PROJECT MANAGEMENT DOCUMENT	Doc. No. PM-391-000-01 R1	LUSI SUB-SYSTEM Management

Quality Implementation Procedure (QIP)

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Rev.	Description	Approved
0	Initial Release	June 29, 2007
1	Formatted to meet cover sheet requirement.	May 2, 2008

QUALITY IMPLEMENATION PROCEDURE (QIP)

for
The Linac Coherent Light Source
Ultrafast Science Instruments (LUSI) Project

Lead Program Office:

Office of Basic Energy Sciences
Office of Science

Stanford Linear Accelerator Center
for the Department of Energy

PM-391-000-01 R1

A. Introduction

The LCLS Ultrafast Science Instruments (LUSI) Project Quality Implementation Procedure's (QIP) is based upon and reflects the project's understanding and approach to the requirements and intent of DOE Order 414.1C, "Quality Assurance". Through a graded approach to quality assurance, the LUSI Project strives to efficiently apply resources to activities and facilities, which will result in achieving the greatest benefit. While ensuring that LUSI is operated in a manner which protects the environment and the health and safety of both the public and SLAC employees, management also strives to eliminate unproductive activities that add to costs, or are unnecessarily burdensome.

Not all items, processes, activities, and services have the same effect on health and safety, reliability, environmental protection, or program objectives. Therefore, the LUSI Project uses a graded approach to determine the applicability of the QIP requirements to specific activities and the rigor with which they should be applied. Considerations include:

- Environment Health and Safety
- Compliance with SLAC Policies and Regulations
- LUSI Project Mission and Programmatic Impact
- Laboratory Protection – Cost/Investment
- Impact on Scientific Results (e.g., importance of data, reproducibility of results, uniqueness of product).

The objective of the LUSI Project graded approach is to ensure that activities are managed through adequate systems that are commensurate with the scale, cost, complexity, and hazards of the work being performed. LUSI project management and cognizant engineers are responsible for identifying the activities that are subject to these requirements, and for carrying out an evaluation to justify the degree of rigor to be applied. The LUSI Project QA (Quality Assurance) Manager's role is to serve in a consulting and assessment capacity with respect to QA issues.

B. Quality Assurance Policy for the LUSI Project

All LUSI Project staff members are responsible for acquiring a sufficient understanding of these QA principles in order to efficiently and effectively implement the specific requirements as it applies to their work. The cognizant engineer of an item, component, system, or process will be the key person for ensuring that an appropriate level of documentation is generated and properly maintained to reflect adequate implementation of the principles herein.

1.0 QA Program

1.1 Purpose and Scope

The purpose of this QIP is to detail the QA plan to promote the functionality, reliability, availability, and maintainability of LUSI. This document contains policies for:

- Designing in quality and reliability.
- Promoting early detection of problems to minimize failure costs and reduce negative impact on schedules.
- Developing appropriate documentation to support fabrication, installation and operational requirements.
- Establishing methods to identify critical systems and to release these systems based on proper review.
- Assuring that personnel are trained as needed before performing critical activities, especially those activities that have environment, safety or health consequences.
- Defining the general requirements for design and reviews including environment, safety, and health issues related to SLAC and interfacing hardware, software, and processes.
- Preventing conditions and situations which might compromise the accomplishment of the scientific and technical goals of the project.

This QIP was prepared to meet the SLAC Office of Assurance "Quality Implementing Procedure Requirements", SLAC-I-770-0A17S-001-R000, and the applicable requirements of DOE Order 414.1C, "Quality Assurance". The LUSI QIP meets the contract requirement of the DOE with Stanford University for a documented Quality Assurance Program.

1.2 Organization

The LUSI Project staff reports to the Project Director for the LUSI Project who in turn reports to the LCLS Project Director. Figure 1 shows the line organization to the division level.

1.3 Responsibilities and Authorities

1.3.1 LUSI Project Director

The Project Director has the overall project management authority and directs the LUSI Project, the associated research and development in support of instrument fabrication and commissioning.

The Project Director is responsible for project planning, for achieving project cost/schedule/quality objectives, for ES&H compliance, and for coordinating the activities of the project. In addition, the Project Director approves LUSI staffing plans and actions.

Other responsibilities and duties of the LUSI Project Director are described in the LUSI Project Execution Plan. Specific QA responsibilities of the Project Director are also described in this QIP and/or QA procedures.

1.3.2 Project Manager, Chief Engineer and Control Account Managers

The Project Manager, Chief Engineer and Control Account Managers are responsible for ensuring the implementation of QA/QC practices and procedures in accordance with the QIP for activities affecting quality within their respective area of responsibility. The other responsibilities key project personnel are described in the LUSI Project Execution Plan.

1.3.3 QA Manager for the LUSI Project

The QA Manager for the LUSI Project is responsible for:

- Maintaining the LUSI Project QIP.
- Providing consultation to the cognizant engineers to implement QA-related activities (for example, the QA Manager may provide guidance on developing inspection plans, developing vendor control programs, etc.).
- Providing or coordinating project-specific QA training for LUSI Project members.
- Reviewing completion of QA-related milestones as provided in project schedules.
- Working with the Project Manger and Chief Engineer to avoid situations where completion of critical planned QA activities are compromised due to cost, schedule or other constraints.
- Recommending to the LUSI Project Director that work be stopped based on an investigation that indicates that work is of inadequate quality.
- Performing QA audits as requested by the LUSI Project Director.
- Participating individually or as part of a team in vendor surveys, vendor qualifications, and source inspections.

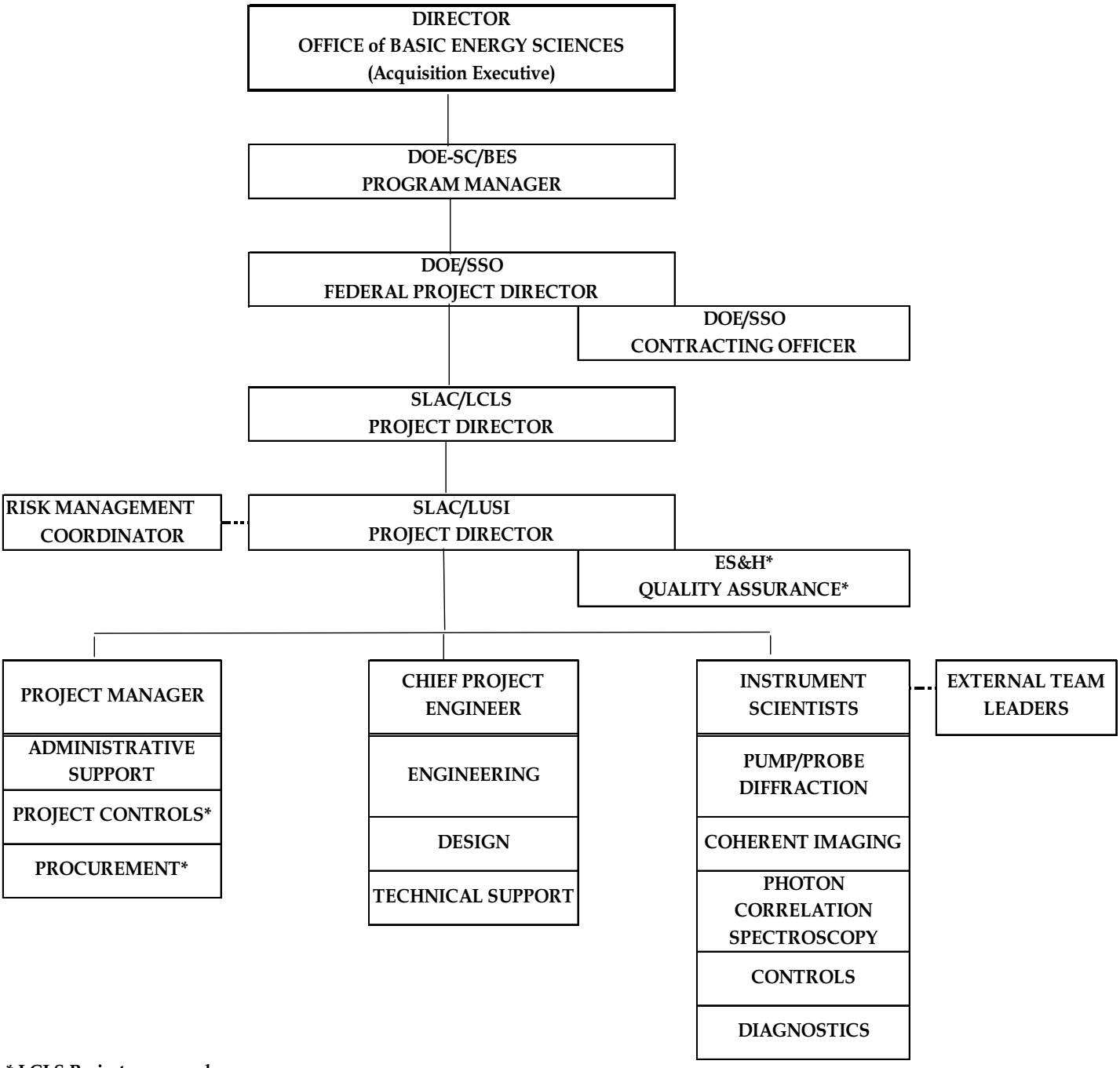
1.4 Stop Activity Authority

1.4.1 Relating to Work of Inadequate Quality

Any individual involved in the project who becomes aware of an activity or workmanship that he or she believes to be of inadequate quality should bring the condition(s) to the attention of the their supervisor. It is the responsibility of the supervisor to investigate the condition(s) believed to be of inadequate quality, to communicate the problem to the LUSI Project Management, and to take appropriate corrective actions based on the condition(s). Project management has the authority to stop work of inadequate quality if deemed appropriate. The role of the Project QA Manager with respect to making recommendations to stop work of inadequate quality has been previously described in Section 1.3.3.

1.4.2 Relating to Hazardous Operation or Conditions

The policy on stop activity authority relating to hazardous operations or conditions is provided in Chapter 2 of the SLAC ES&H Manual. This policy is interpreted to include stop activity authority for any LUSI supervisor or any member of the project team. Issues relating to stop activity based on potentially hazardous operations or conditions shall be communicated to the LUSI/LCLS Project ES&H Office and LUSI Project Management.



* LCLS Project personnel

FIGURE 1.

2.0 Personnel Training and Qualification

2.1 LUSI Training and Job Proficiency

The training program for LUSI staff consists of required and recommended training commensurate with the scope, hazards, and complexity of their job functions to assure proper understanding of the specific principles, techniques, and requirements of their assigned tasks. The program also includes job-specific and task-specific ES&H training and certification. On-the-job training as appropriate, and/or a demonstration of initial proficiency conducted and/or witnessed by the employee's supervisor, is also required. Professional personal development courses are part of the training requirements.

Training is provided by qualified instructors using formal classroom sessions, required reading assignments, hand-on workshops, and other applicable training methods or combinations of methods. Periodic retraining or ongoing training, including courses and seminars given outside of SLAC, is conducted to maintain each employee's job proficiency and to improve performance.

The responsible LUSI supervisor or manager establishes, by means of a position description, the minimum requirements, with respect to education, experience, and other initial qualifications. The selecting supervisor/manager makes a determination of the candidates' initial qualifications as compared with the minimum requirements. The Personnel Department verifies and documents, relevant education and experience.

Employees matrixed from all divisions are treated identically in the development of individual training plans as they relate to ES&H classes. ES&H training for subcontractors and employees of agencies that provide skilled persons for short-term employment by SLAC shall be determined by the LUSI University Technical Representative, Contract Administrator, or working supervisor.

2.2 Monitoring Training Requirements and Status

The SLAC ES&H Training Database identifies the required training for all LUSI personnel, status of training, and completion dates of the training. The database is monitored by the LUSI ES&H Office. Required courses are tracked automatically by the database based on a supervisor's job assessment. Supervisors are responsible for ensuring that their staff complete all required training.

3.0 Quality Improvement

It is LUSI Management's intent that all of our personnel be continually alerted to the LUSI QA Program objectives of preventing conditions and situations that may compromise the successful accomplishment of the technical, scientific, ES&H, and QA goals and obligations of the project. There should be a continually improving level of quality in meeting these goals and obligations with the participation of everyone in the early identification, documentation, and remedy of problems that might results in excess costs or schedule delays, among other consequences.

LUSI management encourages a "no fault" attitude regarding the identification of problems that compromise either facility safety or reliability.

3.1 Corrective Action

Action will be taken, as appropriate, to rectify and prevent recurrence of significant conditions adverse to quality or environment, safety, and health. Quality related information will be reviewed and data analyzed to identify items or processes needing improvement. The decision to initiate any corrective action will also be based upon an evaluation of the seriousness, and the adverse cost and schedule impact of the problem relative to the cost and difficulty of its correction.

The primary responsibility for eliminating defective elements and nonconforming articles, and for correcting conditions which have, or would initiate these problems rests with the individual group responsible for performing the tasks or producing the articles. The cognizant engineer or scientist is responsible for seeing that all appropriate corrective actions are adequate and taken in a timely manner. If the cognizant engineer, scientist, or QA Manager believes that a correction is not adequate or timely, the problem will be documented and brought to the attention of the Project Director for resolution.

3.2 SLAC Occurrence Reporting

Incidents which are required to be reported in accordance with DOE G231.1-1, "Occurrence Reporting and Performance Analysis", are a source of data regarding quality improvement opportunities. Occurrence reporting, investigation, and resolution are conducted in accordance with the provisions of the SLAC Workbook for Occurrence Reporting.

3.3 Segregation of Nonconforming Items by User

Items that do not meet requirements shall be segregated and placed into a designated holding area until their proper disposition can be determined. When segregation is not possible or impractical, other precautions are to be taken to preclude inadvertent use or start-up of such equipment. Locking-out, tagging, or suitably marking are suggested means for controlling these cases.

3.4 Disposition and Tracking of Quality Problems

The cognizant engineers shall expedite the disposition of quality problems and track and verify the completion of the authorized improvement or corrective actions.

Repair histories of beamline components shall be analyzed for trend development that may require redesign of a LUSI designed component, or the commercial procurement of a more reliable item.

Corrective action includes efforts to correct similar conditions at SLAC and to preclude recurrence of the deficiency or problem. A root cause, or lessons-learned analysis may be performed commensurate with the significance of the problems.

The LUSI Project QA Manager shall bring to the attention of the Project Director quality-related deficiency problems with significant impact on the LUSI Project for development of a corrective action plan.

3.5 Improvement Teams

Improvement teams may be appointed by the Chief Engineer or Project Director to work on resolving significant problems or on improving operations. These teams may be composed of persons from several groups. These teams could work on generic problems such as difficulties with the timeliness of procurements, or the lack of coordination of design activities. These groups will be facilitated by a facilitator appointed by the LUSI Project Director.

4.0 Documents and Records

4.1 Document Control

The primary purpose of this QA element is to help prevent the inadvertent use of incomplete, erroneous (unchecked), or superseded information. Also, the options of formally controlled distribution of documents helps assure that the right information has been provided to the right people at the right time.

Documents subject to control under this section are technical documents and include, but are not limited to, the following:

- Drawings
- Specifications
- Technical Procedures
- Procurement Specifications
- Test Plans

4.1.1 Preparation

Documentation shall be initiated and prepared in accordance with the procedures, standards, and requirements of the parent organizations, such as the Mechanical Design Group, ES&H Division, and the Controls Department from which LUSI personnel have been matrixed.

All LUSI quality-related documents shall be uniquely identified, including revision and date. The documents shall be initialed/signed by the originator and the reviewer/checker, who is usually the lead engineer. Critical documents may also be reviewed and signed by the Chief Engineer or Project Director, but no fewer than two sets of approvers, must appear on the document prior to formal distribution.

4.1.2 Distribution

Distribution will be accomplished in accordance with the originator's instructions and general needs of other personnel. File copies will be retained by cognizant staff and Master Records Lists will be continually updated. It will be the document user's responsibility to assure that he or she has the latest version of a document by checking it against one of these list.

Although the authority for control of document distribution may be delegated to clerical staff through appropriate work instructions, the responsibility for the controlled distribution of such documented information rests with the cognizant engineer or other person responsible for the information or data at issue.

4.1.3 Revisions

Technical changes and major revisions to controlled documents are reviewed and approved by the same organization that originally reviewed and approved the documents. The updated documents shall be clearly identified with sequenced revision numbers and dated with the effective date of the new information. Distribution of the document must be made promptly after approval of the revision.

4.2 Records Management

The documented evidence of the quality of completed work will be retained for use during the course of an activity as well as for historical records. Sufficient records will be required and maintained to furnish objective evidence of actions affecting quality. The QA records will be legible and traceable to the phase of the activity, and to the item, process or operation they apply to. The records shall be retrievable for use in evaluation of acceptability and for verification of compliance with the QA program requirements.

Computer files shall be regularly backed up and proper storage techniques used to prevent loss or damage to quality-affecting records.

5.0 Work Processes

LUSI Project Management is expected to provide the resources and support systems needed to enable their staffs to do their work using methods that promote successful completion of tasks, conformance to LUSI requirements, and compliance with ES&H rules and regulations.

Managers and team leaders are responsible for specifying which work is sufficiently complex, involves hazard, has a potential ES&H impact, or is of sufficient programmatic importance that it requires written procedures, instructions, or drawings. Procedures, instructions, and/or drawings are then prepared for those activities and are required to be used.

Prior to use, procedures and instructions are reviewed for applicable technical and administrative content including:

- Approval signatures and effective date
- A unique title or other identifier
- Purpose and scope
- References (sources of requirements)
- Procedure and responsibilities

5.1 Special Process Procedures

To control and verify the results of special processes, such as those used in welding, heat treating, non-destructive examination, critical sub-assembly fabrication, first article component testing, etc., those processes shall be performed by qualified personnel using approved instructions or procedures.

These procedures address the following:

- Acceptance criteria
- Ambient conditions and requirements
- Qualification and certification requirements for procedures, specifications, and personnel
- Equipment or calibration requirements
- Parameters for which verification and/or documentation is required

The cognizant engineer shall be responsible for the researching, incorporating, and referencing the applicable national, industrial, professional, or other technical data, codes, standards, guides, and practices that have been employed for the portion of the work under his supervision. Where it has been appropriate to deviate from applicable codes, standards, and practices, the rationale for doing so should be documented when safety considerations are involved.

5.2 Item Control and Protection

Items, including consumables, shall be identified and controlled to ensure their proper use and prevent the use of incorrect, unaccepted, or unidentified items. The project will define a system of controls to ensure that items are handled, stored, shipped, cleaned, and preserved to prevent them from deteriorating, being damaged, or becoming lost. These controls will be established according to instructions, specifications, drawings, or technical manuals for items that are sensitive, have a high cost, or have been identified as having a significant impact on the environment or schedule.

5.3 Handling, Storage, and Shipping of Items

Special requirements for the handling and shipping of items to prevent damage or deterioration will be contained in specifications, drawings, or supplier documents that become part of the documentation package for the item.

Handling and shipping processes should allow for different methods to provide appropriate care handling and shipping in accordance with the manufacturer's recommendations. Handling and shipping provisions should consider types of containers, preventive maintenance, and other environmental or safety considerations applicable to the items.

Suppliers of items will direct, in procurement documents, any special protective measures that should be observed during storage. If any such measures are required, the recommendations of supplier will be factored into the storage of the subject item(s). Provisions will be established for the control of consumable materials and materials with limited shelf life.

6.0 Design

The Project staff shall plan, develop, define and control the design of LUSI and its components in a manner that will assure the consistent achievement of the producibility, performance, safety, reliability, maintainability, and availability objectives. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into technical specifications, drawings, and engineering notes. These design output documents shall be proposed, completed, reviewed, and approved in accordance with other sections of the LUSI QIP and SLAC engineering standards, procedures, and practices. Designs shall be verified through activities such as independent technical reviews, building of first articles, and first article testing as necessary.

6.1 Design Interface

Design interfaces and corresponding responsibilities are defined so that design efforts are effectively coordinated among participating organizations. Changes to approved design inputs, including reasons for the changes, are identified, approved by the appropriate LUSI group, documented, controlled, and made retrievable.

6.2 Design Outputs

Design outputs, such as drawings, specifications, results of scientific investigations, computer programs, etc., are established in formal written documents that have unique identification and revision status and are approved prior to issue. Design output documents shall be in sufficient detail to permit design adequacy verification and evaluations. These documents show evidence that the required reviews and approvals have been accomplished prior to release for use in other design activities.

6.3 Design Verification

Technical design reviews are performed by review committees made up of persons who possess the necessary expertise to critically evaluate the designs. Generally, these reviews are held for the Conceptual Design, Preliminary Design and Final Design. The reviewers are recognized experts and may include persons from LUSI if they have no direct responsibility for the design. All technical reviews are documented as well as the LUSI Project response to the reviewers' recommendation.

Qualification testing of first articles may be used to verify the design of selected technical components. The tests are planned and the results documented by the cognizant scientist or engineer.

Some designs may be verified by the use of alternative calculations and analyses to verify the correctness and accuracy of the original calculations and analysis. The appropriateness of assumptions, input data used, computer program or other calculation method used are subjected to independent technical reviews in accordance with the appropriate procedure.

6.4 Computer Programs

When new programs are developed or existing programs are modified, planned verification and validation methods shall be employed to confirm the program integrity and evaluate function, performance, and interfaces for consistency.

6.5 Configuration Control

The LUSI Project Execution Plan specifies the basis for establishing the technical baselines and the controls for obtaining the approval of design changes. The control of design documents such as drawings and specifications is specified in Section 4.0 of this QIP.

7.0 Procurement

Procurements from vendors under a purchase order or subcontract are accomplished in accordance with the SLAC procurement policies.

Advance procurement planning is an essential and integral part of the procurement process and includes determination of the anticipated QA/QC activities for a particular procurement. The guidelines for preparing advance procurement plans are contained in the LUSI Acquisition Strategy.

7.1 Selection and Evaluation of Vendors

Potential suppliers of critical, complex, or costly items or services shall, prior to the award of a contract, be evaluated in accordance with predetermined criteria, to ascertain that they have the capability to provide items or services that consistently conform with the technical and quality requirements of the procurement. The determination of which suppliers shall be evaluated will be made by LUSI Project technical personnel, in conjunction with the LUSI QA Manager and the Contract and Procurement Buyer/Contracts Specialist.

The evaluation may be based upon the results of one, or a combination of, the following methods: a review of the supplier's quality history with SLAC; a survey of the supplier's facility for the purpose of reviewing the adequacy of the quality system; a review of the supplier's quality history in providing the same or similar items or services to other national or international laboratories, universities, or companies.

7.2 Procurement Documents

It is essential that documents included in the procurement package be controlled per Section 4.0 of this QIP.

The cognizant engineer is responsible for assuring that applicable design bases and other technical and quality requirements are included or referenced in a specification, statement of work, purchase order or separate enclosure for purchased items and services. The QA requirements specified for a given procurement are based upon considerations of safety, programmatic importance, complexity and intended application of the item or service.

Changes to procurement documents shall be reviewed and approved by the same responsible persons that approved the original procurement document. The Purchase Office has the responsibility to ensure that the contents of the procurement documents are accurately and correctly transferred to the relevant contract or purchase order.

7.3 Inspection, Testing and Surveillance

When necessary for the evaluation of the quality of an item or service, the vendor or SLAC organization, as appropriate, is requested to provide inspection and/or test reports. The cognizant technical representative reviews these reports and determines the acceptability of the data contained in the reports.

For some procured items it is necessary that a LUSI representative visit the vendor's facility to perform source surveillance during the performance period and/or upon completion of the item(s) to verify quality. When such is the case, critical inspections and tests to be witnessed at the vendor's plant are to be specified and documentation of the results made.

7.4 Certificates of Conformance

When certificates of conformance are required from vendors, the requirement is specified in the procurement documents. Certificates of Conformance are required for raw materials and fasteners used in fabrication of items affecting quality. Certificates of conformance may be requested from vendors producing items to LUSI specifications or drawings when other quality verification methods are not employed.

7.5 Counterfeit/Suspect Parts

Counterfeit/suspect parts are prohibited. When counterfeit/suspect parts are found, they will be identified, segregated, and disposed of in accordance with requirements.

7.6 Nonconformances

Any items not meeting the purchase order specifications will be segregated from accepted items. The cognizant engineer may need to stop payment for such items and should initiate action for their return to the vendor.

8.0 Inspection and Acceptance Testing

8.1 Inspection

Inspections of technical components shall be the responsibility of the cognizant engineers. They designate personnel to perform or arrange for inspections of technical components. When personnel within the LUSI Project are designated to perform inspections, independence of responsibility for the item or activity may not be possible due to the uniqueness and special nature of the items or activities being inspected. However, when possible, personnel performing inspections are independent.

Inspections required to verify conformance of an item or activity to specified requirements shall be planned and the execution of the inspections documented. Such plans and instructions shall be included in appropriate specifications, drawings, purchase requisitions, special work instructions, or technical notes.

8.2 Test Control

Tests required to verify conformance of an item to specified requirements and/or to demonstrate that items will perform as intended in service are planned and documented in test plans, procedures or instructions. The characteristics to be verified or tested and the methods to be employed are specified. Test results are to be documented as specified in the test specification documents. Results of tests performed to verify designs are reviewed and evaluated by the cognizant scientist or engineer.

8.3 Control of Measuring and Test Equipment

The cognizant LUSI scientists and engineers specify the requirements for calibration of measuring and test equipment (M&TE) under their control and document such requirements in an appropriate format. The calibration requirements, frequency of calibration, and recall system for each item of equipment shall be established on the basis of purpose, accuracy required, stability, and amount of usage.

When M&TE is suspect or found to be out of tolerance, it is immediately removed from service until the data can be evaluated and corrective action implemented. Pending a calibration check, an investigation is initiated to determine the impact to the Project of any questionable data.

The LUSI QA Manager performs surveillance of the M&TE used for project activities affecting quality.

9.0 Management Assessment

9.1 Self Assessment

The QA Performance objectives that are outlined in this QIP shall be regularly monitored by the LUSI QA Manager on behalf of LUSI Management; the assessments resulting from this ongoing surveillance shall be routinely reported to the Project Director. In addition, the LUSI ES&H Office will conduct random surveillance of project activities to assure that environment, safety, and health requirements are being met by line management and subcontractors. The LUSI ES&H Manager has stop-activity authority in this role, and will report directly to the Project Director to assure that appropriate corrective actions are implemented for any deficiencies that are discovered.

In particular, the LUSI Project Management shall rely upon and evaluate line management and supervisor's routine observations and survey of their group's accomplishment of assigned quality-affecting activities. Line management and supervisors shall take an active role in seeking excellence and improving performance; they shall encourage personnel to look for ways to improve performance and correct problems as an integral part of the normal work routine.

The LUSI Project will participate in formal self-assessments in accordance with SLAC ES&H Manual Chapter 33, "Line Management Self-Assessment".

9.2 Project Reviews

The LUSI Project Director is committed to an on-going of project reviews. Results of project reviews will be used to identify, correct, and prevent management problems that hinder the achievement of the projects objectives.

10.0 Independent Assessment

10.1 Audits of the LUSI Project

The SLAC Office of Assurance is responsible for conducting independent assessment activities throughout SLAC. Thus, Office of Assurance plans, schedules, conducts, reports upon, and tracks corrective action implementation resulting from assessments of the LUSI Project.

10.2 SLAC Citizen Committees

Items with environment, safety, and health impact are subject to citizen committee review. These committees review project proposals for environment, safety and health problems. The SLAC citizen committees and their function are detailed in Chapter 31 of the SLAC ES&H Manual.

10.3 Facility Advisory Committee (FAC) Review

The LUSI Facility Advisory Committee will advise SLAC and LUSI management on the development of the LUSI Project through its several phases. The committee is expected to meet twice a year to review the LUSI Project.

10.4 Department of Energy Review

LUSI will be subject to DOE progress reviews approximately every six months for the duration of the project.