Lawrence Berkeley National Laboratory (LBNL) Institutional Assessment Process Description

Document Number 04.03.009.001, Rev. 2

Office of Institutional Assurance and Integrity

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REVISION HISTORY/ PERIODIC REVIEW TABLE

Revision Number	Revision/ Review Date	Description of Revision/ Review Comments
0	5/15/19	Initial Process Description
1	5/01/22	Minor updates to Attachment A: Definitions and addition of two assessment process templates (Attachment D and G)
2	04/01/24	Attachment of change request form template (Attachment I); Addition of the overdue extension process and template (Attachment J); Added references to new LLBP Process Manual and Recurring Assessments Tracker

1.0   INTRODUCTION

The Lawrence Berkeley National Laboratory (LBNL, Berkeley Lab) assessment process is an essential component in the Contractor Assurance System (CAS), Quality Management System (QMS) and Integrated Safety Management System (ISMS). This document describes the institution's assessment framework and provides guidance on how to plan, execute, and report results of assessments at Berkeley Lab.

The Institutional Assessment process is a key mechanism by which LBNL exercises its stewardship responsibilities by assuring that we have effective, efficient, and safe processes in place to support our scientific mission. This includes:
1. monitoring the performance and effectiveness of controls (i.e. administrative, engineering, etc.);
2. identifying Institutional risks and issues; and
3. sharing lessons learned and best practices that promote continuous improvement in programs, projects and work processes.

2.0   INSTITUTIONAL ASSESSMENT PROCESS OVERVIEW

The Institutional Assessment Process is performed using a risk-based approach and leverages efforts by the tri-parties (i.e. Department of Energy (DOE) Berkeley Site Office (BSO), University of California Office (UC), and LBNL) to minimize duplication and burden on the organizations who will be assessed, to the extent feasible. Every fiscal year, the Office of Institutional Assurance and Integrity (OIAI), in conjunction with BSO and UC, launches and oversees the Institutional Assessment Process. All LBNL Divisions, business areas, programs and/or projects are responsible for performing assessments of their operations to assure that they are designed, implemented, and performing as intended and to assure that identified risks and issues are addressed, and best practices are applied to promote continuous improvement. Correspondingly, senior managers, line managers, program or project managers, and staff are responsible for conducting assessments as determined by contract requirements and/or Institutional policy and performance needs. Assessment results (i.e. findings, issues, risks, observations, etc.) are analyzed by OIAI, and division and line management to identify adverse trends, risks, and issues.

There are many types of Assessment performed at the Laboratory. These assessments are either performed by the LBNL or by external parties, such as UC, DOE (e.g. Headquarter areas, BSO, Office of Inspector General, etc.), the City of Berkeley, the National Institute for Health (NIH), the Food and Drug Administration (FDA), etc. Below is a list of the common types of assessments that comprise our Institutional Assessment Framework *(this list is not all inclusive)*:

- Division Self-Assessments
- Audits
- Regulatory Inspections/Site Visits
- Management Reviews
- Directors Reviews
- Program Reviews
- Quality Assurance Reviews
- Peer Reviews
- Integrated Project Reviews
- Prime Contract Implementation Plan Validations
- Corrective Action Implementation Effectiveness Reviews
- Field Inspections/Walk-arounds

Annually, LBNL develops and maintains an Integrated Assessment Schedule (IAS) that captures all planned assessments of programs, processes, projects and other activities. The IAS is documented on a web-based platform and includes the types of assessments listed above. The IAS is LBNL's official assessments tracking tool, and it demonstrates to DOE, UC, and Laboratory management that the Laboratory and external entities perform rigorous, risk-based, credible assessments, and feedback and improvement activities to assure that LBNL has effective, efficient and safe processes to support our scientific mission. Additionally, the IAS demonstrates that procedures are followed to secure the Lab's assets, and identify and mitigate risks. Lastly, the IAS is a record of the following information for each assessment: the title of the assessment, description of the assessment, the primary driver of the assessment, the quarter the assessment is scheduled to be performed, the organization conducting the assessment, the organization being assessed, and assessment completion dates.

The Institutional Assessment Process is integrated with other Institutional assurance mechanisms, such as Requirements Management, Risk Management, Issues Management, Performance Monitoring and Analysis, and Lessons Learned and Best Practices. Collectively, they represent a comprehensive risk- based approach to monitor performance and Institutional controls, identify and mitigate risks, identify and resolve issues, and enable continuous improvement and learning.

3.0   INSTITUTIONAL ASSESSMENT PROCESS IMPLEMENTATION

This section describes the process for assessment planning, preparation, completion, close out and ongoing performance monitoring and measurement. Detailed guidance and other resources on how to perform these process elements are located in Attachments B through J in this document.

3.1   Integrated Assessment Planning (IAP)

During the 4th quarter of each fiscal year, OIAI initiates the IAP process. OIAI provides an overview of the process and the current FY Integrated Assessment Schedule to Division Directors, Deputy Division Directors of Operation, and Division Assurance Points of Contacts (POCs).

Division management uses a risk-based approach, in addition to routine/annual compliance and performance-driven requirements, to identify, plan and conduct the assessments during the current fiscal year. Important resources of input to the IAP process include the:

- DOE headquarters and BSO Reviews results,
- UC Reviews results,
- Scheduled external reviews,
- LBNL Annual Audit Plan,
- Institutional Risk Registry,
- Annual Assurance Letter identified risks,
- PEMP feedback provided by DOE,
- IAP Recurring Assessments Tracker, and
- Prior year's IAS, specifically carryover and postponed assessments.

Once division management has identified potential areas to assess, they are compared against focus areas identified by other parties (such as BSO, UC/UCNL, other LBNL divisions, regulatory agencies, etc.) to minimize duplication of effort and burden on the organizations who will be assessed, to the

extent feasible. During the mid-year and fiscal year-end PEMP performance review process, division management should discuss with their BSO, UC/UCNL and OIAI counterparts the status of their respective assessments identified on the IAS, outstanding and reprioritized assessments, and new risks that require an assessment to be performed. In some instances, as part of the year-end PEMP performance reporting meetings, Division management also discusses planned assessments for the upcoming fiscal year with their BSO, UC/UCNL and OIAI counterparts.

Once the annual planned assessments for a given division are determined, respective management or their Assurance POCs populate the IAS. Additionally, division management and the Assurance POCs ensure that the IAS for their respective areas is updated as assessments are completed and as ongoing assessment needs are identified or reprioritized, but at a minimum during the mid-year and year-end PEMP performance review process. Completed and signed assessment reports are uploaded to the IAS to leverage the assessment data to reduce duplication of effort, improve efficiencies, and identify high-level institutional trends.

3.2 Change Control

The Division may request a change to the IAS at any point during the year using the formal change control process, which is coordinated by the Office of Assurance & Integrity (OIAI). Division management or the Division Assurance Point of Contact (POC) can request a change by initiating a new the Change Request Form (Attachment I) and completing the change control process. Changes to the IAS may be administrative or substantive. Administrative changes include postponements within the same fiscal year, modifications to assessment area scope, and minor changes to locked IAS columns. Administrative changes only require signed approval from OIAI management. Substantive changes are considered major changes and include requests such as adding a new assessment, deleting an existing assessment, or deferring an existing assessment from the current fiscal year to the next fiscal year. Signed approval by the owning division management and OIAI management are required for substantive change requests. Regardless of change request type, the Division obtains BSO and UCNL concurrence of the change prior to submitting a change request form. Once the change request form has been signed by all required parties, the IAS owner incorporates approved changes into the IAS. The final signed change request form is uploaded as an attachment to the respective line entry in the IAS for recordkeeping and changes are recorded in the annual Change Control Log. BSO may be notified of all changes, regardless of whether they are administrative or substantive.

Change requests to postpone an assessment should be submitted no later than **one week** prior to the quarter due date to allow time for review and edits. Following quarter close, assessments that are not in a completed status are reported as "overdue". Postponement requests received later than one week prior to quarter end will remain in an overdue status until a final report is submitted to the IAS. After 21 days past the assigned quarter due date, any overdue assessment will be escalated to division management and an overdue authorization form (Attachment J) will need to be submitted to postpone or remove the assessment from the IAS. As part of the change authorization process for overdue assessments, division management or the division Assurance POC are required to state the type of change, a description of the change, a change justification/ business rationale, and a risk exposure/ impact assessment for the assessment postponement/ deletion from the IAS.

3.3 Assessment Preparation

3.3.1 Internal Assessment Preparation
Division management defines the scope of the assessment, which specifies the breadth and depth of the area to be assessed, and the assessment criteria (i.e. requirements or expectations against which

the topic area is assessed).

Division management or designee identifies potential team members, including a Team Leader, to perform the assessment based on the assessment criteria. Team selection should include team members' subject matter expertise, skill set, independence from the work being assessed, and experience at the Laboratory. Responsible and affected management ensures that each team member selected has the availability to dedicate the requisite time to performing the assessment.

Depending on the type of assessment being performed, the division director, designee, or the Team Leader may develop a charter and/or an Assessment Plan, which is provided to the team and stakeholders, as appropriate, to formally communicate the intent and scope of an assessment.

3.3.2   External Assessment Preparation and Support

Upon notification by an external entity of an assessment, division management ensures coordination with affected areas to respond to data calls, logistics requests, and staff availability requests for support and participation in the conduct of the assessment. Division management identifies a POC(s) who will communicate with, and field and respond to requests by the external assessment entity. Affected division management and other stakeholders, including BSO, UC/UCNL and OIAI, should be invited to attend assessment meetings, such as the opening, daily report out, and closing meetings, as necessary.

3.4   Assessment Completion

Depending on the type of assessment being performed, the Team Leader may schedule an opening meeting for the team and key stakeholders to ensure all parties clearly understand why the assessment is being performed, the scope of the assessment, the assessment process, and outputs from the assessment. During the assessment, the Team Leader may schedule daily meetings with stakeholders to communicate status of the assessment, significant risks or issues identified that warrant immediate attention, and/or request additional documentation, personnel to interview, or work processes or locations to observe.

The Assessment Team collects all data and performs analysis to determine if the assessment criteria were met, and concludes whether or not the area assessed is performing/implemented as intended. Findings (i.e. noncompliances, issues, deficiencies), risks, and observations are documented, as well as noteworthy accomplishments or best practices. In some instances, recommendations for improvement may be documented.

3.5   Assessment Close Out

The results of the assessment are documented in a formal report, which is signed by the Assessment Team and provided to division management of the area assessed and applicable stakeholders. Depending on the type of assessment, the Assessment Team may provide division management of the area assessed and applicable stakeholders the opportunity to review the report for factual accuracy. If facts are incorrect, the Assessment Team obtains additional facts and analyzes them, which can change the results or conclusions of an assessment. In these instances, the draft assessment report is modified as necessary to reflect the correct results or conclusions prior to finalizing the report.

Upon completion of the assessment and final report, the Team Leader may schedule a closing meeting with the responsible division management and applicable stakeholders to deliver the results

of the assessment, address questions/concerns, and to discuss the next steps following the assessment. The Assessment Team may also provide division management with recommended corrective actions, which may or may not be implemented at the discretion of the division management.

Upon receipt of the final assessment report, Division Management ensures the following occurs:

- the IAS is updated with the completion date and the final signed assessment report is uploaded to the IAS;
- issues are managed in accordance with the Issues Management Program (LBNL/PUB-5519), including documenting issues in the Institutional Corrective Action Tracking System (CATS) and lessons learned and best practices in the Institutional Lessons Learned/Best Practices Database in accordance with the Institutional LLBP Process Manual (Document No. 04.02.003.001,); and
- risks are evaluated, characterized and managed, and significant risks are documented on the Institutional Risk Registry.

Completed records generated by assessment activities are maintained in accordance with the Regulations and Procedures Manual (RPM) and may include, but are not limited to:

- Integrated Assessment Schedule (IAS),
- Assessment Notifications,
- Assessment Plans,
- Opening/ Closing Meeting Attendance Sheets,
- Completed Line(s) of Inquiry/ Checklist(s), including objective evidence (i.e. interviewee responses, documents and records, and observation of work processes), and
- Assessment Results (i.e. PowerPoint or other presentations considered assessment reports, and final signed assessment reports).

3.6   Ongoing Performance Analysis and Monitoring

The Institutional Assessment Process is a key element of ongoing performance analysis, monitoring, and measurement. OIAI performs ongoing analysis of assessment results to identify Institutional adverse trends, risks, and recurring/systemic issues. Significant risks, issues, and trends are elevated to Laboratory management and responsible division management attention through the Institutional risk management framework, the Issues Management Program (LBNL/PUB-5519), and the Quarterly Institutional Performance Analysis Report.

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 and risks. Division management ensures that ongoing analysis of assessment results are performed to identify organizational adverse trends, risks, and recurring issues. Significant risks are documented on the Institutional Risk Registry. Issues identified as a result of performance analysis are managed in accordance with Issues Management Program (LBNL/PUB-5519).

4.0   ROLES AND RESPONSIBILITIES

All levels of management and staff at the Laboratory, in addition to certain groups, share

accountability and responsibility for the Institutional Assessment Framework. Specific roles and primary responsibilities are listed below *(the list is not all inclusive)*:

Role	Responsibilities
Laboratory Deputy Director for Operations/ Chief Operating Officer (COO)	● Monitors operational performance, including significant adverse trends, risks and associated mitigations, issues and corrective actions
Office of Institutional Assurance and Integrity (OIAI)	● Monitors operational performance, develops and tracks institutional performance metrics, identifies and tracks institutional risks and mitigations, coordinates and leads assessments, as applicable. ● Manages and oversees the Institutional Assessment Process and the IAS, including providing framework and tools to ensure consistent application and performance of assessment by division management. ● Reviews assessment results to identify and communicate institutional adverse trends, risks and issues to BSO, UC and LBNL senior leadership.
Internal Audit Services	● Develops the Lab's Annual Audit Plan and incorporates specific audits on the Integrated Assessment Schedule. ● Performs audits to evaluate the adequacy and effective implementation of internal controls and compliance with contractual regulations. ● Performs advisory assessments for Laboratory management to evaluate and improve the effectiveness of the governance and risk-management processes, and operating controls. ● Reviews assessment results to identify and communicate institutional risks and trends to BSO, UC, LBNL senior leadership and OIAI.
Division Management	● Identifies assessments for the current performance year, in conjunction with DOE, UC and OIAI counterparts. ● Ensures assessments are documented on the IAS, performed and completed in accordance with the Institutional Assessment Process as described in this document. ● Communicates assessment(s) status and negotiates changes to the current Integrated Assessment Schedule with DOE, UNCL and OIAI counterparts as part of the PEMP Process. ● Reviews and provides signed approval to substantive change requests and overdue assessment change authorization forms. ● Reviews assessment results to identify and address organizational trends, risks, and issues, including documenting significant risks and associate mitigations on the institutional Risk Registry. ● Ensures issues and associated corrective actions are documented, managed and tracked through resolution in accordance with the LBNL Issues Management Program (LBNL/PUB- 5519). ● Ensures Lessons Learned and Best Practices identified as a result of assessment(s) are developed and shared in accordance with the Institutional LLBP Process Manual (Document No. 04.02.003.001).

Team Leader	• Ensure the integrity and credibility of the assessment. • Identifies the assessment criteria and methodology to be used during the assessment, and prepares assessment plans, including the lines of inquiry (LOIs) in conjunction with team members. • Leads the assessment activities with the team members, including planning, opening and closing meetings, data collection and evaluation, preparation and issuance of assessment reports. • Acts as the liaison between the assessment team and the division management whose systems, processes, programs or projects are being assessed.
Team Member	• Participates in development and coordination of the assessment under the direction of the Team Leader. • Performs various assessment activities as agreed upon by the Team Leader. • Communicates findings that may warrant immediate attention to the Team Leader.
Subject Matter Experts (SMEs)	• Participates in assessments as a technical expert, which includes providing consultation and/or training to the assessment team, as requested.
Interviewees	• Participates in interview(s) conducted by Assessment Team. • Provides accurate, correct and complete information/data, including documents and/or records, to the Assessment Team as requested.

5.0   REFERENCES

5.1   Baseline References
- Contract No. DE-AC02-05CH11231, H.30 Clause, Contractor Assurance System
- Contract No. DE-AC02-05CH11231, I.76, DEAR 970.5203-1, Management Controls, (June 2007) (Deviation)
- DOE O 414.1D, *Quality Assurance*
- LBNL/PUB-3000, *Health and Safety Manual*
- LBNL/PUB-3111, *Quality Assurance Program Description (QAPD)*
- LBNL/PUB-5520, *Contractor Assurance System (CAS) Description*
- 04.03.001.000, *Quality Assurance Policy*
- 04.03.009.000, *Assessment Policy*

5.2   Referenced Documents
- *Institutional Risk Registry*
- *LBNL Annual Audit Plan*
- LBNL/PUB-5519, *Issues Management Program Manual*
- 04.02.003.001, *Institutional Lessons Learned and Best Practices (LLBP) Process Manual*

ATTACHMENTS

ATTACHMENT A – DEFINITIONS

Term	Definition
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.
Assessment, Management	Periodic assessment by management at every level of their organizations and functions to determine how well they meet performance expectations and mission objectives and correct problems, in addition to identifying strengths or improvement opportunities. Management Assessments should address the effective use of resources to achieve the organization's goals and objectives.
Assessment, Self	Periodic assessment by the line of their programs, processes or functions, or elements therein to determine how well they are performing to established requirements and correcting problems, in addition to identifying strengths or improvement opportunities.
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.
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.
Division Management	Accountable and responsible management for the systems, processes, programs, projects and/or tasks under their direction and purview.
Document	Written, visual, audio-video-recorded information stored in the form of hard copy, film, magnetic tape, electronic data, or in an on-line, web-based format.
Finding	A term that is interchangeable with "Issue". 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.
Graded Approach	A method by which the levels of analysis, mitigation, documentation, verification and validation are determined commensurate with risk severity.

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 (LL)	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.
Record	All books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received that are preserved or appropriate for preservation that serves as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities.
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, Divisional	A risk a Division faces that has an adverse effect on its internal operations or on its stewardship of institutional processes and services. These risks adversely affect safety, operations, budget, reputation, and/or accomplishing the Division's specific mission, strategic or business objectives.

Risk, Institutional	A risk the Laboratory faces that has the greatest adverse effect on employee safety and health, operations, finances, environmental, reputation, and/or accomplishing Laboratory mission and/or strategic and tactical objectives. This risk generally is Lab-wide or affects multiple divisions, and is characterized generally as compliance, operational, reputational and strategic.
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.

ATTACHMENT B – RISK SEVERTY GUIDELINES

Risk Determination: Graded Approach to the Application of Controls							
		IMPACT *Impact is determined by considering what the activity, service, or issue results in or could result in.*					
Impact Value	Impact Level	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
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

ATTACHMENT B – RISK SEVERITY GUIDELINES (Continued)

IMPACT DEFINITIONS:
Impact is defined as the magnitude, significance, or severity of an unfavorable effect.
- High Impact: Potential for significant adverse safety incidents, cost, major delay or significant negative institution-wide effect.
- Moderate Impact: Potential for substantive safety consequence or cost, or substantive negative institutional effect.
- Low Impact: Potential for minor safety impact or cost, or minimal negative institutional effect.

Likelihood Value	Likelihood Level	LIKELIHOOD
3	High	• Probable or more likely than not that the issue/ event will occur – Issue/event has occurred multiple times in last 12 months
2	Moderate	• More than remote but less than probable chance that the issue/event will occur – Issue/event has happened in last 18-24 months
1	Low	• Remote chance that the issue/ event will occur – Issue/event has not occurred in the past

EXAMPLE OF QUANTITATIVE APPROACH

How to Calculate Risk Severity

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

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

Combined Risk Severity Definitions

High Risk: high likelihood to occur, near miss or has occurred and results, or could result, in significant injury, loss, damage and/or significantly impacts achievement of mission/ business objectives. Requires immediate attention from senior management and/or follows a formal, rigorous process and/or requires the application of formal, rigorous controls.

Medium Risk: would occur at some point in time, near miss or has occurred and results, or could result, in substantive injury, loss, damage and/or impacts achievement of mission/business objectives. Requires prompt attention from Division management and/or follows a more formal, rigorous process and/or requires the application of some formal, rigorous controls.

Low Risk: is not likely to occur, near miss or has occurred and results, or could result, in nominal injury, loss, damage and/or nominally impacts achievement of mission/business objectives. Requires some attention from line-management, follows less formal or casual process and/or requires the application of less formal, rigorous controls

ATTACHMENT C – ASSESSMENT GUIDANCE

1. Integrated Assessment Planning

The key objectives of the Integrated Assessment Planning (IAP) process are to monitor the effectiveness of controls (administrative, engineering, etc.) and implementation and execution of programs, processes, projects and other activities, and provide feedback that promotes improvement in management systems, programs, projects, and work processes.

Assessment planning should follow a systematic approach and should take place at the end of a performance year (Fiscal Year) as part of the Institutional Assessment Process, so that planned assessments are documented on the Institutional Integrated Assessment Schedule.
When considering which areas to assess, risk and contractual requirements should be the primary driver for determining what assessments will be performed during a fiscal year. Focus areas that are identified as a risk area may not need to have a formal assessment performed if the risk can be monitored with metrics. The Risk Severity Guidelines (Attachment B) and guidance in the Risk Management Description should be used when determining whether or not an area should be assessed.

Once focus areas are identified, they should be evaluated and compared against areas identified by other parties (internal or external) who are planning to perform assessments to minimize duplication of effort and burden on the organizations who will be assessed. For example, if Organization A has determined that one of its highest risk areas is senior leadership compensation, and Internal Audit Services has identified it as an area that they are required to assess each year per the contract, Organization A may decide not to assess that area and rely on/leverage Internal Audit Services' audit or vice versa.

In some instances, contractual requirements may dictate specific areas that must be assessed within certain periods of time. If the area has been assessed in years past and historically, the assessment has not identified adverse performance or significant issues, it may be worthwhile to discuss obtaining a waiver with the DOE, UC/UCNL and OIAI.

Generally, there are three types of assessments performed at LBNL.

- <u>Self-assessments</u> are internal assessments that are conducted by LBNL management and staff responsible for work performed in the assessed areas. Examples of Self-Assessments include:

  o Management Reviews,
  o Project Reviews,
  o Effectiveness Reviews,
  o Field Inspections/Walkarounds,
  o Program Reviews, and
  o Project Reviews.

ATTACHMENT C - ASSESSMENT GUIDANCE (Continued)

- Independent assessments are conducted by internal LBNL staff or external entities who are not responsible for work performed in the assessed areas. Examples of these assessments include:
  - Audit or assessments conducted by Internal Audit Services, OIAI, or peers from other organizations, such as Quality Assurance Review, Financial Reviews, Peer Reviews, and Institutional-level Effectiveness Reviews.
  - Assessments are conducted by UC, DOE Headquarters, DOE Site Office, City of Berkeley, National Institute for Health (NIH), Food and Drug Administration (FDA), peers from other academic or laboratory organizations outside of the Lab, such as 3rd Party Accreditation Reviews (e.g. DOELAP, ISO 9001, etc.), Federal inspections, Corporate Parent Reviews (i.e. UCNL reviews), and Director Reviews coordinated by the Project Management Office (PMO).

- Joint Assessments are conducted in partnership with multiple organizations such as LBNL and/or UC, and/or BSO. These types of assessments may be performed when the tri-parties want to leverage each other's expertise and skill sets, and reduce excessive burden on the organization being assessed or duplication of effort for the same assessment area. When considering a joint-assessment, roles and responsibilities regarding assessment results such as mitigation of identified risks or management of identified issues need to be agreed upon by the assessment organizations and clearly stated/documented.

2. Assessment Scope

Defining the scope of an assessment keeps the assessment manageable and clearly articulates what will be assessed and what will not. Defining the scope of the assessment will also help the Team Leader to identify the assessment criteria, which are the specific requirements against which the focus area will be assessed.

Assessments are designed to look at a performance within a particular area at a particular time. As such, the assessment criteria should align with that particular area. Identifying assessment criteria should not be broader than the specific area that will be reviewed. If one element of a program or process will be assessed, only the requirements for that specific element should be identified as the assessment criteria, not the overarching program requirements in their entirety. For example, if the Document Management element of the Quality Assurance (QA) Program is being assessed, only the specific requirements for Document Management (e.g. DOE 414.1D Criterion 4 - Management/ Documents and Records, ISO 9001:2015 Section 7.5, Documented Information) should be cited and not the overarching QA Program requirements (e.g. DOE 414.1D, ISO 9001:2015).

3. Team Selection

Team selection is a critical aspect of assessment. The size and skill set of the team are key factors in appropriately addressing the scope of the assessment, the time frame within which the assessment needs to be performed, and the overall experience of both the team member and the people who support the assessment (i.e. interviewees, SMEs, personnel who provide documentation, etc.)

A team may be one or more people. If there is one team member, that team member serves as the Team Leader. In some instances, there may be multiple people on an assessment team. For example, establishing a cross-organizational assessment team is a great way for team members to learn new

ATTACHMENT C - ASSESSMENT GUIDANCE (Continued)

requirements, different ways of performing a process within those requirements, and how to perform different assessment activities. However, a team that has too many members can be challenging and may impact the time it takes to get tasks performed, analyze results and establish conclusions, etc. The number of people on an assessment team should be commensurate with the complexity of the assessment.

When identifying potential team members, consider the following:

- independence from the specific work being assessed
- technical expertise in the area being assessed
- ability to effectively communicate, verbally and written
- ability to work collaboratively with others
- ability to carry out various assessment methods/ activities
- experience at the Lab or within a particular discipline/function. Note: sometimes people who are new to the lab or organization within the lab can provide a different perspective than people who have worked at the Lab or within the same organization for a long time.
- experience at the Lab or within a particular discipline/function. Note: sometimes people who are new to the lab or organization within the lab can provide a different perspective than people who have worked at the Lab or within the same organization for a long time.

4. Assessment Preparation

The Team Leader should work with the Team Members to plan the assessment. This may not be feasible for all assessments. The Team Leader should meet with the Team Members to discuss scope, assessment criteria, methodology, lines of inquiry, assignments, roles and responsibilities, time lines, etc. The Team Leader, in conjunction with the team members, should perform the following preparation activities:

- identify roles and responsibilities of team members (e.g. document/record manager, point-of-contact for logistics, etc.);
- identify the methodology(ies) (i.e. document and record reviews, observation of work, and interviews) to use as part of the assessment;
- identify a preliminary list of documents and records to be reviewed;
- identify a preliminary list of people (Lab and/or subcontractor personnel) to be interviewed;
- develop Lines of Inquiry (LOIs) to help guide the assessment and keep it within scope;
- develop a common storage protocol for document and record control (e.g. Google Drive Folders, Website, etc.), and
- review the assessment criteria and associated documents (e.g. policy, procedures, work instructions, protocols, etc.) in order to gain an understanding of the system, process, program or project that will be assessed.

5. Opening Meeting

The opening meeting is a critical element of an assessment. It ensures that the Assessment Team, responsible division management and key stakeholders clearly understand why the assessment is being performed, the scope of the assessment, and the assessment process. It also provides a casual forum to introduce all the key players to each other as well as to the Assessment Team and allows for

ATTACHMENT C - ASSESSMENT GUIDANCE (Continued)

questions to answer prior to the start of the assessment. The entire team should be present for this meeting.

The following items are typically addressed during the opening meeting:

1. introduction of the assessment team members;
2. confirmation of the scope and objectives of the assessment;
3. confirmation of communication channels, resources needed, and other logistics;
4. assessor confidentiality, including confidentiality agreements that may need to be signed by the team;
5. an explanation of the assessment process that will be used, including identification of risks and issues during the course of the assessment;
6. confirmation of the date and time of the closing meeting;
7. preliminary list of documents and records to appropriate stakeholders needed by the team;
8. discussion of safety considerations such as training or personnel protection equipment (PPE) needed by the team to perform its assessment activities or significant hazards that the team may encounter.

6. Lines of Inquiry

Established lines of inquiry will guide the assessment and help to ensure that the assessment stays within scope, and the responses to them serve as the basis of the assessment results and conclusion. There are two levels of Lines of Inquiry (LOIs), or questions, used during an assessment:

1. High-level LOIs address the adequacy of the flow down of requirements or expectations to implementing documents and/or the overarching health or performance of a focus area. These questions are typically close-ended questions (i.e. answered yes or no).

2. Detailed LOIs help answer the high-level questions. Detailed LOIs may be interview questions, questions about work being observed, or questions about a document or record. These questions are typically open-ended questions to allow more data to be gathered.

An example of high-level LOIs for an assessment of the QA Program element of Document Management and Control could be:

● Does the lab community understand document management and control as described in the QA Program Description?
● Are documents being managed and controlled consistently across the Laboratory?

An example of detailed LOIs for the same assessment could be:

● How does your organization manage and controls its documents?
● What procedures exist that govern how documents are managed and controlled?
● What process do you follow when you develop and issue new documents?

LOIs should be documented, and the responses, based on the methodologies used, should also be documented for each LOI. During the assessment the detailed LOIs may be revised or expanded, but must stay within the scope of the assessment.

ATTACHMENT C - ASSESSMENT GUIDANCE (Continued)

Completed LOIs, along with any documents and records reviewed in order to answer them, should be maintained as part of the assessment file.

7. Data Collection

Data collection is an iterative process that begins when the team starts the assessment and ends when the final report is issued. Essential information needed to perform an assessment includes:

- information obtained during interviews with key personnel such as workers, supervisors, individuals who perform the work;
- information obtained during interviews with SMEs, as necessary
- documented objective evidence such as policies; procedures; work instructions; photographs; assessment reports; corrective action records; training records; log books; inspection, testing and maintenance records; purchase requisitions and orders; work requests and orders, etc.;
- observation of work performed;
- other information to better understand the system, process, program or project that is being assessed; and
- other information to validate the data accuracy and address gaps in information already collected.

Any issues (i.e. findings, noncompliances, deficiencies) and/or safety conditions discovered during performance of the assessment should be brought to the attention of the Team Leader immediately. The Team Leader will ensure that the appropriate cognizant management is notified.

7.1.1   Personnel Interviews
Interviews with employees and laboratory management are a key component data collection, and can be a credible source of information when used in conjunction with documented objective evidence (i.e. documents and records) and other sources of information.

In some instances, information collected from interviews can be in conflict and/or be contradictory with information collected from other interviews, and/or with documented objective evidence. In such instances, the documented objective evidence should be relied upon as fact and not the information from interviewees.

Consider the following when performing interviews:

1. Be considerate of individuals'' time by setting realistic and reasonable interview times, and adhere to the interview schedule.
2. Use team resources effectively and efficiently.
    a. One to two team members should interview an individual as opposed to the entire assessment team. Two team members is optimum because one person may hear something during an interview that the other did not.
    b. Organize thoughts prior to beginning of interviews, and be prepared for distractions and have a strategy for resolving them.
3. Use the LOIs to guide the interview and be prepared to adjust as needed.
4. Typically, an interviewee's manager/supervisor should not be invited to interview. This can be seen as intimidation and an interviewee may not provide accurate or complete data.

ATTACHMENT C - ASSESSMENT GUIDANCE (Continued)

     a. In some instances, an interviewee may request that their manager/supervisor and/or union representative be present. In these instances, feel free to invite them.

     b. If a manager/supervisor and/or union representative are invited to an interview, the Team members should clearly articulate that the manager/supervisor and/or union representative are observers only and the questions should be answered only by the interviewee.

5. An interview is not an interrogation. Set the interviewee at ease by addressing the purpose for the interview, establishing rapport, letting the interviewee know he/she may ask questions at any time during the interview, etc.

6. Be calm, courteous, and patient, and let the interviewee complete his/her thoughts without interruption.

7. Do not rush the interview, debate points or argue with the interviewee. Avoid using sarcasm or humor, and do not jump to conclusions.

     a. If emotions of either the interviewee or the Team Member(s) get triggered and become high, and/or the interview starts to get out of control or violent, stop the interview. In these types of instances, it is recommended that the interview be rescheduled.

8. At the end of the interview, thank the person(s) interviewed, and let them know that they can contact the Team Leader if they have additional information they believe will be of value to the self-assessment process.

9. Take notes during the interview. Document the interviewee's responses for each LOI, and maintain them. Bring a laptop to type and save responses during interviews. This will allow the Team to refer back to this information when the interview is over.

7.1.2 Observing Work

Observing work as it is being performed is a good way gather data. It allows the assessor to see the how work is performed; how well workers understand the processes, tasks and requirements; and provides an opportunity to talk with the workers.

Prior to observing work, team members assigned to this activity should become familiar with the work that will be performed and associated implementing documents (e.g. policies, procedures, work instructions, etc.). The manager/supervisor/work lead should be notified in advance of a visit, including the purpose, areas are being evaluated, and advised when the team arrives. The manager/supervisor/ work lead may want to be present during this observation.

During work observation activities, questions/ discussion by the team directed to the worker(s) should not be answered by the manager/supervisor/work lead. Similar to an interview, the Team member(s) observing the work should clearly articulate that the manager/supervisor is an observer only and the questions should be answered only by the worker(s).

8. Assessment Results

After collecting the data required to answer the LOIs, the Team should comprehensively analyze it to determine what it says about the performance of the area assessed. Based on this analysis, the Team will need to document the results and make an overarching conclusion (answer to the high-level LOIs).

Assessment results should be categorized into the following:

● Finding – A term that is interchangeable with "Issue". 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.

ATTACHMENT C - ASSESSMENT GUIDANCE (Continued)

- 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; and/or a minor deficiency that has been promptly corrected on the spot and verified as completed.

- Noteworthy Practice – Practices or conditions that are recognized for their excellence and should be considered for lab-wide application.

Assessment results and conclusions should be documented in an Assessment Report (see Attachment G – Self Assessment Report Template). If a PowerPoint presentation or other reporting format is used, the elements of the Assessment Report Template should be addressed.

Results must be based on fact and objective evidence, and cannot be based on opinion, assumption, speculation, gut feeling, etc. In order to help ensure that the assessment results are factually accurate, the Team Leader ensures that personnel interviewed and/or Subject Matter Experts (SMEs) of a specific system, process or program have the opportunity to perform a factual accuracy review of the draft report to ensure that the data collected by the team is factually accurate. Factually inaccurate data will require the team to collect additional data through document and record review or interviews, and may alter the conclusions of the assessment. In some instances, if additional data cannot be collected, and existing conclusions cannot be substantiated, then such conclusions must be removed from the report.

9. Closing Meeting

The Closing Meeting is another critical element of an assessment. The primary purpose of this meeting is to present the assessment finding and conclusions, ensure a clear understanding of the results, obtain management's ownership of the results and required action, and agree on the timeframe for corrective action development. The Closing Meeting may occur prior to the development of the assessment report, provided the results and conclusion of the assessment have been made.

The Team Leader will schedule and lead the closing meeting with stakeholders. The entire team should be present as team members to discuss, as needed, the areas of the assessment they were responsible for.

If asked by the stakeholders, the Team may use this meeting as an opportunity to recommend corrective actions (particularly for complex processes or equipment where a corrective action could affect a process or experiment). The following items are typically addressed during the closing meeting:
1. Introduce the team members, if there are attendees who were not at the opening meeting.
2. Thank the stakeholder(s) for their time and cooperation.
3. Remind attendees of the assessment scope, purpose and applicable requirements.
4. Discuss the findings, including noteworthy practices, risks and issues.
5. If new objective evidence is provided by stakeholders, ensure findings are reviewed and modified as applicable.
6. Clearly state the conclusions (e.g. overall performance, compliance, effectiveness, etc.).
7. Diverging opinions by the team members and their resolution.
8. Path forward and dates for each activity, such as drafting the report, factual accuracy, and final report issuance.
9. Answer questions from the stakeholders.
10. Keep a list of any comments by the stakeholders that require follow up.

ATTACHMENT C - ASSESSMENT GUIDANCE (Continued)
10. Data Management

Data management is essential to supporting the basis of the assessment conclusions. Supporting records and objective evidence should be retained with the official assessment documentation, including the final, signed assessment report.

Types of information considered supporting records include:
- a copy of each document reviewed and used as part of the assessment,
- a list of personnel interviewed and their written statements,
- lines of inquiry and associated responses for both documents and personnel, and
- data analysis tools and results.

11. Issues Management

Findings (a.k.a. issues, deficiencies, noncompliances, etc.) must be managed and tracked in accordance with the Institutional Issues Management Program (LBNL/PUB-5519). In some instances, there may be conditions discovered during the course of an assessment that warrants broader communication of Lessons Learned or Best Practices. Division management is responsible for initiating and disseminating lessons learned and best practices in accordance with the institutional Issues Management Program (LBNL/PUB-5519).

12. Ongoing Performance Analysis

The results of assessments are analyzed to identify statistical trends, systemic problems and recurring/systemic issues. This involves tracking and trending of both qualitative and quantitative data, identifying statistical trends and recurring issues. The Institutional Integrated Assessment Schedule process is a key component of ongoing performance analysis.

At the organizational level, Division Management is responsible for identification and correction of risks and 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. Issues identified through ongoing performance analysis must be managed following the Issues Management Program (LBNL/PUB-5519). 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, and
- determine the effects of improvement efforts on performance.

At the institutional level, OIAI performs ongoing performance analysis of assessment results to determine whether statistical trends, emerging risks and/or recurring issues exist. Significant risks identified by OIAI and Division Management should be documented on the Institutional Risk Registry, which is a compilation of risks and associated mitigations, including improvement measures. The Institutional Risk Registry serves as a vehicle for UC and Lab leadership to identify and discuss significant risks to the Laboratory mission and reputation, and to monitor risk management through retiring of risks.

ATTACHMENT D – SELF ASSESSMENT CHARTER TEMPLATE

To: Team Lead, [Organization]
        Team Member #1, [Organization]
        Team Member #2, [Organization]
        Team Member #3, [Organization]

From: Responsible Division Director

Date: [Insert Applicable Date]

Subject: Charter for the [Name of Self Assessment]

I am charging you to assess the [Assessment Area] to determine if it [driver and purpose of the assessment, e.g. adequately flows down specific contract requirements, is implemented in accordance with the specific implementation documents, AND/OR validate findings identified in a specific report have been adequately addressed].

[Employee's Name] will serve as the Team Lead, and your assessment will follow the requirements of the [Requirements Document]. You will identify risks, and findings/issues, and recommendations to address identified issues. Please also note performance strengths and best practices.

Once the team has completed the assessment, the results and any recommended corrective actions should be documented in a formal report, and discussed with me and others that I deem appropriate. Following the reviews, the report should be submitted to me no later than [Final Report Due Date].

Thank you for your participation in this important activity.

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

ATTACHMENT E—ASSESSMENT PLAN TEMPLATE

1.0   Assessment Title
       Identify the title of the assessment.

2.0   Assessment Date
       Identify the date(s) the assessment will be performed.

3.0   Assessment Location, if applicable
       Identify the location the assessment will be performed.

4.0   Assessment Team
       Identify the Team Leader and each team member on the assessment team.

5.0   Assessment Purpose
       State the purpose of, or the reason why, the assessment is being performed.

6.0   Assessment Scope and Assessment Criteria
       State the scope of the assessment. The scope may describe:

- Primary concerns addressed by each assessment,
- Locations to be assessed,
- Population to be assessed, and
- Work practices to be assessed.

       The scope should also include the methodology used to perform assessment activities, such as document and record reviews, personnel interviews, work observation.

6.1   Identify focus area
       Identify the focus area(s) to be assessed.

6.2   Identify assessment criteria
       Identify the requirements, external or internal, against which the focus area will assessed. The assessment criteria should reflect the specific requirements applicable with the scope of the assessment.

ATTACHMENT F – ASSESSMENT REPORT GUIDANCE

Assessment results may be documented using this report template or in a different format (e.g. PowerPoint) provided that core report elements are addressed.

1.0   Assessment Title Page
       State the title of the assessment, the date(s) the assessment was performed, and the names and signatures of the assessment team members. Assessments are the independent work of the assessment team and do not need to be approved cognizant management.

2.0   Table of Contents
       Provide the reader a high-level view of the document content and points of reference to quickly and easily locate information.

3.0   Executive Summary
       Summarize the purpose of the assessment, the findings (i.e. noteworthy practices, issues, observations) and the overarching conclusion so that division management and other stakeholders can easily understand the content without having to read the entire report.

4.0   Assessment Scope
       Provide a brief statement describing scope of the assessment and the assessment criteria against which the focus area was evaluated against (i.e. external and/or internal requirements or performance expectations) to which the focus area was assessed.

5.0   Assessment Results
       Provide detailed information about the results (i.e. issues, observations, noteworthy practices, and risks) identified during the assessment.

6.0   Conclusion
       Provide a statement of overall conclusion. Summarize the information obtained during the self-assessment and present conclusions (i.e., what it all means) as well as what the consequences or impacts may be. Examples include: "The assessment concluded that the program documents adequately flow down the Contract 31 requirements and are implemented as required." "The assessment concluded, with the exceptions noted, that the program documents adequately flow down the Contract 31 requirements and are implemented as required."

7.0   Supporting Information
       Provide a listing of documentation reviewed and personnel interviewed during the performance of the assessment that support the results and conclusions of the report. The document list should include the title of the document, the document number and/or other unique identifier, and the revision. The list of personnel interviewed may include the name of the person interviewed, their title, their function and/or the organization (i.e. company, division, group) in which they reside.

       Other documents (i.e. checklists, lines of inquiry, etc.) that were used to collect data as part of the assessment do not need to be attached to the report, but should be maintained in a centralized assessment file (e.g. Google folders) that is easily identifiable and retrievable.

ATTACHMENT G – SELF ASSESSMENT REPORT TEMPLATE

[Insert Optional LBNL or Division Logo]

<p align="center">[Self-Assessment Report Title]
[Final Report Date]</p>

Report Prepared By:

_____   _____

[Team Lead Name],   Date

[Organization]

_____   _____

[Team Member #1],   Date

[Organization]

_____   _____

[Team Member #2],   Date

[Organization]

_____   _____

[Team Member #3],   Date

[Organization]

TABLE OF CONTENTS

I. **EXECUTIVE SUMMARY**

Summarize the purpose of the assessment, the findings (i.e. noteworthy practices, issues, observations) and the overarching conclusion so that division management and other stakeholders can easily understand the content without having to read the entire report.

II. **INTRODUCTION**

Introduce the report and identify the purpose of the assessment including the driver(s) and focus areas of the assessment.

III. **CRITERIA**

Identify the requirements, external or internal, against which the focus area will be assessed. The assessment criteria should reflect the specific requirements applicable with the scope of the assessment.

IV. **ASSESSMENT SCOPE**

Provide a brief statement describing scope of the assessment and the assessment criteria against which the focus area was evaluated against (i.e. external and/or internal requirements or performance expectations) to which the focus area (in your assessment plan) was assessed.

The scope may describe:
- Primary concerns addressed by each assessment,
- Locations to be assessed,
- Specific time frame assessed,
- Population to be assessed (e.g. specific personnel roles, sample versus all purchase orders), and
- Work practices to be assessed.

V. **ASSESSMENT METHODOLOGY**

The assessment methodology section should state the activities used to perform the assessments, such as document and record reviews, personnel interviews, and/or work observations.

VI. **ASSESSMENT RESULTS**
Provide detailed information about the findings (i.e. Findings, Observations, Noteworthy Practices, and Risks) identified during the assessment:
- Findings (aka Issues)
  - Noncompliance with internal or external requirements
  - Program or performance deficiencies
- Observations (aka Opportunities for Improvement)

- Ineffective Practices or conditions that are <u>not</u> technically noncompliant with internal/external regulations or requirements 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
- A minor deficiency that has been promptly corrected on the spot and verified as completed
- Noteworthy Practices (aka Best Practices)
  - Practices or conditions that are recognized for excellence
  - Practices or conditions that should be considered for Lab-wide application
- Risks
  - The possibility of suffering a loss or an unfavorable event, or the failure of achieving a planned outcome
  - May occur at the divisional or institutional level

VII.   CONCLUSION

Provide a statement of overall conclusion. Summarize the information obtained during the self-assessment and present conclusions (i.e., what it all means) as well as what the consequences or impacts may be (e.g. recommended corrective actions). Examples include: "The assessment concluded that the program documents adequately flow down the Contract 31 requirements and are implemented as required." "The assessment concluded, with the exceptions noted, that the program documents adequately flow down the Contract 31 requirements and are implemented as required..."

APPENDIX A—[OPTIONAL: SUPPORTING INFORMATION]

Provide a listing of documentation reviewed and personnel interviewed during the performance of the assessment that support the results and conclusions of the report. The document list should include the title of the document, the document number and/or other unique identifier, and the revision. The list of personnel interviewed may include the name of the person interviewed, their title, their function and/or the organization (i.e. company, division, group) in which they reside.

Other documents (i.e. checklists, lines of inquiry, etc.) that were used to collect data as part of the assessment do not need to be attached to the report, but should be maintained in a centralized assessment file (e.g. Google folders) that is easily identifiable and retrievable.

ATTACHMENT H – ASSESSMENT PROCESS FLOW
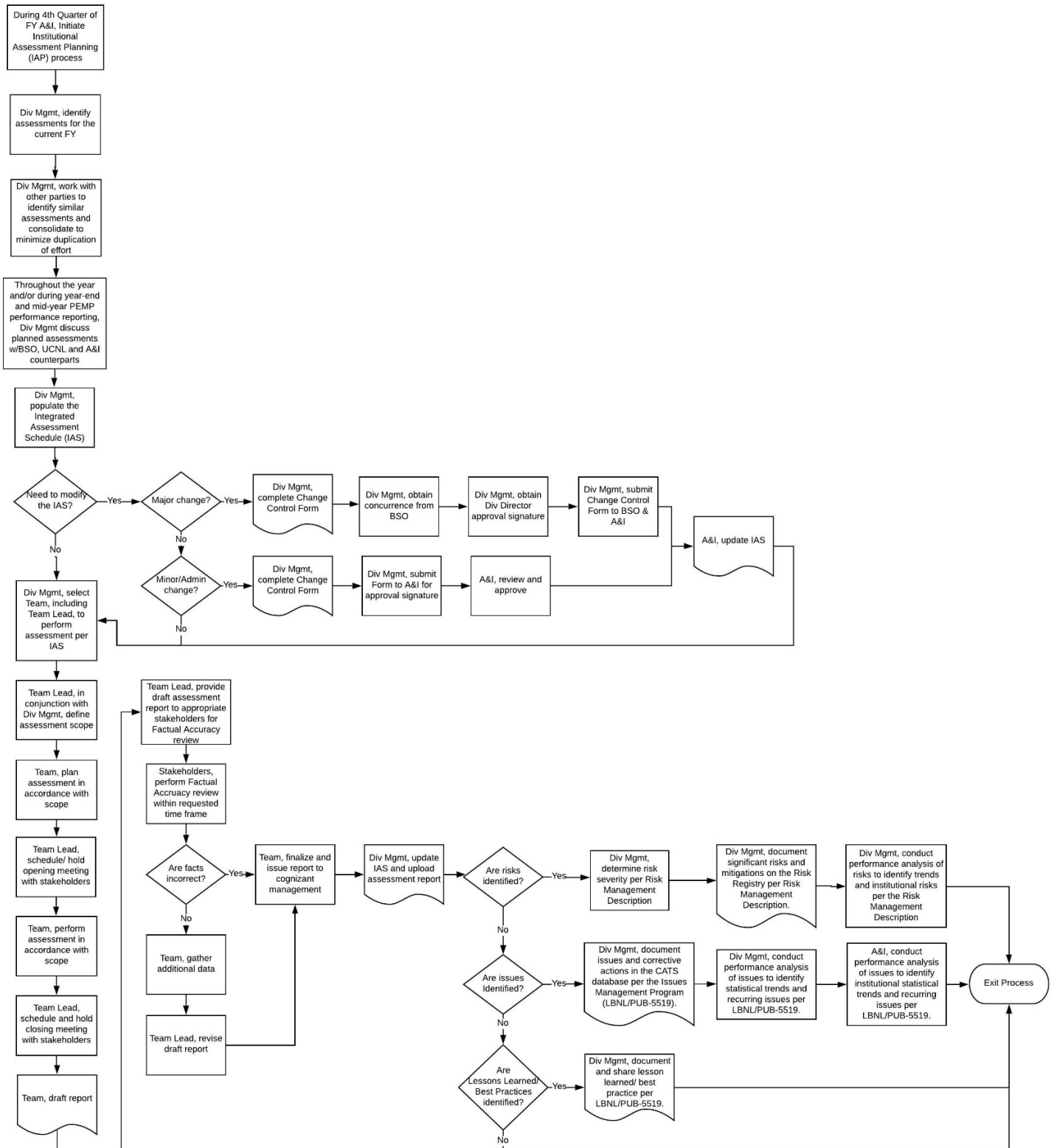
ATTACHMENT I – CHANGE REQUEST FORM

Integrated Assessment Schedule (IAS)
Change Control Process

Instructions

Changes to the IAS can be made throughout the year following a structured change control process, which is coordinated by the Office of Assurance & Integrity (OIAI).

Division management or the Division Point of Contact (POC) can request a change to the IAS by initiating a new change request form. The IAS owner or Division POC uploads the change request form to Dropbox Sign and routes the document for approval to the required division management based on the Request Type.

Request Types may be **administrative** or **substantive**. For administrative changes, only OIAI management signature is necessary. The criteria for administrative changes are:
- Assessment postponed within the Fiscal Year (FY)
- Assessment Area modified: scope could be larger or smaller, but the topical area is the same
- Administrative Changes to locked columns (e.g. grammar or editorial changes)

For substantive changes, both division management and OIAI management signatures are required. Signature requests should be routed to division management prior to OIAI management for review. The criteria for substantive changes are:
- New Assessment Area added
- Assessment Area deleted
- Assessment postponed outside current FY

The **justification** for a change request must meet one or more of the following criteria:
- Completion is dependent upon external contractors or resources that could not be reasonably secured to complete the assessment by the due date
- Completion 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

Once the Change Request Form is signed by all required parties, the IAS owner incorporates approved changes into the IAS. The final signed change request form is uploaded as an attachment to the respective line entry in the IAS for recordkeeping.

Change requests to postpone an assessment should be submitted no later than **one week** prior to the quarter due date to allow time for review and edits. Postponement requests received later than one week prior to quarter end will remain in an overdue status. After 21 days past the assigned quarter due date, any overdue assessment will be escalated to division management and an overdue authorization form will need to be submitted to postpone or remove the assessment from the IAS.

Integrated Assessment Schedule (IAS)
Change Request Form

Date:	
Division Point of Contact:	
Assessment Area:	
Request Type:	☐Administrative ☐Substantive

Change Requested:

Change Justification/ Rationale:

APPROVAL/CONCURRENCE

Administrative Changes (OIAI Only Required)
Substantive Changes (OIAI and Division Management Required)

X	
Division Management	*Date*

X	
OIAI Manager	*Date*

These changes have BSO and UCNL approval/ concurrence.

ATTACHMENT J – OVERDUE CHANGE AUTHORIZATION FORM

![Berkeley Lab logo] BERKELEY LAB Lawrence Berkeley National Laboratory	**Office of Institutional Assurance & Integrity** **Overdue Assessment** **Change Authorization Form**

Requestor Information		
Requestor Name:	**Responsible Division:**	**Date Prepared:**

Assessment Information			
Assessment Area:	**Original Quarter Due Date:**	**Responsible Person:**	**Responsible Manager:**

Type of Change

	Postpone Assessment within Fiscal Year (FY)	New Quarter Due Date:
	Postpone Assessment outside FY	New Quarter Due Date:
	Delete Assessment	

Change Requested:

Change Justification/Rationale:

Risk Exposure/Impact of Assessment Postponement/ Deletion:

Approvals:

_____

Division Management   *Date*

_____

OIAI Manager   *Date*