Principles for Conducting Incident/Event Analyses
January 2013

- In evaluating safety related incidents and other adverse events:
- We do not seek to blame individuals
- We look beyond the individual's actions to understand underlying organizational issues
- We seek to learn, in a timely manner, from both the positive as well as negative actions that occur
- We will promptly share what we learn so that others can benefit from our analyses
- Incident analysis will follow the same collaborative, analytical approach we use in our science
- Incident analysis will be supported by senior management and take place in a timely manner
- Incident analysis results will be openly made available to the Lab community.

These principles are based on the following:

Berkeley Lab is a learning institution – we learn from each other, from our science, from our partners, and from our successes and mistakes. We strive for uncompromising operational and safety performance while producing outstanding science. Yet adverse events, accidents, and injuries can happen from time to time. When they do occur, they present us with a clear choice; either we can learn from them and improve our operational and safety performance, or we can regress by blaming people for errors they made and impose additional requirements. Experience teaches us that the way we handle these events can have an immense impact on our Laboratory culture, so it is critically important that we respond constructively and promptly.

Our goal, then, is to get the most value we can from our response to adverse events. Typically, there are strong pressures to find the simple explanations and obvious causes. Experience, however, shows us that these events are always more complex and are rarely attributable to just the actions of the individuals involved. Our incident analysis process must result in obtaining the most useful understanding of all of the potential lessons to be learned. To do this, incident analyses need to focus on understanding not just the direct causes, but also the context of decisions, why people did what they did, and what underlying organizational strengths and weaknesses may have been present.

Our incident analysis process must also include the goal to identify and understand positive actions of people that contributed to mitigating the adverse impacts. Some of the most significant opportunities to improve are found when we recognize and support the great value of human creativity and initiative.

When incident analyses are needed in our divisions and operating units, we must provide strong, clear and consistent direction that we expect a full account in a timely manner that includes all of the important lessons that we might learn. Only through this deeper understanding comes the ability to develop effective and sustainable solutions that really will improve operations and safety. In addition, we must demonstrate that this full explanation is in all of our interests. Our goal is to find the most effective opportunities to improve, wherever they may be in the organization – including ourselves. The purpose of the incident analysis is not to identify blame; it is to identify opportunities to improve.

To truly take advantage of these opportunities we must be willing to share what we learn in an open, constructive, and trusting manner. By demonstrating a commitment to share this information, we also reinforce our commitment towards a more positive Laboratory culture.

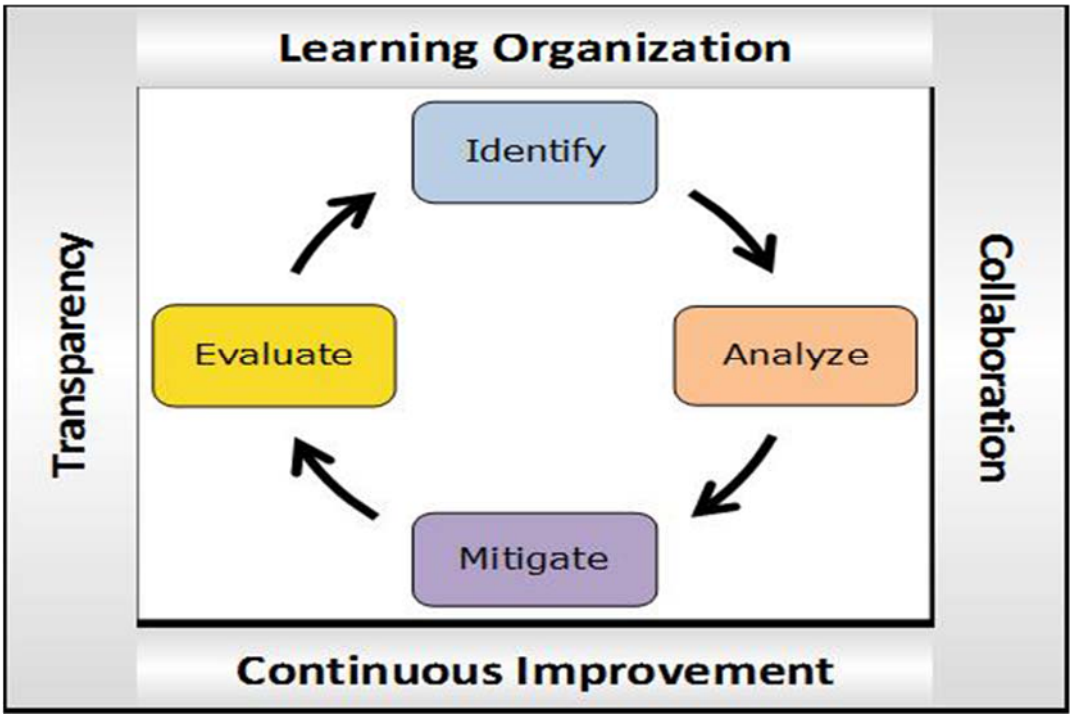
In our environment, where learning at both the individual and organizational level is a core value, developing in-depth understanding of adverse events is simply part of our collaborative approach towards continually striving for improvement in both safety and operational excellence.

Sincerely yours,

A. Paul Alivisatos
Director, Lawrence Berkeley National Laboratory

1.0 Program Description

The Lawrence Berkeley National Laboratory (LBNL) Issues Management Program (IMP) supports the Laboratory's *Issues Management Policy 04.02.003.000* and encompasses identifying, analyzing, mitigating and evaluating issues through issue resolution. Ongoing communication of issues, and sharing of lessons learned and best practices across the Laboratory are vital components of effective issues management. Transparency, collaboration, behaviors of a learning organization and continuous improvement are the pillars of the Issues Management Program.



The issues managed following the IMP pertain to any safety or operational event, condition, or circumstance that:

- results or could result in injury, illness, damage, loss, or noncompliance *(actual or near miss incident);*
- represents a program, safety or operational deficiency *(audit or assessment finding, or performance weakness as identified through walkthroughs, inspections, metrics or performance analyses);* and/or
- adversely affects the achievement of mission, strategic and business objectives *(environmental, financial, operational, compliance and reputational risks).*

Typically, these issues are discovered through actual adverse or near miss occurrences, internal and external audits and assessments, peer reviews, safety concerns, management and program manager safety walkthroughs/inspections, Institution and division metrics,

ongoing performance analysis, process improvement initiatives and risk assessments. This list is not all-inclusive, as there are many mechanisms used to discover issues.

2.0 Exceptions

Employee-sensitive issues and investigations such as, but not limited to, allegations of harassment, intimidation, retaliation and discrimination, and employee/employer relationship issues (such as performance improvement actions and grievances) are not managed through the IMP. These issues should be identified and managed via an appropriate mechanism, such as employee concerns or human resources. Likewise, these issues are not entered in the Corrective Action Tracking System (CATS database).

In addition, immediately corrected issues, service requests, such as Information Technology (IT) help desk tickets, and Facilities general, preventive and corrective maintenance work requests are not entered in the CATS Database. Similarly, ethical/integrity, health services, employee concerns, traffic incidents, security breaches and ergonomics evaluation issues are not entered in the CATS Database.

3.0 Issue Management Program Requirements

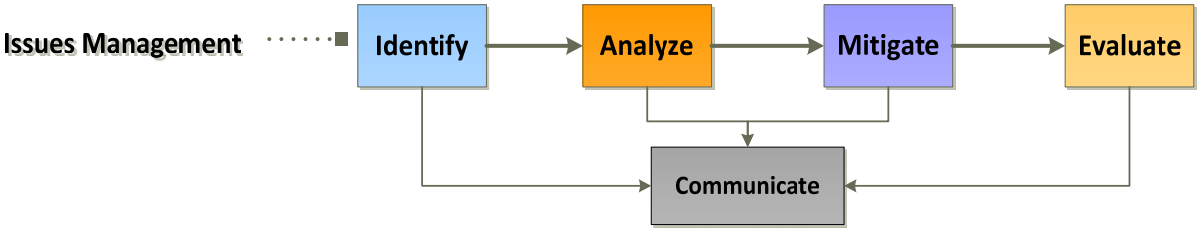
The LBNL IMP requires that all Laboratory employees continuously monitor work programs, processes and procedures to identify safety and operational issues. Based on role, responsibility, authority and accountability in the Institution, employees are responsible for analyzing, correcting/mitigating issues, and evaluating corrective action implementation to assure successful issue resolution and prevention of recurring issues. Laboratory employees also are responsible for sharing lessons learned and best practices to prevent recurrence of issues and to facilitate continuous improvement in support of Integrated Safety Management (ISM) feedback and improvement.

Issues management is performed using a risk-based process that prioritizes and dedicates resources commensurate with issue/risk severity levels. ***Ownership of and accountability for issues management, including risk acceptance decisions, is based on severity levels as follows:***

- ➢ High risk issues – Laboratory Management (Laboratory Director, Deputy Director and Associate Laboratory Directors)
- ➢ Medium risk issues – Division Directors (or designees)
- ➢ Low risk issues – Line Management / Principal Investigators

The Issues Management process involves:

- identifying and analyzing issues;
- mitigating issues through corrective actions;
- documenting and tracking issues through resolution;
- evaluating the effectiveness of implemented corrective actions; and
- communicating lessons learned and best practices.



The components of the Issues Management process are summarized below:

Identify

- Discovery of an adverse condition
- Gathering sufficient information to define the issue and/or risk
- Characterizing the issue and severity in terms of exposure
- Communicating/Discussing the issue with stakeholders, including determining external reportability to the Department of Energy (DOE), Federal and State regulatory agencies
- Determining issue/risk significance as high, medium or low severity

Analyze

- Performing causal analysis and corrective action development based on issue/risk severity
  - Root Cause Analysis (RCA)
  - Apparent Cause (ACA)
- Performing Extent of Condition/Cause (EOC) Review
- Developing Corrective Action Plan (CAP) / Corrective Actions
  - SMART (Specific, Measurable, Accountable, Reasonable, Timely) Analysis
  - Compensatory Actions, as appropriate
- Evaluating risk exposure and making risk acceptance decisions, as appropriate

Mitigate

- Developing CAP Implementation Plan, as appropriate
- Documenting and tracking issues and corrective actions in the CATS Database
- Implementing Corrective Action Plan / Corrective Actions

Evaluate

- Verifying corrective action implementation and closure through objective evidence
- Validating corrective action effectiveness
- Performing ongoing performance analysis (tracking, trending and analyzing issues)

Communicate

- Ongoing communication of issue and issue resolution
- Developing, disseminating and applying lessons learned and best practices
- Concurrence of risk acceptance decisions upward, downward and horizontally

4.0 Issues Management Process Requirements

RISK	IDENTIFY	ANALYZE	MITIGATE	EVALUATE	COMMUNICATE
HIGH	- Characterize - Determine Reportability	- RCA - EOC - CAP and/or - Accept Residual Risk	- CATS Entry - Implementation Plan	- Verify Implementation - Validate Effectiveness - Periodic Performance Analysis *(as needed)*	Lessons Learned (*Required)* Risk Acceptance *(Senior Mgmt.)*
MEDIUM	- Characterize - Determine Reportability	- ACA - EOC *(Optional)* - Corrective Actions; and/or - Accept Risk	- CATS Entry - Implementation Plan *(Optional)*	- Verify Implementation - Validate Effectiveness *(Optional)* - Ongoing Performance Analysis	Lessons Learned (*Recommended)* Risk Acceptance *(Division Mgmt.)*
LOW	- Characterize - Determine Reportability	- Corrective Actions; and/or - Accept Risk	- CATS Entry	- Verify Implementation - Ongoing Performance Analysis	Lessons Learned *(Optional)* Risk Acceptance *(Line Mgmt.)*

RCA: Root Cause Analysis; **ACA:** Apparent Cause Analysis; **EOC:** Extent of Condition/Cause; **CAP:** Corrective Action Plan

4.1 Identify

To support the Laboratory Contractor Assurance System (CAS), Quality Assurance Program (QAP) and ISM core function #5, *Feedback and Improvement*, Laboratory employees conscientiously and proactively identify deficiencies and needed improvements to address and/or prevent issue occurrence or recurrence. The following are elements of identifying issues.

4.1.1 Discovery of an adverse condition

Laboratory programs, processes and performance are assessed to identify and correct issues that hinder the Laboratory from achieving its mission and strategic and tactical objectives. Issues are identified through employee self-discovery and concerns, actual and near miss incidents, day-to-day management oversight activities, internal and external assessments/audits/evaluations, and performance analysis.

4.1.2 Gather preliminary data and define the issue

Once an adverse condition is discovered, generally additional information is gathered to describe clearly the adverse condition and its associated exposure, deficiency, hazard or risk. This is the initial fact finding that occurs immediately following the discovery.

4.1.3 Characterize the issue

After the initial fact finding activity, the issue is characterized in terms of injury, damage, loss, noncompliance, operational deficiency, risk and/or recurrence. *The Risk Level: Risk Severity Guidelines for Issues Management* ***(refer to 10.1 in the Standards section of this manual)*** can be used to assist with characterizing the issue. This may involve collaboration with Laboratory Management, the Office of Institutional Assurance and Integrity Director (OIAI), the Environment, Health, Safety (EHS) Division Director, Occurrence Reporting Processing System (ORPS) and Price Anderson Amendment Act (PAAA) Enforcement Coordinators, Subject Matter Experts (SMEs) and impacted Division management.

4.1.4 Collaborate with key stakeholders and affected groups

To facilitate and validate accurate characterization and severity determination, the issue is discussed upward and horizontally across the Laboratory and affected division management.

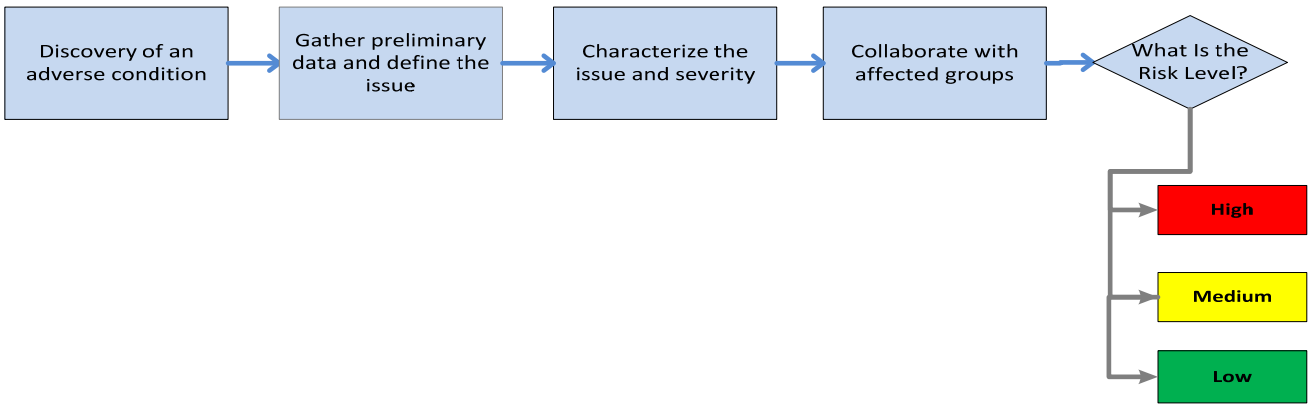
- Upward: Laboratory and responsible division management ensures that issues are characterized appropriately and timely, severity and pervasiveness of the issue is understood, and expectations pertaining to risk tolerances and issues management are communicated and embraced.
- Horizontally: Impacted division management, functions and groups assess and discuss the effect to Institutional services and processes.

4.1.5 Determine issue/risk severity

Based on the issue characterization, which includes appropriate communication and collaboration with key stakeholders, a severity level is assigned to the issue. The severity level informs the depth of analysis, mitigation, evaluation and documentation commensurate with risk. The severity is expressed as high, medium and low using common terminology. *The Risk Level: Risk Severity Guidelines for Issues Management* are used to determine issue/risk severity.

4.1.6 Identify Workflow

Below is the high-level workflow of issue identification:



4.2 Analyze

A risk-based approach is used to analyze issues based on the issue severity. The analysis focuses on what caused the issue, what could have prevented the issue from occurring, the pervasiveness of the issue and appropriate corrective action to effectively resolve the issue and eliminate or significantly minimize recurrence.

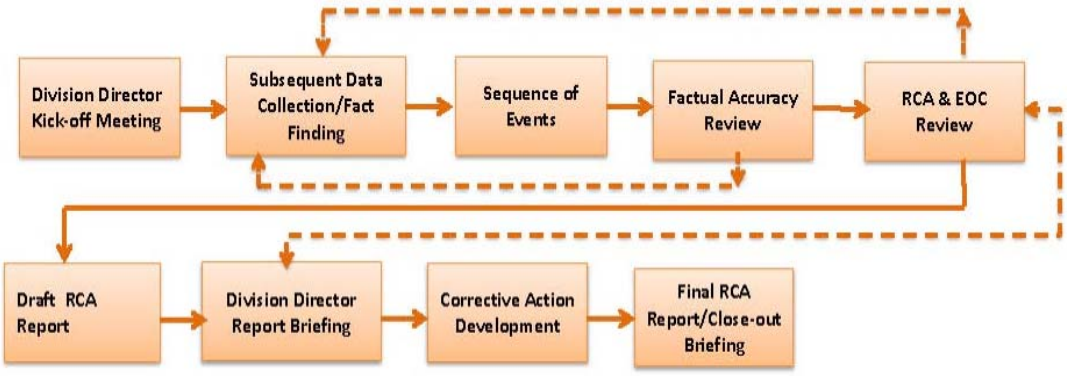
Note: For PAAA reportable issues, both NTS and internally reportable, a graded approach to causal analysis may be used commensurate with the significance and complexity of the issue (Refer to the *Price-Anderson Amendment Act Compliance Program Manual, Document Number 04.02.004.001).*

Depending on the issue severity, a root cause or an apparent cause analysis, and an extent of condition/cause review are completed before developing corrective actions. (***Refer to 10.2 Application of the Investigation and Causal Analysis Process*** in the Standards section of this manual.)

Corrective actions are developed and analyzed using the SMART (Specific, Measurable, Accountable, Reasonable and Timely) criteria. (***Refer to 11.7 SMART Analysis Worksheet*** in the Templates section of this manual.) Analysis also includes evaluation and determination of risk acceptance when appropriate. The following are the elements of analyzing issues in detail.

4.2.1 Root Cause Analysis

A Root Cause Analysis (RCA) is a rigorous analytical process that is used to uncover the underlying cause(s) of an issue. It requires the application of one or more formal problem solving methodologies to analyze the issue cause(s) and the extent of the cause. The Extent of Condition/Cause Review is described in Section 4.2.3. Below is the high-level RCA process:



The following requirements must be followed when performing a RCA:

- A scoping and chartering meeting is held with appropriate Laboratory and/or Division Management and the OIAI Director (or designee) to scope the investigation and root cause analysis. Following the scoping and chartering meeting, a Charter for the RCA Team is generated and distributed to the Team prior to initiating any investigation and causal analysis activities. (***Refer to 10.3 Scoping and Chartering the Causal Analysis*** in the Standards section of this manual.)

- Responsible Laboratory or Division Management schedules, plans and facilitates the investigation and root cause analysis Kick-off Meeting with the RCA team and other key stakeholders as determined by responsible management. (***Refer to 10.4 Division Director Kick-Off Meeting*** in the Standards section of this manual.)

- The RCA team shall include:
  a) a representative from the responsible Division; this representative will serve as the Team Lead.
  b) a trained root cause analyst, who will lead the Team through the causal analysis using one or more of the formal root cause analysis methodologies (***Refer to 10.6 Causal Analysis Methodologies*** in the Standards section of the manual.)
  c) an applicable SME(s).
  d) an independent member, who is outside of the responsible Division.

- Team Members will attend the RCA Just-in-Time (JIT) Training (facilitated by the Issues Management Program Manager or designee) prior to beginning the investigation and causal analysis activities.

- The RCA must be performed using a LBNL approved root cause analysis methodology. (***Refer to 10.6 Causal Analysis Methodologies*** in the Standards section of the manual.)

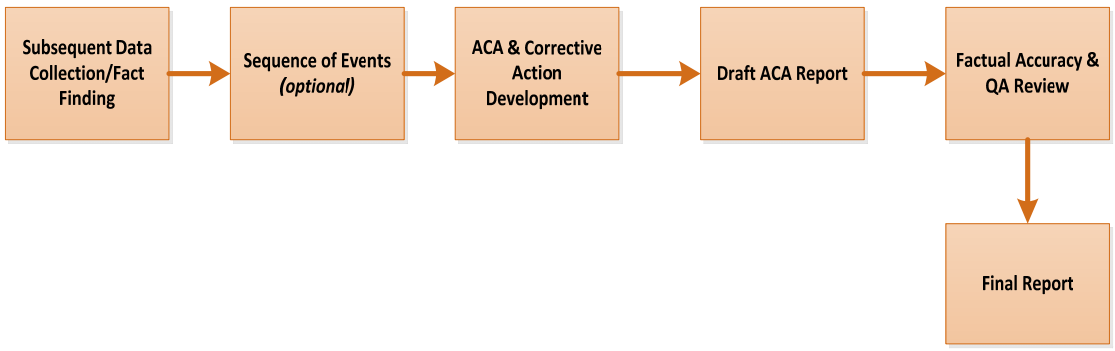
- A factual accuracy review of the facts is completed prior to performing the root cause analysis to ensure that accurate and credible facts are analyzed to determine the issue cause(s). (***Refer to 10.15 Accuracy and Quality Assurance Reviews*** in the Standards section of this manual.)

- The results of the investigation and root cause analysis are documented in a formal report and presented to Laboratory and/or Division Management in a Management Briefing Meeting by the due date documented in the Charter Letter. (***Refer to 11.5 Root Cause Analysis Report*** in the Templates section of this report.)

- The Issues Management Program Manager (or a designated trained root cause analyst) completes a quality assurance (QA) review of the investigation and root cause analysis process, and the RCA Report. (***Refer to 10.15 Accuracy and Quality Assurance Reviews*** in the Standards section of this manual.)

4.2.2 Apparent Cause Analysis

An Apparent Cause Analysis (ACA) is a straightforward/basic analytical process that is used to determine the dominant plausible cause(s) of an issue by analyzing the events and conditions leading up to the issue occurrence. A formal investigation and causal analysis process or methodology is not required for an ACA. Below is the high-level ACA process.



The following requirements apply when performing an ACA:

- A Causal Analyst is appointed by the responsible division or line management to perform the investigation and apparent cause analysis

independently or within a team setting. The Causal Analyst or the ACA Team should involve an appropriate SME(s).

- The Causal Analyst and ACA Team Members will attend the Apparent Cause Analysis Training (facilitated by the Issues Management Program Manager or designee) prior to beginning the investigation and ACA activities.

- At division or line management's discretion, the factual accuracy review may be completed by following the RCA factual accuracy review requirements, or at a minimum, through a review of the draft ACA Report, which includes corrective actions.

- The results of the ACA are documented in a formal report (***Refer to 11.4 Apparent Cause Analysis Report*** in the Templates section of this manual), ORPS or PAAA NTS Reports (as applicable) or another manner at management's discretion.

4.2.3 Extent of Condition (and/or Cause) Review (EOC)

An EOC Review is performed to identify the potential for an issue, or a root or apparent cause to exist (or to have occurred) in other activities, processes, programs, or elsewhere in the Laboratory. This review determines the pervasiveness of the issue and/or cause in order to develop effective corrective actions. (***Refer to 10.7 Extent of Condition/Cause Review*** in the Standards section of this manual.)

The following requirements apply when performing an EOC:

- EOC reviews are required for all high risk issues (generally as part of the investigation and root cause analysis process) because of their seriousness and importance. EOC reviews for medium and low risk issues are initiated at management's discretion to eliminate recurrence and/or to improve safety/operational performance.

- An EOC review may be performed as a stand-alone activity, independent of an investigation and causal analysis process, at division or line management's discretion.

- An EOC review may be documented as part of a causal analysis report or in a separate document. (***Refer to 11.6 Extent of Condition/Cause Report*** in the Templates section of this manual for a stand-alone report.)

4.2.4 Corrective Action Plan (CAP) / Corrective Action Development

Corrective actions are developed to address the conditions, causes, and pervasiveness of the issue using the hierarchy of controls concept. Generally, the actions are compensatory or corrective as described below.

a) *Compensatory Action*

A compensatory action is implemented immediately to address the issue "on-the-spot" and/or to safely and effectively restore normal operations. A compensatory action generally addresses the circumstances surrounding the issue and may help minimize recurrence, but may not address the cause(s) of the issue and is not expected to prevent recurrence.

b) *Corrective Actions*

A corrective action is intended to address the apparent or root cause of an issue, prevent recurrence of issues or reduce the likelihood of recurrence, and demonstrate endurance and sustainability. A corrective action also addresses the pervasiveness of the issue by preventing manifestation of the issue elsewhere in the Laboratory. Corrective actions are required for all risk level issues as follows:

- High risk issues – addresses the root cause(s), prevents recurrence and demonstrates sustainability.
- Medium and low risk issues – addresses the apparent cause(s) or remedies the adverse condition(s) /circumstance(s) of the issue, demonstrates sustainability, but may not prevent recurrence.

The following are requirements for developing a CAP and/or corrective actions:

- A CAP is required for all high risk issues. The CAP must be formally documented, reviewed by OIAI for quality assurance, and approved by Laboratory or Division management.

- A CAP for medium and low risk issues is developed at management's discretion. However, corrective actions for medium and low risk issues are developed as part of the causal analysis process, in partnership with responsible division management and other parties as determined by management.

- The CAP is developed in accordance with ***10.9 Corrective Action Plan Development*** in the Standards section of this manual.

  CAP Development

  - The CAP development Team is chartered by responsible Laboratory or Division management.

- The CAP Team is comprised of the RCA Team Lead, RCA Lead Causal Analyst and representatives appointed by the responsible Laboratory and/or Division management. The RCA Team Lead will oversee the development of the CAP. (***Refer to 11.2 CAP Development Charter Letter*** in the Templates section of this manual.)

- All CAP Team Members will complete BLI2010-Corrective Action Development Training prior to beginning CAP development.

- The CAP development process may be iterative and as such, may require that the CAP Team Lead communicate with responsible Laboratory and/or Division management (or designee) throughout the process to ensure expectations and outcomes are achieved prior to completing the CAP.

- All corrective actions must be SMART: Specific, Measurable, Accountable, Reasonable and Timely. The SMART criteria (Refer to section 4.2.5 SMART Analysis below) is followed for all risk levels corrective action development. Completion of the SMART Analysis Worksheet is required for all high risk issue corrective actions and recommended for medium risk issue corrective actions. ***Refer to 11.7 SMART Analysis Worksheet*** in the Template section of this manual.

- The Issues Management Program Manager (or an OIAI designee) will perform the QA Review of the CAP for high risk issues by attending the CAP Team meeting(s) and providing immediate feedback on the quality of the developed corrective actions using the SMART criteria.

- The CAP is approved by the Laboratory and/or responsible Division Director(s) who will provide the resources (funding, personnel and time) required to successfully implement the corrective action(s). This may involve coordination among various Divisions to complete a single, comprehensive CAP.

4.2.5 SMART Criteria

Regardless of the risk level, a corrective action must be SMART. The SMART criteria are designed to aid in corrective action effectiveness by a) evaluating the intent of the corrective action, b) evaluating how it will prevent recurrence, specifically for root causes, and c) determining what outcome is expected from the implemented corrective action. The

expected outcome should be an objective measurement. Below is an overview of the SMART criteria. A documented SMART Analysis is required for all high risk issues. (***Refer to 11.7 SMART Analysis Worksheet*** in the Templates section of this manual.)

SMART CRITERIA	
Specific	The corrective action eliminates or mitigates the issue/cause and prevents recurrence. • Removes or reduces the hazard/risk • Implements or improves an engineering control • Improves barriers or safeguards • Implements redundant controls (defense in depth) • Improves human performance • Applies a risk mitigation strategy
Measurable	The deliverables (outputs) of the corrective action are objective and quantifiable. The success measures (expected outcomes) are defined and will demonstrate that the corrective action addresses the cause, prevents recurrence, and is sustainable.
Accountable	Individuals who are accountable and responsible for effective implementation and ongoing oversight of the corrective action effectiveness are designated. • Accountable (the individual who has final authority and accountability for the corrective action) • Responsible (the individual who completes – or oversees completion of – the corrective action) Individuals who should be consulted and informed of the corrective action are identified. • Consulted (individuals who provide input and support before, during and after the corrective action is implemented) • Informed (individuals who are notified/updated before, during and after the corrective action is implemented) Required resources to implement the corrective action are identified and dedicated.
Reasonable	The corrective action(s) and implementation are feasible (a cost effective control measure). • Roles, responsibilities, accountability and authority (R2A2s) are in place. • Deliverables and success measures are realistic and achievable, and address the issue cause(s).

SMART CRITERIA	
	• Resources are secured. • The cost to implement the corrective action does not outweigh the benefit of mitigation (cost prohibitive, administratively burdensome, or leads to degradation in other areas).
Timely	The corrective action(s) will be implemented in a realistic timeframe to prevent recurrence. • The high-level milestones to implement the corrective action are identified. • The time-line to complete the corrective action is realistic given resources and other priorities. • Interim compensatory actions (to minimize recurrence) are considered and developed as appropriate.

4.2.6 Risk Acceptance Decisions

The issues management process facilitates making informed decisions to develop corrective actions and/or accept residual and unmitigated risks consistent with the Laboratory's risk management protocol, as documented in the Lawrence Berkeley National Laboratory Chief Operating Officer (COO) Risk Registry Description ***(Doc # 04.02.001.001)***. Issues identified and managed following the Issues Management Program requirements are inputs to the Risk Registry. High risk issues and risk mitigation, which includes risk acceptance decisions, are documented in the Risk Registry and reviewed periodically by Laboratory leadership and University of California, Office of the National Laboratories leadership.

The following requirements are followed when making risk acceptance decisions:

- Risk acceptance decisions are made only by Laboratory, division and line management as follows:
  - ➢ High risk issues – Laboratory Management (Laboratory Director, Deputy Director and Associate Laboratory Directors)
  - ➢ Medium risk issues – Division Directors (or designees)
  - ➢ Low risk issues – Line Management / Principal Investigators

- For high risk issues, with some level of mitigation in place, residual risks may be accepted, and for medium and low risk issues, unmitigated risks may be accepted when:
  - ✓ Cost of mitigation outweighs benefit

Cost prohibitive, administratively burdensome, or leads to degradation in other areas.

- ✓ <u>Residual risks are managed to the lowest level of exposure</u>
  Further corrective action would not be an effective use of resources because the unmitigated risk exposure would not substantially impede safety and/or operational performance.

- ✓ <u>Compensating actions are in place to minimize the effects of the risk</u>
  Corrective action is implemented to alter the exposure, but does not eliminate the risk.

- Risk acceptance decisions and the business rationale are documented and approved in the CATS Database.

4.3 Mitigate

Mitigation of an issue involves implementing CAPs and corrective actions as intended (as developed) to achieve the desired outcome/result. Corrective action implementation must be verifiable through objective evidence, demonstrate sustainability and occur within a reasonable timeframe to prevent recurrence and/or exacerbation of the issue. Change management is applied when the original scope, resources, and schedule are altered, or when new or recurring issues surface while corrective action implementation is in progress. New or recurring issues may indicate that implementation is ineffective and requires improvement.

An Implementation Plan is needed when corrective actions extend beyond one division's responsibility, authority and accountability for resolution, and/or when corrective actions impact more than one institutional policy, process or procedure. The SMART Analysis provides the baseline for an Implementation Plan, and further refinement of the plan is at management's discretion.

The following are requirements for mitigating issues:

- Corrective actions are documented and tracked in the Institutional Corrective Action Tracking System (CATS) for assurance of issue resolution, and the documentation includes:
  a) describing the corrective action in specific and measurable terms or describing the risk exposure and the rationale for accepting the risk;
  b) assigning responsibility for the corrective action or risk acceptance decision based on accountability and authority for implementing the corrective action; and
  c) assigning a realistic due date, which includes high level milestones and interim compensatory actions, as appropriate.

- Responsible Persons and their Managers must proactively manage implementation to meet the corrective action due date. The OIAI will monitor overdue corrective actions and escalate resolution issues to Laboratory leadership as appropriate.

- Change management is applied when unanticipated circumstances occur that impact corrective action implementation (scope, resources and schedule). The changes are documented, reviewed, approved and communicated based on the severity (impact) of the change. The CATS Database has built in controls to help facilitate change management via the Extension Request functionality.

- Extension Requests are used for unanticipated circumstances that impact completion of a corrective action by its original due date; extension requests are not acceptable when corrective actions will not be completed on time due to a lack of oversight or accountability.

- Extension Requests must be entered in the CATS Database at least two weeks (15 days) in advance of the current due date to be considered for approval. Refer to ***10.10 Extension Requests*** in the Standards section of this manual for the detailed requirements and instructions for making an extension request.

4.4 Evaluate

Evaluation of a CAP and corrective action involves verifying that a corrective action has been implemented as intended, and implemented in a manner that addresses the issue/cause of the issue, prevents recurrence and demonstrates sustainability. Verification of corrective action implementation is performed on all corrective actions regardless of the issue severity and occurs before the corrective action is considered completed/closed.

Depending on the issue severity, implemented corrective actions are validated for effectiveness. Validation of effectiveness means that the implemented corrective action is assessed to assure that the corrective action was implemented as intended, addresses the root cause of the issue, prevents recurrence, demonstrates sustainability, and achieves the success outcomes/measures as documented in the CAP. Validation of corrective action effectiveness is performed for high risk issues, is strongly encouraged for medium risk issues and is performed at management's discretion for low risk issues. The validation of effectiveness determines whether or not an issue is fully resolved through a sustainable solution.

Validation of effectiveness may be completed through a formal assessment, an Effectiveness Review or tracking and analyzing metrics/performance measures as described below in section 4.4.2 Corrective Action Validation.

The following are requirements for evaluating a CAP and/or corrective action implementation and effectiveness:

4.4.1 Corrective Action Implementation

- Implementation/closure verification is performed by someone other than the corrective action Responsible Person and Cognizant Manager.

- The verification must confirm that the corrective action was implemented adhering to the SMART criteria, specifically that the corrective action implementation addresses the issue/cause, is completed as intended, and is demonstrated through objective evidence, which is uploaded in the CATS Database.

- A corrective action completion date is entered in the CATS Database only after successfully performing the verification of implementation.

4.4.2 Corrective Action Validation of Effectiveness

Validation of effectiveness involves using one or more of the following evaluation methods: formal assessment, Issues Management Program Effectiveness Review or Division metrics/performance measures. Individuals who were not involved with implementing the corrective action(s) perform the validation. Below is the guidance to select the appropriate validation method.

a) ***Formal Assessment:*** Used to validate effectiveness of corrective actions that address a finding or risk, and/or strengthen program performance. A formal assessment should validate prevention of recurrence, demonstrated sustainability and achievement of the success measures as documented in the CAP. Scoping and conducting the assessment should follow the Responsible Division assessment protocol.

b) ***Effectiveness Reviews (ER):*** Used to validate effectiveness of corrective actions that address a root cause and/or Institutional systemic issues impacting the Laboratory overall or several divisions. The Issues Management Program Effectiveness Review criteria are applied, including achievement of success measures as documented in the CAP. The Effectiveness Review is conducted following ***10.11 Effectiveness Review*** in the Standards section of this manual.

c) ***Metrics:*** Used to validate effectiveness of corrective actions with success metrics/measures (as documented in the CAP) such as *(this list is not all inclusive):*
   - reduction in performance/processing/execution errors
   - downward trend of adverse events
   - percentage of work completion
   - improvement of response time

The development of and validation criteria for metrics/measures follows the responsible Division assessment protocol. The metric/measure result is formally tracked, analyzed and communicated to Senior Management through the Operations Risk and Management Performance Process, appropriate. The metrics validation of effectiveness method can be applied as a stand-alone validation, or incorporated in a formal assessment or an effectiveness review, as appropriate.

- The specific timeline to validate effectiveness is generally 6-12 months after corrective action implementation; however, sufficient implementation ("run-time") should be allowed to fully institutionalize the corrective action before validation of effectiveness is performed.

- Corrective actions that are evaluated as partially effective or not effective will receive increased management attention, such as incorporating the unresolved issue into a Division's assurance process, the Risk Registry or the Operations Risk and Management Performance Process, as appropriate.

4.4.3 Ongoing Performance Analysis

Regardless of issue severity, ongoing performance analysis of issues and issue resolution is performed to identify statistical trends, systemic problems and recurring issues. This involves tracking and trending of both qualitative and quantitative data, and causal analysis of adverse conditions and statistical trends. Ongoing performance analysis is performed in accordance with ***10.12 Ongoing Performance Analysis*** in the Standards section of this manual.

- At the Institutional level, OIAI performs ongoing performance analysis of the PAAA NTS and ORPS reportable incidents to determine whether there are statistical trends and/or recurring issues, which may involve filing a recurring PAAA NTS and/or ORPS report. Additionally, the EHS Division and OIAI analyze internally reportable incidents to determine if statistical trends and/or recurring issues exist and require management.

- At the division level, each Division is responsible for identification and correction of adverse trends before they become significant issues. This involves developing an internal ongoing performance analysis methodology to track, trend, analyze, resolve and communicate issues upward and horizontally. Performance metrics/measures that are in place and effectively monitor adverse conditions and risks are considered a method of ongoing performance analysis.

- The Institutional Integrated Assessment Schedule process is considered a method of ongoing performance analysis. (*Refer to the annual Integrated Assessment Schedule Guidance for more information.)* This process includes developing a division's portfolio of assessments, tracking the status of assessments, using the assessment data and results to identify adverse trends/issues, and documenting and managing identified issues following the Issues Management Program requirements.

- All issues identified through ongoing performance analysis should be managed following the Issues Management Program requirements.

4.5 Communicate

Ongoing communication of issues and issue resolution, and sharing of knowledge through lessons learned and best practices up, down and across the Laboratory and all staff levels are vital components of effective issues management. Sharing and applying lessons learned and best practices by all employees support the Integrated Safety Management Core Function 5, Feedback and Improvement. Lessons learned and best practices should be applied during working planning and work activities, and incorporated in policies, processes, procedures and training classes as appropriate.

The following are requirements for developing and disseminating Lessons Learned and Best Practices:

- Lessons Learned and Best Practices communications are developed and shared that focus on preventing adverse conditions and trends, and improving performance, including cost savings, in accordance with ***10.13 Lessons Learned and Best Practices*** in the Standards section of this manual.

- For high risk level issues, a Lessons Learned/Best Practices communication must be developed and shared via the LBNL Lessons Learned and Best Practices Database. They are recommended for medium level issues and optional for low level issues.

- Lessons Learned/Best Practices communications are shared across the Department of Energy (DOE) complex when issues have a significant impact on safety and operations, and/or may be applicable to other national laboratories. All management levels, supervisors, SMEs, program managers, and safety and business professionals/coordinators should share LBNL-specific lessons learned and best practices through the DOE Corporate Lessons Learned Database. This may be coordinated by the Issues Management Program Manager, who is the LBNL Lessons Learned and Best Practices Administrator.

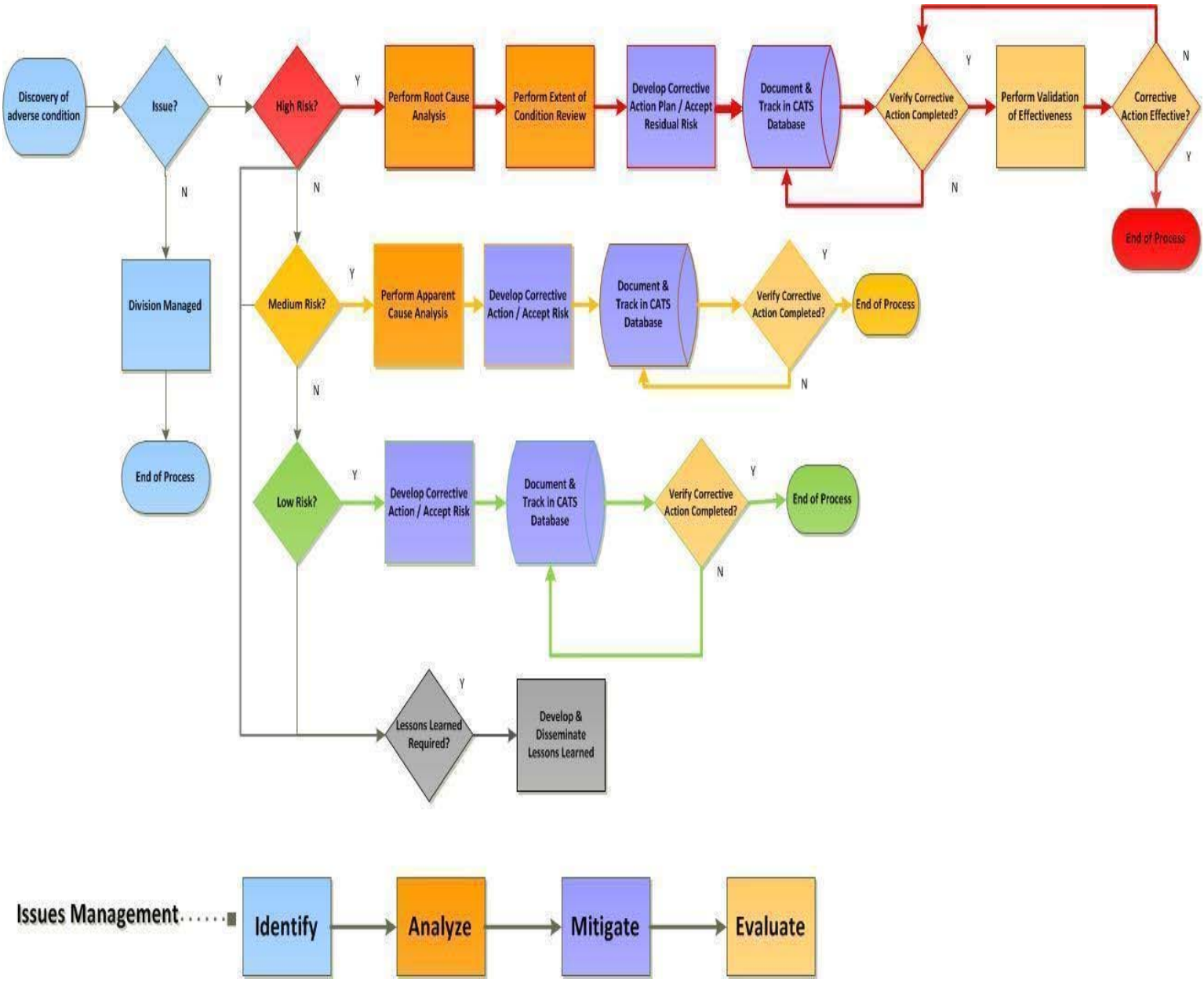
- Line management, supervisors, SMEs, program managers and safety and business professionals/coordinators should review and screen relevant DOE lessons learned, safety alerts and operating summaries, and other external lessons learned and best practices for LBNL applicability, and enter the relevant communication in the LBNL Lessons Learned and Best Practices Database for dissemination.

- Line management, supervisors, subject matter experts, program managers and safety professional/coordinators should incorporate relevant lessons learned and best practices in work planning hazard and control records (via the Work Planning and Control System), work processes and training classes.

- All employees should incorporate applicable lessons learned and best practices into work planning activities and work processes.

- Lessons Learned and Best Practices communications should be developed and shared following a significant project or process implementation where learnings can be captured and applied to future, similar events. (***Refer to 10.14 Lessons Learned/Event Debriefing Session*** in the Standards section of this manual.)

5.0 High-Level Overview of the Issues Management Processes



Click on the link below to print a copy of the IMP Risk Based High-Level Workflows document.

IMP Risk Based High-Level Workflows

6.0 Issues Management Program Roles and Responsibilities

<u>Overarching</u> roles and responsibilities for the Issues Management Program:

- Laboratory Management is responsible for communicating and reinforcing the importance of proactively identifying, reporting and managing issues.

- Division and Line Management are responsible for assuring that issues management requirements are implemented effectively, which includes assuring that issues are identified, analyzed, mitigated and evaluated as prescribed in this manual.

- The Office of Institutional Assurance and Integrity (OIAI) provides oversight and administration of the Issues Management Program through the Issues Management Program Manager. The Issues Management Program Manager, who also serves as the Laboratory's Lessons Learned Administrator:
  - maintains and revises the Issues Management policy, program manual, processes and tools;
  - maintains the CATS and Lessons Learned Databases;
  - performs quality assurance of the program, processes and processes outputs;
  - determines Issues Management Program effectiveness; and
  - provides technical guidance to Laboratory management and staff pertaining to implementation of issues management and program components.

- Team Leads for RCA, CAP Development, EOC Review and Effectiveness Review:
  - serve as the Division representative on the investigation and causal analysis, CAP Development, EOC Review and Effectiveness Review teams;
  - oversee the respective issues management processes for the responsible Division in accordance with this manual; and
  - ensure that the responsible Division accepts ownership of the analyses results, corrective actions and expected outcomes.

- Lead Root Cause Analyst:
  - leads the root cause analysis, including the EOC Review, for high risk issues and other issues at management's discretion;
  - ensures the quality and integrity of the root cause analysis in accordance with this manual;
  - participates in the development of the CAP in accordance with this manual; and
  - maintains proficiency in the LBNL-approved causal analysis methodologies.

- Team Members for RCA, CAP Development, EOC Review and Effectiveness Review:
  - must be objective and independent, with no bias or vested interest in the results of the causal analysis, EOC Review and ER; and
  - participate in the respective processes in accordance with this manual.
- Quality Assurance Reviewer:

- must be independent and objective, with no bias or vested interest in the outcome of the RCA, ACA, EOC, CAP and ER;
- ensures that the IMP process for each activity (RCA, ACA, EOC, CAP, ER) is followed;
- reviews working documents and reports for high risk issues prior to report finalization and issuance to ensure the quality and integrity of the conclusions and corrective actions; and
- works with team members to resolve process and quality issues.

- Laboratory employees are responsible for conscientiously and proactively identifying issues and needed improvements, implementing corrective actions to address issues and prevent recurring problems, and developing and sharing lessons learned and best practices.

<u>Specific primary</u> roles and responsibilities for the Issues Management Program processes and elements *(the list is not inclusive)***:**

ROLE	RESPONSIBILITIES
Laboratory Management	• Charters RCA, EOC, CAP development and ER teams for Institutional issues (generally those that are owned by multiple divisions). • Ensures that thorough, credible and timely investigations, root cause analyses, CAPs and ERs are performed. • Makes risk acceptance decisions for high risk issues' residual risks and concurs with Division Management risk acceptance decisions as documented in the Operations Risk and Management Performance Process and/or in the CATS Database.
OIAI	• Approves Extension Requests for high and medium risk issues. • In conjunction with the responsible Laboratory Management and/or Division Director(s), selects the RCA, EOC, and ER team members for high risk issues. • Works with Laboratory staff to document and disseminate lessons learned and best practices briefings through the Lessons Learned and Best Practices Database. • Performs analysis of issues that meet the external reporting threshold for ORPS and PAAA NTS to determine statistical trends and/or recurring issues.

ROLE	RESPONSIBILITIES
Division Director *(or designee)*	• Initiates the Scoping and Chartering Meeting with the OIAI Director (or designee) to scope the investigation and root cause analysis for high risk issues. • In conjunction with OIAI Director (or designee), selects and charters RCA, EOC Review, CAP and ER teams for issues that his/her division owns prior to initiation of these activities. • Schedules, plans and facilitates the Division kick-off meetings for investigations and root cause analyses and ERs. • Ensures that corrective actions resulting from RCAs, EOC Reviews and ERs are developed, implemented and sustained to address issues and prevent recurrence. • Ensures that issues and associated corrective action(s) are entered into the Corrective Action Tracking System (CATS) Database. • Makes risk acceptance decisions for medium risk issues and concurs with Line Management risk acceptance decisions as documented in the CATS Database.
Line Management *(or designee)*	• Notifies external reporting coordinators (PAAA Enforcement and ORPS Coordinators) of issues when they are characterized and consults with the coordinators to determine risk severity. • Scopes and initiates ACA for medium risk issues, EOC Reviews, and Effectiveness Reviews, as appropriate, in accordance with this manual. • Ensures that corrective actions from ACAs are developed, documented and implemented in accordance with this manual. • Assigns independent personnel to perform verification of completed corrective actions and ensures that objective evidence of corrective action implementation is uploaded into the CATS Database. • Determines the need for and ensures that Lessons Learned or Best Practice communications are developed and disseminated in accordance with this manual. • Ensures that ongoing performance analysis is performed in accordance with this manual.

ROLE	RESPONSIBILITIES
	• Makes risk acceptance decisions for low risk issues and documents decisions in the CATS Database.
Subject Matter Expert (*includes Program Managers, Division Safety Coordinators, Division Safety Liaisons***)**	• Participates in characterizing issues, as appropriate. • When designated by management, reviews and approves (or denies) CATS Database entries in accordance with issues management requirements. • Reviews and approves (or denies) Lessons Learned or Best Practices communication for applicability, technical accuracy, and inclusion in program documents, the Work Planning and Control system and the DOE Lessons Learned database.
Team Lead	• Completes the RCA Team Training, the online BLI2010-Corrective Action Development training, and Effectiveness Review Overview training, as appropriate, prior to commencing Team activities. • Elevates significant issues (including Team disputes) that arise during team activities to the Responsible Division Director and the Issues Management Program Manager for consultation and assistance with resolution. • Ensures that a common document storage protocol and document control is established and a Team Member is designated as the document controller. • Ensures that the RCA report is written in accordance with this manual. • Schedules and facilitates the Division Director Report Briefings (RCA, EOC, CAP and ER) and ensures that the respective report is submitted to the chartering official (and/or designee) and other designated attendees prior to the Briefing in accordance with this manual. • Following the completion of Team activities, forwards the complete data package (analysis worksheets, objective evidence and final report) to the Issues Management Program Manager for Institutional document storage and archive.

ROLE	RESPONSIBILITIES
Lead Root Cause Analyst	• Selects the RCA methodology(ies) to identify causal factors and analyze causes (root and contributing) in accordance with this manual. • Identifies appropriate line management, subject matter experts and/or other designated individuals who will perform the factual accuracy review. • Writes (or delegates responsibility to another Team Member) the Incident/Issue Summary and distributes it to appropriate individuals for the factual accuracy review in accordance with this manual. • Writes the Conclusion section of the RCA report in accordance with this manual.
Team Members	• Complete the RCA Team Training, online BLI2010-Corrective Action Development training and Effective Review Overview training, as appropriate, prior to commencing Team activities. • Defer decisions and analyses results pertaining to Team activities to the Team Lead and/or Lead Causal Analyst, as appropriate. • If team members do not agree with the outcome of the Team's analysis, disputing party(ies): 1. document the issue(s) in a formal correspondence to the Team Lead; 2. sign and date the formal correspondence; 3. Obtain acknowledgment of correspondence from The Team Lead; 4. and ensure that the Team Lead attaches the formal correspondence to the RCA or ER Report, as well as discusses its contents during the management briefings, as appropriate. • At the direction of the Team Lead, participate in writing the RCA or ER report in accordance with this manual.
Apparent Cause Analyst	• Performs the ACA as scoped and prescribed by the responsible Division management. • Completes the factual accuracy and QA reviews in accordance with this manual.

7.0 Issues Management Program Databases

Two databases are used to support implementation of the Issues Management Program requirements and processes, and the documentation of issues, corrective actions, objective evidence, lessons learned and best practices. The databases and associated Program requirements are described below in detail.

7.1 Corrective Action Tracking System (CATS) Database

The CATS Database is the official LBNL issues and corrective action tracking system. The database enables LBNL employees to document, track and formally close issues and their associated corrective actions. The database is the central repository for issues management information, which includes retrieval and reporting capabilities to gauge implementation and effectiveness of corrective actions, and to monitor and trend adverse conditions. The CATS Database has three core functions:

1. ***Issues and Corrective Action Management***
   The database supports the documentation workflow of the issues management process. The workflow includes entry, review and approval, tracking and closure of issues and associated corrective action(s) based on risk severity levels.

2. ***Records Management / Data Warehouse***
   The database supports electronic documentation and retrieval of issue, corrective action and objective evidence data. This includes the capability to upload multiple documents and file types and URLs to demonstrate issue resolution/corrective action implementation.

3. ***Ongoing Performance Analysis***
   The database supports trending and analysis of issues, with various search and reporting capabilities. This aids in monitoring, analyzing, and identifying recurring issues/trends and areas of improvement for quality, efficiency and reliability.

The following are requirements for CATS Database documentation, tracking and monitoring:

- Issues and risks pertaining to injury, damage, loss, noncompliance and safety or operational deficiencies **(Refer to section 1.0 Program Description)** and associated corrective actions, regardless of risk level, are entered into the CATS Database. The entry of observations or recommendations in the database is at management's discretion. Personnel performance (human

resources) issues and associated corrective actions are not entered in the CATS Database. The requirements and instruction for entering issues and corrective actions into CATS are found in the ***OIA-OCA-0001, Rev.3 Corrective Action Tracking System (CATS) Database User Manual.***

- Documenting immediately corrected issues/fixed upon identification ("on-the-spot") in the CATS Database is a recommended practice to demonstrate assurance of issues management. However, the decision to document these issues in the database is at management's discretion based on risk severity and administrative burden.

- An issue should be entered in the CATS database as soon as it is characterized and compensatory and/or corrective actions are identified. For high and medium risk issues, issues should be entered in the CATS Database following the CAP development/corrective action development process to enable a more comprehensive and collaborative approach to managing and resolving the issue.

- All issues and associated corrective actions as described above must be tracked through effective resolution in the CATS Database.

7.2 Lessons Learned and Best Practices Database

The Lessons Learned and Best Practices (LL/BP) Database is LBNL's official database for documenting and disseminating Laboratory operating experiences, which includes lessons learned, best practices and awareness communications. The sources for lessons learned and best practices may come from actual adverse incidents, near miss incidents, assessments, peer reviews, safety concerns, safety walkthroughs and inspections, and process improvement initiatives at LBNL, from other DOE sites operating experiences and from relevant industry organizations. These sources are not inclusive, as there are many sources of lessons learned and best practices. The LL/BP Database has two core functions:

1. ***Knowledge/Information Sharing***
   Lessons Learned and Best Practices are entered in and disseminated from the LL/BP Database that focus on: 1) preventing safety and operational adverse conditions and trends, 2) strengthening reliability and performance, 3) saving/reducing operating costs and 4) implementing corrective/preventative actions to avoid recurring issues and ensure continuous improvement. These communications are generated internally or externally, and are disseminated to specified target audiences and linked to specific hazard and/or control records in the Laboratory's Work Planning and Control system.

2. ***Data Warehouse***
   Lessons Learned and Best Practices communications are maintained in and are accessible to employees via the database. These communications can be

searched and retrieved for general information/awareness, incorporation into work planning, work processes and training classes, and for trending and ongoing performance analyses.

The following are requirements for the Lessons Learned and Best Practices Database:

- Employees should develop and enter lessons learned and best practices communications in the LL/BP database that pertain to preventing adverse conditions and trends, reliability and performance improvements, and cost savings. Contact the Issues Management Program Manager for assistance with developing, entering and disseminating lessons learned and best practices via the database.

8.0 Program Assurance

OIAI will perform ongoing monitoring and assessment of the Issues Management Program implementation effectiveness and sustainability in the following manner:

1. Monitoring and analyzing performance metrics/measures and correcting deficiencies as identified through the metrics;
2. Leveraging the integrated assessment schedule to validate that identified issues are characterized, analyzed, mitigated, documented, and evaluated in accordance with the Issues Management Program requirements;
3. For high and medium risk issues, periodically reviewing the CATS Database entries to ensure appropriate closure of corrective actions; and
4. Performing a triennial end-to-end review of each program component (*refer to section 3.0 in this manual*) and associated processes to identify and address implementation gaps, deficiencies and improvement opportunities.

9.0 Recordkeeping Requirements

The following are the records generated from implementing the Issues Management Program requirements. These records shall be maintained in accordance with the records management requirements as outlined in the Requirements and Policies Manual (RPM):

- CATS Database Entries
- Causal Analysis Reports
- Extent of Condition/Cause Reviews (may be included in the RCA Report)
- Corrective Action Plans
- Effectiveness Review Reports
- Lessons Learned / Best Practices Communications
- Performance Analysis Report of PAAA NTS and ORPS Reportable Issues