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QUALITY ASSURANCE PROGRAM DESCRIPTION

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LBL/PUB-3111, Rev. 11

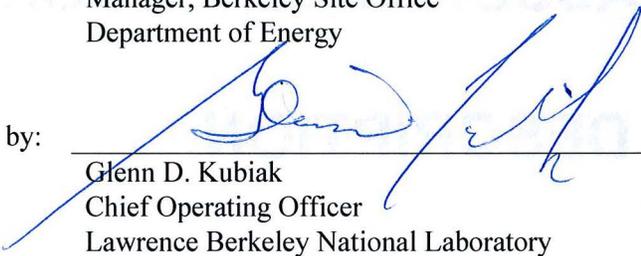
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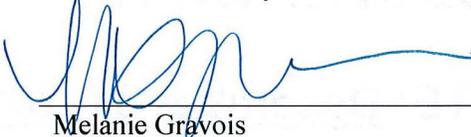
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Record of Revision

Rev. No.	Date	Description
3	DRAFT (11/11/92)	Rewrite of the LBL <i>Institutional Quality Assurance Program Plan, Rev. 2</i> , dated December 21, 1988, to incorporate requirements of DOE Order 5700.6C.
3	2/3/93	Comments incorporated. Issued to Laboratory for use.
4	6/15/94	Updated in the following areas: -suspect/counterfeit parts program -maintenance management -DOE Order 5480.25, <i>Accelerator Safety</i> -total quality management -general editorial
5	1/15/96	Rewrite of OAP, Rev. 4
6	1/15/98	Revise to integrate with ISMS
7	4/18/00	Updated in the following areas: - 10 CFR 830.120 and 414.1, <i>Quality Assurance</i> - conduct of operations - maintenance management
8	12/06	Rewrite of the LBNL <i>Operating and Quality Management Plan</i> , dated April 18, 2000, to incorporate requirements of DOE Order 414.1C and ISO 9001-2000. Also updated to reflect current LBNL organizations and operations. Appendix D demonstrates how QAPD addresses DOE O 414.1C requirements.
9	06/08	Clarified section 2.7, Document Control policy.
10	10/08	Clarified and expanded upon section 2.6.5, Software Quality Assurance
11	12/31/13	Changed the title of this document from “Operating and Quality Management Plan” to “Quality Assurance Program Description” (QAPD); rewrote to describe how the Lab implements QA requirements; moved policy to the RPM and removed procedural steps; aligned QAPD with the Contractor Assurance and Integrated Safety Management systems; better aligned QAPD elements with DOE O 414.1D and ANSI/ISO/ASQ Q9001-2008; added definitions and quality clauses; and revised the Graded Approach Risk Methodology.

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Objectives and Applicability

The Lawrence Berkeley National Laboratory (LBNL) Quality Management System (QMS) complements, and is integrated with, the Integrated Safety Management System (ISMS) and the Contractor Assurance System (CAS). The QMS provides processes and tools to ensure that quality, reliability and sustainability are achieved, in conjunction with the ISMS and CAS objectives. The QMS ensures compliance with contract requirements so that the expectation for safe work within controls is met. Additionally, this ensures that workers the environment and the public are reasonably protected from harm.

The QMS is designed to assist the Lab in:

- a) Determining the processes needed for the quality management system and their application at all functions of business
- b) Determining the sequence and interaction of these processes,
- c) Determining criteria and methods needed to ensure that both the operation and control of these processes is effective
- d) Ensuring the availability of resources and information necessary to support the operation and monitoring of these processes
- e) Monitoring, measuring and analyzing these processes
- f) Implementing actions necessary to achieve planned results and continual improvements of these processes.

In addition to the Quality Assurance Policy, documented in the Requirements and Policies Manual (RPM), the LBNL Quality Assurance Program Description (QAPD) documents the operating principles and practices used by organizations to achieve reliable, safe, and quality performance in their work activities. The QAPD is designed to:

- Describe the elements necessary to integrate quality assurance, management systems, and process controls into Laboratory operations.
- Provide the framework for LBNL administrators, managers, supervisors, and staff to plan, manage, perform, and assess their work.

The QAPD applies to all LBNL organizations. All LBNL operating units are engaged with organizing their resources, managing and ensuring the safety and quality of their processes and activities, and evaluating the results of their performance. Where the Laboratory outsources processes that affect the safety and quality of items, services and activities, it ensures that controls are in place to govern these processes.

The level of rigor in applying the QAPD principles, requirements, and practices is based on a graded approach, with consideration given to the organization's mission, its programmatic or operational significance, and its environmental, safety, and health consequences to personnel, environment, and the general public. Attachment B, *Graded Approach Risk Determination*, contains a methodology that is suggested to grade processes, items, and activities to determine the applicable level of control and rigor with which the control is applied.

Depending on contractual or regulatory requirements, certain organizations may require additional program- or facility-specific plans to ensure that relevant policies, administrative and work procedures, and technical information are provided to affected individuals. The use of national or international consensus standards is encouraged for organizations that have unique or specific work activities that require consistent results and/or conformity to specifications.

SOURCE DOCUMENTS

- 10 CFR 830, Nuclear Safety Requirements, Subpart A, *Quality Assurance Requirements*
- Contract 31, Clause H30, *Contractor Assurance System*
- DOE O 414.1D Admin Chg1, *Quality Assurance*
- DOE P 450.4A, *Integrated Safety Management System Policy*
- ANSI/ISO/ASQ 9001:2008, *Quality Management Systems – Requirements*

REFERENCED DOCUMENTS

- DOE O 221.1A, *Reporting Fraud, Waste, and Abuse to the Inspector General*
- DOE M 232.1, *Occurrence Reporting*
- *Engineering Process Guide*
- LBNL/PUB-3140, *Integrated Environment, Safety & Health Management Plan*
- LBNL/PUB-3193, *Design and Construction Management Procedures Manual*
- LBNL/PUB-5519 (1), *Issues Management Program Manual*
- LBNL/PUB-5519 (2), *Causal Analysis Program Manual*
- LBNL/PUB-5519 (4), *Lessons Learned and Best Practices Program Manual*
- Policy 04.03.0001.000, *Quality Assurance*
- Procedure 10.06.001.101, *Developing, Reviewing and Approving Non-Policy Institutional Documents*
- Procedure 10.06.001.102, *Developing, Reviewing and Approving Institutional Policies*
- Procedure 04.03.001.002, *Safety System Software Quality Assurance*
- Requirements and Policies Manual (RPM)

1.0 Organization and Quality Assurance Program

An appropriate management structure, a proficient staff, clear roles, strong accountability and a systematic approach in planning work are key elements in sustaining a safe and high level of performance. This section describes the organizational structure and general principles that are the basis for the LBNL QA Program.

1.1 Organization

The Laboratory is organized hierarchically by divisions, departments, groups, and offices. A description of the organization is maintained for each of these levels. This information is the basis for identifying the functional responsibilities, levels of authority, and interfaces both within and among organizations. Organizational information is communicated to all affected Laboratory personnel and guests. The description of the organization includes the following information:

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

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

1.1.1 Office of Institutional Assurance (OIA)

The OIA manages implementation of contractor and quality assurance and provides oversight of LBNL's management systems and operating processes to ensure that compliance, best practices, and continuous improvement are achieved at LBNL in support of excellence in science. OIA works with managers, supervisors, and staff to manage contract requirements, establish performance measures, develop assessment protocols, identify deficiencies, and implement improvements. OIA has critical oversight, feedback, and process-improvement roles with respect to performance deficiencies, and maintains centralized tracking of issues/corrective actions and lessons learned/ best practices for regular reporting to relevant line managers, LBNL Management, UC Governance, and DOE.

The Director of the OIA is the senior LBNL manager who has the responsibility and authority to develop, implement, assess, and improve the LBNL QAPD.

The Director of OIA ensures that the QAPD is in conformance with the requirements of DOE O 414.1D, *Quality Assurance*, and with applicable elements of ANSI/ISO/ASQ Q 9001-2008, the international consensus standard for quality assurance.

1.1.2 Office of Contractor Assurance

Under the Director's charge, staff from the Office of Contractor Assurance (OCA) has the day-to-day operational responsibility to ensure that compliance in support of scientific excellence, best practices, and continuous improvement are achieved at LBNL.

Office of Contractor Assurance (OCA, part of the OIA), is responsible for establishing and maintaining the system and processes for managing contractually-based requirements, which includes:

1. Providing a structure for oversight and assurance activities; and
2. Developing, maintaining and overseeing an institutional quality assurance program including:
 - a. Graded Approach: Using a risk-based approach, apply the appropriate level of control and rigor to procurement, design, development, fabrication, inspection, testing, assessment and issues management.
 - b. Work Processes: Designing, documenting and implementing engineered and administrative controls to ensure work performed is sustainable and reliable.
 - c. Continuous improvement: Performing assessments and reviews; establishing and maintaining measures to monitor DOE contract performance; establishing and maintaining an issues management program for Laboratory operations; developing and maintaining mechanisms for regular reporting to stakeholders on LBNL performance developing and maintaining a Laboratory-wide Operating Experience Program for communication within the Laboratory and the DOE complex.

OCA is an internal assurance organization, independent from line management and is authorized to have unrestricted access to personnel, records, and other information sources necessary to carry out its duties. OCA staff possesses the requisite experience, training, and skills to manage the QA Program, as documented in staff position descriptions.

1.1.3 Management

LBNL management has overall responsibility for successfully accomplishing activities subject to this QAPD. Management provides the necessary planning, organization, direction, control, resources and support to achieve their defined objectives. Additionally, management is responsible and accountable for establishing and

implementing policies, plans and procedures that control the quality of work, consistent with the provisions of this QAPD.

1.1.4 Employees

Employees are responsible for the quality of their work and for promptly reporting all existing, developing or potential conditions adverse to quality to the responsible management for evaluation and action.

1.2 Grading Items and Services and Applying Management Controls

LBNL uses a graded approach to determine the level of controls and the rigor with which those controls are applied to items, services or activities. The objective of the graded approach is to ensure that work activities are managed commensurate with the risks involved.

The extent of controls applied to an item or activity vary as a function of the degree of confidence needed to achieve the desired quality of the item or activity. The graded approach process provides the flexibility to design and implement controls that best suit the facility or activity. Organizations should develop their own method to determine that the defined grading process is effective.

Attachment B, *Graded Approach Risk Determination*, may be used by organizations to determine the risk of an item or activity, which drives the level of controls and the rigor with which quality requirements are applied.

1.3 Planning

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

- Funding
- Organizational interfaces and authorities for those managing, performing, and assessing work
- Resource allocation
- Requirements for written procedures, instructions and drawings
- Identification of work standards and requirements
- Identification of controls
- Staff training needs

Examples of planning include:

- Strategic/Business plans
- Risk assessment meetings
- Operation and planning meetings (e.g., staff meetings, project meetings, program reviews)
- Research and program proposals that describe the work objectives and the proposed actions/steps
- Work plans or work authorizations that address work objectives, resource requirements, work hazards, and the implementation of controls
- Work or project schedule
- Operational policies and procedures
Performance measures and results

1.4 Staff Proficiency

LBNL ensures that personnel selected to perform work have the education, skills, experience and training commensurate with the work to be performed.

To ensure consistent hiring practices, the Human Resources Department provides the institutional policies and procedures for personnel qualification, selection, and training. Additionally line management ensures that personnel receive indoctrination and training, including on-the job and hands-on training, as needed, to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, job responsibilities and implementing procedures necessary to perform work:

- **Position requirements** are established at the time of recruitment and selection. Each job position is analyzed to determine the task responsibilities of the position. The position requirements define the minimum education, experience, and skills necessary to fill the position. Requirements for certification and licenses are also identified at this time. Candidates' qualifications must also be verified during the hiring process.
- **Training needs** for each position are determined and documented based on the scope, hazards, and complexity of the job and on any institutional and regulatory training requirements
- **Job orientation, required reading, and on-the-job training** is completed as early as possible after the job assignment. Some training is required prior to the actual performance of work. On-the-job training is administratively controlled to ensure that such training is not allowed to adversely affect work quality or operational safety.
- **Guest/visitor or affiliate training or orientation** may be required based on the scope, length, hazards, and complexity of the job assignment. Training for affiliates, guests and visitors is documented.
- **Periodic training and refresher training** is provided to ensure continued job proficiency and to improve overall performance and safety.
- **Performance evaluations** are conducted at least annually for every position to ensure that job proficiency is being maintained and improved. This process is described in the Performance Evaluations Guidance issued annually by Human Resources.
- **Where appropriate, professional development plans** are developed to encourage staff to improve their knowledge, abilities, and skills. These plans require management approval. This process is described in the Performance Evaluations Guidance issued annually by Human Resources.

2.0 Quality Improvement

Quality improvement is a management process carried out to improve items, services, products or processes. All aspects of work that affect quality and the management system are subject to continuous improvement through assessment and feedback processes.

Assessments are performed using a graded approach, based on the risk inherent in the involved organizations, systems, and processes. Managers regularly assess their organizations and functions. As appropriate, independent internal and/or external assessments are performed to provide LBNL managers with additional insight into their operations. Results of management and independent assessments are considered collectively in improving quality. Findings and corrective actions from all assessments; are managed in accordance with the LBNL Issues Management Program (LBNL/PUB-5519 (1)). Causes of findings are determined and corrective actions are developed and tracked in the LBNL Corrective Action Tracking System (CATS), in accordance with the LBNL Causal Analysis Program (LBNL/PUB-5519 (2)). Findings that may benefit the Laboratory community should be considered for dissemination through the LBNL Lessons Learned and Best Practices Program (LBNL/PUB-5519 (4)).

2.1 Management Assessment

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

- Planning
- Organizational interfaces (internal and external to the organization)

- Integration of management systems (e.g., safety, security, quality)
- Organizational effectiveness, including customer satisfaction
- Use of performance metrics and peer reviews
- Training and qualifications
- Supervisory oversight and support

The management assessments include an internal evaluation of such conditions as the state of employee knowledge, motivation, and morale; communication among workers; the existence of an atmosphere of creativity and improvement; and the adequacy of human and material resources. The assessments also involve direct observation of work so that the manager is aware of the interactions at a work location. The observations can be supplemented with worker and customer interviews, safety and performance documentation reviews, and drills or exercises. The results of management assessments are documented and used as input to the organization's improvement process. The documentation can include agendas and minutes of staff and operations meetings, progress reports, performance evaluations, inspection reports, and self-assessment reports.

2.2 Assessment

2.2.1 Independent Assessment

Independent assessments advise LBNL managers on the quality of products, services, and processes produced by or for the organization. The type and frequency of independent assessments are based on the status, complexity, risk, and importance of the activities or processes being assessed. The assessments are performed by technically and programmatically knowledgeable personnel within LBNL who are free of direct responsibility in the areas they assess. The lead assessors must work for organizations that have sufficient authority and independence to gain access to senior Laboratory managers capable of directing line organizations to take actions in response to the assessment results.

Independent assessments review operational effectiveness and adherence to missions, goals, and objectives. Independent assessments are formal assessments that include established protocols for conducting assessments and providing feedback to the assessed organizations. The type and frequency of independent assessments are based on the status, complexity, risk, and importance of the activities or processes being assessed. Independent assessments provide an objective form of feedback to Laboratory management that is useful in evaluating performance and identifying performance deficiencies and noteworthy practices.

Independent assessment results are documented in an assessment report. The assessed organization is responsible for responding to the assessment findings. This includes tracking deficiencies, developing and implementing corrective actions, and communicating noteworthy practices as appropriate.

Independent assessments are performed by:

- LBNL organizations that may conduct independent assessments include OCA; Internal Audit Services; and the Safety Advisory Committee.
- Parties external to LBNL. These reviews may be performed by the General Accountability Office, the DOE Inspector General, regulatory agencies, DOE representatives, peers within the DOE complex, or experts from private industry. Reviews may be initiated by external regulatory agencies intent on ensuring that LBNL operations are compliant with federal, state, and local regulations. DOE headquarters and BSO representatives may also perform reviews to evaluate operations and assess implementation of applicable DOE orders and directives. Reviews may also be initiated by the Laboratory.

2.2.2 Self-Assessment

Self-assessments are internal assessments of the LBNL functions performed by functional managers, line managers, and staff. Scope, criteria, and methodology for assessments are based on the primary risks inherent in work activities.

LBNL functional managers regularly assess the performance of their organizations and functions to determine how well objectives and goals are met. Self-assessments focus on identifying and resolving both singular and systematic management issues and problems that may hinder the organization in achieving its scientific and operational objectives. Management also considers any previous findings from self-assessments and independent assessments.

Assessments may involve direct observation of work, testing controls, worker and customer interviews, documentation reviews, and benchmarking against other organizations. Self-assessment results are documented and used for continuous improvement. Assessment reports identify findings, observations, and noteworthy practices.

2.3 Continuous Improvement

Continuous improvement is an ongoing process that uses feedback to manage risks; improve processes, products, and services; and prevent or minimize operational problems (i.e. contractual, legal, financial, quality, safety deficiencies). Improvement involves:

- Engaging management in prioritizing risk management and improvement opportunities
- Learning from operating experiences and the experiences of others, and developing and disseminating the associated lessons learned and best practices within specific Laboratory organizations, Lab-wide, and/or to the DOE complex.

A quality or safety problem is a collective term that involves a deficiency in an activity, product, service, item characteristic, program or process; or with an internal or external requirement.

Managers at all levels have the responsibility to correct deficiencies and improve, whenever possible, the processes, products, and services under their supervision.

2.3.1 Issues Management

Through the Issues Management Program, LBNL promptly identifies and manages issues to:

- Determine risk and significance
- Identify causes
- Develop and effectively implement corrective actions to ensure successful resolution and prevent the same or similar problems from occurring

Issues are addressed on a risk-based graded approach. Depending on significance, issues may merit corrective action plan development, causal analysis, extent-of-condition review, and verification and validation.

LBNL/PUB-5519(1), *Issues Management Program Manual*, and LBNL/PUB-5519(2), *Causal Analysis Program Manual*, outline these requirements.

2.3.2 Lessons Learned & Best Practices

The LBNL Operating Experience Program is designed to ensure ongoing performance improvement, prevent the recurrence of significant adverse events/trends, and communicate implementation strategies that will help LBNL successfully meet the missions and goals set forth by DOE. LBNL reviews lessons learned and best practices from external sources (e.g., DOE corporate Lessons Learned, industry notifications, etc.) for applicability to the Lab.

LBNL/PUB 5519(4), *Lessons Learned and Best Practices Program Manual*, outlines the requirements for sharing internal and external operational experiences within specific Laboratory organizations, Laboratory-wide, or with other facilities across the DOE complex.

2.3.3 Nonconforming and Suspect/Counterfeit Items

Organizations that perform inspection, testing and maintenance activities have established processes for dispositioning items and services that do not meet design requirements. Nonconforming items, including suspect/counterfeit items (S/CI), are uniquely identified and/ or segregated to prevent inadvertent use, and their dispositioned accordingly.

Examples of conditions that result in nonconformance include:

1. failure to meet technical or material requirements,
2. failure to meet a requirement in design documents,
3. a nonconformance cannot be corrected by continuation of the original manufacturing process or by rework, and
4. an item does not conform to the original requirement even though it can be restored to a condition such that its capability to function is unimpaired.

When nonconforming items are identified, the responsible engineer is notified to determine the disposition, which is either “use as is”, “repair”, “scrap”, “replace”. For “use as is” or “repair” dispositions, the responsible engineer reviews and approves the technical engineering justification for the disposition.

When nonconforming items are thought to be suspect or counterfeit), the OCA is notified by the organization that owns the S/CI to make the final determination regarding whether the item is suspect or counterfeit. Upon confirmation by the OCA that an item is an S/CI, the organization that owns it ensures that it is reported in the:

1. Occurrence Reporting and Processing System (ORPS) database, in accordance with DOE O 232.1, *Occurrence Reporting*; and
2. Corrective Action Tracking System (CATS) database in accordance with LBNL/PUB-5519 (1), *Issues Management Program*.

S/CIs are reported to the DOE Inspector General in accordance with DOE O 221.1A, *Reporting Fraud, Waste, and Abuse to the Inspector General*, via the ORPS database.

3.0 Document and Records Management

3.1 Document Control

Document control ensures that documents are prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, establish design, or provide results of scientific or technical research and associated activities. Document control also ensures that the most current version of a document is available for those who perform work. Divisions are responsible for ensuring that documents are controlled to ensure the correct documents are being used.

LBNL organizations identify and describe the key processes used to meet the organization’s scientific or operational objectives.

Core functions have descriptions, procedures, instructions, and/or drawings to direct and inform personnel how to perform the functions in an efficient and safe manner. Modification of approved procedures for core functions and other significant work processes requires use of a formal change control process if the changes impact the quality and/or safety of the activity. Change control must include approval signatures, effective date, and revision number for the changed procedure.

Notes, desk manuals, memos, operator aids, logbooks, notebooks, postings, and drawings are acceptable methods of written communication.

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

Document control requirements are outlined in Procedure 10.06.001.101, *Developing, Reviewing and Approving Non-Policy Institutional Documents* and Procedure 10.06.001.102, *Developing, Reviewing and Approving Institutional Policies*.

3.2 Consensus Standards

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

ANSI/ISO/ASQ Q9000:2008 is the international consensus standard that LBNL uses for quality management.

3.3 Records Management

The Lab implements a records management process to ensure that records of policies, procedures, activities, and decisions are generated, maintained, and readily retrievable. Information and data that document the organization's research, operational, or administrative activities are retained as evidence of completed work and adherence to standards and procedures. A records or file inventory is established and maintained by the organizations. Records are transmitted to the LBNL Archives and Records Office in accordance with retention and disposition requirements.

4.0 Work Processes

Work is performed in accordance with established technical standards and administrative controls. Items are controlled to ensure their proper use and are maintained to prevent their damage, loss or deterioration. Equipment used for process monitoring or data collection is calibrated and maintained.

Personnel performing work are responsible for the quality of their work and line management is responsible for ensuring that the desired quality is achieved and improvement opportunities are identified.

4.1 Design

LBNL uses sound engineering and scientific principles and appropriate standards to develop and design items and processes. The design process includes:

1. conceptualization of the item or process being developed;
2. identification of business, technical and requirements;
3. feasibility assessment;
4. detailed design and analysis;
5. verification of the design; and
6. production.

Organizations implement configuration management procedures, techniques, and tools to manage, evaluate proposed changes, track the status of changes, and to maintain an inventory of system and support documents as the system changes. Configuration management, applied throughout the lifecycle, establishes and maintains the consistency of an item's performance, functional and/or physical attributes with its requirements, design and operational information throughout its life. A configuration management process allows management to track requirements throughout the life cycle through acceptance and operations and maintenance. As changes are inevitably made to the requirements and design, they are approved and documented, creating an accurate record of the system status.

Additional requirements for design may be found in the *Engineering Process Guide* and LBNL/PUB-3193, *Design and Construction Management Procedures Manual*.

4.2 Procurement

LBNL ensures that procured items and services meet established technical, quality and business requirements, and that they perform as intended. Prospective suppliers are evaluated and selected based the supplier's capability to provide items or services in accordance with technical, quality and business requirements. The responsible organization verifies that suppliers continue to provide acceptable items and services.

Items known to have been suspect or counterfeit in the past (e.g., Grades 5 and 8 high-strength bolts, circuit breakers, and other S/CIs listed on the DOE S/CI web site), particularly items intended for use in safety systems or critical applications, are be procured from qualified or dedicated suppliers. These types of items are purchased directly through the Procurement Department and specific supplier submittals such as Certificates of Conformance (CoCs) and/or Certified Material Test Report (CMTRs) are requested by the end user of the supplier to ensure the end user received what he/she requested.

The Procurement Department's suite of Standard Practices outline specific requirements for procuring items and services.

4.3 Acceptance of Procured Items or Services

To ensure that items and services meet specified technical and quality requirements prior to use, the purchaser or designee accepts them through verification methods. Verification includes inspection and testing of components, structures or systems to acceptance criteria. Verification methods include:

- Source Inspection
- Receiving Inspection
- Post Installation Testing
- Supplier Certificate of Conformance

4.3.1 Control of Supplier Nonconformances

The purchaser and supplier establish a process for dispositioning items and services that do not meet procurement document requirements. Nonconforming items are uniquely identified and/ or segregated to prevent inadvertent use. Examples of conditions requiring a report of nonconformance include:

1. failure to meet technical or material requirements,
2. failure to meet a requirement in supplier documents that have been approved by the purchaser,
3. a nonconformance that cannot be corrected by continuation of the original manufacturing process or by rework, and
4. an item that does not conform to the original requirement even though it can be restored to a condition such that its capability to function is unimpaired.

When nonconforming items are identified, the purchaser works with the supplier to determine the disposition (e.g. "use as is", "repair", "scrap", "replace").

4.3.2 Commercial Grade Items

Commercial grade items are identified in an approved design output document, such as a drawing, specification, or other document translated from a design input document. An alternative commercial grade item may be applied as long as the responsible design organization provides verification that the alternative commercial grade item performs the intended function and meets design requirements that are applicable to both the replaced item and its application.

Commercial grade items may be specified in the procurement document by the manufacturer's published product description. After receipt of a commercial grade item, the purchaser may perform inspections to ensure that:

1. damage was not sustained during shipment;
2. the item received was the item ordered;
3. inspection or testing is accomplished, to the extent determined by the purchaser, to ensure conformance with the manufacturer's published requirements; and
4. documentation, as applicable to the item, was received and is acceptable.

4.4 Inspection

Inspection is performed during the manufacturing or construction process of items or equipment. The extent of inspection is a function of the relative importance, complexity, and quantity of items or services. Inspections are performed by technically competent personnel are documented.

In some instances, hold points are used to control work that should not proceed without the specific consent of the organization placing the hold point. The specific hold points are indicated in appropriate documents (e.g. inspection plans, manufacturing travelers). Only the organization responsible for the hold point may waive the hold point.

There are various types of inspections that used to determine whether the system, structure, component or service performs as intended. Such as:

1. in-process inspections and monitoring,
2. final inspections, and
3. in-service inspections.

Documented inspection results are retained in accordance with Section 3.0, *Document and Records Management*. Nonconforming items, including S/CIs, are identified and dispositioned in accordance with Section 2.3.3, *Nonconforming and Suspect/Counterfeit Items*.

4.5 Testing

LBNL performs testing to determine the capability, reliability and sustainability of an item against specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions. Examples of such tests include prototype qualification tests, production tests, proof tests prior to installation, construction tests, and pre-operational tests.

Test results are documented and their conformance with acceptance criteria is evaluated by a qualified individual within the responsible organization to ensure that all test requirements have been satisfied. Documented testing results are retained in accordance with Section 3.0, *Document and Records Management*. During testing activities, if nonconforming items, including S/CIs are identified they are dispositioned in accordance with Section 2.3.3, *Nonconforming and Suspect/Counterfeit Items*.

4.6 Monitoring, Measuring, Testing, and Data Collection Equipment

Measuring and Testing Equipment (M&TE) includes inspection and test equipment, measuring and data collection equipment, equipment (either hand-held or installed) used for data indication, and other equipment used for data indication, collection, or evaluation. Calibration and control measures may not be required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy.

Organizations that use M&TE are responsible for establishing and documenting a system to control the use and calibration of M&TE. This system includes a process to recall for calibration or removal from service M&TE that:

1. has exceeded its calibration interval;

2. has broken calibration seals;
3. has been modified, repaired, or has had components replaced; or
4. is suspected to be malfunctioning because of mishandling, misuse, or unusual results.

Additionally, an assurance mechanism is included in the process to evaluate the adequacy of the calibration system.

When M&TE is found to be out-of-calibration, an evaluation of the validity of previous inspection and test results and the acceptability of related items, data collected, and processes are monitored.

M&TE schedules, calibration records and other records are maintained by the organizations that own the M&TE. Records of calibration include:

1. a description or identification of the item,
2. calibration interval,
3. date calibrated,
4. identification of the calibration source,
5. calibration results (data and status),
6. calibration action taken (e.g., adjusted, repaired, new value assigned), and
7. evaluation and corrective action taken in response to out-of-calibration conditions.

M&TE is labeled to indicate the calibration status, the date calibrated, the calibration due date or usage equivalent, and the identification of any limitations. When it is impractical to apply a label directly to an item, the label may be affixed to the instrument container or some other suitable means may be used to reflect calibration status.

M&TE is handled, stored and transported in a manner that does not adversely affect the accuracy of the equipment. Due consideration is given to temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference, and any other factors affecting the results of measurements.

4.7 Calibration

M&TE requiring calibration is calibrated at periodic intervals established and maintained to ensure acceptable reliability. Reliability is described as the probability that M&TE will remain in tolerance throughout the interval.

Intervals are established for M&TE requiring calibration unless the equipment is regularly monitored through the use of check standards in a documented measurement assurance process. Check standards closely represent the item parameters normally tested in the process, and the check standard is verified periodically. Where intervals are used to ensure reliability, the interval setting system is systematically applied and states reliability goals and a method of verifying that the goals are being attained. Intervals may be based on usage or time since last calibration.

Exemptions from periodic calibration may be approved. The recall system may provide for the temporary extension of the calibration due date for limited periods of time under specified conditions that do not unreasonably impair the satisfaction of task objectives.

If M&TE is found to be significantly out-of-tolerance during the calibration process, the cognizant organization notifies the appropriate personnel of the out-of-tolerance condition, and provides them with the associated measurement data so appropriate action can be taken.

4.8 Safety Software Quality Assurance

The LBNL approach to Safety Software Quality Assurance is based on the principle that software which is part of a system where degradation of the confidentiality, integrity, or availability of the software can have a foreseeable,

significant impact on human safety, taking into account compensating controls, must be appropriately controlled and tested.

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

The SSQA approach sets four core requirements:

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

Safety software includes:

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

Procedure 10.01.003.03, *Safety Software Quality Assurance Requirements*, contains the expectations for safety system software quality assurance including the evaluation of software, graded approach, types of software, configuration management, and documentation.

ATTACHMENT A – Definitions

Acceptance	The documented determination by the receiving organization that an item, service or work project is suitable for the intended purpose
Administrative Controls	Provisions relating to organization and management, procedures, recordkeeping, assessment and reporting necessary to ensure safe operation of a facility.
Assessment, Management	Periodic assessment by managers at every level of their organizations and functions to determine how well they meet customer and performance expectations and mission objectives, identify strengths or improvement opportunities, and correct problems. Assessments should address the effective use of resources to achieve the organization's goals and objectives.
Assessment, Self	Periodic assessment by the line of their programs, processes or functions, or elements therein to determine how well they are performing to established requirements, identify strengths or improvement opportunities and correct problems.
Calibration	The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or system, and the corresponding standard or known values derived from the standard.
Certificate of Conformance	A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.
Certification	The act of determining, verifying and attesting to, in writing the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.
Commercial Grade Item	An item that is 1) not subject to design or specification criteria unique to a LBNL program or facility, 2) used in applications other than the nuclear industry and 3) ordered from the manufacturer or supplier on the basis of specifications set forth in the manufacturer's published product description.
Configuration Management	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 the recording and reporting of the status of configuration items and change requests.
Corrective Action	An action that eliminates a deficiency and/or a cause of an issue/finding and prevents or significantly reduces the likelihood of the same problem occurring again.
Design Input	Those criteria, parameters, bases or other design requirements upon which the detailed final design is based.
Design Output	Drawings, specification, system descriptions and other documents resulting from the translation of design input requirements.
Design Process	The technical process that begins with the identification of design input and ends with the issuance of design output documents.
Design Review	A documented evaluation of design output during the design process to determine the design adequacy and the conformance to specified acceptance criteria.
Document	Written, visual, audio-video-recorded information stored in the form of hard copy, film, magnetic tape, electronic data, or in an on-line, web-based format.
Document Control	The process that provides for document adequacy review, approval for release by authorized personnel and distribution for use at the prescribed work locations.
Document, Controlled	A document that is prepared, reviewed, approved and distributed in accordance with established implementation procedures that are subject to controlled distribution and to a defined and controlled change process.

Graded Approach	The process by which the level of analysis, documentation, verification and other controls are developed commensurate with the risk of the item, service or work performed.
Item	An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, data or software.
Line Management	The management positions that are directly responsible for task products and services.
Line Organization	The organization that is directly responsible products and services.
Measurement and Test Equipment (M&TE)	All devices used to calibrate, measure, gage, test, inspect or otherwise determine compliance with prescribed technical requirements.
Nonconformance	A deficiency in a characteristic or record that renders the quality of an item or sample unacceptable or indeterminate.
Procurement Document	Purchase requisitions, orders, contracts, specification or other documents used to define technical and quality assurance requirements for the procurement of items and services.
Quality	The condition achieved when an item, service or process meets or exceeds the user's requirements and expectations.
Quality Assurance	Actions taken that provide confidence that quality is achieved.
Quality Assurance Program	The overall program or management system established to assign responsibilities and authorities, define policies and requirements and provide for the performance and assessment of work.
Quality Assurance Record	A completed record or any authenticated portion of a record that provides objective evidence of the quality of items or activities.
Record	All books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received that are preserved or appropriate for preservation that serves as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities.
Requirement	A specific obligation to perform an action mandated by LBNL senior management or the federal, state, or local government; or to comply with the Laboratory's contract with the Department of Energy; or to comply with agreements made between the Laboratory and its corporate manager, the University of California.
Receipt/Receiving Inspection	A method of accepting an item or related service from a supplier by examination or testing of the item or related service to verify conformance to specified requirements.
Repair	The process of restoring an item to a condition such that the capability of an item to function reliably and safety is unimpaired even though that item still does not conform to the original requirement.
Rework	The process by which an item is restored to original specifications by completion or correction.
Service	The performance of work, such as design, construction, fabrication, inspection, nondestructive examination, testing, calibration, environmental qualification, equipment qualification, repair, installation or similar activities.
Safety and Hazard Analysis Software and Design Software	Software that is used to classify, design or analyze nuclear/radiological facilities.

Safety Management and Administrative Controls Software	Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or Technical Safety Requirements or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards.
Software	Computer programs, procedures, rules and associated documentation and data pertaining to the operation of a computer system.
Software Quality Assurance Plan	A plan for the development of software products necessary to provide adequate confidence that the software conforms to established requirements.
Software Validation	The process of test and evaluation of the completed software to ensure compliance with software requirements.
Software Verification	The process of determining whether or not the product of a given phase of the software development cycle fulfills the requirements imposed by the previous phase.
Software Verification and Validation	The process of determining whether the requirements for a system or component are complete and correct, the products of each development phase fulfill the requirements or conditions imposed by the previous phase and the final system or component complies with specified requirements.
Source Inspection	A method of accepting an item or service from a supply by monitoring, auditing, surveilling, witnessing, or observing activities performed by the supplier.
Supplier	An all-inclusive term to mean any internal or external individual or organization who furnishes items or services in accordance with a contract and used in place of vendor, seller, source, participant, contractor or subcontractor.
Testing	An element of verification to determine the capability of an item to meet specified requirements or processes that facilitate the collection of data in conducting scientific investigations by subjecting the item or environment to a set of physical, chemical, environmental or operating conditions.
Traceability	The ability to trace the history, application and location of an item, data or sample using recorded documentation. As related to metrology, traceability means the ability to relate individual measurement results through an unbroken chain of calibrations to one or more of the following: <ul style="list-style-type: none"> • U.S. national standards maintained by the National Institution of Standards Technology (NIST) or the U.S. Naval Observatory; • Fundamental or natural physical constants with values assigned or accepted by NIST. • National standards of other country which are correlated with NIST.
Validation	An activity that demonstrates or confirms that a process, item, data set or service satisfies the requirements defined by the user.

ATTACHMENT B - Graded Approach Risk Methodology

LBNL uses a risk-based graded approach to the application and rigor of quality controls when performing work. LBNL personnel may use the risk methodology outlined in this Attachment to determine the controls commensurate with the impact and severity of the work to be performed.

Risk is defined as the possibility of suffering a loss or an unfavorable event, or the failure of achieving a planned outcome. Conventionally risk is estimated as the product of the likelihood (or frequency) of the event and the magnitude of its impact (or consequence) should the event occur.

To use the Risk Methodology, identify the risk(s)/issue(s) in your division that you want to evaluate/monitor. Define the severity of the actual or potential exposure by considering the impact and likelihood following the Risk Methodology – Risk Determination guidelines.

To calculate the Combined Risk Level, multiply the Impact Risk Value by the Likelihood Risk Value. The resulting Risk Value number correlates to the appropriate Combined Risk Level of High, Moderate or Low. Based on that ranking, the commensurate level of controls should be applied to the item, service or work activity.

Risk Determination: Graded Approach to the Application of Controls

Risk Value	Risk Level	IMPACT					
		Impact is determined by considering what the activity, service, or issue results in or could result in.					
		Environmental	Injury	Financial	Reputational	Research & Operational Impacts	Compliance
3	High	<ul style="list-style-type: none"> Significant hazard to safety and health of workers, environment or public: <ul style="list-style-type: none"> Exposures above regulatory limits Environmental release off site or above regulatory limit 	<ul style="list-style-type: none"> Significant impact to the safety of LBNL: <ul style="list-style-type: none"> Death Serious/ irreversible illness/injury Permanent Disability Hospitalization ≥ 24Hrs 	<ul style="list-style-type: none"> ≥ \$1M property loss or damage ≥ \$1M excess costs due to inefficiencies 	<ul style="list-style-type: none"> Significant negative publicity or public opinion Significant political pressure Significant potential for litigation or civil penalty 	<ul style="list-style-type: none"> Significant impacts on LBNL research activities <ul style="list-style-type: none"> Inability to perform research to meet objectives Significant impacts on LBNL operations <ul style="list-style-type: none"> Extended facility shutdown or operational restrictions 	<ul style="list-style-type: none"> Civil penalties or fines levied by external regulatory agencies Significant potential for litigation or criminal action UC loss of contract award year and/or fee reduction Requires immediate notification to external regulatory agencies External regulatory agency investigation Recurring issue as determined by data monitoring and analysis Systematic non-compliance with regulations/contract and risks are analyzed, deemed high, controls in place to keep risks low
2	Moderate	<ul style="list-style-type: none"> Hazard to the safety and health of workers, public and environment <ul style="list-style-type: none"> Exposures near regulatory limits Minor environmental release outside of building but on site Major release within building 	<ul style="list-style-type: none"> Moderate impact to the safety of LBNL: <ul style="list-style-type: none"> Hospitalization ≤24Hrs. Partial Disability/temporary total disability >3 mos. Restricted or Alternate Duty Reversible illness/injury 	<ul style="list-style-type: none"> ≥ \$25K to < \$1M property loss or damage ≥\$100K to < \$1M excess costs due to inefficiencies 	<ul style="list-style-type: none"> DOE HQ Notification Negative publicity or public opinion Some political pressure Some potential for litigation or civil penalty 	<ul style="list-style-type: none"> Some impact to LBNL research activities Some impact to LBNL research operations <ul style="list-style-type: none"> Short-term facility shutdown or operational restrictions 	<ul style="list-style-type: none"> External regulatory agency review Noncompliance with moderate impact to LBNL Adverse trend over an extended period of time
1	Low	<ul style="list-style-type: none"> Minor hazardous material released within building 	<ul style="list-style-type: none"> Minor or negligible impact to the safety of LBNL: <ul style="list-style-type: none"> No hospitalization No or minor illness/injury No restrictions No disability 	<ul style="list-style-type: none"> < \$25K property loss or damage < \$100K excess costs due to inefficiencies 	<ul style="list-style-type: none"> BSO concerns Lab Management concerns Political pressure Little potential for litigation Little or no impact on perception of LBNL and UC 	<ul style="list-style-type: none"> Minor or negligible impact to LBNL research activities and/or operations 	<ul style="list-style-type: none"> Noncompliance with regulations/contract with minor/negligible impact to LBNL

IMPACT DEFINITIONS:

Impact is defined as the magnitude, significance, or severity of an unfavorable effect.

- High Impact: Potential for significant adverse safety incidents, cost, major delay or significant negative institution-wide effect.
- Moderate Impact: Potential for substantive safety consequence or cost, or substantive negative institutional effect.
- Low Impact: Potential for minor safety impact or cost, or minimal negative institutional effect.

Risk Value	Risk Level	LIKELIHOOD
3	High	<ul style="list-style-type: none"> • Probable or more likely than not that the issue/ event will occur <ul style="list-style-type: none"> – Issue/event has occurred multiple times in last 12 months
2	Moderate	<ul style="list-style-type: none"> • More than remote but less than probable chance that the issue/event will occur <ul style="list-style-type: none"> – Issue/event has happened in last 18-24 months
1	Low	<ul style="list-style-type: none"> • Remote chance that the issue/ event will occur <ul style="list-style-type: none"> – Issue/event has not occurred in the past

HOW TO CALCULATE COMBINED RISK LEVEL

Multiply the Impact Risk Value by the Likelihood Risk Value to determine the combined Risk Level

- High Risk = Total RV of 6-9
- Moderate Risk = Total RV of 3-4
- Low Risk = Total RV of 1-2

Combined Risk Level Definitions

High Risk: high likelihood to occur, near miss or has occurred and results, or could result, in significant injury, loss, damage and/or significantly impacts achievement of mission/business objectives. Requires immediate attention from senior management and/or follows a formal, rigorous process and/or requires the application of formal, rigorous controls.

Medium Risk: would occur at some point in time, near miss or has occurred and results, or could result, in substantive injury, loss, damage and/or impacts achievement of mission/business objectives. Requires prompt attention from Division management and/or follows a more formal, rigorous process and/or requires the application of some formal, rigorous controls.

Low Risk: is not likely to occur, near miss or has occurred and results, or could result, in nominal injury loss, damage and/or nominally impacts achievement of mission/business objectives. Requires some attention from line-management, follows less formal or casual process and/or requires the application of less formal, rigorous controls

		IMPACT		
		RV1 (1)	RV2 (2)	RV3 (3)
LIKELIHOOD	RV3 (3)	3	6	9
	RV2 (2)	2	4	6
	RV1 (1)	1	2	3

ATTACHMENT C - QUALITY CLAUSES

Using a risk-based graded approach (Attachment B, of this QAPD), the end user, purchase requisitioner or Procurement buyer may identify what quality clauses they want to include in procurement documents to provide confidence that items and services from a supplier and its sub-tier suppliers will meet all of the requisite quality and technical requirements and specifications.

A1 - Supplier Work Performed Under the LBNL QAPD

Unless otherwise specified, Suppliers performing on-site work who's Quality Assurance programs have not been reviewed by the Office of Contractor Assurance (OCA) will work under LBNL/PUB-3111, LBNL Quality Assurance Program Description (QAPD). Specify in the purchase requisition that the Supplier shall conduct all work activities/services in accordance with the LBNL QAPD. (This includes the identification of all work that will be performed in accordance with the LBNL QAPD, applicable LBNL procedures, and any additional QA Program indoctrination that may be required.) Quality Assurance personnel, where applicable, shall inspect activities via work packages or instructions, as appropriate.

A2 - Contractor Assurance Requirements for Subcontractors Performing Work on LBNL Sites

The Subcontractor, when performing work on LBNL sites, shall meet the applicable environment, safety, and health; quality assurance and integrated safety management; safeguards and security and cyber security; and emergency management requirements, in accordance with applicable LBNL programs and procedures.

A3- Quality Program/System Requirements

The Supplier shall plan, implement, and maintain a QA program International Organization of Standards ("ISO"), Aerospace Standard ("AS") or Military Standard-equivalent quality system acceptable to Buyer for the Items (including "items" and "Work" as such terms may be used in the PO definitions) covered herein. Widely recognized Government or Industry Quality system standards shall be used as guidelines.

In addition, the QA specifications identified with this Purchase Requisition apply to the Supplier's QA program. This program may be subject to a pre-contract award survey and subsequent QA audits by LBNL. The Supplier shall require, in writing, subcontractors of all tiers to comply with all applicable quality program/system requirements. The quality system and control of "Special Processes" of the Supplier and subcontractors of all tiers shall be subject to audit by LBNL to the extent practicable at all times and places.

Upon buyer's request, Seller shall provide to Buyer documentation that describes Seller's quality system. All quality system documentation, and on-site performance of that system, is subject to review and approval by LBNL. Seller's system shall include right of access by buyer, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records.

The Supplier shall tender for acceptance only those item(s), supplies, or services that have been inspected and tested in accordance with its quality program/system and have been found to conform with contract requirements. When post-installation testing is identified as a method of acceptance, then post-installation test requirements and acceptance documentation shall be identified and agreed upon by the purchaser and supplier.

B1 - Software Quality Program

The seller shall have defined and implemented a software quality program that meets all requirements of NQA-2, Subpart 2.7 or Institute of Electrical and Electronics (IEEE) Computer Society standards prior to award of contract. This software quality program may be required to pass an on-site audit, to the requirements of NQA-2.7, subpart 2.7, or IEEE Computer Society standards, prior to award of any contract for the design, development, testing or maintenance of software.

If the seller is developing or modifying software under the LBNL QA program, they shall be developing or modifying this software physically at LBNL (or with prior written approval at a designated location), and shall adhere to all requirements of the LBNL QA program, as described in LBNL/PUB-3111, LBNL QAPD.

B2 - Software Quality Plan

The supplier shall have a software quality plan (SQAP) that describes the program, controls, activities, and documentation that will be used to control software quality. The supplier shall submit the SQAP for approval by LBNL (e.g. QA, cognizant organization, as applicable).

B3 - Software Life Cycle Documentation

The supplier shall provide the required life cycle and user documentation as specified by LBNL.

B4 - Software User Documentation

Supplier shall provide software user documentation that includes the following:

- (a) The software name and version identifier
- (b) Description of functional requirements and system limitations, including hardware
- (c) Explanation of the mathematical models and derivation of the numerical methods used in the software design (physical and mathematical assumptions on which the software is based shall be included, along with an explanation of the capabilities and limitations of the software)
- (d) Instructions that describe user interaction with the software, user messages initiated as a result of improper input and how the user can respond, the identification and description of input and output specifications and formats, and input parameters
- (e) Description of any required training necessary to use the software
- (f) Information for obtaining user and maintenance support

B5 - Software Test Documentation

Supplier shall provide documentation of software testing.

B6 – Reporting Software Errors or Failures

Supplier shall report software errors or failures to LBNL.

B7 – Supplier/Subcontractor Use and Control of Spreadsheets, Databases, Macros, Detailed Formulas, and Other Related Software Applications Developed Within Commercial Software Programs

The supplier and its subcontractors shall apply appropriate controls to spreadsheets, databases, macros, detailed formulas, and other related software applications developed within commercial software programs. Appropriate controls shall result in the following:

- (a) Completed documentation indicating that the application provides the correct results for the specified range of input parameters, including appropriate testing;
- (b) Completed documentation of the approval of the software for operational use including installation/integration testing for each system that the software is installed on;
- (c) A listing of the software code (i.e., a printout of the macro, spreadsheet, formulas, file/table/cell references, etc.); and
- (d) Completed documentation listing the controls necessary to permit authorized, and prevent unauthorized, access to the application.

The documentation listed above shall be delivered to LBNL upon completion, and at anytime upon request during the life of the contract.

C1 - Submittal(S) Required Before Contract Award

When specified by LBNL in the Statement of Work, the prospective Suppliers shall submit, prior to any Pre-award Survey:

- (a) a complete description of its quality program/system. Such description may consist of a copy of the Offeror's approved QA/QC Manual, a QA/QC plan, or a combination thereof, and shall specify the standard(s) upon which the system is based. Alternately, if a QA/QC manual/plan has been previously submitted, an Offeror may, provided its manual/plan has not since been revised, specify in its proposal the date and/or revision of its current QA/QC manual/plan.
- (b) planning techniques and processes to be used by the Supplier in fulfilling procurement document requirements
- (c) a complete description of its calibration system, which must comply with ANSI/NCSL Z540-1, ISO 10012-1, or MIL-STD-45662. The description may be extracted from the Offeror's documented quality program/system.
- (d) any national or international recognized certification program (i.e. ISO9000, NAVLAP, etc.).

C2 - Submittal of Subtier Supplier Requirements

Any portion of this PO which is subcontracted, including procurement of material and parts, shall include the applicable PO specifications that affect quality or manufacturing requirements. Those portions of unpriced copies of Supplier's subcontracts reflecting these requirements shall be forwarded to LBNL concurrently with the subcontracting action.

C3 - Rights of Access

Right of access to supplier's facilities and records for inspection or audit by the purchaser, LBNL, or other designee authorized by the purchaser shall be established.

C4 - Assessment of Suppliers and Subtiers QA Activities

The Supplier shall assess the effectiveness of the control of quality by subtier suppliers at intervals consistent with the importance, complexity, and quantity of the product or service being provided pursuant to this purchase order (PO).

C5 - Certification of Personnel

Supplier personnel responsible for performing and verifying processes that require special skills, including inspectors, foam application technicians, welders, nondestructive examination (NDE) examiners (radiography, ultrasonic, magnetic particle, eddy current, liquid penetrant, leak testing, visual, foam void detection), and similar skills, shall be certified. The certification shall be in writing, and shall be the result of formalized training and proficiency testing programs. The effective period of each certification shall be specified, and each individual must be recertified at the end of such period of retesting. Personnel failing a test shall be removed from operations until recertified. Training, testing, and certification of personnel shall be in accordance with criteria described in specified and recognized codes, standards, and specifications such as SNT-TC-1A.

D1 - LBNL's Surveillance and Source Inspection

All items furnished on this PO are subject to a verification and/or inspection at the Supplier's and/or Supplier's subtier facility by a LBNL QA representative. This verification and/or inspection shall be subsequent to the Supplier's acceptance. Inspection Hold Points will be selected and identified by LBNL to the supplier. The Supplier shall notify the LBNL buyer at least five working days before the items will be at any Hold Point.

D2 - First-Article Inspection

A first-article inspection shall be performed or witnessed at the Supplier's facility by a designated LBNL QA representative. The first-article inspection shall be accomplished using the first deliverable item of several of the same design or same type. The process used and standards of workmanship shall be representative of all items to be produced. To assure this, the QA representative may advise the Supplier of subsequent inspections. The Supplier shall notify the LBNL buyer at least five working days before the first article is available for inspection.

D3- Product Part Approval Process

In order to assure that there is no variation between the first article and subsequent articles, the Supplier shall use the same production process for initial and subsequent design and/ or manufacturing activities.

E1 - Certificate of Conformance

The Supplier shall provide a Certificate of Conformance (C of C), certifying that the purchased item or service meets specified requirements. Unless otherwise specified, the C of C shall accompany each shipment.

E2 - Supplier's Certificate of Conformance

The Supplier shall provide a Certificate of Conformance (C of C) certifying that the purchased item or service articles delivered under this contract conform to the requirements set forth in the Procurement Specification and applicable Detail Specification for the article ordered. The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the supplier's QA program.

The Contractor shall submit with each shipment, a certification as to the origin of manufacture and procurement, applicable traceability information for articles delivered, (e.g., date code/lot number), and part number. The certification shall identify any procurement requirements that have NOT been met, together with an explanation and the means for resolving the nonconformance(s). The certification shall be dated and bear the signature and title of an authorized representative of the Contractor supplying the article(s).

E3 - Chemical/Physical Test Reports

Suppliers shall furnish chemical and physical test reports, traceable to the heat, lot and mill-certified, Certified Material Test Report, or equivalent. Copies of the test reports containing actual results of chemical analysis or tests of the physical properties of raw materials used for this contract shall be submitted to LBNL. The tests and resulting data shall be in accordance with, and meet, the acceptance criteria of the referenced material specification. These reports shall contain the signature and title of the authorized representative of the agency performing the test; shall state that the test results meet specified material requirements; and shall bear evidence of review and acceptance by the Supplier. The test reports shall be traceable to each piece of material by identification of the lot and/or heat treat number and shall provide traceability to the material manufacturer (mill).

E4 - Material Traceability

All items purchased in fulfilling this scope of work (except as specifically noted) shall be traceable to raw materials and the raw material manufacturer. The method of identifying material, parts, and components and the Supplier's traceability procedure shall be approved by LBNL.

E5 – Calibration and Control of Measuring and Test Equipment

Tools, gauges, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled and, at specified periods, calibrated with a source traceable to the National Institute of Standards and Technology (NIST) or other nationally recognized standards. The requirements of American National Standards Institute (ANSI)/NCSL Z540-1-1994, ISO 10012-1, or MIL-STD-45662 shall apply.

The Supplier's calibration system must comply with ANSI/NCSL Z540-1, ISO 10012-1, or MIL-STD-45662. All Certificates of Calibration will state, as a minimum, that all standards used are traceable to the National Institute of Standards and Technology, date of calibration, date of expiration, list those standards used, the condition of the equipment (Pass / Fail), and the technician's signature.

E6 - Process Certification

Special processes used in the manufacture or examination of items supplied on this contract, such as (but not limited to) foam application, heat treating, bending, welding, leak testing, magnetic particle inspection, penetrant inspection, ultrasonic inspection, foam void detection, radiography, surface treatment, and cleaning/cleanliness control, shall be qualified prior to use by the Suppliers. The qualification shall be documented and shall list the

applicable specifications (including revision) to which the processes conform, the name of the agency that performed them (if other than the Supplier), the date, and the authorized signature of a responsible representative of the Supplier. LBNL's QA representative or designee shall be afforded the opportunity to witness or approve special process qualification.

F1 - Nondestructive Examination (NDE)

All NDEs shall be conducted in compliance with the applicable provisions of the specifications and the scope of work document. Personnel and equipment used in performance of such tests shall have been evaluated and certified for the type of tests performed. For those NDE methods for which the American Society for Nondestructive Testing (ASNT) has defined certification criteria, those criteria shall be used. Supplier shall furnish reports of such NDEs, including technique sheets where applicable. These reports shall be as specified in the applicable specifications and/or the PO and shall be identifiable to the item or material tested, including specific sections, joints, or views of the item. These reports shall contain a statement of acceptance, the signature and title of the performer, and the signature and title of the authorized contract representative of the agency performing the tests. If that agency is other than the Supplier, review and acceptance by the Supplier shall also be shown. When items are serialized, the serial numbers shall appear on the report.

F2 - Welding Procedures and Weld Performance

The Supplier shall prepare detailed procedures for each type of welding and each characteristically different welding point to be used in performance of this scope of work. Welding procedures are subject to audit and approval by LBNL. The Supplier shall qualify welders, welding operators, tackers, brazers, and brazing operators, the welding/brazing/tacking procedures, and equipment to be used to the specification requirements. Qualification tests shall be performed in accordance with the detailed procedure and shall be documented by the Supplier prior to actual use in fabrication. All weld procedures are to be qualified to ASME Section IX, AWS, or other recognized national standards.

Repair of welds shall be performed by weld repair procedures approved by the Supplier's QA organization. Repair of welds is defined as correction of unacceptable conditions as noted by NDE, including visual inspection. Repairs shall receive the same level and type of NDE as the original weld and shall be documented.

Supplier shall provide a record of each weld made on the items furnished on this order. Welds shall be numbered sequentially and be traceable to each item on which they were performed. Weld maps, which give a pictorial guide to the location of each weld-by-weld number, may be provided to the vendor at the discretion of the LBNL Cognizant Engineer and OCA. A weld map shall accompany each weld record. Alternatively, as agreed to by the Buyer, in place of a weld map the Seller may vibroetch the weld number adjacent to the weld, having the placement of that number verified on the weld record.

G1 - Pressure or Leak Test Report

Each shipment shall be represented by test reports of actual test results of pressure and leak tests performed on the equipment. Reports shall be identifiable to the acceptance criteria of the items submitted and shall meet the requirements of the approved drawings and specifications. Such reports shall contain the signature and title of the authorized representative performing the tests and, if different from the Supplier, indicate acceptance by the Supplier.

G2 - Functional Test Plans

Functional testing of items shall be performed in accordance with documented test plans or procedures, and reported. Test plans shall include or reference test objectives, test prerequisites, needed instrumentation, environmental conditions required, applicable drawings and specifications, and acceptance criteria. Test plans or procedures shall be submitted for LBNL review and approval prior to test performance. Results of tests shall be reported and identifiable to the acceptance criteria and the items submitted. Reports shall contain the signature and title of the authorized contract representative of the agency performing the tests, and review and acceptance by the Supplier.

G3 - Functional Test Reports

Each shipment shall be represented by reports of test results which shall be identifiable to the acceptance criteria and the items submitted, and which shall meet the requirements of the contract document and applicable drawings and specifications. These reports shall contain the signature and title of the authorized contract representative of the agency performing the tests, and review and acceptance by the Supplier.

H1 - Material Marking

Material shall be marked with manufacturer's name or trademark, specification, type and grade of material, and heat and/or control numbers in accordance with the following applicable method:

Raw Material (sheet, strip, plate, bar, pipe, angle, beam, tubing) - Ink stamp or stencil applied to each piece along its entire length with 36-in. maximum between parallel markings. For austenitic stainless steels, the ink shall not contain more than trace amounts of harmful metals or metal salts such as zinc, lead, or copper, or halides such as chlorides or fluorides. Markers approved for nuclear use are acceptable type markers. In any event, ink or markers must be traceable to certifications by lot or batch numbers. Further, the use of gummed labels and tape identification is prohibited unless analytically determined to not cause damage to the materials.

NOTE: Material less than ½ inch in diameter or width may be tagged in place of strip marking. The tag shall include the data required above, and shall be attached to the material by tying or with tape. Wire may be used for this purpose. On stainless steel, wire shall be stainless steel. Use of ink or markers is acceptable providing it does not damage material and must be traceable to certifications by lot or batch numbers. Further, the use of gummed labels and tape identification is prohibited unless analytically determined to not cause damage to the materials.

Fittings - Vibrating marking tool may be used if the material thickness is .083 inch or greater.

When used, physical markings shall:

- (a) Be applied using materials and methods that provide a clear, permanent, and legible identification;
- (b) Not be detrimental to the function or service life of the item;
- (c) Be transferred to each part of an identified item when the item is subdivided; and
- (d) Not be obliterated or hidden by surface treatments, coatings, or installation unless other means of identification are substituted.

I1 - Supplier Submittal of Nonconformances and Corrective Actions

Supplier's program shall include control and documentation of nonconformances and corrective actions. Nonconformances and corrective actions shall be reviewed and approved by LBNL on an Approval Request/Variation Request(s) (AR/VR) prior to corrective action being implemented. Any approved nonconformance report shall be annotated on the receive C of C for each respective shipment.

The nonconformance report shall address:

- (a) The supplier-recommended disposition (for example, "use as is" or "repair") and provide technical justification for such disposition;
- (b) The technical or material requirements violated;
- (c) The requirement in the Supplier documents that has been approved by the Purchaser is violated;
- (d) The nonconformance can NOT be corrected by continuation of the original manufacturing process or by rework;
- (e) The item does NOT conform to the original requirement even though the item can be restored to a condition such that the item's capability to function is unimpaired; and
- (f) The purchaser shall evaluate and approve the supplier's recommended disposition to include verification of implementation of the disposition.

I2 - Approval/Variation Request Documentation and Reporting

Supplier, complete an AR/VR to request approval prior to effecting any change in LBNL approved (1) design, (2) workmanship standards, (3) manufacturing process, (4) test requirements, or (5) other documents that are required to be submitted for LBNL information, review, or approval, or to request LBNL approval for departure from subcontract or PO requirements applying to this procurement, in accordance with purchasing administrative requirements. The approved changes shall be identified in the supplier data package in accordance with Clause 310.

J1 - Proprietary Designs and Process

Supplier shall notify LBNL prior to effecting any change in the Supplier's or subtier supplier's proprietary processing or design. A meeting between the Supplier and LBNL shall be called to determine the method by which PO requirements will be met while accommodating the Supplier's proposed change. The results of this meeting shall be reconciled with the Supplier's approved design specifications and documented in accordance with Clause 220.

J2 - Supplier-Controlled Products

Copies of applicable specifications; drawings; installation, operation and maintenance instructions; and/or catalogues shall accompany the initial shipment of material. No changes in these documents shall be made for subsequent like shipments unless approved by LBNL.

J3 - Design/Shop/As-Built Drawings

Unless otherwise directed in the contract, two copies of design, shop, or as-built drawings shall be furnished. These drawings shall be reproducible, size "E," and on electronic media. Standard ANSI Y14.5 symbols will be used.

J4 - Assembly and Parts List

Supplier shall furnish for each assembly, or other end item, a reproducible copy of an assembly parts list tabulating the part number versus the serial or lot control number, age, and environmental data or lot control number, and traceability data of each part incorporated, including any LBNL/DOE-furnished components or subassemblies.

J5 - Identification and Control of Age-Controlled Items

Supplier shall identify each item, package, or container of material or chemicals having limited shelf life with the lot or batch number traceable to the manufacturer and to certifications. Additionally, the cure date or date of manufacture, expiration date, storage temperature, humidity, and special handling conditions shall be provided. This information may be provided with written instructions or certifications traceable to the item. Material having less than 90 percent of the shelf life still available shall not be supplied to LBNL, except with the approval of LBNL.

J6 - Cleaning and Cleanliness Controls

For design contracts, the design shall take into consideration the requirements for cleaning and cleanliness controls that must be imposed before and during fabrication, shipment, and use of assemblies. For fabrication contracts, controls shall be imposed to comply with said requirements or the cleanliness controls specified by the PO. Cleaning and cleanliness control procedures shall be submitted for LBNL review and approval prior to initiation of the fabrication process.

K1 - Package Identification

All packaged items delivered in fulfilling this contract shall be identified by a visible, permanent method on an exterior surface of the package. Package identification shall include at least the following:

- (a) Drawing and Revision Number;
- (b) Part Number; and
- (c) PO Number.

K2 – Packaging, Shipping and Handling

Parts shall be individually packaged and preserved to prevent damage in shipment. Boxes, crates, and other shipping containers will be of sufficient strength to prevent breakage in transit. Seller shall provide adequate inspection control of the preservation, packaging, and shipping process to assure all products are complete and all required data has been provided.

K3 - Supplier Data Package (SDP) Guidelines

Supplier shall deliver to LBNL procurement, two copies of data in the form of an SDP as required by the PO. The content and form of the package are specified on the order either as a QA clause or in the procurement specification. The size of the data package may range from a few pages consisting of a certification of conformance and nonconformance reports to a large volume of documentation including such things as inspection reports, test reports (including NDE reports), manufacturing and inspection travelers, checklists, performance data, installation procedures, operating procedures, maintenance procedures, as-built drawings, and specifications. It shall reference the contract/PO number and be mailed to:

Lawrence Berkeley National Laboratory, One Cyclotron Road, Berkeley, California 94720
Attention: *“Purchasing representative's name as it appears on the order”*, LBNL Procurement Department

Such documentation shall be suitable for microfilming.

LBNL requires the submittal of SDPs for a number of reasons other than the need for QA documentation of the order. The package is retained and used to (1) revise drawings and specifications, (2) provide a history file in case of an unexpected failure, and (3) provide as-built data for future reference as required by our customers, which may be verified by audit. It is essential that SDPs be complete, accurate, legible, and submitted in a timely manner as required by the order.

The following direction is provided to assist in complying with LBNL requirements:

(a) Completeness

Advanced planning and organization are key elements in achieving a complete data package. It is suggested that a list of order requirements for submittals be made in the form of an index which references paragraph numbers in the order. The index should be used to assemble and check the data package. A copy of the index should be submitted with the data package. An independent review should be made to ensure that forms have been properly completed; drawing numbers, part numbers, and serial numbers have been included; test reports contain actual results and are signed; inspection data identifies each characteristic to the drawing; and applicable limits are identified.

(b) Accuracy

Accuracy depends upon the discipline of the personnel taking and recording the data. LBNL prefers a copy of the raw data or a computer printout to a neatly transcribed tabulation of data. Errors are not to be erased or obliterated but shall be corrected by lining out the incorrect data and entering the correct data so that the corrected data is identifiable. The use of correction fluid is not permitted. Each corrected entry shall be signed and dated by the corrector. Inspection and test data that must meet a tolerance or limit should have an independent review to ensure compliance. Any nonconformance must be identified, properly documented, and dispositioned.

(c) Legibility

Supplier data submitted to LBNL must be legible and in compliance with ANSI Y-14. Most Supplier data are reviewed by LBNL personnel upon receipt; however, in some cases, data may not be reviewed until after they have been microfilmed; therefore, the original data must be clear enough to be copied and microfilmed. Data must be reviewed to ensure that the submitted copies are legible and reproducible.

Data that are of poor quality, illegible, or not reproducible may be rejected and rework may be required by the Supplier at no added cost to LBNL.

(d) **Timeliness**

LBNL requires that the SDP accompany each shipment. Supplier schedule should allow sufficient time to generate the required data, assemble the data into a package, and obtain the required reviews. A final review should be performed by responsible Supplier management. Where LBNL source inspection is required, time should be allowed for LBNL QA representative review. LBNL QA representatives have instructions to withhold release for shipment until the SDP is in order.

K4 - Supplier QA Records Requirements

The Supplier shall maintain quality assurance records prepared under this purchase order for the period of time established in its LBNL Qualified Suppliers List-accepted quality assurance program or for a minimum of * [time in months, years, etc.], whichever is longer. At the end of this period, and prior to making final disposition (including destruction) of these records, the Supplier shall notify the Buyer in writing and allow the Buyer the opportunity to take possession of the records. The Supplier shall also notify the Buyer in the event that the Supplier is being purchased by another entity or is going out of business, to allow the Buyer the opportunity to take possession of the quality assurance records prepared under this purchase order.

*Specify the retention time of the QA records (e.g., 6 months, 6 years, etc...)