



# **OPERATING AND QUALITY MANAGEMENT PLAN**

**LBNL/PUB-3111, Rev. 10**

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## Review and Approval

The Department of Energy and Lawrence Berkeley National Laboratory Office of Institutional Assurance approve the Operating and Quality Management Plan.

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## Record of Revisions

Rev. No.	Date	Description
3	DRAFT (11/11/92)	Rewrite of the LBL <i>Institutional Quality Assurance Program Plan, Rev. 2</i> , dated December 21, 1988, to incorporate requirements of DOE Order 5700.6C.
3	2/3/93	Comments incorporated. Issued to Laboratory for use.
4	6/15/94	Updated in the following areas: -suspect/counterfeit parts program -maintenance management -DOE Order 5480.25, <i>Accelerator Safety</i> -total quality management -general editorial
5	1/15/96	Rewrite of OAP, Rev. 4
6	1/15/98	Revise to integrate with ISMS
7	4/18/00	Updated in the following areas: - 10 CFR 830.120 and 414.1, <i>Quality Assurance</i> - conduct of operations - maintenance management
8	12/06	Rewrite of the LBNL <i>Operating and Quality Management Plan</i> , dated April 18, 2000, to incorporate requirements of DOE Order 414.1C and ISO 9001-2000. Also updated to reflect current LBNL organizations and operations. Appendix D demonstrates how OQMP addresses DOE O 414.1C requirements.
9	06/08	Clarified section 2.7, Document Control policy.
10	10/08	Clarified and expanded upon section 2.6.5, Software Quality Assurance

## Statement of Laboratory Policy

It is the policy of the Ernest Orlando Lawrence Berkeley National Laboratory (LBNL) to carry out all our activities in a reliable, safe, and quality manner. The Operating and Quality Management Plan (OQMP) provides the framework for a results-oriented management system that focuses on performing work safely and meeting mission and customer expectations efficiently through continuous process improvement. It is line management's responsibility to set and execute annual performance objectives. In addition, every LBNL employee is individually responsible for the quality and safety of his or her work.

It is our policy to implement the OQMP in a way that enables compliance with DOE quality assurance requirements and other customer's agreements, that ensures our continued scientific research and programmatic success, and that is resource-efficient. The OQMP is integral towards keeping the Laboratory on course in achieving its mission and eliminating non-conformances and unacceptable risks. Our program emphasizes three principles:

- The most essential resources at LBNL 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.

Director  
Ernest Orlando Lawrence  
Berkeley National Laboratory

## Objectives and Applicability

The LBNL Operating and Quality Management Plan (OQMP) is a set of operating principles, requirements, and practices used to support LBNL organizations in achieving reliable, safe, and quality performance in their work activities. The OQMP is designed to fulfill three main objectives:

- Describe the elements necessary to integrate quality assurance, management systems, and process controls into Laboratory operations.
- Provide the framework for LBNL administrators, managers, supervisors, and staff to plan, manage, perform, and assess their work.
- Comply with the contractual and regulatory requirements specified in DOE-University of California (UC) Contract No. DE-AC02-05CH11231, DOE O 414.1C, *Quality Assurance*, 10 CFR 830, Subpart A, *Quality Assurance Requirements*, DOE O 5480.19, Paragraph 4, *Conduct of Operations*, DOE P 450.4, *Safety Management System Policy*, and DOE O 226.1, *Implementation of DOE Oversight Policy*.

The OQMP applies to all LBNL organizations. All LBNL operating units should be engaged, at some level, with organizing their resources, managing and ensuring the safety and quality of their processes and activities, and evaluating the results of their performance. However, the level of rigor in applying the OQMP principles, requirements, and practices 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, environment, and the general public. Appendix A contains one methodology that can be used to grade processes, activities, and facilities to determine the applicable level of rigor. Alternate methodologies, such as the use of DOE guidance documents or EH&S hazard reviews, may be used if the rationale is appropriately documented and approved.

Depending on contractual or regulatory requirements, certain organizations may require additional program- or facility-specific plans to ensure that relevant policies, administrative and work procedures, and technical information are provided to affected individuals. LBNL radiological facilities apply the OQMP through the Lab's Radiation Protection Program to meet the quality assurance requirements of 10 CFR 830, Subpart A. The use of national or international consensus standards is encouraged for organizations that have unique or specific work activities that require consistent results and/or conformity to specifications.

### Offices of Institutional and Contract Assurance

The Director of the Office of Institutional Assurance (OIA) is the senior LBNL manager who has the responsibility and authority to develop, implement, assess, and improve the LBNL Operating and Quality Management Plan. Under the Director's charge, staff from the Office of Contract Assurance (OCA) has the day-to-day operational responsibility to ensure that compliance, scientific excellence, best management practices, and continuous improvement are achieved at LBNL. In partnership with LBNL line management, the OCA regularly monitors project performance, develops and tracks performance metrics and leading indicators, identifies and

records deficiencies, and organizes independent project and performance reviews. The OCA has critical oversight, feedback and process improvement roles with respect to performance deficiencies and maintains centralized tracking of corrective actions and lessons-learned for regular reporting to relevant line managers, the Laboratory Directorate, UC Office of the President (UCOP), the UC LBNL Contract Assurance Council, and the DOE/ Berkeley Site Office.

The Director of OIA ensures that the OQMP is in conformance with the requirements of DOE O 414.1C, *Quality Assurance*, and with applicable elements of ANSI/ISO/ASQ Q 9001-2000, the international consensus standard for quality assurance. Appendix D delineates OQMP conformance with quality assurance requirements and standards.

# Section 1

## Organization

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

### 1.1 Organizational Structure

The Laboratory is 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 responsibilities, levels of authority, and interfaces both within and among organizations. Organizational information must be clearly communicated to all affected Lab personnel and guests.

The description of the organization should include the following information:

- The organization name
- The core function(s) or mission of the organization
- The roles, responsibilities, and authorities of manager(s) and staff, including clear and concise safety responsibilities

The recommended and official vehicle to describe Laboratory organizations is through the LBNL internet web site (<http://www.lbl.gov/Workplace/organization.html>). Each division is responsible for maintaining the currency of its organization chart in both printed and electronic versions.

Roles, responsibilities, and authorities of managers and staff must be clearly defined in position descriptions and/or job expectations. Environment, safety, and health responsibilities and duties must be part of the description and expectation. Such information should be reviewed and updated at least annually. Safety roles and responsibilities for managers and staff are detailed in the LBNL Health and Safety Manual (LBNL PUB-3000).

### 1.2 Planning

Planning is a vital step in implementing a quality work process. Planning is a systematic approach used to identify, in advance, the parameters and actions necessary to execute or arrange an activity, function, or project. Good planning generally results in higher efficiency, effectiveness, safety, quality in products and services, and customer satisfaction. It is an ongoing process that begins as early as practical to allow sufficient time to address issues such as the following:

- Funding
- Organizational interfaces and authorities for those managing, performing, and assessing work

- Resource allocation
- Requirements for written procedures and drawings
- Identification of work standards and requirements
- Identification of safety, environmental and security requirements and controls
- Staff training needs

Evidence of organizational planning is required. Examples of planning include:

- Strategic plans
- Operation and planning meetings (e.g., staff meetings, project meetings, program reviews)
- Research and program proposals that describe the work objectives and the proposed actions/steps
- Work plans or work authorizations that address work objectives, resource requirements, work hazards, and the implementation of safety controls
- Work or project schedule
- Operational policies and procedures
- Division integrated safety management plans that describe each division's environment, safety and health management system
- Performance measures and results

### 1.3 Staff Proficiency

Staff proficiency involves hiring and retaining staff who have the appropriate skills, experience, and qualifications to carry out their work assignments successfully and safely. To ensure consistent hiring practices, the Human Resources Department provides the institutional policies and procedures for personnel qualification, selection, and training. [See the LBNL *Regulations and Procedures Manual (RPM)*, Chapter 2, *Personnel*.] Supervisors and managers must follow these requirements in hiring 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. Candidates' qualifications must also be verified 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 adversely affect work quality 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 and safety (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. This process is described in the Performance Evaluations Guidance issued annually by Human Resources. (See RPM 2.03.)
- **Where appropriate, professional development plans** are developed to encourage staff to improve their knowledge, abilities, and skills. These plans require management approval. This process is described in the Performance Evaluations Guidance issued annually by Human Resources. (See RPM 2.03, 2.04D.)



## Section 2

# Management Systems and Process Controls

### 2.1 Managing Principles

Management develops and implements the management systems and controls to direct the execution of work at the Laboratory. To address the interaction between people, materials, equipment, and actions unique to a national laboratory, the systems and controls must include the following underlying principles of good management:

- **Conduct of Operations:** Management, in particular the Laboratory Director, sets the tone for conduct and behavior in the work environment. The foundation for appropriate conduct and behavior is integrity, ethics, and competency. This draws people to follow rules and regulations, produce quality services and products, embrace Laboratory stewardship, and interact with co-workers appropriately.
- **Information and Communication:** Pertinent information is identified and communicated in a form and timeframe that enables personnel to carry out their duties and responsibilities. At the onset of employment, all personnel must receive clear information of management expectations and the operating principles described herein. During employment, means of communication should be two-way and on-going, allowing both management and staff to initiate discussions on work issues. Information systems should readily provide reports and data on Laboratory performance and results so that line managers, supervisors, and staff can act upon the information as necessary. Key Laboratory functions, such as operations, finance, and compliance, are especially dependent on having timely and accurate reports and data.
- **Risk Assessment:** At all organizational levels and functions, risks to achieving work objectives and risks to workers, the public, and the environment must be continuously assessed and controlled. Organizational units must assess work activities to minimize adverse impacts while maximizing reliability and performance of work. Risk assessments by Laboratory units are in addition to the assessments conducted by independent third parties or the LBNL Office of Institutional Assurance.
- **Controlled Work:** Work is executed by following prescribed policies and procedures. Work within the framework of policies and procedures helps to ensure that Laboratory Management's directives are carried out. When the policies and procedures are not followed, the work is not authorized, and actions must be taken to address the nonconformance and potential risks arising from the non-authorized work. For work that has higher risk significance, authorization requires greater formality than only policies and procedures. Formal work authorizations can take the form of written approvals, authorizations, and verifications; documented reconciliation processes, and formal reviews of operating conditions, security of assets, and delineation of duties.
- **Monitoring:** Management systems and process controls need to be monitored – a process that assesses the efficiency and effectiveness of the systems and controls over time. This is accomplished through on-going monitoring by managers, supervisors, and staff in the course of performing their duties. The scope and frequency of monitoring is dependent on the assessment of risks and the effectiveness of the monitoring procedures. Monitoring by Laboratory units is in addition to the reviews conducted by independent third parties or the LBNL Office of Institutional Assurance.

## 2.2 Safety Management

### 2.2.1 Hazards in the Work Process

Safety must be integrated into the work process. For all core functions and other significant activities, line managers must implement an integrated safety management process as outlined in Appendix B to ensure that safety-related work issues have been addressed comprehensively. At a minimum, line management must have auditable evidence of the identification and control of hazards in their responsible workplace. Managers must follow the requirements in Chapter 6 of LBNL PUB-3000, *Health and Safety Manual*, to identify hazards and implement appropriate controls. LBNL's Environment, Health and Safety Division (EH&S) and division ES&H personnel provide the support and guidance to line managers for identifying and mitigating the hazards in their workplaces.

All line managers must perform the following safety functions:

- Define the scope of work
- Analyze the hazards
- Develop and implement controls
- Perform work within the controls
- Provide feedback and continuous improvement

Documentation of the above functions can be in work plans, division ES&H reports, or authorization/contract agreements.

### 2.2.2 Formal Work Authorization

Depending on the programmatic or operational significance and environment, safety, and health consequences, some work processes may require formal work authorization from the management of LBNL organizations. Formal authorization is a review and approval process by management to ensure that appropriate procedures, controls, and resources are in place before the work begins. Formal authorization results in a written document that describes:

- The scope of work
- Required procedures and controls
- Authorized materials and equipment to be used
- Authorized staff to conduct the work

The document must be signed off by the appropriate manager(s) and/or staff to signify approval of such work.

When formal authorization is not warranted based on a graded approach (see Appendix A), line managers must still review and approve work under their supervision. Line authorization need not be formalized into an authorization document. Work plans, position descriptions, and job expectations are acceptable vehicles for line authorization.

Regardless of the type of authorization, all managers and staff must consider the following work principles in the review and approval of their work:

- Line management accountability
- Clear roles and responsibilities

- Competence commensurate with responsibilities
- Balanced priorities
- Identification of work quality and safety standards
- Conditions and requirements for performing work
- Work and hazard controls tailored to the work being performed

### 2.2.3 Stopping Unsafe Work

All LBNL employees, contractors, and participating guests are responsible for stopping work activities considered to be an imminent danger. Stopping unsafe work applies to all activities conducted at the Laboratory and to all off-site facilities operated by Laboratory personnel (PUB-3000, section 1.5).

An “imminent danger” is defined as any condition or practice that could reasonably be expected to cause death or serious injury, or environmental harm. Whenever an employee, contractor, or participating guest encounters conditions or practices that appear to constitute an imminent danger, such individuals have the authority and responsibility to:

- Alert the affected employee(s) or contractor(s) engaged in the unsafe work creating an imminent-danger condition and request that the work be stopped.
- Call LBNL incident notification telephone number (x6999) and report the incident. EH&S staff will investigate.
- Notify the immediate supervisor and/or responsible division/department manager (if known).

EH&S staff will ensure that the supervisor is notified and will assist the supervisor in preparing a report to the EH&S Division Director, describing the unsafe activity and identifying corrective actions and responsibilities.

## 2.3 Environmental Management

Executive Order 13148, *Greening the Government Through Leadership in Environmental Management*, and DOE Order 450.1, *Environmental Protection Program*, have both mandated the development of Environmental Management Systems (EMS) to implement sound environmental stewardship practices that:

- Protect the air, water, land, and other environmental resources potentially impacted by facility operations and
- Meet or exceed applicable environmental laws and regulations.

LBNL has established a documented EMS that: 1) Complies with applicable environmental and public health laws and regulations; 2) prevents pollution and conserves natural resources; and 3) continually improves the Laboratory’s environmental performance. Detailed information on the LBNL EMS, including environmental aspects, current objectives and targets, and environmental assessment reports can be found at: <http://www.lbl.gov/ehs/esg/emsplan/emsplan.htm>.

LBNL managers, employees, and guests who have activities that may impact the environment must assume their individual responsibility for environmental stewardship. At a minimum, they must:

- Strictly comply with all LBNL environmental policies and procedures as promulgated by the Environmental Services Group and Waste Management Group of the EH&S Division.

- Support the Lab's effort to meet environmental objectives and targets as identified in the LBNL EMS plan.
- Prevent pollution, conserve natural resources, and practice sustainability at all opportunities.

## 2.4 Safeguards and Security Management

LBNL achieves a balance between protecting its critical assets and maintaining an open working environment that fosters collaborative science. The Lab's Integrated Safeguards and Security Management Plan (ISSM) identifies and implements protection programs capable of assuring graded safeguards to theft, sabotage, and other malicious acts. The ISSM plan includes programs for cyber security, export control, physical and intellectual property control, and counterintelligence.

LBNL managers, employees, and guests are directed to comply with all prescribed safeguard and security policies and procedures and adhere to the following ISSM principles:

- Line management is responsible for integrating appropriate security controls into his/her work and for ensuring active communications of security expectations up and down the management line and with the workforce.
- Clear security roles and responsibilities are defined and communicated in position descriptions, performance reviews, and other forms of feedback.
- Without compromising the security, an open environment is promoted to support the Laboratory mission.
- Security controls are tailored to LBNL organizations through the development of integrated security plans, as appropriate, to meet the mission of the organization.

## 2.5 Other LBNL Management Systems

The use of documented management systems is the preferred method of operation for all LBNL organizations, but in particular, units in Operations and other support organizations should use accepted management practices and systems common to their work discipline or field. Selected management systems should be cost effective, process efficient, and improve customer satisfaction.

LBNL managers and employees who utilize the services of Operations and other support organizations are required to follow the policies and procedures of the applicable management system.

## 2.6 Process Control

Process control is intended to reduce variation in the work process, thereby improving performance, safety, 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
- Use of safety standards and requirements necessary and sufficient to mitigate the hazards of the work process
- Assurance that only qualified and trained personnel are assigned to perform the work
- Assurance that only the appropriate equipment and material are used, maintained, and safeguarded

- Assurance that up-to-date written procedures to direct the work are being used
- Acceptance criteria for final review of end product or service

### **2.6.1 Core Functions**

LBNL organizations must identify and describe the key processes used to meet the organization's scientific or operational objectives. The description of core functions is part of the organization description (see Section 1.1).

### **2.6.2 Descriptions, Procedures, Instructions, and Drawings**

Core functions must have descriptions, procedures, instructions, and/or drawings to direct and inform personnel how to perform the functions in an efficient and safe manner. In addition to the core functions, other LBNL 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 written formally to ensure clarity and proper review and approval. The procedures 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)

Modification of approved procedures for core functions and other significant work processes requires use of a formal change control process if the changes impact the quality and/or safety of the activity. Change control must include approval signatures, effective date, and revision number for the changed procedure.

Activities with low or moderate significance or consequences (as determined by the supervisor or manager) may have less formal procedures or instructions. Notes, desk manuals, memos, operator aids, logbooks, notebooks, postings, and drawings are acceptable methods for this level of written communication. Modification of these types of procedures requires, at a minimum, written concurrence by the immediate supervisor if the changes have an impact on the quality and/or safety of the activity.

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

### **2.6.3 Consensus Standards**

The use of consensus standards where practicable and consistent with contractual or regulatory requirements is the preferred method on which to base a controlled work process or program. Consensus standards, for the purpose of the OQMP, include national and international standards, DOE technical standards, and standards and codes from nationally recognized professional societies. These standards, as applicable, may supplement or replace written procedures, instructions, and drawings.

The LBNL Work Smart Standards (WSS) Set provides a listing of standards that the Laboratory utilizes in its contract with DOE. Consensus standards, such as ANSI, ASME, ACGIH, and NFPA, are listed

along with local, state, and federal laws in the WSS Set. For the most current Work Smart Standards Set, go to: [http://labs.ucop.edu/internet/comix/contract/LBNL/wss\\_lbnl.pdf](http://labs.ucop.edu/internet/comix/contract/LBNL/wss_lbnl.pdf).

ANSI/ISO/ASQ Q 9001-2000 is the international consensus standard for quality management. LBNL is committed to the use of all applicable elements of the standard (see Appendix D for conformance with the standard).

#### **2.6.4 Suspect/Counterfeit Items**

Line managers must be cognizant of the presence of suspect/counterfeit items (S/CIs) in their work processes. A suspect item is one in which there is an indication by visual inspection, testing, or other information that it may not conform to established government or industry-accepted specifications or national consensus standards. A counterfeit item is a suspect item that is a copy or substitute without legal right or authority to do so, or one whose material, performance, or characteristics are knowingly misrepresented by the vendor, supplier, distributor, or manufacturer. The use of suspect/ counterfeit items can lead to unexpected failures and undue risk of mission impacts, environmental impacts, and personal injury, contamination, or death.

To mitigate the use of suspect/counterfeit items in Laboratory work processes, line managers must implement the Laboratory Policy and Procedure for Controlling S/CIs, as described in Appendix C. The controls include:

- Guidance on identifying S/CIs
- Procurement procedures to prevent the purchase of S/CIs
- Detection and disposition of S/CIs from Laboratory facilities and installed equipment
- Reporting requirements for discovered S/CIs

#### **2.6.5 Safety Software Quality Assurance**

The LBNL approach to Safety Software Quality Assurance is based on the principle that software which is part of a system where degradation of the confidentiality, integrity, or availability of the software can have a foreseeable, significant impact on human safety, taking into account compensating controls, must be appropriately controlled and tested.

Software which forms part of a safety chain in high-risk facilities, but for which adequate non-software controls exist to prevent a degradation of the software from impacting human safety may adopt a subset of these controls at management discretion, but is not covered by this policy directly.

The SSQA approach sets four core requirements:

1. The process owner must consider the system as a whole in considering the risks, taking into account software and non-software components.
2. The Software must be documented to a level where users, developers, and those providing oversight can understand its functions.
3. Tests must be created and executed which clearly show that the software is performing as intended across a range of operating conditions. These tests must be repeated at any time that the environment or the software changes in a way that could create differences in behavior.
4. Changes to the software must be approved, documented, tested, and archived to provide for rigorous, continuous oversight

Safety software includes safety system software, safety and hazard analysis software and design software, and safety management and administrative control software, and performs a safety function as part of a system, structure or component (SSC), and is cited in either a DOE-approved safety analysis document (SAD) or a Lab Directorate-approved hazard analysis document (HAD).

- Safety and Hazard Analysis Software and Design Software is used to classify, design or analyze nuclear/radiological facilities.
- Safety Management and Administrative Controls Software performs a hazard control function in support of nuclear facility or radiological safety management programs or Technical Safety Requirements or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards.

#### 2.6.5.1 Applicability

##### [A] System Software

System Software includes operating systems such as Windows, Linux, and system utilities such as compilers, assemblers, translators, interpreters, query languages, word processing programs, spreadsheet programs, database managers, and graphing programs.

System Software **is exempt** from these requirements.

##### [B] Library (Data) Files

Library files [e.g., nuclide library files used for Nondestructive Assay (NDA)] containing vendor-supplied data shall be controlled by the qualified supplier. Change control is required for the initial library files when they are introduced into the LBNL program for installation, and when they are updated with qualified supplier changes.

Data files that do not affect accuracy or precision, or the quality and correctness of the information, **are exempt** from these requirements.

##### [C] Applications Developed Within Commercial-Off-The-Shelf (COTS) or System Software

Specific applications developed for use that fall under the applicability of this Plan, based on COTS or System Software (e.g., Microsoft (MS) Excel spreadsheets, MS-Access databases, detailed formulas, or macros) **are not exempt** from these requirements.

Calculations that are 100% validated by an alternate calculation method **are exempt** from these requirements.

**[D] Acquired Software**

Software that's initial design, programming, and testing is performed by a third party. Supplier Software can be categorized as COTS, System Software, or Firmware and could be supplied by either a Qualified or Non-qualified Supplier.

**[D-1] COTS Software**

COTS is short for Commercial Off-The-Shelf, an adjective that describes software products that are general purpose, ready-made and available for sale to the general public. COTS products are mass-produced, and are designed to be implemented easily into existing systems without the need for customization by the vendor. COTS excludes Sections A and B above.

COTS software **is not exempt** from these requirements.

**[D-2] Firmware**

Firmware is vendor-supplied software that is included as an integral part of an instrument (e.g., programmed in a read-only memory [ROM] chip) and cannot be modified by another party.

Firmware that cannot be removed or updated **is exempt** from the requirements of this plan. Firmware that is updated by the vendor without respect to particular LBNL requirements is treated as COTS software above.

**[D-3] Firmware, modified**

Firmware, modified, is vendor-supplied software that is included as an integral part of an instrument (e.g., programmable logic controller) and can be modified by another party. Firmware that is removable or updated will be treated as software if the specifications are created by LBNL.

Firmware that can be removed or updated **is not exempt** from these requirements.

**[D-4] Vendor-Developed Software**

Vendor-Developed software is software that is developed for LBNL to perform a specific end-user function.

Vendor-Developed software **is not exempt** from these requirements.

**[E] LBNL-Developed Software**

LBNL-Developed Software is software developed for use by LBNL to perform a specific end-user function.

LBNL-Developed Software **is not exempt** from these requirements.

**2.6.5.2 Software Evaluation**

New and modified safety software used in facilities will be evaluated to determine the applicable criteria of Software Quality Assurance.

Table 2, *Software Evaluation Checklist*, will be used for this evaluation.

### 2.6.5.3 Software Lifecycle

Changes to software will be uniquely identified and cataloged. An inventory of related systems will be maintained at the system-owner or functional-owner level. An inventory of safety software systems (broadly) will be maintained by the Office of Contract Assurance (OCA).

#### [A] Labeling System

A labeling system for configuration items shall be implemented by the responsible organization that:

- Uniquely identifies core configuration items.
- Identifies changes to configuration items by revision or version identifier.
- Provides the ability to uniquely identify each approved configuration of the revised software that is available for use.

#### [B] Change Control

Changes to software shall be systematically proposed, evaluated, documented and approved to ensure that the impact and rationale for making the change is carefully assessed prior to updating the software baseline. Changes to previously accepted software will be subject to the same level of control as the original software.

Information concerning approved changes will be transmitted to affected organizations if software functionality is impacted. A system of change management will be developed and documented. Software verification activities will be performed for the changes, as necessary, to ensure that the change is appropriately reflected in the software documentation and to ensure traceability is maintained. The degree of software validation will be commensurate with the nature and scope of change.

#### [C] Software Inventory

A software inventory of all applicable software/systems will be maintained that identifies the software name, version classification, , operating environment and the person and responsible organization for the software (i.e. the organization that owns and/or uses the software).

The Software Inventory List (SIL) is maintained as an institutional document by the Office of Contract Assurance, and will be updated by the responsible organization (i.e. the organization that owns and/or uses the software).

The SIL will be evaluated periodically by all responsible organizations, at least once annually, to ensure the data is accurate, current and complete.

**[E] Software Problem Reporting**

Problems with software, the potential impact of the problem and the corrective action(s) taken are documented by the responsible organization (e.g. may be the organization that owns and/or uses the software or the assigned software developer(s)).

**[F] Software Removal and Retirement**

The removal and retirement of software applications will be documented by the responsible organization (e.g. may be the organization that owns and/or uses the software or the assigned software developer(s)). Software covered by this policy must be archived in accordance with archive and records schedules for the safety-area they supported.

**2.6.5.4 Software Documentation****[A] Verification and Validation Plan (V&VP)**

V&V processes are used to determine if developed software products conform to their requirements, and whether the products from each development phase fulfill the requirements or conditions imposed by the previous phase (verification) and whether the final systems or components comply with specified requirements (validation). This includes analysis, evaluation, review, inspection, assessment, and testing of the software products and the processes that produced the products. Also, the software testing, validation, and verification processes apply when integrating purchased or customer-supplied software products into the developed product. The verification plan should document the verification tasks and the validation plan should document the validation tasks.

Each plan defines the verification and validation tasks and required inputs and outputs needed to maintain the appropriate software integrity level. It also provides a means of verifying the implementation of the requirements of the Requirements Document in the design as expressed in the Design Document and in the testing as expressed in the project's test documentation.

If desired, the verification plan and validation plan may be packaged together in a single document (i.e. V&V P).

**[B] Change Control Document**

Change control documentation define the methods and facilities used to maintain, store, secure and document controlled versions and related artifacts of the software through all software life cycle phases.

**[C] Requirements Document**

The software requirements will be identified, documented and reviewed. The Requirements Document will specify requirements for a particular software product, program, or set of programs that perform certain functions in a specific environment. The Requirements Document may be written by the supplier (internal or external), the customer, or by both. The Requirements Document should address the basic issues of functionality, external interfaces,

performance, attributes, and design constraints imposed on implementation. Each requirement will be specified in sufficient detail to permit the accomplishment of design and validation activities. Software Requirements will be traceable throughout the software development cycle, and a V&V Plan will be prepared after the requirements have been documented and approved.

**[D] Design Document**

The software design will be based on the software requirements and will be documented and reviewed. The Design Document specifies the overall structure of the software (control and data flow) and the reduction of the overall structure into physical solutions (e.g. algorithms, control logic, data structures). The Design Document should describe the components and subcomponents of the software design, including databases and internal interfaces. The Design Document may be prepared first as the architecture design but should be subsequently expanded to address additional detail. The design may necessitate the modification of the Requirements Document and the V&V Plans.

**[E] Test Plan**

Test Plans identifies the scope, approach, resources and schedule of the testing activities. They also identify the items and features that will be tested, the tests that will be performed, the people responsible for each test and any risks associated with the Plan.

Test Plans define the test approach and identifies the features that are covered by the design and its associated tests. This plan identifies the specific test cases and test procedures, if nay, required to accomplish the testing and specifies the acceptance criteria.

**[F] Test Results**

Test results are documented and reviewed. Test results describe the results of designated testing activities. Test results identify the summary of the results, any variances that occurred during the test, a summary of activities, the person(s) who performed the tests, the name of the reviewers of the test results

**[G] User Documentation**

User documentation guides users in installing, operating, managing and maintaining software products. This does not include modifying source code. User documents should describe the data control inputs, input sequences, options, program limitations, error messages and corrective actions to correct those errors, and other essential information for the software product.

### 2.6.5.5 Software Reviews

Software Reviews are conducted at various stages of software development and may include managerial reviews, acquirer-supplier reviews, technical reviews, inspections, walk-throughs, and audits. Software reviews will be documented as well as further actions, implementation of those actions and verification of those actions, if applicable. The following are examples of possible reviews:

- [A] A Requirements Review will be performed to assure the adequacy of the requirements, as appropriate.
- [B] A Design Review will be performed to determine the acceptability of the detailed software designs as depicted in the detailed Design Description in satisfying the requirements of the Requirements Document, as appropriate.
- [C] The V&VP Review will be performed to evaluate the adequacy and completeness of the verification and validation methods defined in the verification and validation plans.
- [D] Other reviews and audits may include the user documentation review. This review is held to evaluate the adequacy (e.g., completeness, clarity, correctness, and usability) of the user documentation.

All reviews performed will be documented by the responsible organization.

### 2.6.5.6 Software Testing

Testing will be performed to ensure that the design as implemented in code to assure adherence to the requirements and to assure that the software produces the correct results for the test cases.

To evaluate technical adequacy, the software test case results can be compared to results from alternative test methods such as:

- a. Hand calculations
- b. Comparison with other validated software of similar purpose
- c. Calculations using comparable proven problems
- d. Empirical data and information from confirmed published data and correlations
- e. Manual inspections or qualitative checks not involving numerical manipulations (visual inspection of database reformatting or data plotting)

Tests may be performed by persons who did not implement the design who are technically competent.

### 2.6.5.7 Supplier Control

Applicable quality assurance requirements will be specified and the required vendor-supplier software documentation, plans, and procedures will be identified in software procurement documentation.

Procured software will be tested in accordance with documented and approved test plans using approved test case specification to ensure that the acquired software will perform satisfactorily in its operating environment. Test plans, and the results of the tests will be identified, documented and retained by the responsible organization.

The responsible organization will perform an acceptance test prior to use of procured software to verify the functional capability of the software and the acceptability of the supplier's supporting documentation (e.g. user documentation, technical specifications and results of supplier testing). In cases of multiple components from a single vendor, a sampling process approved by the functional owner may be utilized. In some cases, then a representative sample may be one component.

#### **2.6.5.8 Records**

Software quality assurance documentation will be retained by the responsible organization in accordance with the records requirements outlined in the RPM.

#### **2.6.5.9 Training**

Training requirements needed to develop or use the software application, if required, will be identified by the responsible organization

#### **2.6.5.10 Graded Approach**

Software Quality Assurance is performed using a graded approach, considering aspects such as software applications that are important to safety that may be included or associated with SSCs.

This graded approach takes into consideration that LBNL has multiple radiological and accelerator facilities that have been determined to need a documented and DOE-approved SAD or a Lab Directorate-approved HAD. Radiological and accelerator facilities where a documented SAD is required are considered to be medium to high hazard facilities, and LBNL applies the complete process detailed here to software which meets the definitions in Section 1.

**Table 1: Software Quality Assurance Graded Approach**

Software Type	Software Evaluation	Change Control Document	V&VP	Requirements Document	Design Document	Source Code Review	Test Plan/ Results	Installation & Checkout Test Plan/Results	User Document
Applications developed within COTS or System Software	X	X	-	X	-	-	-	X	-
COTS	X	-	-	-	-	-	-	X	X
Firmware, modified	X	X	-	X	X	-	X	X	X
Acquired	X	X	VD	VD	VD	VD	VD	X	X
Vendor-developed	X	VD	VD	VD	VD	VD	VD	VD	VD
LBNL-developed	X	X	X	X	X	X	X	X	X

- = Requirement Not Required  
X = Requirement to be Satisfied  
VD = Vendor-Developed

**Table 2: Software Evaluation Checklist**

1. Initiator: (Print Name)	2. Date:	3. Bldg/Facility:
4. Software Name:	5. Software Version:	6. Process Affected:
7. Purpose/function of software (including whether software is used for data collection, design, analysis or scientific reasons):		
8. If any of the answers to <b>c</b> through <b>g</b> are "Yes", then the Software Quality Assurance requirements are applicable.		
<p>a. Is this System Software as defined below? (System Software includes operating systems such as Windows, Linux, and system utilities such as compilers, assemblers, translators, interpreters, query languages, word processing programs, spreadsheet programs, database managers, and graphing programs.)</p> <p>If YES, this software is exempt from the requirements of this Plan. Designate Blocks <b>b</b> through <b>f</b> as "N/A", and complete Block 9. If NO, continue to Block 8<b>b</b>.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>b. Can the software output adversely impact hazard control functions in support of nuclear facility or radiological safety management program or Technical Safety Requirements or other control functions necessary to provide adequate protection from nuclear facility or radiological hazards; or the classification, design or analysis of nuclear or radiological facilities?</p> <p>If YES, continue to Block 8c. If NO, this software is exempt from the requirements of this Plan. Designate Blocks <b>c</b> through <b>f</b> as "N/A", and complete Block 9.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> N/A	
<p>c. Is this an application developed within COTS or System Software as defined below? (Applications developed within COTS or System Software are those applications that may include formulas or calculations that are easily reproduced by hand or with a calculator. This would include databases that transfer data or interface with other software.)</p> <p>If YES, Section 2.6.5 of the OQMP is applicable. Designate Blocks <b>d</b> through <b>f</b> as "N/A", and complete Block 9. If NO, continue to Block 8<b>d</b>.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> N/A	
<p>d. Is this COTS Software as defined below? (Commercial off the shelf software is software that is downloaded onto a system or PC, Instrument, or tool that interacts with system software defined in 8a.)</p> <p>If YES, Section 2.6.5 of the OQMP is applicable. Designate Blocks <b>e</b> through <b>f</b> as "N/A", and complete Block 9. If NO, continue to Block 8e</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> N/A	
<p>e. Is this Vendor-Developed Software as defined below? (Vendor-Developed Software includes software that is owned and/or maintained by a Vendor)</p> <p>If YES, Section 2.6.5 of the OQMP is applicable. Designate Block <b>f</b> as "N/A", and complete Block 9. If NO, continue to Block 8f.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> N/A	
<p>f. Is this LBNL-Developed Software as defined below? (LBNL-Developed Software is software developed and/or maintained by LBNL)</p> <p>If YES, Section 2.6.5 of the OQMP is applicable. Complete Block 9.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> N/A	
9. Evaluation performed by:		Approved by:
Initiator (Print Name/Sign)	Date	Responsible Person      Date

### 2.6.6 Function-Specific Controls

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

#### 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> <li>– Security considerations</li> </ul> </li> <li>• Review and approve design 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 that 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 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 that the final design is technically adequate and complies with the design specifications and applicable standards and codes.

**B. Procurement**

Activity	Application	Controls
General	LBNL scientific, operations, and administrative functions	Follow institutional procurement procedures as described by the University of California Procurement Policy and Standard Practices and on the LBNL web site.
Procurement planning	High-risk 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, security, and compliance with codes and technical specifications.</li> <li>• Complete the Advance Acquisition Plan (AAP) for procurements costing more than \$500k.</li> </ul>
Supplier and subcontractor selection	Nonstandard and non-off-the-shelf items or services	<ul style="list-style-type: none"> <li>• Evaluate and periodically monitor vendor's capability and quality assurance record in collaboration with the appropriate QA and user organizations, as requested.</li> <li>• Document selection.</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> <li>– Screening for suspect/counterfeit items</li> </ul> </li> <li>• Segregate unaccepted items from satisfactory items.</li> </ul>

**C. Manufactured Items 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>• Preoperational</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 retest or reinsertion that documents correction of the nonconforming item.</li> </ul>

## D. Construction Inspection and Testing

Activity	Application	Controls
Inspection to verify compliance with design drawings and specifications	Building new or remodeling existing facilities	<ul style="list-style-type: none"> <li>Quality acceptability determined by the project's approved design drawings and specifications</li> <li>Quality assurance inspectors are independent of project managers' project schedule and cost concerns</li> </ul>
	Building new or upgrading existing plant infrastructure	
Testing	Construction materials, alone or as an assembly.	<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>
	New utilities and services.	
Follow-up on nonconforming items	Building new or remodeling existing facilities	<ul style="list-style-type: none"> <li>Projects don't close until all deficiencies in workmanship or materials are resolved</li> <li>Inspector's signature required to close out project</li> </ul>
	Building new or upgrading existing plant infrastructure	

## E. 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> <li>Waste management</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> <li>Waste management</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>

## F. Asset Management

Activity	Application	Controls
Traceability	Equipment and other items determined by LBNL Property Management as being capital and sensitive items and requiring property control	<ul style="list-style-type: none"> <li>• Identify responsible person for each item and piece of equipment requiring accountability.</li> <li>• Conduct periodic physical inventory.</li> <li>• Trace equipment and items back to specification, procurement records, maintenance manual, and other support documents.</li> <li>• Identify and implement appropriate security measures.</li> </ul>
Calibration	Measuring and test equipment (M&TE)	<ul style="list-style-type: none"> <li>• Physically mark M&amp;TE with unique identifier and recalibration 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>
Storage	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>
Shipping, transfer, and disposal	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 that mode of transportation is adequate.</li> <li>• Retain shipping, transfer, and disposal documents (i.e., ensure traceability).</li> </ul>

## 2.6.7 Facility-Specific Controls

Most facility operations require controls for facilities operations and asset management.

### A. Operating Practices

Activity	Application	Controls
Operating practices	Moderate- to high-hazard facilities	<ul style="list-style-type: none"> <li>• Ensure that programmatic quality and safety standards and requirements are identified and communicated to affected staff.</li> <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 safety procedures, including 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 that duties of the control room operator are known and available.</li> </ul>
Emergency procedures	All occupied facilities	<ul style="list-style-type: none"> <li>• Identify the facility manager. Ensure current information for reporting an emergency, including an LBNL Emergency Response Guide, is prominently posted.</li> <li>• Ensure that current emergency evacuation signs are posted in all buildings two stories or higher.</li> </ul>
Communication systems	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. Facility Management

LBNL operations take place on its 200+ acre Hill site, on portions of UCB Campus, and in leased space in Berkeley, Oakland, and Walnut Creek. Most of the Laboratory's scientific, administrative, and support activities are housed on the Hill, where LBNL currently occupies approximately 1.7 million gross square feet in over 100 buildings and 50 trailers. The Facilities organization is responsible for establishing a

corporate, holistic, and performance-based approach to real property life-cycle asset management that links real property asset planning, programming, budgeting, and evaluation to program mission projections and performance outcomes. Acquisitions, sustainment, recapitalization, and disposal must be balanced to ensure real property assets are available, utilized, and in a suitable condition to accomplish DOE missions.

## **2.7 Document and Records Management**

### **2.7.1 Document Control**

The institutional Document Control policy is managed by the Information Technology Division.

Document control is applied using a graded approach, which considers:

- Publication in scientific or technical journals
- Monetary investment or value
- Risk levels associated with hazards or operations.

This graded approach is the institutional documented Document Control Policy and addresses all document types. Documents may be hard copy or electronic.

Divisions will identify documents that are considered controlled by reference (e.g. AHDs) or grouping (e.g. SOPs). As necessary, Divisions should formally document the justification of exception from these requirements.

Implementation of document control requirements is outlined in RPM Section 1.0, *Document Control Implementation*.

**Document Control Graded Approach Matrix**

<b>Document Types</b>	<b>Review/ Approval Process</b>	<b>Distribution Process</b>	<b>Change Control Process</b>	<b>List of Controlled Documents</b>
<b>Institutionally-Managed</b>				
Institutional Documents <ul style="list-style-type: none"> <li>RPM</li> </ul>	X	X	X	X
<b>Science &amp; Research-Managed</b>				
Final distribution of Scientific or Technical publications to DOE	X	X	N/A	X
<b>Directorate/Division-Managed</b>				
Documents directly supporting projects that require a Quality Assurance Plan (QAP) per DOE O 413.3B for which a breakdown of document control could risk immediate impact on the safety and health of the employee, environment or public.	X	X	X	X
Documents directly supporting work for a High Hazard Facility/Activity for which a breakdown of document control could risk immediate impact on the safety and health of the employee, environment or public. <ul style="list-style-type: none"> <li>High hazard facilities are defined as facilities with DOE-approved safety analysis documents and/or LBNL-Directorate approved safety analysis documents.</li> <li>High hazard activities are defined as activities that require formal work authorizations</li> </ul>	X	X	X	X
Documents directly supporting work for a High Operational Risk Activity for which a breakdown of document control could result in immediate degradation of the ability to complete mission activities or substantial financial loss. <ul style="list-style-type: none"> <li>RPM section 1.01 establishes applicable listing of high operational risk activity documents.</li> </ul>	X	X	X	X
Documents directly supporting work for medium Hazard Facilities/Activities that have some impact on the safety and health of the employee, environment or public	DBM	DBM	DBM	DBM
Documents directly supporting work for medium Operational Risk Activities that: <ul style="list-style-type: none"> <li>Have some impact on science, research, operations, or safety</li> <li>May result in losses of &gt; \$100K or excess costs of &gt;\$500K due to inefficiencies</li> </ul>	DBM	DBM	DBM	DBM
<b>Not Required</b>				
Documents directly supporting work for low Hazard Facility/Activity that have a minor or negligible impact on safety and health of the employee, environment or public.	-	-	-	-
Documents directly supporting work for low Operational Risk Activity that <ul style="list-style-type: none"> <li>Have a minor or negligible impact on science, research, operations, or safety</li> <li>May result in losses of &lt;\$25K or excess costs of &lt;\$100K due to inefficiencies</li> </ul>	-	-	-	-

X = Required      DBM = Determined by Management      - = Not required

*Note:* Desktop instructions or other tools that assist personnel in performing a specific job task and are not used to prescribe actions to be compliant with internal or external requirements are exempt from this policy.

- **Document Control Implementation**

Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, establish design, or provide results of scientific or technical research and associated activities. Divisions are responsible for ensuring that documents are controlled in accordance with the criteria outlined below to ensure the correct documents are being used.

- **Document Preparation, Review, Approval, and Issuance**

- A. Documents are uniquely identified.
- B. Documents are reviewed for technical adequacy, correctness and completeness prior to approval and issuance.
- C. Documents will identify the individuals or organizations responsible for the review and approval.
- D. Review criteria will consider technical adequacy, accuracy, completeness, and compliance with established requirements.
- E. Reviews will be performed by individuals other than the originator, as appropriate.
- F. Reviews will be performed by individuals who are technically competent in the subject area being reviewed.
- G. Approvals will be documented.

- **Document Distribution and Use**

- A. Documents will be made available to affected personnel.
- B. Effective dates will be established and identified on approved documents.
- C. The disposition of obsolete or superseded documents and forms shall be controlled to avoid their inadvertent use.
- D. Controls will be established and maintained to identify the current status or revision of controlled document and forms.

- **Document Changes**

- A. Changes to documents, other than editorial changes, shall be reviewed and approved.
- B. Editorial or minor changes may do not require formal review.
  - a. The originating individual or organization is responsible for identifying, reviewing and approving editorial changes.
  - b. Change in an organization title accompanied by a change in responsibilities may not be considered an editorial change.

## **2.7.2 Records Management**

Records Management ensures that records of policies, procedures, activities, and decisions are generated, maintained, and readily retrievable. Information and data that document the organization's research, operational, or administrative activities are retained as evidence of completed work and adherence to standards and procedures. Most organizations should 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. Semi-active records must be transmitted to the LBNL Archives and Records Office in accordance with retention and disposition requirements (see RPM 1.17).

## **2.7.3 Scientific and Technical Publications**

Scientific and technical publications are processed through the Report Coordination Office, which assigns report numbers, obtains patent releases, coordinates the printing of required copies, and makes the required DOE/Laboratory distribution. All publications receiving a Laboratory, LBNL/PUB, or LBID number must be reviewed by a designated division reviewer other than the author. Each division is expected to maintain a current list of qualified reviewers designated by the division director and to furnish the Creative Services Office (CSO) with a copy of this list. The review must be completed, and the reviewer must sign a Publications Work Order before the document leaves the Laboratory (see RPM 5.02).



## Section 3

# Performance Assessment and Improvement

Assessments are performed using a graded approach, based on the risk inherent in the involved organizations, systems, and processes. At a minimum, managers must regularly assess their organizations and functions. As appropriate, independent assessments are performed to provide LBNL managers with additional insight into their operations. Results of management and independent assessments should be considered collectively in improving quality. Findings and corrective actions from all assessments, management and independent, should be tracked in the LBNL Corrective Action Tracking System (CATS), as appropriate. Findings that may benefit the Laboratory community should be considered for dissemination through the LBNL Lessons Learned Program.

### 3.1 Management Assessment

LBNL managers at all levels must regularly assess the performance of their organizations and functions to determine how well objectives and goals are being met. Assessments by line managers focus on identifying and resolving both singular and systematic management issues and problems that may hinder the organization in achieving its scientific and operational objectives. Managers should assess their processes for the following:

- Planning
- Organizational interfaces (internal and external to the organization)
- Integration of management systems (e.g., safety, security, quality, project)
- Organizational effectiveness, including customer satisfaction
- Use of performance metrics
- Training and qualifications
- Supervisory oversight and support

The management assessments should include an internal evaluation of such conditions as the state of employee knowledge, motivation, and morale; communication among workers; the existence of an atmosphere of creativity and improvement; and the adequacy of human and material resources. The assessments should also involve direct observation of work so that the manager is aware of the interactions at a work location. The observations can be supplemented with worker and customer interviews, safety and performance documentation reviews, and drills or exercises.

The results of management assessments must be documented and used as input to the organization's improvement process. The documentation can include agendas and minutes of staff and operations meetings, progress reports, performance evaluations, inspection reports, and self-assessment reports.

### 3.2 Independent Assessment

#### 3.2.1 Independent Assessment

Independent assessments advise LBNL managers on the quality of products, services, and processes produced by or for the organization. The type and frequency of independent assessments are based on the

status, complexity, risk, and importance of the activities or processes being assessed. The assessments are performed by technically and programmatically knowledgeable personnel within LBNL who are free of direct responsibility in the areas they assess. The lead assessors must work for organizations that have sufficient authority and independence to gain access to senior Lab managers capable of directing line organizations to take actions in response to the assessment results. LBNL organizations that routinely conduct independent assessments include the Environment, Health and Safety Division; the Internal Audit Services Department; the Office of Institutional Assurance; and the Safety Review Committee. These organizations have established protocols for conducting assessments and providing feedback to the assessed organizations.

Independent assessments include:

- Evaluating work performance and process effectiveness
- Evaluating compliance to the management system requirements
- Identifying abnormal performance and potential problems
- Identifying opportunities for improvement
- Documenting and reporting results
- Verifying satisfactory resolutions of reported problems

Results of independent assessments provide an objective form of feedback to Lab management that is useful in confirming acceptable performance and identifying improvement opportunities. The results must be documented in an assessment report.

### 3.2.2 Peer Review

Peer reviews are a form of independent assessment. These reviews are used to assure the quality of research and operations, and they are performed by peers in that particular field who have no direct responsibility in the areas being assessed. Peer reviews are often used to review research proposals; review work in progress; review results prepared for publication in professional journals; and review and evaluate the research program for both quality and adherence to missions, goals, and objectives.

### 3.2.3 ES&H Self-Assessment

The LBNL ES&H self-assessment program is a four-tiered system that focuses on different aspects of Integrated Safety Management (see Section 2.3). Two forms of the ES&H self-assessments are independent and internal assessments of the LBNL divisional environment, safety, and health (ES&H) programs: the Safety Review Committee Management of ES&H (MESH) Review and the Integrated Functional Appraisal (IFA). The MESH review is conducted by LBNL Safety Review Committee members from outside the subject division, and the IFA is conducted by subject matter experts from the Environment, Health and Safety Division.

Assessment	Type of Review	Performed by
Division Self-Assessment	Workplace safety	Line management with EH&S support  Independently validated by OCA

Integrated Functional Appraisal	In-depth technical	EH&S subject matter experts
Safety Review Committee MESH	Safety management	Peer researchers and staff with EH&S support
Appendix B Self-Assessment	DOE/UC Contract performance	Functional managers

Program elements and requirements of the LBNL’s ES&H self-assessment are described in PUB-5344, *Environment, Safety, and Health Self-Assessment Program*.

### 3.3 Continuous Improvement

Continuous improvement is a combination of quality improvement and corrective actions that (1) uses feedback information to improve processes, products, and services; (2) prevents or minimizes quality or safety problems; and (3) corrects discovered problems. A quality or safety problem is a collective term that involves a deficiency in an activity, product, service, item characteristic, or process parameter; in an environment, safety, and health requirement; or in a legal and contractual requirement. Managers at all levels have the responsibility to correct deficiencies and improve, whenever possible, the processes, products, and services under their supervision.

#### 3.3.1 Quality Improvement

Quality improvement is a disciplined management process based on the premise that all work can be planned, performed, measured, and improved. Line managers should ensure a focus on improving the quality of processes, products, and services by establishing priorities, promulgating policy, allocating resources, communicating lessons learned, and resolving significant management issues and problems that hinder the organization from achieving its objectives. Management must balance safety and mission priorities when considering improvement actions.

A quality improvement process includes:

- Planning work and allocating resources to account for quality and safety in work process
- Reviewing information and data on processes, products, and/ or services to identify conditions adverse to quality and safety
- Reviewing and analyzing assessment results, including the collective results from complementary assessments.
- Analyzing the adverse conditions and determining the causes
- Segregating the processes, products, or services if the adverse conditions may lead to significant consequences, as determined by line management
- Developing corrective actions to address adverse conditions and prevent recurrence (e.g., reducing process variability or cycle time)
- Implementing the approved actions
- Evaluating the improvements or corrections and assuring customer satisfaction
- Providing lessons learned to other organizations

The quality improvement process should be part of the normal operation of all Berkeley Lab working groups and should be documented in the normal operational records and reports (e.g., minutes from staff and operations meetings; progress and activity reports; readiness reviews; assessment and inspection reports). Conditions that have significant adverse consequences require separate disposition reports that document the actions taken to correct the problems.

### **3.3.2 Corrective Action**

Identified findings, concerns, and deficiencies should be addressed as soon as possible. If the findings cannot be immediately resolved, corrective actions should be tracked in CATS.

A corrective action plan is often necessary for findings that require multiple corrective actions implemented over an extended time period (i.e. several weeks). A corrective action plan (CAP) must be prepared by the responsible manager to allow for additional planning and scheduling. The corrective action plan may require senior Lab management review and approval to address risk management, funding, and resource allocation issues. Once approved by the appropriate Laboratory authority, the individual corrective actions from the CAP are tracked to completion and management verification in CATS.

The Office of Contract Assurance provides regular status reports on the corrective actions to advise Laboratory management on progress and completion. The Office of Contract Assurance, EH&S Division, and others perform trending and root cause analysis to prevent recurrence of the finding, concern, or deficiency.

### **3.3.3 Lessons Learned**

The LBNL Lessons Learned Program, managed by OCA, helps the Laboratory community learn from its experiences, both positive and negative. Through various sources, the program identifies and analyzes adverse events such as accidents and near misses, and communicates the causes and corrective actions to prevent their recurrence. Lessons Learned also communicate best practices from which others may benefit. The ultimate goal of the program is to continually improve performance across all Laboratory functions.

The program uses several different sources of information. The most common sources are lessons developed in response to adverse conditions, accidents, near misses, and best practices that occur at the Laboratory. Other sources include DOE Lessons Learned websites and Lessons Learned websites from other DOE Office of Science Laboratories.

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# Appendix A

## The Graded Approach Methodology at LBNL

### Introduction

A graded approach is used to determine the rigor with which the elements of the Operating and Quality Management Plan (OQMP) should be applied to a given Laboratory activity. The objective of the graded approach is to ensure that work activities are managed commensurate with the risks involved. Risks include potential impact to staff and/or public health and safety, threats to the environment, institutional and programmatic consequences of noncompliance, and Laboratory mission and cost impacts.

The methodology for assessing hazards and risks in order to grade processes, activities, or facilities follows. Alternate methodologies, such as the use of DOE guidance documents or evaluation of existing hazard documentation, may be used if the rationale is appropriately documented and approved.

### Methodology

- In determining risk, Laboratory managers must assess the activities associated with a facility or function and consider the primary risks inherent in these activities. Once risks are identified, managers must evaluate the potential impact of an adverse event or condition and the likelihood of occurrence. Risk is a function of the negative consequence that may result if an appropriate level of management control is not applied to prevent these negative consequences.
- Managers should evaluate the potential impact or consequence of an event or condition by considering the eight risk-potential categories described in the LBNL Risk-Based Priority Planning Grid (Table A-1). 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 a measure of the probability that an event will occur. In analyzing the risk inherent in each activity, managers 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 an adverse occurrence. 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 and the potential impact against the potential consequence (or cost) of achieving an effective set of controls.
- Based on this risk analysis, line management determines the rigor to use in applying the OQMP requirements to their operations. As higher risk activities require a higher level of rigor, managers use this approach to determine requirements for documentation, training, and other controls. For example, a high-risk activity may require a formal authorization, as required by chapter 6 of PUB-3000, while a similar low-risk activity may 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 OQMP requirements continue to be met in an appropriate and cost-effective manner.

**Table A-1. Risk Analysis Using the Berkeley Lab 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 nonreportable events
	Researcher and staff safety	Loss of life or serious injury; exposure to hazardous materials in excess of standards	Reportable onsite work accident involving lost work time or restricted duty; 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	Major noncompliance with laws or regulations with significant possible penalties; major contractual noncompliance with potential impact on conditional payment of fee.	Major noncompliance with laws or regulations but not involving significant possible penalties; major contractual noncompliance.	Minor technical or administrative violation(s); little or no adverse regulatory results; minor contractual noncompliance.
	Best management practice		Significant deviation from good practice	Minor deviation or slow implementation
	LBNL mission/ programmatic impact/LBNL support services	Failure to meet critical milestone; could lead to LBNL shutdown; nondelivery 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, or 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

## Appendix B

# Integrated Safety Management (ISM)

**Table B-1. Seven ISM Guiding Principles**

ISM Provision	Resource/Policy References	Sample Mechanisms
Line management is responsible for the protection of the public, the workers, and the environment.	RPM, Chap. 7 PUB-3000, Chap. 1 & 6 PUB-3140 OQMP, Section 1.1	<ul style="list-style-type: none"> <li>• Organization charts (roles and responsibilities)</li> <li>• Position descriptions</li> </ul>
Clear and unambiguous lines of authority and responsibility for ensuring safety are established and maintained.	RPM, Chap. 7 PUB-3000, Chap. 1 & 6 PUB-3140 OQMP, Section 1.1	<ul style="list-style-type: none"> <li>• Organization charts (roles and responsibilities)</li> <li>• Position descriptions</li> <li>• Authorizations via SADs, AHDs, RWAs, and division-approved protocol</li> </ul>
Personnel possess the experience, knowledge, skills, and abilities necessary to discharge their responsibilities.	RPM, Section 2.01 PUB-3140 OQMP, Section 1.3 PUB-3000, Chap. 24	<ul style="list-style-type: none"> <li>• Position descriptions</li> <li>• PRD performance evaluations</li> <li>• Authorizations via SADs, AHDs, RWAs, and division-approved protocol</li> <li>• ESH training</li> </ul>
Resources are effectively allocated to address safety, programmatic, and operational considerations.	PUB-3140 OQMP, Section 1.2 PUB-5344	<ul style="list-style-type: none"> <li>• Work plans</li> <li>• Research proposals (e.g., WFO, FTP)</li> <li>• NEPA/CEQA</li> <li>• Division self-assessment/MESH</li> </ul>
Before work is performed, the associated hazards are evaluated and an agreed-upon set of safety standards and requirements is established.	PUB-3000 PUB-3140 OQMP, Section 2.2	<ul style="list-style-type: none"> <li>• Authorizations via SADs, AHDs, RWAs, and division-approved protocol</li> <li>• NEPA/CEQA</li> <li>• EH&amp;S functional programs</li> </ul>
Administrative and engineering controls to prevent and mitigate hazards are tailored to the work being performed and associated hazards.	PUB-3000 PUB-3140 OQMP, Section 2.2	<ul style="list-style-type: none"> <li>• Authorizations via SADs, AHDs, RWAs, and division-approved protocol</li> <li>• NEPA/CEQA</li> <li>• EH&amp;S functional programs</li> </ul>
The conditions and requirements to be satisfied for operations to be initiated and conducted are clearly established and agreed upon.	PUB-3000 PUB-3140 OQMP, Sections 1.2, 2.2	<ul style="list-style-type: none"> <li>• Authorizations via SADs, AHDs, RWAs, and division-approved protocol</li> <li>• NEPA/CEQA</li> </ul>

**Table B-2. Five ISM Core Functions**

ISM Function	Resource/Policy References	Sample Mechanisms
Define the scope of work.	OQMP, Sections 1.2, 2.2 PUB-3140	<ul style="list-style-type: none"> <li>• Work plans</li> <li>• Research proposals (e.g., WFO, FTP)</li> <li>• NEPA/CEQA</li> <li>• Authorizations via SADs, AHDs, RWAs, and division-approved protocol</li> </ul>
Identify and analyze hazards associated with the work.	PUB-3000 OQMP, Section 2.2.1 PUB-3140	<ul style="list-style-type: none"> <li>• Work plans</li> <li>• Research proposals (e.g., WFO, FTP)</li> <li>• NEPA/CEQA</li> <li>• Authorizations via SADs, AHDs, RWAs, and division-approved protocol</li> <li>• Self-assessment</li> </ul>
Develop and implement hazard control.	PUB-3000 OQMP, Sections 2.2.1, 2.2.2 PUB-3140	<ul style="list-style-type: none"> <li>• Work plans</li> <li>• Research proposals (e.g., WFO, FTP)</li> <li>• NEPA/CEQA</li> <li>• Authorizations via SADs, AHDs, RWAs, and division-approved protocol</li> <li>• Self-assessment</li> </ul>
Perform work within controls.	PUB-3000 OQMP, Section 2.2 PUB-3140	<ul style="list-style-type: none"> <li>• Work plans</li> <li>• Research proposals (e.g., WFO, FTP)</li> <li>• NEPA/CEQA</li> <li>• Authorizations via SADs, AHDs, RWAs, and division-approved protocol</li> </ul>
Provide feedback on adequacy of controls, and continue to improve safety management.	PUB-5344 OQMP, Section 3.3 PUB-3140	<ul style="list-style-type: none"> <li>• Self-assessment</li> <li>• Integrated functional appraisals</li> <li>• IASA appraisals</li> <li>• CATS</li> </ul>

# Appendix C

## Policy and Procedure for Controlling Suspect/Counterfeit Items

A suspect item is one in which there is an indication by visual inspection, testing, or other information that it may not conform to established government or industry-accepted specifications or national consensus standards. A counterfeit item is a suspect item that is a copy or substitute without legal right or authority to do so, or one whose material, performance, or characteristics are knowingly misrepresented by the vendor, supplier, distributor, or manufacturer. The use of suspect/counterfeit items (S/CIs) can lead to unexpected failures and undue risk of mission impacts, environmental impacts, and personal injury, contamination, or death. For these reasons, LBNL has instituted mitigating measures for the prevention, detection, and disposition of S/CIs at the Laboratory.

### Identification

The range of items at the Laboratory that should be considered as possible S/CIs includes the following:

- High-strength fasteners (bolts, screws, nuts, and washers)
- Electrical/electronic components: circuit breakers, current and potential transformers, fuses, resistors, switch gear, overload and protective relays, motor control centers, heaters, motor generator sets, DC power supplies, AC inverters, transmitters, computer components, semiconductors
- Piping components: fittings, flanges, valves and valve replacement products, couplings, plugs, spacers, nozzles, pipe supports
- Pre-formed metal structures, elastomers (O-rings, seals), spare/replacement kits from suppliers other than original equipment manufacturers, weld filler material, diesel generator speed governors and pumps

DOE maintains a list of S/CIs and identification guidance on the DOE web site at <http://www.sci.doe.gov>.

### Procurement

1. Any item known to have been counterfeited in the past (e.g., Grades 5 and 8 high-strength bolts, circuit breakers, and other S/CIs listed on the DOE S/CI web site), particularly items intended for use in safety systems or critical applications, should be procured only from qualified or dedicated suppliers. The LBNL Procurement Department can qualify suppliers and provide technical specifications and quality clauses prohibiting delivery of S/CIs in the purchase orders and contracts.
2. High-strength fasteners (graded bolts, screws, nuts, and washers) must be purchased directly through the Procurement Department. Procurement buyers will purchase from prequalified suppliers and will retain the manufacturer's certificate of conformance and/or certified material test report. Once on site, high-strength fasteners must be segregated and secured from the general stock to eliminate mixing with nongraded fasteners and to prevent general purpose use.

3. Onsite stores, shops, and end users should inspect newly received items known to have been counterfeited in the past. S/CI identification guidance is provided on the DOE S/CI web site. Periodic inspection of open stock and storage areas should continue to ensure they have been purged of S/CIs.

## Installed Items

1. During routine Laboratory inspections of facilities and equipment (e.g., self-assessment, EH&S functional inspections, maintenance and construction inspections), consideration should be given to identify S/CIs (identification guidance provided on the DOE S/CI web site). Additional training for personnel to recognize S/CIs can be arranged through the Office of Contract Assurance (OCA).
2. If an installed item is suspected of being an S/CI, OCA must be contacted to coordinate any engineering evaluation, verification testing, or disposition process.
3. If it is determined that the S/CI in safety systems and critical applications (e.g., heavy equipment, critical load paths in lifting equipment, and facility structures) can adversely affect the environment or create a safety hazard, the system or application must be locked/tagged out and the S/CI removed and replaced. If there is no adverse affect or creation of a hazard, the S/CI must be identified and entered into the LBNL Corrective Action Tracking System (CATS), and either removed and replaced during routine maintenance or determined to remain in place. If the S/CI is to remain in place, the structure or equipment must be tagged or marked, and the CATS entry so annotated and closed out.
4. For non-safety systems and noncritical applications, the S/CI must be identified and entered into CATS, and either removed and replaced during routine maintenance or determined to remain in place. If the S/CI is to remain in place, the structure or equipment must be tagged or marked, and the CATS entry so annotated and closed out.

## Disposition and Reporting

1. If an S/CI requires removal, OCA must coordinate and document the disposition. S/CIs must be removed from the work/use site and transferred to the LBNL Warehouse to be temporarily stored in a segregated area. Efforts will be made by the Procurement Department to identify the supplier, manufacturer, or distributor to seek restitution for the Laboratory.
2. OCA must report all discovered S/CIs to the local DOE Office of Inspector General (OIG) and the cognizant DOE operations office manager by means of the Occurrence Reporting and Processing System (ORPS).
3. After the S/CI is no longer needed as material evidence by OIG, the LBNL Warehouse will coordinate the destruction or alteration of the S/CI to render them unusable.
4. OCA will perform quarterly trending of suspect/ counterfeit item discoveries. Results will be reported in the quarterly Performance Analysis and Identification of Recurring Occurrences. As appropriate, lessons learned will be communicated via the DOE and LBNL lessons learned programs.

## Appendix D

# LBNL Conformance with Quality Assurance Requirements and Standards

The LBNL Quality Assurance Program, as documented in its Operating and Quality Management Plan (OQMP), PUB-3111, Rev. 8, conforms to all requirements identified in the Contractor Requirements Document (CRD) of DOE Order 414.1C, *Quality Assurance*. The LBNL OQMP also integrates the principles and practices of ANSI/ISO/ASQ Q 9001-2000 so as to conform as applicable and practicable to the international quality assurance standard.

DOE O 414.1C, Attach. 2, CRD	10 CFR 830, Subpart A	ANSI/ISO/ASQ Q 9001-2000	LBNL OQMP (PUB-3111, Rev. 8)
<p><b>2.a Quality Assurance Program Development and Implementation</b></p> <p>Assign and identify a senior management position responsible for the development, implementation, assessment, and improvement of a QAP that does the following:</p> <ol style="list-style-type: none"> <li>(1) Use the graded approach</li> <li>(2) Use national or international consensus standards</li> <li>(3) Apply additional voluntary standards</li> <li>(4) Integrate with other quality or management systems</li> </ol>		<p>5.1 Management Commitment</p> <p>5.2 Customer Focus</p> <p>5.3 Quality Policy</p> <p>5.4.1 Quality Objectives</p> <p>5.4.2 Quality Management System Planning</p> <p>5.5.2 Management Representative</p> <p>6.1 Provision of Resources</p>	<p>Statement of Laboratory Policy (pg vi)</p> <p>Objectives and Applicability (pg. viii)</p> <p>Offices of Institutional and Contract Assurance (pg. viii)</p> <p>Section 2, Management Systems and Process Controls</p> <p>Section 2.6.3, Consensus Standards</p> <p>Appendix A, The Graded Approach Methodology at LBNL</p>
<p><b>2.b Quality Assurance Program Approvals and Changes</b></p> <ol style="list-style-type: none"> <li>(1) Submit a QAP to DOE for approval</li> <li>(2) Implement the QAP</li> <li>(3) Indicate any third-party certification</li> <li>(4) Revise an existing QAP to address enhancements required by this CRD</li> <li>(5) Regard a QAP as approved by DOE 90 calendar days after DOE receipt, unless approved or</li> </ol>		<p>4.1 Quality Management System - General Requirements</p> <p>4.2.1 Documentation Requirements - General</p> <p>4.2.2 Quality Manual</p>	<p>PUB 3111, Rev. 8, is the LBNL documented quality management and quality assurance manual.</p>

DOE O 414.1C, Attach. 2, CRD	10 CFR 830, Subpart A	ANSI/ISO/ASQ Q 9001-2000	LBNL OQMP (PUB-3111, Rev. 8)
<p>rejected by DOE at an earlier date</p> <p>(6) Submit QAP changes made the previous year annually to DOE for review and approval</p>			
<p><b>2.c Quality Guidance Usage</b></p> <p>The Contractor must consider QA guidance in developing and implementing a QAP</p>			<p>LBNL uses for its QA guidance: <i>DOE G 414.1-1A, DOE P 450.4, DOE P 450.5, DOE G 414.1-2A, DOE G 414.1-3, DOE G 414.1-4.</i></p>
<p><b>3.a Management/Criterion 1— Program.</b></p> <p>(1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.</p> <p>(2) Establish management processes, including planning, scheduling, and providing resources for work.</p>	<p>1. Management/ Program</p>	<p>5.5.1 Responsibility and Authority</p> <p>5.5.3 Internal Communication</p> <p>6.4 Work Environment</p>	<p>Section 1.1, Organizational Structure</p> <p>Section 1.2, Planning</p> <p>Section 2.1, Managing Principles</p>
<p><b>3.b Management/Criterion 2— Personnel Training and Qualification.</b></p> <p>(1) Train and qualify personnel to be capable of performing assigned work.</p> <p>(2) Provide continuing training to personnel to maintain job proficiency.</p>	<p>2. Management/ Personnel Training and Qualification</p>	<p>6.2.1 Human Resources - General</p> <p>6.2.2 Competence, Awareness, and Training</p>	<p>Section 1.3, Staff Proficiency</p>
<p><b>3.c Management/Criterion 3— Quality Improvement.</b></p> <p>(1) Establish and implement processes to detect and prevent quality problems.</p> <p>(2) Identify, control, and correct items, services, and processes that do not meet established requirements.</p> <p>(3) Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.</p> <p>(4) Review item characteristics, process implementation, and other quality-related information to</p>	<p>3. Management/ Quality Improvement</p>	<p>8.5.1 Continual improvement</p> <p>8.5.2 Corrective Action</p> <p>8.5.3 Preventive action</p>	<p>Section 3.3, Continuous Improvement</p> <p>Section 3.3.1, Quality Improvement</p> <p>Section 3.3.2, Corrective Action</p> <p>Section 3.3.3, Lessons Learned</p>

DOE O 414.1C, Attach. 2, CRD	10 CFR 830, Subpart A	ANSI/ISO/ASQ Q 9001-2000	LBNL OQMP (PUB-3111, Rev. 8)
identify items, services, and processes needing improvement.			
<p><b>3.d Management/Criterion 4— Documents and Records.</b></p> <p>(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.</p> <p>(2) Specify, prepare, review, approve, and maintain records.</p>	4. Management/ Documents and Records	<p>4.2.3 Control of documents</p> <p>4.2.4 Control of Records</p>	Section 2.7, Document and Records Management
<p><b>3.e Performance/Criterion 5—Work Processes.</b></p> <p>(1) Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.</p> <p>(2) Identify and control items to ensure proper use.</p> <p>(3) Maintain items to prevent damage, loss, or deterioration.</p> <p>(4) Calibrate and maintain equipment used for process monitoring or data collection.</p>	5. Performance/ Work Processes	<p>6.3 Infrastructure</p> <p>7.1 Planning of product realization</p> <p>7.2.1 Determination of requirements related to the product</p> <p>7.2.2 Review of requirements related to the product</p> <p>7.2.3 Customer communication</p> <p>7.5.1 Control of production and service provision</p> <p>7.5.2 Validation of processes for production and service provision</p> <p>7.5.3 Identification and traceability</p> <p>7.5.4 Customer property</p> <p>7.5.5 Preservation of product</p> <p>8.2.4 Monitoring and measurement of product</p> <p>8.3 Control of nonconforming product</p> <p>8.4 Analysis of data</p>	<p>Section 2.1, Managing Principles</p> <p>Section 2.2, Safety Management</p> <p>Section 2.3, Environmental Management</p> <p>Section 2.4, Safeguard and Security Management</p> <p>Section 2.5, Other LBNL Management Systems</p> <p>Section 2.6.1, Core Functions</p> <p>Section 2.6.2, Written Procedures, Instructions, and Drawings</p> <p>Section 2.6.3, Consensus Standards</p> <p>Section 2.6.6 Function-Specific Controls</p> <p>Section 2.6.7, Facility-Specific Controls</p>
<p><b>3.f Performance/Criterion 6— Design.</b></p> <p>(1) Design items and processes using</p>	6. Performance/ Design	<p>7.3.1 Design and development planning</p> <p>7.3.2 Design and</p>	Section 2.6.6.A, Function-Specific Controls, Design

DOE O 414.1C, Attach. 2, CRD	10 CFR 830, Subpart A	ANSI/ISO/ASQ Q 9001-2000	LBNL OQMP (PUB-3111, Rev. 8)
<p>sound engineering/scientific principles and appropriate standards.</p> <p>(2) Incorporate applicable requirements and design bases in design work and design changes.</p> <p>(3) Identify and control design interfaces.</p> <p>(4) Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.</p> <p>(5) Verify/validate work before approval and implementation of the design.</p>		<p>development inputs</p> <p>7.3.3 Design and development outputs</p> <p>7.3.4 Design and development review</p> <p>7.3.5 Design and development verification</p> <p>7.3.6 Design and development validation</p> <p>7.3.7 Control of design and development changes</p>	
<p><b>3.g Performance/Criterion 7— Procurement.</b></p> <p>(1) Procure items and services that meet established requirements and perform as specified.</p> <p>(2) Evaluate and select prospective suppliers on the basis of specified criteria.</p> <p>(3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.</p>	7. Performance/ Procurement	<p>7.4.1 Purchasing process</p> <p>7.4.2 Purchasing information</p> <p>7.4.3 Verification of purchased product</p>	Section 2.6.6.B, Function-Specific Controls, Procurement
<p><b>3.h Performance/Criterion 8— Inspection and Acceptance Testing.</b></p> <p>(1) Inspect and test specified items, services, and processes using established acceptance and performance criteria.</p> <p>(2) Calibrate and maintain equipment used for inspections and tests.</p>	8. Performance/ Inspection and Acceptance Testing	<p>7.6 Control of Monitoring and Measuring Devices</p> <p>8.1 Measurement, Analysis, and Improvement - General</p> <p>8.2.1 Customer satisfaction</p>	<p>Section 2.6.6.C, Function-Specific Controls, Manufactured Items Inspection and Testing</p> <p>Section 2.6.6.D, Function-Specific Controls, Construction Inspection and Testing</p>
<p><b>3.i Assessment/Criterion 9— Management Assessment.</b></p> <p>Ensure that managers assess their management processes and identify and correct problems that hinder the</p>	<p>3. Management/ Quality Improvement</p> <p>9. Assessment/ Management</p>	<p>5.6.1 Management Review - General</p> <p>5.6.2 Review input</p> <p>5.6.3 Review output</p> <p>8.2.3 Monitoring and</p>	<p>Offices of Institutional and Contract Assurance (pg. viii)</p> <p>Section 3.1, Management Assessment</p> <p>Section 3.3.2, Corrective Action</p>

DOE O 414.1C, Attach. 2, CRD	10 CFR 830, Subpart A	ANSI/ISO/ASQ Q 9001-2000	LBNL OQMP (PUB-3111, Rev. 8)
organization from achieving its objectives.		measurement of processes	
<p><b>3.j Assessment/Criterion 10— Independent Assessment.</b></p> <p>(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.</p> <p>(2) Establish sufficient authority and freedom from line management for independent assessment teams.</p> <p>(3) Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.</p>	10. Assessment/ Independent Assessment	8.2.2 Internal audit	Section 3.2, Independent Assessment
<p><b>4.a Supplemental Quality Management System Requirements for Suspect / Counterfeit Items</b></p> <p>An S/CI prevention process must be developed and implemented as a part of the contractor’s QAP and must be commensurate with the facility/activity hazards and mission impact.</p>	8. Performance/ Inspection and Acceptance Testing		Section 2.6.4 Suspect/Counterfeit Items Appendix C, Policy and Procedure for Controlling Suspect/Counterfeit Items
<p><b>4.b Work Process Controls</b></p> <p>Work processes must be developed and implemented using available S/CI information.</p>			Appendix C, Policy and Procedure for Controlling Suspect/Counterfeit Items
<p><b>5. Safety Software Quality Requirements</b></p> <p>Work processes involving safety software must be developed and implemented.</p>	6. Performance/ Design		Section 2.6.5, Safety Software Quality Assurance