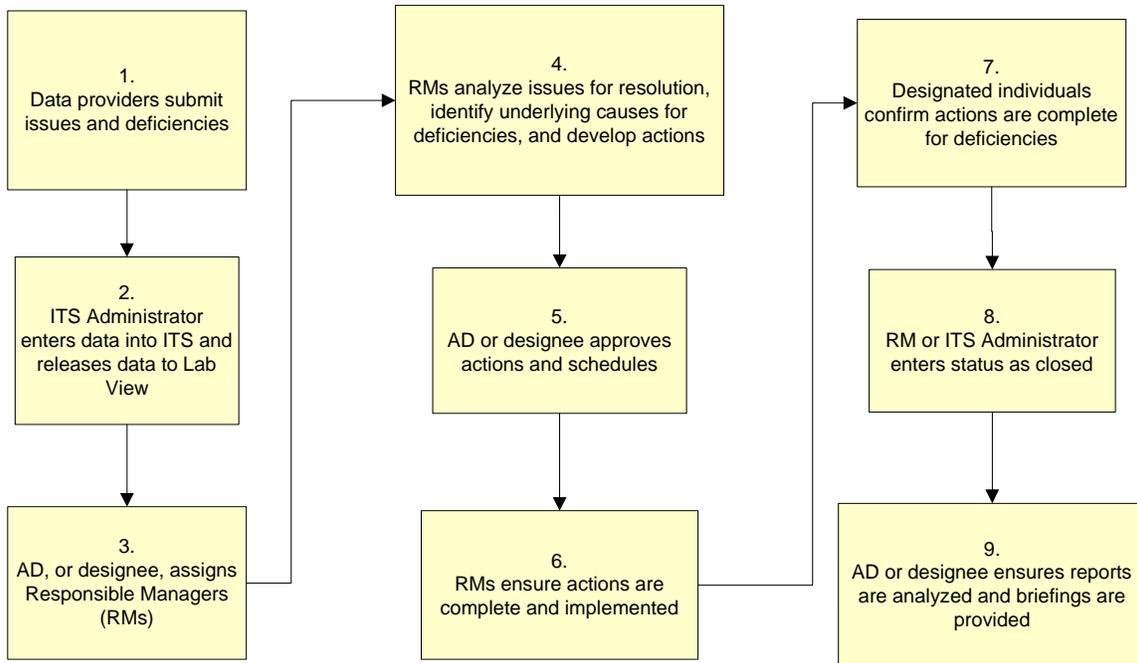


Figure 5. Directorate-Level Process Flow.

Table 1. Directorate Level ITS Responsibilities and Sequence of Actions.

No.	Persons responsible for the action	Action to be performed
1.	Data providers	Submit assessments, issues and deficiencies to the ITS Administrator for entry into the Directorate-Level ITS, using defined directorate and Laboratory criteria.
2.	ITS Administrators	<ul style="list-style-type: none"> Enters data in the Directorate Level using the ITS software, as required by the directorate policies and procedures. Releases deficiency information to the Laboratory View on a regular schedule in accordance with the criteria. Updates the ITS Directorate-Level data as directed.
3.	AD or designee	<ul style="list-style-type: none"> Assigns Responsible Manager (RM) from each directorate for issues and deficiencies entered in the Directorate Level. Coordinates with the SEP AD the actions which are assigned to his or her directorate from DOE assessments and ARO institutional assessments.
4.	RMs assigned issues and deficiencies	<ul style="list-style-type: none"> Analyzes issues for resolution. Identifies underlying causes for deficiencies and extent of conditions, using established methods for analysis in a manner consistent with the characteristics of the deficiencies. Develops actions to resolve issues and correct deficiencies to minimize the opportunity for recurrence. Consults with the assessment organization, if needed.

Table 1. Directorate Level ITS Responsibilities and Sequence of Actions (cont'd).

No.	Persons responsible for the action	Action to be performed
5.	AD or designee	<ul style="list-style-type: none"> • Approves schedules and actions and any revisions to assure they are appropriate, practical, and effective. • For DOE assessments and ARO institutional assessments, report to the ARO and the DDO (or SEP AD, if delegated) any anticipated slippage in delivery dates in advance of CAP milestones so that impacts can be assessed and new milestones negotiated.
6.	RM	Ensures that the actions are fully complete and implemented in practice.
7.	Designated Individuals	<ul style="list-style-type: none"> • Confirm corrective actions for deficiencies have been completed. • For Priority 1 deficiencies, the Assurance Manager confirms completion of the corrective action.
8.	RMs or ITS Administrators	Enter the status of issues and deficiencies in the Directorate Level as "closed."
9.	AD or designee	Ensures ITS reports are analyzed and briefings are provided to identify additional actions or follow up.

Issues are defined as higher-level conditions requiring management attention. There are three levels of issues: Institutional, Directorate, and Local. All commitments that are made to the director's office or to external entities in response to issues shall be entered and tracked in ITS. Issues shall be entered into the ITS within sixty days of discovery or notification. Directorate and Local issues are to be periodically evaluated at the directorate level and the results reported upon in the annual directorate ES&H performance report described in Document 4.1 of the *ES&H Manual*.

Some directorates may wish to designate a priority level for issues. Table 2 shows how issue priorities could be assigned. There may be some times when there is no value to assigning a priority to an issue. In addition, an issue may involve multiple consequences and characteristics; therefore, the table is guidance and its use is not mandatory.

Table 2. Issue Priorities.

Priority A	Issue related to the fundamental ability of an organization to demonstrate that it can operate effectively.
Priority B	Issue is of concern now but temporary compensatory measures are implemented until the issue is resolved.
Priority C	Issue that needs to be watched; the impact of this issue may increase over time if not addressed, or the issue may affect only a portion of LLNL.

An ES&H deficiency is any identified activity, occurrence, or condition not in compliance with the environmental, health, and safety requirements of applicable federal, state and local laws and regulations; Contract 48, or the LLNL *ES&H Manual*.

To facilitate deficiency analysis and the study of trends, each deficiency shall be assigned a compliance code when entered into the ITS. The ES&H Information Management Office (ESH IMO) maintains the ITS compliance code list, which is periodically reviewed and updated by Subject Matter Experts (SMEs) and changes are approved by the ES&H Working Group. Deficiencies shall be assigned priorities as shown in Table 3.

Table 3. Deficiency Priorities.

Priority	Description
Priority 1A: Imminent Danger	A non-compliant condition or practice where danger exists that could reasonably be expected to cause death or immediate serious, permanent physical harm.
Priority 1B: Serious	A non-compliant condition, practice, means, method, operation or process for which there is a substantial probability that a lack of correction or mitigation could result in death or serious harm.
Priority 2: Significant	A non-compliant condition, practice, means, method, operation or process which could harm employees, the public or the environment, or with significant regulatory concern; or is reflective of a systemic weakness.
Priority 3: Minor	A non-compliant situation where there is little probability of injury or harm to employees, the public or the environment; or one that reflects an isolated weakness. Lack of action would not significantly change the risk to employees, the public, or the environment and would not impede LLNL's ability to conduct its work.

Each directorate shall enter into the ITS database sufficient information to facilitate Directorate-Level and Institutional-Level trending, analysis and continuous improvement. Deficiencies and issues that are commitments to external agencies or the Director's Office shall be entered into ITS. All priority 1A, 1B, and 2 deficiencies shall be entered and tracked in ITS. Priority 3 deficiencies identified in scheduled Directorate-Level assessments shall be entered into ITS as individual items. Priority 3 deficiencies identified by other assessment activities that are worthy of institutional note (e.g., arising from an OR or Incident Analysis) or as otherwise mandated (e.g., potential Price-Anderson Amendments Act office non-compliance) shall also be entered into ITS as individual items. Other deficiencies that are repetitive in nature shall be entered as summary or individual deficiencies. Summary entries are intended to capture like items. An appropriate compliance code is to be associated with each individual and summary deficiency entry. Deficiencies shall be entered into the ITS within sixty days of discovery or notification. These requirements for entering deficiencies are illustrated in Figure 6. Each directorate is responsible for tracking deficiencies to closure.

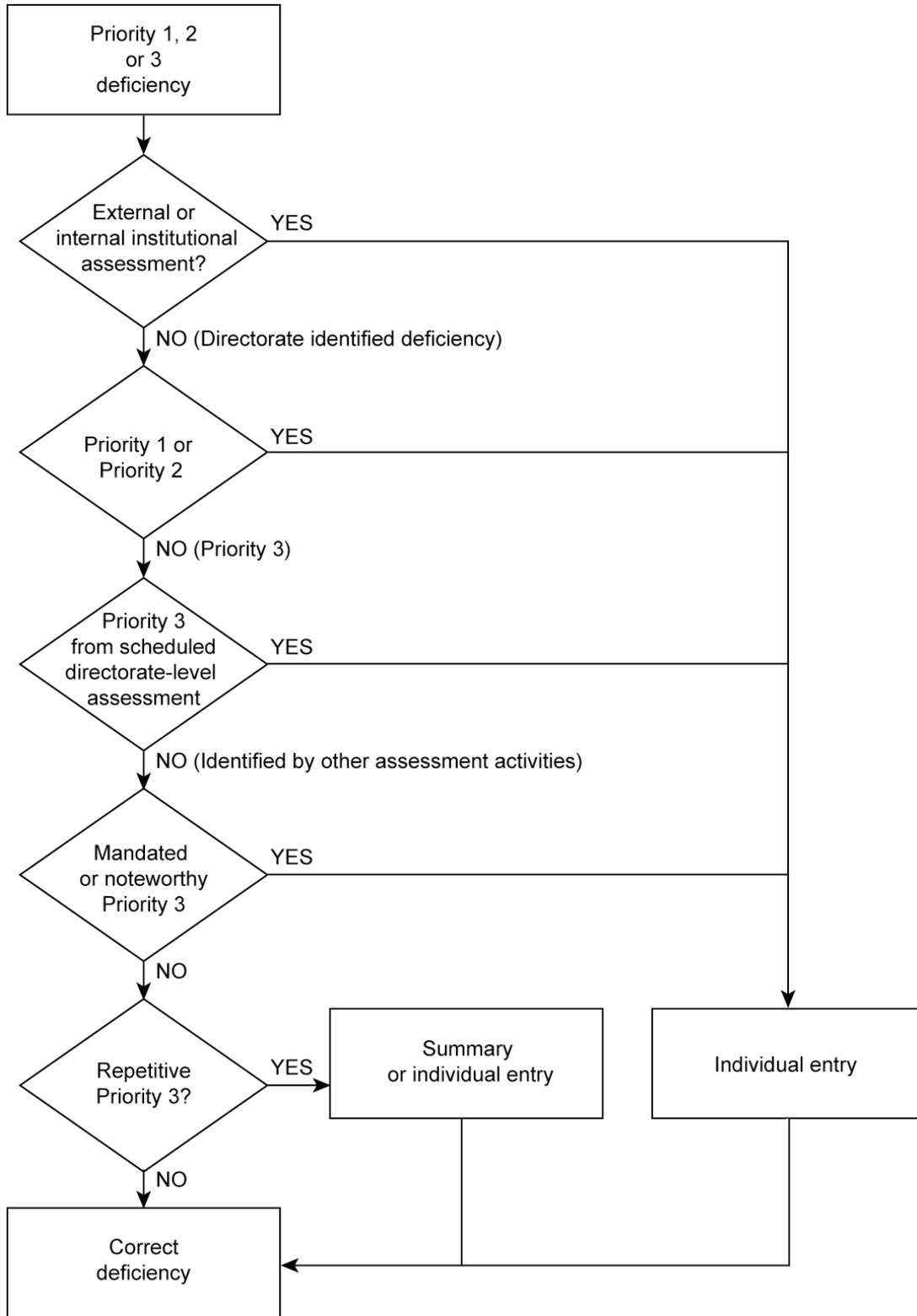


Figure 6. Deficiency entry.

All items that are required to be entered into ITS are also released to Laboratory View. Additional issues or deficiencies entered by the directorate are released at the discretion of the directorate. Once deficiency information meets the quality standards specified by the directorate, it is entered into ITS and can be released into the Laboratory View. These released deficiencies still remain the responsibility of the originating directorate.

Specific requirements exist for handling ITS Priority 1A and 1B deficiencies. Priority 1A items cannot be abandoned once discovered and shall be mitigated or completely corrected before leaving the scene unattended. Priority 1B items shall be mitigated or completely corrected within 5 working days of discovery. If the item cannot be corrected or mitigated within 5 working days, a mitigation plan shall be generated and approved by LSO within the 5-day window. A technical justification is required if a deficiency with a suggested priority code of 1A or 1B is entered into the ITS at a lower priority level and the justification shall be documented in the ITS.

The ES&H deficiencies entered into the Directorate Level may not be transferred unilaterally from one directorate to another. Agreement shall be obtained from the proposed receiving organization before transfer of any ITS item can take place. The *ITS Users Manual* describes the procedures for transferring items between directorates.

Management shall delegate authority in accordance with the line-management chain described in the ISMS Description. The originally responsible AD retains responsibility for the items, even though people or organizations in other directorates may be in the management chain.

4.2 Institutional Level

The Institutional Level is used to identify, track, and resolve institutional and crosscutting ES&H issues that require senior management attention. Forward-looking issues emerging as broader than single-directorate in scope, or posing significant challenges, can be entered directly at the Institutional Level. Institutional-Level items can be linked to related Directorate-Level items in the Laboratory View. Other items needing to be tracked at the Institutional Level can be marked as such in the Laboratory View. Institutional issues and deficiencies shall be entered into ITS using the same criteria as for directorate issues and deficiencies.

4.3 Laboratory View

The Laboratory View is a window where items can be viewed by authorized individuals in all directorates. The Laboratory View is used to communicate information about items that may impact more than one directorate or the entire Laboratory. In addition, items originating at the Institutional Level may be placed in the

Laboratory View when senior management deems it necessary. The placement of items into the Laboratory View is either mandatory or discretionary, depending on the item characteristics. The process for placing items in the Laboratory View is illustrated in Figure 7.

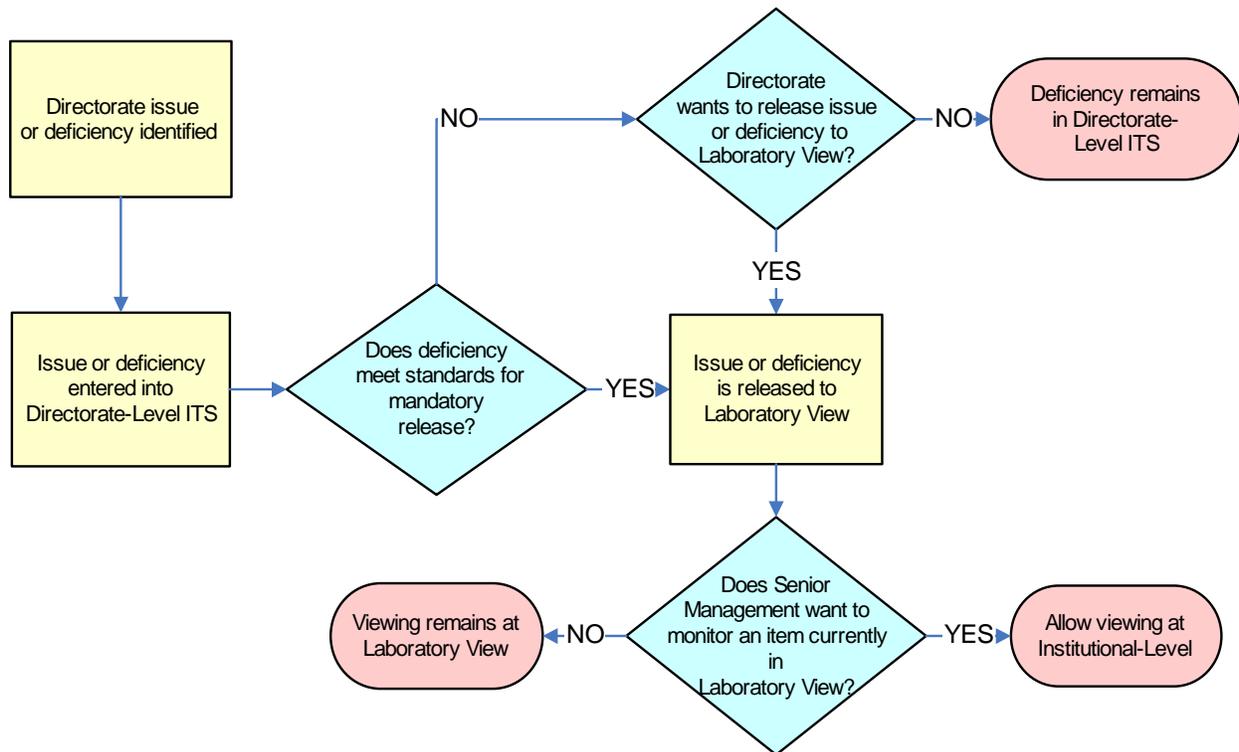


Figure 7. Process for Releasing Items to the Laboratory View.

The Laboratory View is used to:

- Help senior management identify trends in separate directorates or organizations that could emerge as inter-directorate or institutional issues and deficiencies.
- Assist SMEs in identifying trends when looking at deficiencies occurring in multiple directorates, which can then help the SEP AD identify crosscutting issues and deficiencies.
- Allow the ARO to analyze and report trends based on the contents of the Laboratory View.

5.0 Roles and Responsibilities

This section describes the roles and responsibilities for personnel involved in ITS.

5.1 Issue Tracking System Administrators

ITS Administrators shall:

- Enter data using the ITS software as required by directorate and institutional policies and procedures to fulfill established ES&H requirements.
- Release deficiency information to the Laboratory View on a regular schedule in accordance with specified criteria.
- Update the ITS data as directed.

5.2 ES&H Team Members and Subject Matter Experts

Subject Matter Experts and ES&H Team Members shall:

- Review deficiencies occurring in multiple directorates to identify trends within their specific areas of expertise and report these trends to their department heads.

Subject Matter Experts shall:

- Review and update the ITS compliance codes periodically and upon incorporation of new or revised Work Smart Standards for submittal to the ES&H Working Group for review and approval.

5.3 Responsible Managers

Responsible Managers (RMs) work with the Directorate Assurance Manager in resolving Directorate-Level items and with the SEP AD, or designee in resolving Institutional-Level items. Responsible Managers shall:

- Analyze issues for resolution.
- Identify underlying causes for deficiencies and extent of conditions, using established methods for analysis in a manner consistent with the characteristics of the deficiencies.
- Develop actions, plans, and schedules to resolve issues and correct deficiencies, as assigned in consultation with the assessment organization.

- Ensure actions are complete and implemented in practice.
- Close issues and deficiencies in the ITS database.

5.4 Issues Tracking System Manager

The ITS Manager shall:

- Develop and maintain the ES&H ITS.
- Establish institutional training for ITS.
- Develop electronic report formats from the ITS.
- Provide database support to ITS Administrators and Assurance Managers

5.5 Laboratory Assurance Manager and the Department Heads for Environmental Protection, Hazards Control, and Health Services

These managers shall:

- Provide trend results developed by SMEs to the SEP AD for possible entry of issues and deficiencies into the Institutional Level.

5.6 Assurance Managers

The Assurance Managers shall:

- Confirm the completion of planned corrective actions for Priority 1A and 1B deficiencies.
- Provide appropriate assistance to Responsible Managers in confirming completion of planned actions addressing directorate deficiencies and issues.
- Periodically review and analyze the ITS data for the directorate.
- Review results from assessments to assure that deficiencies and issues are managed according to this document.
- Identify trends, if any, associated with deficiencies and issues at Directorate Level in the ITS.
- Provide periodic reports and brief the AD on the status of deficiencies and issues at Directorate Level entered in the ITS.

5.7 Price Anderson Amendments Act Office

- Review data in the ITS to identify potential PAAA noncompliances not otherwise identified.
- Use the ITS as the official tracking system for PAAA noncompliances and corrective actions.

5.8 Assurance Review Office

The Assurance Review Office shall:

- Plan and conduct institutional crosscutting assessments in accordance with an annual audit plan approved by the DDO.
- Identify trends based on the contents of the Laboratory View.
- Review and comment on draft formal Corrective Action Plans (CAPs) developed for ARO institutional assessments and DOE assessment reports.
- Track progress of closure of formal CAP commitments and distribute quarterly status reports. Provide periodic reports and brief the DDO and SEP AD on the status of issues and deficiencies entered in the ITS. Provide status reports on DOE assessment corrective actions to LSO as required.
- Confirm that planned actions in response to DOE assessments and ARO institutional assessments have been completed.
- Coordinate validation of CAP item closure with LSO for DOE assessments as required.
- Be the primary LLNL point of contact for external ES&H audits.
- Periodically review the implementation of the ITS processes to determine its effectiveness in meeting management needs.

5.9 Associate Director for Safety & Environmental Protection Directorate

The SEP AD shall:

- Ensure that accepted Institutional-Level issues and deficiencies are entered into the ITS.
- Coordinate the development of formal CAPs in conjunction with affected directorates for DOE assessment reports and ARO institutional assessments.

- Propose the assignment of personnel to act as RMs for the resolution of Institutional-Level issues and deficiencies.
- Review Institutional-Level actions and plans, as needed, to assure they are appropriate, can be implemented, and will be effective.
- Approve, as delegated, Institutional-Level actions and schedules for closing Institutional-Level issues and deficiencies.
- Track and obtain updates on progress to close issues and deficiencies.
- Identify trends, if any, associated with issues in the ITS.

5.10 Associate Directors

Associate Directors shall:

- Define appropriate criteria, periodically review criteria, and provide procedures to identify Directorate-Level issues and deficiencies within their directorate.
- Ensure that deficiencies are reported in a timely manner.
- Ensure that processes for confirming completion of actions entered into ITS are documented.
- Designate an ITS Administrator and ensure the person is trained.
- Assign RMs for resolution and correction of Directorate-Level issues and deficiencies.
- Review causal analysis for Directorate-Level deficiencies to determine if crosscutting directorate deficiencies exist. Determine if action should be taken in other parts within the directorate organization to identify and close similar items.
- Approve actions and schedules, with RMs, for closure of Directorate-Level issues and deficiencies.
- Review and comment on formal institutional CAPs affecting their directorates.
- Track and obtain updates on the progress to close Directorate-Level issues and deficiencies.
- Ensure reports and briefing are provided to identify additional actions or follow up.

5.11 Deputy Director for Operations

The Deputy Director for Operations shall be responsible for the overall effectiveness of the ITS and shall:

- Hold AD and line managers accountable for ITS implementation.
- Resolve, in a timely and effective manner, any institutional crosscutting disagreements or potential conflict of interest issues.
- Receive issues from external organizations for entry into the ES&H ITS and transmit resolution of issues as appropriate.
- Assign RM for resolution of Institutional-Level issues and correction of Institutional-Level deficiencies.
- Approve CAPs, actions, and schedules with RMs for closure of Institutional-Level issues and deficiencies.
- Discuss the status of Institutional-Level issues and deficiencies with managers as appropriate.
- Review the overall issues and deficiency management process to determine its effectiveness in meeting management needs.

6.0 Work Smart Standards

DOE O 414.1A, "Quality Assurance," Attachment A, "Contractor Requirements Document."

10 CFR 830, Subpart A, "Quality Assurance Requirements."

7.0 Resources for More Information

7.1 Contacts

Contact the following for additional information:

- Assurance Review Office
- Directorate ITS Administrator
- Directorate Assurance Manager
- ES&H Information Management Office

7.2 Related LLNL Feedback and Improvement Documents

Additional information related to operational deficiencies and issues can be found in the following *ES&H Manual* documents:

- Document 2.3, “LLNL Exemption Process.”
- Document 4.1, “Directorate Environment, Safety, and Health Self-Assessment.”
- Document 4.3, “Occurrence Reporting and Processing of Operations Information.”
- Document 4.4, “Identification, Reporting, and Tracking of Noncompliance with Nuclear Safety Requirements.”
- Document 4.5, “Incidents – Notification, Analysis, and Reporting.”
- Document 4.6, “Incident Analysis Manual.”
- Document 41.1, “LLNL Quality Assurance Program.”

Appendix A

Terms and Definitions

Condition	Any as-found state, whether or not resulting from an event, that may have adverse safety, health, quality assurance, operational, or environmental implications.
Corrective action	Measure taken to rectify deficiencies and, where necessary, to preclude repetition.
Corrective Action Plan	A defined and documented strategy for deficiency correction. Defines the deficiency, describes the actions that will be taken, assigns responsibility for the actions, discusses how the actions will address and correct the finding, and indicates the dates by which the actions will be complete.
Deficiency	An ES&H deficiency is any identified activity, occurrence, or condition not in compliance with the environmental, health, and safety requirements of applicable federal, state and local laws and regulations; Contract 48, and the LLNL <i>ES&H Manual</i> .
Issue	Issues are defined as higher-level conditions requiring management attention and all commitments, which are not deficiencies, that are made to the director's office or to external entities.
Noncompliance	A situation in which a requirement is not met.
Confirmation	The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting that planned actions have been completed.