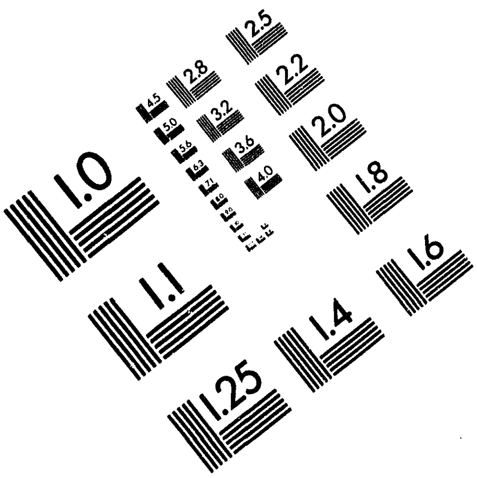

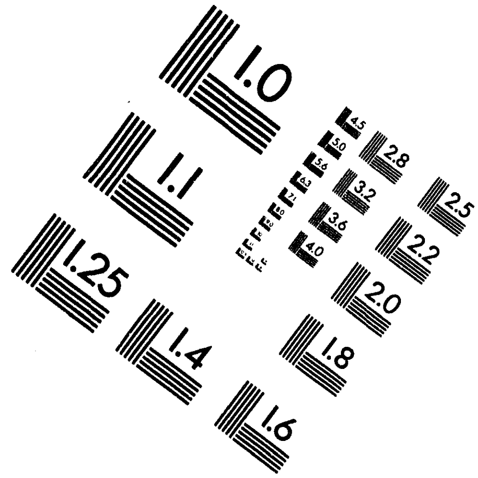

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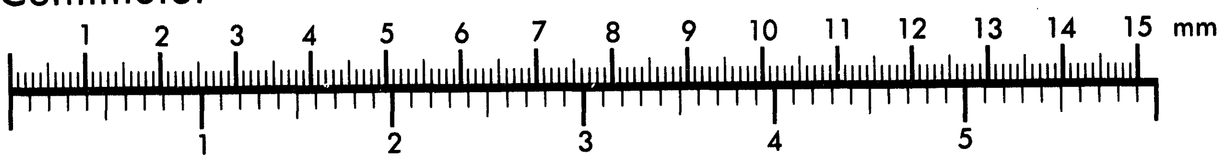

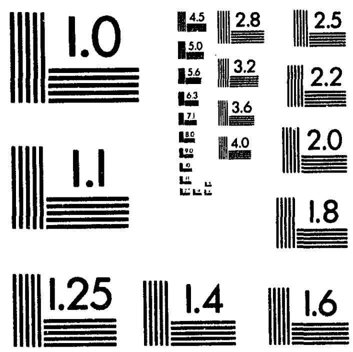

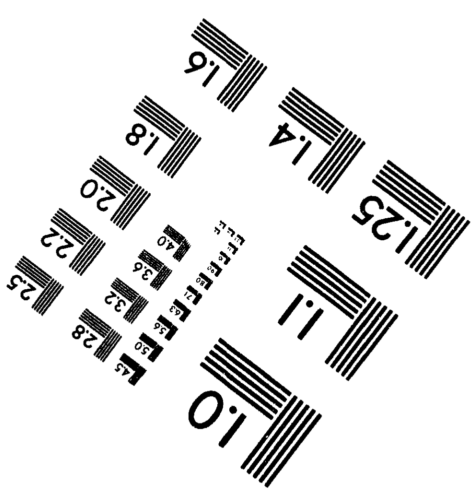

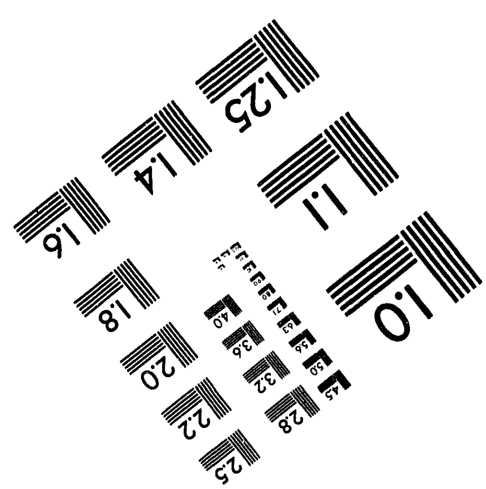

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OPERATING AND ASSURANCE PROGRAM PLAN

Revision 4
Effective Date: July 1, 1994

Prepared:	Manager, Office of Assessment and Assurance	6/21/94 Date
Approved:	Associate Laboratory Director, Operations	6/24/94 Date
Approved:	Laboratory Director	6/27/94 Date

Lawrence Berkeley Laboratory
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Berkeley, CA 94720

Prepared for the U.S. Department of Energy
under Contract DE-AC03-76SF00098

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RECORD OF REVISIONS

Rev. No.	Date	Description
3	DRAFT (11/11/92)	Rewrite of the LBL *Institutional Quality Assurance Program Plan, Rev. 2*, 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, *Accelerator Safety* -total quality management -general editorial

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STATEMENT OF LABORATORY POLICY

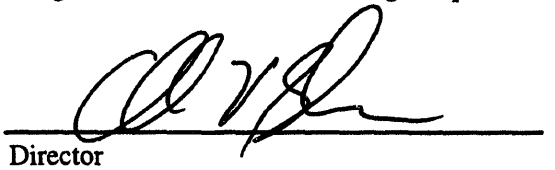
It is the policy of Lawrence Berkeley Laboratory to carry out all our activities that contribute to the scientific and operational objectives of the Laboratory in accordance with the requirements of this Operating and Assurance Program. It is line management's responsibility to plan for and achieve compliance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

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

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

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

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



Director
Lawrence Berkeley Laboratory

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OAP OBJECTIVES AND APPLICABILITY

The LBL Operating and Assurance Program (OAP) is a management system and a set of requirements designed to

- Maintain the level of performance necessary to achieve LBL's programmatic and administrative objectives effectively and safely through the application of *quality assurance* and related *conduct of operations* and *maintenance management* principles.
- Implement an LBL management philosophy that supports and encourages continual improvement in performance and quality at the Laboratory.
- Provide an integrated approach to compliance with applicable regulatory requirements and DOE orders.

The OAP is intended to meet the requirements of DOE Order 5700.6C, **Quality Assurance**. The Program also contains management system elements of DOE Orders 5480.19, **Conduct of Operations Requirements for DOE Facilities**; 5480.25, **Safety of Accelerator Facilities**; and 4330.4A, **Maintenance Management Program**, and is meant to integrate these elements into the overall LBL approach to Laboratory management.

The requirements of this program apply to LBL employees and organizations, and to contractors and facility users as managed by their LBL sponsors. They are also applicable to external vendors and suppliers as specified in procurement documents and contracts.

LBL distinguishes between managing Laboratory resources (facilities and infrastructure) that *support* research and managing the actual *performance* of research. In both cases, the extent and detail of the management systems are commensurate with the scale, cost, complexity, and hazards of the work being performed. However, the outcome of basic and applied research is not necessarily predictable and may not be amenable to written procedures. For that reason, the application of OAP requirements to research activities is heavily dependent upon the judgment of the principal investigator or senior scientist. Planning, materials management, documentation, experimental apparatus calibration, software control, inspections and tests, and review of work by collaborating scientists are all within the purview of the principal investigator, consistent with LBL ES&H and other institutional requirements.

It is the intent of the OAP to provide adequate flexibility for the researchers' unique and diverse needs while retaining an LBL management system that ensures the safe and effective implementation of the Laboratory's mission and objectives.

An additional objective of the OAP is to contribute to and support the Director's Quality Initiative to implement total quality management (TQM) in a common-sense manner. TQM is a business philosophy that asserts that all work is a process that can be continuously improved to achieve greater customer satisfaction. This philosophy, when applied toward strategic planning objectives in an open, interactive human environment, can significantly increase organizational effectiveness.

Application of quality management principles leads to an "integrated" management system that involves everyone, supports real gains in performance, consistently satisfies customer needs, and is used by all employees—who are empowered to improve it as well as to use it.

PROGRAM DESCRIPTION

The Operating and Assurance Program (OAP) is LBL's management system and set of requirements for ensuring that our mission is carried out effectively and safely by meeting the performance objectives articulated in organizational mission statements, division self-assessment plans, and other planning documents. For example, the Laboratory's mission is stated in its **Institutional Plan** (PUB-5334) and the "LBL Vision 2000" statement issued by the Laboratory Director.

The five elements of the OAP constitute LBL's approach to managing its resources for both research and research support. The elements reflect a "plan-do-check-act" logic for structuring quality assurance, conduct of operations, maintenance management, and related programs. This logic is illustrated in the following table.

	Element
Plan	1—Planning and Organization
Do	2—Staff Proficiency
	3—Work Processes
	4—Document and Records Control
Check or Act	5—Performance Assessment and Assurance

The organization of this document, the OAP Plan, reflects this same structure. In the Program Elements section, which starts on page 7, each element is considered in turn, according to the order and numbering system given above; that is, Element 1 is Planning and Organization, and so on. Under each element you will find a general discussion; a summary list of LBL requirements—the actions necessary to comply with the OAP and associated orders; a list of specific responsibilities organized by Laboratory position; and a description of the LBL approach to implementing the element.

Four appendices provide background and support information, as follows:

- **Appendix A** contains a matrix that maps each of the criteria from DOE 5700.6C to its location in the OAP.
- **Appendix B** contains the methodology used by LBL management to analyze activities, facilities, projects, and functions when grading the application of OAP requirements.
- **Appendix C** describes the LBL approach to preparing and using LBL Notebooks.
- **Appendix D** contains a graphic showing how the main requirements of DOE 5480.25 map onto the five OAP elements.
- **Appendix E** defines the terminology used in this document to ensure consistent understanding and communication by LBL personnel.

The OAP Plan is part of the LBL management document hierarchy, as shown in Figure 1.

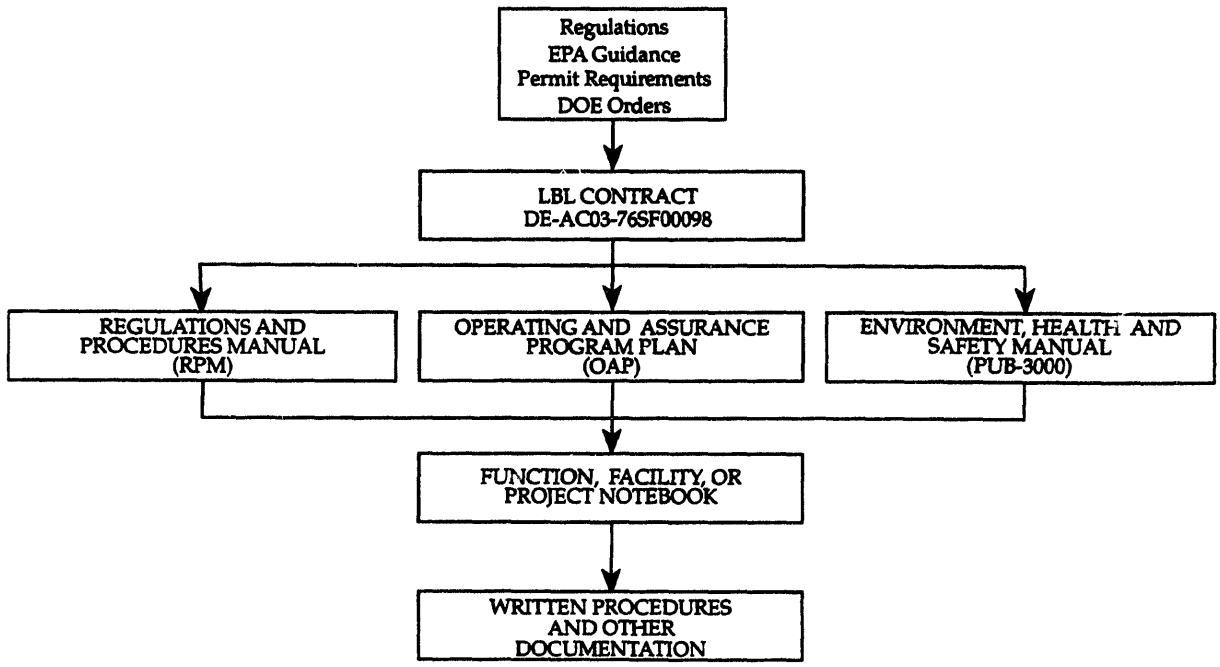

Figure 1: Hierarchy of LBL Management Documents

LBL Notebooks

Along with the OAP, LBL Notebooks provide documentation of LBL's implementation of DOE requirements for quality assurance, conduct of operations, and maintenance management. LBL Notebooks describe requirements and document how these requirements have been fulfilled by providing information on the activities associated with each of the Laboratory's functions, facilities, and projects. The information is presented at a level of detail commensurate with the potential risk of each activity, and the related support for each activity is similarly prioritized. This scheme, known as the graded approach, assists LBL in effective allocation of resources (see Appendix B).

LBL Notebooks contain such material as written procedures, instructions, training records, and copies of (or references to) this OAP Plan. A Laboratory-wide written procedure is used to guide the preparation, review, and maintenance of each Notebook. Appendix C, **Preparation and Maintenance of LBL Notebooks**, provides the general methodology for Notebook development.

There are three types of LBL Notebooks, as follows:

- FUNCTION NOTEBOOKS pertain to (1) Laboratory or division office management, or (2) any of the support or service organizations funded from overhead, scientific burden, or recharge. These Notebooks contain information on quality assurance. The function supervisor or manager is responsible for developing and maintaining the Function Notebook.
- FACILITY NOTEBOOKS pertain to an entity or location that provides the physical resources to facilitate scientific research. An example might be a research building or laboratory and its equipment, operators, and staff. These Notebooks contain information on quality assurance, conduct of operations, and maintenance management. The facility supervisor or manager is responsible for developing and maintaining the Facility Notebook.
- PROJECT NOTEBOOKS pertain to groups of personnel and supporting equipment dedicated to a specific research or construction effort. These Notebooks contain information on quality assurance and maintenance management. The principal investigator or project leader is responsible for developing and maintaining the Project Notebook.

Some Laboratory activities may require more than one type of Notebook to completely document the management of quality and conduct of operations. For example, a specific facility may support more than one project with differing requirements.

A division's organizational structure need not be modified to implement the Notebook system. Rather, the number and types of Notebooks are closely aligned with the existing divisional structure. For ease of maintenance and optimum utility, only the minimum number of Notebooks is produced.

LBL Notebooks are subject to assessment as part of the process of ensuring that the Laboratory is meeting OAP requirements.

Continuing assessment of LBL's performance, as documented in audit reports, appraisals, and the Self-Assessment Program, provides the basis for periodic revision of the OAP Plan and LBL Notebooks. This ensures that all current requirements are incorporated and that implementation of requirements is adequate.

Integration of Conduct of Operations and Maintenance Management Requirements

The OAP's five program elements reflect LBL's understanding and approach to the requirements and intent of the DOE quality assurance order (5700.6C). Additional requirements in the DOE orders for conduct of operations (5480.19) and maintenance management (4330.4A) at DOE facilities complement and support the basic quality assurance system requirements. Each of these requirements has been analyzed and mapped to one of the five OAP elements, as depicted in Figure 2 for conduct of operations requirements and in Figure 3 for maintenance management requirements. Similarly, applicable requirements of the DOE order for accelerator safety (DOE 5480.25) have been analyzed and included in the appropriate OAP element(s). See Appendix D for a mapping of these requirements onto the five OAP elements.

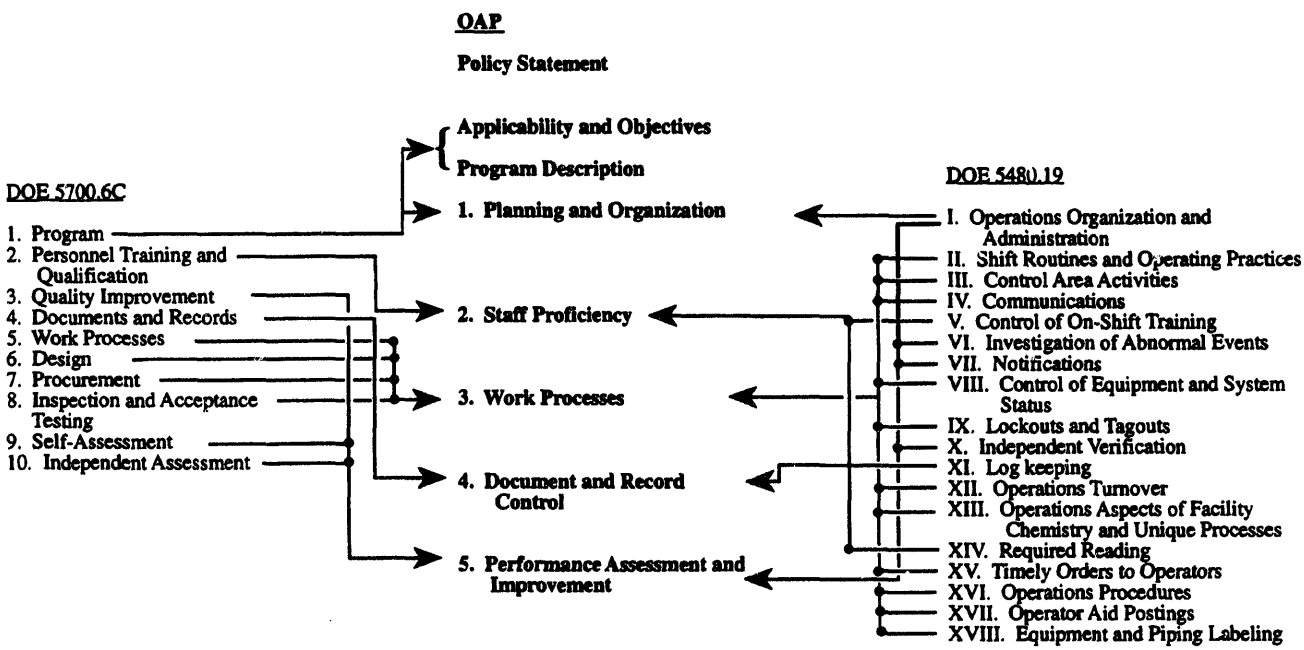

Figure 2: Comparison of Quality Assurance and Conduct of Operations Requirements

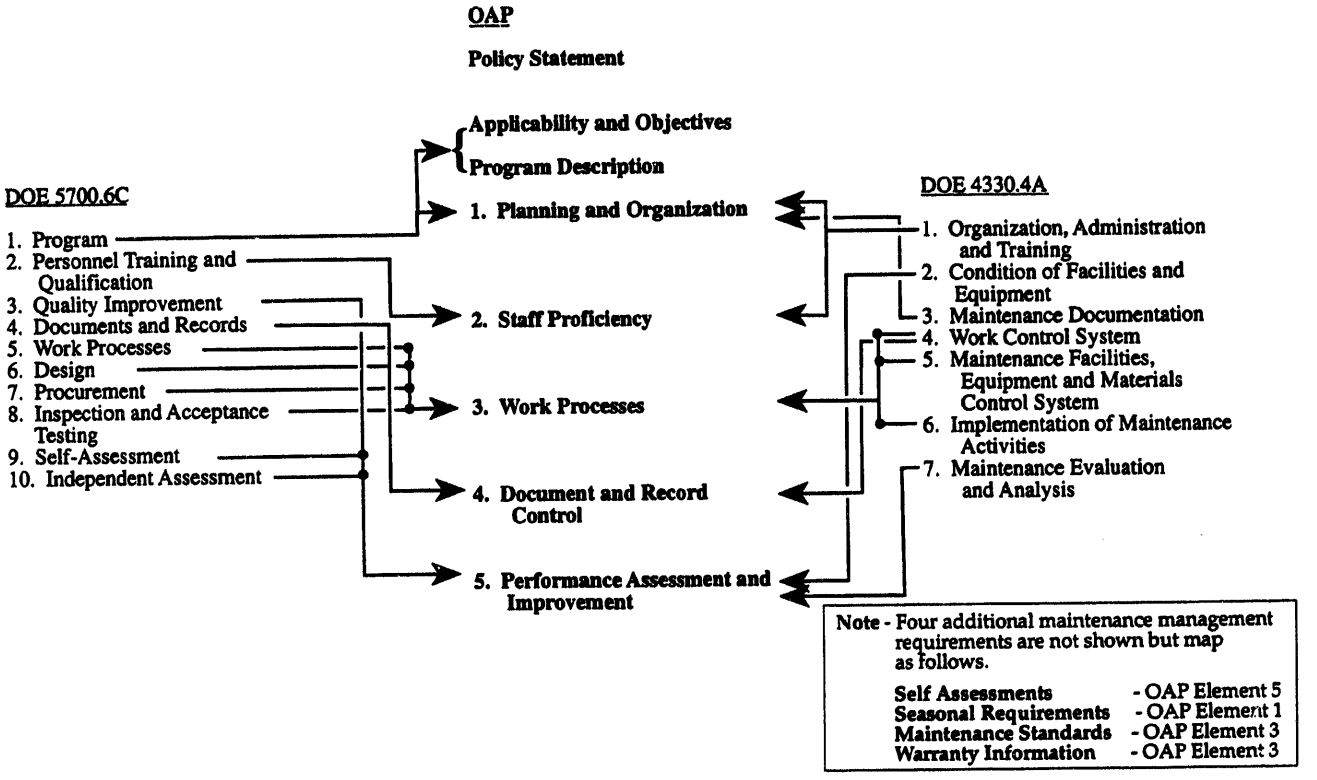

Figure 3: Comparison of Quality Assurance and Maintenance Management Requirements

Based upon this mapping, the instructions for preparing the LBL Notebooks include conduct of operations and maintenance management requirements, as appropriate for each LBL Notebook type. For example, the Facility Notebook emphasizes requirements from the Conduct of Operations Order (with specific additional requirements for accelerator facilities), and maintenance management requirements are addressed primarily in the Project and Facility Notebooks. (See Appendix C for further discussion of the LBL Notebook preparation process.)

Many other DOE orders also apply to the operation and management of LBL. The OAP structure is intended to accommodate compliance with these orders to the extent that their requirements map onto those of the OAP.

The Graded Approach

LBL management strives to apply resources in a way that will yield the greatest benefits. Management also strives to eliminate unproductive activities that add to costs or are unnecessarily burdensome, while ensuring that LBL activities are performed in a manner that protects the environment and the health and safety of the public and of LBL employees.

Not all items, processes, activities, and services have the same effect on health and safety, reliability, environmental protection, or programmatic

objectives. Therefore, LBL uses a graded approach to determine the applicability of the OAP requirements to specific Laboratory activities and the rigor with which they should be applied. Considerations include

- Public health and safety.
- Personnel health and safety.
- Environmental protection.
- Compliance with regulations.
- LBL mission and programmatic impact.
- Protection of Laboratory assets.
- Public perception.
- Impact on scientific results (e.g., importance of data, reproducibility of results, uniqueness of product).
- Life cycle stage of facility.

The objectives of LBL's graded approach are to assist in identifying quality-affecting activities or components and to ensure that these activities are managed through systems that are commensurate with the scale, cost, complexity, and hazards of the work being performed.

LBL line managers are responsible for identifying the activities that are subject to these requirements and for carrying out an analysis that justifies the degree of rigor to be applied. Appendix B provides an introduction to the LBL methodology for accomplishing and documenting that analysis.

Total Quality Management

The OAP is also designed to promote continuous improvement at LBL in support of the Director's Quality Initiative:

- Baselining and reporting against performance measures in the UC-LBL/DOE management contract,
- Quality-related management and team training,
- Renewing "customer" focus, and
- The use of process-improvement teams to improve LBL's support services

are all supported by the requirements and guidance contained in the OAP.

The DOE's *Total Quality Management Implementation Guidelines* are also reflected in our program, primarily in the areas of integration of requirements and managing process quality.

1. Planning and Organization

Planning is a key component in achieving performance objectives, including quality objectives. Planning of an activity should be carried out to the extent necessary to understand and systematically implement all requirements. It should also take into account cost and schedule.

Planning should be done as early as practical prior to the start of quality-affecting activities. An early start allows sufficient time to address organizational interface compatibility and to identify activities requiring written procedures, peer reviews, work instructions, drawings, equipment, or personnel training to attain the requisite quality.

Organizational responsibilities, authorities, and interfaces are important parameters addressed in the planning effort. To achieve our objectives, LBL management must be certain that

- LBL policies and corresponding implementation requirements are clearly communicated to all appropriate LBL personnel.
- The results of (or problems associated with) the implementation of those requirements are communicated to management.
- Communication flows freely in both directions.

Each person is responsible for achieving his or her own performance objectives within the LBL organizational framework. This framework includes the definition of the individual's organizational role(s), responsibilities, and authority, relative to the work and to other personnel. By clearly defining such relationships for each individual, LBL maximizes its institutional ability to efficiently provide the resources and support necessary to conduct its research programs successfully and safely.

LBL Requirements

- **An Operating and Assurance Program** (OAP) Plan describing the management system for meeting quality assurance, conduct of operations, accelerator safety, and maintenance management requirements must be written.
- **The organizational structure, responsibilities, and interfaces for managing**, performing, and assessing work must be clearly described and communicated.
- **Notebooks must be prepared, used, and maintained** as the primary planning and implementing documents for the OAP. [Alternatives to Notebooks must be approved by the Office of Assessment and Assurance (OAA)].
- **Applicable requirements of DOE Order 5480.19, Conduct of Operations Requirements for DOE Facilities; 5480.25, Safety of Accelerator Facilities, and 4330.4A, Maintenance Management Program**, must be addressed as described in this OAP Plan.
- LBL management must oversee the **quality-affecting activities of external organizations**, such as suppliers of goods and services.
- **All LBL and associated personnel** performing LBL quality-affecting activities must take responsibility for identifying practices or conditions that may be unsatisfactory and for recommending the cessation of work, as appropriate.
- **The OAP Plan must be an approved, controlled document**, and any substantial, approved changes to it must be submitted to DOE for review.

LBL Responsibilities

The following responsibilities are assigned to ensure that the Planning and Organization Element of the OAP is implemented.

Laboratory Director

- Establish the quality assurance, conduct of operations, accelerator safety, and maintenance management requirements for LBL activities and provide policy on their application.
- Approve the OAP Plan, provide adequate resources for its implementation, and ensure that the program is executed.
- Define and clearly communicate the LBL organizational structure, authorities, and responsibilities.
- Provide an independent assessment function in the Laboratory organization.

Associate Laboratory Director for Operations

- Approve the LBL OAP Plan and provide adequate resources for its administration.
- Provide Laboratory-wide written procedures for implementation where required (e.g., procedure for preparation of LBL Notebooks).

Division Directors and Department Heads

- Exercise management authority and cooperate with other divisions and supporting organizations to ensure that OAP requirements are met.
- Ensure that the LBL OAP requirements are appropriately implemented through the use of LBL Notebooks or plans and written procedures using the graded approach.
- Administer the division self-assessment process, which supports the assessment requirements of the OAP.
- Provide sufficient divisional resources to support the objectives and implementation of OAP requirements.

Line Managers

- Apply and document OAP requirements using the LBL graded approach.
- Periodically assess performance against established performance objectives and OAP requirements, and take corrective action as necessary.
- Develop, issue, maintain, and control LBL Notebook(s) for their technical scope of responsibility (managers of facilities, projects, or functions).

Manager, Office of Assessment and Assurance

- Manage development, revision, and maintenance of the LBL OAP Plan.
- Manage development and maintenance of institutional procedures supporting the OAP Plan, including those for the LBL Notebook system.
- Review and recommend approval of the LBL OAP Plan and supporting institutional procedures.
- Provide overall direction for the LBL Self-Assessment Program in support of OAP assessment requirements (see OAP Program Element 5).
- Provide independent assessment services to LBL functional groups and facilities.
- Provide quality assurance/conduct of operations (QA/CO) guidance, consultation, and training to LBL Divisions and QA representatives.
- Staff and maintain OAA at a level adequate to provide these services.

Division Quality Assurance Representatives

- Provide guidance and consultation to division personnel and management regarding QA/CO requirements and methods.
- Act as a primary point of contact with the OAA for divisional QA/CO matters such as coordinating independent assessments, promulgating new requirements or information, and training.

All LBL Personnel

- Understand LBL organizational responsibilities and authorities as described in this OAP Plan and elsewhere.
- Perform assigned tasks in accordance with OAP requirements as described in LBL Notebooks, written procedures, and Laboratory policy.
- Identify noncompliances or unsafe LBL work practices, and understand and implement (as appropriate) the LBL stop work policy.
- Identify and report to management deficiencies, in this OAP or other management systems, that hinder the ability to achieve performance objectives.

LBL Implementation

1.1 Personnel and Organizational Responsibility

The organizational structure and the responsibilities of those involved in performing quality-affecting activities at LBL are clearly established in plans, written procedures, LBL Notebooks, and other documented work instructions. The overall organizational structure of LBL is shown in Figure 4.

The **Responsibilities** section of each element in this OAP Plan describes the specific responsibilities of various levels of management. In addition, all LBL personnel are responsible for achieving their own performance objectives, including achievement of quality in their work. This responsibility includes:

- Achieving appropriate qualification, training, and proficiency.
- Ensuring that correct requirements and other applicable standards are developed, complied with, and documented for their assigned tasks.
- Ensuring that OAP deficiencies and other problems are promptly reported and addressed.
- Demonstrating appropriate continued professional development and quality improvement.

Assigned OAP tasks may be delegated at any management level as warranted; however, active personal participation in the OAP by senior and other line management personnel demonstrates commitment to the concepts

of quality achievement, assurance, and improvement. Delegation of tasks does not exempt anyone from responsibility for achieving quality.

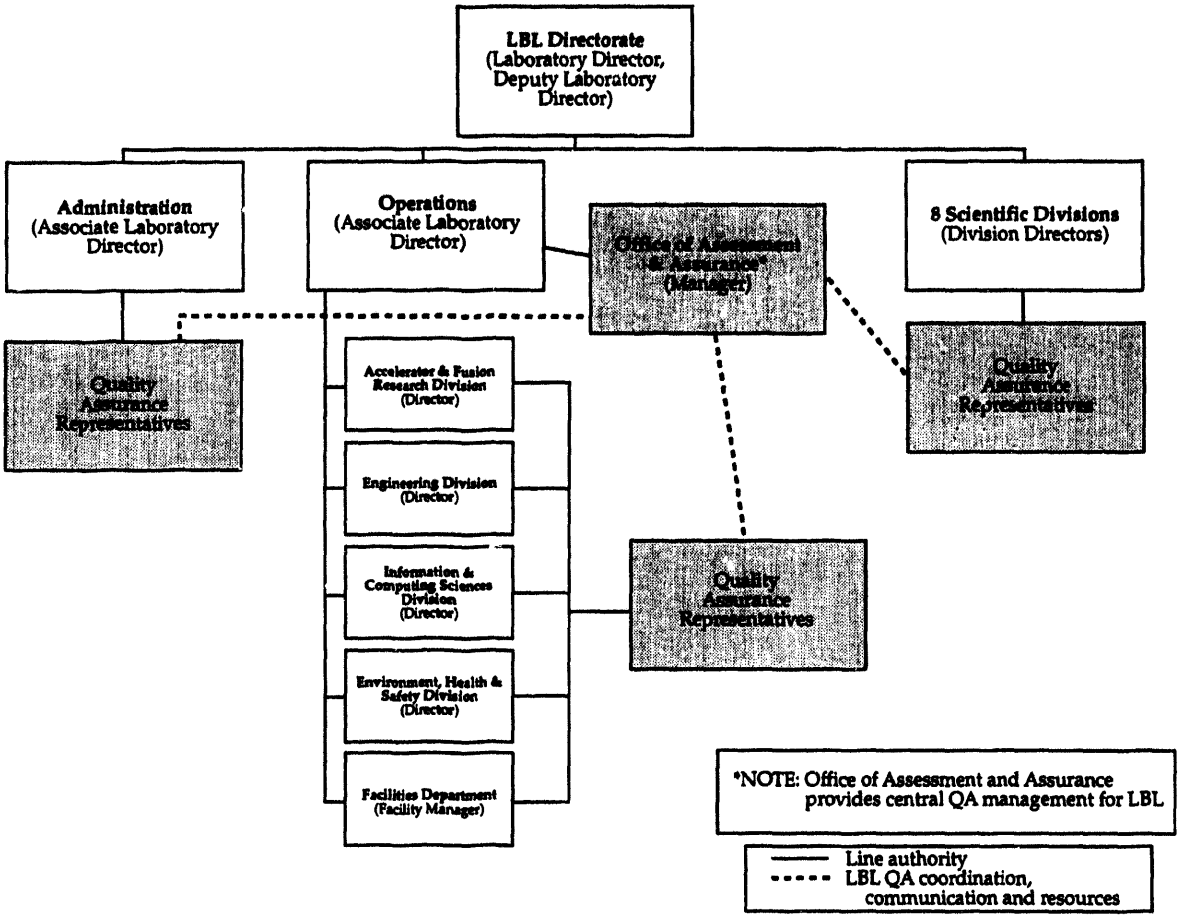

Figure 4: LBL Organizational Chart

1.2 LBL Quality Assurance Organization

The LBL quality assurance function is centrally coordinated and administered through the OAA. This organization is chartered to provide assurances that Laboratory activities and operations are conducted to a high level of proficiency and quality, through implementation of the OAP.

In addition to the OAA staff, quality assurance representatives (QA reps) implement quality assurance at the division level. Each division has one or more QA reps, who support their division's QA-related activities, participate in assessment activities, and help disseminate QA information (such as lessons learned and programmatic changes) to their division's staff.

Details of the LBL quality assurance organization can be found in Figure 4.

1.3 Coordination with External Organizations

Quality-affecting activities performed for LBL outside the Laboratory's direct management are subject to oversight controls. These controls include assigned responsibilities and lines of communication. Subcontractors, vendors, consultants, outside users of our facilities, or others performing or contributing to quality-affecting activities must either abide by the provisions of the LBL OAP or develop their own quality assurance, conduct of operations, and maintenance management programs, which must be approved by LBL prior to implementation. External organizations are assessed as an integral part of the OAP according to contractual requirements, either at the vendor's facility or on-site through surveillance of vendors and contractors.

1.4 Stop Work Responsibility and Authority

All personnel are responsible for identifying unsafe or unsatisfactory work at LBL and for stopping their own work if it becomes unsafe or unsatisfactory. Supervisors hold general responsibility for stopping unsafe or unsatisfactory work at LBL. This responsibility and authority overrides planning, cost, and schedule considerations.

The Laboratory Director has delegated to the technical staff of the LBL EH&S Division the authority to stop operations that appear to constitute an imminent danger when cognizant management fails to take such action. If operations are suspended for safety reasons, the work stoppage must be investigated and reported in accordance with the occurrence reporting guidelines specified in PUB-3000. Operations may be resumed when authorized by the LBL EH&S division director or designee.

When operations are suspended for quality (non-safety) reasons, the appropriate level of line management authorizes resumption of work. This may occur only after line management has verified that suitable corrections have been made to the process, facility, or equipment to be used.

1.5 OAP Preparation and Maintenance

The OAP Plan is a document containing Laboratory policy and requirements. It is controlled in accordance with the LBL document-control policy and institutional procedure. The OAP Plan is submitted for approval to DOE after LBL management approval. Changes to the plan are made through the OAA and are submitted annually to the DOE for review.

2. Staff Proficiency

Staff proficiency is vital to the success of LBL's mission of achieving scientific excellence within organizational requirements and standards.

LBL management must provide for systems of personnel selection, training, and qualification to ensure that LBL personnel have the appropriate skills, experience, qualifications, and certifications to carry out assignments successfully. In turn, each individual at LBL helps to ensure quality by effectively applying his or her qualifications, training, and proficiency in assigned tasks.

LBL Requirements

- **Job requirements** must be established and documented, and the qualifications of job candidates must be verified.
- **The training needs** for each position must be determined and documented.
- **An Operating and Assurance Program (OAP) orientation** must be provided for LBL management personnel.
- **Initial training** (and periodic training as required) must be provided for personnel in order to ensure job proficiency.
- **ES&H training** appropriate to the facility must be provided for facility and project personnel, outside users who perform research in an LBL facility, and line management.
- **On-the-job training** must be administratively controlled to ensure that such training is not allowed to impact workplace or operational safety.
- **Professional and personal development activities** must be included, as appropriate, in training requirements.
- **A documented evaluation of job proficiency** must be conducted, at least annually, for all personnel.
- **The LBL training program** must be periodically evaluated for effectiveness.

LBL Responsibilities

The following responsibilities are assigned to ensure that the Staff Proficiency Element of the OAP is implemented:

Line Managers

- Ensure that personnel are qualified for, trained for, and proficient in performing assigned tasks.
- Determine and document job requirements and qualifications and evaluate the initial qualifications of personnel for a position.
- Determine and document the initial and ongoing training requirements for employees, including specialized job training, mentoring, on-the-job training, ES&H training, and OAP orientation training.
- Periodically evaluate and document staff proficiency.
- Provide administrative control for on-the-job training.

Head, Human Resources Department

- Administer LBL system of employee hiring, including verification of initial qualifications, education, and experience.

Training Manager

- Administer LBL internal training program.
- Provide resources for training, including qualified trainers, lesson plans, and other materials.
- Evaluate training effectiveness periodically.

Manager, Office of Assessment and Assurance

- Develop an OAP orientation training lesson plan.

All LBL Personnel

- Understand the assigned tasks (and position description) for their position.
- Perform only those assignments for which they have the requisite qualifications, training, and proficiency, unless under the direct supervision of a qualified instructor.
- Effectively apply qualifications and abilities in performing assigned tasks.

LBL Implementation

2.1 Position Requirements and Selection

The immediate supervisor or manager establishes a position description that defines the minimum education, experience, and other initial qualifications for positions that require performance of quality-affecting activities. The selecting supervisor or manager determines and documents the candidates' initial qualifications as compared with the minimum requirements. The

Human Resources Department verifies and documents relevant education and experience. When position descriptions are revised, a corresponding determination of incumbent qualifications should be performed.

2.2 Determination of Training Needs

Staff training requirements address the specific needs of employees as well as those of the Laboratory. Cognizant supervisors or managers, in consultation with the manager of OAA, training manager, and other appropriate personnel, determine and document the training needs for each staff position. Training assignments are based on these determinations. Appropriate training may include technical, administrative, process improvement, or ES&H instruction at the institutional, function, facility, or project level. Training may also include instruction in supervisory, management, communication, or interpersonal skills.

2.3 Orientation

LBL management personnel receive an orientation to the LBL OAP. This orientation is an overall introduction to the purpose, scope, terminology, methods of implementation, applicability, and relation of the OAP Plan to the Regulations and Procedures Manual, the Health and Safety Manual (PUB-3000), applicable regulations, and the LBL Notebook system at the facility, function, and project levels.

2.4 Training and Job Proficiency

Personnel receive specialized training commensurate with the scope, hazards, and complexity of their jobs to ensure proper understanding of the specific principles, techniques, and requirements of their assigned tasks. Training is successfully completed and documented prior to the assignment of corresponding quality-affecting activities. As appropriate, on-the-job training and/or a demonstration of initial proficiency is required.

Qualified instructors train personnel by a variety of methods, including formal classroom sessions, required reading assignments, hands-on workshops, and mentoring, as appropriate. For example, a required reading file may be appropriate for an LBL facility where management needs to ensure that critical information is passed to all operations personnel and that transmittal of this information is achieved and documented. Periodic retraining (or ongoing training) is conducted to maintain each employee's job proficiency and to improve performance.

2.5 ES&H Training

The detail and extent of the training is commensurate with the hazards associated with the activities being performed. Identification of and response to abnormal events or emergencies is included in this training.

2.6 Control of On-the-Job Training

On-the-job training (mentoring) may be necessary for employees of LBL facilities, projects, or functions that require a formal qualification program for equipment operation or maintenance, or that have systems or components that, if improperly operated or maintained, could have an ES&H impact or could result in significant damage to LBL equipment. In such cases, administrative control of that training is required, including supervision by qualified operators, documentation of qualification requirements and training, and limitations on the maximum number of trainees.

2.7 Professional Development

Personnel are encouraged to continually increase their knowledge, abilities, and skills beyond the requirements of their current positions. Their intellectual development may be fostered through educational advancement, certification or other professional recognition, and mentoring by technically competent professionals. As appropriate, professional development activities are included in personnel training assignments. Outside seminars, conferences, and presentations are encouraged.

2.8 Proficiency Evaluation

Supervisors conduct and document a formal evaluation of proficiency at least annually. They evaluate personnel based upon established and documented job expectations. Competent performance *and* improvement in capability and proficiency is considered. While this evaluation of proficiency may be part of an individual's normal periodic performance review, it may also stand alone as a simple assurance of continued qualification to perform assigned tasks. If a less than fully satisfactory level of proficiency is evident, supervisors may suspend the applicable job task, counsel the individual, and assign appropriate training or professional development.

2.9 Training Effectiveness Review

The training program is subject to ongoing review by management to determine its effectiveness. Upgrades to training requirements, course content, instructional performance, or increased frequency of training are determined and made when deficiencies are noted. (See also Element 5, **Performance Assessment and Improvement**.)

3. Work Processes

At LBL, each person who performs scientific research, provides a support function, or operates or maintains a facility is responsible for ensuring that activities are performed in accordance with appropriate technical standards and administrative controls. Each employee is essential in ensuring quality. The LBL management system requirements included in this program element are designed to provide confidence that our work is being accomplished in a manner that is consistent with regulations and that achieves and demonstrates quality.

LBL Requirements

- **Management must determine when written procedures, instructions, or drawings** are required for doing work. If required, they must be used.
- **Design activities** must be managed so that design input, output, and interfaces are identified, documented, and controlled.
- **Design products** must be verified.
- **Items that require traceability** must be assigned a unique identification to ensure proper use.
- **LBL items that affect quality** must be controlled to prevent damage or loss and to minimize deterioration.
- **Measuring and test equipment (M&TE)** used for monitoring and collecting data or for acceptance inspection or testing of an item must be suitable for use and properly calibrated and maintained.
- **Management must identify requirements for inspections and tests** and conduct inspections and tests using acceptance criteria to demonstrate that items will perform as intended and that processes will yield the intended results.
- **Equipment status indicators** must be used to prevent inadvertent operation of an item or process that is unsafe, incompletely installed, or otherwise not ready for operation.
- **The procurement of items and services** must be controlled to ensure that they meet documented requirements and perform as specified.
- **Processes to prevent the purchase or use of counterfeit items**, to identify items susceptible to counterfeiting, and to identify and control previously installed or stocked counterfeit parts, must be used.

LBL Responsibilities

The following responsibilities are assigned to ensure that the Work Processes Element of the OAP is implemented.

Line Managers

- Specify which activities require written procedures, instructions, or drawings.
- Develop and approve appropriate administrative, quality assurance, conduct of operations, maintenance management, and operating procedures.
- Plan, review, and document design activities.
- Ensure that M&TE is calibrated and maintained in accordance with its actual or intended use.
- Utilize the LBL procurement system to ensure that items meet requirements and perform as specified.
- Perform procurement activities and support related inspections and surveys of programmatic equipment so as to ensure the prevention of acquisition or use of counterfeit parts.
- Ensure the use of properly identified and controlled items to prevent the use of incorrect or defective items.
- Plan and perform inspections or tests of completed work at appropriate intervals.

Manager, Office of Assessment and Assurance

- Review and approve institutional written procedures related to quality assurance (QA) and conduct of operations (CO).
- Review and concur with QA- and CO-related written procedures for facilities and activities with comparatively higher risk levels. (See **Program Description** and **Appendix B** for information on the graded approach to assessing risk potential.)
- Provide evaluation of contractor and vendor quality assurance programs and capabilities.

All LBL Personnel

- Perform activities in accordance with approved written procedures, instructions, or drawings (when required).

LBL Implementation

The following paragraphs regarding LBL implementation of work processes apply to quality-affecting activities. Notebooks (or the equivalent) will identify specific activities subject to these requirements. All of the identified

criteria are considered in the preparation of LBL Notebooks or other planning documents.

3.1 Procedures and Instructions

3.1.1 General

LBL management is responsible for planning, authorizing, and specifying the conditions under which the work for which it is responsible will be performed. As part of this responsibility, management specifies which work is sufficiently complex, involves sufficient hazard, has a potential ES&H impact, or has sufficient programmatic importance to be performed according to written procedures, instructions, or drawings. Procedures or instructions are then prepared for these activities, including maintenance, and are required to be used.

Written guidance includes (or references) criteria for determining whether the described work or maintenance activity has been acceptably performed and is completed. These criteria provide a mechanism for regular feedback on the acceptability of work performance and a way to identify opportunities for improvement in the work process.

Prior to use for LBL quality-affecting activities, written procedures and instructions are reviewed for applicable technical and administrative content including:

- Approval signatures and effective date.
- A unique title or other identifier.
- Purpose and scope.
- References (sources of requirements).
- Definitions (for unique acronyms or terms).
- Procedural work steps and associated responsibilities.
- Records identification (per LBL Records Management System requirements).

In addition, reviews are performed to evaluate the implementation methods and responsibilities presented. The line manager having first-line authority for directing and accomplishing the work approves written procedures or instructions. They are controlled in accordance with LBL document-control requirements (see Program Element 4, **Document and Records Control**). When required, concurrence is obtained from interfacing organizations. Revisions to written procedures or instructions are controlled by the same process used to review and approve the original documents.

The performance of quality-affecting activities in compliance with applicable plans, written procedures, operating standards, or other requirement sources, is documented in LBL Notebooks (or the equivalent) corresponding to facilities, functions, and projects. The LBL Notebook system is described in **Program Description** and **Appendix C**.

3.1.2 Special Process Procedures

Written procedures for special processes (i.e., processes in which the results are highly dependent upon the control of the process or the skill of the processor, such as nonstandardized analytical laboratory analyses or welding) are identified in the applicable LBL Notebook and written in accordance with applicable codes or standards. These procedures address the following:

- Acceptance criteria.
- Ambient conditions and requirements as defined by the applicable specifications, codes, or standards.
- Qualification and certification requirements for written procedures, specifications, and personnel.
- Equipment or calibration requirements.
- Parameters for which verification or documentation is required.

3.2 Design

Design activities include hardware designs as well as the planning of scientific investigations and data collection. Software-design control is addressed in Section 3.11.

3.2.1 Design Inputs

"Design inputs" refers to the criteria, parameters, or other requirements upon which a final detailed design is based. Design inputs are defined in written documents that have unique identification and revision status. These documents must be approved prior to use. Inputs such as design bases; performance and regulatory requirements, codes, and standards; and ES&H criteria are identified and recorded. Design procedures ensure that specifications are written so as to prevent unnecessary inclusion of counterfeit-prone items in designs and ensure that proper and complete specifications are developed when such items *are* required. Design inputs are reviewed and approved by the design organization and the organization requesting the design. The LBL document-control requirements and written procedure (see Section 4.1) apply to design input and changes.

3.2.2 Design Interface

Design interfaces and corresponding responsibilities are defined and documented so that design efforts are effectively coordinated among participating organizations. Effective coordination includes the concept of early design reviews by interfacing organizations (e.g., EH&S). Changes to approved design inputs, including reasons for the changes, are identified, approved by the originating organizations, and documented in a retrievable fashion.

3.2.3 Design Outputs

"Design outputs," such as drawings, specifications, results of scientific investigations, or computer programs, are presented in formal written documents that have unique identification and revision status. These

documents must be approved prior to issue. Design output documents relate to the design inputs in sufficient detail to permit evaluation and verification of the adequacy of the design. These documents show evidence that the required reviews and approvals have been completed prior to release for use in other design activities. Design records are incorporated into the LBL Records Management System (see Element 4, **Document and Records Control**).

3.2.4 Design Change Control

Final designs, field changes, and modifications are approved by the original design organization or a technically competent designee.

3.2.5 Design of Data Collection Systems

When "quality-affecting" data are collected, the design process for the data collection system is described or referenced in the applicable LBL Notebook. Based on the results of an analysis of the potential risks associated with collection of the data, the design includes some or all of the following elements:

- The system design ensures that data are traceable to sampling and analytical procedures, performance standards, analysts, and measuring and test equipment.
- Data transfer, reduction, and validation and verification requirements are determined and specified.
- Data interpretation and analysis needs are also determined and specified.
- Correct application of statistical methods are implemented during the design process.
- Oversight requirements, verification methods, and validation activities are specified.
- Reports to management regarding status of work, interim results of work, and results of assessment activities are identified and specified.

System designs include specifications that ensure that all relevant activities pertaining to environmental or waste data operations are identified, have established performance specifications, and are controlled appropriately. These activities include:

- Sample type and sampling location requirements.
- Sample handling and custody requirements.
- Sampling and analysis personnel requirements and qualifications.
- Health and safety considerations.
- Selection of analytical methods.
- Analytical facility requirements.
- Calibration and performance evaluation samples for analytical methods used.
- Sampling or analytical instrumentation requirements.
- Plans for readiness reviews prior to data collection.

3.3 Design Verification

A design review is a documented verification process to ensure that the review material (e.g., report, plan, work assessment, data, analysis assessment, evaluation) is technically adequate to satisfy applicable requirements. Reviews are performed by qualified personnel not directly involved in original design activities. The level of detail of verification and the methods used are appropriate to the design (conceptual, detailed, or final) under consideration, level of complexity, reliability requirements, and potential ES&H impact. Designs of apparatus brought to LBL by "outside users" are reviewed to ensure compliance with LBL ES&H requirements. As a minimum, design reviews address the following:

- Were the design inputs correctly selected?
- Are the assumptions that were necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverification when detailed design activities are completed?
- Was an appropriate design method used?
- Were the design inputs (e.g., fire protection requirements, reliability requirements, or design bases) correctly used in the design activity?
- Does the design comply with all appropriate standards and specifications?
- Are the necessary design input and verification requirements specified in the design document or in supporting written procedures and instructions?

Alternate calculations may be used to verify the correctness of the original calculations or analyses. The alternate method may be simpler and less rigorous, such as a hand calculator used to check a computer analysis.

When design activities involve state-of-the-art or untried technologies, peer reviews of data, reports, conceptual designs, etc. are performed. A peer review team is appointed by the cognizant line manager. The team consists of qualified subject experts who are independent of the information and activities to be reviewed. Review and approval of team members' credentials, including verification of education and experience, is documented. A peer review plan or checklist is prepared by the peer review team leader and approved by the cognizant manager. Review comments and comment resolution are documented. Minority dissenting opinions that cannot be resolved are also clearly indicated.

The adequacy of a design is normally verified prior to its release for use. This can include incorporation in other designs and manufacturing or use of the designed item. When such timing cannot be met, the portions of the design that have not yet been verified are identified and controlled. Design verifications are completed before installation and before relying on an item to perform its function.

3.4 Identification and Control of Items

3.4.1 Engineered Items

When necessary, items (materials, maintenance supplies and replacement parts, components, etc.) that have been specifically designed to LBL requirements or that require traceability are identified uniquely by identification numbers, color coding, or similar means. Specifications and/or procurement documents require that the unique identification be applied to the item and/or the container as well as to accompanying support documentation. Identification is maintained on or near the item and in documents traceable to the item for the life of the item.

3.4.2 Non-Engineered Items

Commercially available items may have special identification requirements established by LBL. These special requirements are included in procurement documents if traceability is to be maintained. Identification is maintained on installed items and in documents traceable to these items.

3.4.3 Data Control

Quality-affecting data generated as a result of scientific investigations, sampling, monitoring, or remedial activities are identified in all documents or information systems in which such data appear. The identification of research data includes reference to the origin of the data (e.g., task, test, experiment, report, publication, or sample). To ensure traceability to the source, identification of data must be verified prior to release for use.

Limitations on data use are identified and documented in written procedures. Reports containing ES&H data are independently reviewed.

3.4.4 Physical Identification of Items

When it is important to safety, environmental, or programmatic concerns that items be identified for positive traceability, physical identification of items is performed to the maximum possible extent. Examples include the identification of materials with critical shelf lives, identification of components during disassembly of complex equipment, and use of serial numbers on hazardous waste disposal drums.

When identification on the item is impractical, physical segregation, record traceability, or other methods are used. If a part of an item is removed from the sample lot, it is identified with an appropriate unique identification number. The number is protected to avoid obliteration or other degradation that could affect the part's traceability.

3.4.5 Sample Identification and Control

Quality-affecting samples are identified and controlled in a manner that is consistent with their intended use, that is in compliance with regulatory requirements, and that provides traceability to related documentation.

LBL personnel collecting the sample assign a unique identifier that is maintained throughout the sample's existence. The identifier traces the

sample to its source and to related documentation (e.g., date, conditions prevailing at the time of sampling, method of sample collection, chain of custody).

Methods for collecting, handling, transporting, and storing samples are described in written procedures. These procedures identify the required protocols for ensuring the technical validity and safety of the samples and their protection from adverse environmental conditions. Requirements for off-site transportation comply with local, state, and federal regulations. Special handling requirements and traceability between organizations are also described in written procedures when applicable.

3.5 Handling, Storage, and Shipping of Items

3.5.1 Storage of Items

Specific limited-access areas are designated for storing quality-related items. These areas are controlled by responsible personnel.

Quality-affecting items with finite shelf life are physically identified and controlled to ensure that they are provided the maximum protection. Written procedures identify the methods for disposal of items with expired shelf lives.

When required for particular items, special equipment (such as containers, shock absorbers, or accelerometers), special protective environments (such as inert gas atmospheres, specific moisture-content levels, or specific temperature levels) are provided, and the conditions are verified. When required, limited-access areas are designated.

3.5.2 Shipping of Items

Personnel responsible for shipping items ensure that correct documentation (e.g., carrier shipping forms, chain-of-custody forms, labels, property release forms) is prepared and, if required, signed by the appropriate person(s). Shipping documentation accurately reflects tag and serial numbers for tagged items. Traceability is maintained at all times for the items to be shipped, from the point of origination to the final receipt of the item.

Packaging requirements are specified for protection against corrosion, contamination, physical damage, or any condition that would affect the item or cause deterioration during the time it is handled, stored, or shipped.

3.6 Control of Measuring and Test Equipment (M&TE)

3.6.1 Selection of M&TE

The selection and procurement processes for M&TE ensure that such equipment is of the proper type, range, accuracy, and tolerance for its planned application. These selection and procurement processes apply to M&TE used for in-process, maintenance, or final inspection of items. The M&TE for a process is specified so as to ensure it can provide accurate information influencing the quality of the end product of the process.

3.6.2 Identification of M&TE

M&TE is identified through controlled inventory and physical marking with unique name, identification number, status tag, color code, and/or calibration sticker. The identifier is recorded on a data sheet, logbook page, or other designated register, along with the corresponding data. An M&TE inventory is maintained.

M&TE used only for rough or relative-magnitude measurements or for tests yielding relative indications is identified as such in the M&TE inventory. Calibration requirements (if any) for such equipment are prescribed accordingly.

3.6.3 Calibration of M&TE

M&TE is calibrated, adjusted, and maintained at prescribed intervals—or prior to use—against certified equipment having known valid relationships to nationally recognized standards such as those of the National Institute for Standards and Technology. If no nationally recognized standards exist, the basis for calibration is documented.

Prior to use of M&TE, personnel verify that the return-for-calibration date has not expired. If past the date of recall, the item is removed from service, tagged, segregated if possible, and identified to management. If, upon recalibration, M&TE is found to be out of tolerance, it is immediately removed from service, tagged, and segregated if possible. An evaluation to determine the effect and significance of using suspect data is performed and documented. If the evaluation discloses an adverse effect on items, work, or data previously accepted, appropriate corrective action is undertaken.

3.6.4 Handling and Storage of M&TE

Appropriate protection, storage, handling, and environmental conditions are maintained for all M&TE. The effect of environmental or other factors on an item's uncertainty is considered when calibration specifications are established. Limitations on the handling, use, and storage of M&TE are defined.

3.7 Inspection and Testing

LBL line management specifies which activities and processes require inspection or testing, including receipt inspection prior to acceptance of results or to demonstrate that items will perform as intended (see also Section 3.9.3, **Acceptance of Items or Services**), Characteristics and processes to be inspected, as well as techniques, hold points, and acceptance criteria, are also defined by line management. M&TE used for acceptance inspection or test are controlled in accordance with the requirements given in Section 3.6, **Control of Measuring and Test Equipment**.

3.7.1 Inspection

The inspection process involves the real-time quality-control examination or observation of activities and items in relation to acceptance criteria defined in written procedures, specifications, drawings, or checklists. When required by

an LBL Notebook, inspections are conducted according to written procedures that establish the frequency and type of inspection to be performed. Inspections should be performed as early as practical in new processes to identify opportunities to enhance effectiveness. Inspections intended to prevent the acquisition or use of counterfeit or suspect components are performed whenever appropriate.

Administrative controls and status indicators are incorporated into the inspection procedures to preclude inadvertent bypassing of required inspections and to prevent operation of the item or process before inspection.

Inspections may be performed by the organization responsible for the work, or management may require (per written procedure) an independent organization to perform the inspections. Individuals should inspect their own work to ensure that they have achieved the desired quality; however, personnel may not inspect their own work for acceptance. The level of inspection and degree of independence of inspection personnel are described in the applicable Notebook and are based on risk and complexity.

Inspection activities are documented in written procedures that address:

- Item or process inspected.
- Date of inspection.
- Name of inspector.
- Inspection techniques.
- Unique identification of M&TE.
- Acceptance criteria, including those preventing acquisition or use of suspect or counterfeit components.
- Hold points.
- Results or acceptability.
- Any nonconformances and dispositions of nonconformances.

3.7.2 Acceptance Testing

Tests (identified in the applicable LBL Notebook) are conducted to demonstrate that quality-affecting items and processes will perform as intended. Testing activities (e.g., bench tests and proof tests before installation, nonstandardized analytical laboratory tests, pre-operational tests, post-maintenance tests, post-modification tests, or operational tests) are planned by LBL personnel prior to starting tests and documented in written procedures or test plans. Acceptance criteria are identified. The LBL Notebook distinguishes between tests used to prove designs and tests conducted to evaluate the adequacy of work. Tests used to prove designs are more critical, and written procedures that prescribe these types of tests should include supervisory hold points.

Post-maintenance testing is performed to verify that equipment, systems, and components fulfill their design function and have been restored to their correct operating configuration prior to being returned to service following maintenance. The tests performed and the formality of documentation of

such tests are commensurate with the maintenance work performed and the importance of the equipment to facility safety and reliability.

Testing may be performed by the organization responsible for the work or by an independent organization. The level of testing and degree of independence of testing personnel is described in the applicable LBL Notebook and is based on risk and complexity.

All testing employs established and proven test requirements and acceptance criteria. The test requirements should be provided by the original design organization or a qualified alternate design organization knowledgeable of the item or process being tested.

Administrative controls and status indicators are incorporated into the written test procedures to preclude inadvertent bypassing of required tests and to prevent operation of the item or process before acceptance.

Testing activities are carried out according to written procedures that require documentation of:

- Item, system, or sample tested.
- Date of test.
- Unique identification of item and test equipment.
- Tolerance requirements and acceptance criteria.
- Results and acceptability.
- Deviations and actions taken with regard to the deviations.
- Names of personnel performing tests and evaluating results.

3.7.3 Readiness Review

Prior to the initial start-up of major Laboratory quality-affecting activities or the first application of power or the beginning of operation of new or heavily modified facilities, readiness reviews of prerequisites are performed by responsible personnel to provide assurance of satisfactory preparation. Prerequisites include :

- Personnel proficiency.
- Plans and written procedures.
- ES&H controls.
- Equipment, material, other resources.
- Access, permits, funding.
- Software quality assurance (see Section 3.11).
- Procurement.

Accelerator facilities are commissioned and commence routine operation only after authorization by DOE, based upon DOE determination that the level of potential risk associated with operation is acceptable.

3.8 Equipment and System Status

Physical status indicators are used to ensure that operations, support, and experimental activities important to quality, ES&H, and security are properly controlled. When it is necessary to ensure that required inspections and tests have been performed and that items failing the required inspections and tests are not inadvertently installed, used, or operated, the status of inspection and test activities is identified either on the items or in documents traceable to the items. Physical status indicators (e.g., markings, tags, and other identification) and status documentation address the following:

- The operating status of the system or component.
- The activities that require the use of status indicators.
- Appropriate unique identification to provide for traceability.
- Out-of-service conditions (following written LBL lock-out/tag-out procedures).

3.9 Procurement

A systematic approach is used to purchase goods and services that support LBL quality-affecting activities to ensure that purchased items and services meet expectations, are not counterfeit or otherwise substandard, and are available when needed. LBL applies controls to procurements and subcontracts in conformance with applicable DOE orders, DOE acquisition regulations, and federal acquisition regulations. OAP requirements do not require new procurement systems but can be satisfied through the use of the existing LBL systems.

3.9.1 Planning and Document Review

Procurement planning is carried out as early in the planning process as practical. Planning results in the documented identification of procurement methods, a sequence of actions, and milestones that represent completion of these activities.

Managers are responsible for initiating and maintaining a procurement document package that contains a copy of all documentation for the procurement. They are also responsible for ensuring that procurement documents and changes thereto are reviewed. This review ensures that documents transmitted to subcontractors include applicable ES&H, cost and schedule, and technical specifications for services and deliverables, including anti-counterfeiting measures when applicable. Reviews also verify that procurement documents contain applicable regulatory requirements and require subcontractors to implement appropriate quality assurance, conduct of operations, and maintenance management programs, if initially requested as part of the technical requirement. After appropriate review, managers are responsible for approving all procurement documents prior to submittal to Purchasing. Changes to procurement documents are subjected to the same review and approval process required for the preparation of the original document.

3.9.2 Supplier and Subcontractor Selection and Management

Prospective suppliers are evaluated to ensure that they are capable of providing the required item or service. Once selected, suppliers are periodically monitored to ensure that acceptable items or services continue to be supplied.

Suppliers are involved early in the procurement process to ensure an understanding of LBL's needs and to participate in the planning that establishes those needs. Suppliers are also involved in evaluating the quality or performance of their product or service, as required by LBL procurement specifications.

The initial selection and subsequent continued qualification of contractors and vendors is based on an evaluation of their capability to provide items, services, or other products in accordance with the requirements of procurement documents (including schedule requirements). Selection is coordinated between the requester and Purchasing as early in the procurement process as possible. Measures for evaluating and selecting procurement sources and the results are documented. These measures include one or more of the following options:

- Evaluation of the contractor's or vendor's history or capability of providing the service or product required.
- Review of contractor's or vendor's current quality assurance plan and records.
- Evaluation of contractor's or vendor's technical and quality assurance capability as determined by inspection of the facilities and by contractor's or vendor's implementation of the quality assurance program.

3.9.3 Acceptance of Items or Services

Methods for accepting items or services used in LBL research, operations, maintenance, and support activities are incorporated into contractual agreements. Methods of acceptance include:

- Receipt inspection through technical or peer review of the information, or through physical inspection of the product, including evaluation against counterfeit or suspect component-identification aids.
- Acceptance of Certificates of Conformance from the supplier.
- Pre-installation or post-installation tests of the item, software, or other product.
- Technical verification or validation of data produced.
- Reviews of objective evidence for conformance to the procurement document requirements, such as certifications or reports.
- Surveillance of service providers.

Written procedures identify methods for disposition of any items and services that do not meet contractual documentation requirements. Methods include

acceptance of the product through technical evaluation, rejection of the product, or repair.

3.10 Conduct of Operations and Maintenance Management

3.10.1 Conduct of Operations

All Laboratory facilities are managed, organized, and operated in a way that ensures an acceptable level of safety. Operations are managed at a level commensurate with risk through written procedures or other appropriate means. Implementation of these conduct of operations requirements at LBL is accomplished primarily through Facility Notebooks, with a greater level of rigor at the facilities with higher potential risk levels. See also "Integration of Conduct of Operations and Maintenance Management Requirements" in the **Program Description** section of this Plan.

3.10.2 Design and Operation of Accelerator Facilities

The design and operation of accelerator facilities are controlled through appropriate active, passive, and administrative measures to ensure that personnel exposures are minimized, facility access is controlled, personnel are protected, and written procedures are followed. Accelerator facility operations are confined to analyzed risks, as prescribed within a written Accelerator Safety Envelope (ASE) in the facility's Safety Analysis Document (SAD). Any activities found to exceed ASE limitations or involving unresolved safety issues are immediately stopped.

3.10.3 Maintenance Management

Laboratory equipment and facilities are maintained in a manner that promotes operational, environmental and personnel safety; property preservation; and cost-effectiveness while supporting the objectives of the LBL programmatic mission. Maintenance is performed at a level of rigor commensurate with the level of risk associated with the equipment and facilities being maintained.

The LBL maintenance program encompasses five main elements:

- Identification and Grading of Equipment. Each organization keeps an inventory of its maintained equipment, prioritized by potential consequence of failure.
- Establishment of Maintenance Requirements. Maintenance requirements are identified and documented in written procedures, in maintenance and inspection schedules, in equipment logbooks, or by other appropriate means. These requirements may specify the performance of independent verification, post-maintenance testing, and/or configuration control; special tools or materials needed; and appropriate manufacturer recommendations.
- Training and Qualification of Maintenance Personnel. Training and qualification programs ensure that personnel are qualified to perform maintenance activities at a level commensurate with the relative criticality of the equipment.

- Scheduling of Maintenance Activities. Scheduling of corrective and preventive maintenance activities is done in such a way as to promote efficient execution of the work within reasonable time limits.
- Maintenance of Equipment Repair Histories. Historical equipment performance and repair information is maintained for analysis and trending in support of preventive maintenance activities.

These maintenance management requirements are implemented primarily through Facility and Project Notebooks. See also "Integration of Conduct of Operations and Maintenance Management Requirements" in the **Program Description** section of this Plan.

3.10.4 Equipment Monitoring

Line management at a project or facility ensures that procedures are written and used for the routine monitoring and recording of operating parameters for important equipment. These procedures are identified in the applicable LBL Notebook.

3.10.5 Personnel Exposure Minimization

Line management ensures that procedures and practices are written, identified in the applicable LBL Notebook, and used to ensure that personnel exposure to radiation and toxic materials is maintained as low as reasonably achievable (ALARA).

3.11 Computer Software Control

3.11.1 General

Development and use of computer software are significant and essential elements of LBL research and support programs and are managed in accordance with established LBL computer software policy as written in the Regulations and Procedures Manual, Section 9.03. OAP requirements are complementary to that policy.

The degree to which the following criteria apply to a facility, project, or function is identified in the appropriate Notebook. Applicability is additionally limited to the following types of software:

- Experimental design.
- Design analysis.
- Modeling of environmental processes and conditions.
- Operation or process control of equipment systems (including automated data acquisition and laboratory instrumentation).
- Databases or document-control registers when used as the controlled source of quality records.

Computer and computer-controlled hardware and hardware/software configurations (computer program software, operating software, and models of computer hardware) used in LBL quality-affecting activities are installed, tested, used, and maintained as described in the LBL Notebook or in written procedures. Hardware/software configurations are tested prior to actual use,

and the results are documented and maintained. Changes to hardware/ software configurations are assessed to determine their impact on the technical and quality objectives of the facility, project, or function. Appropriate action is then taken (e.g., retest).

Computer software used in LBL quality-affecting activities should meet the needs of the user and conform to applicable consensus standards for software development or data management criteria. Acceptance criteria are established for commercially acquired software when the need to do so is documented in the applicable LBL Notebook.

Program documentation such as reference manuals and users' guides are maintained and easily accessible to users. Software developed specifically by LBL is developed using documented software development methodology including requirements, design, and implementation reviews, when appropriate. When necessary, user-developed programs are independently validated, verified, and documented, according to the intended use of the software. Such software is installed, tested, used, and maintained as prescribed by the requirements of the applicable Notebook.

3.11.2 Acceptance Testing

LBL users test software to ensure that unintended functions that could degrade the software system will not be performed. Such testing also identifies boundary conditions and provides suitable benchmark or sample problems. Acceptance testing is performed commensurate with the possible consequences of its failure. Testing should include whole-system (i.e., combined hardware and software) testing and should exercise the full range of system capability. Testing is not limited to detection of problems that cause system degradation but includes considerations of integrity and validity as well.

Software used for quality-affecting activities that has not been developed or originated by LBL requires documentation demonstrating that the software correctly performs according to its stated capabilities and functions. Examples include software for design and design analysis, modeling, operations or process control, and databases.

3.11.3 Software Change Control

Changes to user-developed and commercial software should be assessed to determine the potential impact of the change on the performance of the software, and appropriate actions should be taken. Changes are documented and approved by responsible line management.

3.11.4 Software Documentation

Software documentation is provided at the time of installation and use. Such documentation consists of:

- Software development plan.
- Description of software development history.
- Physical and mathematical models on which software is based along with appropriate assumptions and explanations.
- User's instructions or manual.
- Results of reviews and testing activities.

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4. Document and Records Control

The LBL Operating and Assurance Program (OAP) provides for adequate documentation to demonstrate to management and to others that the activities required by this plan have been accomplished. Two fundamental aspects of providing adequate documentation are document control and records management. Document control ensures that only approved documents establish policy, prescribe work, specify requirements, or establish design and that this information is available to users when it is needed. Records management ensures that sufficient records of completed activities are generated, maintained, and readily retrievable.

LBL Requirements

- **Management must determine which documents are to be controlled** and establish a written procedure for preparing, reviewing, approving, distributing, and revising those documents.
- **A records management policy and implementation procedure** must be established to ensure that sufficient records are specified, prepared, reviewed, approved, and maintained to accurately reflect completed work or other activities. The maintenance of records includes provisions for retention, protection, preservation, traceability, accountability, and retrievability.
- **A scientific and technical publications policy** must be established to ensure high-quality publications and conformance with government requirements.

LBL Responsibilities

The following responsibilities are assigned to ensure that the Document and Records Control Element of the OAP is implemented:

Associate Laboratory Director for Operations

- Approve, issue, and provide resources for maintaining the LBL policy and accompanying written procedure for Laboratory-wide document-control activities.

Associate Laboratory Director for Administration

- Provide resources for implementing and maintaining the LBL records management procedure for quality assurance-related records.

Division Directors and Department Heads

- Determine which documents (instructions or drawings) are controlled and maintain a master list of these documents.
- Ensure that sufficient records are generated, identified, and maintained to accurately demonstrate completed division or department work or activities.
- Ensure that all scientific and technical publications are properly reviewed and submitted to DOE.

Line Managers

- Ensure the control and use of those documents associated with a specific facility, project, or function that provide instructions or direct the work.
- Ensure that records are generated, identified, and maintained to demonstrate completed facility, project, or function work.

Report Coordination Office, Technical and Electronic Information Department (TEID)

- Ensure that LBL publications meet the requirements of the LBL publication policy and government requirements.

LBL Implementation

4.1 Document Control

A Laboratory policy and supporting institutional written procedures are established to control the identification, preparation, review, approval, issuance, use, and revision of selected documents that establish policies, prescribe work, specify requirements, or establish design. The documents are selected by Laboratory or division management to describe the organization, functions, policies, decisions, procedures, and essential transactions of the Laboratory at an appropriate level of detail. A document hierarchy (Figure 1) is established for the Laboratory to organize requirements and implementation documents for use.

4.1.1 Scope

The scope of the document control system considers all written communication that (1) guides, instructs, or informs employees in their work and (2) pertains to environment, health, safety, or quality assurance matters. Examples of document types to be considered for control include drawings, data files (including various media), calculations, specifications, computer codes, purchase orders and related documents, vendor-supplied documents, written procedures, work instructions, operator aids, data sheets, emergency notification call lists, and administrative controls for operating and

maintaining a facility. Software documentation, as defined in Section 3.11.4, is also included in this scope.

4.1.2 Revisions

Revisions to controlled documents are reviewed and approved by the same organization that originally reviewed and approved the documents. For new or revised controlled documents, the document control procedure provides guidelines on ensuring that distribution is made in a timely manner.

4.1.3 Document Distribution

Controlled documents are promptly distributed to and used by personnel who perform work to ensure that only the correct documents are in use. If record copies are kept, they are marked "superseded" or "canceled," and retained for a retention period specified procedurally. Otherwise, outdated documents are destroyed.

4.2 Records Management

A records management system is established to specify, approve, and maintain records that accurately demonstrate completed work.

4.2.1 Activity Logs

Activity logs, repair histories, and vendor information are maintained (1) for facilities and projects for which a record of operations and maintenance activities is important to ensure the integrity of the facility and (2) to support the ability to report any abnormal event to DOE. Written guidance defines the type, scope, and format for entries, and requires periodic review by management and retention as records.

4.2.2 Special Records

Records that require special processing and control, such as computer codes or information on high-density media (e.g., microfilm) or optical disks, along with hardware and software required to maintain and access records, are controlled (in accordance with written procedure) to ensure records are usable.

4.2.3 Recordkeeping Standards

When other standards that provide interpretive quality assurance guidance differ in records management terminology from the requirements in the LBL *Regulations and Procedures Manual* (RPM), Section 1.17, Archives and Records Management, the requirements of both the RPM and the other standards are interpreted and reconciled for use at the Laboratory.

4.2.4 Retention and Disposition

Appropriate inactive records are transmitted to designated record-holding facilities in accordance with the requirements for retention and disposition of records in the RPM, Section 1.17. Procedural (and when appropriate, physical) safeguards against the unauthorized removal or destruction of records are established.

4.2.5 Inventory

A records inventory is established and maintained. The contents of the inventory are defined in the written record-keeping procedure.

4.3 Scientific and Technical Publications

The **LBL Policy for Scientific and Technical Publications** (RPM 5.02) contains the requirements for the publication of LBL reports, PUB reports, and LBID reports. These publications are processed through the TEID Report Coordination Office, which assigns a report number, coordinates distribution, and ensures that all aspects of the policy are met. All publications receiving an LBL, PUB, or LBID number are reviewed by a qualified reviewer and are further reviewed by the Report Coordination Office to ensure compliance with DOE Order 1430.2A.

5. Performance Assessment and Improvement

At LBL, each employee directly contributes to meeting performance objectives, including those related to quality assurance, conduct of operations, and maintenance management. An ongoing critical assessment of work activities and management systems that support these activities is essential, to prevent quality problems and to determine whether we have accomplished what we set out to do. The Operating and Assurance Program (OAP) requires that an assessment and improvement system be in place to ensure that:

- Quality objectives have been attained.
- Problems receive prompt and appropriate corrective action.
- All LBL employees are supported in constantly seeking new and innovative ways to improve quality, efficiency, and effectiveness.

The LBL Self-Assessment Program is one LBL management system for implementing the requirements of this element of the OAP. This program is described in the LBL Self-Assessment Program Implementation Plan (PUB-5344). The OAP integrates the assessment activities of LBL divisions and offices in a comprehensive process of information gathering, evaluation, analysis and trending, corrective action tracking, and reporting.

LBL Requirements

- Management must establish **performance objectives and criteria for quality assurance.**
- **Management at all levels must evaluate the performance** of their organizations **routinely and periodically** to identify, correct, and prevent management problems that hinder the achievement of objectives.
- **Planned and periodic independent performance assessments** must be conducted to evaluate the implementation of the OAP and quality and organizational effectiveness.
- **Personnel must continually evaluate their areas of responsibility** and take or recommend actions to prevent problems, identify and correct existing problems, and improve quality in the planning, performance, documentation, and assessment of LBL quality-affecting activities.
- **Management must document corrective actions** performed in response to assessments and track them to completion.

LBL Responsibilities

The following responsibilities are assigned to ensure that this element of the OAP is implemented:

[Note: The responsibilities listed here are consistent with those listed in the LBL Self-Assessment Program Implementation Plan (PUB-5344), an LBL system through which many of the OAP performance assessment and improvement requirements are implemented.]

Laboratory Director

- Approve the LBL Self-Assessment Program, and through the Director's Action Committee (DAC), approve performance objectives and criteria.

Associate Laboratory Director for Operations

- Establish institutional self-assessment program requirements.
- Provide the resources required to support efficient LBL implementation of the Self-Assessment Program.
- Ensure that the performance of the Office of Assessment and Assurance (OAA) is reviewed as required by the LBL Self-Assessment Program.
- Provide support and direction to the Safety Review Committee in its periodic reviews of health and safety aspects of Laboratory operations.

Associate Laboratory Director for Administration

- Provide the resources required to support the Internal Audit Services Department.

Division Directors

- Develop and issue annually an implementation plan for the division's Self-Assessment Program.
- Administer the division's self-assessment process and provide adequate resources for its implementation, including maintenance of the LBL self-assessment database (LSAD).
- Participate in the division self-assessment process to ensure that a division focus is on achievement of performance objectives and quality improvement.
- Provide lessons-learned reports to the EH&S Division as deemed appropriate.
- Ensure that deficiencies are tracked, monitored, and corrected in a timely manner.

Facility, Project, and Function Managers (Line Managers)

- Regularly and routinely survey activities, and take an active role in preventing quality problems, correcting deficiencies, and improving performance (ongoing assessment).
- Cooperate with independent assessment teams.
- Support division self-assessment activities.
- Track problems and manage corrective actions in systematic fashion (e.g., LSAD).
- Perform root-cause analysis of significant or recurring problems.

Manager, Office of Assessment and Assurance

- Provide guidance to divisions in the implementation of their self-assessment programs.
- Maintain the LBL Corrective-Action Tracking System (LCATS) and provide periodic reports as required.
- Perform trend analysis of LBL assessment findings, root causes, and performance indicators, and report the results to the Laboratory Director and to the DAC through the Associate Laboratory Director for Operations.
- Provide independent assessment services for line management functions through the LBL OAA management appraisal process (see PUB-5344).
- Conduct and report on independent assessments (functional appraisals) of LBL quality assurance, conduct of operations, and maintenance management performance.
- Facilitate external quality assurance, conduct of operations, and maintenance management audits of LBL.
- Concur with corrective actions for quality-related assessment findings and verify completion (as required).
- Select, train, and certify team members for independent assessment of quality assurance, conduct of operations, and maintenance management.
- Provide training for the LBL Self-Assessment Program.
- Receive, analyze, and verify suspect or counterfeit item reports and facilitate related corrective action and occurrence-reporting activities.

EH&S Division Director

- Ensure that ES&H-related lessons learned are communicated to affected LBL and DOE organizations.
- Ensure that functional appraisals are performed as part of the LBL Self-Assessment Program.
- Update ES&H training requirements and lesson plans as necessary.

All Personnel

- Continuously assess individual performance to prevent quality problems and identify nonconforming conditions and opportunities for improvement in process or item quality.

LBL Implementation

5.1 Performance Objectives

One method of achieving quality and quality improvement is to determine performance objectives and criteria for the work and then strive to meet those objectives. This method also provides a means of measuring accomplishment and of identifying and tracking changes in work performance. A benchmark of the current status of LBL quality-affecting activities is determined at appropriate intervals by cognizant personnel and their line managers, and objectives for upcoming work are developed and documented. Activity-specific performance criteria emphasize the quality, rather than the quantity, of work performed. These performance objectives and criteria are submitted to and approved by DAC each fiscal year. Examples of general performance objective areas include:

- Increased ability to identify and meet or exceed minimum levels of compliance with controls, requirements, regulations, and standards.
- Anticipation and avoidance of problem areas.
- Reduced or eliminated potential or realized hazards.
- Identification of procedural or process inadequacies.
- Reduced cost of compliance through use of effective management systems.

5.2 Assessments

5.2.1 Management Assessment

Division self-assessment (as part of the LBL Self-Assessment Program) is the primary mechanism for management assessment at LBL. Readiness reviews, design reviews, quality control checks, and other inspections and tests conducted to gain and document immediate confidence in the work are also management assessments.

The information presented here is consistent with that in LBL's Self-Assessment Program Implementation Plan (PUB-5344). Guidance for management assessments conducted as part of the LBL Self-Assessment Program is found in the LBL Self-Assessment Manual (PUB-3105).

Line managers regularly and routinely observe and survey the performance of quality-affecting activities under their purview and take an active role in improving performance and seeking excellence. They encourage personnel to look for ways to improve performance and correct problems as an integral

part of the normal work routine. Monitoring begins as early as possible in the planning stage of an activity to verify that personnel have adequate support to perform their assigned functions. Line managers determine what constitutes meeting or exceeding performance objectives, adequacy of training, effectiveness of written procedures, and the ability of the tools provided to produce the desired product. They also identify possibilities for failure and opportunities for improvement.

Ongoing assessment

The real-time monitoring of work activities by line managers, ongoing assessment, is the most effective and timely method for recognizing when control of a process or activity requires improvement. This facilitates prompt quality improvement actions and minimizes possible rework, injury, equipment damage, or costly delay. Monitoring is accomplished by observation, direct personal interaction, and review of acceptance criteria, performance indicators, and attributes included in other documentation such as:

- Site office appraisal reports.
- Prior assessment reports.
- Performance indicator evaluations.
- Management, regulatory, or other status reports.
- Corrective action, trend analysis, and lessons-learned reports.

Management also conducts periodic evaluations of ongoing work performed as part of a field task proposal or experiment, including the scientific or technical result at the conclusion of a research program or experiment.

Management Overview

Management overviews are formal reviews conducted by divisions as part of the self-assessment process. These reviews are conducted annually or more often, in accordance with the division Self-Assessment Implementation Plan. They evaluate how well the division is meeting performance objectives by examining:

- Effectiveness of the OAP and other management systems in achieving continuous quality improvement.
- Adequacy of human and material resources, including maintenance facilities and equipment.
- State of worker knowledge, motivation, and morale.
- State of worker health and safety.
- Effectiveness of environmental protection measures.
- Degree of success in meeting management objectives.
- Identification and connection of problems that hinder the organization from achieving its objectives.

Management overviews are not strict compliance checks.

LBL management overviews are documented and reported in accordance with the requirements of the LBL Self-Assessment Program.

5.2.2 Independent Assessments

Independent assessments at LBL include the review activities of various groups, including EH&S (functional appraisals), the Safety Review Committee and its subcommittees (triennial reviews and technical reviews, respectively), Internal Audit Services (internal audits), and OAA (OAA assessments). All of these reviews are performed by technically and programmatically knowledgeable personnel within LBL who are free of direct responsibility in the areas they assess. The following paragraphs present the requirements for performance of such assessments by OAA only.

Assessments by OAA are the primary means of independently evaluating LBL organizational units' performance against OAP requirements. These independent assessments are not solely document reviews but are performance-based. They consider:

- The intended function of an item or process.
- Attributes required to perform these functions and the processes or activities that impart these attributes.
- Success in meeting acceptance criteria and performance objectives, including the requirements of the OAP.
- Areas of previously identified concern.

OAA Assessment Frequency and Schedule

OAA assessments are scheduled by the manager of OAA, in consultation with division directors and line managers. These assessments are conducted in a timely and comprehensive manner, based on the following considerations:

- An activity's relative impact and importance to OAP objectives.
- Past independent assessment scope, frequency, and results.
- Past results of other OAP and external audits.

Selection and Qualification of OAA Assessment Personnel

Independent assessments for quality assurance, conduct of operations, and maintenance management are directed by OAA staff members familiar with the programmatic elements and requirements of the OAP, experienced in assessment practices, and certified as qualified independent assessment team leaders by the manager of OAA, in accordance with written procedures. Additional technically qualified assessment team members are selected and appointed by the manager of OAA, or other team leader, in consultation with appropriate line managers. Instruction in planning, conducting, and reporting OAA assessments is provided to these personnel by the OAA. The makeup of an assessment team is commensurate with the scope and time frame of the assessment.

OAA Assessment Planning

A documented plan that identifies the subject(s), dates, assessment methods, assessment team members, and other necessary information is prepared by the team leader and distributed to affected personnel prior to the scheduled assessment date. Planning may also require the development of assessment checklists. Checklists consist of pertinent questions designed to evaluate the subject under review, based on the methods, reference documents, acceptance criteria, and other information identified in the assessment plan. Checklists are tools to assist in information gathering. They may be lengthened, shortened, or changed during the course of an assessment, as deemed necessary to assess the performance and quality-improvement status of the activity adequately. They serve as a guide and record of the assessment but are not meant to be a strict, inflexible means of performing the evaluation.

Information Gathering

Cognizant management gives the assessment team access to necessary personnel, work areas, and other resources. Findings are discussed with responsible personnel at the time of identification. At the conclusion of the assessment, a post-assessment conference with management is held to discuss the findings.

OAA Assessment Reporting and Follow-Up

At the conclusion of information gathering, the assessment team prepares a report detailing the results of the assessment and recommendations for quality improvement. The report is approved by the manager of OAA within one month of the conclusion of information gathering and distributed to the cognizant division director and line management.

If immediate corrective actions are warranted, team members coordinate with cognizant management for resolution.

Each division or office follows up on findings with a corrective action or quality improvement plan that describes the planned actions and schedule for completion and identifies personnel responsible for implementation. The management of a division or office is responsible for allocating the necessary staff and budget resources to accomplish the actions and for tracking them to completion (see Section 5.3, **Problem Prevention, Correction, and Continuous Quality Improvement,** below).

5.3 Problem Prevention, Correction, and Continuous Quality Improvement

Principal objectives of the OAP are to prevent conditions and situations that hinder the successful accomplishment of the technical, scientific, ES&H, quality assurance, conduct of operations, and maintenance management goals and obligations of the Laboratory; to remedy identified problems; and to continually improve the level of quality in meeting these goals and obligations. These objectives are achieved by:

- Hiring technically knowledgeable, skillful, and otherwise qualified people to perform the work.
- Providing training that imparts necessary administrative, ES&H, quality assurance, conduct of operations, and maintenance management information.
- Change the system, if performance so warrants.

5.3.1 Identification of Quality Problems and Opportunities for Improvement

When personnel recognize a condition or situation that does not conform to technical, quality assurance, conduct of operations, maintenance management, or other requirements and expectations, or that has the potential to become nonconforming, or that is an opportunity for quality improvement, they are required to promptly inform their manager, the OAA, or other applicable personnel. LBL management encourages a "no-fault" attitude toward this identification process. Personnel are required to identify and document operational, item quality, and management problems that compromise safety or reliability. Line managers discuss the problem or idea with the initiator, validate the documentation, and determine the appropriate response. The performance of assigned work, as well as readiness and design reviews and other analyses, assessments, and reviews, are situations in which problems and opportunities for quality improvement may be identified.

Incidents that are reported under the LBL occurrence reporting system in compliance with DOE 5000.3A, Occurrence Reporting, are an additional potential source of data regarding quality-improvement opportunities. Occurrence reporting, investigation, and resolution are conducted in accordance with the provisions of PUB-3000, Chapter 1, Appendix E.

5.3.2 Segregation of Nonconforming Items

Items found not to meet requirements during assessments are removed from use and kept (when practical) in a clearly identified holding area until properly dispositioned. When such nonconforming items cannot be held aside in this way, other precautions are taken to prevent their inadvertent use.

5.3.3 Disposition of Quality Problems and Opportunities for Improvement

Responsible personnel expedite and document immediate corrective action or other disposition for problems requiring immediate attention. For less critical situations, responsible personnel recommend corrective action and establish a completion date. Management reviews and concurs with the planned correction before a record is entered into the LBL tracking system. Managers then ensure implementation and verification (self-assessment) of the corrective action using established acceptance criteria.

Corrective action also includes efforts to correct similar conditions found elsewhere and to preclude recurrence of the problem. A root cause analysis may be performed, if appropriate.

The OAA evaluates and concurs with the proposed corrective action if it relates to quality assurance, conduct of operations, or maintenance management. Using established acceptance criteria, the OAA also provides

independent verification of the completion of selected corrective actions, such as those with Lab-wide impact or those resulting from external audits.

The independent verification is accomplished by checking that the planned corrective action has actually been performed, that the action adequately corrects the deficiency as intended, that adequate supporting documentation exists, and that the action has been reported correctly. The graded approach is used to determine the level of rigor for such verifications.

5.3.4 Tracking of Quality Problems and Opportunities for Improvement

Line managers ensure tracking of quality problems and opportunities for quality improvement from initial identification through final verification and closure. Managers take appropriate action when tracking indicates incomplete disposition within specified time frames. Tracking by facility, project, function, or other administrative level is consolidated periodically to allow for Laboratory-wide trend analysis, through the use of LCATS and LSAD.

5.3.5 Root Cause Analysis and Lessons Learned

To ensure effective corrective action, line management, with assistance from EH&S and OAA, performs a root cause analysis and/or a lessons-learned analysis to prevent significant problems from recurring. The analysis performed is commensurate with the significance of the problem. The lessons-learned program provides both positive and negative lessons from assessment findings. These supplement other lessons identified from investigations of laboratory occurrences (see Section 5.3.1, **Identification of Quality Problems and Opportunities for Improvement**) and DOE-provided lessons learned.

5.3.6 Trend Analysis

As part of the LBL Self-Assessment Program, OAA maintains a trend analysis process that identifies overall positive and potentially negative trends in the implementation of the OAP. The OAA reports trending information through the annual *LBL Self-Assessment Report*. Trend analysis provides a proactive management tool for early warning of potential problems, identification of beneficial practices, and decision-making on corrective action. Adverse trends require root cause analysis, lessons-learned analysis, or other investigation to determine trend validity and corrective action. Data for trend analysis comes from quality problem or improvement documents, assessment reports, personnel concerns, and other performance indicators.

5.3.7 Process Improvement Teams

To achieve the objective of continuous improvement, LBL management periodically forms Process Improvement Teams. These teams apply work process improvement techniques to management systems or specific

problems. Each team is brought into existence with a specific charter and performs such tasks as work process review, work flow assessment, cause-and-effect analysis, identification of redundancy, and general problem identification. After such evaluation of a work process, the teams propose, test, and recommend work- and cost-effective solutions or improvements.

APPENDICES

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DOE Order 5700.6C Requirements Location Matrix

DOE ORDER	CRITERION / REQUIREMENT / GUIDELINE	REQUIREMENT STATEMENT	OAP PLAN LOCATION
5700.6C	1. **Program**	Organizations develop, implement, and maintain a written QAP. The QAP describes the organization structure, functional responsibilities, level of authority, and interfaces of those managing, performing, and assessing adequacy of work. The QAP describes the management systems, including planning, scheduling, and cost control considerations.	Program Description Program Element 1
	2. **Training and Qualification**	Personnel are trained and qualified to ensure that they are capable of performing their assigned work. Personnel are provided continuing training to ensure that job proficiency is maintained.	Program Element 2
	3. **Quality Improvement**	The organization establishes and implements processes to detect and prevent quality problems and to ensure quality improvement. Items and processes that do not meet established requirements are identified, controlled, and corrected. Correction includes identifying the causes of problems and preventing recurrence. Item reliability, process implementation, and other quality-related information are reviewed and the data analyzed to identify items and processes needing improvement.	Program Element 5

DOE Order 5700.6C Requirements Location Matrix, continued

DOE ORDER	CRITERION / REQUIREMENT / GUIDELINE	REQUIREMENT STATEMENT	OAP PLAN LOCATION
5700.6C	4. **Documents and Records**	Documents are prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records are specified, prepared, reviewed, approved, and maintained.	Program Element 4
	5. **Work Processes**	Work is performed to establish technical standards and administrative controls. Work is performed under controlled conditions using approved instruction, written procedures, or other appropriate means. Items are identified and controlled to ensure their proper use. Items are maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection is calibrated and maintained.	Program Element 3
	6. **Design**	Items and processes are designed using sound engineering and scientific principles and appropriate standards. Design work, including changes, incorporates applicable requirements and design bases. Design interfaces is identified and controlled. The adequacy of design products is verified or validated by individuals or groups other than those who performed the work. Verification and validation work are completed before approval and implementation of the design.	Program Element 3

DOE Order 5700.6C Requirements Location Matrix, continued

DOE ORDER	CRITERION / REQUIREMENT / GUIDELINE	REQUIREMENT STATEMENT	OAP LOCATION
5700.6C	7. **Procurement**	The organization ensures that procured items and services meet established requirements and perform as specified. Prospective suppliers are evaluated and selected on the basis of specified criteria. The organization ensures that approved suppliers can continue to provide items and services.	Program Element 3
	8. **Inspection & Acceptance Testing**	Inspection and acceptance testing of specified items and processes are conducted using established acceptance and performance criteria. Equipment used for inspection and test is calibrated and maintained.	Program Element 3
	9. **Management Assessment**	Management at all levels periodically assesses the integrated QA plan and its performance. Problems that hinder the organization from achieving its objectives are identified and corrected.	Program Element 5
	10. **Independent Assessment**	Planned and periodic independent assessments are conducted to measure item quality and process effectiveness and to promote improvement. The organization performing independent assessments has sufficient authority and freedom from the line organization to carry out its responsibilities. Persons conducting independent assessments are technically qualified and knowledgeable in the areas assessed.	Program Element 5

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The Graded Approach Methodology at LBL

Introduction

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

Methodology

- Line management defines each facility, project, and function for which it is responsible. These definitions should include a characterization of each quality-affecting activity performed, space and types of equipment utilized, and personnel involved (both LBL and non-LBL).
- Each activity associated with a facility, project, or function is analyzed to determine the level of risk it entails. 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. (See also the definition of "risk" in Appendix E.) The analysis is performed by considering the nine risk-potential categories described in Table B-1. The categories are consistent with those contained in the LBL Risk-Based Priority Planning Grid.* Three sets of consequence statements are provided for each category: high risk (H), moderate risk (M), and low risk (L).
- Critical to assessing risk is the probability that an event will occur. In analyzing the risk inherent in each quality-affecting activity, one must estimate the likelihood that the potential risk level may be encountered. Operating experience, commonly accepted statistical probabilities, best-management information, or other relevant data can be used to estimate the likelihood of the worst-case scenario. Care should be taken to consider cost effectiveness when developing management controls for an event. Laboratory line managers should balance the probability of an event occurring with the potential consequence (or cost) of achieving an effective set of such controls.

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

- Based upon this risk analysis, line management determines the rigor to use in applying the OAP requirements to each quality-affecting activity. This approach will result in determining the degree to which documentation and training are to be implemented. The line organization then has a documented approach to why one or more activities within a facility, function, or project have a high level of rigor (e.g., a very detailed written procedure) while others rely on standard operating procedures or guidelines (e.g., RPM, PUB-3000, or standard laboratory, shop, or business practices). Guidelines for this determination are provided in Table B-2.
- The risk analysis and determination of the rigor with which OAP requirements will be applied are documented in the associated LBL Notebook. As conditions change, as a result of the self-assessment process, or as performance problems are identified, the graded approach for each facility, project, and function is reviewed to determine whether OAP requirements continue to be met in an appropriate and cost-effective manner.

TABLE B-1: RISK POTENTIAL ANALYSIS USING THE LAWRENCE BERKELEY LABORATORY PRIORITY PLANNING GRID (RISK BASED)

For each risk category pick the statement that best characterizes the potential consequence of a failure to apply Quality Assurance, Conduct of Operations, and Maintenance Management principles to your activity.

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

TABLE B-2: GUIDELINES FOR THE GRADED APPLICATION OF REQUIREMENTS BASED ON RISK POTENTIAL ANALYSIS

Table B-2 provides guidelines for the application of OAP and LBL Notebook requirements based upon the results of the Risk Analysis completed using Table B-1.

	H	M	L
QUALITY ASSURANCE (Function and Project Notebooks)	All applicable elements of the LBL OAP are implemented in a manner that provides confidence and traceability. A formal written QA plan is produced and placed in the Function or Project Notebook.	A Function or Project Notebook is produced that documents implementation of OAP requirements for each of the five chapters in the instructions.	Function or Project Notebook instructions are reviewed for applicability and as guidelines for achieving quality. At a minimum, Chapters 1 - Planning and Organization, and 5 - Performance Assessment and Improvement must be addressed and documented fully.
CONDUCT OF OPERATIONS and MAINTENANCE MANAGEMENT (Facility and Project Notebooks)	Detailed, facility-specific documentation is required, including a documented assessment of the facility operations with regard to the 18 guidelines of 5480.19. Formally document in the Facility or Project Notebook the applicability of and method of compliance with the requirements. The full range of maintenance activities specified in 4330.4A that are applicable is utilized and documented, to ensure that the structure, system, or component operates within design requirements.	Facility-specific documentation is required in the form of a completed Facility or Project Notebook, with provisions of each chapter considered and documented. The maintenance emphasis is on those activities that significantly enhance safety or reliability.	Facility or Project Notebook is required. At a minimum, Chapters 1 - Planning and Organization, and 5 - Performance Assessment and Improvement must be addressed and documented fully. Operations and Maintenance activities are applied based on good business practice, productivity, or economic factors.

Preparation and Maintenance of LBL Notebooks

Introduction

The Laboratory requires the preparation, use, and maintenance of LBL Function, Facility and Project Notebooks as the primary planning and implementing documents for the Operating and Assurance Program (OAP) (see **OAP Program Elements, Planning and Organization**). The complete process and instructions for development of these Notebooks is provided in LBL Procedure OAP-IP-001, "Preparation and Maintenance of LBL Notebooks."

LBL Notebooks establish, describe, or reference requirements, responsibilities, and methodologies necessary to perform given activities. They also provide a repository for documenting such performance. Each of the three types of LBL Notebooks, Function, Facility, and Project, corresponds to the needs of an identified grouping of work relationships based on location, research mission, or common organizational responsibility.

- FUNCTION NOTEBOOKS pertain to (1) Laboratory or division office management, or (2) any of the support or service organizations funded from overhead, scientific burden, or recharge. These Notebooks contain information on quality assurance. The function supervisor or manager is responsible for developing and maintaining the Function Notebook.
- FACILITY NOTEBOOKS pertain to an entity or location that provides the physical resources to facilitate scientific research. An example might be a research building or laboratory and its equipment, operators, and staff. These Notebooks contain information on quality assurance, conduct of operations, accelerator safety, and maintenance management. The facility supervisor or manager is responsible for developing and maintaining the Facility Notebook.
- PROJECT NOTEBOOKS pertain to groups of personnel and supporting equipment dedicated to a specific research or construction effort. These Notebooks contain information on quality assurance and maintenance management. The principal investigator or project leader is responsible for developing and maintaining the Project Notebook.

Determination of the Type of Notebook(s) Required

Generally, the assignment of personnel and equipment groups into function, facility, and project categories by the division director should reflect a division's existing organization. Buildings or grounds, or portions of buildings or grounds with a common purpose and containing equipment or space used to perform identified activities constitute a facility. A specifically planned activity with a defined mission, schedule, and resulting deliverable (usually for research) is a project. An ongoing activity that has a specific management or support role is a function. Projects and functions correspond to the organization of people, whereas facilities correspond to the organization of locations.

Some of the differences in the three LBL Notebook categories are shown below:

	Project	Facility	Function
Initiation	• Research proposal(s)	• Equipment or construction proposal • (Note: The construction of a facility is a project)	• Designated organizational unit dedicated to common task
Term of existence	• Until proposed work is completed or funding stops	• Until decommissioned or dismantled	• Ongoing
ES&H concerns	• Ensuring that project personnel using facilities are properly trained and are complying with written procedures	• Training of operators or users, safety at facility, inventory of hazards, environmental protection, waste disposal, preparing for periodic ES&H inspections	• Ensuring that function personnel are properly trained
Research concerns	• Experimental design, validity of data taken at facilities (usually using internal checks), data analysis, publication of results	• Validity of data (usually using periodic calibration checks)	• Management and other support of research activities

	Project	Facility	Function
Funding source	• Set of activities that receive funding from one or more sources to address an area of inquiry	• One or more account numbers, depending on the number of projects using the facility	• Account number or budget
Purpose	• To answer scientific or technical research questions, or to construct a facility	• To provide the physical resources to facilitate scientific research	• To provide specific support to research efforts
Examples	• Heavy Ion Fusion Accelerator Research • SNO Project • CAM High Performance Metals	• A research building or a set of laboratories and their equipment, operators and staff • A machine shop and its machinists • The firehouse and its equipment and crews • Advanced Light Source • Silicon Development Lab	• Division administrative offices • Purchasing • Facilities Department • Environmental Protection Group

Notebook Preparation

LBL Notebooks are developed, reviewed, and maintained per a written Laboratory-wide procedure. The procedure contains detailed sets of instructions for preparing each type of LBL Notebook. These instructions are organized into the same five elements as the OAP and include references and background discussion to guide Notebook preparers in assembling or developing the material required. If required information is not immediately available for reference or insertion into a Notebook, a "placeholder" is inserted instead. The placeholder includes a schedule for adding the material at a later date. Some sections of the instructions may not be relevant to a particular facility, project, or function. In this case, the responsible manager so notes and provides a brief written justification in the LBL Notebook at the appropriate location.

Notebook Maintenance

Updates to the contents of the LBL Notebooks are made as requirements, organizational structure and responsibilities, or written procedures change. Changes and updates to materials in LBL Notebooks require the same level of review and approval as was required at the initial issue of those materials.

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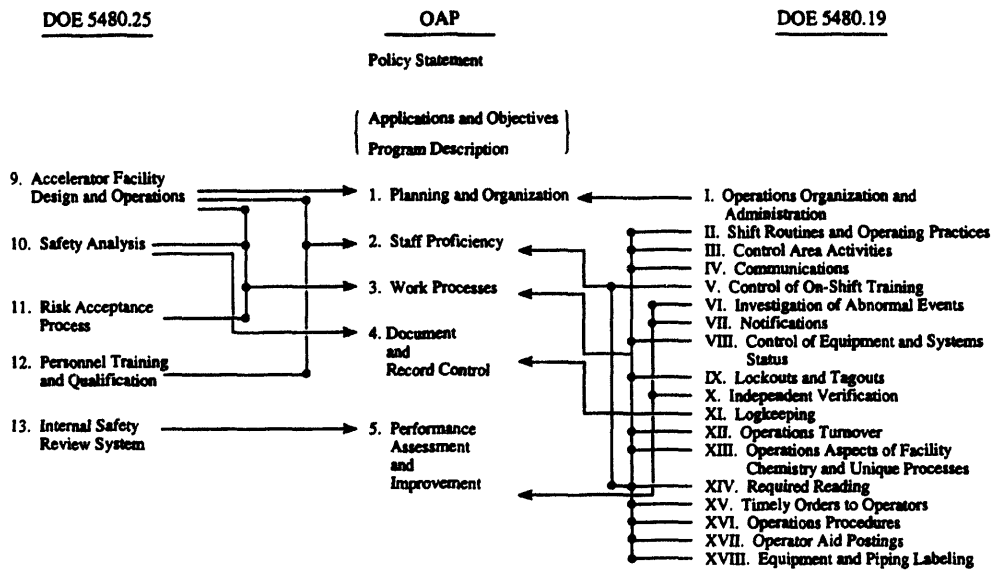
Mapping of DOE Order 5480.25 Requirements onto OAP Elements

The graphic below depicts the relationship between the basic requirements of DOE 5480.25, Safety of Accelerator Facilities, the five elements of the OAP, and DOE 5480.19, Conduct of Operations.

Mapping of "Safety of Accelerator Facilities" and "Conduct of Operations" Requirements Into the LBL Operating and Assurance Program (OAP)



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Terminology

The terms defined below are mentioned and used in this OAP Plan or elsewhere in the LBL Operations and Assurance Program or related documents. Lower-tier plans, written procedures, instructions, or other documents specific to a given LBL facility, project, function, or other work area may contain additional definitions.

ACCELERATOR - A device employing electrostatic or electromagnetic fields to impart kinetic energy to molecular, atomic, or sub-atomic particles (e.g., the 88-Inch Cyclotron and the Advanced Light Source). Contact OAA for a detailed definition.

ACCELERATOR FACILITY - The accelerator and associated plant and equipment utilizing or supporting the production of accelerated particle beams to which access is controlled to protect the safety and health of personnel. This includes experimental enclosures and experimental apparatus utilizing the accelerator, regardless of where that apparatus may have been designed, fabricated, or constructed.

ACTIVITIES AFFECTING QUALITY - See Quality-Affecting

ACTIVITY - Any time consuming effort (operation, task function, or service) that influences or affects the achievement or verification of the objectives of LBL.

ALARA - As low as reasonably achievable.

APPROVAL - An act of endorsing or adding positive authorization as shown by signature or initials and date.

ASE - Accelerator safety envelope, a set of physical and administrative conditions that define the bounding conditions for safe operation at an accelerator facility.

ASSESSMENT - A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the extent to which applicable elements of the LBL Operating and Assurance Program have been developed and documented in accordance with specified plans, written procedures, instruction notebooks, or other direction; the adequacy of compliance with established procedures, instructions, drawings, or other direction; and the effectiveness of implementation. Assessments should not be confused with other verification activities performed for process control or checking work product acceptability.

CERTIFICATES OF CONFORMANCE - A written statement, signed and dated by a qualified party, certifying that items or services comply with specific requirements.

CERTIFICATION - The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, written procedures, or items in accordance with specified requirements.

COMPLIANCE - Conformance to a code, specification, or written procedure.

CONFIGURATION MANAGEMENT - A means of control over how items, including work products, components, and systems, are assembled or configured relative to each other and the systematic method for maintaining that control over the life of the item. The process includes identification, documentation, and accounting functions.

CONTRACTOR or VENDOR - Any individual or organization furnishing items or services in accordance with a procurement document.

CONTROLLED AREA - An enclosed area to which entry is controlled.

CORRECTIVE ACTION - Measures taken to rectify conditions that are adverse to quality and, where necessary, to preclude repetition.

DAC - Director's Action Committee

DESIGN INPUT - Those criteria, parameters, bases, or other design requirements upon which a detailed final design is founded.

DESIGN OUTPUT - Documents defining technical requirements of structures, systems and components.

DISPOSITION - The action taken to resolve a non-conforming condition and to restore acceptable conditions.

DOCUMENT - Any written, pictorial, or electronically stored information describing, defining, specifying, reporting, or certifying activities, requirements, plans, written procedures, or results. Some documents are QA records (see definition of "QA Record").

DOCUMENT CONTROL - The process of controlling the identification, preparation, review, approval, issuance, distribution, revision, and cancellation of documents that prescribe work to ensure that only correct and current versions of the documents are used in the workplace or transmitted to outside entities.

DOCUMENTATION - Any written or electronically stored information describing, defining, specifying, reporting or certifying activities, written procedures or results.

DOE - U.S. Department of Energy.

DOE-ER - The Department of Energy's Office of Energy Research, charged with supporting the energy, environmental restoration and waste management, and science and technology missions of DOE through fundamental research and development.

EH&S - At LBL, the Environment, Health and Safety Division, charged with supporting ES&H initiatives. The "EH&S" Division is so titled to avoid confusion with "ES&H."

ES&H - The group of all topics and activities pertaining to environmental, safety, and health matters.

EXAMINATION - Specific actions by qualified personnel using qualified procedures to verify that items are in conformance with specified requirements.

EXPERIENCE - Knowledge, skill, or practice derived from direct participation in identified activities.

FACILITY - See Appendix C.

FUNCTION - See Appendix C.

GRADED APPROACH - The application of Laboratory resources toward those activities, structures, and systems that will result in the greatest benefit, commensurate with risk. This approach is used by the Laboratory to achieve management control in a cost-effective manner. LBL Notebooks are developed to a level of rigor determined through application of the graded approach. (See also RISK.)

HOLD POINT - A designated stopping place during or following a specific activity at which inspection or examination is required before further work can be performed.

INDEPENDENT ASSESSMENT - The practice of assessing the performance of an organizational unit, by individuals and/or organizations with no line authority over the unit's management or other direct interest in the unit's activities. Independent assessment is a management advisory function. Examples of independent assessment at LBL include review of a project by individuals from other, technically similar projects (peer review); review of a division or program by technically qualified individuals from other divisions (SRC, OAA, IAS, and/or EH&S); and review of LBL by an external agency.

INSPECTION - An examination or measurement to verify conformance to specific requirements.

INSTITUTIONAL DEFICIENCY - A problem or noncompliance, found through the LBL self-assessment process, by the DOE Tiger Team, or by other means, that to be corrected requires a change in LBL policy, organization, services, or physical structure.

ITEM - An all inclusive term used in place of any of the following: Appurtenance, assembly, component, data, equipment, material, module, part, sample, structure, subassembly, subsystem, system, or unit.

LBL NOTEBOOK - See Appendix C.

LCATS - The LBL Corrective Action Tracking System, used to track institutional deficiencies found by the DOE Tiger Team and through the self-assessment process, and to manage the corresponding corrective actions.

LINE ORGANIZATION (LINE MANAGEMENT) - Those personnel having assigned responsibility and delegated authority to affect, by direct commands and instructions, the conduct of an activity or group of activities. Line organizations are responsible for both the achievement and assurance of quality in their activities.

LSAD - The LBL Self-Assessment Database, used at the division level to track deficiencies found through the self-assessment process and to manage the corresponding corrective actions.

MANAGEMENT ASSESSMENT - The practice of assessing performance of an organizational unit from within (or above) that unit by the unit's workers or line management. Examples of management assessment at LBL include periodic review of division activities by division personnel and management, per the LBL Self-Assessment Program Implementation Plan, and daily observation of group performance by the group's manager.

M&TE - See MEASURING AND TEST EQUIPMENT.

MEASURING AND TEST EQUIPMENT (M&TE) - Devices or systems used to calibrate, measure, monitor, gauge, test, or inspect in order to control or to acquire data to verify conformance to specified requirements.

NONCONFORMANCE - A deficiency in characteristics, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate. Examples of nonconformance include physical defects, test failures, incorrect or inadequate documentation, and deviation from prescribed written procedures.

OAA - Office of Assessment and Assurance, the LBL organization responsible for developing the Operating and Assurance Program and supporting procedures, and for providing to LBL organizations guidance on self-assessment, quality assurance, and conduct of operations.

OAP - Operating and Assurance Program, management system for achieving LBL's objectives effectively and safely through application of quality assurance, conduct of operations, and maintenance management principles. (For a full description, see the "OAP Objectives and Applicability" section of this document.)

OBJECTIVE EVIDENCE - Any documented statement of fact, other information, or record, either quantitative or qualitative, that pertains to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

PEER - A person having technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter to be reviewed) to a degree at least equivalent to that needed for the original work.

PEER REVIEW - A documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer (a) was not involved as a participant, supervisor, technical reviewer, or advisor in the work being performed, and (b) to the extent practical, has sufficient freedom from funding considerations to ensure the work is impartially reviewed. A peer review is an in-depth critique of assumptions, calculation, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the adequacy of work.

PEER REVIEW GROUP - An assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed and varying in size based on the subject matter and importance of the subject matter to safety or environmental concerns.

PROCEDURE - A document that specifies or describes how an activity is to be performed.

PROCESS - A system of actions that achieves an end or result.

PROCUREMENT - Purchasing of items or services from vendors and contractors.

PROCUREMENT DOCUMENTS - Contractually binding documents that identify and define the requirements that items or services must meet in order to be considered acceptable by the purchaser.

PROJECT - See Appendix C.

QUALIFICATION OF PERSONNEL - Determination that the knowledge, skills, and abilities gained through training and experience, as measured against established requirements, qualify an individual to perform a required job or task in a safe and proficient manner.

QUALITY - The degree to which an item or process meets or exceeds the end user's requirements and expectations.

QA - See QUALITY ASSURANCE.

QUALITY-AFFECTING - Critical to achieving the mission and objectives of an LBL organizational unit; essential to maintaining the financial and operational integrity of the University and Laboratory; necessary to ensure the validity of data or information that could affect the Laboratory's reputation; potentially representing an unacceptable risk to the environment or to the health and safety of the public or staff; or potentially having a serious impact on the mission of the Laboratory.

QUALITY ASSURANCE (QA) - Actions that provide confidence that quality is achieved.

QUALITY ASSURANCE PLAN - A document that identifies requirements judiciously selected from the overall QA Program that are applicable to a particular activity or project and provides a general idea or description of the written procedures that implement these requirements. The document also includes specific responsibilities and authorities for the implementation of the activity or project. A QA plan may be a part of an activity or task plan.

QUALITY ASSURANCE RECORD - A completed document that furnishes evidence of the quality of items or quality-affecting activities.

QUALITY CONTROL - Those actions that provide a means of control and measurement of the characteristics of an item, process, or facility to established requirements.

QUALITY IMPROVEMENT - Activities or policies that are implemented for the purpose of improving products, services, or processes within an organizational unit. One of the major goals of quality improvement is to develop mechanisms for identifying problems that prevent an organization from meeting or exceeding its assigned performance objectives. Examples of quality improvement include peer reviews, design reviews, trend analysis, or converting manual systems to machine readable systems to enhance performance or effectiveness.

RECEIPT INSPECTION - An inspection that occurs after delivery, but prior to acceptance at LBL with the purpose of determining whether a delivered item meets the material and quantity requirements of the purchase order. When receipt inspection is required by an LBL purchase order, the supplier performs its own tests and inspections prior to shipment.

REPAIR - The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still may not conform to the original requirement.

REWORK - The process by which an item is made to conform to original requirements by completion or correction.

REVIEW - A documented evaluation of a QA program element.

RISK - An expression of possible loss that considers both the probability that an event will cause harm and the consequences of that event. The credible exposure to loss or failure related to presence of hazards that could threaten public or worker safety or significantly impact the environment; high visibility or requirements for high assurance of quality, due to programmatic importance or impact upon Laboratory services; and noncompliance with laws or regulations.

RPM - LBL *Regulations and Procedures Manual.*

SAD - Safety Analysis Document.

SELF-ASSESSMENT - The practice of line management and staff performing appraisals against performance objectives, including review of Laboratory operations against the performance measures provided in Appendix F of UC/DOE Contract DE-AC03-76SF00098. The LBL policy for these activities at the division level only is found within the LBL Self-Assessment Program Implementation Plan (PUB-5344). Guidance for implementation of this policy by division personnel and management is presented in the LBL Self-Assessment Manual (PUB-3105).

SPECIAL PROCESS - A process in which the results are highly dependent on the control of the process or skill of the processor, or both.

TESTING - An element of verification for the determination of the capability of an item meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operation conditions.

TRACEABILITY - The ability to verify the history, location, or application of an item by means of recorded identification.

TRAINING PROGRAM - An identifiable group of training activities that consists of one or more training courses, classes, or methods that make up a total learning process.

USE-AS-IS - A disposition for a nonconforming item when it is established that the item is satisfactory for its intended use.

VALIDATION - An activity that demonstrates that an item or process will perform under conditions of actual use and will satisfy requirements of the end user.

VERIFICATION - The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

WORK - Process of performing a defined task or activity; for example, research and development, operations, maintenance and repair, administration, software development and use, inspection, safeguards and security, data collection, and analysis.

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