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 A&I.

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

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- 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, A&I, 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 BASO, City of Berkeley, National Institute for Health (NIH), Food and Drug Administration (FDA), peers from other academic or laboratory organizations outside of the Lab, etc, 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 BASO. 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

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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.
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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

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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.

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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. 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.

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   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:

- <u>Finding</u> – 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.

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- <u>Observation</u> – An ineffective practice or condition that is compliant with a regulation or requirement, but, if left unaddressed, could lead to a noncompliance.

- <u>Noteworthy Practice</u> – 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 E - 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.

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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 track 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, A&I performs ongoing performance analysis of assessment results to determine whether statistical trends, emerging risks and/or recurring issues exist. Significant risks

identified by A&I 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.