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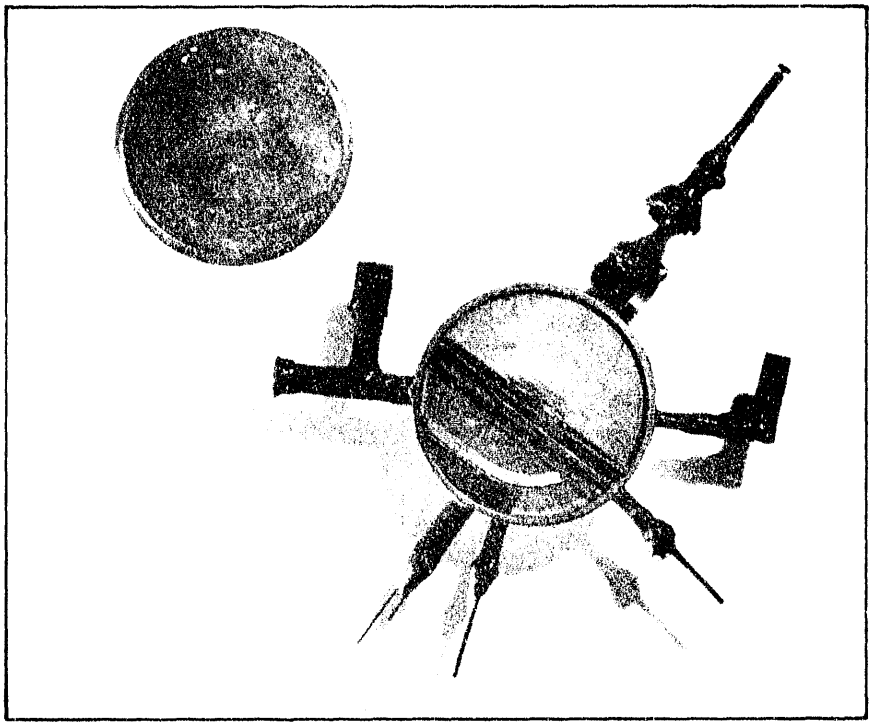
Lawrence Berkeley Laboratory
UNIVERSITY OF CALIFORNIA

ENVIRONMENT, HEALTH AND SAFETY DIVISION

Waste Management Quality Assurance Implementing Management Plan (QAIMP)

June 1992



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LAWRENCE BERKELEY LABORATORY

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WASTE MANAGEMENT QUALITY ASSURANCE IMPLEMENTING MANAGEMENT PLAN (QAIMP)

REVISION 1

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David McGraw, EH&S Division Director — Date

Concurrence: [redacted] 6-15-92

K.H. Berkner, Associate Laboratory Director for Operations — Date

Waste Management Quality Assurance Implementing Management Plan	6/92	Rev. 1

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The University of California Lawrence Berkeley Laboratory (LBL) Environmental Restoration and Waste Management (ERWM) Department, and the Waste Management (WM) Section of ERWM, endorse the application of Quality Management and recognizes 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 Implementing Management Plan (QAIMP) is to identify and implement elements of the LBL Institutional Quality Assurance Program Plan (IQAP), EH&S Quality Assurance (QA) tenets, 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 Quality Assurance Specialist and the LBL Quality Assurance Staff.

Full authority and organizational freedom are provided to the QA Specialist 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 QAIMP establishes and presents the framework of requirements that must be met in planning, performing, documenting, and verifying WM quality-affecting activities.

[redacted]

Kam Tung
ERWM Department Manager

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 QAIMP is an integral part of the management system that provides controls necessary to ensure that the department's activities are planned, performed, documented, and verified.

This WM QAIMP defines the requirements of the WM QA Program. These requirements are derived from the Quality Assurance DOE Order 5700.6C, the LBL IQAP, 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 QAIMP 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)
- HWHF Quality Assurance Plan
- IQAPP (Institutional Quality Assurance Program Plan) (Draft 5-17-90)

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

GENERAL:

The Environment Department has developed this document, the WM Quality Assurance Implementing Management Plan (WM QAIMP), which is the written Quality Assurance Program (QAP) description required by the IQAP. 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, DOE Order 5700.6C, Criterion 1, and applicable portions of the IQAP.

PLAN:

1.1 Environment, Health and Safety Division (EH&S)

WM must comply with applicable EH&S QA tenets. 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 QA 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 hazardous 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 QAIMP are listed in Sections 1.2.3 through 1.2.7.

In addition to the responsibilities and QA System functions for Environment Department personnel shown in Sections 1.2.3 through 1.2.7, the Laboratory Associate Director for Operations and the EH&S Division Director have the responsibilities under the same context, as depicted in Sections 1.2.1 and 1.2.2, respectively (see Figure 1-4).

1.2.1 The Associate Laboratory Director for Operations is responsible for the functions listed below. The ALD for Operations may delegate oversight for specific aspects of these functions to the EH&S Division Director, but retains overall management responsibility for these functions.

- Providing hazardous waste management services and facilities at LBL.
- Directing the LBL Quality Assurance Program for hazardous waste processing, packaging, and transportation activities.
- Providing resources, as necessary, for WM operations through the EH&S Division Director.

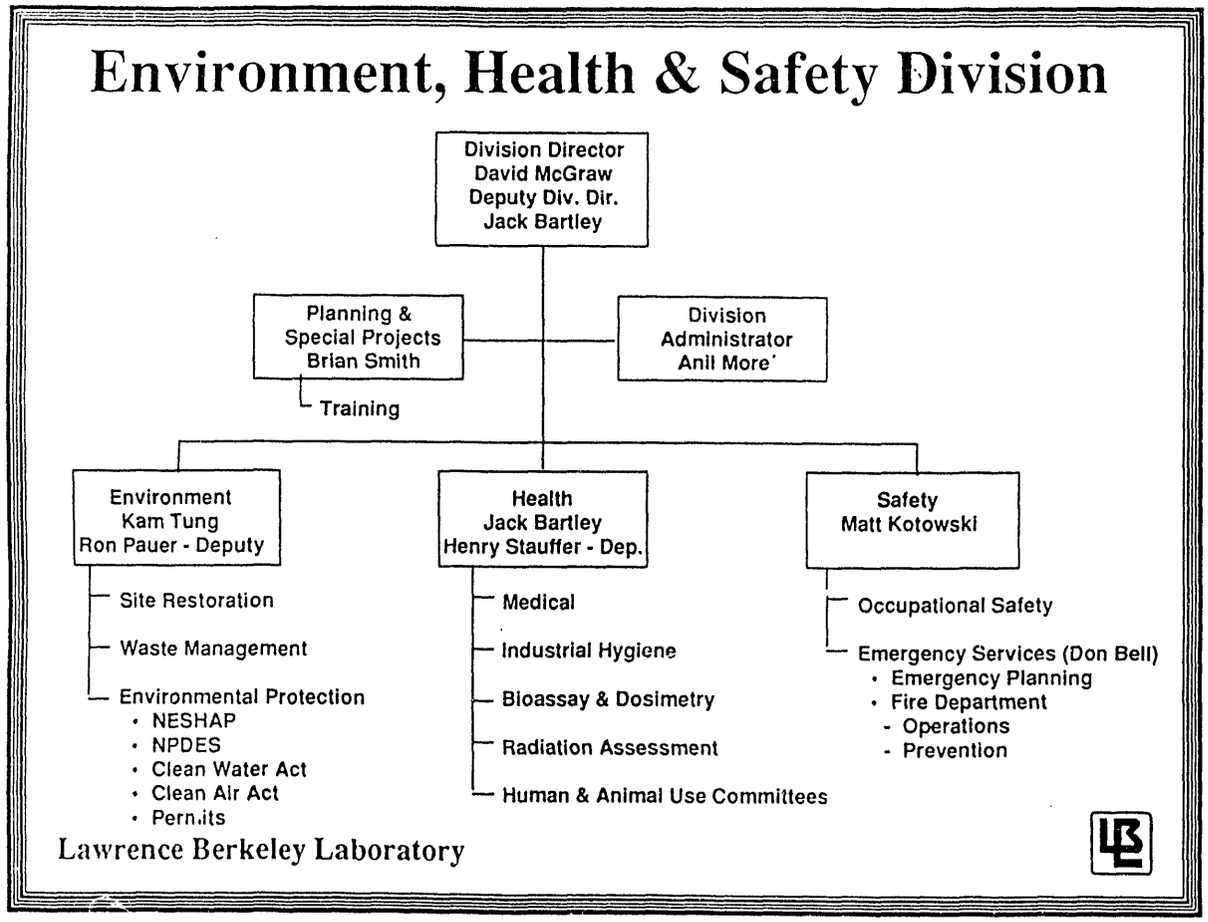
Environment, Health & Safety Division
Division Director
David McGraw
Deputy Div. Dir.
Jack Bartley
Planning &
Special Projects
Brian Smith
Training
Division
Administrator
Anil More'
Environment
Kam Tung
Ron Pauer - Deputy
Site Restoration
Waste Management
Environmental Protection
• NESHAP
• NPDES
• Clean Water Act
• Clean Air Act
• Permits
Health
Jack Bartley
Henry Stauffer - Dep.
Medical
Industrial Hygiene
Bioassay & Dosimetry
Radiation Assessment
Human & Animal Use Committees
Safety
Matt Kotowski
Occupational Safety
Emergency Services (Don Bell)
• Emergency Planning
• Fire Department
- Operations
- Prevention
Lawrence Berkeley Laboratory

Figure 1-1

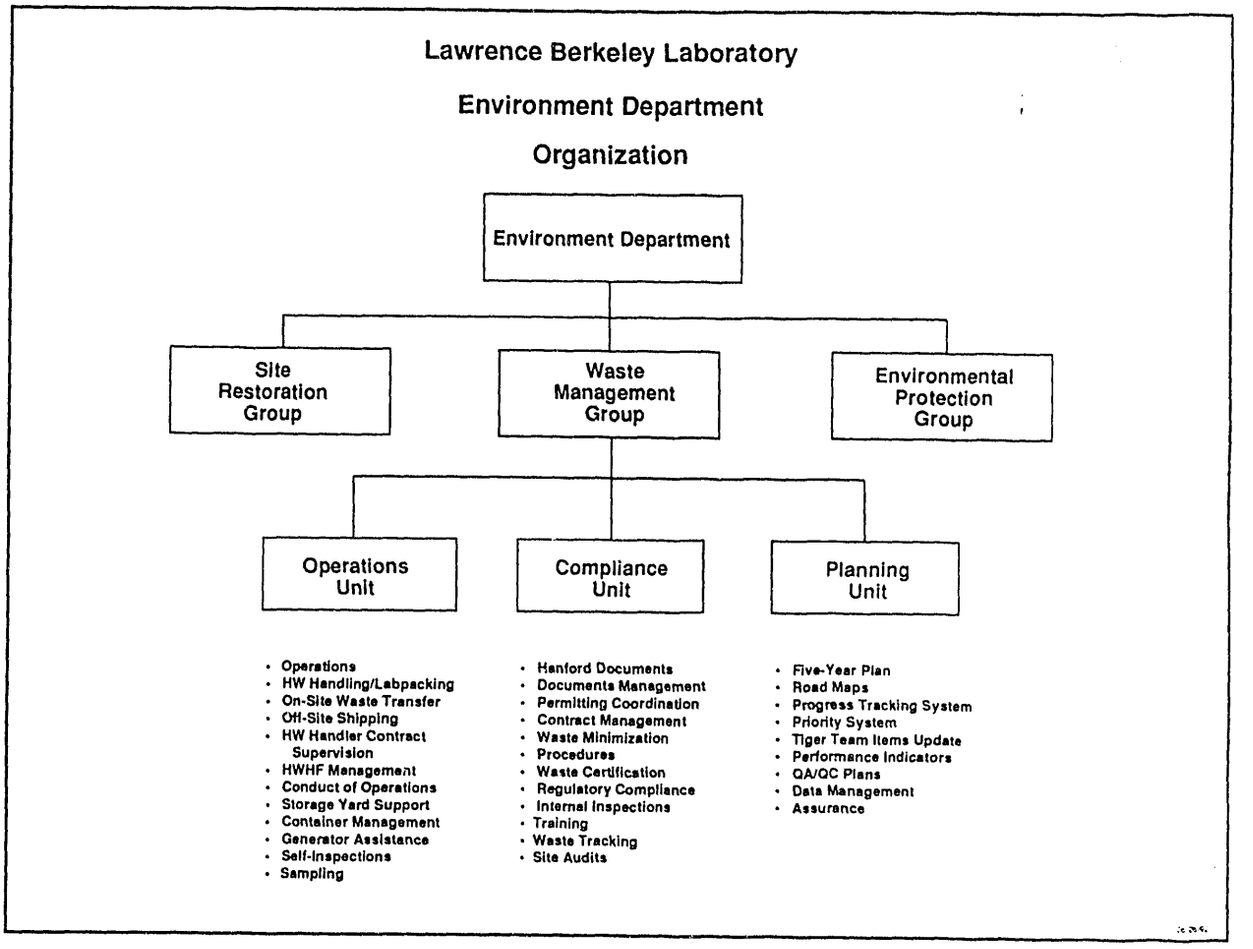
Lawrence Berkeley Laboratory
Environment Department
Organization
Environment Department
Site Restoration Group
Waste Management Group
Environmental Protection Group
Operations Unit
Compliance Unit
Planning Unit
• Operations
• HW Handling/Labpacking
• On-Site Waste Transfer
• Off-Site Shipping
• HW Handler Contract Supervision
• HWHF Management
• Conduct of Operations
• Storage Yard Support
• Container Management
• Generator Assistance
• Self-Inspections
• Sampling
• Hanford Documents
• Documents Management
• Permitting Coordination
• Contract Management
• Waste Minimization
• Procedures
• Waste Certification
• Regulatory Compliance
• Internal Inspections
• Training
• Waste Tracking
• Site Audits
• Five-Year Plan
• Road Maps
• Progress Tracking System
• Priority System
• Tiger Team Items Update
• Performance Indicators
• QA/QC Plans
• Data Management
• Assurance

Figure 1-2

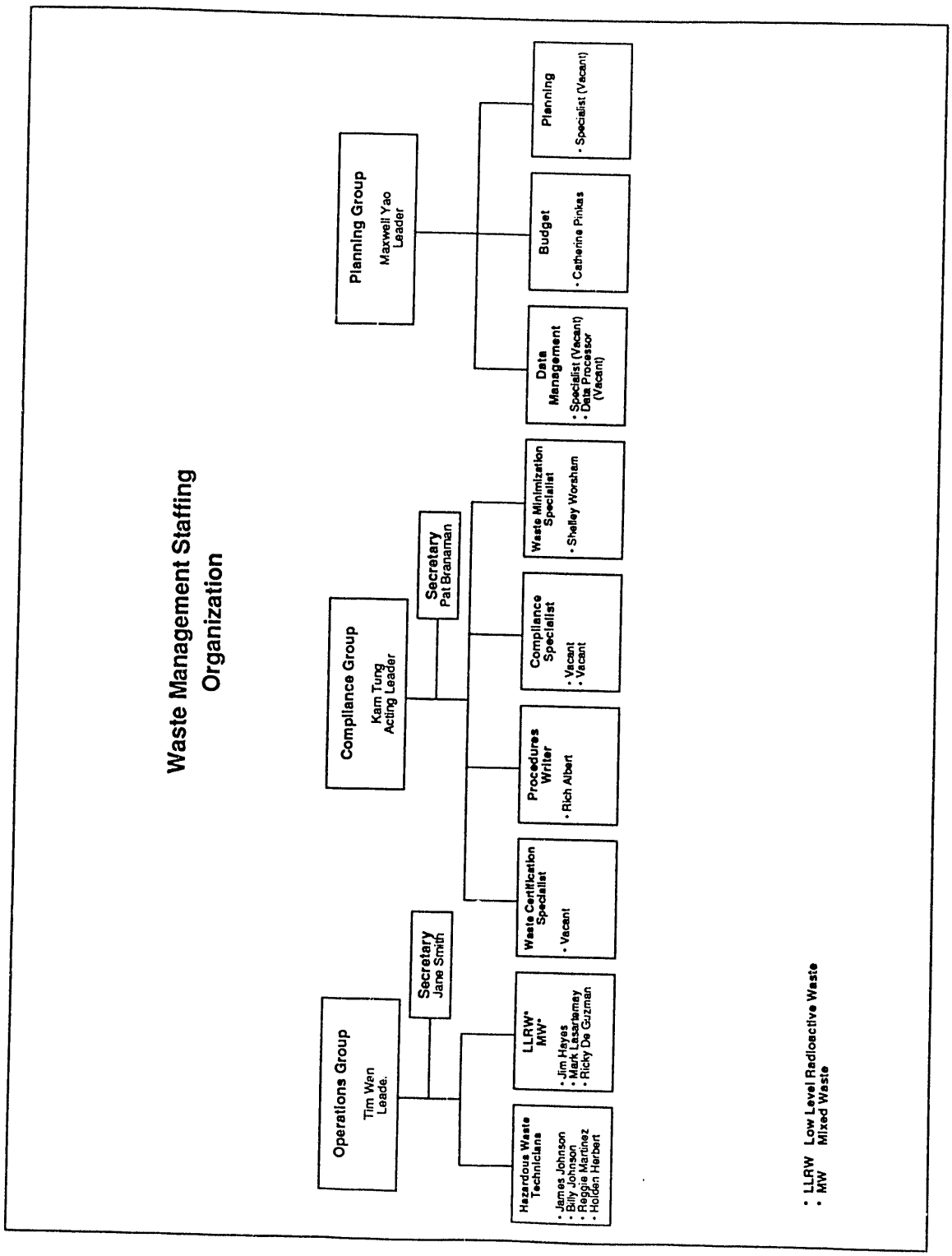
Waste Management Staffing Organization
Planning Group
Maxwell Yao
Leader
Planning
• Specialist (Vacant)
Budget
• Catherine Pinkas
Data Management
• Specialist (Vacant)
• Data Processor (Vacant)
Compliance Group
Kam Tung
Acting Leader
Secretary
Pat Branaman
Waste Minimization Specialist
• Shelley Worsham
Compliance Specialist
• Vacant
• Vacant
Procedures Writer
• Rich Albert
Waste Certification Specialist
• Vacant
Operations Group
Tim Wan
Leade.
Secretary
Jane Smith
LLRW*
MW*
• Jim Hayes
• Mark Lasariamay
• Ricky De Guzman
Hazardous Waste Technicians
• James Johnson
• Billy Johnson
• Reggie Martinez
• Holden Herbert
* LLRW Low Level Radioactive Waste
* MW Mixed Waste

Figure 1-3

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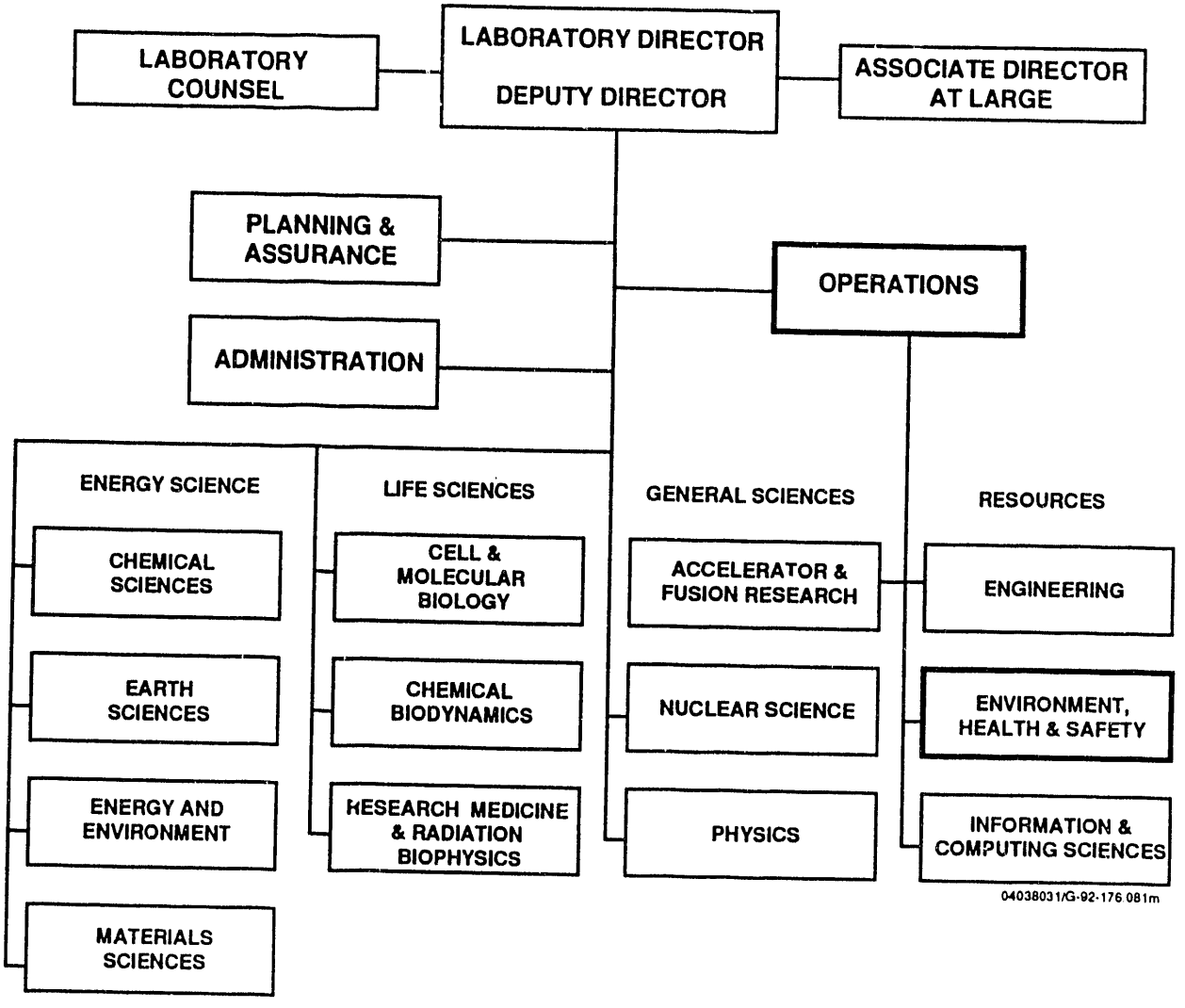

Figure 1-4

1.2.2 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.

- Establishing and executing the EH&S QA Program.
- Providing support to EH&S QA Program activities, e.g., scheduling, cost, and technical performance.
- Assuring that EH&S QA management has sufficient authority, access to work areas and personnel, and organizational freedom to fulfill the responsibilities assigned to the EH&S QA professionals.
- Resolving disputes arising from differences of opinion between EH&S QA personnel and other EH&S personnel.
- Assuring that management self-assessments and independent audits by the Office of Assurance and Assessment of the EH&S QA program are conducted periodically.
- Establishing the personnel qualification and training functions relating to the EH&S QA program.
- Reviewing and approving all procedures and instructions and revisions issued at the department level.
- Establishing the Document Control System.
- Overseeing of the procurement process of EH&S items or services.
- Assuring that nonconforming items or activities are properly identified and dispositioned and that corrective actions are addressed.
- Establishing a Records Management System.
- Establishing a system for instrument calibration and measurement accuracy.
- Assuring that EH&S personnel are made available to support quality verification activities.
- Direction of the activities of the EH&S QA professionals and the development, issuance, maintenance, and verification of an EH&S QA Management Plan (EH&S QAMP) and its corresponding quality implementing procedures.

- Reviewing and approving Departmental Quality Assurance Plans (QAPs), QIPs, and reviewing a sampling of operational plans and procedures to assure inclusion of QA requirements.

- Monitoring EH&S quality-affecting activities by conducting reviews, quality surveillances, audits, and other assessments.

- Assisting EH&S personnel in QA matters through guidance, consultation, and participation in training activities, document reviews, meetings, presentations, and task forces.

- Monitoring computer software code development and verification activities.

- Monitoring design activities by participating in design reviews, conducting surveillances and audits, and reviewing appropriate output documents.

- Monitoring the procurement process to verify that applicable procurement documents and procurement actions include appropriate QA requirements.

- Directing contractor and vendor QA surveillances and audit processes, approving contractor and vendor qualifications, and reviewing contractual documents for inclusion of appropriate QA provisions.

- Verifying that personnel performing special processes, inspections, tests, and other quality-affecting activities are properly trained, qualified, and certified, as applicable to the activity.

- Verifying that inspections are performed at appropriate activity intervals and that tests are properly planned.

- Verifying that Measuring and Test Equipment (M&TE) used in EH&S activities affecting quality are controlled, calibrated, and documented by the applicable EH&S organization.

- Concurring with the release of nonconforming items, based on justification by the Department Managers.

- Maintaining the status tracking system for nonconformance reports and monitoring the control of nonconforming conditions and status indicators.

- Initiating corrective-action documentation for conditions adverse to quality, and investigating and validating corrective action reports.

- Identifying quality verification activities, and developing quality verification activity schedules. Selecting, training, and certifying audit personnel and other quality verification personnel.

- Verifying corrective action implementation.

- Assessing compliance to the EH&S QAMP by the departments, and reporting effectiveness to the Associate Laboratory Director for Operations on an annual basis.

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

- Managing Environment Department operations, personnel, and activities, including the implementation and application of this WM QAIMP.
- Fulfilling 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.
- Defining corrective action and improvement details with the objective of assuring that they are completed, effective, properly documented, and closed.
- Approving and issuing the WM QAIMP and any revisions.
- Controlling the WM QA Records system.
- Performing periodic management reviews of the WM QAIMP and System, in order to direct corrections and improvements.
- Implementing the EH&S QA program as it relates to the activities of WM.
- Determining the need for and assuring that appropriate QA plans, procedures, and instructions are developed for applicable department activities.
- Assuring that personnel performing quality-affecting activities are trained, qualified, and certified as applicable to the activity; and identifying the job requirements and training needs of their staff.
- Approving software design plans and code validation and verifying requirements applicable to WM.
- Planning design activities and reviewing design inputs, outputs, and reports.
- Participating in design verification as appropriate, and implementing configuration management and design procedures.
- Assuring 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.
- Approving procedures and instructions and revisions thereto issued at WM.

- Approving procedures and instructions and revisions thereto issued at WM.
- Developing and implementing appropriate controls for assuring that only properly identified and controlled items are used in quality-affecting activities.
- Reviewing, approving, identifying, and qualifying special process procedures within WM's area of responsibility.
- Developing test plans, overviewing testing activities, and assuring that test results are properly documented.
- Assuring that Measuring & Test Equipment (M&TE) used in the acceptance of data are properly calibrated.
- Assuring that procedures are generated for handling, storage, and shipping items.
- Assuring that procedures are available for controlling status indicators.
- Assuring that nonconforming conditions are promptly addressed and documented.
- Assuring that conditions adverse to quality are identified and documented.
- Assuring that personnel generate and maintain QA records, and directing divisional document and records management functions.
- Providing input into quality verification schedules, and assuring the availability of personnel participating in these activities.

1.2.4 The Waste Management QA Specialist (QAS) is responsible for the following functions. This responsibility is currently assigned to the leader of the WM Planning Group.

- Identifying WM quality-related problems.
- Maintaining direct communication and liaison with the EH&S QA personnel and having line authority for the implementation of the QA program.
- Developing Quality Assurance procedures.
- Initiating, recommending, or providing solutions to WM quality-related problems.
- Providing a method to verify that activities affecting quality in WM have been correctly performed.
- Reporting information directly to the EH&S Division Director on issues affecting quality in WM where independence from WM is deemed necessary.

- Providing for annual WM QA Plan briefings.
- Providing the Quality Control inspection function at the Environment Department.
- Providing Quality Engineering requirements for procurement specifications.

1.2.5 The WM Operations Group Leader is responsible for:

- Assuring that WM is operated in a safe manner, meeting applicable requirements of LBL, Federal, state, local, and QA regulations.
- Assuring that the proper work environment exists for WM personnel.
- Managing/coordinating maintenance activities for WM.
- Managing/coordinating facility activities for WM.
- Assisting with safety and control measures for employee and environmental protection during WM operations.
- Providing support for the accountability, tracking of documents, and regulatory guidance for the preparation of radioactive and mixed hazardous waste shipments.
- Preparing manifests and related shipping documents.
- Providing technical support and expertise to LBL personnel as related to packaging and labeling.

1.2.6 The WM Compliance Group Leader is responsible for:

- Providing technical support to the WM Operations group in reporting, emergency planning, compliance issues, computations, RCRA, LLW, certification, procedure writing, safety coordinating, record-keeping, computer production, and other major systems activities.
- Reviewing procurement documents for technical content affecting WM.
- Approving WM procedures for issuance.
- Providing technical input, guidance, and assurance to the Environment Department to assure compliance with Federal and state regulations, DOE Orders, and waste management acceptance requirements of treatment/disposal sites.

- Providing and maintaining a document control system for WM procedures.
- Maintaining records as required.
- Inspecting waste packaging and loading.
- Assisting WM in meeting the radioactive criteria and hazardous waste acceptance criteria for shipments off site to other DOE treatment/disposal facilities.
- Arranging for the shipment and disposal of the Laboratory's hazardous and radioactive waste at Hanford/WIPP facilities.

1.2.7 The WM Planning Group Leader is responsible for:

- Assuring that reports to DOE are generated periodically.
- Training personnel on computer usage and applications.
- Providing Quality Control (QC) verification.
- Assuring that safety procedures and standard operating procedures are followed.
- Assisting in the review of purchase orders dealing with DOE radioactive waste management facilities.
- Preparing reports to comply with DOE Orders and additional regulatory and management requirements as applicable.
- Assuring compliance with applicable safety measures.
- Assuring that chemical and radioactive waste treated on site is in compliance with the appropriate regulations and DOE Orders.
- Assuring compliance with waste treatment and disposal regulations.
- Assuring that field operations are carried out in a safe manner, meeting applicable requirements of LBL, DOE, DOT, and other Federal and state regulations.

1.3 WM Implementing Management Plan (WM-QAIMP)

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 QAIMP. The hierarchy of governing documents applicable to the WM QA Program is shown in Figure 1-5.

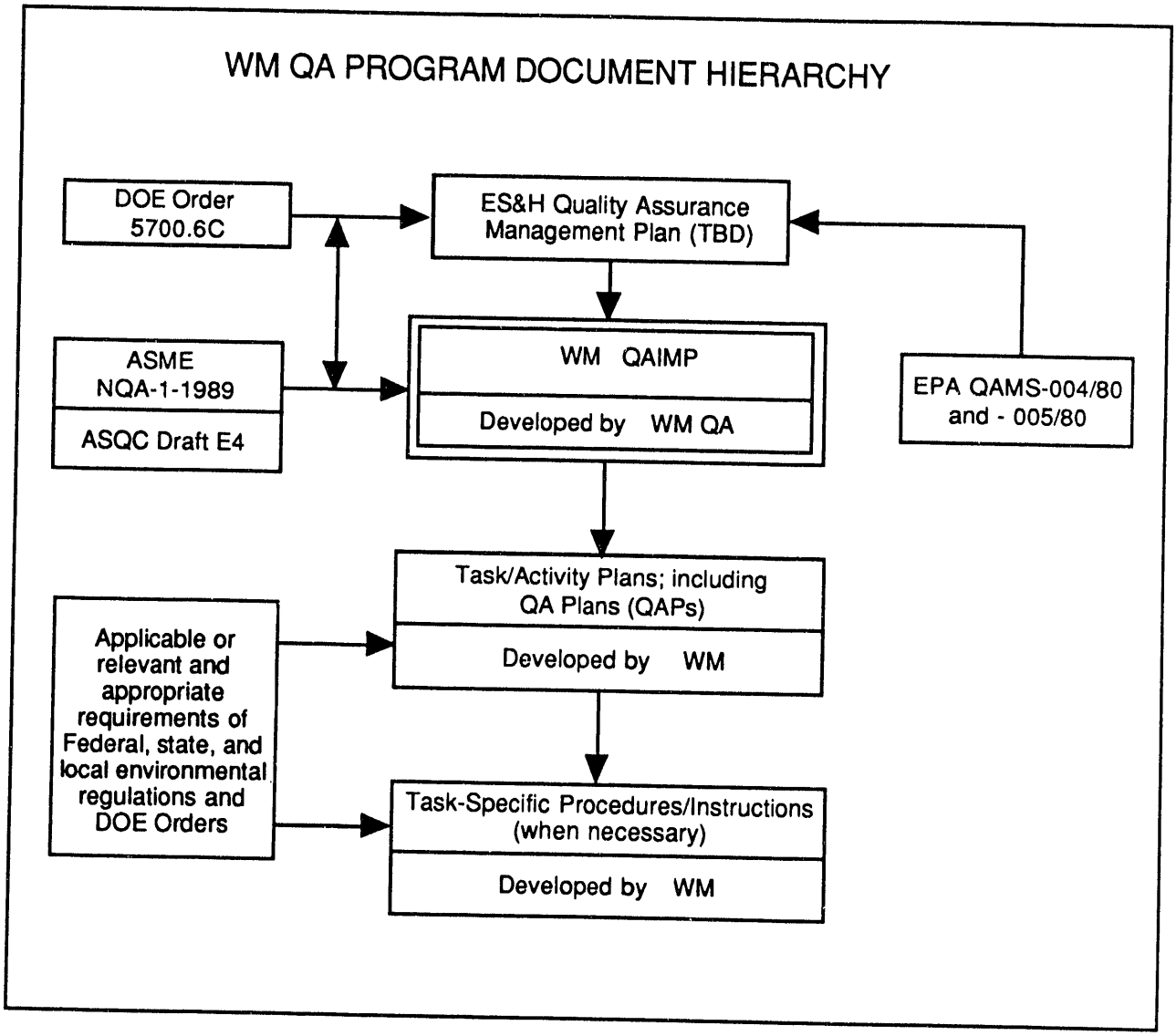

Figure 1-5 WM QA Program Document Hierarchy

This WM QAIMP 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:

a. Risk to programmatic objectives
b. Consequence of failure of the program.
c. Importance of the data.
d. Complexity of function.
e. Reliability of process.
f. Reproducibility of results.
g. Uniqueness of product.
h. Degree of standardization.
i. Impact on schedule or cost to replace in the event of failure.
j. Necessity of special controls or process.
k. Significance to regulatory compliance.
l. Worker health and safety
m. 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:

a. 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 QAIMP.

b. Assurance that activities requiring special procedures, QA Plans, peer reviews, work instructions, drawings, controls, equipment, or personnel training are identified, developed, and implemented.

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 WM Quality Assurance Specialist (QAS) 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 QAIMP and implementing procedures.

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 IQAP.

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 Manager must assure that training needs are identified and that training assignments are made.

Completion of training activities must be documented. The WMQAS 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 Manager must assure that assigned staff receive complete training commensurate with the scope and complexity of their assigned tasks.

2.2 Qualification of WM Personnel

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

2.3 Orientation 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.

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 WMQAS or designee must prepare implementing procedures that provide specific requirements and methods for training, qualifying, and certifying assessment personnel.

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 TQM 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 IQAP.

PLAN:

3.1 Identification of Nonconforming Conditions

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 can be input to a trend analysis system.

3.4 Approvals of NCAR Dispositions

The Environment Department Manager must review and approve all dispositions to nonconformance reports. In situations where the QAIMP or procedures may be affected by the resolution of the NCAR, or action is required by the WMQAS, the WMQAS must also review and concur with this disposition.

3.5 Tracking, Verification, and Closure of NCARs

The WMQAS must track the status of all open NCARs until closure. The WMQAS 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 WMQAS 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 WMQAS must evaluate responses to NCARs to verify that all the requirements have been addressed. Upon approval of the proposed corrective action, the WMQAS must verify implementation of NCAR corrective action on a sampling basis. Upon satisfactory implementation, the WMQAS 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 WMQAS must establish a trend analysis program that identifies the overall WM QAIMP trends. The trend analysis must include, but not be limited to, NCARs, assessment findings, and root cause analysis. Trend analysis reports must be issued quarterly, and submitted to the Environment Department Manager.

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.

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 IQAP.

Some elements in this section and their implementation will eventually be contained in either the EH&S Divisional or the LBL QAIMP. This plan will be modified to reflect that change in QA responsibilities at that time.

PLAN:

4.1 Document Preparation, Review, Approval, and Issuance

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.

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 records management system must be described in a Records Management Plan or in implementing procedures. The Records Management Plan and implementing procedures must be consistent with the requirements of this QAIMP and DOE Order 1324.2A.

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 QA Records. QA Records must contain a document title and a unique identification number.

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 Validation

The originator of records must authenticate, by signature or initial, any document that is a QA Record. Documents are authenticated to assure that those records designated as official QA Records are legible and complete. Authentication may occur at time of issue or at receipt by the records management personnel. Records may be originals or reproduced copies.

4.7 Record Index

Records management personnel must generate a records index that will assure that records are readily retrievable.

4.8 Retention Status

The Environment Department Manager or designee must assign a retention status to their records consistent with DOE Order 1324.2A. Retention periods for these records must be identified in the Records Management Plan or in implementing procedures, as appropriate.

4.9 Record Revisions or Corrections

The Records Management Plan or implementing procedures must identify the methods for correcting records once the documents have been designated as QA Records, and these records must provide protection from damage or loss during the time that the records are in the possession of the individuals who are revising the records.

4.10 Records Receipt

The Records Management Plan or implementing procedures must address the requirements and methods for receipt of QA Records.

4.11 Records Storage, Preservation, and Safekeeping

Records must be stored in a manner that protects them from loss. The Records Management Plan or implementing procedures must address the dual storage facilities and measures to be taken to protect these records. A list must be maintained designating those personnel who must have access to the QA Record files.

4.12 Records Disposition

The Records Management Plan or implementing procedures must identify the methods for dispositioning records and must identify when records may be purged from the system, records turnover requirements, and permanent records storage. The frequency of record turnover to records management personnel must be identified.

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, 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 or document control registers (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 IQAP.

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 B). 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.
- QA Records: identification of QA 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 as a minimum, by the Environment Department Manager or designee, and the WMQAS to evaluate the adequacy of the requirements and responsibilities for implementing the procedure or instruction.

5.4 Procedure Approval

WM procedures, instructions, and subsequent revisions or cancellations must be approved by the Environment Department Manager or designee, prior to use. At a minimum, approval and review 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 QAIMP.

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.

The document author must identify changes on the revised procedure or instruction by the use of lines or asterisks in the margin denoting revised portions of the procedure. When a revision incorporates a change, a summary of the change must be issued with the revised procedure or instruction.

5.7 Waste Container Control

Waste Container 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.

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.

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 QAIMP.

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.

5.17 Handling and Storage of M&TE

The Environment Department Manager 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.

5.22 Software Control

Software used for quality-affecting activities that has not been developed or originated by WM and that is commercially available requires documented verification to demonstrate that the software correctly performs its stated capabilities and functions.

5.23 Software Development Plan

WM groups performing computer analysis in support of site assessment, characterization, numerical modeling, etc., must prepare a Software Development Plan (SDP) that describes the software development, test, maintenance, and configuration management system. The plan must also address:

- Criteria for application of these requirements based on the complexity and importance of the software used to support these activities.
- Methods to be used to develop functional performance requirements that translate into a detailed design, which is implemented in a computer program.
- Types of documentation to be prepared, reviewed, and maintained during software design, development, implementation, test, and use.
- Methodology for establishing software baselines and baseline updates, and for tracking changes throughout the phases of the software life cycle.
- Process to be used for verification and validation of the software developed for or applied to environmental site assessment processes.
- Identification of the procedure for reporting and documenting software errors, evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective actions.

5.24 Software Configuration Management

Software must be placed under configuration control as each baseline element is approved. Baseline elements must be uniquely identified to assume control of revisions and to provide traceability between the software documentation and the computer program revision. Changes to software must be systematically evaluated, coordinated, and approved by the Environment Department Manager or designee.

Information regarding the changes must be transmitted to the affected organizations through a document control system in accordance with the requirements in Criterion 4 of the QAIMP.

Changes to the software must be subject to the same level of approval, verification, and validation as the original software.

5.25 Software Testing

WM groups must test software for those inputs and conditions necessary to assure that unintended functions that could degrade the software system will not be performed. Such testing must also identify boundary conditions and provide suitable benchmark or sample problems.

5.26 Software Documentation

Software documentation must be provided at the time of installation and use. Such documentation must consist of:

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

5.27 Software Security

Access to computer software must be monitored to prevent possible accidental or malicious misuse, modification, or disclosure.

5.28 Procedures for Characterization of Waste Processes and Conditions

Procedures that include requirements for characterization of waste processes and conditions must include:

- 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.

5.29 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.

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 IQAP.

PLAN:

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

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 IQAP.

Some elements in this section and their implementation will eventually be contained in either the EH&S Divisional or the LBL QAIMP. This plan will be modified to reflect that change in QA responsibilities at that time.

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.

7.2 Initiation of Procurement Document Packages

The Environment Department Manager 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 Manager 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 Manager 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:

- Evaluation of the contractor or vendor history and capability of providing the service or product required by the purchaser.
- Contractor/vendor current 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 must 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 WM procedures and must subsequently be incorporated into contractual agreements. Methods for accepting final products must include:

- 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.

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 Division'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 annually to be assured that the Criterion 7 requirements are followed. Receipt inspection by WM personnel helps provide this assurance as an ongoing process.

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, 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 IQAP are implemented herein.

PLAN:

8.1 Inspection Personnel

Inspection procedures must describe the methods and requirements for the qualification of inspection personnel and must include, as a minimum, the following:

- Inspection personnel must not report directly to immediate supervisors who are responsible for performing the work being inspected.
- Implementing procedures must describe the methods and requirements for 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:

a. 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.

b. Sampling. When a sample is used to verify acceptability of a group of items, the sampling procedure must be based on accepted sampling practices.

c. 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.

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 QAIMP.

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 as 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.

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 Manager for release, publication, or distribution.

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 IQAP.

Implementation of a WM management assessment plan is an integral part of LBL's overall Self-Assessment Program. This program is in the final stages of development, and all elements and requirements are compatible with this portion of the WM QAIMP. The LBL Self-Assessment Program has three primary QA oversight levels: Internal Assessment, 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 provided to the QA Program.
- Effectiveness of personnel training.

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 Manager 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 WMQAS and must include an evaluation of the effectiveness of management's actions.

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 IQAP.

PLAN:

10.1 Scheduling

The WMQAS 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-QAIMP activities. The Environment Department Manager 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 WMQAS 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 WMQAS, Environment Department Manager, or EH&S Division Director, as appropriate (see also Criterion 3 requirements). An NCAR may be used to document this requirement.

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. An NCAR 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 WMQAS 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 WMQAS 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 WMQAS must verify implementation of corrective action prior to closure of the findings, problems, or reports.

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

ASSESSMENT/VERIFICATION - The act of reviewing, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining whether items, processes, or services meet specified requirements. The terms assessment and verification, as used in DOE 5700.6C, are synonymous; their use is determined by who is performing the work. Assessments are performed by or for senior management. Verifications are performed by the line organization.

BASELINE - Software that has been formally reviewed and agreed upon, and that can only be changed through formal change control procedures.

BASELINE ELEMENTS - Any individual element of a software baseline. A distinct document, specification, or product that is part of the baseline set of documents, specification, or products necessary to design, develop, test, operate, and maintain a specific version of software.

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 CONTROL - The process of identifying and defining the configuration items in a system, controlling the release and change of these items throughout the system life cycle, and recording and reporting the status of configuration items and change requests.

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 based.

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. A document is not considered to be a QA Record until it satisfies the definition of a QA Record.

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, facility, assembly, component, data, equipment, material, module, part, sample, structure, subassembly, subsystem, system, documented concepts, or unit.

NONCONFORMANCE - A deficiency in characteristic, 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, 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, acceptance criteria, and 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 contractors or vendors.

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 that, if not performed properly, could compromise the validity of information or data, could result in an unacceptable risk to health or safety of the public or the workers involved, or could have a detrimental effect on the achievement of the objectives of the Environment Department.

QUALITY ASSURANCE - All those planned and systematic actions necessary to provide adequate confidence that an activity, item, or facility will perform satisfactorily in service.

QUALITY ASSURANCE PLAN - A document that identifies the requirements judiciously selected from an overall QA Program that are applicable to a particular activity or project and that provides 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 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 does not conform to the original requirement.

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

SOFTWARE DEVELOPMENT PLAN (SDP) - A document that describes the breakdown of the software development project into manageable tasks arranged into a hierarchical refinement of detail. The SDP should identify all technical and managerial activities associated with computer program development.

SOFTWARE LIFE CYCLE - The period of time that starts when a software product is conceived and ends when the software product is no longer available for routine use. The software life cycle typically includes a requirements phase, a design phase, an implementation phase, a test phase, an installation and checkout phase, an operation and maintenance phase, and sometimes a retirement phase.

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 - 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 or classes 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.

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