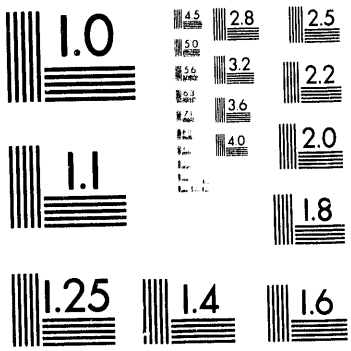
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1 of 1

Lawrence Berkeley Laboratory

Environment, Health and Safety Division

Environment Department

Waste Management Group

Waste Management Quality Assurance Plan

Effective Date: November 30, 1993

Issue Date: November 30, 1993

Approved By: _____ Date: November 4, 1993

Tim Wan, Group Leader,
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Environment, Health and Safety Division

Approved By: _____ Date: Nov 11, 93.

Kam Tung, Head
Environment Department
Environment, Health and Safety Division

MASTER

Revision Record

Document title	Effective date	Revision
Quality Assurance Program Plan for the Hazardous Waste Handling Facility (HWHF)	8/90	–
Waste Management Quality Assurance Implementing Management Plan	6/92	Rev. 1
Waste Management Quality Assurance Plan	11/93	Rev. 2

Contents

Statement of Policy

The Lawrence Berkeley Laboratory (LBL) Environment, Health and Safety (EH&S) Division, and the Waste Management (WM) Group of EH&S's Environment Department, endorse the application of quality management and recognize the role of a coordinated quality assurance management program.

Quality assurance is one of the tools that WM uses to accomplish its goals. The goal of the WM Quality Assurance Plan (QA Plan) is to identify and implement elements of the LBL Operating and Assurance Program Plan (OAP, LBL PUB-3111), EH&S Quality Assurance (QA) tenets as documented in the EH&S Division Function Notebook, and DOE Order 5700.6C that are relevant to the activities of WM. Quality is defined as the degree to which an item or process meets or exceeds the end user's requirements and expectations. When integrated with appropriate requirements of environmental regulations and guidance documents, this plan provides for the management and assurance of quality in those activities. The *achievement of quality* is the responsibility of all personnel assigned to the Department and is accorded top priority. The *verification of the achievement of quality* is a responsibility of the LBL Quality Assurance staff.

Full authority and organizational freedom are provided to the LBL Quality Assurance staff to identify quality concerns, assist in recommendation of solutions, verify corrective actions, and recommend cessation of unacceptable activities or practices that may affect quality.

This QA Plan establishes and presents the framework of requirements that must be met in planning, performing, documenting, and verifying WM quality-affecting activities.

Tim Wan
Waste Management Group Leader

Introduction

Lawrence Berkeley Laboratory's Environment Department addresses its responsibilities through activities in a variety of areas. The need for a comprehensive management control system for these activities has been identified by the Department of Energy (DOE). The WM QA Plan is an integral part of a management system that provides controls necessary to ensure that the department's activities are planned, performed, documented, and verified.

This WM QA Plan defines the requirements of the WM QA program. These requirements are derived from DOE Order 5700.6C, *Quality Assurance*, the LBL Operating and Assurance Program Plan (OAP, LBL PUB-3111), and other environmental compliance documents applicable to WM activities. The requirements presented herein, as well as the procedures and methodologies that direct the implementation of these requirements, will undergo review and revisions as necessary.

The provisions of this QA Plan and its implementing documents apply to quality-affecting activities performed by and for WM. It is also applicable to WM contractors, vendors, and other LBL organizations associated with WM activities, except where such contractors, vendors, or organizations are governed by their own WM-approved QA programs.

References used in the preparation of this document are

- ASME NQA-1-1989
- ANSI/ASQC E4 (Draft)
- Waste Management Quality Assurance Implementing Management Plan (LBL PUB-5352, Rev. 1)
- LBL Operating and Assurance Program Plan (OAP), LBL PUB-3111, 2/3/93

A list of terms and definitions used throughout this document is included as Appendix A.

Section 1. Management

Criterion 1: Program

General

The Environment Department has developed this document, the WM Quality Assurance Plan (WM QA Plan), which is the required written Quality Assurance Program description. The Plan description that follows provides the details of the organization and management system. This Criterion implements Criteria 1 and 2 from ASME NQA-1-1989, Criterion 1 from DOE Order 5700.6C, and applicable portions of the OAP.

Plan

1.1 Environment, Health and Safety Division

WM must comply with applicable QA requirements. All staff performing EH&S activities affecting quality are responsible for assuring that operational (technical) procedures are developed for their assigned tasks, that applicable quality standards have been identified, and that compliance with these standards is verified.

The structure of EH&S is shown in Figure 1-1.

The EH&S Division Director is responsible for direction of the activities of the EH&S professionals and for the development, maintenance, and verification of the EH&S QA program.

1.2 Environment Department Organizational Structure and Responsibilities

Those positions accountable for waste management that have leadership responsibilities within Environment Department are shown in Figures 1-2 and 1-3. The areas of responsibility and principal functions of each position that relate to this QA Plan are listed in Sections 1.2.7 through 1.2.11.

In addition to the responsibilities and QA functions for Environment Department personnel shown in Sections 1.2.7 through 1.2.11, the Associate Laboratory Director (ALD) for Operations, the ALD for Administration, the Manager of the Office of Assessment and Assurance (OAA), the Leader of OAA's Quality Assurance/Conduct of Operations Group, the EH&S Division Director, and the EH&S QA Manager have the responsibilities under the same context, as listed in Sections 1.2.1 through 1.2.6, respectively (see Figures 1-1 and 1-4).

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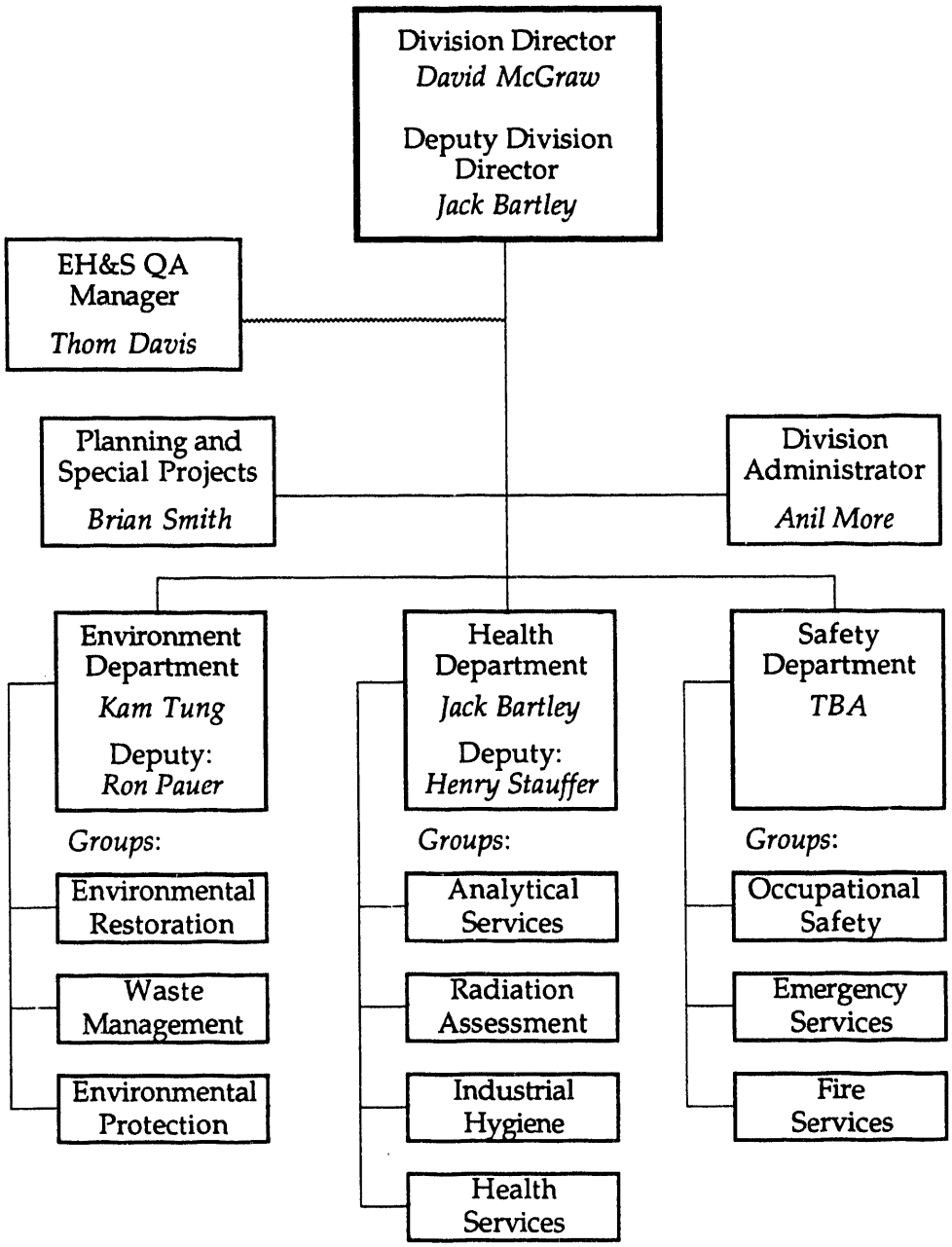
Section 1. Management (continued)

Criterion 1: Program (continued)

Figure 1-1 **EH&S Organization Chart**



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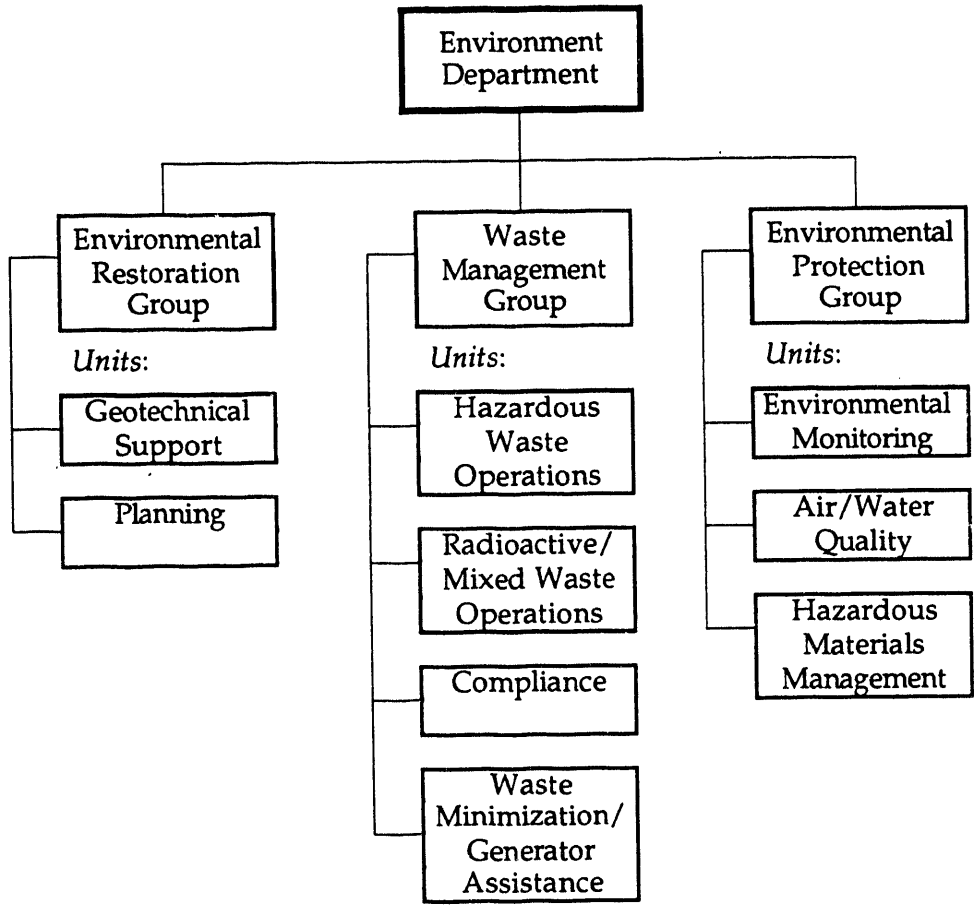
Section 1. Management (continued)

Criterion 1: Program (continued)

Figure 1-2 **Environment Department Organization Chart**



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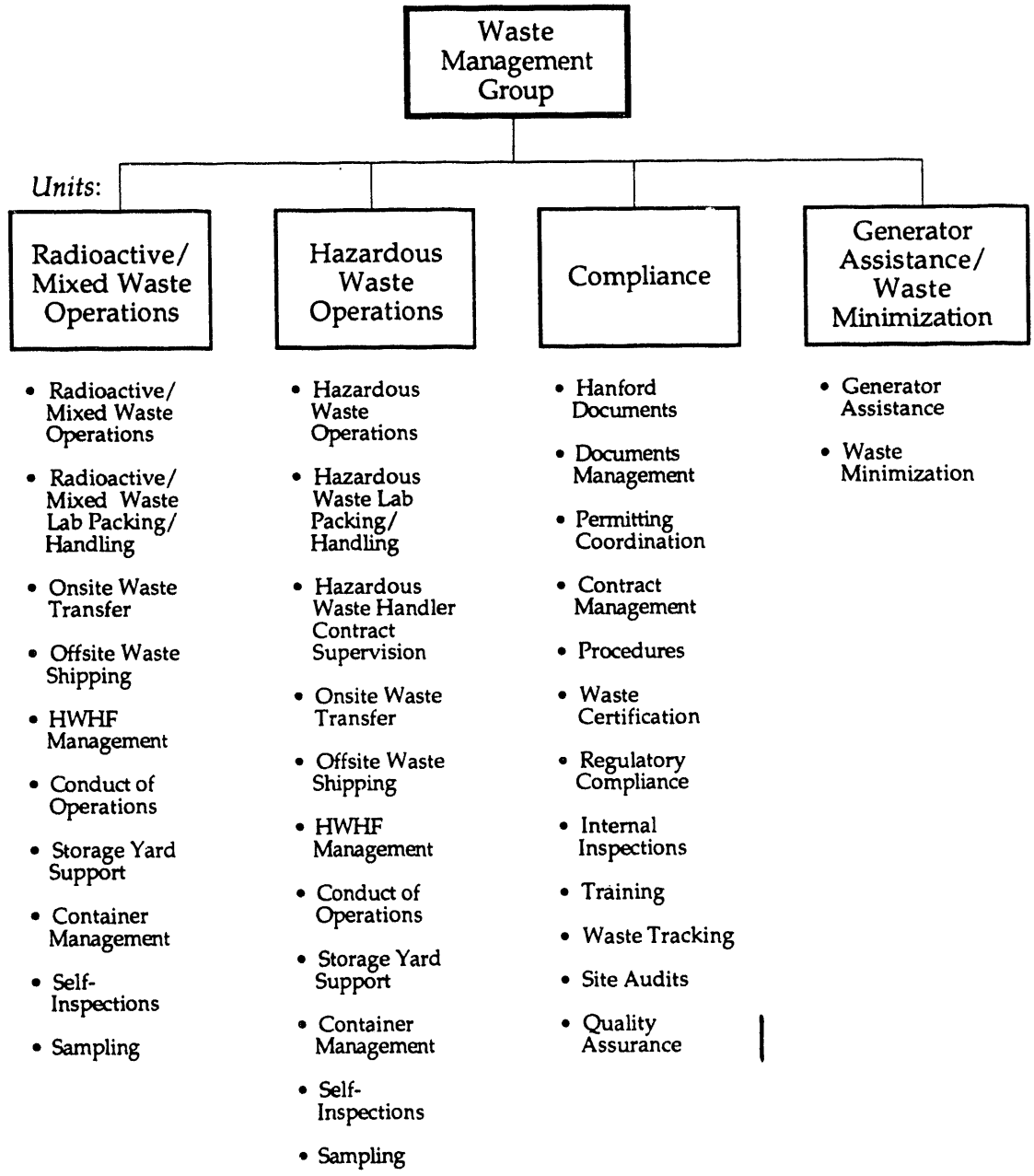
Section 1. Management (continued)

Criterion 1: Program (continued)

Figure 1-3 **Waste Management Group Organization Chart**



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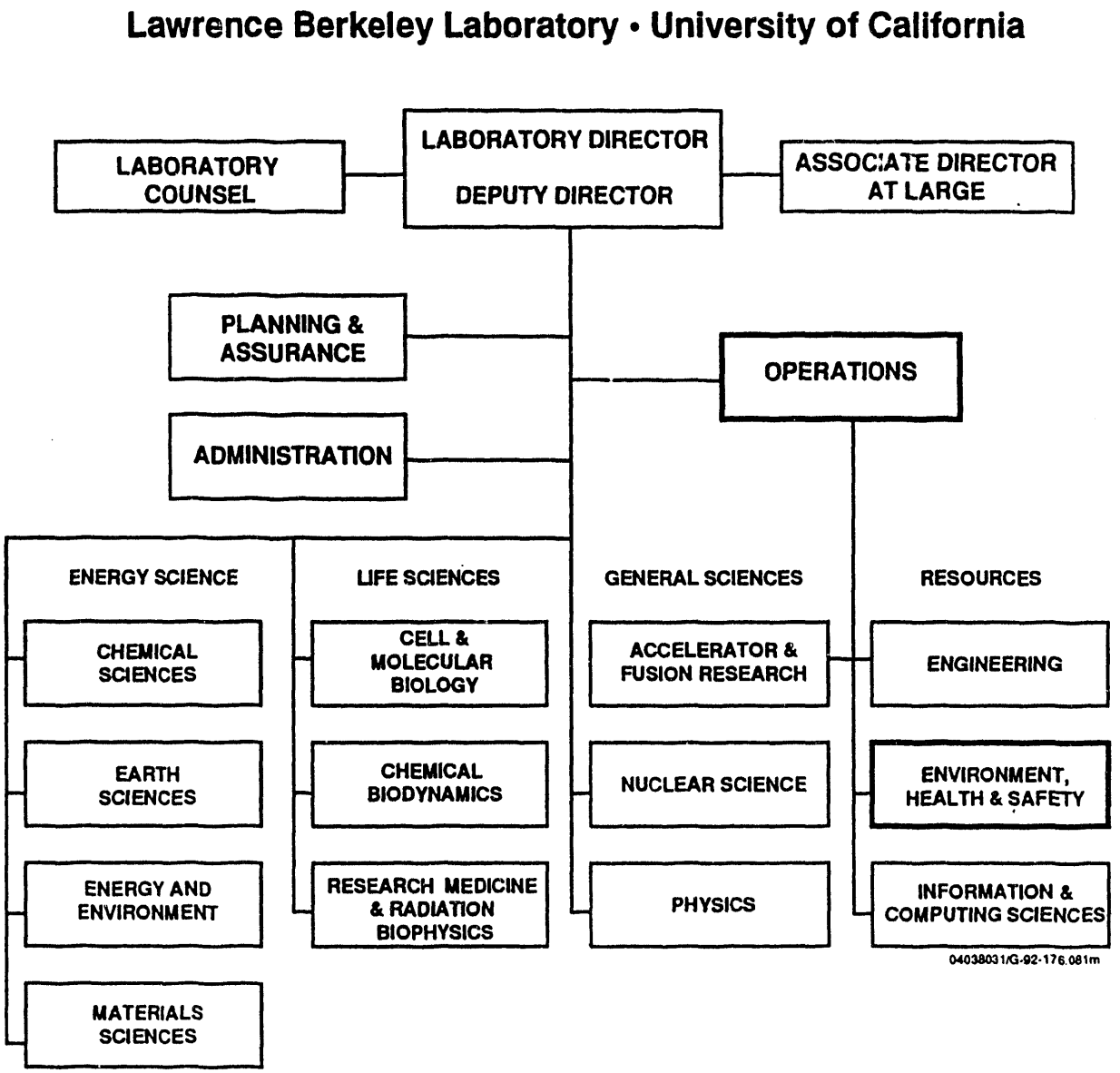
Section 1. Management (continued)

Criterion 1: Program (continued)

Figure 1-4 LBL Organization Chart



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Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.2.1 *Associate Laboratory Director for Operations*

The Associate Laboratory Director (ALD) for Operations is responsible for the functions listed below. The ALD for Operations may delegate oversight for specific aspects of these functions to others but retains overall management responsibility for these functions.

- Provides Laboratory-wide procedures for implementation of the OAP where required (e.g., procedure for preparation of facility and function notebooks).
- Approves, issues, and provides resources for maintenance of the LBL policy and accompanying written procedure for Laboratory-wide document control activities.
- Establishes self-assessment programmatic requirements for all divisions and offices.
- Provides the required resources to support efficient LBL implementation of the Self-Assessment Program.

1.2.2 *Associate Laboratory Director for Administration*

The Associate Laboratory Director for Administration is responsible for the functions listed below. The ALD for Administration may delegate oversight for specific aspects of these functions to others but retains overall management responsibility for these functions.

- Provides resources for implementation and maintenance of the LBL records management procedure for QA-related records.

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.2.3
Manager, Office of Assessment and Assurance

The Manager of the Office of Assessment and Assurance (OAA) is responsible for the functions listed below. The OAA Manager may delegate oversight for specific aspects of these functions to others but retains overall management responsibility for these functions.

- Assists in implementing division self-assessment programs and plans.
- Maintains the LBL Corrective Action Tracking System (LCATS), and provides periodic reports, as required.
- Provides independent assessment services for line-management functions through the LBL OAA Management Appraisal process, as described in LBL PUB-5344, the LBL *Self-Assessment Program Implementation Plan*.

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.2.4 *Group Leader, Quality Assurance/ Conduct of Operations*

The Group Leader, Quality Assurance/Conduct of Operations (QA/CO), is responsible for the functions listed below. The QA/CO Group Leader may delegate oversight for specific aspects of these functions to others but retains overall management responsibility for these functions.

- Develops and maintains the LBL instructions for facility, function, and project notebooks.
- Provides QA/CO guidance, consultation, and training to LBL divisions and quality assurance representatives as required.
- Reviews and concurs or approves QA- and CO-related procedures and instructions for those facilities and activities that have been determined to be in the highest risk category or that provide institutional or LBL-wide direction (using the graded approach, as discussed in the OAP).
- Conducts and reports on independent assessments (functional appraisals) of WM QA, CO, and maintenance management performance.
- Facilitates external QA, CO, and maintenance management audits and assessments of WM.
- Concurs with corrective action for quality-related assessment findings, and verifies completion as required.
- Selects, trains, and certifies QA, CO, and maintenance management independent assessment team members.

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.2.5 *EH&S Division Director*

The Division Director, Environment, Health and Safety Division, is responsible for the functions listed below. The Director may delegate any or all of the EH&S QA program functions to the Deputy Division Director or other appropriate personnel but retains overall management responsibility for such functions.

- Ensures that the LBL OAP requirements are appropriately implemented through the use of notebooks and/or plans and procedures, using the graded approach outlined in the OAP.
- Administers the division self-assessment process, which supports the assessment requirements of the OAP.
- Provides sufficient divisional resources to support the objectives and implementation of OAP requirements.
- Determines which EH&S documents, instructions, and drawings are controlled, and maintains a master list of these documents.
- Ensures that sufficient records are generated, identified, and maintained to accurately demonstrate completed Division, department, and group work and activities.
- Develops and issues the Division Self-Assessment Program Implementation Plan.
- Administers the Division self-appraisal process, and provides adequate resources for implementation, including the Laboratory Self-Assessment Database (LSAD).
- Participates in the Division self-assessment process to ensure that the Division focus is on achievement of performance objectives and quality improvement.

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.2.6
EH&S QA Manager

The Environment, Health and Safety Division QA Manager is responsible for the functions listed below. The EH&S QA Manager may delegate any or all of these functions to other appropriate personnel but retains overall management responsibility for such functions.

- Provides guidance and consultation to Division personnel and management regarding QA/CO requirements and methods.
- Acts as a primary point of contact with OAA's QA/CO Group for Division QA/CO matters, such as independent assessment coordination, promulgation of new requirements or information, and training.
- Reviews and approves WM Group quality assurance plans, quality implementation plans, and operational plans and procedures to assure inclusion of QA requirements.
- Monitors WM quality-affecting activities by conducting reviews, quality surveillances, audits, and other assessments.
- Assists WM personnel in QA matters through guidance, consultation, and participation in training activities, document reviews, meetings, presentations, and task forces.
- Monitors computer software code development and verification activities.
- Monitors design activities by participating in design reviews, conducting surveillances and audits, and reviewing appropriate output documents.
- Monitors the procurement process to verify that applicable procurement documents and procurement actions include appropriate QA requirements.

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.2.6 *(continued)*

- Directs contractor and vendor QA surveillances and audit processes, approves contractor and vendor qualifications, and reviews contractual documents for inclusion of appropriate QA provisions.
- Verifies that personnel performing special processes, inspections, tests, and other quality-affecting activities are properly trained, qualified, and certified, as applicable to the activity.
- Prepares implementing procedures that provide specific requirements and methods for training, qualifying, and certifying assessment personnel. Personnel are trained and qualified per the requirements described in Section 5.3.2 of the OAP.
- Verifies that inspections are performed at appropriate activity intervals and that tests are properly planned.
- Verifies that measuring and test equipment items used in WM quality-affecting activities are controlled, calibrated, and documented by the applicable EH&S organization.
- Reviews and concurs with dispositions of nonconformance and corrective action reports (NCARs), where the WM QA Plan or related procedures are affected by the resolution of the NCAR.
- Initiates corrective-action documentation for conditions adverse to quality, and investigates and validates corrective-action reports.
- Verifies corrective-action implementation.

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.2.7 *Environment Department Head*

The Environment Department Head is responsible for the functions listed below. The Environment Department Head may delegate any or all of the QA program functions to staff members but retains overall management responsibility for such functions.

- Manages Environment Department operations, personnel, and activities, including the implementation and application of this WM QA Plan.
- Fulfills the objective of assuring that operations are carried out in a safe manner, meeting applicable requirements of LBL, and complying with appropriate DOE, DOT, EPA, Cal/EPA, and QA regulations in handling, storage, and transportation of hazardous and/or radioactive wastes.
- Defines corrective-action and improvement details with the objective of assuring that they are completed, effective, properly documented, and closed.
- Approves and issues the WM QA Plan and any revisions.
- Performs periodic management reviews of the WM QA Plan and system, in order to direct corrections and improvements.
- Implements the EH&S QA program as it relates to the activities of WM.
- Determines the need for and assuring that appropriate QA plans, procedures, and instructions are developed for applicable department activities.

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.2.7 *(continued)*

- Approves software design plans and code validation and verifying requirements applicable to WM.
- Plans design activities, and reviews design inputs, outputs, and reports.
- Participates in design verification as appropriate, and implements configuration management and design procedures.
- Assures that procurement documents include the appropriate technical, regulatory, LBL Procurement Department, and QA requirements applicable to that item or service, including receipt, inspection, and acceptance.
- Develops and implements appropriate controls for assuring that only properly identified and controlled items are used in quality-affecting activities.
- Develops test plans, overviews testing activities, and assures that test results are properly documented.
- Assures that measuring and test equipment used in the acceptance of data is properly calibrated.
- Assures that conditions adverse to quality are identified and documented.
- Assures that personnel generate and maintain QA records, and directs departmental document and records management functions.
- Provides input into quality verification schedules, and assures the availability of personnel participating in these activities.
- Reports information directly to the EH&S Division Director on issues affecting quality in WM where independence from WM is deemed necessary.

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.2.8 *Waste Management Group Leader*

The Waste Management Group Leader is responsible for the functions listed below. The Waste Management Group Leader may delegate any or all of the QA program functions to staff members but retains overall management responsibility for such functions.

- Applies and documents OAP requirements using the LBL graded approach outlined in the OAP.
- Periodically assesses WM performance against established performance objectives and OAP requirements, and takes corrective action as necessary.
- Develops, issues, maintains, and controls the WM Function Notebook and the Hazardous Waste Handling Facility (HWHF) Facility Notebook.
- Ensures that personnel are qualified, trained, and proficient for assigned tasks.
- Determines and documents job requirements and qualifications, and evaluates initial qualifications of personnel for a position.
- Determines and documents 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 evaluates and documents staff proficiency.
- Provides administrative controls for on-the-job training.
- Specifies those activities that require written procedures, instructions, or drawings.
- Develops and approves administrative, QA-related, CO-related, maintenance management–related, and operating procedures as required for the appropriate activities.

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.2.8 *(continued)*

- Plans, reviews, and documents design activities.
- Ensures that measuring and test equipment items are calibrated and maintained in accordance with their actual or intended use.
- Ensures the use of properly identified and controlled items to prevent the use of incorrect or defective items.
- Plans and performs inspections or tests of completed work at appropriate intervals.
- Uses the LBL procurement system to ensure that items meet requirements and perform as specified.
- Ensures the control and use of those documents associated with WM that provide instructions or direct the work.
- Ensures that records are generated, identified, and maintained to demonstrate completed WM work.
- Regularly and routinely observes and surveys activities, and takes an active role in prevention of quality problems, correction of deficiencies, and improvement of performance (ongoing assessment).
- Performs, documents, and reports on management assessment (self-assessment).
- Cooperates with the independent assessment (functional appraisal) process and assessors.
- Tracks identified problems and corrective actions using LSAD.
- Assures that nonconforming conditions are promptly addressed and documented.
- Performs root-cause analysis of significant or recurring problems.

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.2.9 *Waste Management Operations Units Managers*

The Waste Management Operations Units Managers are responsible for the functions listed below.

- Assure that the HWHF is operated in a safe manner, meeting applicable requirements of LBL, Federal, state, local, and QA regulations.
- Assure that the proper work environment exists for HWHF personnel.
- Manage and coordinate maintenance activities for HWHF.
- Manage and coordinate facility activities for the HWHF.
- Assist with safety and control measures for employee and environmental protection during HWHF operations.
- Provide support for the accountability, tracking of documents, and regulatory guidance for the preparation of radioactive and mixed hazardous waste shipments.
- Assure that field operations are carried out in a safe manner, meeting applicable requirements of LBL, DOE, DOT, and other Federal and state regulations.

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.2.10 *Waste Management Compliance Unit Manager*

The Waste Management Compliance Unit Manager is responsible for the functions listed below. The Compliance Unit Manager may delegate any or all of the QA program functions to staff members but retains overall management responsibility for such functions.

- Provides technical support to the WM Operations units in emergency planning, compliance issues, computations, RCRA, LLW, certification, procedure writing, record-keeping, computer production, and other major systems activities.
- Identifies WM quality-related problems.
- Initiates, recommends, or provides solutions to WM quality-related problems.
- Provides a method to verify that activities affecting quality in WM have been correctly performed.
- Provides the quality control inspection function for WM.
- Reviews procurement documents for technical content affecting WM.
- Develops quality assurance procedures.
- Provides and maintains a document control system for WM procedures.
- Maintains records as required.
- Assures that safety procedures and standard operating procedures are followed.
- Provides technical input, guidance, and assurance to WM to assure compliance with Federal and state regulations, DOE Orders, and waste management acceptance requirements of treatment/disposal sites.

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.2.10 *(continued)*

- Assumes responsibility for communications, permitting, reporting, and correspondence between LBL and regulatory agencies.
- Prepares reports to comply with DOE Orders and additional regulatory and management requirements as applicable.
- Assures compliance with applicable safety measures.
- Assures that chemical and radioactive waste treated on site is in compliance with the appropriate regulations and DOE Orders.
- Assures compliance with waste treatment and disposal regulations.
- Maintains the status tracking system for nonconformance reports, and monitors the control of nonconforming conditions and status indicators.
- Assures that reports to DOE are generated periodically.
- Trains personnel on computer usage and applications.
- Assists in the review of purchase orders dealing with DOE radioactive waste management facilities.
- Prepares manifests and related shipping documents.
- Provides technical support and expertise to LBL personnel as related to packaging and labeling.
- Inspects waste packaging and loading.
- Assists WM in meeting the radioactive criteria and hazardous waste acceptance criteria for shipments off site to other DOE treatment/disposal facilities.
- Arranges for the shipment and disposal of the Laboratory's hazardous and radioactive waste at Hanford/WIPP facilities.

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.2.11
All Waste Management Personnel

- Understand LBL organizational responsibilities and authorities as described in the OAP and elsewhere.
- Perform assigned tasks in accordance with OAP requirements as described in the WM Facility Notebook and the HWHF Function Notebook.
- Identify noncompliances or unsafe work practices, and understand and implement (as appropriate) the LBL stop-work policy.
- Identify, and report to management, deficiencies in the OAP or other management systems that hinder the ability to achieve performance objectives.
- Understand the assigned tasks and position description for their position.
- Perform only those assignments for which they have the requisite qualifications, training, and proficiency.
- Effectively apply qualifications and abilities in proficient performance of assigned tasks.
- Perform activities in accordance with approved procedures, instructions, and drawings (when required).
- Continuously assess individual performance to prevent quality problems and identify nonconforming conditions and opportunities for improvement in process or item quality.

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.3 WM Implementing Management Plan (WM QA Plan)

One purpose of the WM QA program is to select the QA requirements and measures that are consistent with WM objectives. The overall requirements of the WM QA program are defined in this governing QA Plan. The hierarchy of governing documents applicable to the WM QA program is shown in Figure 1-5.

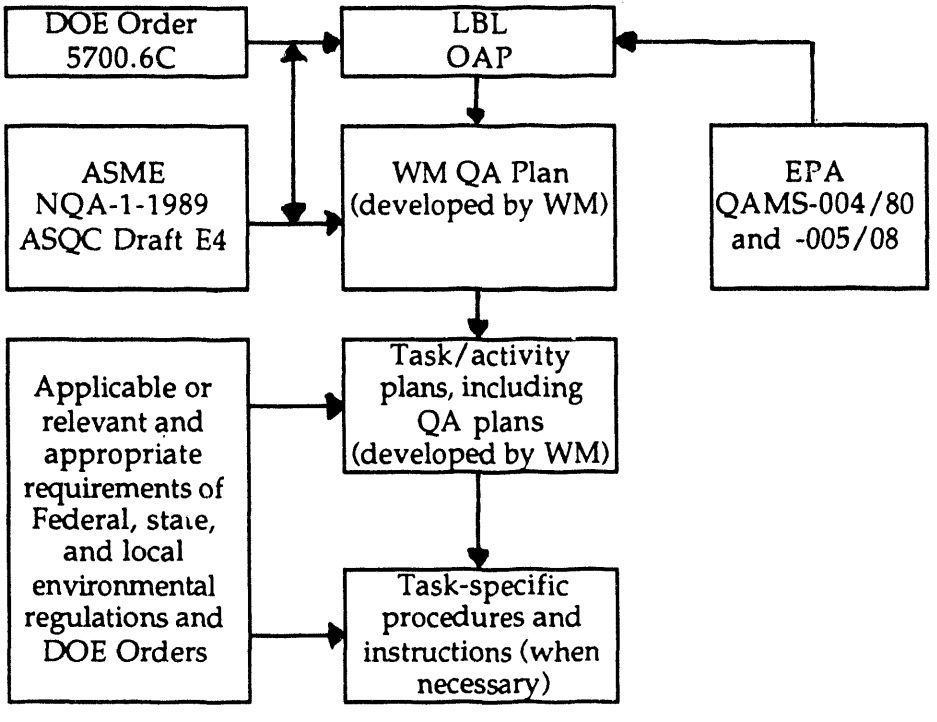

Figure 1-5. WM QA program document hierarchy

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.3 (continued) This WM QA Plan has been developed by selective applications of QA requirements to the overall activities to be performed. Whether QA requirements are applied to specific WM activities depends on the following factors:

- Risk to programmatic objectives
- Consequence of failure of the program
- Importance of the data
- Complexity of function
- Reliability of process
- Reproducibility of results
- Uniqueness of product
- Degree of standardization
- Impact on schedule or cost to replace in the event of failure
- Necessity of special controls or process
- Significance to regulatory compliance
- Worker health and safety
- Public health, safety, and environment

1.3.1 *Planning and Scheduling* Application of QA requirements to WM activities must be planned and documented to assure that a comprehensive and systematic approach is used. Planning and scheduling must be performed as early as practical, and prior to the start of activities that are to be controlled, to assure an exchange of information and adequate implementation of quality requirements. Planning must be accomplished to provide

- identification and documentation of the methods and organizational responsibilities that are necessary to assure a systematic approach to, and compliance with, the requirements of this WM QA Plan; and

- assurance that activities requiring special procedures, QA plans, peer reviews, work instructions, drawings, controls, equipment, or personnel training are identified, developed, and implemented.

Continued on next page.

Section 1. Management (continued)

Criterion 1: Program (continued)

Plan (continued)

1.3.2 *Independent Verification*

Independent verification methods include audits, surveillances, peer reviews, technical reviews, design reviews, inspections, and independent management assessments. Verification must be performed by persons or organizations not directly responsible for the activity being verified.

1.3.3 *Subcontractor/ Vendor QA Programs*

The Compliance Unit Manager must perform assessments of the quality-affecting activities of external organizations contributing supportive work to the department. Subcontractors, vendors, or other LBL organizations interfacing with WM on quality-affecting activities must develop and implement applicable QA programs approved by WM prior to use or must comply with the provisions of the WM QA Plan and implementing procedures.

Section 1. Management (continued)

Criterion 2: Personnel Training and Qualification

General

The EH&S Division is responsible for HW training. This requirement is satisfied through training, seminars, and other educational opportunities available through outside organizations or in-house activities. WM personnel or supervisors attend these continuing training activities whenever personnel request such training, if resources and time allow. When supervisors identify the training need, the training must be provided within a reasonable time (months) and prior to the performance of any functions or operations that depend on, or are related to, that training. Training and qualification activities that WM must perform are outlined in the plan below. This Criterion implements portions of Criteria 2, 9, 10, and 18 from ASME NQA-1-1989, Criterion 2 to DOE Order 5700.6C, and applicable portions of the OAP.

Plan

2.1 Orientation and Training of WM Personnel

Personnel involved in quality-affecting activities must receive sufficient orientation and training to assure proper understanding of these requirements prior to initiation of those activities. Specialized orientation and training measures must be provided to assure that personnel, including quality-verification personnel, achieve and maintain suitable proficiency in the activities they perform. The Environment Department Head must assure that training needs are identified and that training assignments are made.

Completion of training activities must be documented. The Compliance Unit Manager must verify on a sampling basis that appropriate training is provided, as assigned. Training may be provided in the form of required reading, formal classroom sessions, or other methods. The Environment Department Head must assure that assigned staff receive complete training commensurate with the scope and complexity of their assigned tasks.

Continued on next page.

Section 1. Management (continued)

Criterion 2: Personnel Training and Qualification (continued)

Plan (continued)

2.2 Qualification of WM Personnel

The EH&S Division Director must assure that an appropriate personnel qualification system is developed. The Environment Department Head is responsible for assuring that personnel performing activities affecting quality are properly qualified as identified in job descriptions. The Environment Department Head must assure that documentation is available that indicates the verification of education and experience required for these positions.

2.3 Orentation and Training of HW Generators

LBL staff who generate waste must be trained sufficiently to ensure the quality of initial waste accumulation and characterization. Special training must be provided for staff overseeing accumulation of waste in excess of 100 kg/month (WAAs), for staff generating waste in radioactive materials management areas (RMMAs), and for staff generating acutely hazardous waste.

Proficiency of this training must be verified initially and annually thereafter by examination and compliance with assessments and audits (see Section 3, *Assessment*). Refresher training must be provided to maintain uniformly high proficiency in generator waste management.

Completion of training and refresher training must be documented. Training may be in the form of classroom presentations, required reading, interactive video presentations, a combination of these, or other methods, such as on-the-job training. To assure that generators meet the training requirements to characterize waste sufficiently for offsite disposal, waste will not be accepted from generators who lack documented proficiency of waste generator training.

2.4 Proficiency Evaluation

Supervisors must assure that the job proficiency of personnel performing quality-affecting activities is adequately monitored and documented at least annually.

Continued on next page.

Section 1. Management (continued)

Criterion 2: Personnel Training and Qualification (continued)

Plan (continued)

2.5 Special Process Personnel

Personnel performing or controlling special processes must be qualified. Qualification records for individuals who perform or control special processes must include results of a written proficiency examination, or results of a practical examination in which the process was performed, and evaluated by a qualified examiner. A documented technical evaluation by management may be used in lieu of an examination.

2.6 Inspection Personnel

Inspection personnel who verify conformance of work activities for purposes of acceptance must be qualified to perform the assigned inspection task.

2.7 Personnel Selection and Training for Assessments

Personnel selected for assessments or other evaluators must collectively have training and experience commensurate with the scope and complexity of the activities to be evaluated. Individuals participating in a quality-verification activity must be independent of any direct responsibility for performance of the activities that they will evaluate. Personnel selected for assessments must have training and must be qualified for conducting assessment activities. The EH&S QA Manager or designee must prepare implementing procedures that provide specific requirements and methods for training, qualifying, and certifying assessment personnel. Personnel are trained and qualified per the requirements listed in Section 5.3.2 of the OAP.

Section 1. Management (continued)

Criterion 3: Quality Improvement

General

Management, at all levels in WM, is responsible for quality and fosters a 'no-fault' attitude to encourage the identification of problems. WM management must be the leader in the total-quality-management and quality-improvement process to ensure that proper focus is given, adequate resources are provided, difficult issues are resolved, and that customer-supplier understanding of problem resolution is achieved. WM management encourages staff at all levels to identify and correct problems and to offer solutions to those problems. WM management encourages continuous quality improvement and encourages staff and other managers to exceed the expectations of their customers whenever possible as a quality-improvement goal. This Criterion implements portions of Criterion 15 and 16 of ASME NQA-1-1989, Criterion 3 to DOE Order 5700.6C, and applicable portions of the OAP.

Plan

3.1 Identification of Nonconforming Items

Upon the discovery of a nonconforming condition, the responsible individual must initiate a nonconformance and corrective action report (NCAR). The NCAR must identify the requirements that were not met, the actual nonconforming condition, and any immediate disposition to correct the condition. Implementing procedures must further define the process for reporting, tracking, issuing, dispositioning, evaluating, and closing nonconformance reports.

3.2 Segregation of Nonconforming Items

Nonconforming items must be segregated, when practical, by placing them in a clearly identified and designated hold area until they are properly dispositioned. When segregation is impossible or impractical due to physical conditions, environmental conditions, size, weight, access limitations, or other such reasons, other precautions must be taken to preclude inadvertent use of a nonconforming item. Such measures include tagging, flagging, securing, or posting security measures.

3.3 Determination of Cause

To assure effective corrective action, the root cause of the problem must be identified and documented. Root cause analysis must be performed on recurring significant problems to prevent recurrence. The root cause determination may be input into the LBL Self-Assessment Database (LSAD) for trend analysis.

Continued on next page.

Section 1. Management (continued)

Criterion 3: Quality Improvement (continued)

Plan (continued)

3.4 Approvals of NCAR Dispositions

The Compliance Unit Manager must review and approve all dispositions to nonconformance reports. In situations where the QA Plan or procedures may be affected by the resolution of the NCAR, or where action is required by the EH&S QA Manager, the EH&S QA Manager must also review and concur with this disposition.

3.5 Tracking, Verification, and Closure of NCARs

The Compliance Unit Manager must track the status of all open NCARs until closure. The Compliance Unit Manager must verify implementation of corrective action prior to closure of the NCAR. Upon verification of implementation of corrective actions and the generation of the required records, the Compliance Unit Manager must close the NCAR.

3.6 Responding to NCARs

Personnel who are assigned or required to respond to NCARs and/or to implement corrective actions must do so in accordance with the requirements of the appropriate procedure(s). The planned corrective actions should be commensurate with the type, importance, complexity, and priority of the condition; and with health and safety of the public and LBL personnel.

3.7 Evaluation and Closure of NCARs

The Compliance Unit Manager must evaluate responses to NCARs to verify that all the requirements have been addressed. Upon approval of the proposed corrective action, the Compliance Unit Manager must verify implementation of NCAR corrective action on a sampling basis. Upon satisfactory implementation, the Compliance Unit Manager must close the corrective action report. The status of NCARs must be tracked from the time of origination to closure.

3.8 Trend Analysis

The EH&S QA Manager must input WM QA Plan deficiencies into the LSAD for trend analysis. Trend analysis should include, but not be limited to, NCARs, assessment findings, and root cause analysis.

The ultimate purpose of this trend analysis is to proactively attempt to note trends that require a management response before the trend becomes an actual problem.

3.9 Management Assessments

Criterion 9 describes another proactive program that will allow WM to spot issues before they become problems. The Management Assessment activity is part of the quality-improvement process.

Section 1. Management (continued)

Criterion 4: Documents and Records

General

WM complies with the LBL policy regarding records management. This policy includes provisions for retention, protection, preservation, traceability, and retrievability per DOE Order 1324.2A. WM's implementation of this policy is outlined below. This Criterion implements portions of Criteria 6 and 17 of ASME NQA-1-1989, Criterion 4 to DOE Order 5700.6C, and applicable portions of the OAP.

Plan

4.1 Document Preparation, Review, Approval, and Use

Documents that specify QA requirements or prescribe quality-affecting activities must be prepared; reviewed for adequacy, completeness, and correctness; and approved and released for issuance and distribution in accordance with written procedures. The preparation and review of procedures, instructions, reports, and other documents must address, as a minimum, the following requirements:

- Identification of WM personnel responsible for the preparation, review, approval, and issuance of the document.
- Review by individuals with responsibility for implementation.
- Review by individuals other than the author of the document.
- Sufficient access by the reviewers to pertinent background data.
- Resolution of review comments.
- Management resolution of unresolved issues.
- Review and approval of changes by the same organization that performed the original review and approval.

Continued on next page.

Section 1. Management (continued)

Criterion 4: Documents and Records (continued)

Plan (continued)

4.2 Document Distribution

Control of documents involves distributing revisions to individuals and assuring that the latest documents are available prior to the commencement of work. Document control procedures must be developed to include the following as a minimum:

- Identifying and marking documents, including documents released prior to completion of the approval process.
- Maintaining controlled-document distribution lists.
- Marking, removing, or destroying obsolete or superseded documents.
- Maintaining an index of revision status for controlled documents.
- Using receipt acknowledgment document transmittal forms, as applicable.

4.3 Records System

The LBL records management system is described in Section 1.17 of the LBL Regulations and Procedures Manual (RPM), which is consistent with the Paperwork Reduction Act of 1980, the Federal Records Act of 1950, as amended, the Freedom of Information Act, and the Privacy Act.

4.4 Generation of Records

Completed documents that support or provide objective evidence of the planning and accomplishment of quality-affecting activities must be designated as records. Records must be uniquely identified.

4.5 Acceptance Criteria

Documents that specify qualitative or quantitative acceptance criteria must identify the required types of records to furnish documentary evidence of the achievement of the specified requirements.

4.6 Record Index

As part of the process of transmitting inactive records to LBL's Archives and Records Office, the originator of the records, in cooperation with the Group Records Liaison Officer and EH&S Records Analyst, will generate a records index that will assure that records are readily retrievable.

Continued on next page.

Section 1. Management (continued)

Criterion 4: Documents and Records (continued)

Plan (continued)

4.7 Retention Status	The EH&S Records Analyst, in cooperation with the Environment Department Head or designee, will assign a retention period to Waste Management records consistent with the appropriate DOE Order, Federal regulation, and administrative and legal needs of Waste Management. Retention periods for these records are identified in the relevant Records Inventory form and will be identified in the EH&S Division Records Management Plan and disposition schedule.
4.8 Record Revisions or Corrections	Revisions of documents identified as records (see Section 4.4 above) are considered to be records and should be authenticated, retained, and retired according to the same procedures and schedules as pertain to the original documents.
4.9 Records Receipt	Inactive records are transferred to the Archives and Records Office by means of a Records Transmittal form, a copy of which is returned to the person transferring the records as their receipt of records transfer.
4.10 Records Storage, Preservation, and Safekeeping	Inactive records retired to the Archives and Records Office are stored at the Federal Records Center under conditions that protect them from loss or damage. The records inventories must identify vital records, and the EH&S Records Management Plan will address measures required to protect vital records. Access to retired records by appropriate personnel is managed by the Archives and Records Office.
4.11 Records Disposition	File cutoffs, frequency of transfer of inactive records to the Archives and Records Office, and records disposition (records destruction or permanent storage), are identified in the Records Inventory form and will be identified in the EH&S Division Records Management Plan and disposition schedule.

Section 2. Performance

Criterion 5: Work Processes

General

WM projects involving the generation, acquisition, and use of compliance data (e.g., waste analyses) must be planned and documented. The type and quality of compliance data needed for their intended use must be defined and documented. Determination of the type and quality of compliance data needed must involve key users of the data as well as those responsible for activities affecting data quality. Planning activities must be documented to assure that participants in the compliance data operations are informed and understand the requirements.

For convenience, the calibration objective from DOE Order 5700.6C in Criterion 7, "Equipment used for inspections and tests must be calibrated and maintained," is implemented in this Criterion. Additionally, this Criterion implements the requirements for computer software controls in ANSI/ASQC E-4 (Draft), Part A, as well as the Part B Planning and Scoping requirements, which deal with characterization of compliance processes and conditions.

Computer programs used in compliance data operations and engineered compliance systems must be developed using an approved software development methodology. Such programs must be independently validated, verified, and documented according to the intended use of the software. Changes must be controlled to assess the potential impact of the change on the performance of the software. Computer programs subject to these controls include design, design analysis, modeling of compliance processes and conditions, operations or process control, and data bases (when used as the controlled source of quality information).

This Criterion implements portions of Criteria 5, 8, 9, 12, and 13 of ASME NQA-1-1989, Criterion 5 to DOE Order 5700.6C, and applicable portions of the OAP.

Continued on next page.

Section 2. Performance (continued)

Criterion 5: Work Processes (continued)

Plan

5.1 Preparation of Procedures and Instructions

Procedures or instructions must be prepared for each quality-affecting activity to the level of detail necessary to assure that the activity can be performed as required. Procedures and instructions must include or refer to appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been completed as specified. Procedures and instructions must be uniquely identifiable, retrievable, and reproducible.

5.2 Procedure Format

Procedures and instructions must be formatted to include the following sections as appropriate and as specified in a Procedure Development procedure:

- Approval signatures and effective date.
- Unique identifier, including revision.
- Purpose: A short statement of why the procedure or instruction was written and what it contains.
- Applicability or Scope: A concise description of the requirements and to which organization they apply.
- References: Identification of the source of requirements.
- Responsibilities: Description of specific positions/organizations identified within the procedure.
- Definitions: Descriptions of unique acronyms or unique terms that are not included in the overall QA program glossary (Appendix A). Definitions can be based on reference to standards, codes, regulations, DOE Orders, LBL practices, etc.
- Procedure: Description of the actions necessary to accomplish the objectives identified in the purpose statement.
- Records: Identification of records produced or retained by compliance with the procedure.

5.3 Procedure Review

Procedures and instructions must be reviewed for applicable technical and administrative details. These reviews must be performed, at a minimum, by the Waste Management Group Leader or designee, the EH&S QA Manager, and the Complance Unit Manager to evaluate the adequacy of the requirements and responsibilities for implementing the procedure or instruction.

Continued on next page.

Section 2. Performance (continued)

Criterion 5: Work Processes (continued)

Plan (continued)

5.4 Procedure Approval	WM procedures, instructions, and subsequent revisions or cancellations must be approved by the Waste Management Group Leader prior to use. At a minimum, approval signatures must be affixed to the procedure or instruction.
5.5 Procedure Control and Issue	Approved procedures and instructions must be issued through the document control process identified in Criterion 4 of this QA Plan.
5.6 Procedure Revisions	Revisions to procedures and instructions must be controlled by the same process used to review and approve the original procedures or instructions.
5.7 Waste Container Control	Waste containers and appropriate appurtenances that have been specifically designed to WM requirements and that require traceability will be assigned a unique identifier through the use of identification numbers, color coding, bar coding, or other means. Procurement documents must require that the unique identifier be applied to the item or container, and supplied with support documentation. Identification must be maintained on or near the item and in documents traceable to the item, for the life of the item.
5.8 Physical Identification of Items	Physical identification of items must be used to the maximum extent possible. Identifying markings must be permanent and legible and must not adversely affect the function, service, or archival life of the item. When identification directly on the item is impractical, physical segregation, record traceability, or other tracking methods must be described in implementing procedures. Physical identification is required on waste containers, waste storage areas and buildings, operating components, and emergency equipment. Each part or piece of an item, when removed from the sample lot, must have a unique identifier affixed.

Continued on next page.

Section 2. Performance (continued)

Criterion 5: Work Processes (continued)

Plan (continued)

5.9 Control of Items with Finite Shelf Life

Items with finite shelf life must be controlled and physically identified to assure that they are provided the maximum protection. Procedures must identify the methods for disposal of items with expired shelf lives.

5.10 Storage

Storage areas must be protected, must provide for access control, and must maintain appropriate environmental storage conditions, (e.g., temperature, humidity, light, etc.).

5.11 Distribution

When items with specific traceability requirements are distributed outside of the Environment Department, a distribution record must be completed to assure that chain-of-custody requirements are met. The transfer of the item must be documented.

5.12 Special Process Procedures

Special process procedures such as those used for chemical sampling must be written and qualified in accordance with requirements of applicable codes or standards. These procedures should address the following:

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

5.13 Selection of Measuring and Test Equipment (M&TE)

M&TE selection and procurement processes must assure that such items are of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements.

Continued on next page.

Section 2. Performance (continued)

Criterion 5: Work Processes (continued)

Plan (continued)

5.14 Identification of M&TE

M&TE must be identified through controlled inventory and by physically marking of the equipment with a unique identification number, status tag, color code, or calibration sticker. The identifier must be recorded on the data sheet, log book, etc., along with the data taken when using that item.

A controlled M&TE inventory must be maintained. The inventory must include

- a brief description of the item
- unique identifier on the item
- calibration recall frequency
- date of last calibration
- next calibration recall date
- date of each inventory/log entry and the name of the individual recording the entry

5.15 Calibration of M&TE

M&TE must be calibrated, adjusted, and maintained at prescribed intervals, or immediately before and after use. M&TE must be certified against equipment having known valid relationships to nationally recognized standards such as the National Institute for Standards and Technology (formerly known as National Bureau of Standards). If no nationally recognized standards exist, the basis for calibration (e.g., items' required accuracy, intended use, and frequency of use) must be documented.

5.16 Nonconformance Control with Respect to M&TE

Prior to use of M&TE, WM personnel must verify that the calibration recall date has not expired. If it is past the date of recall, the item must be tagged, and segregated if possible, and a Nonconformance and Corrective Action Report must be prepared in accordance with Criterion 3 of this QA Plan.

If, upon any recalibration, M&TE is found to be out of tolerance, it must be immediately removed from service, tagged, and segregated if possible. An evaluation to determine the effect and significance of the use of suspect data must be performed and documented. If the evaluation discloses an adverse effect on items, work, or data previously accepted, appropriate corrective action must be taken.

Continued on next page.

Section 2. Performance (continued)

Criterion 5: Work Processes (continued)

Plan (continued)

5.17 Handling and Storage of M&TE

The Environment Department Head or designee must assure that proper protection, storage, handling, and environmental conditions are maintained for M&TE. The effects of the environment or other factors on an item must be considered when calibration specifications are established. If appropriate, limitations on the handling, use, and storage of items must be defined in the applicable calibration procedures, in the test procedures, and in the specific M&TE procedures.

5.18 Shipping Procedures

Shipping of waste must be conducted in accordance with established instructions or procedures specified for use in conducting the activity.

All items (e.g., hazardous waste) to be shipped must be processed by appropriately assigned WM personnel. The cognizant individual must assure that 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 should accurately reflect tag and serial numbers for tagged items. Traceability must be maintained at all times for the items to be shipped, from the point of origination to the final receipt of the item or material. Requirements for offsite transportation must be in accordance with local, state, and Federal regulations.

5.19 Special Handling Equipment

When required for particular items, special equipment (such as containers, forklifts, shock absorbers, and accelerometers), special protective environments (such as inert gas atmosphere), and specific moisture content levels and temperature levels must be provided, and the special conditions must be verified by independent inspection or by peer inspection.

5.20 Storage of Waste

Limited-access areas must be designated for storage of waste items. These areas must be controlled by WM personnel.

5.21 Packaging of Items

Packaging requirements must be specified for protection against corrosion, contamination, physical damage, or any effect that would negatively impact the item or cause deterioration during the time it is handled, stored, or shipped.

Continued on next page.

Section 2. Performance (continued)

Criterion 5: Work Processes (continued)

Plan (continued)

5.22 Software Control

Development and usage of software used for quality-affecting activities by WM conforms to the requirements of Section 3.11 (*Computer Software Control*) of the OAP.

5.23 Procedures and Other Documentation for Characterization of Waste Processes and Conditions

Procedures and other documentation that include requirements for characterization of waste processes and conditions must include the following:

- Definition of program/task scope and objectives and listings of the primary requirements and activities involved in the work. When appropriate, this includes the definition of the precise problem and the associated action to be taken.
- Identification of the specific environmental waste data to be collected and analyzed, including those data that measure the success or failure of the project.
- Identification of the applicable technical, regulatory, or program-specific quality standards, criteria, or objectives such as acceptable sampling and measurement uncertainty, and identification of procedures for quality verification.
- Identification of personnel, equipment (including field and laboratory testing equipment, along with performance and calibration requirements), and other resources required to perform activities needed.
- Identification of controlled conditions required for the collection and analysis of environmental waste samples and data.
- Determination of assessment tools needed (e.g., program technical reviews, peer reviews, surveillances, and technical audits as needed and/or specified by the QA program).
- Identification of methods or procedures for field and laboratory sampling, testing, and analysis activities, as well as the appropriate mechanism for making changes to sampling and analysis plans produced.
- Definition of records required.

Continued on next page.

Section 2. Performance (continued)

Criterion 5: Work Processes (continued)

Plan (continued)

5.24 Sample Identification and Control

Samples must be identified and controlled in a manner consistent with their intended use, that is in compliance with EPA guidelines, and that provides traceability to related documentation.

The Department personnel collecting the sample must assign a unique identifier that must be maintained throughout its existence. The identifier must trace samples to the source(s) and related documentation (e.g, date, conditions prevailing at the time of sampling, method of sample collection, chain of custody, etc.)

The identification must be placed directly on the sample or container and on records traceable to the sample. If it is impractical to place all the identification on the sample, the implementing procedures must include requirements to assure that samples are not interchanged.

Methods for collecting, handling, transporting, and storing samples must be described in implementing procedures. The procedures must identify the required protocols to assure the technical validity, safety, and environmental conditions to avoid degradation. Requirements for offsite transportation are to be in accordance with local, state, and Federal regulations. Special handling requirements and traceability between organizations must also be described in implementing procedures.

Section 2. Performance (continued)

Criterion 6: Design

General

WM performs no hardware design work in a quality-affecting sense. Designs or design modifications that are done for WM consist of standardized products that are adapted for use by WM. The design process, therefore, is limited to those activities that verify the acceptability of the adaptation. This Criterion implements Criterion 3 of ASME NQA-1, Criterion 6 of DOE Order 5700.6C, and applicable portions of the OAP.

Plan

No design work is performed under the Environment Department's auspices.

Section 2. Performance (continued)

Criterion 7: Procurement

General

WM is not primarily responsible for procurement or source selection activities. The LBL Procurement Department is primarily responsible for these activities. However, WM's portion of the procurement process specific to meet WM's needs is outlined in the plan description provided below. This Criterion satisfies portions of Criteria 4 and 7 of ASME NQA-1, Criterion 7 to DOE Order 5700.6C, and applicable portions of the OAP.

Plan

7.1 Procurement Planning

Procurement activities must be planned and documented to assure that a systematic approach to the procurement process is accomplished. Planning must be accomplished as early as practical.

Planning must result in the documented identification of methods in procurement activities, the sequence of actions, and milestones indicating the completion of these activities. Planning must also result in the preparation of applicable procedures prior to the initiation of each individual activity listed below. Planning should provide for integration of these activities, as applicable:

- Procurement requisitioning document preparation, review, and change control.
- Recommendation of procurement sources.
- Purchaser monitoring of vendor technical performance.
- Verification of QA compliance.
- Control of nonconformances.
- Corrective action.
- Acceptance of item or service.
- Quality assurance records.

Continued on next page.

Section 2. Performance (continued)

Criterion 7: Procurement (continued)

Plan (continued)

7.2 Initiation of Procurement Document Packages

The Environment Department Head or designee is responsible for initiating and maintaining a Procurement Document Package containing a copy of all documentation for the procurement. Quality-affecting procurement documents must be controlled to assure that the procurement cycle has been implemented effectively. The procurement cycle begins when the need for an item or service has been identified. The appropriate procurement requirements are developed, and the decision to purchase from a qualified subcontractor or vendor is made.

7.3 Review of Procurement Document Packages

The Environment Department Head or designee is responsible for assuring that a review of procurement documents and changes thereto are made. The review assures that documents transmitted to subcontractors include provisions that services and associated deliverables will meet specified requirements. Reviews must also verify that procurement documents contain applicable regulatory requirements. Furthermore, the review must verify that procurement documents contain provisions for requiring subcontractors to implement appropriate QA programs when, and if, initially requested as part of the technical requirement.

7.4 Approval of Procurement Documents

After appropriate review, the Environment Department Head or designee is responsible for the approval of procurement documents prior to submittal to the LBL Procurement Department.

7.5 Procurement Document Changes

Changes to procurement documents must be subjected to the same review and approval process as required for the preparation of the original document.

7.6 Selection of Contractors/ Vendors

Selection of contractors/vendors must be based on an evaluation of their capability to provide items, services, or other products in accordance with the requirements of procurement documents. Selection is coordinated with the LBL Procurement Department.

Measures for evaluation and selection of procurement sources and the results there from must be documented and must include one or more of the following:

Continued on next page.

Section 2. Performance (continued)

Criterion 7: Procurement (continued)

Plan (continued)

7.6 (continued)

- Evaluation of the contractor or vendor history and capability of providing the service or product required by the purchaser.
- Current contractor/vendor QA records, supported by documented qualitative and quantitative information that can be objectively evaluated.
- Contractor/vendor technical and QA capability, as determined by evaluation of the facilities and implementation of the QA program.

7.7 Verification of Acceptability of Contractor or Vendor Performance

The extent of verification activities must be a function of the relative importance, complexity, and quantity of the item or services procured, and the contractor or vendor QA performance. Verification activities must be accomplished by qualified personnel assigned to monitor these activities through inspection, surveillance, audit, or test. Verification activities should be coordinated with the LBL Procurement Department.

7.8 Acceptance of Items or Services

Methods for acceptance of items or services must be identified in contractual agreements. Methods for accepting products or services must include any or all of the following:

- receipt inspection through technical or peer review
- receipt inspection through physical inspection of the product
- acceptance of certificates of conformance from the supplier
- post-installation testing of item, software, or other product
- surveillance or audit of activity
- technical verification of data produced
- review of objective evidence for conformance to the procurement document requirements such as certifications, reports, etc.

7.9 Control of Contractor or Vendor Nonconformances

WM procedures must identify methods for the disposition of items and services that do not meet contractual documentation requirements as appropriate. Methods must include accept, reject, or repair, based on a technical evaluation of the item or service.

Continued on next page.

Section 2. Performance (continued)

Criterion 7: Procurement (continued)

Plan (continued)

7.10 Procurement Control by Designees

WM Management may delegate Criterion 7 requirements to others at LBL. WM procurements may be delegated to other LBL organizations as long as the requirements stated in Criterion 7 are followed. For example, container-procurement quality assurance activities are provided by the Procurement Department's processes and others. The WM responsibility in this case must be to support the container procurement process actively and perform audits or quality surveillances to be assured that the Criterion 7 requirements are followed. Receipt inspection by WM personnel helps provide this assurance as an ongoing process.

Section 2. Performance (continued)

Criterion 8: Inspection and Acceptance Testing

General

Data from environmental/waste data operations used to characterize environmental/waste processes and conditions must be qualified according to the intended use of the data. This Criterion implements Criteria 10, 11, and 14 of NQA-1. This Criterion also implements ANSI/ASQC E-4 (Draft), Part B-4, regarding characterization of environmental/waste processes and conditions' assessment of data useability. Finally, Criterion 8 of DOE Order 5700.6C and applicable portions of the OAP are implemented herein.

Plan

8.1 Inspection Personnel

Inspection procedures or notebooks must describe the methods and requirements for the qualification of inspection personnel.

8.2 Inspection Planning

Planning for inspection must be accomplished prior to or concurrent with planning the work activities. Planning must consider the following:

- Inspection "Hold Points." If mandatory inspection hold points are required beyond which work must not proceed without the specific consent of WM representatives, these specific hold points must be indicated in appropriate documents.
- Sampling. When a sample is used to verify acceptability of a group of items, the sampling procedure must be based on accepted sampling practices.
- Documentation must include the following:
  - item or process inspected
  - date of inspection
  - name of inspector
  - inspection techniques
  - acceptance criteria
  - hold points
  - results or acceptability
  - nonconformances and dispositions of nonconformances

Continued on next page.

Section 2. Performance (continued)

Criterion 8: Inspection and Acceptance Testing (continued)

Plan (continued)

8.3 Inspection Process

The inspection process involves real-time examination and/or observation of activities and items to acceptance criteria defined in specifications, drawings, checklists, etc. A combination of inspection and process monitoring methods, when used, must be performed in a systematic manner to assure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process. Controls, where required, must be established and documented for the coordination and sequencing of these activities at established inspection points during successive stages of the conducted process or construction. When final inspections are performed, they must include a review of the results and resolution of nonconformances identified in prior inspections. The acceptance of items must be documented and approved by authorized personnel.

8.4 Test Plans

Testing activities must be planned by WM personnel prior to starting the test. Test plans must establish characteristics to be verified. Test plans must include or refer to test objectives and must make provisions for assuring that proper instrumentation is available and is used, necessary monitoring is performed, and suitable environmental conditions are maintained to avoid degradation of the test. Test plans must also address

- instrument calibration
- qualification and certification requirements of test personnel
- type of testing and measuring equipment required and calibration requirements
- testing parameters and acceptance criteria
- environmental conditions

8.5 Performance of Test Activities

WM personnel must conduct test activities in accordance with the requirements identified in test plans and procedures. Personnel must assure that proper environmental conditions are maintained in the requisite activities and any deviations or nonconformances that may occur during these tests must be documented and dispositioned in accordance with the requirements identified in Criterion 3 of this QA Plan.

Continued on next page.

Section 2. Performance (continued)

Criterion 8: Inspection and Acceptance Testing (continued)

Plan (continued)

8.6 Test Documentation

Test results must be documented and evaluated by responsible and qualified personnel to assure that test requirements have been met. Personnel are not to test their own work for acceptance. Test records must contain, at a minimum,

- 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
- names of personnel evaluating results

8.7 Status Identification

The status of inspection and test activities must be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated. Physical status indicators (e.g., markings, tags, and other identification) and status documentation must address

- the operating status of the system or component
- activities that require the use of these indicators
- proper unique identification to provide for traceability
- out-of-service conditions

The use of these indicators must not adversely affect the characteristics or function of the item.

8.8 Removal of Status Indicators

The removal of status indicators must be strictly controlled to assure that they are removed only by authorized personnel.

Continued on next page.

Section 2. Performance (continued)

Criterion 8: Inspection and Acceptance Testing (continued)

Plan (continued)

8.9 Experimental Activities

The use of physical status indicators is necessary to assure that operational, support, and experimental activities important to health, safety, and security are properly controlled. The following items and systems must be identified with a physical status indicator when they do not conform to specified requirements or when out-of-normal conditions exist:

- facility or experimental systems
- security systems
- emergency systems
- environmental or biological samples taken from geological sources

8.10 Characterization of Environmental/ Waste Processes and Conditions; Assessment of Data Useability

Any limitations on data use must be identified quantitatively and fully documented in procedures. Reports containing data or reporting the results of environmental/waste data operations must be reviewed independently to confirm that the data or results are presented correctly. Such reports must be approved by the Environment Department Head for release, publication, or distribution.

Section 3. Assessment

Criterion 9: Management Assessment

General

This Criterion is intended to augment the assessments performed by external or independent organizations and should provide a mechanism for management to determine the effectiveness of the management control systems and to determine the adequacy of resources and personnel. Management may not delegate this responsibility. This Criterion implements a portion of Criterion 2 from ASME NQA-1-1989, Criterion 9 to DOE Order 5700.6C, and applicable portions of the OAP.

Implementation of a WM management assessment plan is an integral part of LBL's overall self-assessment program. The LBL self-assessment program has three primary QA oversight levels: internal assessment (including management assessments), professional functional assessments (e.g., Safety, Industrial Hygiene, Environmental Protection), and independent audits by the Office of Assessment and Assurance, which is an independent office reporting directly to the Associate Laboratory Director for Operations.

Plan

9.1 Management Assessments

The adequacy and effectiveness of the QA program must be determined by conducting proceduralized management assessments on a periodic basis (at least each eighteen months). The management assessment must consider the following:

- Identity of management problems that hinder the organization from achieving its objectives in accordance with quality, safety, and environmental requirements.
- Effectiveness of controls that achieve and assure quality.
- Adequacy of resources and personnel with respect to providing a quality program.
- Effectiveness of personnel training.

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Section 3. Assessment (continued)

Criterion 9: Management Assessment (continued)

Plan (continued)

9.1 (continued) The most common methods of performing management assessments are

- review of management reports (status reports, technical reports, etc.)
- review of quality-verification reports (independent assessment reports, inspection reports, test reports, etc.)
- review of corrective-action reports, including trend-analysis reports, on a regular basis
- performance of interviews and independent assessments of compliance

9.2 Performance The Environment Department Head and other senior Environment Department managers must retain overall responsibility for management assessments. Direct participation by all levels of Environment Department managers is essential.

9.3 Documentation Management assessment results must be documented per procedure. Senior management must take prompt action and document resulting decisions in response to recommendations resulting from the process.

9.4 Follow-up Follow-up must occur by the Department Head and the EH&S QA Manager and must include an evaluation of the effectiveness of management's actions.

Section 3. Assessment (continued)

Criterion 10: Independent Assessment

General

The focus of independent assessments is on improving items and processes by emphasizing the line organization's achievement of quality. Assessment results should be tracked and resolved by management having responsibility in the area assessed. This Criterion replaces Criterion 18 of ASME NQA-1-1989, and implements Criterion 10 to DOE Order 5700.6C, along with applicable portions of the OAP.

Plan

10.1 Scheduling

The EH&S QA Manager is responsible for developing schedules for comprehensive assessment activities. These activities must be scheduled in a manner to provide coverage and coordination with ongoing WM QA Plan activities. The Environment Department Head or designee must review the schedule and provide input to assure that assessment activities are timely and are conducted at proper intervals commensurate with the importance and complexity of the activities.

10.2 Preparing for Assessment Activities

The EH&S QA Manager must assure that personnel performing assessment activities have made the necessary preparation for the activity. Preparation activities must be in accordance with appropriate procedure(s).

10.3 Performing Assessment Activities

Assessments must be performed in accordance with written procedures or checklists whenever possible. Evaluations of activities or tasks must be performed against specific requirements, criteria, and objectives. Objective evidence must be reviewed to the maximum extent possible, to assure that results reflect the goals of planned activities.

10.4 Corrective Actions

Conditions requiring corrective action must be identified and actions taken to correct the immediate situation as well as similar conditions, and actions to prevent recurrence must be specified and initiated as soon as practical. Conditions requiring prompt corrective action must be reported immediately to the EH&S QA Manager, Compliance Unit Manager, Environment Department Head, or EH&S Division Director, as appropriate. (See also Criterion 3 requirements.) LSAD deficiencies or NCARs may be used to document this requirement.

Continued on next page.

Section 3. Assessment (continued)

Criterion 10: Independent Assessment (continued)

Plan (continued)

10.5 Reporting

Assessment reports must be written in a format that provides the most information to the target audience and in accordance with the appropriate procedure.

Reports must detail the necessary action to correct the deficiency, root cause identification, actions to prevent recurrence, lessons learned, and actions to be taken for improvement, as appropriate. LSAD deficiencies or NCARs may satisfy this requirement.

10.6 Responses

Management of the organizations that receive assessment reports must investigate adverse findings; schedule corrective actions, including measures to prevent recurrence; identify the probable root cause of the problem; and notify the EH&S QA Manager in writing of the planned action or the action taken to correct the problem. Personnel involved in the assessment activity must evaluate the response(s) for adequacy.

10.7 Follow-up and Closure

The EH&S QA Manager must follow up on corrective action responses to assure that responses are received on a timely basis and that committed corrective actions are completed according to the planned completion milestones. The EH&S QA Manager must verify implementation of corrective action prior to closure of the findings, problems, or reports.

Appendix A

Definitions

Activities Affecting Quality: See Quality-Affecting Activities.

Activity: Any time-consuming effort (operation, task, function, or service) that influences or affects the achievement or verification of the objectives of the Environment Department.

Approval: An act of endorsing or adding positive authorization as shown by signature/initial and date.

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 Operations and Assessment Program have been developed and documented in accordance with specified plans, 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, procedures, or items in accordance with specified requirements.

Compliance: Conformance to a code, specification, or 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/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.

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 nonconforming condition and to restore acceptable conditions.

Document: Any written, pictorial, or electronically stored information describing, defining, specifying, reporting, or certifying activities, requirements, plans, procedures, or results. Some documents are records (see the definition of "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, procedures, or results.

Error: A discrepancy between a computed, observed, or measured value or condition and the true, specified, or theoretically correct value or condition.

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.

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.

Inspection: An examination or measurement to verify conformance to specific requirements.

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.

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 procedures.

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.

Overview: An analysis and assessment by management of the scope, status, adequacy, and effectiveness of quality achievement and assurance activities. Overview encompasses effectiveness assessments, technical reviews, readiness reviews, audits, and surveillances, as appropriate.

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 that the work is impartially reviewed. A peer review is an in-depth critique of assumptions, calculations, 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.

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.

Quality-Affecting Activities: Activities of a Laboratory organizational unit that are critical to achieving the mission and objectives of that unit; and functions, processes, and procedures that (a) are essential to maintaining the financial and operational integrity of the University and the Laboratory, (b) are necessary to ensure the validity of data or information that could affect the Laboratory's reputation, (c) could result in an unacceptable risk to the environment or to the health or safety of the public or staff, and/or (d) could seriously impact 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 an overall QA Program that are applicable to a particular activity or project, and that provide an index or a description of the procedures that implement these and any necessary supplementary requirements. The Plan also includes specific responsibilities and authorities for the implementation of the activity/project.

Quality Assurance Record: A completed document that furnishes evidence of the quality of items and/or quality-affecting activities.

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 for meeting or exceeding its assigned performance objectives. Examples of quality improvement include peer reviews, design reviews, trend analyses, or converting manual systems to machine-readable systems to enhance performance or effectiveness.

Quality Control: Those actions that provide a means of control and measure of the characteristics of an item, process, or facility to established requirements.

Quality Surveillance: The act of monitoring or observing to verify whether or not an item or activity conforms to specified requirements or common sense.

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.

Review: A documented examination or evaluation of a QA program element.

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

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 to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating 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.

WM QAIMP: The document that describes the WM QA Program, the applicable QA requirements, and the responsibility for the implementation of the Program and compliance with the 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.

Appendix B

Acronyms and Other Initialisms

ALD:	Associate Laboratory Director
ANSI:	American National Standards Institute
ASME:	American Society of Mechanical Engineers
ASQC:	American Society of Quality Control Professionals
Cal/EPA:	The State of California's Environmental Protection Agency
CO:	Conduct of Operations
DOE:	The U.S. Department of Energy
DOT:	The U.S. Department of Transportation
EH&S:	The Environment, Health and Safety Division at LBL
EPA:	The U.S. Environmental Protection Agency
ES&H:	Environment, safety, and health
HWHF:	The Hazardous Waste Handling Facility at LBL
LBL:	Lawrence Berkeley Laboratory
LLW:	Low-level radioactive waste
LSAD:	Laboratory Self-Assessment Database
M&TE:	Measuring and test equipment
NCAR:	Nonconformance and Corrective Action Report
NQA:	Nuclear Quality Assurance
OAA:	The Office of Assessment and Assurance at LBL
OAP:	The *LBL Operating and Assurance Program Plan*, LBL PUB-3111, February 1993
QA:	Quality Assurance
QAM:	Quality Assurance Manual
RCRA:	Resource Conservation and Recovery Act (U.S.)
RMMA:	Radioactive Material Management Area (at LBL)
RPM:	LBL's *Regulations and Procedures Manual*, PUB-201
TBA:	To be announced
WAA:	Waste Accumulation Area (at LBL)
WIPP:	Waste Isolation Pilot Project
WM:	The Waste Management Group of LBL's EH&S Division

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