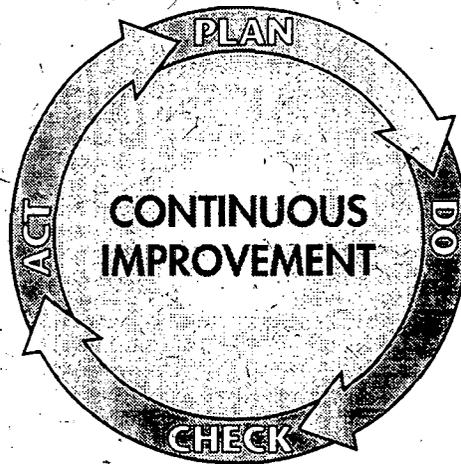




# OPERATING AND ASSURANCE PLAN

Revision 5  
Effective Date: February 15, 1996



Ernest Orlando Lawrence  
Berkeley National Laboratory  
University of California  
Berkeley, CA 94720

Prepared for the U.S. Department of Energy  
under Contract DE-ACO3-76SF00098

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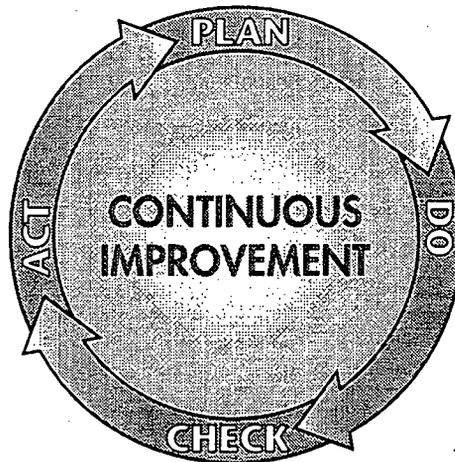
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## STATEMENT OF LABORATORY POLICY

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It is the policy of the Ernest Orlando Lawrence Berkeley National Laboratory to carry out all our activities that contribute to the scientific and operational objectives of the Laboratory in accordance with the requirements of this Operating and Assurance Program (OAP). It is line management's responsibility to plan for and achieve compliance with the requirements and to provide sufficient resources to accomplish the OAP objectives. In addition, every Berkeley Lab employee is individually responsible for the quality of his or her work.

It is our policy to implement the requirements of this program in a way that is adequate to enable compliance with DOE requirements, that ensures our continued scientific research and programmatic success, and that is resource-efficient. Our program emphasizes three principles:

- The most essential resources at Berkeley Lab are the creative scientists, engineers, and support personnel.
- People who perform the work have the greatest effect on outcome and process quality.
- Problem prevention is more cost effective than problem correction.

Accordingly, our program establishes a management system that (1) recognizes that managing a laboratory that supports research is different from managing the research itself and (2) provides a process for continuous improvement in our performance in both aspects of Laboratory management.

Each of us has a critical role to play in the achievement of our institutional objectives. This program is designed to aid all of us, including our partners at DOE, in that effort.

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Director  
Ernest Orlando Lawrence  
Berkeley National Laboratory

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## OBJECTIVES AND APPLICABILITY

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The Berkeley Lab Operating and Assurance Plan (OAP) is a set of operating principles used to support Berkeley Lab organizations in achieving consistent and quality performance in their work activities. The OAP is designed to fulfill three main objectives:

- The OAP is the program document for the Berkeley Lab's **Quality Assurance Program**. It describes the program elements necessary to implement quality assurance in Laboratory operations.
- The OAP establishes a **performance standard** for Berkeley Lab administrators, managers and supervisors to ensure an acceptable level of performance and quality for Laboratory work activities. It describes basic guidelines for organizing, planning, managing, and assessing work.
- The OAP is the **compliance document** that meets DOE and federal rule requirements for quality assurance (DOE Order 5700.6C, 10 CFR 830.120) and facility operations (DOE Order 5480.19).

The OAP is applicable to all Berkeley Lab organizations. All Berkeley Lab operating units should be engaged, at some level, with organizing their resources, managing their processes and activities, and evaluating the results of their performance. The level of rigor in applying the OAP principles, however, is based on a *graded approach* with consideration given to the organization's mission, its programmatic or operational significance, and its environmental, safety and health consequences to personnel and the general public. Appendix A contains a methodology to grade processes, activities, and facilities for determining the applicable level of rigor.

Implementing the OAP requires Berkeley Lab organizations to develop and maintain documents that establish their method of operation. Either Function Notebooks or Facility Notebooks are the prescribed method for this implementation, although other equivalent operating documents may be substituted for these Notebooks.

- Function Notebooks describe organizational structure, work processes, and performance assessments.
- Facility Notebooks describe the operations within a facility.

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The implementation matrix in Appendix B is designed to assist organizations in determining where Notebooks are needed and in developing the requisite Notebooks.

Notebooks or other equivalent documents must be kept up-to-date to ensure that operating procedures are the most current information. At the minimum, annual review and updating of Notebooks or equivalents are required.

### **Office of Assessment and Assurance**

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The Office of Assessment and Assurance (OAA) is the Laboratory organization that supports the OAP. OAA provides the following services:

- It assists Berkeley Lab operating units in developing their Function Notebooks and Facility Notebooks.
- It conducts appraisals to evaluate the effectiveness of the OAP in Berkeley Lab operations.
- For organizations requiring more rigorous controls, it assists in preparing customized quality assurance plans, operating manuals, or similar documents.
- It maintains the OAP.

These OAA services, as an integral part of the Berkeley Lab QA/CO system (see Figure 1), ensure that quality assurance and conduct of operations principles are fully implemented at Berkeley Lab.

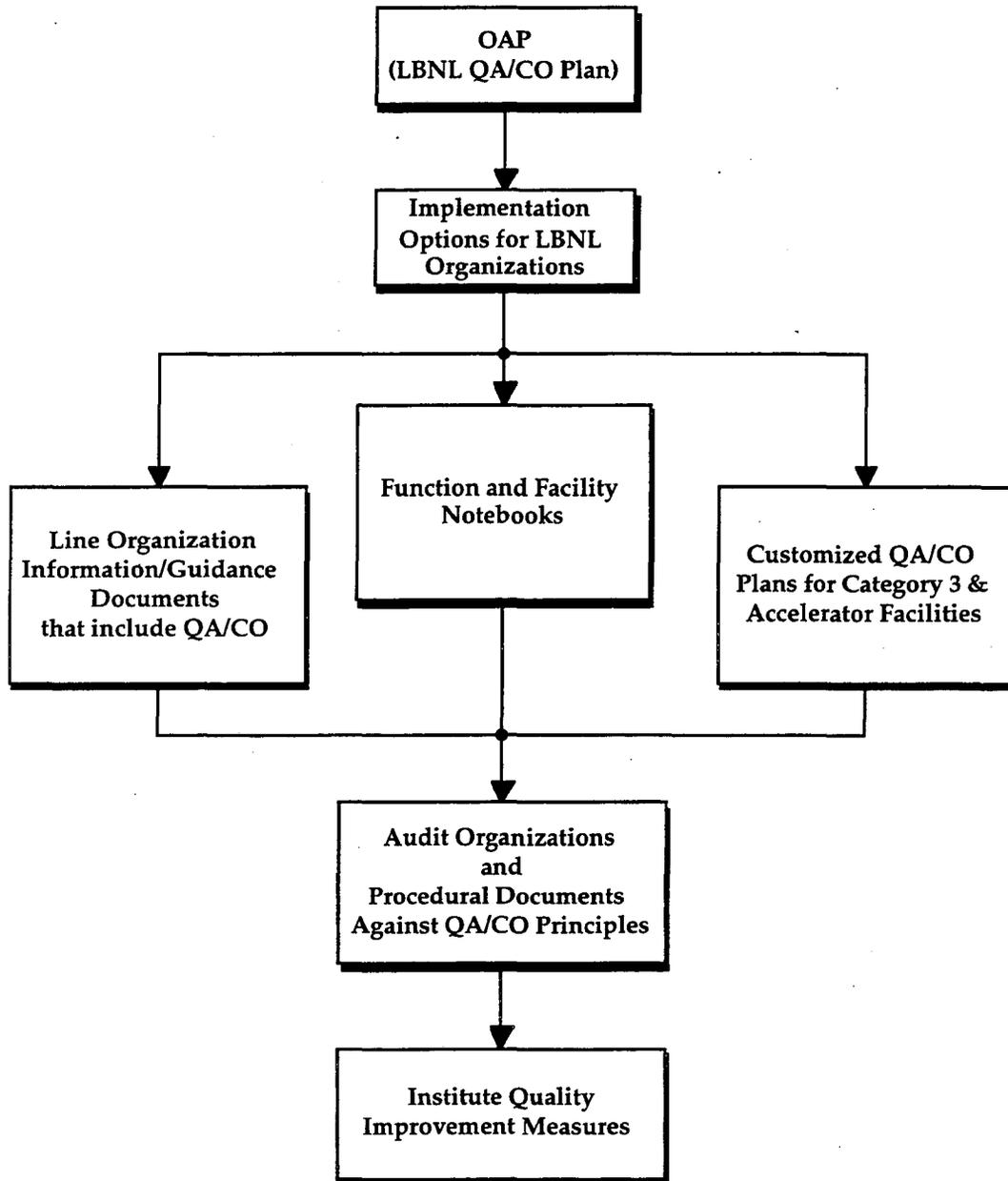


Figure 1: Berkeley Lab Quality Assurance and Conduct of Operations System

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## SECTION 1

### ORGANIZATION

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#### 1.1 Policy

Berkeley Lab organizations must:

- Describe their organizational structure.
- Plan for their functions and activities.
- Hire and retain staff proficient to perform their functions and activities.

An appropriate management structure, a proficient staff, and a systematic approach in planning work are key elements in sustaining a high level of performance. This section describes the steps for implementing these concepts throughout Berkeley Lab organizations.

#### 1.2 Organizational Structure

The Laboratory is, in general, organized hierarchically by divisions, departments, groups, and offices. A description of the organization must be maintained for each of these levels. This information is the basis for identifying the functional interfaces both within and between organizations.

The description of the organization should include the following information:

- The organization name.
- The primary function(s) or mission of the organization.
- The roles, responsibilities, and authorities of manager(s) and staff.

Organizational structure must be clearly communicated to all affected personnel. The organization should be described in institutional (Lab-wide), division, and/or unit documents. For Berkeley Lab divisions, the Function Notebook (see Appendix B) is the recommended vehicle to describe their organizations. For organizations operating in laboratories, shops, and other distinct work areas, the Facility Notebook (see Appendix B) is the appropriate document. Organization charts and position descriptions are the most common means to describe an organization.

## 1.3 Planning

Planning is a systematic approach to identifying beforehand the parameters and actions necessary to execute or arrange an activity, function, or project. It is an on-going process that begins as early as practical to allow sufficient time to address organizational interfaces; requirements for written procedures, drawings and equipment; and training needs for staff. Good planning generally results in higher efficiency, effectiveness, and quality in products and services.

Evidence of planning by Berkeley Lab organizations is required. Examples of planning include:

- Operation meetings (i.e., staff meetings, project meetings, program reviews, etc.).
- Research and program proposals that describe the work objectives and the proposed actions/steps.
- Implementation plans.
- Organizational policies and procedures.
- Performance measures and results.

## 1.4 Staff Proficiency

Staff proficiency involves hiring and retaining staff who have the appropriate skills, experience, and qualifications to carry out their work assignments successfully. To ensure consistent hiring practices, the Berkeley Lab Human Resources Department provides the institutional policies and procedures for personnel qualification, selection, and training (see the *Berkeley Lab Regulations and Procedures Manual [RPM]*, Section 2.00, Personnel). Berkeley Lab supervisors and managers must follow these requirements in their hiring of new staff.

Supervisors and managers must also ensure that the following activities related to staff proficiency are accomplished and documented for each individual in their organization:

- **Position requirements** must be established at the time of recruitment and selection. The requirements define the minimum education, experience, and skills necessary to fill the position. Requirements for certification and licenses are also identified at this time. Verification of the qualifications of the job candidates must also be done during the hiring process (see RPM 2.01).
- **Training needs** for each position must be determined and documented based on the scope, hazards, and complexity of the job and on any institutional and regulatory training requirements (see RPM 2.04).
- **Job orientation, ES&H training, required reading, and on-the-job training** must be completed as early as possible after the job assignment. Some training is required prior to the actual performance of work. On-the-job training must be administratively controlled to ensure that such

training is not allowed to impact workplace or operational safety (see RPM 2.01, 2.04).

- **Guest/visitor training or orientation** may be required based on the scope, length, hazards, and complexity of the job assignment. Training for guests and visitors must be documented (see RPM 1.06).
- **Periodic training and retraining** must be provided to ensure continued job proficiency and to improve overall performance (see RPM 2.04).
- **Performance evaluations** must be conducted at least annually for every position to ensure that job proficiency is being maintained and improved (see RPM 2.03, and the Annual *Human Resource Guidance on Performance Evaluations*).
- **Where appropriate, professional development plans** are developed to encourage staff to improve their knowledge, abilities, and skills. These plans are normally discussed during the individual's performance evaluation (P<sup>2</sup>R) (see RPM 2.03, 2.04F; and the annual *Human Resource Guidance on Performance Evaluations*).

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## SECTION 2

### PROCESS MANAGEMENT

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#### 2.1 Policy

Berkeley Lab organizations must manage their work processes by:

- Communicating clearly to affected staff the goals, objectives, and procedures of the work processes.
- Identifying and mitigating the hazards and risks of the work processes.
- Instituting process controls to enhance performance and quality.
- Establishing document and records control measures to ensure the availability of accurate information.

Process occurs when a combination of people, materials, equipment, and actions interacts to produce a given product or service. The management of the process is by the application of system controls to assure the quality of the product or service. This section describes the management controls deemed necessary for Berkeley Lab work processes.

#### 2.2 Communicating Processes

##### 2.2.1 Core Functions

---

Berkeley Lab organizations must identify and describe their core functions. Core functions are the key processes used to meet the organization's scientific or operational objectives. The description of core functions can be part of the organization description (see section 1.2).

##### 2.2.2 Written Procedures, Instructions, and Drawings

---

Core functions must have written procedures, instructions, and/or drawings to direct and inform personnel how to perform the functions in an efficient and safe manner. In addition to procedures for core functions, other Berkeley Lab work activities may require similar written procedures, based on the activity's complexity, ES&H hazard, programmatic or operational significance, and consequences to other organizations.

Procedures for core functions and other significant work processes must be formally written to ensure clarity and proper review and approval. The procedure should contain the following:

- Approval signatures and effective date.
- A unique title or other identifier.
- Purpose and scope.
- Definitions (for special acronyms or terms).
- Procedural work steps with associated responsibilities and controls.
- References (sources of requirements).

Activities with low or moderate significance or consequences (as determined by the supervisor or manager) may have less formal procedures or instructions, but these must be clear and concise. Notes, desk manuals, memos, operator aids, logbooks, notebooks, postings, and drawings are acceptable methods for this level of written communication.

Oral instruction, when it is the only communication method used, is not considered sufficient for directing and informing personnel on core functions or other significant work processes.

## 2.3 Hazards and Risks in the Work Process

Line managers must be cognizant of the hazards in their work processes and must institute safety controls to mitigate these hazards. The Berkeley Lab Environment, Health and Safety Division (EH&S) provides support and guidance to line managers for identifying and mitigating the hazards in their workplaces.

### 2.3.1 Identifying and Mitigating Hazards and Risks

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Materials, equipment and processes that are hazardous to personnel or the environment must be identified and communicated to affected personnel (see *Berkeley Lab Health and Safety Manual*, PUB 3000, for hazard information). All hazards in the work environment must be listed and available in the organization's operating document (e.g., Facility Notebook). For each hazard, a description of the effects of the hazard and the mitigation procedures must also be available. Mitigation procedures can be stand-alone safety procedures or integrated into the written operating procedures described in section 2.2.

### 2.3.2 Stop Work Authority

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All Berkeley Lab personnel are responsible for identifying unsafe work processes and for stopping the work if it is imminently dangerous. Berkeley Lab supervisors hold line responsibility for stopping unsafe work. This responsibility and authority overrides planning, cost, and schedule considerations.

Representatives of the EH&S Division also have the authority to stop work activities that constitute an imminent danger. If work processes are suspended for safety reasons, the work stoppage must be investigated and reported in accordance with the Occurrence Reporting Guidelines specified in the *Berkeley Lab Health and Safety Manual*. Work is resumed when authorized by the Berkeley Lab EH&S Division Director or designee.

## 2.4 Process Control

### 2.4.1 General Controls

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Process control is intended to reduce variation in the work process, thereby improving performance and quality. Line managers must review their core functions and other significant activities to ensure that appropriate controls are in place. Examples of process controls include:

- Check points in the process where management review and approval are required.
- Assurance that only qualified and trained personnel are assigned to perform the work.
- Assurance that only the appropriate equipment and material are being used.
- Assurance that up-to-date written procedures to direct the work are being used (see Section 2.2.2).
- Acceptance criteria for final review of end product or service.

**2.4.2 Function-Specific Controls**

If the Berkeley Lab organization's core functions include any of the activities listed in the tables below, additional controls as described are required.

**A. Design**

Activity	Application	Controls
Input	<ul style="list-style-type: none"> <li>• Hardware design</li> <li>• Facility design</li> </ul>	<ul style="list-style-type: none"> <li>• Identify and record:                             <ul style="list-style-type: none"> <li>– Design basis and performance criteria</li> <li>– Applicable codes, standards and regulatory requirements</li> <li>– ES&amp;H considerations</li> </ul> </li> <li>• Review and approve design input by the design organization and the requesting group</li> <li>• Control the design documents</li> </ul>
Interface	<ul style="list-style-type: none"> <li>• Hardware design</li> <li>• Facility design</li> </ul>	Define the coordination among participating organizations
Output	<ul style="list-style-type: none"> <li>• Hardware design</li> <li>• Facility design</li> </ul>	Ensure final documents resulting from the design input are: <ul style="list-style-type: none"> <li>• Approved prior to issuance</li> <li>• Identified uniquely and by revision status</li> <li>• Retained as part of the design organization's and requesting group's records management</li> </ul>
Change control	<ul style="list-style-type: none"> <li>• Hardware design</li> <li>• Facility design</li> </ul>	Approve and record all modifications to the final design by the original design organization or a technically competent designee
Verification	<ul style="list-style-type: none"> <li>• Hardware design</li> <li>• Facility design</li> </ul>	Conduct an independent review to verify the final design is technically adequate and complies with the design specifications and applicable standards and codes

**B. Procurement**

Activity	Application	Controls
General	Berkeley Lab scientific, operations, and administrative functions	Follow institutional procurement procedures as described by the University of California Procurement Policy and Standard Practices and on the Berkeley Lab World Wide Web.
Procurement planning	High cost items or services	<ul style="list-style-type: none"> <li>• Document procurement process to ensure adequate consideration for ES&amp;H, cost and schedule, quality assurance, and compliance with codes and technical specifications.</li> <li>• Complete the Advance Acquisition Plan (AAP) for procurements costing more than \$100K.</li> </ul>
Supplier and subcontractor selection	Nonstandard and non-off-the-shelf items or services	<ul style="list-style-type: none"> <li>• Evaluate vendor's capability and quality assurance record</li> <li>• Document selection</li> <li>• Periodically monitor to ensure continued qualification</li> </ul>
Acceptance of items and services	Services and items under contractual agreement	<ul style="list-style-type: none"> <li>• Document method of acceptance which can include: <ul style="list-style-type: none"> <li>– Receipt inspection</li> <li>– Verification testing</li> <li>– Surveillance of service provider</li> <li>– Certificate of conformance</li> </ul> </li> <li>• Segregate non-accepted items from satisfactory items</li> </ul>

**C. Inspection and Testing**

Activity	Application	Controls
Inspection	Operations requiring regular inspections as determined by line management	<ul style="list-style-type: none"> <li>• Include inspections as part of written operating procedures</li> <li>• Calibrate and maintain inspection equipment</li> <li>• Establish inspection schedule</li> <li>• Identify acceptance criteria</li> <li>• Retain inspection reports and follow-up actions</li> </ul>
Testing	<ul style="list-style-type: none"> <li>• Bench tests</li> <li>• Analytical laboratory</li> <li>• Pre-operational</li> <li>• Maintenance</li> <li>• Post-modification</li> </ul>	<ul style="list-style-type: none"> <li>• Identify acceptance criteria</li> <li>• Calibrate and maintain testing equipment</li> <li>• Retain test results that verify process or equipment are performing as specified</li> <li>• Place equipment test results on or near equipment to signify status of equipment or work process</li> </ul>
Follow-up on nonconforming items	Equipment or product that failed an inspection or test	<ul style="list-style-type: none"> <li>• Mark, tag, label, or post failure status on or near equipment or product</li> <li>• Segregate nonconforming item, if feasible</li> <li>• Retain re-test or re-inspection records that document correction of the nonconforming item</li> </ul>

**D. Data Collection**

Activity	Application	Controls
Design of data collection systems	Data from: <ul style="list-style-type: none"> <li>• Scientific investigations</li> <li>• Sampling and monitoring</li> <li>• Environmental remediation</li> </ul>	Develop operating procedures that include: <ul style="list-style-type: none"> <li>• Traceability to data collection or sampling activity</li> <li>• Validation of procedures to accepted standard or reference</li> <li>• Verification that all procedures are being followed</li> <li>• Handling and custody requirements</li> <li>• Statistical analysis</li> </ul>
Data and sampling control	Data from: <ul style="list-style-type: none"> <li>• Scientific Investigations</li> <li>• Sampling and monitoring</li> <li>• Environmental remediation</li> </ul>	<ul style="list-style-type: none"> <li>• Assign unique identifiers</li> <li>• Identify limitation of data or samples</li> <li>• Calibrate and maintain data and sampling equipment</li> <li>• Date and sign data collection and sampling document</li> <li>• Retain collection and sampling documents</li> </ul>

### 2.4.3 Facility-Specific Controls

Most facility operations require controls on operating practices, equipment, and hazards.

#### A. Operating Practices

Activity	Application	Controls
<b>Operating Practices</b>	Moderate to high hazard facilities	<ul style="list-style-type: none"> <li>• Ensure that the primary equipment and work processes have written operating procedures, including lockout/tagout procedures</li> <li>• Ensure that hazardous materials, equipment, and areas are labeled/posted</li> <li>• Ensure that appropriate hazardous waste procedures are being followed</li> <li>• For facilities with multiple shifts, use logbooks to issue directives, instructions, or status change information to incoming staff</li> <li>• For facilities with control rooms, ensure limited access; ensure duties of the control room operator are known and available</li> </ul>
<b>Emergency Procedures</b>	All occupied facilities	<ul style="list-style-type: none"> <li>• Identify the facility supervisor</li> <li>• Provide an emergency notification list with work and home phone numbers and alternate contacts</li> <li>• Have available an up-to-date building emergency plan</li> </ul>
<b>Communication Systems</b>	All occupied facilities	<ul style="list-style-type: none"> <li>• Regularly test emergency communication, radios and public address systems</li> <li>• Establish operating procedures for local systems</li> <li>• Ensure that posting and labeling in the facility are managed</li> </ul>

**B. Asset Management**

Activity	Application	Controls
<b>Traceability</b>	Equipment and other items determined by Berkeley Lab Property Management as being capital and sensitive items and requiring property control	<ul style="list-style-type: none"> <li>• Identify responsible person for each equipment and item requiring accountability</li> <li>• Conduct periodic physical inventory</li> <li>• Trace equipment and items back to specifications, procurement records, maintenance manuals, and other support documents</li> </ul>
<b>Calibration</b>	Measuring and test equipment (M&TE)	<ul style="list-style-type: none"> <li>• Physically mark M&amp;TE with unique identifier and re-calibration due date</li> <li>• Calibrate at prescribed intervals and against traceable standards</li> <li>• Specify limitations on range, accuracy and tolerance</li> <li>• Retain calibration records</li> </ul>
<b>Storage</b>	Physical assets with moderate to high cost value, hazard, or operational importance	<ul style="list-style-type: none"> <li>• Physically identify and control items with finite shelf life</li> <li>• Verify any special equipment or protective environment required for storage</li> <li>• Designate limited-access storage areas</li> <li>• Prevent damage, loss, or deterioration</li> </ul>
<b>Shipping, transfer and disposal</b>	Physical assets with moderate to high cost value, hazard, and/or operational importance	<ul style="list-style-type: none"> <li>• Conform to packaging requirements</li> <li>• Verify mode of transportation is adequate</li> <li>• Retain shipping, transfer and disposal documents (i.e., ensure traceability)</li> </ul>

**C. Maintenance Management**

Maintenance of research equipment (also referred to as programmatic equipment) is the responsibility of the operating organizations, since program/research funds are usually allocated for the purchase, maintenance, and operation of this type of equipment. Maintenance depends on the risk consequences of failure due to a lack of maintenance. Appendix A provides a graded approach for categorizing programmatic equipment based on risk consequences.

After categorizing the equipment, operating organizations should institute the following maintenance controls. Sample forms for organizing a maintenance program are provided in Appendix C. Blank forms are available electronically through the Facilities Department Work Request Center.

Activity	Application	Controls
<b>Equipment Identification</b>	All research (programmatic) equipment	Identify equipment by maintaining a completed Master Equipment List (MEL) (Appendix C, Form 1)
<b>Maintenance Requirements and Procedures</b>	Moderate to high risk equipment	<ul style="list-style-type: none"> <li>• Complete equipment profiles (Appendix C, Form 2) for moderate and high risk equipment from the MEL; the profile includes a general description of the equipment and the maintenance requirements as specified by the manufacturer or appropriate technical expert</li> <li>• Establish written maintenance procedures for high risk equipment</li> <li>• Perform independent verification that equipment is functioning after shutdown, repair, or regular time intervals</li> </ul>
<b>Training and Qualification</b>	Moderate to high risk equipment	Document the qualification of service contractors performing maintenance or repairs on moderate and high risk equipment; ensure that training records and certifications are on file
<b>Maintenance Schedule</b>	Moderate to high risk equipment	Establish maintenance schedules (Appendix C, Form 3) for moderate to high risk equipment; utilize the manufacturer's or in-house technical expert's recommendation for maintenance intervals
<b>Repair History</b>	Moderate to high risk equipment	<ul style="list-style-type: none"> <li>• Use the Equipment Maintenance Record (Appendix C, Form 4) or equipment logbooks to document all maintenance/repair performed</li> <li>• Retain the work orders for the predictive and preventive maintenance performed by the Facilities Department</li> </ul>

## 2.5 Document and Records Management

To ensure the availability of accurate information for Berkeley Lab work processes and other activities, documents and records are managed to provide for retention, preservation, assurances of currency, and retrievability.

- **Document Control** ensures that only approved and up-to-date documents establishing policy, prescribing work, or specifying requirements are available to users when needed. The Berkeley Lab Technical and Electronic Information Department (TEID) provides the institutional procedures for controlling the identification, preparation, review, approval, issuance, and cancellation of documents to ensure that only correct and current versions of documents are used in the work place or transmitted to outside entities. Documents requiring control are

selected by Laboratory or division management according to the hazard, complexity, and programmatic or institutional significance of the topic.

- **Records Management** ensures that records of completed activities are generated, maintained, and readily retrievable. Information and data that authenticate the organization's research, operational, or administrative activities are retained as evidence of completed work and adherence to standards and procedures. Most organizations will have records filed within their offices for easy retrieval. A records or file inventory must be established and maintained by the organization's administrative unit. Inactive records must be transmitted to the Berkeley Lab Archives and Records Office in accordance with retention and disposition requirements (see RPM 1.17)
- **Scientific and Technical Publications** are processed through the TEID Report Coordination Office, which assigns a report number, provides editing and printing services, and coordinates distribution. Publications receiving an LBL, PUB, or LBID number must be reviewed by a qualified reviewer for content and further reviewed by the Report Coordination Office to ensure compliance with Berkeley Lab publication requirements (see RPM 5.02) and DOE requirements (DOE Order 1430.2A).

## PERFORMANCE ASSESSMENT AND IMPROVEMENT

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### 3.1 Policy

Berkeley Lab organizations must regularly evaluate and improve the performance of their units by:

- Conducting self-assessments and peer reviews.
- Conducting independent performance assessments.
- Correcting any performance deficiencies noted from the assessments.

### 3.2 Self-Assessments

Berkeley Lab organizations must routinely (at least annually) evaluate their performance to identify, correct, and prevent problems that may hinder the organization in achieving its scientific or operational objectives. Self-assessments can also affirm that objectives and goals are being met. The primary Berkeley Lab management systems for self-assessments are:

- **Management Assessments.** Line managers and division administrators routinely evaluate the performance of their work processes and take an active role in improving performance and seeking excellence. These assessments can be readiness reviews, design reviews, quality control inspections, program reviews, and other reviews to ensure that performance is at a satisfactory level.

A major management assessment activity is the self-assessment of performance against objectives identified in the UC-DOE Contract Agreement ("Contract 98, Appendix F"). Designated functional managers must measure the performance of their units in meeting these contract performance objectives.

- **Berkeley Lab Self-Assessment Program.** This program conducts reviews to ensure that environment, safety and health (ES&H) and quality assurance concerns are routinely addressed by Berkeley Lab organizations. The Self-Assessment Program provides a structured process to perform routine inspections, track corrective actions, and conduct root cause analyses, institute lessons learned, and perform trend

analyses. The program elements and requirements are described in the *Berkeley Lab Self-Assessment Program Implementation Plan* (PUB-5344) and the *Berkeley Lab Self-Assessment Manual* (PUB-3105).

- **Peer Reviews.** These reviews are evaluations of scientific or operational programs and projects conducted by peers in that particular field. Reviewers cannot have direct responsibility in the areas being reviewed.

### **3.3 Independent Assessments**

Berkeley Lab independent assessments are internal reviews performed routinely by the Environment, Health and Safety Division, the Internal Audit Services Department, the Office of Assessment and Assurance, and the Safety Review Committee. All of these reviews are performed by technically and programmatically knowledgeable personnel within Berkeley Lab who are free of direct responsibility in the areas they assess. Each assessment organization has established a protocol for conducting assessments. This protocol is made available to assessed organizations before the review.

### **3.4 Corrective Actions**

Findings, concerns and deficiencies identified in an assessment should be addressed immediately. If corrective action cannot be done on-the-spot, a corrective action plan should be prepared to allow for additional planning and scheduling. The tasks identified in a corrective action plan are tracked through the Berkeley Lab Corrective Action Tracking System (LCATS) for external assessments and institutional concerns and the Berkeley Lab Self-Assessment Tracking Database (LSAD) for divisional concerns. Corrective actions are tracked until completion and management verification.

To ensure effective corrective action, line management, with assistance from EH&S and OAA, performs root cause analysis and develops lessons-learned to prevent problems from recurring. Such activity is commensurate with the hazard, significance and consequence of the problem.

## APPENDICES

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## The Graded Approach Methodology at Berkeley Lab

### Introduction

A graded approach is used to determine the rigor with which the requirements of the Operating and Assurance Program (OAP) should be applied to a given Laboratory activity. The objective is to ensure that work activities are managed through systems that are adequate and commensurate with the risk involved in the activity. Risks include potential impact to health and safety, threats to the environment, consequences of noncompliance, and impact on cost.

### Methodology

- Line management defines the facilities and functions for which it is responsible. These definitions should include a characterization of the on-going activities performed, space and types of equipment utilized, and personnel involved (both Berkeley Lab and non-Berkeley Lab).
- The activity associated with a facility or function is analyzed to determine the level of risk it entails. Risk is a function of the negative consequences that may result if an appropriate level of management control is not applied to prevent these negative consequences. The analysis is performed by considering the nine risk-potential categories described in Table A-1. The categories are consistent with those contained in the Berkeley Lab Risk-Based Priority Planning Grid.\* Three sets of consequence statements are provided for each category: high risk (H), moderate risk (M), and low risk (L).
- Critical to assessing risk is the probability that an event will occur. In analyzing the risk inherent in each activity, one must estimate the likelihood that the potential risk level may be encountered. Operating experience, commonly accepted statistical probabilities, best-management information, or other relevant data can be used to estimate the likelihood of the worst-case scenario. Care should be taken to consider cost effectiveness when developing management controls for an event. Laboratory line managers should balance the probability of an event occurring with the potential consequence (or cost) of achieving an effective set of such controls.
- Based upon this risk analysis, line management determines the rigor to use in applying the OAP requirements to their operations. This approach

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\*Note: The Berkeley Lab Grid is based upon the Risk Prioritization Methodology contained in the DOE-EH 5-Year Safety and Health Planning Guidance.

will result in determining the degree to which documentation and training are to be implemented. The line organization then has a documented approach as to why one or more activities within a facility or function have a high level of rigor (e.g., a very detailed written procedure) while others rely on standard operating procedures or guidelines (e.g., RPM, PUB-3000, or standard laboratory, shop, or business practices).

- As conditions change, as a result of the self-assessment process, or as performance problems are identified, the graded approach for each facility and function is reviewed to determine whether OAP requirements continue to be met in an appropriate and cost-effective manner.

**TABLE A-1. RISK POTENTIAL ANALYSIS USING THE  
BERKELEY LABORATORY PRIORITY PLANNING GRID (RISK BASED)**

For each risk category pick the statement that best characterizes the potential consequence of a failure to apply Quality Assurance principles to your activity.

RISK CATEGORY		CONSEQUENCE CATEGORY		
		High	Moderate	Low
E S & H  H A Z A R D  R E G U L A T O R Y  P R O G R A M M A T I C	Public Safety	Loss of life or serious injury; exposure to hazardous materials in excess of standards	Reportable non-process-related accident	Minor non-reportable events
	Researcher and Staff Safety	Loss of life or serious injury; exposure to hazardous materials in excess of standards	Reportable on-site work accident; exposure near acceptable limits	Minor events not resulting in hospitalization; exposures below 20% of limits
	Environmental Protection	Serious damage to the environment	Release of hazardous material exceeding established limits; repairable damage	Unplanned release within established limits; minor reportable events
	Compliance with Law, Contract Agreement, Regulation	Noncompliance with laws or regulations with possible penalties	Minor technical or administrative violation(s)	Little or no adverse regulatory results
	Compliance with DOE Orders		Noncompliance with DOE orders	Little or no adverse regulatory results
	Best Management Practice		Significant deviation from good practice	Minor deviation or slow implementation
	Berkeley Lab Mission/ Programmatic Impact/Berkeley Lab Support Services	Failure to meet critical milestone; could lead to Berkeley Lab shutdown; non-delivery of significant services; results in corrective action by DOE	Failure to meet internal DOE program commitments; high impact service reductions	Minor degradation in performance, cost, schedule
	Laboratory Protection	Facility or equipment damage >\$500K	Facility or equipment damage <\$500K; increased operations cost to \$250K	Equipment damage or operations cost to \$50K
	Public Perception	National press coverage; public demonstrations	Local press coverage; some public concern by special interest groups	Little or no public concern

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## Implementation Matrix for the Operating and Assurance Plan

The enclosed implementation matrix describes the requirements of the OAP. For each requirement, the line organization must identify their implementing document, with the title and applicable section(s) specified. Berkeley Lab line organizations can utilize three types of documents to implement the OAP:

- **Institutional Documents** are Berkeley Lab publications, manuals, directives, etc. that provide Laboratory-wide guidance for performing certain functions. Examples of institutional documents are the *Environment, Health and Safety Manual* (PUB-3000) and the *Regulations and Procedures Manual* (RPM). Users should always contact the functional organization providing the guidance to ensure that the most current policies and procedures are being followed. The most current documents on many occasions are also available electronically on the Laboratory's World Wide Web pages.
- **Line Organization Documents** are documents and manuals developed and maintained by the line organization to direct and document their operations. Examples of line organization documents include operating procedures and policies, logbooks, operational records, and customized quality assurance and conduct of operations plans.
- **Notebooks** are the prescribed documents designed specifically to implement the requirements of the OAP. There are two types of Berkeley Lab Notebooks:

**Function Notebooks** pertain to the administrative activities of Berkeley Lab divisions and any support or service organization funded from overhead, scientific burden, or recharge. These Notebooks focus on the quality assurance of the organization's functions. Examples include: Division administrative offices, Procurement Department, Facilities Department, and Environment, Health and Safety Division.

**Facility Notebooks** pertain to the operations or research activities conducted within a location or major work area. These Notebooks focus on the quality assurance and conduct of operations in the use of material and equipment to support the facility activities. Typically, Facility Notebooks are necessary when there is a significant hazard in the operation or research. Examples include: a research building or laboratory, a machine shop, or a plating shop.

Matrix forms are available electronically in the Public Folder on the OPS OAA Server, ALD zone (Appleshare).

The completed matrix is retained by the line organization in the implementing document. A copy should be readily available for auditing purposes.

## **Preparing Notebooks**

If Notebooks are to be utilized for the operation, the completed matrix provides guidance on the type and content of the Notebooks. The check marks in the two right-hand columns of the matrix designate which type of Notebook—Function or Facility—is the most appropriate vehicle to meet OAP requirements. In many cases, either Notebook is appropriate.

For each applicable OAP requirement, the Notebook should describe the operating procedures or reference the operating records that fulfill that requirement. There is no prescribed format for the Notebooks, although it is recommended that Notebooks be organized to follow the sections of the OAP.

Notebooks should be updated at least annually to ensure that information on the organization and operating procedures are the most current.

## Implementation Matrix for Operating and Assurance Plan (OAP)

Department/Group: \_\_\_\_\_ Division: \_\_\_\_\_ Location: \_\_\_\_\_  
 Preparer: \_\_\_\_\_ Phone Number: \_\_\_\_\_ Date: \_\_\_\_\_

**Instructions:** Berkeley Lab line organizations must identify the documents used to implement the requirements of the OAP. *Institutional documents* are Berkeley Lab publications, manuals, directives, etc. that provide Laboratory-wide guidance. *Line org. documents* are operating procedures and records developed and maintained by the line organization. *Notebooks* are the OAP-specific implementing manuals prepared by the line organization. All documents should be identified by their title and the applicable section(s). If an OAP requirement is not applicable to the line organization, check the "NA" column. If Notebooks are used as the implementing document, the recommended type of Notebook (i.e., either Facility or Function Notebooks) is designated by the check marks in the two far right columns.

OAP		Implementing Documents					
Section	OAP Requirements	NA	Institutional Documents	Line Org. Documents	Notebooks	Func	Fac
<b>1. Organization</b>							
1.2	The organizational structure, functions, roles, responsibilities, and authorities are described.					√	√
1.3	Planning of functions and activities is routinely conducted and documented.					√	
1.4	Personnel are hired who have the skills, experience, and qualifications to carry out their work assignments successfully.		RPM, Chap. 2			√	√
1.4	Personnel receive initial and on-going training to ensure continued job proficiency.		RPM, Chap. 2			√	√
<b>2. Process Management</b>							
2.2.2	Core functions and other work activities have written procedures, instructions, and/or drawings.					√	√
2.3.1	Workplace hazards are identified and documented.		PUB 3000				√
2.3.1-2	Hazard mitigation measures are communicated to personnel.						√

Section	OAP Requirements	NA	Institutional Documents	Line Org. Documents	Notebooks	Func	Fac
2.4.1	Process controls are in place to ensure proper personnel, procedures, equipment, and/or materials are used for functions and activities.						√
<b>2.4.2 Function-Specific Controls</b>							
2.4.2.A	Controls are in place for design input, interface, output, and design change.					√	
2.4.2.A	Final designs are independently verified and validated for adequacy.					√	
2.4.2.B	Procured items and services meet established procurement requirements		Univ. of Calif. Procurement Policy & Standard Practices			√	
2.4.2.B	Prospective suppliers and subcontractors are evaluated and selected on the basis of specified criteria.		Univ. of Calif. Procurement Policy & Standard Practices			√	
2.4.2.B	Method of acceptance of procured items and services is established.		Univ. of Calif. Procurement Policy & Standard Practices			√	
2.4.2.C	Inspection and testing of items, services, and processes are conducted using established acceptance and performance criteria.					√	
2.4.2.D	Data collection and sampling are conducted using established operating procedures and performance criteria.					√	
<b>2.4.3 Facility-Specific Controls</b>							
2.4.3.A	Written procedures are in used to direct personnel to operate in moderate to high hazard facilities.						√
2.4.3.A	A <i>Facility Supervisor</i> has been designated.						√
2.4.3.A	Building emergency plans and notification phone lists are up-to-date.						√
2.4.3.A	Facility communication systems have established protocol and are tested.						√

Section	OAP Requirements	NA	Institutional Documents	Line Org. Documents	Notebooks	Func	Fac
2.4.3.B	Equipment is identified and controlled.		<ul style="list-style-type: none"> <li>• UC Laboratories Joint Property Management Policies and Procedures</li> <li>• Property Management Guide (PUB 3032)</li> <li>• RPM, sec. 6.02-6.03</li> </ul>				√
2.4.3.B	Measuring and test equipment (M&TE) are calibrated as required.						√
2.4.3.B	Equipment is handled and stored to prevent damage, loss, or deterioration.		<ul style="list-style-type: none"> <li>• UC Laboratories Joint Property Management Policies and Procedures</li> <li>• Property Management Guide (PUB 3032)</li> <li>• RPM, sec. 6.02-6.03</li> </ul>				√
2.4.3.C	Research equipment is identified and categorized on a <i>Master Equipment List</i> .						√
2.4.3.C	Research equipment profiles and maintenance schedules are maintained.						√
2.4.3.C	Research equipment repair histories are on file.						√
<b>2.5 Document and Records Management</b>							
2.5	Documents are prepared, reviewed, approved, issued, used, and revised in accordance with prescribed procedures.					√	√
2.5	Records are specified, prepared, reviewed, approved, and maintained.					√	√
2.5	Scientific and technical publications are reviewed and approved prior to publication.		RPM, sec. 5.02			√	
<b>3. Performance Assessment and Improvement</b>							
3.2	Managers and staff routinely assess their processes to detect and prevent quality problems.		<ul style="list-style-type: none"> <li>• Self-Assessment Program Implementation (PUB 5344)</li> <li>• Self-Assessment Manual (PUB 3105)</li> </ul>			√	√

Section	OAP Requirements	NA	Institutional Documents	Line Org. Documents	Notebooks	Func	Fac
3.3	Independent assessments are planned and conducted according to established protocol.					√	√
3.4	Deficiencies noted from assessments are identified and corrected.		<ul style="list-style-type: none"> <li>• Berkeley Lab Corrective Action Tracking System (LCATS)</li> <li>• Berkeley Lab Self-Assessment Tracking Database (LSAD)</li> </ul>			√	√
3.4	Root-cause and lessons-learned analyses are conducted to prevent recurrence of the deficiencies.					√	√

**Maintenance Management of Programmatic Equipment  
(Forms)**



	LAWRENCE BERKELEY LABORATORY <b>System/Equipment Profile</b>	Form 2
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**General System/Equipment Information**

Description MOCVD Reactor

Manufacturer Emcore Model GS 3000

Property ID No. 6146770 Serial No. N/A Acquisition Date 1989

Pr. Investigator: Jack Armstrong Div: MSD Bldg: 2 Room: 256 Ext: 2200

**Connections / Interface of Programmatic Equipment to LBL Facility Utilities**

Water  
  Gas/ventilation  
  Sanitary sewer  
  Other \_\_\_\_\_  
 LCW  
  Vacuum  
  Acid waste

**Hazards and Hazard Prevention**

Hazard Category moderate

Safety documentation for equipment/system:  AHD    SAR    SAD

Toxic, flammable or radioactive substances used with equipment (yes/no): yes

Lockout/Tagout considerations: Breakers 12A33 and 12B23C12 must be locked out

Safety systems related to safe operation:

Support Equipment interlocks (yes/no) <u>yes</u>	Gas Monitors/Detectors
Electrical interlocks (yes/no) <u>yes</u>	<u>MDA &amp; Rad 80</u>
Radiation interlocks (yes/no) <u>no</u>	_____
Audible alarms (yes/no) <u>yes</u>	_____

**Maintenance Information**

Frequency of use (will affect maint frequency):  heavy (daily)    frequent (weekly)    occasional

Maintenance performed by:  Service Contract with: \_\_\_\_\_  
 In-house personnel trained for calibration/maintenance  
 M&O

Training verified: \_\_\_\_\_

Maintenance procedures:

mfr manuals

in-house developed \_\_\_\_\_

other: \_\_\_\_\_

Location of Procedures/Manuals: In cabinet next to equipment

Location of Repair History Records: Maintenance logbook in cabinet beside equipment



LAWRENCE BERKELEY LABORATORY

Form 3

## Maintenance Program/Schedule

### General System/Equipment Information

Description MOCVD Reactor  
 Manufacturer Emcore Model GS 3000  
 Property ID No. 6146770 Serial No. N/A Acquisition Date 1989  
 Pr. Investigator: Jack Armstrong Div: MSD Bldg: 2 Room: 256 Ext: 2200

### Maintenance Program/Schedule

<u>Device/Component</u>	<u>Planned Maint. or Calibration</u>	<u>Maint Freq (wks)</u>	<u>To be done by</u>	<u>Post Mnt Tst</u>
<b>Hazard Prevention Devices</b>				
<u>Pressure Regulator Valve</u>	<u>calibrate</u>	<u>52</u>	<u>Reg Shop</u>	<u>yes</u>
<u>Pressure Gauges</u>	<u>calibrate</u>	<u>52</u>	<u>Reg Shop</u>	<u>yes</u>
<u>Indicator Lights</u>	<u>verify operation</u>	<u>13</u>	<u>Reg Shop</u>	<u>yes</u>
<u>Panic Switch</u>	<u>verify operation</u>	<u>13</u>	<u>Reg Shop</u>	<u>yes</u>
<u>Sensors</u>	<u>verify operation</u>	<u>13</u>	<u>Reg Shop</u>	<u>yes</u>
<u>Audible Alarms</u>	<u>verify operation</u>	<u>13</u>	<u>Reg Shop</u>	<u>yes</u>
<b>Major Components</b>				
<u>Motor</u>	<u>inspect</u>	<u>13</u>	<u>Fac</u>	<u>no</u>
<u>Drive Belts</u>	<u>inspect</u>	<u>13</u>	<u>Fac</u>	<u>no</u>
<u>Bearings</u>	<u>inspect</u>	<u>13</u>	<u>Fac</u>	<u>no</u>

### Additional Information

Exhaust gases piped to CDO for safe disposal. CDO to have maintenance with MOCVD.



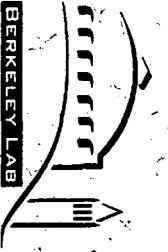
LAWRENCE BERKELEY LABORATORY

**Equipment Maintenance Record**

Equip. Description: Exhaust gas conditioner (CDO) Prop ID#: 6219982 Serial # \_\_\_\_\_ Pr. Investigator: \_\_\_\_\_

Complaint Date	Nature of Complaint	Repairs/Calibration Done	Parts Replaced	Done By	Hrs	W.O./P.O. No.	Post Maint Testing	
							Date	Done by

Comments



BERKELEY LAB

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