Quality Assurance Program Plan
for the
Thomas Jefferson Site Office

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Revision Log

Revision No.	Description of Change	Effective Date
0	To comply with DOE Order 414.1C, *Quality Assurance*.	August 14, 2006
1	Plan was better aligned with the ten (10) criteria from DOE Order 414.1C and the content of the revised standard operating plans and procedures.	April 18, 2008

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Policy Statement

The mission of the U.S. Department of Energy (DOE) Thomas Jefferson Site Office (TJSO) is to ensure, through partnership with the Thomas Jefferson National Laboratory Facility (JLab) contractor, the successful conduct of the research mission of the laboratory. We provide enabling support to further the laboratory's mission to operate a world class user facility for conducting nuclear physics research.

It is TJSO's policy to establish, implement, and maintain an effective Quality Assurance Program (QAP) that supports compliance with applicable Federal, State, and local regulations and DOE Orders and requirements. In doing this, the TJSO helps fulfill the mission and ensures that the risks and environmental impacts are identified and minimized and that safety, reliability, and performance are optimized. Further, it is TJSO's intent to establish a quality culture and work environment that encourages setting and maintaining effective standards, identifying and resolving problems, and emphasizing a continual pursuit of improvement within the TJSO and with JLab, its suppliers, the public and other stakeholders.

The TJSO QAP Plan establishes quality requirements for all programs, projects, and activities implemented by the TJSO. It is the responsibility of all TJSO personnel to achieve quality, identify problems, and recommend improvements. TJSO's employees define and achieve quality, recommend and promote improvements in the quality of their work and oversight processes, and identify, document, and resolve problems. The TJSO QA Coordinator verifies the achievement of quality.

Employees are provided with the necessary information, tools, support, and encouragement to perform their tasks in a quality manner. In addition, employees are provided the authority to make decisions at the lowest effectual level where technical expertise is localized. By empowering employees with authority, they are encouraged to look for better, safer, and more efficient ways of accomplishing their work.

The TJSO QAP requirements, as described in this QAP Plan, have my full endorsement and complete support. Implementation of the applicable QAP Plan requirements, responsibilities, and authorities is mandatory for all TJSO personnel.

James A Turi
James Turi, TJSO Manager

April 18, 2008
Date

1.0 OBJECTIVE

The main objective of the U.S. Department of Energy (DOE) Thomas Jefferson Site Office (TJSO) Quality Assurance Program (QAP) is to ensure that its oversight processes meet or exceed the Office of Science's expectations. The Thomas Jefferson National Accelerator Facility (JLab) has been designated as a low hazard, non-nuclear facility. The TJSO QAP is a management system which ensures that the TJSO's missions, policies, and objectives are integrated into standard business practices and work processes for Federal operations and contractor oversight.

The QAP is designed to assure that the employees are responsible for achieving and maintaining quality. One of the specific goals is to improve performance through continuous improvement that includes rigorous assessment and corrective action. In consideration of the provision in DOE Order 414.1C, *Quality Assurance*, that encourages incorporation of existing consensus standards for managing QA programs, the TJSO selected American National Standards Institute (ANSI)/International Organization for Standardization (ISO)/ASQ 9001-2000, *Quality Management Systems - Requirements*, as the consensus standard to utilize.

The QAP is fully integrated with the TJSO Integrated Safety Management System. The principles of quality assurance (QA) and Integrated Safety Management are embedded in all TJSO's activities. Safety, health, and quality requirements are integrated at all levels of activities. In addition, the TJSO has the responsibility to ensure that JLab's Environmental Management System is integrated with its QAP and Integrated Safety Management System.

2.0 SCOPE

This QAP Plan (QAPP) applies to all management and staff engaged in the conduct of TJSO work (primarily contract oversight) activities. This QAPP outlines the goals and provides the overall framework for incorporating quality assurance elements into TJSO's operations and procedures.

3.0. REFERENCES

1. DOE Order 414.1C, *Quality Assurance*, dated June 17, 2005.
2. *Office of Science Quality Assurance Program*, dated July 2006.
3. ANSI/ISO/ASQ 9001-2000, *Quality Management Systems – Requirements*, dated December 13, 2000.
4. DOE Guide 414.1-1A, *Management Assessment and Independent Assessment Guide*, dated May 31, 2001.
5. DOE Guide 414.1-2A, *Quality Assurance Management System Guide for Use with 10 CFR Part 830, Subpart A; and DOE O 414.1C, Quality Assurance*, dated June 17, 2005.
6. SC-Wide Quality Assurance Program Description, SCMS Revision 1.0, April 1, 2008

4.0 QUALITY ASSURANCE PROGRAM CRITERIA

The TJSO QAP has three major criteria: management, performance, and assessment. Management criteria include requirements for QAP, training and qualification, quality improvement, and documents and records. Performance criteria include requirements for work processes, design, procurement, and acceptance and testing. Assessment criteria include management and independent assessment.

4.1 Program

The TJSO organizational structure is described in an approved organization chart. The responsibilities and authorities for implementing the TJSO's mission are described in the TJSO Functions, Responsibilities, and Authorities Manual (FRAM). The high-level responsibilities that are specific to implementing the QAP are presented below.

Site Manager

- Defines the QA Policy for TJSO.
- Has overall responsibility for establishment and implementation of the TJSO QAP.
- Ensures that implementing plans and procedures are developed and maintained.
- Submits revisions to QAPP to the Office of Science, Deputy Director for Field Operations, for approval.
- Approves revisions to the JLab QA Plan, as delegated by the Program Secretarial Officer.
- Periodically reports the results of management assessments and self-assessments to the Deputy Director for Field Operations.

Deputy Manager

- Supports the TJSO Manager and is responsible for the Manager's duties when the Manager is not available.
- Ensures that JLab implements its QA Plan.
- Directs the performance of management assessments and self-assessments.

QA Coordinator

- Is responsible for revision and maintenance of the QAPP.
- Advises senior management on all issues associated with implementing the TJSO QAP (including any issues associated with the JLab QAP implementation).
- Prepares and/or reviews implementing plans and procedures.
- Provides QA training to TJSO staff.
- Reviews revisions to the JLab QA Plan.
- Reviews changes to the JLab contract that could affect the quality of its products and services.

- Ensures that periodic QA assessments are conducted to verify that the JLab QAP and this QAPP are being effectively implemented.
- Responsible for monitoring and providing feedback to TJSO staff on suspect/ counterfeit items (S/CI) identified by JLab.

Facilities Operations Managers and Federal Project Directors

- Monitors JLab's activities to assure that applicable QA requirements are being met.

TJSO Office Manager

- Manages the TJSO records management and document control systems.

All TJSO Staff

- Ensures that the applicable QA and technical requirements are included in contracts and purchase orders, including the contract with JLab.
- Implements the standard operating plans and procedures (SOPPs) that implement the QAPP in accordance with management direction.
- Makes recommendations to management and the QA Coordinator on ideas and ways to improve the QAP and the SOPPs.
- Stop work in progress or notify appropriate personnel when unsafe work conditions are observed.

Interface controls between TJSO and JLab are described in the contract with the laboratory and the Contract Management Plan. Purchase orders with other TJSO suppliers also discuss interfaces. Interfaces with Office of Science and other DOE organizations and Site Offices are documented in memorandums of understanding, service arrangements, etc., as appropriate.

It is the intent that the TJSO staff utilizes a graded approach to implement the QAP such that resources are committed at a level commensurate with the risks being managed. Not all items, services, and processes have the same effect on safety and reliability. The graded approach focuses on plans and schedules and considers cost impacts using the following criteria:

- The relative importance to safety, safeguards, and security.
- The magnitude of any hazard involved.
- The lifecycle stage of a facility or item.
- The programmatic mission of the laboratory.
- The particular characteristics of a facility or item.
- The relative importance of radiological and nonradiological hazards.
- Any other relevant factors.

The adequacy, implementation, and effectiveness of the QAP are reviewed on a continuing basis. The TJSO QAPP will be revised and updated, as needed.

The TJSO Manager has been delegated the approval authority for the JLab QA Plan document. Oversight of the JLab QA Plan is accomplished through direct observation of laboratory activities in the field during inspections, assessments, and other operational awareness activities.

4.2 Personnel Training and Qualification

All TJSO personnel are trained and qualified to perform their assignments. The TJSO FRAM identifies the TJSO staff titles and functional areas of responsibility that serve as the basis for determining who needs what training and qualification.

Training and qualification skills are identified and documented through each staff member's existing Individual Development Plan and as part of the Technical Qualification Program. The Individual Development Plans are tailored to the needs of each staff member and the work they perform. The objective is to ensure employees are not only competent for their current assignment but have access to professional development training to increase their skills portfolio and further strengthen the competencies and capabilities of the TJSO team. When specialized skills and qualifications are warranted that are beyond the capability of the TJSO staff, resources are obtained from the Office of Science Integrated Service Center (ISC).

Specific requirements for staff performing environment, safety, health, quality, and security oversight activities are contained in SOPPs. In addition to initial training and qualification, continuing training is an important factor in maintaining job proficiency.

4.3 Quality Improvement

The TJSO management approach to promoting continuous improvement is to maintain a culture in which every employee believes that he or she can make a difference in the quality of products and services. To ensure success, a “no fault” attitude is fostered that encourages employees to participate in solving problems and suggesting improvements.

If quality problems or negative performance observations are identified during self-assessments, surveillances, or walkthroughs, they are entered into the ORION database. A formal process is implemented to document, track, and correct the quality problems or negative performance.

TJSO staff members are assigned to assure that correction action plans are adequate and to assure that competed actions have corrected the issue. Quality problems are required to be analyzed, the apparent causes identified (where applicable), and effective corrective actions identified and implemented. Corrective actions for significant problems are directed towards preventing recurrence and address the identified root cause(s) according to the importance of the problem and the work affected. The level of review and subsequent verification (as described in an SOPP) is based on a graded approach relative to the associated risk of the issue and should have an emphasis to assure that repetitive deficiencies do not occur.

Findings documented in ORION are reviewed and analyzed to identify any additional items and processes needing improvement. Any QA-related findings that are identified

during Office of Health, Safety and Security Office of Independent Oversight assessments or QA-related findings identified by the Secretary or Deputy Secretary pertinent to the TJSO are tracked in the DOE Corrective Action Tracking System, which is part of the DOE Corrective Action Management Program.

4.4 Documents and Records

The TJSO records and documents having specific retention and storage requirements are controlled, filed, and archived by management and staff in accordance with an SOPP. Computer hardware and software used to maintain, index, store, or access records are controlled to ensure accountability, accessibility, and protection from loss.

The TJSO records system ensures records are specified, prepared, reviewed, approved, and maintained to accurately reflect completed work and include the following features:

- Provisions for the retention and disposition of records to satisfy the requirements of DOE Order 200.1, *Information Management Program*, and the National Archives and Records Administration's methods to preclude unauthorized access to TJSO records.
- Provisions for record storage areas that minimize the risk of damage from natural disasters and environmental conditions.
- Methods for maintaining record accountability.
- Provisions for the retrieval of TJSO's records.

TJSO's plans and procedures are controlled to assure that only current, approved documents are available for use. TJSO's document control system is described in an SOPP. It establishes requirements to assure that the TJSO's controlled documents that specify requirements, establish policy, or prescribe work are properly prepared, reviewed, approved, and issued.

4.5 Work Processes

The TJSO's work (primarily contract oversight) is planned, authorized, and performed by technically competent individuals who provide leadership, direction, and oversight. Work processes are performed using technical standards developed or adopted from commercial practice, policies, procedures, and other appropriate means and contain a level of detail commensurate with the complexity and importance of the work being performed (i.e., graded approach). Environment, quality, safety, and health requirements are integrated into all TJSO's work processes.

The TJSO has developed a set of SOPPs to implement its work processes. These plans and procedures provide specific details and senior management expectations for performing work.

The JLab QA plan encompasses all phases from design and construction through acceptance and occupancy. The industry standard practices for industrial construction projects apply. The contractor must comply with Federal Acquisition Regulation Part

46 to formally accept completed work. This constitutes acknowledgement that design and construction activities conform to applicable contract quality requirements. Inspection and acceptance can be performed in-house, by another agency, or delegated to a subcontractor independent of the contractor performing the work. Any construction activity directly managed by TJSO would require a commensurate level of QA policies and procedure prior to executing such work.

Oversight of JLab's work processes must assure that: (1) items are identified and controlled to ensure their proper use, (2) items are maintained to prevent their damage, loss, or deterioration, and (3) equipment used for process monitoring or data collection is being calibrated and maintained. In the performance of oversight duties, the TJSO staff is required to adhere to JLab's processes for hazard identification, analysis, and mitigation.

4.6 Design

The TJSO does not design items; however, the TJSO staff performs oversight on design related activities at JLab. The oversight activities are performed in accordance with applicable SOPPs. QA assessments are performed that consider the following:

- Any design, construction, or modification of engineered safety systems or structures.
- Unique design requirements.
- Impact to accelerator or normal JLab operations risks and environment, safety, and health hazards.
- Item and processes must be designed using sound engineering/scientific principles and appropriate standards.
- Design work, including changes, must incorporate applicable requirements and design bases.
- Design interfaces are identified and controlled.
- The adequacy of design products must be verified or validated by individuals or groups other than those who performed the work.
- Verification and validation work must be completed before approval and implementation of the design.

The TJSO maintains operational awareness over significant construction activities through participation in design meetings and by utilizing the Critical Decision Review process to determine project readiness. The TSJO staff also:

- Ensures that Federal QA oversight is performed on project construction activities.
- Ensures that JLab is conducting QA oversight of project construction activities.
- Monitors Project Risk Management Programs to ensure that appropriate construction risk is considered

The JLab contractor manages the design and construction contracts for essentially all structures, systems and components; therefore, the laboratory must apply the applicable QA-related requirements (i.e., compliance with DOE Order 420.1B, *Facility Safety*, and DOE Order 420.2B, *Safety of Accelerator Facilities*) in the contract to ensure the necessary considerations are incorporated into the planning and execution of such projects. JLab workers must conform to the requirements in the JLab performance-based contract.

During our oversight activities at JLab, the TJSO staff verifies that safety software (as defined in DOE Order 414.1C) meets applicable requirements. The TJSO does not use any safety software to perform our work.

4.7 Procurement

The TJSO Contracting Officer sets the terms of any contract or purchase order (including the one with JLab). The TJSO performs contract administration duties as prescribed in Federal Acquisition Regulation Part 42, the DOE Acquisition Regulations, and in the Contract Management Plan. An annual Performance Measurement and Evaluation Plan is developed that sets the standards for the contractor's performance through objectives, measures, and expectations. The measures are negotiated annually with the contractor and incorporated into the contract. The TJSO performs contract performance oversight in accordance with the TJSO Contract Management Plan.

The TJSO staff uses a graded approach to incorporate QA elements into the contract documents for contracted products and services through some or all of the following means:

- Establishes specifications and standards for product or service being requested.
- Prior to awarding contract, ensures the supplier(s) is capable of providing item, product, or service at specified quality level.
- Establishes and verifies the acceptance criteria for procured products or services.
- Ensures deviations from the requester's requirements are documented, controlled, reviewed, and approved.
- Performs periodic reviews to determine the supplier's continued ability to provide acceptable items and services, including reviews of the JLab procurement system.

Materials ordered and used by the TJSO are procured through direct purchase as indicated above or by using the JLab procurement system. JLab's procurement policies and procedures are required to address issues such as supplier qualifications and receipt inspection. Additional services for TJSO are provided by the Office of Science ISC.

The DOE Order 414.1C requirements pertaining to S/CIs do not apply directly to the TJSO, as we do not procure items that could affect accelerator safety, health, quality, or the environment. During oversight activities at JLab, the TJSO staff must ensure that any procured materials or equipment that appears to meet the definition of an S/CI is impounded pending a determination on conformance with procurement specifications

and/or design standards. This determination is the responsibility of the JLab person initiating the purchase, with assistance provided by the QA organization. If equipment or services are confirmed to be unacceptable, notification and reporting are conducted in accordance with DOE Order 414.1C and DOE Manual 231.1-2, *Occurrence Reporting and Processing of Operations Information.*

4.8 Inspection and Acceptance Testing

The TJSO does not procure items for systems nor perform acceptance testing for items that are important to the safety of JLab personnel or facilities. The TJSO does not use calibrated equipment for test and inspections in support of safety equipment for the JLab. However, the TJSO staff is required to perform oversight to ensure that JLab's processes for inspection and testing are being conducted using established acceptance and performance criteria.

4.9 Management/Self-Assessment

Self assessments are performed to identify strengths and good practices that should be preserved, as well as lessons learned and areas for improvement that should be factored into the QAP. TJSO's self-assessment process (implemented in accordance with an SOPP) focuses on how well the QAP is working and identifies management problems that prevent effective implementation of quality, safety, health, and environmental requirements. This process not only assists the TJSO in achieving our objectives but also allows the TJSO to evaluate customer and employee perceptions relative to the following key elements:

- The organization's mission and strategic objectives.
- The employees' role in the organization.
- The customers' expectations and the degree to which those expectations are being met.
- Opportunities for improving quality and cost-effectiveness.
- Recognizing and enhancing human resource capabilities.

Issues that hinder the TJSO's quality, safety, health, and environmental goals and objectives are identified and corrected. Decisions and recommendations are documented, acted upon, and evaluated for effectiveness.

4.10 Independent Assessment

Work processes are monitored, assessed, and improved in the TJSO to achieve a rising standard of excellence in the quality and safety of our programs, projects, products, and services. The TJSO's functions and activities (including those of the contractors) are independently assessed on a periodic basis in accordance with an SOPP. The TJSO staff evaluates JLab's compliance and performance with respect to the requirements and other terms and deliverables identified in the contract as described below.

- Independent assessments ensure that the following goals are achieved:
  - Problems preventing the TJSO from meeting our established goals, including potential or fundamental causes, are identified.
  - Actions are taken to correct identified problems.
  - Actions to prevent recurrence are identified and documented.
  - Lessons learned are applied, where applicable.
  - Actions are taken to improve the condition(s) causing the problem.
- Independent assessment personnel meet the following criteria:
  - Are technically knowledgeable in the areas being assessed.
  - Do not have direct responsibilities in the areas being assessed.
  - Act in a management advisory function.
  - Have sufficient freedom and authority to identify problems.
  - Monitor work performance.
  - Identify abnormal performance and precursors of potential problems.
  - Focus on improving the quality of the processes that lead to the end product.
  - Document assessment results.
  - Verify satisfactory resolution of problems.
  - Perform follow-up reviews of deficient areas, as necessary.

5.0 ACRONYMS AND DEFINITIONS

5.1 Acronyms

ANSI	American National Standards Institute
DOE	Department of Energy
FRAM	Functions, Responsibilities, and Authorities Manual
ISC	Integrated Service Center
ISO	International Organization for Standardization
JLab	Thomas Jefferson National Accelerator Facility
QA	quality assurance
QAP	Quality Assurance Program
QAPP	Quality Assurance Program Plan
S/CI	suspect/counterfeit item
SOPP	standard operating plans and procedures

TJSO Thomas Jefferson Site Office

5.2 Definitions

Assessment – A review, evaluation, or surveillance to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.

Document – Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

Item – An all-inclusive term used in the place of any of the following: appurtenance, assembly, component, equipment, material, module, part, software, structure, subassembly, subsystem, system, unit, or support system.

Procedure – A document that specifies or prescribes how an activity is to be performed.

Process – A series of actions resulting in a product or service to meet a customer's requirements.

Qualification – The knowledge and skills gained through education, learning activities, and experience that, when measured against established qualification standards, ensure that an individual is competent to perform the required functions, duties, and responsibilities of his or her job position.

Quality – The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Quality Assurance – All those actions that provide confidence that quality is achieved.

Quality Assurance Program (QAP) – The overall program (management system) established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Record – A completed document or other media that provides objective evidence of a service or process.

Root Cause – The fundamental reason which, if corrected, will prevent recurrence of these and similar occurrences throughout the facility or organization.

Root Cause Analysis – Analysis of a condition or event that results in an accurate description of how and why the condition or event was produced.

Service – The performance of work such as design, construction, fabrication, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

Software – Computer programs and associated documentation and data pertaining to the operation of a computer system.

Supplier – Any individual or organization that furnishes services in accordance with a procurement document. This is an all-inclusive term that is used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their sub-tier levels.

Training – The process of providing for/making available to an employee and placing or enrolling the employee in a planned, prepared, and coordinated program, course, curriculum, subject, system, or routine of instruction or education in scientific, professional, technical, mechanical, trade, clerical, fiscal, administrative, or other field that will improve the individual's and organization's performance and assist in achieving DOE's missions and performance goals.

Work – The process of performing a defined task or activity; for example, TJSO work is primarily contract oversight which includes: reviewing plans and schedules for completion, reviewing contract modifications, monitoring JLab activities, and conducting assessments of JLab work activities.