Lawrence Berkeley National Laboratory
Issues Management Program Manual

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Rev. 3

Effective Date: October 1, 2023

Office of Institutional Assurance and Integrity

REVISION HISTORY

Revision	Date	Revision Description
0	4/25/16	- Revised the legacy manual to incorporate program improvements; refinement of requirements, processes, procedures, guidance and templates; and consolidation of program manuals 5519 (1), (2), (3) & (4) into one program manual (5519).
1	10/1/2017	- Minor updates to align with revised DOE Order 232.2A, *Occurrence Reporting and Processing of Operations Information*.
2	6/1/2022	- Minor edits to the Glossary terms.
3	8/1/2023	- Added new template for Apparent Cause Analysis (ACA) and Report. Removed ACA Report only template. - Lessons Learned and Best Practices sections removed and incorporated into *04.02.003.001, Institutional Lessons Learned and Best Practices (LLBP) Process Manual.* - Incorporated principles to be adhered to while Analyzing an Incident/Event.

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GLOSSARY

TERM	DEFINITION
Adverse Condition	A failure, defect, deviation, malfunction, deficiency, loss, nonconformance, actual or near miss incident, or risk, which has or could have a negative effect on the safety and health of employees, the operational efficiency of the Laboratory, the public or the environment.
Apparent Cause	The dominant reasonable cause(s) of an issue that management has the control to fix through effective corrective actions.
Apparent Cause Analysis (ACA)	A basic analytical approach to identify evident causes of an issue or risk by gathering and evaluating the facts pertaining to the occurrence.
Best Practice (BP)	A technique or methodology that, through experience and research, has proven time-after-time to lead to a positive result, with the potential for significant operational improvements or cost savings.
Causal Factor	A mistake, failure, event or condition that led to an actual adverse condition or near-miss situation.
Circumstances	Occurrences or activities associated with an issue that pertain to who, what, when, where, and how based on factual, credible and accurate information.
Compensatory Action	An action that addresses the adverse condition(s) and/or circumstance(s) of an issue, but not necessarily the underlying cause(s) of the issue. A compensatory action may be implemented immediately to bring a process or program back into control, and is not expected to prevent recurrence or demonstrate sustainability.
Contributing Cause	Events or conditions that contributed to an issue, but by itself would not have caused the occurrence.
Corrective Action	An action that addresses the apparent or root cause of an issue, prevents recurrence or significantly reduces the likelihood of recurrence, and demonstrates endurance.
Corrective Action Plan (CAP)	A formal, documented plan that addresses how an issue will be addressed and resolved to prevent recurrence. A CAP includes compensatory actions, corrective actions, roles, responsibilities, authorities and accountabilities for corrective actions, major milestones and deliverables, and expected outcomes/success measures.

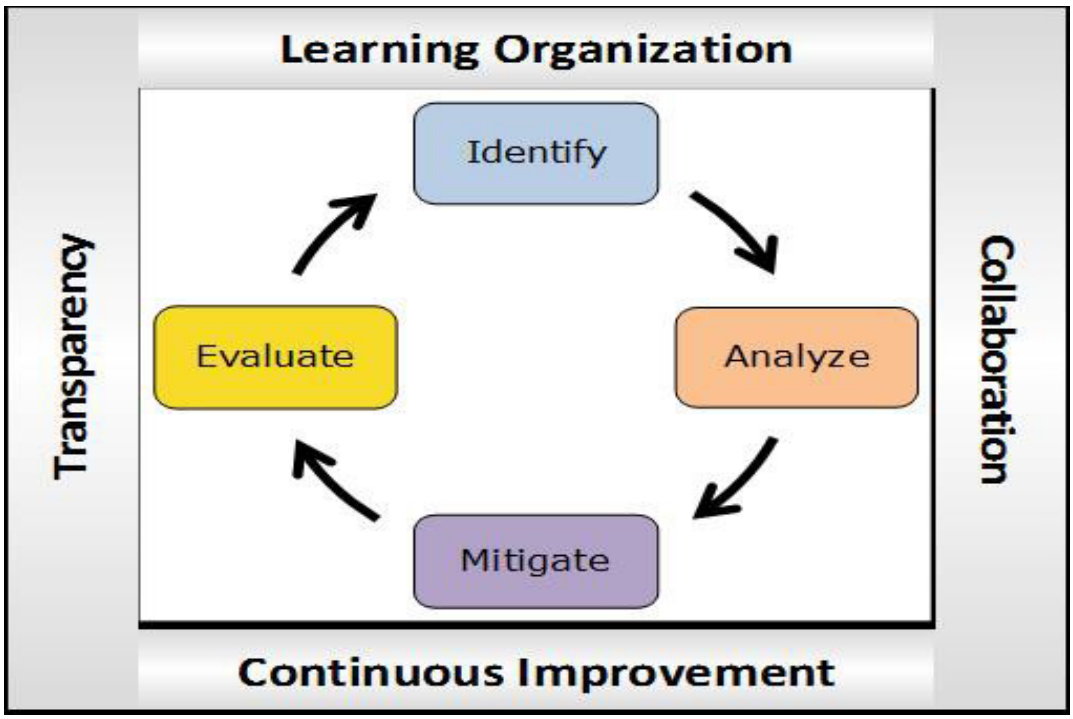
Direct Cause	The basic reason for an issue, generally, the immediate event or condition that caused the issue.
Effectiveness Review (ER)	A validation that an implemented corrective action resolved the issue. Specifically, an ER validates that a corrective action was implemented as designed, addresses the root cause(s) of the issue, prevents recurrence of future issues and demonstrates endurance.
Extent of Condition/Cause (EOC)	The extent to which an identified issue or a cause of an issue has the potential to impact other activities, projects, programs, facilities, organizations or processes or has done so in the past. The extent of condition/cause informs whether corrective action is needed for a localized issue or is needed to address multiple activities, locations and/or systems.
Finding	A term that refers to a programmatic or performance deficiency and/or a regulatory, policy or procedural noncompliance generally identified in a formal assessment or audit.
Formal Assessment	The act of reviewing, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining and documenting whether activities, processes, or services meet specified requirements. Generally, a formal assessment requires an assigned Lead Assessor and/or Assessment Team and the generation of a formal report, identification of findings, recommended corrective action and follow-up activities.
Graded Approach	A method by which the levels of analysis, mitigation, documentation, verification and validation are determined commensurate with risk severity.
Immediately corrected action	An action that quickly resolves the issue at the time of discovery (“on-the-spot”).
Incident	An actual or near miss occurrence that could adversely impact DOE, contractor personnel, the public, property, the environment, or the intended mission of the Laboratory.
Issue	A broad term that refers to any safety or operational incident, condition, or circumstance that: • results or could result in injury, damage, loss, or noncompliance (actual or near miss incident) • represents a program, safety or operational deficiency (audit or assessment finding, or performance deficiency as identified through trending and analysis or metrics) • adversely affects the achievement of mission, strategic and business objectives (risks).

Lessons Learned	A good work practice or innovative approach that is captured and shared to promote repeat application or an adverse work practice or experience that is captured and shared to prevent recurrence.
Noteworthy Practice	Practices or conditions that are recognized for their excellence and should be considered for lab-wide application.
Observation	An ineffective practice or condition that is: •compliant with a regulation or requirement, but, if left unaddressed, could lead to a noncompliance •an opportunity for improvement that can be gained in process, performance, or efficiency for continuous improvement •minor deficiency that has been promptly corrected on the spot and verified as completed.
Objective Evidence	Concrete measurable demonstration of corrective action implementation and/or issue resolution. Objective evidence must align with the corrective action description, deliverables and success measures, and validate that a corrective action was fully completed and implemented, and/or the issue was resolved as designed.
Occurrence Reporting and Processing System (ORPS)	A Department of Energy (DOE) system that notifies and keeps Laboratory management and applicable elements of the DOE informed of abnormal occurrences that could adversely affect: a) the health and safety of employees, guests, visitors, and the general public; b) the environment; c) the intended purpose of LBNL facilities; or d) the credibility of the DOE and/or LBNL.
Outlier	An abrupt change in the level of performance from the historical mean or trend line. Outliers are usually excluded when determining shifts, performance means, spreads, and trends.
Price Anderson Amendment Act (PAAA) Non-Tracking System (NTS)	A DOE system that Laboratory management utilizes to report adverse issues to the DOE Office of Enforcement, which could result in a reduction of fee, civil and/or criminal penalties or a discontinuation of a program or project.
Quality Assurance Review	A review of analyses, reports, and process implementations to validate that outputs and outcomes of issues management are credible, technically sound and accurate.
Recommendation	A suggested way of correcting an issue and/or observation, or a way to state a Judgment of Need (JON). A recommendation should be considered during CAP development, but is not required to be implemented.
Risk	The possibility of suffering a loss or an unfavorable event, or the failure of achieving a planned outcome. Risk in this context is defined as the product of the (i) probability (or

	frequency) of the event occurring and (ii) magnitude of its impact (or consequence) should the event occur.
Risk Level	The severity / significance rating assigned to an issue to ensure that appropriate levels of analysis oversight and resolution are commensurate with Laboratory requirements. Risk levels are stated as high, medium, or low.
Root Cause	The underlying or basic cause of an issue that can reasonably be identified and management has the control to fix, and when fixed, will preclude recurrence or significantly reduce the likelihood of recurrence of the same or similar issue. The root cause is typically one level further in analysis beyond an apparent cause.
Subject Matter Expert (SME)	The functional title for a person who has technical expertise and knowledge in a specific program, operations, process or professional area; or a Point-of-Contact for a particular functional area.
Trend	A general inclination, tendency, movement, or course that indicates a significant change in performance over time or from the previous time period. When used as a verb, to "trend" means to perform statistical analysis.
Validation	The act of reviewing, checking, evaluating or otherwise determining whether the corrective action(s) has been effective in mitigating the issue and preventing recurrence of an issue due to the same or similar causes. Validation is performed by an independent person (or persons), who did not perform the work associated with the corrective action(s).
Verification	The act of reviewing, checking and documenting whether the corrective action(s) address the issue and has been fully completed and implemented as required. Verification is performed by someone who did not perform the work associated with the corrective action(s).

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, injury and illness events, suspect/counterfeit items, 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

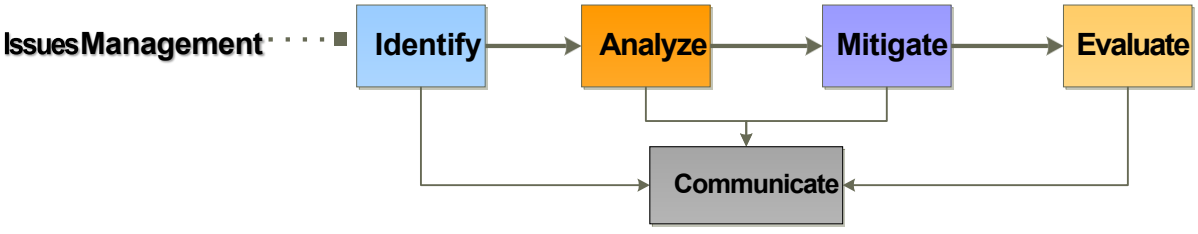
The LBNL IMP requires that all Laboratory employees continuously monitor work programs, processes, and procedures to identify safety and operational issues. Based on role, responsibility, authority and accountability in the Institution, employees are responsible for analyzing, correcting/mitigating issues, and evaluating corrective action implementation to assure successful issue resolution and prevention of recurring issues. Laboratory employees are also 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, additional information is gathered to clearly describe 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.

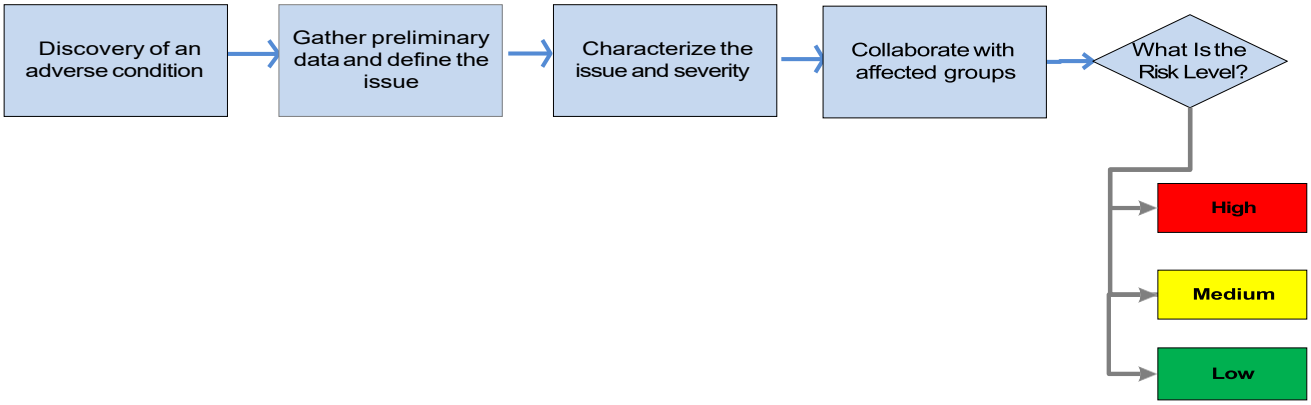
- Upward: Laboratory and responsible division management ensures that issues are characterized appropriately and timely, severity and pervasiveness of the issue is understood, and expectations pertaining to risk tolerances and issues management are communicated and embraced.
- Horizontally: Impacted 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 *Enforcement 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.)

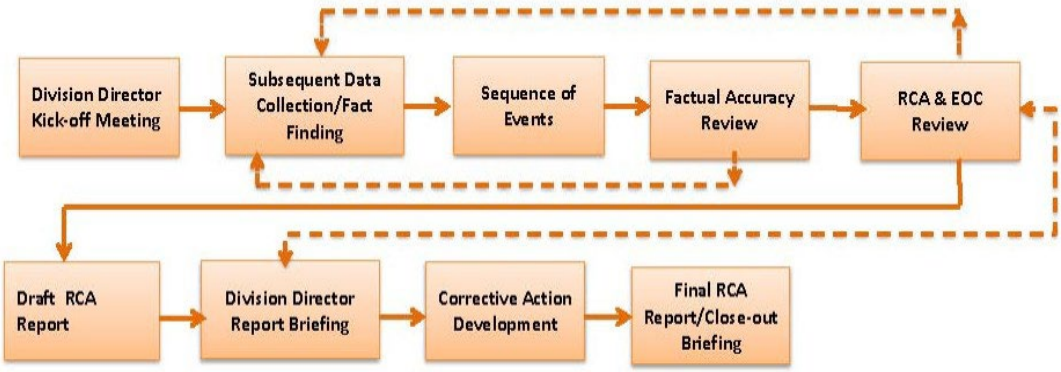
Corrective actions are developed and analyzed using the SMART (Specific, Measurable, Accountable, Reasonable and Timely) criteria. (***Refer to 11.7 SMART Analysis Worksheet*** in the Templates section of this manual.) Analysis also includes evaluation and determination of risk acceptance when appropriate.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

The following principles should be adhered to while Analyzing an Incident/Event:

- 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.

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.)

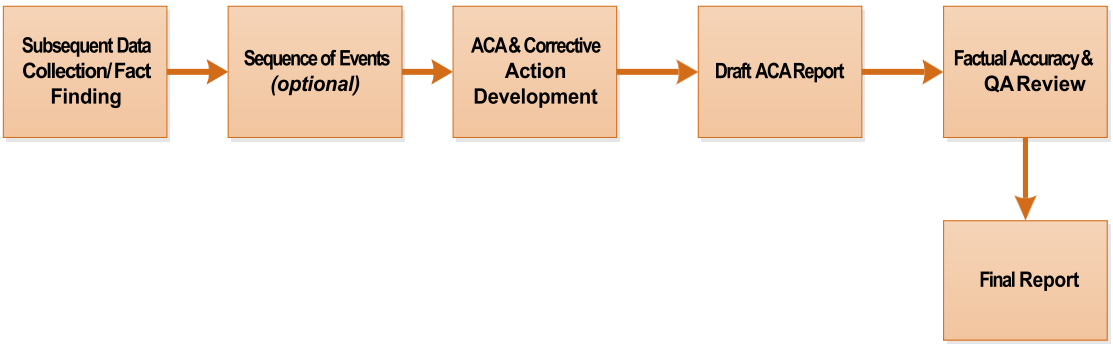
- The results of the investigation and root cause analysis are documented in a

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 and 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.

  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). • 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 Integrated Institutional Risk Management Framework. Issues identified and managed following the Issues Management Program requirements are inputs to the Integrated Institutional 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.
  - □ Residual risks are managed to the lowest level of exposure
    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.

□ Compensating actions are in place to minimize the effects of the risk
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 are entered in the CATS Database generally 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 issues to determine whether there are statistical trends and/or recurring issues., Additionally, the EHS Division and OIAI analyze internally reportable incidents to determine if statistical trends exist and require further review.

- 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.

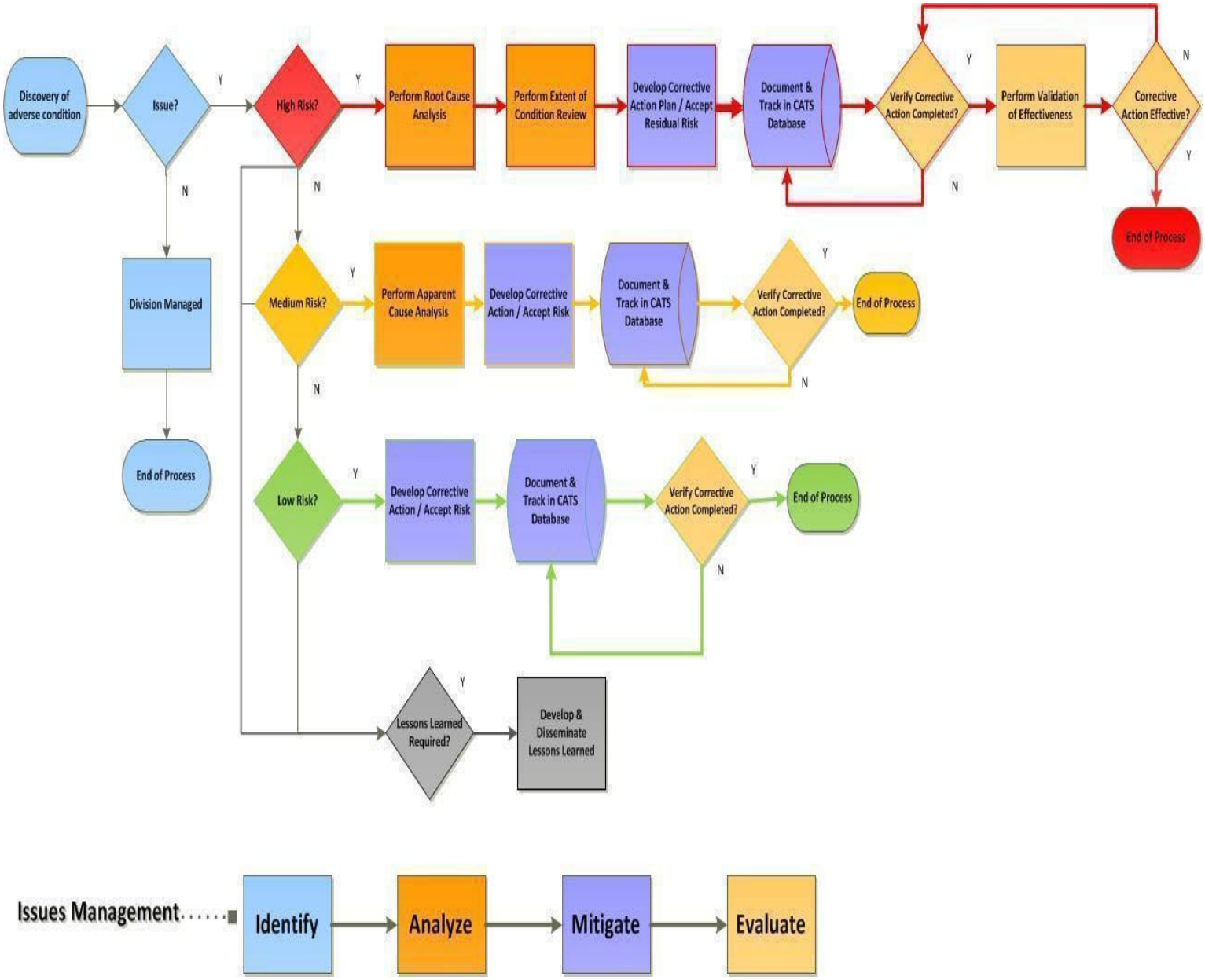
- The Institutional Integrated Assessment Schedule (IAS) process is considered a method of ongoing performance analysis. (Refer to the *Institutional Assessment Process Description, Document Number 04.03.009.001*, for more information.) This process includes developing a division's portfolio of assessments, 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 *Institutional Lessons Learned and Best Practices (LLBP) Process Manual, Document Number 04.02.003.001* describes the framework, database, and resources available to identifying, creating, and disseminating lessons learned and best practices.

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 to determine statistical trends and/or recurring issues.
Division Director *(or*	• Initiates the Scoping and Chartering Meeting with the OIAI

ROLE	RESPONSIBILITIES
designee)	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

ROLE	RESPONSIBILITIES
	accordance with this manual. • 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.
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; and 4. 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.

8.0 Program Assurance

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

i. Monitoring and analyzing performance metrics/measures and correcting deficiencies as identified through the metrics;
ii. 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;
iii. For high and medium risk issues, periodically reviewing the CATS Database entries to ensure appropriate closure of corrective actions; and
iv. 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
- Institutional Performance Analysis

10.0 Issues Management Program Standards

10.1 The Risk Level: Risk Severity Guidelines for Issues Management
10.2 Application of the Investigation and Causal Analysis Process
10.3 Scoping and Chartering the Causal Analysis
10.4 Division Director Kick-Off Meeting
10.5 Investigation Data Collection
10.6 Causal Analysis Methodologies
10.7 Extent of Condition/Cause Review
10.8 Senior Management/Division Director Report Briefings
  10.8.1 RCA Report Briefing
  10.8.2 Investigation and Causal Analysis Close-Out Briefing
10.9 Corrective Action Plan Development
10.10 Extension Requests
10.11 Effectiveness Review
10.12 Ongoing Performance Analysis
10.13 Factual Accuracy and Quality Assurance Reviews

10.1 The Risk Level: Risk Severity Guidelines for Issues Management Application

The Risk Severity Guidelines below can be used to determine the significance of an issue by considering its actual or potential adverse impact on safety, operational, financial or reputational loss, and/or its adverse impact on accomplishing mission/business objectives. Significance also includes determining the likelihood of an issue to occur, if it has not already materialized.

Impact Value	Impact Level	IMPACT *Impact is determined by considering what the activity, service, or issue results in or could result in.*					
		Environmental	**Injury**	**Financial**	**Reputational**	**Research & Operational Impacts**	**Compliance**
3	High	• Significant hazard to safety and health of workers, environment or public: – Exposures above regulatory limits – Environmental release off site or above regulatory limit	• Significant impact to the safety of LBNL: – Death – Serious/ irreversible illness/injury – Permanent Disability – Hospitalization ≥ 24Hrs	• ≥ $1M property loss or damage • ≥ $1M excess costs due to inefficiencies • ≥ $1M negative cost impact	• Significant negative publicity or public opinion • Significant political pressure • Significant potential for litigation or civil penalty	• Significant impacts on LBNL research activities – Inability to perform research to meet objectives • Significant impacts on LBNL operations – Extended facility shutdown or operational restrictions	• Civil penalties or fines levied by external regulatory agencies • Significant potential for litigation or criminal action • UC loss of contract award year and/or fee reduction • Requires immediate notification to external regulatory agencies • External regulatory agency investigation • Recurring issue as determined by data monitoring and analysis • Systematic non-compliance with regulations/contract and risks are analyzed, deemed high, controls in place to keep risks low

Impact Value	Impact Level	IMPACT *Impact is determined by considering what the activity, service, or issue results in or could result in.*					
		Environmental	**Injury**	**Financial**	**Reputational**	**Research & Operational Impacts**	**Compliance**
2	Moderate	• Hazard to the safety and health of workers, public and environment – Exposures near regulatory limits – Minor environmental release outside of building but on site – Major release within building	• Moderate impact to the safety of LBNL: – Hospitalization <24Hrs. – Partial Disability/temporary total disability >3 mos. – Restricted or Alternate Duty – Reversible illness/injury	· ≥ $25K to < $1M property loss or damage · ≥$100K to < $1M excess costs due to inefficiencies · ≥ $100K to <$1M negative cost impact	• DOE HQ Notification • Negative publicity or public opinion • Some political pressure • Some potential for litigation or civil penalty	• Some impact to LBNL research activities • Some impact to LBNL research operations – Short-term facility shutdown or operational restrictions	• External regulatory agency review • Noncompliance with moderate impact to LBNL • Adverse trend over an extended period of time
1	Low	• Minor hazardous material released within building	• Minor or negligible impact to the safety of LBNL: – No hospitalization – No or minor illness/injury – No restrictions – No disability	• < $25K property loss or damage • < $100K excess costs due to inefficiencies • <$100K negative cost impact	• BSO concerns • Lab Management concerns • Political pressure • Little potential for litigation or civil penalty • Little or no impact on perception of LBNL and UC	• Minor or negligible impact to LBNL research activities and/or operations	• Noncompliance with regulations/contract with minor/negligible impact to LBNL

IMPACT DEFINITIONS:
Impact is defined as the magnitude, significance, or severity of an unfavorable effect.

- **High** Impact: Actual (or potential for) **significant** adverse safety incident, costs, major delay or significant negative institution-wide effect.
- **Moderate** Impact: Actual (or potential for) substantive adverse safety incident, costs, or negative institutional effect.
- **Low** Impact: Actual (or potential for) minor safety impact, costs, or negative institutional effect.

Likelihood Value	Likelihood Level	LIKELIHOOD
3	High	• Has occurred, has occurred multiple times in last 12 months, or probable that the issue/ event will occur within 12 months
2	Moderate	• Has occurred, has occurred in the last 18-24 months, or more than remote but less than probable chance that the issue/event will occur within 18-24 months
1	Low	• Has occurred, but had not occurred in the past, or a remote chance that the issue/ event will occur again

QUANTITATIVE APPROACH

How to Calculate Risk Severity

Multiply the Impact Value by the Likelihood Value to determine the combined Risk Severity Level

High Risk = Total value 6-9
Moderate Risk = Total value 3-5
Low Risk = Total value 1-2

		IMPACT		
		Low (1)	Moderate (2)	High (3)
LIKELIHOOD	High (3)	3	6	9
	Moderate (2)	2	4	6
	Low (1)	1	2	3

Combined Risk Severity Definitions

High Risk: high likelihood to occur, near miss or has occurred and results in significant loss, damage and/or significantly impacts achievement of mission/business objectives. Requires immediate attention from Senior Laboratory management and follows a more formal, rigorous issues management process.

Medium Risk: would occur at some point in time, near miss or has occurred and results in substantive loss, damage and/or impacts achievement of mission/business objectives. Requires prompt attention from Division management and follows a graded issues management process.

Low Risk: is not likely to occur, near miss or has occurred and results in nominal loss, damage and/or nominally impacts achievement of mission/business objectives. Requires some attention from Line-management and follows a Division-driven issues management process.

10.2 Application of the Investigation and Causal Analysis Process

Elements May Not Be Sequential; They May Be Concurrent and Iterative

ELEMENT	APPLICABLE	
	RCA	ACA
Initial Fact Finding/Characterizing the Issue	**X**	**X**
Scoping & Chartering The Causal Analysis	**X**	**--**
Division Director Kick-Off Meeting *(Quality Assurance Review Begin)**	**X**	**--**
Subsequent Data Collection/Fact Finding *(Refer To 10.5 Investigation Data Collection)*	**X**	**X**
Sequence Of Events *(Quality Assurance Review)** *(Time-Order Of Events (TOE) including conditions and causal factors)*	**X**	***Optional***
Factual Accuracy Review *(Quality Assurance Review)** *(Refer To 11.3 Issue Summary For Factual Accuracy Review)*	**X**	**X**
Causal Analysis *(Quality Assurance Review)** *(Refer to 10.6 Causal Analysis Methodologies)*	**X** ***Formal Methodology***	**X**
Extent Of Condition/Cause (EOC) *(Quality Assurance Review)**	**X**	***Optional***
Documented Causal Analysis Report *(Quality Assurance Review)**	**X**	***X***
Division Director Report Briefing *(Refer To 10.8 Senior Management Report Briefings)*	**X**	**--**
Corrective Action Development *(Quality Assurance Review)**	**X** ***Formal CAP***	**X**
Final Report *(Quality Assurance Review Ends)**	**X**	**X**
Division Close-Out Briefing	***Optional***	***Optional***

A Quality Assurance Review is applicable for RCAs and at management discretion for ACAs.

10.3 Scoping and Chartering the Investigation and Root Cause Analysis

Scoping the Investigation and RCA

The Scoping Meeting should be held no later than two days following the initial fact finding and determination that a Root Cause Analysis must be performed. The Responsible Division Director (or designee) initiates the Scoping Meeting. The participants of the Scoping Meeting are the Responsible Division Director (or designee), OIAI Director (or designee) and other participants as determined by the responsible Division Director. For issues that are not owned by a single Division, generally the OIAI Director will serve as the Responsible Division Director. During the Scoping Meeting, the participants accomplish the following tasks:

1. Define the purpose and goal(s) of the investigation and analysis;
2. Identify the Division Team Lead, Lead Causal Analyst and supporting team members as prescribed in section 4.2.1 of this manual;
3. Establish the commitment level of Team members and duration of the Team;
4. Establish the due date for completing the investigation and root cause analysis process, which generally includes the development the corrective actions and completion of the final RCA Report; and
5. Identify the QA Reviewer when the Issues Management Program Manager is the Lead Causal Analyst.

Chartering the Causal Analysis

Prior to generating and distributing the Charter Letter, the Responsible Division Director (or designee) must secure the Team member's participation and commitment-level from the prospective Team member's manager. The Charter Letter should be distributed to the Team members and other applicable individuals within one day of the Scoping Meeting.

The Charter Letter should include the following information:

1. The purpose and goal(s) of the investigation and root cause analysis;
2. The Team members, including the identification of the Team Lead and Lead Causal Analyst;
3. The Team member's commitment level and time duration; and
4. The due date for the final RCA Report, which includes the CAP/corrective actions.

Refer to ***11.1 Investigation and Root Cause Analysis Charter Letter*** in the Templates section of this manual for an example of a Charter Letter.

10.4 Division Director Kick-Off Meeting

The Division Director Kick-off Meeting is designed to set the tone for completing a timely, rigorous and credible investigation and root cause analysis to prevent a recurring issue. The goals of the kick-off meeting are to:

- Establish ownership of the investigation and root cause analysis by the responsible Division Director
- Provide greater transparency on how the issue is analyzed and addressed
- Reinforce that the primary purpose of the investigation and root cause analysis is learning what happened and why, not affixing blame
- Improve communication of expectations for all key players (responsible Division Director and line management, Team Lead, Lead Causal Analyst, Team members, QA Reviewer, Interviewees, BSO Representative)

Kick-off Meeting Activities

- The responsible Division Director (or designee) schedules, plans and facilitates the kick-off meeting. Meeting participants should include the following individuals:
  a) Key stakeholders – those who have a vested interest in the outcome of the investigation and root cause analysis
  b) Team members and QA Reviewer
  c) Key personnel involved in the occurrence, as appropriate

Below is an example of a standard agenda for the kick-off meeting.

I. Introductions
- *Acknowledge meeting participants, as necessary*

II. Purpose of the investigation and analysis
- *High-level summary of the issue/incident*
- *Communicate purpose of the process is to prevent recurring issues; not to seek blame*
- *Reiterate goals from Charter Letter*

III. Roles, Responsibilities and Expectations
- *Division Director – accountability and ownership of the investigation and analysis process, outcomes and resolution*
- *Line Management – cooperation, factual accuracy and CAP/corrective action development*
- *Team Member, time commitment, scheduling of activities, and RCA Team Training*
- *Interviewees – cooperation, honesty and confidentially*
- *QA Reviewer – refer to 10.15 Accuracy and Quality Assurance Reviews*

IV. Expected outcomes of the process
- *Division Director's personal message / concluding thoughts*

10.5 Investigation Data Collection

Data collection is an iterative process that begins once the occurrence happens and may continue through corrective action development. Following the initial fact finding (initial data gathering and characterizing the issue), subsequent data collection may be needed to perform the causal analysis. The essential information that is needed to perform the causal analysis includes:

- Conditions and activities before, during, and after the occurrence
- Testimony from key personnel, such as workers, supervisors, individuals on the scene to respond to and/or witness the occurrence
- Testimony from SMEs, as necessary
- Physical evidence (photographs, operating logs, correspondence, inspection/surveillance records, maintenance records, procedures and instructions in place at the time of the occurrence, drawings, work orders, etc.), as appropriate
- Other information to better understand who was involved, what happened, and how, where and when it happened, as necessary
- Other information to validate data accuracy and address any gaps in the information

Data Collection Completeness

The following are key questions to answer to determine if sufficient information has been collected to complete the causal analysis:

a) What do we know already?
b) What do we need to know?
c) What do we need to see (physical location, correspondence, documents, photographs, etc.)?
d) What do we need to validate/corroborate?
e) Are all of the facts known to develop an accurate and comprehensive Time Order of Events (TOE) Chart, identify the causal factor(s) and complete the causal analysis (*refer to the 10.6 Causal Analysis Methodologies)*?
f) Are there any unexplainable gaps in the sequence of events (TOE Chart) that need to be closed?

Data Management

Supporting records and objective evidence should be retained with the official investigation and causal analysis documentation, including the final, signed RCA report. The types of information that are considered supporting records include:

- a copy of each document reviewed and used in the investigation and causal analysis
- a list of personnel interviewed and their corresponding testimony (written statements)
- the lines of inquiry and responses for the physical location, document review and key individuals; consolidate the responses into one document
- the list of questions and/or information clarified with the interviewees
- the TOE Chart and the causal analysis worksheet(s) used to determine the causal factors and causes

The Team Lead should ensure that a common storage protocol for document control is established (such as storing all documents on a Google Drive or Google Site, etc.), and a Team Member is designated as the document controller to ensure the integrity of data collection and archival. Following the investigation and analysis, the Team Lead should forward the complete data package to the Issues Management Program Manager.

10.6 Causal Analysis Methodologies

There are several tools and techniques to use to perform a causal analysis. Each has proven to be successful depending on the issue. The trained Lead Causal Analyst will select the appropriate methodology(ies) for the RCA from the LBNL approved methodologies listed below.

TapRooT® Incident Investigation System

A highly tested, proven and comprehensive system for finding fixable root causes of human error and equipment-related incidents. It utilizes a seven-step investigation and analysis process to examine, analyze and develop corrective actions to solve problems. TapRooT® encompasses Safeguard Analysis, Change Analysis, and Critical Human Action Profile.

Barrier Analysis

Barrier Analysis is based on the premise that hazards are associated with all tasks. For an issue to occur there must be a hazard that comes into contact with a target because barriers or controls were not in place, in place but not used, less than adequate, or they failed. Barrier Analysis is useful to identify controls that should be strengthened or added to improve safety, quality and productivity.

Change Analysis

Change Analysis evaluates planned or unplanned deviations that caused undesired outcomes. More specifically, this technique analyzes the differences between what actually occurred and what should have occurred in an ideal (expected) or issue free situation, to determine whether the differences caused or contributed to the issue. Change Analysis is most effective when work is described in procedures, the ideal situation is well defined or a prior safe and effective situation is already documented or can be reconstructed.

Critical Human Action Profile (CHAP) Analysis

CHAP is used to determine the critical human actions that caused or could have prevented an incident; it can be used in the TapRoot® System or as an independent analysis. CHAP compares the necessary steps, tools and information needed for successful performance of a critical task against how the task was actually performed. The causal factors and root causes are identified by comparing what should have been done to what was actually done.

Events and Causal Factors Charting and Analysis

Events and Causal Factors Charting and Analysis is a graphic representation or narrative description of the incident: both the sequence of events (from the initiating event through the final loss-producing occurrence) that led to the incident and the conditions that were causal factors. It is used in conjunction with other key methodologies (such as Barrier, Change or Five Whys analysis) to achieve optimal analytical results.

Five Whys Analysis (5-Whys)

The 5-Whys analysis explores the cause and effect relationships underlying a particular problem by continually asking: "Why?". A question and answer sequence is repeated until the root cause of the problem becomes apparent. Because it is so elementary in nature, it can be adapted quickly and used to analyze the causes for most any issue/incident. It is often used with other causal analysis methodologies.

Human Performance Improvement (HPI) Analyses

Human Performance Improvement Analyses are important management tools used to better understand human performance as it relates to an issue. These analyses are intended to help focus on what could have prevented the issue rather than concentrating on “who” caused an issue. It balances human and organizational contributions to the issue.

Latent Organizational Conditions Analysis

Latent Organizational Conditions Analysis evaluates unfavorable conditions embedded in the organization that make issues more likely to occur. The conditions include culture, programs, processes and practices. Root causes are identified by defining the undesirable condition(s) that led to the issue/incident. The Latent Organizational Conditions Analysis should consider the results of the HPI and Barrier Analyses.

Apparent Cause Analysis

Apparent Cause Analysis is a straightforward/basic approach to identify cause(s) for smaller-scale, low complexity-level issues that do not require the rigor of a root cause analysis. This type of analysis involves examining the facts associated with the issue (who, what, when, where and how), and based on the best available information, determining the most probable cause(s) of the issue.

Affinity Diagram

The Affinity Diagram is an analytical tool that can be used to organize and group facts based on natural relationships. Once the facts are grouped, the groups can be analyzed to determine common themes of failure, cause and effect relationships, and ultimately, an apparent cause(s). This approach is best suited to identify causal factors and apparent causes.

Customized Causal Analysis

Complex institutional issues that involve multiple work activities, circumstances, conditions, and non-compliances may require a customized causal analysis approach. In these situations, Division management should work with the OIAI Director and the Issues Management Program Manager to customize the causal analysis process.

10.7 Extent of Condition/Cause Review

An Extent of Condition/Cause (EOC) Review determines the potential for an issue to exist or to have occurred in other activities, processes, programs, divisions or systems elsewhere in the Laboratory. EOC Reviews are required for high risk issues and generally are included as part of the Investigation and Root Cause Analysis process.

The EOC Review may include the following:

- Looking for the same/similar issue and conditions in other areas than where originally found
- Looking for other manifestations of the root cause(s) in other areas
- Anticipating additional issues based on the identified issue and root cause(s)
- Reviewing prior implementation/applications of the deficient process, procedure or system to see if earlier deficiencies have gone unnoticed

The following actions are taken to conduct the EOC Review, as appropriate:

- Scope the EOC Review by:
  a) Reviewing the circumstances and conditions that led to the issue
  b) Determining the activities or facilities to which the issue applies
  c) Reviewing the root causes identified in the RCA

- Determine the EOC Review Methodology, which may include one or more of the following methodologies
  a) Precursor/Historical Review
     - analyze corrective action effectiveness
     - analyze related assessment findings
  b) Performance Analysis Reports (prior ORPS and PAAA reports)
     - analyze prior similar issues/occurrence for recurrence
  c) Personnel interviews coupled with document reviews
  d) Performance measures/metrics
  e) Observation of similar work activities and processes
  f) Sampling testing

- Develop lines of inquiry, gather objective evidence and conduct interviews, as appropriate. Consider:
  1. Does the same or similar problem exist in other applications, locations or facilities than where originally found?
  2. Have the same or similar problems occurred prior to this issue?
  3. Are there other manifestations of the root cause(s)?
  4. Are there similar or related conditions elsewhere, or can be anticipated based on the identified conditions of this issue?

- Analyze the data gathered to identify whether the issue conditions and causes applies to other areas within the Laboratory. Consider whether the existence of similar conditions and causes elsewhere in the Laboratory:
  a) heightens the issue severity
  b) requires refining the root and/or contributing causes
  c) identifies deeper systemic issues that may warrant management's attention and resolution

- Document the results of the EOC Review in the RCA Report or in a separate report, which includes a description of the conditions and/or causes pervasiveness, and broader-scale corrective action(s) to prevent recurrence.

10.8 Senior Management/Division Director Report Briefings

10.8.1 RCA Report Briefing

The purpose of the RCA Report Briefing is to provide Division management with clear and concise information on what happened, how it happened and why it happened, so that effective corrective actions can be developed to prevent recurrence. This translates into discussing the key facts of the issue/incident, causal factors, root and contributing causes, and the extent of condition/cause.

The Briefing is provided for all high risk issues RCAs prior to finalizing the RCA Report and commencing with CAP development. The Lead Causal Analyst will oversee the documentation of the causal analysis for the Briefing, which should follow the same format of the RCA Report Conclusion section, excluding the corrective actions (***Refer 11.5 Root Cause Analysis Report*** in the Templates section of this manual*).* However, the Team should be prepared to discuss recommended corrective actions for management's consideration. The Team Lead will schedule and facilitate the Briefing, as well as ensure that the causal analysis document is submitted to the Division Director (and/or designees) and other Briefing attendees prior to the Briefing.

Report Briefing Activities

The Briefing may include the following elements:

- Introduction: the purpose of the Briefing, as described in the Charter, and introduction of Team members, as necessary.

- Definitions: a discussion of common terminology that the Team used to describe the issue, causal factors and causes, as necessary. Standard terms may include causal factors, root and contributing causes and extent of condition/cause. (*Refer to the **Glossary** section in this manual.)*

- Investigation and RCA conclusions (as documented in the draft report):
  a) Issue/Incident Summary
  b) Causal Factors, root and contributing causes and key facts
  c) Extent of Condition/Cause: in other activities, processes, programs, or divisions, etc.

- CAP Development Suggestions:
  a) Highlight potential corrective actions to address the causes for management's consideration
  b) Discuss CAP development team composition and potential members, if requested by management
  c) Highlight BLI2010: Corrective Action Development Training requirement

10.8.2 Investigation and Causal Analysis Close-Out Briefing

The purpose of the Close-Out Briefing is to transition the final RCA Report and the CAP from the Teams to responsible Division Management. This briefing is optional and is held at the Division Director's discretion. The structure of the meeting may vary based on the Division Director's (or designee's) and other key stakeholders' interaction/communication with the Teams throughout the investigation and causal analysis process. The Team Lead will work with the Division Director (or designee) and other key stakeholders (as necessary) to determine the need and structure for the Close-Out Briefing. The Lead Causal Analyst and QA Reviewer should participate in the Close-Out Briefing.

To ensure a successful transition of the RCA and CAP, as well as effective corrective action implementation, the following should occur during the Briefing, or during the investigation and causal analysis process (in lieu of the Briefing):

1. Responsible Division Management understands the root cause(s) and extent of condition/cause.

2. Responsible Division Management agrees that the corrective action(s) are SMART, address the root cause(s) and should prevent recurrence if implemented effectively.

3. Responsible Division Management accepts ownership of the investigation and root cause analysis conclusions, CAP/corrective actions and expected outcomes.

4. Responsible Division Management commits to entering the approved corrective action(s) (as documented in the CAP) in the CATS Database within five (5) days of approval and commits resources to completing the corrective action(s) as designed.

5. Responsible Division Management will assign a division representative to work with the reporting coordinators (ORPS, PAAA, etc.), as applicable, to complete the outstanding reporting requirements.

10.9 Corrective Action Plan Development

Following the RCA Report Briefing, a Joint Team, comprised of the Investigation and RCA Team Lead, Lead Causal Analyst and Division Director appointed representatives, will develop a CAP for high risk issues. This may involve coordination among various Divisions to complete a single, comprehensive CAP. The Team Lead will oversee CAP development in accordance with this manual.

The Joint Team should take the following actions:

1. Complete the BLI2010: Corrective Action Development Training prior to commencing CAP development activities to ensure that the corrective action(s) are Specific, Measurable, Accountable, Reasonable and Timely (SMART).

2. Evaluate each cause/finding as documented in the RCA Report and/or Formal Assessment Report to determine the most appropriate corrective actions to implement. Appropriate corrective actions must have the following attributes:
   a) address the root, apparent and contributing cause(s), as appropriate;
   b) robustness to prevent issue recurrence and demonstrate endurance;
   c) no adverse/unintended consequences; and
   d) improves overall performance and reliability.

3. Develop corrective actions using the SMART Analysis Worksheet (Refer to ***11.7 SMART Analysis Worksheet*** in the Template section of this manual). The SMART Analysis Worksheet is reviewed by the Issues Management Program Manager (or designee) as part of the QA review.

4. Document the corrective actions in a CAP Report (***Refer to 11.8 Corrective Action Plan*** in the Templates section of this manual), ensuring that the documentation of corrective actions includes:
   a) specific, actionable corrective actions
   b) expected deliverables (objective measurable outputs)
   c) an accountable person and a responsible person for corrective action implementation and effectiveness
   d) an estimation of resources, including dedicated personnel and funding
   e) high-level milestones with realistic start and due dates, including interim compensatory actions as needed
   f) measurable expected outcomes/success measures for each corrective action
   g) immediate/compensatory actions taken following the issue discovery, at Division management's discretion
   h) two standard corrective actions for high risk issues:
      - validation of corrective action effectiveness
      - development and dissemination of a lessons learned communication

5. Discuss the CAP with the responsible Division Director(s) in the Close-Out Briefing or other type of management briefing, ensuring that there is concurrence on how the corrective action(s) address the cause(s) and will be effective in preventing recurrence, and on the expected measurable outcomes/success measures of the implemented corrective action.

6. Once the CAP is approved by the appropriate Division Director(s), responsible Division Management ensures that the issue and associated corrective actions are entered into the CATS Database within five (5) days of approval and managed through to effective resolution.

10.10 Extension Requests

During the implementation of corrective actions, operating conditions and management decisions may arise that impact completion of a corrective action as originally designed and/or by its original due date. When this occurs, Extension Requests may be used to adjust the due date to reflect the impacts/changes. Extension Requests should not be used to mask untimely completion of corrective actions due to lack of management oversight (accountability) or poor project management.

Corrective Action Responsible Persons (or designee) enter an Extension Request in the CATS Database generally before the corrective action due date to be considered for approval. When entering the justification statement for a due date extension in the CATS Database, the reason for the extension must be stated clearly and include a rationale consistent with criteria stated below.

The justification (business rationale) for an Extension Request must meet one or more of the following criteria:

- Completion of a corrective action is dependent upon external contractors or resources that could not be reasonably secured to complete the corrective action by the due date
- Completion of a corrective action is contingent upon another corrective action that has an approved extension
- Unforeseen changes to scope, schedule, budget/funding, or available personnel, including but not limited to SME or special skill set
- Unexpected changes to business priorities, needs, objectives or processes
- Reprioritization of resources due to unforeseen events, activities or budget cuts
- Alternative solution identified from continuous improvement activities
- Alternative solution identified through a recurring issue that indicates continued implementation of a corrective action will be ineffective and/or indicates a course correction is required

The approver(s) of an Extension Request is/are generally the same individuals who reviewed and approved the original issue and corrective action(s) in the CATS Database. Other individuals may be added as approvers in the CATS Database at the discretion of responsible management or the corrective action Responsible Person. OIAI personnel also review and approve all Extension Requests for high and medium risk issues.

Approvers of an Extension Request should validate that the justification meets the criteria as stated above, and the new due date is reasonable and timely to prevent recurring issues (or exacerbating the issue). In addition, approvers should resolve any issues with the Responsible Person (or designee) before approving or denying the Extension Request in the CATS Database.

10.11 Effectiveness Review

Overview

An Effectiveness Review (ER) is one of the three validation methods used to assure that an issue is resolved. The ER is designed to evaluate the effective resolution of high risk issues and is recommended to evaluate the effective resolution of medium risk issues. Specifically, an ER validates that a corrective action was implemented as intended, addresses the root cause(s) of the issue and prevents recurrence of similar issues. The following criteria are applied to validate effectiveness of implemented corrective actions:

1. is appropriate to address the root cause and (contributing cause if corrective actions to preclude recurrence were created for them);
2. is implemented as intended and in a manner that addresses the cause of the issue;
3. prevents occurrence of similar issues and demonstrates endurance; and
4. improves performance, with no unintended adverse consequences.

An ER is generally performed 6-12 months after the last corrective action for a given issue is implemented to allow sufficient time for the corrective actions to be integrated into ongoing practices and processes. This time period may be shorter or longer depending on the complexity of the issue and corrective actions, and should be determined as part of the SMART Analysis. Immediate and Compensatory corrective actions are not included in the ER.

The Responsible Person (the individual who has ownership of performing or overseeing the ER completion) should contact the Issues Management Program Manager (or designee) to initiate the ER. The Issues Management Program Manager (or designee) will provide technical guidance on the ER process and work with the Effectiveness Review Team throughout the process.

Scoping the ER

The Responsible Person, with assistance from the Issues Management Program Manager (or designee), determines the corrective actions in scope for the ER based on the corrective action's intent to prevent recurrence, excluding compensatory corrective actions. The Responsible Person and the Issues Management Program Manager (or designee) select one or more of the methodologies below to use based on the issue, cause(s) and corrective action(s) in scope for the ER. Often, more than one methodology is used to perform the ER.

Methodology #1

An effectiveness review of individual corrective actions that are implemented to address a single issue where corrective actions are completed within a 12-18 month period.

Methodology #2

An effectiveness review of sequential corrective actions that are implemented to address a single issue where the corrective actions will be collectively evaluated to determine the

effectiveness of implemented corrective actions. Corrective action implementation will be verified for each corrective action, and the entire suite of corrective actions collectively, not the individual corrective actions, will be assessed for effectiveness.

Methodology #3

An effectiveness review of corrective actions that are implemented to address a single area of exposure or a single hazard from two or more related issues/incidents, with similar conditions and causes. This ER collectively assesses corrective action implementation and effectiveness in addressing the cause(s) of the exposure area/hazard and preventing recurrence. Corrective actions will be grouped and assessed for implementation, and the entire suite of corrective actions collectively, not the individual corrective actions, will be assessed for effectiveness.

ER Evaluation Methods

An evaluation of effectiveness may be determined by using all or a combination of the following methods:

1. Effectiveness Review Methodology *(Lines of Inquiry – Document Review and Personnel interviews to determine understanding and compliance with the implemented actions)*
2. Objective Evidence of implemented corrective actions *(deliverables, output/products and other physical evidence to demonstrate implementation)*
3. Observation of work performance
4. Performance metrics/measures and indicators *(success measures, trending analysis, and other measurable documentation)*
5. Performance/Sample testing

Resources/Tools

The following are resources/tools to use to perform an ER:

- The Assessment Report and/or Root Cause Analysis / Extent of Condition Report that pertains to the issue.
- A list of the implemented corrective actions in scope for the ER.
- Objective evidence of corrective action(s) completion and closure.
- Effectiveness Review Methodology, Analysis and Report Templates.

ER Conclusions and Definitions

- **Effective** - Corrective actions are implemented as intended, have addressed the causes of the issue/finding, will prevent recurrence of the issue/finding and demonstrate sustainability. No new corrective actions are recommended.

- **Partially Effective -** Corrective actions are implemented as intended, and have partially addressed the causes of the issue/finding, but do not prevent recurrence or demonstrate sustainability. Revised or new corrective actions are recommended to enhance the effectiveness of the correction action.

- **Ineffective** - Corrective actions were not implemented as intended, do not address the causes of the issue/finding, do not effectively prevent recurrence of the issue/finding, and

do not demonstrate sustainability. New corrective actions are recommended to achieve effective resolution.

Effectiveness Review Activities

1. The Responsible Division Director (or designee) selects and charters the Effectiveness Review Team to perform the ER as described in this manual.
2. The Issues Management Program Manager (or designee) facilitates the Effectiveness Review Overview Training for the Effectiveness Review Team and provides oversight and guidance to the Effectiveness Review Team throughout the process as necessary.
3. Effectiveness Review Team
   a) Plans and schedules the ER activities, which include developing lines of inquiry, gathering and analyzing data, and maintaining objective evidence. (***Refer to 11.9 Effectiveness Review Methodology (Lines of Inquiry) and 11.10 Effectiveness Review Analysis*** in the Templates section of this manual.)
   b) Documents the results of the ER, including recommendation of additional corrective actions as necessary. (***Refer to 11.11 Effectiveness Review Report*** in the Templates section of this manual.)
   c) Maintains supporting/objective evidence of the ER analysis and conclusions.
   d) Submits the draft ER Report to the Issues Management Program Manager (or designee) for a quality assurance review prior to distributing the final report.
   e) Submits the draft ER Report to responsible line management for a factual accuracy review prior to distributing the final report.
   f) Resolves concerns with the draft report, as necessary.
   g) Signs the final ER Report and submits the report to the Responsible Division Director. *Note: Generally, a report briefing is scheduled with the Division Director to eliminate any communication issues with the report.*
   h) Compiles and submits a copy of the data package, including all of the supporting documentation, to the Issues Management Program Manager (or designee) for Institutional recordkeeping and archive.
4. If the ER concluded that corrective actions to prevent recurrence were partially effective or ineffective, the Responsible Division Director (or designee) should:
   - determine the corrective actions that will be implemented to prevent recurrence or will identify the risk exposure and accept the residual risk per the guidelines in section 4.2.6 Risk Acceptance Decision.
   - document the corrective action(s), or risk acceptance decision and rationale in the CATS Database and manage resolution accordingly.

10.12 Ongoing Performance Analysis

Ongoing performance analysis is conducted to assure that issues and adverse trends are identified and corrected before they become significant systemic, programmatic or recurring issues. This analysis also is used to gauge sustained performance and identify improvement areas. Ongoing performance analysis involves using both qualitative and quantitative methods to track, monitor, trend, and analyze data to gauge performance. The process for ongoing performance analysis is:

1. Identify the performance area(s) to monitor or measure.
2. Define the data to collect.
3. Identify and document the source(s) to obtain the data (***Refer to the Performance Area and Data Sources section below***).
4. Develop and document the performance analysis methodology (***Refer to the Performance Analysis Methodologies section below***).
5. Determine the monitoring and reporting frequencies (*for example, daily, weekly, monthly, quarterly, etc.; the common frequencies are monthly or quarterly to get meaningful information for assurance and continuous improvement*.)
6. Establish targets, performance indicators, or thresholds/control limits to gauge performance, where applicable.
7. Collect and analyze the data.
8. Consult with appropriate SMEs/management for information on and/or explanation of identified variations (*positive or adverse*).
9. Report findings and observations to management for resolution.
10. Correct adverse issues and trends.

<u>Performance Area and Data Sources</u>

Divisions are responsible for tracking issues (regardless of reportability), actual and near miss incidents, assessment findings and other unexpected adverse events to identify trends and recurring issues. Before selecting the data source(s), Divisions should identify the specific condition, event, program, process, behavior or quality-related characteristic to be monitored, measured and/or controlled. Once the performance area is identified, there are many sources of data. Below is a list of the common sources (*this list is not inclusive)*:

- ORPS Reportable Incidents
- Sub-ORPS Incidents
- PAAA Reportable Incidents
- Regulatory Findings
- Assessment / Audit Findings
- Safety Concerns
- Division-specific incident logs
- Field Observation/Walkaround inspection logs or worksheets
- Stand-downs / Stop works
- CATS Database entries
- CHESS injuries entries

- Lessons Learned Database submissions
- Metric Results
- Risk Registry
- Operations Quad Charts

To select the appropriate data source for a given performance area, the rule of thumb is to use a data source that is:

- *Credible* – is a measurable source rather than based on anecdotal/subjective information.
- *Timely* – is available on the periodicity required to evaluate the performance area effectively.
- *Reliable* – is a proven, sustainable and cost effective method to collect data.
- *Easy to obtain/retrieve* – is readily accessible with no (or little) administrative burden.
- *Recognized and understood by management* – is a familiar and relevant data source that management views as important.
- *Comparable over time* – has sufficient historical data to develop baselines and trends, and to assess past and present performance from period to period.

Performance Analysis Methodologies

Performance Analysis methodologies may include qualitative analysis, trend charting, and analyzing performance metrics (*which may include error precursors*). The methodology should be robust enough to:

- Identify changes in performance (upward, stable or downward trends).
- Ensure performance is within specified limits/tolerances.
- Identify opportunities for improvement.
- Determine the effects of improvement efforts on performance.

Qualitative Analysis

Qualitative Analysis, generally, is based on non-quantifiable data. Qualitative data, such as surveys, logbook entries, processes/field observations, incident summaries, causal analysis, and personnel interviews must be interpreted carefully and thoroughly analyzed through fact-based reasoning. To perform this analysis, qualitative data often is converted to quantitative data, for example, numerical values, categories or trend codes. Once the data is in quantitative or an absolute form, it can be aggregated and analyzed.

Assigning trend codes to qualitative data is commonly used at LBNL to facilitate trending and analysis, and the identification of systemic and recurring issues. In general, a trend code represents the most probable cause of an issue. The trend codes assigned to issues in the CATS database can be used to trend and analyze issues. ***Appendix A*** contains a list of common trend codes that are consistent with ORPS cause codes and common cause areas.

Trend Charting (*Trend Charts*)

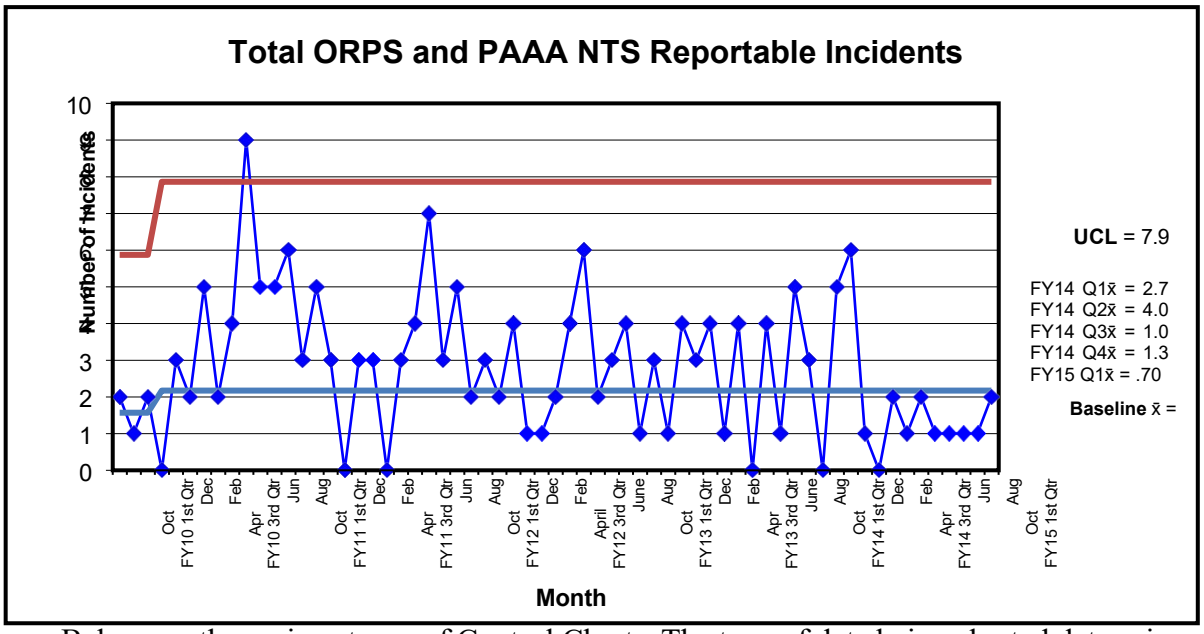
Trend Charts are used to monitor performance over time to detect trends, variations and issues. Trend Charts display patterns in a simple, visible and easy to understand format, and make it easy to identify issues and improvements.

There are several basic types of trend charts, such as Control Charts, Run Charts and Pareto Charts, that can be used to identify variations in performance, understand the magnitude and sources of variations, and anticipate future performance. Runs Charts and Pareto Charts are easier to produce and simple to interpret. Control charts require more knowledge and special calculations. Consult with management, OIAI personnel and/or a Laboratory statistician to assist with selecting the appropriate chart(s) for ongoing performance analysis. Below is a description and example of each trend chart.

- *Control Chart*

  The Control Chart is useful to identify variations and their sources over time. The Control Chart can be used to determine whether a value is within an acceptable statistical threshold and if a statistical trend is present. The control chart also plots a single line of data over time and can identify whether a performance area is stable and in control.

  A Control Chart has a baseline, average or performance mean, and usually has both an upper control limit (UCL) and a lower control limit (LCL). There are many types of Control Charts and different methods of calculating the performance mean and control limits. Generally, at least 25 data points are required to determine the performance mean and control limits. When control limits are calculated, data points that are outliers generally are excluded from the calculations. Below is an example of a Control Chart.



Below are the various types of Control Charts. The type of data being charted determines the type of Control Chart that should be used.

Type of Data	Type of Chart	Use
Variable*	X chart	To plot percentages, ratios, counts and other non-measurement data
Variable	R chart	To plot the sample ranges
Variable	S chart	To plot the sample standard deviations
Variable	chart	To plot the sample means
Attribute**	C chart	To plot the number of deficiencies if the distribution of failures is rare (constant sample size).
Attribute	U chart	To plot the number of deficiencies if the distribution of failures is rare (variable sample size).
Attribute	Np chart	To plot the number of deficiencies if the distribution of failures is not considered rare.
Attribute	P chart	To plot the percent of deficiencies.

* Variable = measured and plotted on a continuous scale (time, cost, etc.)

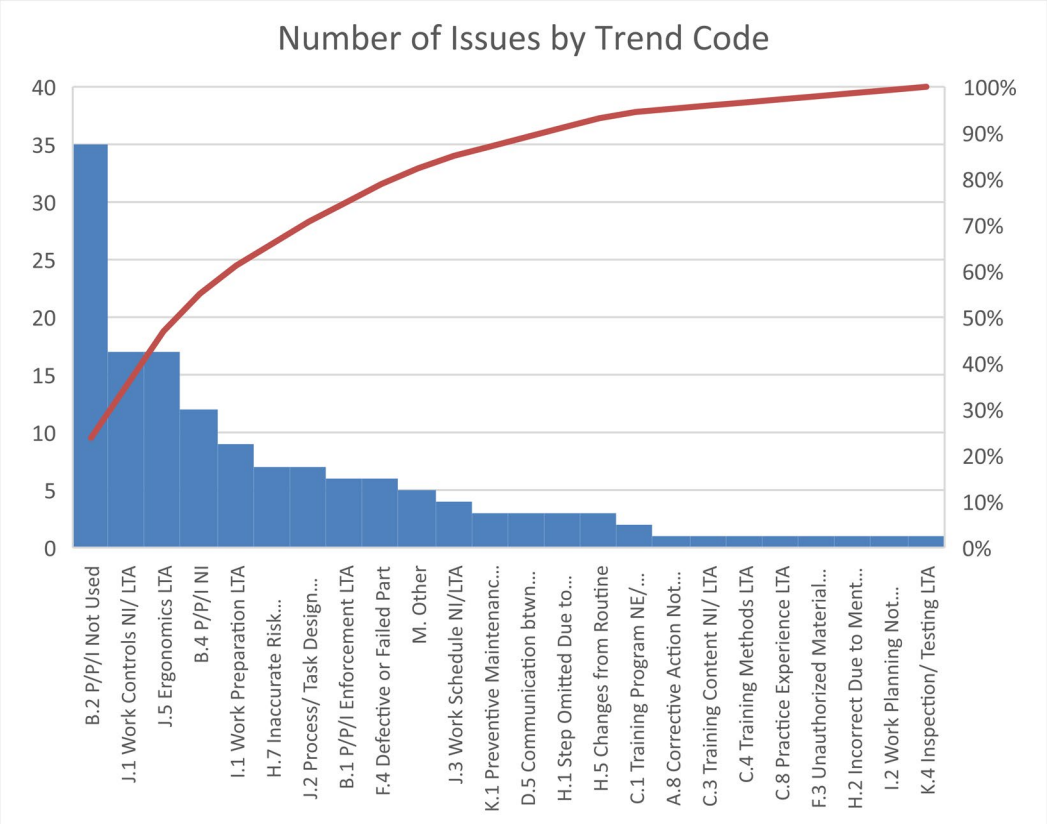
** Attribute = counted and plotted as discrete events (errors, occurrences, etc.)

- *Run Chart*

  The Run Chart is used to track and analyze trends or patterns over a specified period. This chart assists with detecting statistical trends, shifts or cycles. A Run Chart consists of a single line plotting data points in time sequence and may contain a centerline, which is the mean or median. A Run Chart can help identify upward, downward and stable trends over time.

- *Pareto Chart*

  The Pareto Chart is used to identify aspects of performance, such as causes, errors or non-compliance. A Pareto Chart shows the relative frequency and size of the performance element to focus attention and effort on fixing significant issues and adverse trends. Below is an example of a Pareto Chart.



Determining Trends

Numerous criteria can be applied to identify trends and other changes using trend charts. The following criteria can be used to determine positive, stable or adverse trends, statistical trends, shifts and outliers based on data points or patterns.

A trend may exist if there is:

- a noticeable change in performance, such as upward or downward movement; or
- a series of consecutive increases or decreases.

A statistical trend is defined as:

- one point outside the control limits;
- two out of three points two standard deviations above or below the baseline average;
- four out of five points one standard deviation above or below the baseline average;
- seven points in a row above or below the baseline average; or
- seven points in a row that are increasing or decreasing.

A shift may exist if:

- seven points in a row are above or below the average; or
- four out of five points are one standard deviation above or below the average.

An Outlier (or Outliers) may exist if:

- one point is outside the control limits; or
- two out of three points are two standard deviations above or below the average.

Performance Metrics

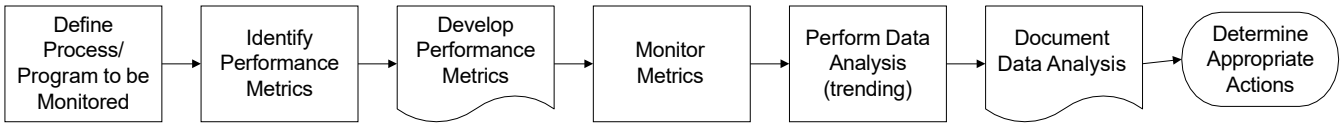
Performance Metrics are used to evaluate progress toward stated performance goals or targets, evaluate identified risk exposure/vulnerabilities, and to proactively identify emerging risks and recurring issues. The rule of thumb is to develop and track a performance metric that:

- has a defined target/goal (acceptable range), cautionary, and warning level, and an escalation trigger to prompt line, division or senior management action;
- is easily quantifiable as a number, percentage, amount, etc.;
- reflects an objective measurement rather than subjective judgment; and
- is comparable over time for trend analysis and benchmarking.

There should be a balance of leading and lagging metrics when evaluating a particular performance area. Depending on perspective, a given metric can be leading or lagging. Management will need to determine whether a metric is leading or lagging, and determine the appropriate balance of metrics to evaluate a performance area. Below is a general characterization of leading and lagging metrics:

- A **leading** metric signals future events and anticipates and predicts patterns or trends (precursors – indicates a future direction).
- a **lagging** metric confirms that a pattern exists or is about to occur (trailing – indicates achievement of goals).

Below is a general process flow to develop and manage performance metrics.



Corrective and Improvement Actions

When issues and adverse trends are identified through ongoing performance analysis, corrective action should be taken to address the issues or adverse trends per the Issues Management Program requirements. Similarly, when there is a desire to strengthen performance, improvement actions should be initiated to obtain the desired performance.

Occasionally, ongoing performance analysis also may identify a need to modify targets, goals and/or control limits. To determine if modification is necessary, consider the following:

- Was there a significant change to a policy, process, procedure or other activity?
- Is the performance stable/sustained?
- Is the cause of the change understood and can be addressed?

If the answer is "yes" to any of the questions, then a target, goal or control limit may warrant an adjustment.

10.13 Factual Accuracy and Quality Assurance Reviews

Prior to finalizing the work product, factual accuracy reviews are completed by management (or designees) and appropriate SMEs, and quality assurance reviews are completed by OIAI personnel for Causal Analyses, Corrective Action Plans and Effectiveness Reviews. The purpose of these reviews is to assure that the data collection, processes, analyses, and reports are thorough, credible, technically sound and accurate. The reviews are participatory and

support the pillars of the Issues Management Program, which are learning environment, transparency, collaboration and continuous improvement. Each review is described in detail below.

Factual Accuracy Reviews

RCA

The Factual Accuracy Review for a RCA includes a description of the issue (Issue/Incident Summary) and the issue's key circumstances and causal factors. This Issue/Incident Summary version (upon factual accuracy completion) will be included in the RCA Report. For a RCA, the Factual Accuracy Review is completed once all of the data collection has been completed and the causal factors have been identified, and prior to beginning the root cause analysis. Additional facts may be uncovered during the RCA and will need to be validated with another Factual Accuracy Review or during the Division Director Report Briefing, at the discretion of the Lead Causal Analyst. Below are key steps to completing a RCA Factual Accuracy Review:

1. The Lead Causal Analyst coordinates the development of the Issue/Incident Summary once all of the data is collected, the TOE Chart is finalized and causal factors are identified.
2. The Team Lead and Lead Causal Analyst identify appropriate line management, SMEs and other individuals who will perform the review.
3. The Lead Causal Analyst (or designee) will distribute the Summary to the appropriate individuals to complete the review, with a due date (generally within two to three business days) to respond with concurrence or edits.
4. The Team resolves any questions, comments or concerns with the Factual Accuracy Reviewers.
5. The Lead Causal Analyst (or designee) edits the Issue/Incident Summary and includes the edited version in the RCA Report.
6. The Lead Causal Analyst (or designee) updates the TOE Chart and causal factors, as appropriate, and begins the root cause analysis.

ACA

The same steps above may be used to complete a factual accuracy review for an ACA, or the review can be completed by appropriate individuals via a review of the draft ACA report, which includes the apparent causes and corrective actions.

CAP
The Factual Accuracy Review for a CAP is completed during the Investigation and Analysis Close-Out Briefing, or through a review and concurrence of the documented CAP by the Responsible Division Director(s).

ER
The Factual Accuracy Review for an ER is completed through review, discussion and concurrence of the documented ER Report. This may be accomplished in a management briefing of the report.

Quality Assurance Review

A Quality Assurance (QA) Review is completed on all high risk issue RCAs, EOCs, CAPs and ERs by OIAI personnel (or designee). The ORPS Coordinator completes a QA Review of the ACA that are documented in ORPS Reports.

The RCA, EOC and CAP QA Review starts with the Division Director's Kick-off Meeting and is performed as follows:

- Review the Team's lines of inquiry prior to conducting interviews
- Review the Team's TOE Charts
- Attend the Team's causal analysis meetings to provide immediate feedback on the application of the methodology, process, and outputs (issue/incident summary, causal factors, causes and extent of condition review)
- Review the Team's draft RCA Report prior to the Division Director's briefing
- Attend the Team's corrective action development meetings to provide immediate feedback on the quality of corrective actions
- Review the Team's SMART Analysis
- Review the Team's CAP prior to the Division Close-out Meeting or distribution to responsible Laboratory or Division management.

The ER QA Review involves a review of the Team's ER Methodology (lines of inquiry), Analysis and Report.

The checklist below is used as a guide for completing RCA, EOC and CAP processes and report QA Reviews. For an ER QA Review, the following criteria is used as applicable to ER activities.

QA CRITERIA		SATISFIED YES / NO
1.	**Lines of inquiry (LOIs)** • All of the individuals and witnesses pertinent to the specific issue are identified and interviewed • Straightforward, open-ended questions are used to collect information • Questions are not biased, leading or judgmental, nor appear to	

	QA CRITERIA	SATISFIED YES / NO
	support a particular "hypothesis" • Conflicting/inconsistent information is resolved through additional questioning	
2.	**Time Order of Events (TOE) Chart** • Accurate, complete and pertinent facts are gathered to clearly understand the issue • Adequately documents the sequence of events: what happened, when and where it happened, how it happened and who was involved • Dates and times are noted, as applicable • Timeline does not have any unexplained gaps or conflicting information	
3.	**Application of Causal Analysis Methodologies** • LOIs and responses are documented • Causal Factors are identified and documented clearly • Approved methodology(ies) is (are) used and documented to establish the basis for the identified causes • Causes are justified through facts/objective evidence (documents, physical evidence, and testimony) • Speculation and assumptions are not considered in the analysis	
4.	**Causes** <u>Root Cause:</u> • Are described clearly and concisely, with an appropriate level of detail to explain the underlying reason **"why"** an incident/finding occurred • Are what management has control to fix • Are credible/valid and supported by objective evidence • Are not causal factors <u>Apparent Cause:</u> • Are clearly stated in terms of the mistake(s) or failure(s) that led to the incident/finding • Are the most dominant reason why the incident/finding occurred • Are not direct causes <u>General Notes</u> • Apparent Causes may be evaluated in the development of the Root Causes, but should not be stated as Root Causes. • Terminology such as "less than adequate" ("LTA") or "as intended" is avoided in favor of more precise descriptions of specific inadequacies. • Issues with immediate actions (actions that pertain to the incident response) and other unrelated issues identified during the analysis are discussed in the report separate from the causes.	
5.	**Extent of Condition/Cause Review** • An EOC Review is completed and included:	

	QA CRITERIA	SATISFIED YES / NO
	a) Looking for the same or related issues, conditions and causes in areas other than where originally found b) Anticipating problems based on the identified issues, conditions and causes c) Reviewing prior activities to determine if earlier deficiencies have gone unnoticed • An EOC Review is documented in the RCA Report or in a separate report and included in development of corrective actions, as appropriate	
6.	**CAP/Corrective Actions** • Corrective actions are developed and validated using the SMART Analysis Worksheet, and are Specific, Measurable, Accountable, Reasonable and Timely • Corrective actions address the root cause(s) • Corrective actions address the pervasiveness of the condition/cause (extent of condition) • Corrective actions are designed to prevent recurrence • Two standard corrective actions are included in the CAP: 1. Perform an Effectiveness Review 2. Submit a Lessons Learned Communications	
7.	**Causal Analysis Report** • The issue/incident summary is documented in a clear, logical and comprehensive manner that provides all pertinent facts associated with the incident/finding to support the analysis • The Executive Summary provides a detailed, high-level explanation of the causes and management concerns • PAAA NTS and ORPS noncompliance/occurrence report numbers or Assessment Report Titles are noted in the Executive Summary, as applicable • Jargon is omitted and abbreviations are defined and minimized • Names of individuals involved in the issue/incident are not included in the report	

11.0 Issues Management Program Templates

These templates are also available on the OIAI webpage in the Issues Management Section.

11.1 Investigation and Root Cause Analysis Charter Letter
11.2 CAP Development Charter Letter
11.3 Issue/Incident Summary for Factual Accuracy Review
11.4 Apparent Cause Analysis and Report
11.5 Root Cause Analysis Report
11.6 Extent of Condition/Cause Report
11.7 SMART Analysis Worksheet
11.8 Corrective Action Plan
11.9 Effectiveness Review Methodology (Lines of Inquiry)
11.10 Effectiveness Review Analysis
11.11 Effectiveness Review Report

11.1 Investigation and Root Cause Analysis Charter Letter

To Team Member #1
Team Member #2
Team Member #3
Team Member #4

From: Responsible Division Director

Date: [Enter applicable date]

Re: Charter for the XYZ Issue

I am charging you to perform an investigation and root cause analysis of the issue involving XYZ on XX-XX-XXXX. Specifically, you will identify the cause(s) of this issue, [state other goals if applicable] and the extent of condition/cause. This assignment will require XX% of your time for the next XX days. Your Manager has been asked to re-assign your responsibilities to allow for your participation in this investigation and causal analysis.

XXXX will serve as the Team Lead for the Division and XXXX will serve as the Lead Causal Analyst for the root cause analysis. Your investigation and root cause analysis shall follow the requirements of the LBNL Issues Management Program Manual, LBNL/PUB-5519.

Once you have completed your investigation and root cause analysis, the results should be documented in a Root Cause Analysis Report and discussed with me and [name other individuals, Division representatives and external parties as applicable] no later than XX-XX-XXXX.

Upon completion of the Root Cause Analysis Report, the XXXX and XXXX Divisions will develop corrective actions that address the root cause(s) of the issue/incident. Following the development of corrective actions, the final Root Cause Analysis Report, including the official corrective actions, should be submitted to me no later than XX-XX-XXXX.

Thank you for your participation in this important endeavor.

Cc: Appropriate Laboratory Management, as necessary
Appropriate Responsible Division Personnel
Other affected Division Management, as necessary
Team Member's Respective Management
OIAI Director
Issues Management Program Manager
BSO Representative
PAAA Enforcement Coordinator, if reportable

11.2 CAP Development Charter Letter

To Team Member #1
Team Member #2
Team Member #3
Team Member #4

From: Responsible Division Director

Date: [Enter applicable date]

Re: Charter for the XYZ Issue Corrective Action Plan Development

I am charging you to develop a Corrective Action Plan (CAP) that addresses the root causes of the XYZ issue, which occurred on XX-XX-XXXX. Specifically, you will evaluate each root cause as documented in the Root Cause Analysis Report and determine the most effective corrective actions to implement. Effective corrective action(s) are specific, measurable, accountable, reasonable and timely (SMART) and have the following attributes:

a) specifically address the root cause(s);
b) designed to prevent recurrence;
c) demonstrate endurance and sustainability;
d) will not introduce negative unintended consequences; and
e) will improve process/program performance.

This assignment will require XX% of your time for the next XX days. Your Manager has been asked to re-assign your responsibilities to allow for your participation in this activity.

XXXX will serve as the Team Lead for the CAP development. Your CAP development activities shall follow the requirements of the LBNL Issues Management Program Manual, LBNL/PUB-5519. In addition, team members should complete the BLI2010: Corrective Action Development Training to ensure that corrective action(s) are SMART. The training can be found at http://www2.lbl.gov/ehs/training/webcourses/BLI2010/.

Once you have completed the CAP, the plan should be documented in the Root Cause Analysis Report [or documented in a separate CAP report], and discussed with all responsible parties and me. Following this discussion, the final Root Cause Analysis Report [or independently documented CAP] should be submitted to me no later than XX-XX-XXXX.

Thank you for your participation in this important endeavor.

Cc: Appropriate Laboratory Management, as necessary
Appropriate Responsible Division Personnel
Other affected Division Management, as necessary
Team Member's Respective Management
OIAI Director
Issues Management Program Manager
BSO Representative
PAAA Enforcement Coordinator, if PAAA reportable

11.3 Issue/Incident Summary for Factual Accuracy Review Example

Title of the Document

The XYZ Issue
Issue/Incident Summary
Factual Accuracy Review

Describe the issue in chronological order and include dates and times

On June 29, 2011, at approximately 10:30 a.m., a LBNL Construction Safety Engineer observed a XYZ subcontractor electrician, working on the Building 37 (B37) ABC Project, performing work in an electrical box without having signed onto the LOTO permit or having affixed his lock and tag to the group lock-box. The subcontractor electrician involved is a licensed electrician.

At approximately 10:00 a.m., the XYZ subcontractor electrician arrived at B37 and received a briefing by the XYZ superintendent on the project Pre-Task Hazard Analysis (PTHA). The electrician did not receive a LOTO briefing by the XYZ superintendent and the superintendent did not have the electrician review and sign onto the LOTO permit, site Safety Checklist (SCL) or Job Hazard Analysis. Note: the daily PTHA identified the task as a hazard, but did not identify LOTO as a control. Contrary to an established work practice, the XYZ superintendent chose not to contact the LBNL Responsible Individual when the XYZ subcontractor electrician arrived onsite to ensure the electrician completed the LOTO process.

After the PTHA briefing, the XYZ superintendent instructed the electrician to apply his lock and tag to the group lockbox that had been put in place approximately one week earlier. As he was preparing a LOTO tag, he was asked by the XYZ superintendent to change into steel-toed boots. While changing into his boots, the electrician placed his LOTO lock in his pocket and left his LOTO tag on the bumper of his truck. The electrician then returned to B37 and proceeded to work. The electrician did not attach his lock and tag to the group lock box before completing the work.

The XYZ superintendent and the XYZ electrician did not follow LBNL LOTO permit process, which require a LOTO briefing and attachment of locks and tags before working near potentially energized sources. Since LBNL personnel had previously de-energized the hazardous energy (the electrical box) and applied the first lock, the electrician was not exposed to hazardous electrical energy.

11.4 Apparent Cause Analysis Report

Apparent Cause Analysis for the
{Name of Incident/Finding Title}
{Date of the Incident/Finding}

Report Prepared By:

Team Member and Division	Date
Team Member and Division	Date
Team Member and Division	Date

11.4 Apparent Cause Analysis Report *(Continued)*

1. Issue/Event Summary *Document the issue in sufficient detail to understand the occurrence. This information may be taken from the Executive Summary of a Quad Chart, Assessment, ORPS or NTS Report.*	
2. Issue/Event Severity *(Institutional Issues Management Program, 10 CFR 851 Severity Level and/or ORPS Ratings)*	
3. Problem Statement *Develop a detailed but clear problem statement. This should also guide the scope of the Analysis.*	
4. Data Collection *To determine the facts of the incident/event, collect data via interviews, and review of documents and records.* *A 'Timeline of Events' can be developed to determine what other data needs to be collected and understand the sequence of the actions taken that lead to the incident/event. Start as early as possible. Capture event response as well. Data collection should identify "Who" did "What"?* *Who – who was involved?* *What – what happened? What should have happened?* *When – when did it happen?* *Where – where did it happen?* *How – how did it happen?*	
5. Other Key Facts *Any relevant information not captured in Section 4.*	

6. Sub-Issue # 1: *More likely than not, an issue/event arises from sub-issues/events. State the sub-issue/problem based on data and facts collected in Sections 4 & 5.*
7. **Apparent Cause(s):** *The apparent cause which is a mistake, failure, event or condition that led to an actual adverse condition or near-miss situation. Write a clear Apparent Cause statement based on the common themes from the WHYs.*
8. Contributing Cause *Events or conditions that contributed to an issue, but by itself would not have caused the occurrence.*

9. **Human and Organizational Performance Issues** *E.g., Error precursors.*

6. Sub-Issue # 2: *More likely than not, an issue/event arises from sub-issues/events. State the sub-issue/problem based on data and facts collected in Sections 4 & 5.*

7. **Apparent Cause(s):** *The apparent cause which is a mistake, failure, event or condition that led to an actual adverse condition or near-miss situation. Write a clear Apparent Cause statement based on the common themes from the WHYs.*

8. Contributing Cause
Events or conditions that contributed to an issue, but by itself would not have caused the occurrence.

9. **Human and Organizational Performance Issues** *E.g., Error precursors.*

10. Compensatory Measures/Actions
Compensatory measures which have been, or are planned to be taken, until Corrective Actions to address the Apparent Causes are implemented.

Compensatory measure # 1:
Owner:
Due date:

11. Planned Corrective Actions and Due Dates
All corrective actions must be SMART: Specific, Measurable, Accountable, Reasonable, and Timely. You may use the SMART analysis worksheet.

SMART Corrective Action # 1:
Owner:
Due date:

SMART Corrective Action # 2:
Owner:
Due date:

SMART Corrective Action # 3:
Owner:
Due date:

12. Extent of Condition
Identify the extent and impact of the condition/cause, such as the existence of other issues, activities, processes, or program failures that are similar to this incident, or the potential for the condition/cause to exist elsewhere in the Area, Division, or Laboratory.

13. Management Concerns *Any issue(s) uncovered during the investigation and causal analysis that is not an apparent cause but has the potential to result in an adverse condition if not addressed.*
14. Lessons Learned *Plan to disseminate and communicate Lessons Learned. It can be local (within the area where the incident happened), Division-wide, Lab-wide, or DOE complex-wide.*
15. Assurance Plan *Assurance validation of effectiveness involves using one or more of the following methods: Formal Assessment, Effectiveness Review, or Division metrics/performance measures. Which method will be used for the Assurance of Corrective Actions for the prevention of recurrence?*

APPENDIX A: PICTURES

Event Pictures, Location on LBNL site as applicable

APPENDIX B: PERSONNEL INTERVIEWED

Interviewee's Name, Position Title, Division Name

[Repeat for each interviewee]

APPENDIX C: DOCUMENTS REVIEWED

Document title, document date (as applicable)

[Repeat for each document]

11.5 Root Cause Analysis Report

Note: Causal Analysis worksheet(s) should not be attached to the Final RCA Report, but should be made available for review upon request by the responsible Division Management.

Root Cause Analysis Report for the XYZ Issue on [date]

Prepared By:

Team Member #1, Division Name, Team Lead	*(signature)*	*(date)*
Team Member #2, Division Name, Lead Causal Analyst	*(signature)*	*(date)*
Team Member #3, Division Name	*(signature)*	*(date)*
Team Member #4, Division Name	*(signature)*	*(date)*

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11.5 Root Cause Analysis Report *(Continued)*

EXECUTIVE SUMMARY
[Recommended wording: This report documents the Team's investigation and root cause analysis of the XYZ issue and includes corrective actions for management to implement that address the causes of the issue, and prevent or minimize recurrence of similar issues.]

Overview of the Issue
[Document the issue in sufficient detail to understand the occurrence. This information may be taken from the Executive Summary of the Assessment, ORPS or PAAA NTS Report (as appropriate).]

Root Causes of the Issue
[Recommended wording: The Team completed the investigation and root cause analysis in a manner that is consistent with the LBNL Issues Management Program Manual LBNL/PUB-5519. The Team used three different root cause methodologies to determine the root causes of the issue, which include XYZ. As a result of the analyses, the Team identified the following causal factor(s), root cause(s) and corresponding corrective action(s) to prevent recurrence:]

- Causal Factor #1:
- Root Cause #1: ***[Document the root cause statement/ description]***

  Key Facts
  [Provide a high level overview to support the root cause statement – detail follows in Conclusion section]
- Corrective Action #1

[Recommended wording: The Team also identified the following contributing causes (if applicable):]
- Contributing Cause #1

[Recommended wording: As a proactive measure, the following corrective action will minimize the possibility of the contributing cause leading to further issues:]
- Corrective Action CC #1

INVESTIGATION BACKGROUND
[Recommended wording: The purpose of this investigation and root cause analysis was to review and analyze the circumstances surrounding the XYZ issue that occurred on XX-XX-XXXX. The Team conducted this investigation and analysis by taking the following actions:
- *Gathering relevant facts through interviews, document reviews, and a walk-through of the location where the incident took place. Parties interviewed are listed in Appendix A. The documents reviewed are listed in Appendix B.*
- *Completing a [**identify the root cause analysis methodologies, for example, Barrier Analysis, TapRoot® analysis**] to analyze the facts, and identify the causal factors and root causes of this issue. Refer to the Conclusion section for more information on the analytical methods.*
- *Developing corrective actions to address the causes of the issue and prevent recurrence.*

ISSUE / INCIDENT FACTS
[Should be the validated narrative used for the Factual Accuracy Review]

11.5 Root Cause Analysis Report *(Continued)*

ANALYTICAL METHODS
[Recommended wording: The Team used three different root cause methodologies [Barrier Analysis, Change Analysis, and TapRooT®] to determine the root causes of the recurring issue. Each of these methodologies and the results are discussed below.]

Note: a description of each methodology is in 10.6 Causal Analysis Methodologies in the Standard section of this manual.

CONCLUSIONS
[Recommended wording: Based on interviews with XYZ Division personnel and a review of pertinent documents (refer to Appendix A & B), the Team identified the following causal factors, root and contributing causes of the issue and the corresponding corrective actions to address the causes and prevent recurrence.]

ROOT CAUSES

Causal Factor #1: ***[Document the causal factor statement/description]***

Root Cause #1: [Document the root cause statement/ description]

Key Facts
[Include the key facts related to the root causes that allowed those events to occur, such as physical hazards, and controls and management systems failures.]

Compensatory Actions
[Identify any immediate actions that were taken to mitigate the situation/circumstances.]

Corrective Actions
[Document the corrective action(s) to address the cause and prevent recurrence. Corrective actions should adhere to the SMART criteria]

*****[Repeat for each causal factor and root cause as necessary]****

CONTRIBUTING CAUSES

Contributing Cause #1: [Document the contributing cause statement /description]

Key Facts
[Include the key facts related to the contributing cause.]

Corrective Action CC #1 (optional)
[Recommended wording: As proactive measures, the Team recommends the following corrective actions to minimize the possibility of the contributing cause leading to further issues:]

EXTENT OF CONDITION REVIEW

[Identify the extent and impact of the condition/cause, such as the existence of other issues, activities, processes or program failures that are similar to this incident, or the potential for the condition/cause to exist elsewhere in the Laboratory.] Refer to 10.7 Extent of Condition/Cause Review in the Standards section of this manual for additional guidance. Note: Depending on the issue and analysis, the Extent of Condition/Cause Review could be placed at the end of the Conclusion section (similar to this example), before the Conclusion Section or at the end of each root cause.

APPENDIX A: PERSONNEL INTERVIEWED

Interviewee's Name, Position Title, Division Name
[Repeat for each interviewee]

APPENDIX B: DOCUMENTS REVIEWED

Document title, document date (as applicable)
[Repeat for each document]

11.6 Extent of Condition/Cause Review Report

This EOC Review Report template may be used when the EOC Review is completed separate from the root cause analysis and is not included in the RCA Report.

Extent of Condition Report
For the XYZ Issue
on [date]

Prepared By:

Team Member Name and Division _____
(signature) *(date)*

Team Member Name and Division _____
(signature) *(date)*

Team Member Name and Division _____
(signature) *(date)*

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I. REPORT SUMMARY

*The Lawrence Berkeley National Laboratory (LBNL) **[name of chartering official]** chartered a team (the Team) to perform an extent of condition/cause review of the **[name of issue and date of occurrence].** This report documents the Team's conclusions and recommended corrective actions.*

OVERVIEW OF THE EXTENT OF CONDITION REVIEW
The purpose of the Extent of Condition/Cause (EOC) Review is to determine the potential for similar conditions and causes identified in this issue/incident to occur (or to have occurred) elsewhere in the Laboratory, such as other activities, processes, programs or organizations. This analysis may heighten the severity of the issue through the identification of deeper-level causes and additional issues that warrant management's attention.

The scope of this EOC Review included a review of **[*describe the scope in terms of similar equipment used elsewhere in the Laboratory, similar issues that have occurred elsewhere in the Laboratory, similar work processes/activities that have been performed elsewhere, etc.*]**

EOC REVIEW METHODOLGY
The Team performed the EOC Review following the requirements of LBNL PUB-5519, Issues Management Program Manual. Specifically, The Team **[*describe the process, such as gathered addition facts through interviews with LBNL line management, program managers and subject matters experts, interviews with general contractors and subcontractors working on the XYZ project, reviewed several documents and records, etc.]***

SUMMARY OF CONCLUSIONS
The results of the review and recommended corrective actions are summarized below. A detailed discussion of each condition is in the Detail Report of the Conditions section of this report.

EOC #1: [*Name of the Condition*]

[*Summarize the extent and impact of the condition, such as other issues, activities, processes or program failures that are similar to this issue and the conclusion of the potential for the condition to exist elsewhere in the Laboratory.*]

[*Repeat for each condition as noted in the Detail Report of the Conditions*]*

RECOMMENDED CORRECTIVE ACTIONS
The Team identified several recommended corrective actions for management's evaluation to address the pervasiveness of causes, programmatic and systemic issues.

[Document the corrective action(s) to address the cause and prevent recurrence as documented in the Detail Report of the Conditions]

II. DETAIL REPORT OF THE CONDITIONS

EOC #1: [*Name of the Condition*])

Description of the Condition
(What is the condition, why is it important & how important is it?)

Discussion
(What facts were uncovered in the EOC Review that indicate whether the condition is widespread and how widespread?)

Recommended Corrective Action(s)
(What corrective action(s) is required to prevent the issue from recurring? Corrective Actions should adhere to the SMART criteria)

*****[*Repeat for each condition as necessary*]******

III. APPENDIX A: PERSONNEL INTERVIEWED

- Interviewee's Name, Position Title, Division Name
  [Repeat for each interviewee]

IV. APPENDIX B: DOCUMENTS REVIEWED

- Document title, document date (as applicable)
  [Repeat for each document]

11.7 SMART Analysis Worksheet

For more information, refer to PUB 5519 Issues Management Program Manual and BLI2010: Corrective Action Development Training

CAUSE/ISSUE	SPECIFIC	MEASURABLE	ACCOUNTABLE	REASONABLE	TIMELY
Document the cause or issue.	***Describe how the corrective action addresses the root or apparent cause and prevent recurrence.***	***The corrective action must be actionable and completion of the corrective action(s) must address the cause(s), be verifiable through objective evidence and demonstrate endurance.***	***Responsibility for implementing the action must be assigned to someone who has the authority, accountability and resources to complete the action.***	***Corrective action must be feasible (a cost effective control measure.) and not introduce negative, unintended consequences.***	***Corrective action should be implemented in a realistic timeframe to prevent recurrence. Mini-steps should be included, with completion dates, as appropriate.***
Document the cause/issue as stated in the Causal Analysis, Extent of Condition Review or Assessment Report.	What is the corrective action? How does the corrective action eliminate or mitigate the cause/issue and prevent recurrence? Consider hierarchy of controls • Remove/Reduce the hazard/risk • Apply/Improve Engineering controls (automation, eliminate/ minimize human interaction & knowledge based decision) • Apply/Improve barriers or safeguards (barricades, PPE, spatial, QA, signage) • Implement redundant controls (defense in depth) • Improve performance o Human and machine/ equipment interface o Administrative controls: policies, procedures, processes, o Human factors: worker selection, training, coaching/developing, supervision, etc. Consider risk mitigation: Eliminate, Transfer, Mitigate or Accept	What are the deliverables (measurable outputs) of the corrective action? What are the success measures (expected outcomes) that demonstrate the corrective action addresses the cause, prevents recurrence, and is sustainable?	Who is accountable and responsible for effective implementation and ongoing oversight of corrective action? Accountable (the one who has final authority and accountability for the corrective action): Responsible (the one who completes the corrective action): Who should be consulted and informed of the corrective action? Consulted (individuals who are consulted and provide support before and during implementation of the corrective action): Informed (individuals who are informed before, during and after the corrective action is implemented): What resources are needed to implement the corrective action?	Roles, responsibilities, accountability and authority (R2A2s) are in place. Deliverables and success measures are realistic and achievable, and address the cause(s) of the issue. Resources are secured. The cost to implement the corrective action does not outweigh the benefits of mitigation (cost prohibitive, administratively burdensome, or leads to degradation in other areas).	What are the high-level milestones to implement the corrective action? What is a realistic time-line to complete the corrective action? Are interim compensatory actions needed?

11.8 Corrective Action Plan

Corrective Action Plan
For the XYZ Issue/Incident
on [Date]

Prepared By:

Team Member Name and Division

Team Member Name and Division	*(signature)*	*(date)*
Team Member Name and Division	*(signature)*	*(date)*
Team Member Name and Division	*(signature)*	*(date)*
	(signature)	*(date)*

Approved By:

Responsible Laboratory or Division Director		
	(signature)	*(date)*

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I. INTRODUCTION

The purpose of this Corrective Action Plan (CAP) is to address the root (and contributing causes, if applicable) of the XYZ issue that occurred [date]. This CAP identifies corrective actions that are intended to:

a) address the causes of the issue
b) prevent recurrence of similar issues
c) demonstrate endurance and sustainability
d) not introduce negative unintended consequences
e) improve performance

Overview of the Issue
Insert Issue/Incident Summary from the RCA Report

II. ROOT CAUSE CORRECTIVE ACTIONS

Below are the corrective actions that are necessary to address the root causes of the issue and prevent or significantly minimize the potential of a recurring issue. These corrective actions will be entered into the Laboratory Corrective Action Tracking System (CATS) Database and be tracked through resolution, which includes a validation of corrective action effectiveness.

Causal Factor #1*: *Insert from the RCA Report

Root Cause #1: ***Insert from the RCA Report***

Key Facts: ***Insert from the RCA Report***

Corrective Actions:

CA 1.1: ***Insert corrective actions statement as documented in the SMART Analysis Worksheet***

Accountable Person: ***name of person as documented in the "Accountable" column in the SMART Analysis Worksheet***

Responsible Person: ***name of person as documented in the "Accountable" column in the SMART Analysis Worksheet***

Initiation Date: xx-xx-xxxx

Completion Date: xx-xx-xxxx

Work Breakdown Structure:
Milestone Tasks:
Insert tasks as documented in the "Timely" column in the SMART Analysis Worksheet
Deliverables to Close Corrective Action(s):
Insert deliverables as documented in the "Measurable" column in the SMART Analysis Worksheet
Success Measures / Expected Outcome:
Insert measures/expected outcomes as documented in the "Measurable" column in the SMART Analysis Worksheet

*****[Repeat for each corrective action as necessary]****

III. LESSONS LEARNED CORRECTIVE ACTION

As part of the ISM Core Function 5, Feedback and Improvement, and the Laboratory's goals of continuous improvement, a lessons learned will be created to share learning experiences from this issue/incident. The lessons learned will be shared within the Laboratory community via the Laboratory's Lessons Learned and Best Practices Database and within the DOE complex via the DOE Lessons Learned Database, as applicable.

CA #: Develop and disseminate a Lessons Learned Communication, as prescribed in the LBNL PUB 5519, Issues Management Program Manual.

Accountable Person: name of person
Responsible Person: name of person
Initiation Date: xx-xx-xxxx
Completion Date: xx-xx-xxxx

IV. CONTRIBUTING CAUSE CORRECTIVE ACTIONS

As a proactive measure, the following corrective actions are necessary to minimize the possibility of the contributing cause recurring and aiding in further issues.

Contributing Cause #1: ***Insert from the RCA Report***

Key Facts: ***Insert from the RCA Report***

Corrective Actions:

CA 1.1: ***Insert corrective actions statement as documented in the SMART Analysis Worksheet***

Accountable Person: ***name of person as documented in the "Accountable" column in the SMART Analysis Worksheet***

Responsible Person: ***name of person as documented in the "Accountable" column in the SMART Analysis Worksheet***

Initiation Date: xx-xx-xxxx

Completion Date: xx-xx-xxxx

Work Breakdown Structure:
Milestone Tasks:
Insert tasks as documented in the "Timely" column in the SMART Analysis Worksheet
Deliverables to Close Corrective Action(s):
Insert deliverables as documented in the "Measurable" column in the SMART Analysis Worksheet
Success Measures / Expected Outcome:
Insert measures/expected outcomes as documented in the "Measurable" column in the SMART Analysis Worksheet

*****[Repeat for each contributing cause corrective action as necessary]****

V. CORRECTIVE ACTION IMPLEMENTATION RESOURCES

Summarize the information documented in the "Accountable" sections in the SMART Analysis Worksheet from "What resources are needed to implement the corrective action".

VI. CORRECTIVE ACTION PLAN MANAGEMENT AND OVERSIGHT

Insert the name of individual(s)/division/group/program manager, who will provide management and oversight of this CAP implementation and sustainability, which includes a validation of corrective action effectiveness. *Management and oversight includes accountability and responsibility for review and approval of corrective action implementation activities, such as:*
a) monitoring progress;
b) communicating, reviewing and approving baseline changes to corrective action scope, resources and timeline;
c) reviewing objective evidence and closure of individual corrective actions; and
d) reporting on project milestones and deliverables to pertinent stakeholders, as warranted.

VII. VALIDATION OF CORRECTIVE ACTION EFFECTIVENESS

The evaluation of this CAP corrective actions' effectiveness will be performed using one or more of the validation of effectiveness methodologies described in the Issues Management Program Manual. ***[Insert name of the individual], with assistance from the Laboratory's Issues Management Program Manager, will determine the appropriate validation methodology (or methodologies) to use based on the causal factors, causes and corrective actions described in this CAP. This validation also will assess the achievement of the CAP success measures, as they relate to the overall sustainability of the corrective actions.***

Effectiveness Review 1.1: *Perform an Effectiveness Review of the implemented CAP corrective actions, as prescribed in LBNL/PUB 5519, Issues Management Program Manual.*

Accountable Person: name of person
Responsible Person: name of person
Initiation Date: xx-xx-xxxx
Completion Date: xx-xx-xxxx

11.9 Effectiveness Review Charter

To Team Members (list them)

From: COO, Deputy COO, Division Director or Department Head Name

Date: [Enter applicable date]

Subject: Charter for the Effectiveness Review of the XYZ Incident / (or Assessment) Corrective Actions

I am charging you to review and evaluate the effectiveness of the corrective actions that were implemented in response to the [XYZ incident] /or [XYZ Assessment] that occurred on [enter applicable date.]

[Team Member Name] will serve as the Team Lead, and your effectiveness review will follow the requirements of the LBNL Issues Management Program Manual, LBNL/PUB-5519. You will determine if the corrective actions properly addressed the root causes of the event, have prevented similar incidents, and demonstrate sustainability.

Once the team has completed its review, the results and any recommended corrective actions should be documented in a formal report, and discussed with appropriate line management for factual accuracy and the Laboratory's Issues Management Program Manager (or designee) for quality assurance. Following the reviews, the report should be submitted to me no later than [enter applicable date.].

Thank you for your participation in this important activity.

Cc: **[List appropriate names as follows]**
Appropriate Laboratory Management, as necessary
Appropriate Responsible Division Personnel
Impacted Division Management, as necessary
Team Member's Respective Management
Issues Management Program Manager
BSO Representative

11.10 Effectiveness Review Methodology (Lines of Inquiry)

Effectiveness Review Methodology – *(Insert Effectiveness Review Name)*

Root Cause: **Corrective Action number and statement:**	
METHODOLOGY	**EVALUATION**
DOCUMENT REVIEW	
Name of Document #1	
List the questions regarding this document	Document answers/observations/assessment/key points
Name of Document #2	
List the questions regarding this document	Document answers/observations/assessment/key points
Name of Document #3	
List the questions regarding this document	Document answers/observations/assessment/key points
OBSERVATION OF WORK	
Name and description of Work Process	Document observations/assessment/key points
PERSONNEL INTERVIEWS	
Name of Interviewee #1	
List the questions for this interviewee	Document answers/observations/assessment/key points
Name of Interviewee #2	
List the questions for this interviewee	Document answers/observations/assessment/key points
Name of Interviewee #3	
List the questions for this interviewee	Document answers/observations/assessment/key points
Name of Interviewee #4	
List the questions for this interviewee	Document answers/observations/assessment/key points

11.11 Effectiveness Review Analysis

Effectiveness Review Analysis – *(Insert Effectiveness Review Name)*

Root Cause: **Corrective Action number and statement:**							
CORRECTIVE ACTION EFFECTIVENESS							
CRITERIA		**YES**		**PARTIALLY**		**NO**	**JUSTIFICATION**
1. Has the corrective action been implemented as intended? a) Does the corrective action resolve the root cause?							Considerations: – Eliminates or mitigates the cause of the issue – Objective evidence demonstrates that the corrective action was completed, implemented and addresses the root cause
2. Does the corrective action prevent recurrence of similar issues?							Considerations: Procedures, polices, standards, etc. are documented and applied Applicable staff are aware and understand requirements Performance successfully demonstrates implementation
3. Does the corrective action demonstrate endurance and sustainability?							Considerations: – Ongoing training/guidance – Performance monitored (ongoing assessments, walkarounds, inspections, metrics – Management and staff accountability and enforcement demonstrated
4. Overall, has the implemented corrective action improved performance and not introduced adverse consequences?							Considerations: No degradation of services or performance No adverse outcomes in process or another process or system Fully compliant No repeat issues/incidents – Efficiency / productivity gains

Rating Definitions:

- **Effective *(Yes)***—Corrective actions are implemented as intended, have addressed the causes of the issue/finding, will prevent recurrence of the issue/finding and demonstrates sustainability. No new corrective actions are recommended.
- **Partially Effective *(Partially)*** —Corrective actions are implemented as intended, and have partially addressed the causes of the issue/finding, but do not prevent recurrence or demonstrate sustainability. Revised or new corrective actions are recommended to enhance the effectiveness of the correction action.
- **Ineffective *(No)***—Corrective actions were not implemented as intended, do not address the causes of the issue/finding, do not effectively prevent recurrence of the issue/finding, and do not demonstrate sustainability. New corrective actions are recommended to achieve effective resolution.

11.12 Effectiveness Review Report

Effectiveness Review Report for the
XYZ Issue
Corrective Actions

Report Prepared By:

Team Member Name and Division		
Team Member Name and Division	*(signature)*	*(date)*
Team Member Name and Division	*(signature)*	*(date)*
Team Member Name and Division	*(signature)*	*(date)*
	(signature)	*(date)*

Effectiveness Review Report for the
XYZ Issue
Corrective Actions

Description of Issue:
Insert Issue/Incident Summary from the RCA Report or CAP

Effectiveness Review Conclusion:
This ER was scoped and performed using a methodology that involved ***(describe the methodology).***

Overall, performance has improved (or has not improved) in a number of ways, such as (provide specific, credible and factually accurate examples). The conclusions of effectiveness for the specific corrective actions are summarized below.

Corrective Action number and description:	**Effectiveness Rating**:
Justification: *Guidance: State how the corrective action addresses the root cause(s), prevents recurrence and demonstrates endurance.* *Discuss, as appropriate, what is working well; what is working but needs improvement, and what is not working and the adverse impact to safety, operations, mission and/or strategic/business objectives.*	

Recommended Corrective Actions:
The following recommended corrective actions are to address the partially effective (or ineffective corrective actions) as discussed above.

Summary of Effectiveness for Corrective Actions

CA #	CA Description	**Inherent Risk** High (red) Medium (yellow) Low (green)	**CA Effectiveness** Effective Partially Effective Not Effective	**Assurance Effectiveness** Effective Partially Effective Not Effective	**Residual Risk** High (red) Medium (yellow) Low (green)	**Recommended Actions** None Needed Supplemental CA Needed Rely on Assurance System Accept Residual Risk

- High Risk: high likelihood to occur, near miss or has occurred and results in significant loss, damage and/or significantly impacts achievement of mission/business objectives. Requires immediate attention from Senior Laboratory management and follows a more formal, rigorous issues management process.
- Medium Risk: would occur at some point in time, near miss or has occurred and results in substantial loss, damage and/or impacts achievement of mission/business objectives. Requires prompt attention from Division management and follows a graded issues management process.
- Low Risk: is not likely to occur, near miss or has occurred and results in nominal loss, damage and/or nominally impacts achievement of mission/business objectives. Requires some attention from Line-management and follows a Division-driven issues management process.

Rating Definitions:

- **Effective *(Yes)***—Corrective actions are implemented as intended, have addressed the causes of the issue/finding, will prevent recurrence of the issue/finding and demonstrates sustainability. No new corrective actions are recommended.
- **Partially Effective *(Partially)*** —Corrective actions are implemented as intended, and have partially addressed the causes of the issue/finding, but do not prevent recurrence or demonstrate sustainability. Revised or new corrective actions are recommended to enhance the effectiveness of the correction action.
- **Ineffective *(No)***—Corrective actions were not implemented as intended, do not address the causes of the issue/finding, do not effectively prevent recurrence of the issue/finding, and do not demonstrate sustainability. New corrective actions are recommended to achieve effective resolution.

APPENDIX A – TREND CODES

TREND CODE		DESCRIPTION
A.	**Management System: Management actions or methods (directing, monitoring, assessing, enforcing accountability, and corrective action) are inadequate or non-existent; resource allocation is inadequate; and supervisory oversight and change management practices are less than adequate (LTA).**	
A.1	Organizational Standards, Policies or Administrative Controls (SPAC) NI/LTA	The organizational system/structure/culture failed to establish SPAC that can be implemented, followed and do not hinder performance. SPAC are missing or systemically not used throughout the organization.
A.2	Job performance standards LTA	The knowledge and skills required to perform the task or job were not identified or defined. Lack of defined standards for a specific job function resulted in ineffective performance.
A.3	Supervisory Levels NI/LTA	Insufficient supervisory resources to provide necessary supervision; supervision resource was less than that required by task analysis, considering the balance of procedures, supervision and training.
A.4	Supervisory Oversight LTA	The administrative load on immediate supervisor adversely affected his/her ability to supervise ongoing activities; too many administrative duties assigned to immediate supervisor.
A.5	Worker Selection is LTA	Staff or team selection was incorrect, inadequate or not qualified to perform the work/task. Insufficient number of trained or experienced workers assigned to task. The overall number of personnel assigned matched the planned man-hour allotment, but the organization methods failed to identify personnel with adequate experience or training to perform the work.
A.6	Accountability/Responsibility of Personnel NI	Accountability/responsibility of personnel was not well defined or personnel were not held accountable. Responsibility for work or process elements (procedures, engineering, training, etc.) or accountability for failures of work or process elements was not placed with individuals.
A.7	Corrective Action LTA	Corrective action for previously identified problem or event was not adequate to prevent recurrence.
A.8	Corrective Action Not Implemented/Implemented timely	Corrective action to a known or a recurring issue was not performed at or within the proper time; the response was untimely.
A.9	Corrective Action Not Used	Management failed to take meaningful corrective action to address events.

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TREND CODE		DESCRIPTION
A.10	Needed resource changes not approved / funded	Corrective actions for existing deficiencies were not approved or funded.
A.11	Change Management NI/LTA	Risks/consequences associated with change were not adequately reviewed/assessed to determine the adverse impact or increased risk prior to implementing the change; Changes to processes were not communicated to affected personnel effectively.
A.12	Procurement Control LTA	Inadequate control of changes to procurement specifications or purchase orders; A fabricated item failed to meet requirements, an incorrect item was received, or product acceptance requirements failed to match design requirements or were otherwise unacceptable.
A.13	Vendor support of change NI/LTA	Management failed to adequately assess the ability of vendors to supply products or services in support of changing expectations for a particular objective.
B.	**Policy /Procedure/Instruction: Institutional policies, procedures and work instruction to communicate standardized work practices, processes and rules to minimize errors/risks and establish management's expectations for how work is performed.**	
B.1	Policies/Procedures/Instructions Enforcement LTA	Personnel exhibit a lack of understanding or acceptance of policies/procedures/instructions and/or expectations; or policy/procedures/instructions/ expectations are not established or not enforced.
B.2	Policies/Procedures/Instructions Not Used	Policy, procedure or other written instruction exists, but was not used, not followed or intentionally followed incorrectly.
B.3	Policies/Procedures/Instructions Used Incorrectly	Policy, procedure or other written instruction was used, but was mistakenly followed or used for an incorrect activity.
B.4	Policies/Procedures/Instructions Needs Improvement (NI)	Policy, procedure or other written instruction was incorrect, lacked adequate information, was not strict enough to prevent errors, contained confusing or conflicting information, was difficult to follow due to formatting; or no policy, procedure or other written instruction exist.
B.5	Checklist LTA	The checklist was confusing, inconsistent or conflicting; steps did not clearly indicate what was required or were missing; or checklist impossible to follow as written.
C.	**Training: An event or condition can be traced to a lack of training or insufficient training to enable a person to perform a desired activity/process or task adequately.**	
C.1	Training Program non-	Organizational training program is not offered or is

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TREND CODE		DESCRIPTION
	existent/NI/LTA	inadequate in providing the necessary knowledge and skills development for staff to successfully complete a task/perform work.
C.2	Training objectives LTA	Training objectives were incomplete or insufficient in covering all of the requirements necessary to successfully complete the task; the objectives were not written to accurately represent the task analysis; job/task analyses were inadequate or incorrectly identified the knowledge and skills necessary to complete the task.
C.3	Training Content NI/LTA	The training content was inadequate; training materials did not adequately address new work methods; the lesson content did not address all the training objectives or contain all the information necessary to perform the task.
C.4	Training Methods LTA	The correct training setting was not used and/or had inadequate instructors and facilities; the proper setting in which to train the operator was not identified or training updates were not performed.
C.5	Training requirements not identified	The training requirements had not been identified for a task, considered part of the employee's proficiency requirements or defined for the job description, or had not adequately addressed performance standards for the job/task.
C.6	Decision not to train	The decision was made not to provide specific training on a task. Employees were not required to receive training. Work experience was considered a substitute for training.
C.7	Work incorrectly considered "skill-of-the-craft"	The work was not a "skill" that could be developed through job experience; the worker did not have the appropriate skill level to perform the task and no assurance was in place to validate that the worker had proper training prior to task assignment.
C.8	Practice or "hands-on" experience LTA	There was not enough practice (or hands-on) time allotted during training to demonstrate proficiency; the on-the-job training (OJT) did not provide opportunities to learn skills necessary to perform the job or the employee had not previously performed the task under direct supervision before performing the activity independently.
C.9	Testing LTA	Testing did not adequately measure/reflect the employee's ability to perform the task/job or did not cover all the knowledge and skills necessary to do the job..

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TREND CODE		DESCRIPTION
C.10	Refresher training LTA	The task was not identified for refresher training or continual training was not performed to keep employees equipped to perform tasks/job. The frequency of continuing training was insufficient to maintain employee proficiency.
C.11	Change-related training / retraining not performed or not adequate	New or revised training was not performed or was not adequate to meet the needs of the new process or changes to an existing process.
D.	**Communication: Inadequate presentation or exchange of information occurred between people performing the work; lack of communication or communication was misunderstood or misinterpreted.**	
D.1	Ambiguous instructions / requirements	The instructions in the written communication were unclear, uncertain, or interpretable in more than one way.
D.2	Facts wrong / requirements not correct	Specific information in the written communication was incorrect; written communication contained outdated requirements or did not reflect the current status of operations or the environment.
D.3	Information not accessible/available	The information was not readily available; copy of the written communication was not in a designated file or rack. A "master copy" of the written communication was not available for reproduction.
D.4	Verification / repeat back not used	A communication error was caused by failure to repeat back a message to the sender for the purpose of verifying that the message was heard and understood correctly.
D.5	Communication between work groups LTA	Lack of communication between work groups (production, technical, or support) led to an adverse condition.
D.6	Shift communications LTA	Incorrect, incomplete or otherwise inadequate communication between workers during a shift or a shift change; detailed instructions and other important status information was not exchanged during turnover of responsibility.
D.7	Data/Information NI/LTA	Data or information used to perform work or make decisions was inaccurate, not available within a timely manner, or non-existent.
E.	**Equipment/Software Design NI/LTA: Equipment and/or software code design caused the equipment or software to fail.**	
E.1	Incorrect or inconsistent design output	The drawings and other specifications were incorrect; drawings and other design documents did not agree;

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TREND CODE		DESCRIPTION
		or the final design output did not include all changes. Software/code was defective or inappropriate for the system.
E.2	Design / documentation not complete	The designs and other documentation for equipment were incomplete; Items were missing from the documentation; A complete baseline did not exist.
E.3	Design / documentation not up-to-date	Drawings and documents were not updated when changes were made; Documents/drawings did not reflect the current status.
E.4	Independent review of design / documentation non-existent or LTA	A required review was not performed on the design or was not performed by an independent reviewer; the review was inadequate in detecting issues/errors.
E.5	Testing of design / installation LTA	Testing was not included as part of the design acceptance process. The testing did not verify the operability of the design. Design parameters did not successfully pass all testing criteria.
E.6	Independent inspection of design / installation LTA	Independent Inspection attributes were not included in the design installation. Required Hold/Witness points were not verified by Quality Assurance (QA). Hold / witness points did not pass the acceptance criteria. Commercial Grade Material was not adequately dedicated and documented.
E.7	Acceptance of design / installation LTA	The customer had problems with acceptance of the design, testing, and/or verification.
F.	**Equipment / Material Problem: Failure, malfunction, or deterioration of equipment, systems or parts, including instruments or material, resulted in an adverse event or condition.**	
F.1	Calibration for Instruments Less Than Adequate (LTA)	Calibrations did not include all the essential elements. Equipment as-found condition was less than adequate.
F.2	Material Control LTA	The problem was due to the inadequate handling, storage, packaging or shipping of materials or equipment. The shelf life for material was exceeded. Spare parts were inadequately stored. There was an error made in the labeling or marking.
F.3	Unauthorized Material Substitution	Incorrect materials or parts were substituted. Material or parts were substituted without authorization. The requirements specified no substitution.
F.4	Defective Or Failed Part	A part/instrument lacked an essential component necessary to perform its intended function; An item was not

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TREND CODE		DESCRIPTION
		fabricated according to the requirements/specifications; manufactured improperly; was not adequate for the application; or a part or component performance degradation contributed to the failure of the equipment or system.
G.	**Non-Fault Tolerance System: a system, process or procedure that is designed where errors are undetectable or unrecoverable.**	
G.1	Errors Not Detectable	The design prevented discovery of errors before an issue occurred; controls were ineffective in detecting a system failure due to error; or a serious error went unnoticed because there was no way to monitor system status.
G.2	Errors Not Recoverable	The system was designed such that personnel were unable to recover from error discovered before a failure occurred.
H.	**Human Performance LTA: An event or condition resulting from the failure, malfunction, or deterioration of the human performance associated with the process.**	
H.1	Step was omitted due to distraction	Attention was diverted to another issue during performance of the task and the individual committed an error in performance due to the distraction.
H.2	Incorrect performance due to mental lapse	The individual knew appropriate action(s) to take, but failed to initiate the correct action(s) based on inattention/over-attention.
H.3	Infrequently performed steps were performed incorrectly	The individual was not completely familiar with the tasks required based on not frequently performing the tasks and not operating at a fluency level.
H.4	Wrong action selected based on similarity with other actions	The individual selected a wrong action out of a series of actions that appeared to be the same, but are not.
H.5	Changes / Departure from Routine	The individual departed from a well-established routine, or unfamiliar or unforeseen task or job site conditions that potentially disturb an individual's understanding of a task or equipment status.
H.6	Complacency / Overconfidence	Self-satisfaction or overconfidence with a situation resulting in misjudging actual hazards or dangers; Underestimating the difficulty or complexity of a task based upon past experiences.
H.7	Inaccurate Risk Perception	Personal appraisal of hazards and uncertainty based on either incomplete information or assumptions; Degree of risk-taking behavior based on individual's perception of possibility of error and understanding of consequences.
H.8	Deliberate violation	The action on the part of the individual was a deliberate

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TREND CODE		DESCRIPTION
		action to commit human error. Caution: There is usually some form of personal gain associated with this action. Deliberate actions are cited in ~ < 5% of issues. If this trend code is identified in more than ~5% of the issues for a given facility, there most likely is some other underlying cause.
I.	**Work Planning: Preparation for work was deficient or did not take place prior to the start of work.**	
I.1	Work Preparation LTA	No work planning occurred for the task/job. Scheduling of the task did not adequately address the time frame required for workers to prepare the task; insufficient time allocated to adequately address known conditions or account for reasonable emergent issues; or the work package did not accurately reflect the work that was to be completed.
I.2	Work planning not coordinated with all departments involved in task	Interdepartmental communication pertaining to the task did not occur prior to initiating work, resulting in insufficient or non-existence teamwork and support of the work process.
J.	**Work Processes/Packages:** The work process and/or package was not developed or was deficient in successful completion of work; or did not accurately reflect the required work to be performed.	
J.1	Work Controls not implemented/NI/LTA	Job walkthrough, permit, pre-job briefing, tools, hazard assessment and/or other safety/administrative controls was/were non-existent or LTA.
J.2	Process/Task Design Deficiency	The process/task design, or a portion thereof, was deficient prior to being used.
J.3	Work Schedule NI/LTA	Errors occurred due to schedule conflicts, inadequate scheduling of work, and/or too much work scheduled for the allocated time or available staff.
J.4	Check of work was LTA	Quality check was not performed prior to proceeding to the next step in the process/procedure/job or completing work; Check of work did not catch/uncover errors/issues.
J.5	Ergonomics LTA	The worker was physically incapable of performing the required task, had difficulty reaching the equipment or assumed an awkward position to complete a task. Personnel mobility or vision was restricted or illumination levels were not sufficient for task performance.
K.	**Maintenance: Maintenance program, including inspection and testing, was developed but was not used or the maintenance was inadequate.**	

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TREND CODE		DESCRIPTION
K.1	Preventive Maintenance For Equipment LTA	An equipment malfunction was caused by a failure to carry out scheduled preventive maintenance. Preventive maintenance was not established for the equipment or component that failed. Preventive maintenance was scheduled too infrequently. The preventive maintenance was incomplete. Preventive maintenance was performed on some of the components but not on others.
K.2	Predictive Maintenance LTA	Predictive maintenance was not established for the equipment. The established frequency was inadequate to prevent or detect equipment degradation. The established method used to prevent or detect equipment degradation was inadequate.
K.3	Corrective Maintenance LTA	Corrective maintenance was performed but failed to correct the originating problem. The equipment or component was reassembled improperly during corrective maintenance. Other problems were noted during maintenance activities that were not corrected. The actual job of performing a maintenance activity was complete, but was not performed correctly.
K.4	Inspection / Testing LTA	Scheduled inspection/testing did not exist for the instrument or equipment; required testing / inspection was not established or performed for the equipment; the inspection/testing was inadequate or not performed as required; the inspection/testing did not include all the essential elements.
K.5	Start-Up Testing LTA	Functional testing did not exist for the equipment or system prior to placing them in service. Start-up testing was inadequate for the equipment or system being placed into service.
L.	**Vendor Deficiency: Vendor performance NI or is LTA; Vendor internal assessment methods for detecting and correcting discrepancies is LTA; Vendor inability to supply products or services for a particular activity as agreed upon in contract; Vendor program, inspection and testing activities, or oversight methodologies are LTA.**	
M.	**Other: Using appropriate causal analyses, no cause can be reasonably determined. Adverse condition is a natural phenomenon.**	