QUALITY MANAGEMENT PLAN

1.0 Purpose

The purpose of the Quality Management Plan (QMP) is to formally establish Brookhaven Site Office's (BHSO's) Quality Assurance Program. This plan outlines general requirements, assigns organizational responsibilities and describes the graded process for implementing a Quality Assurance Program. This plan emphasizes the graded approach to ensure that efforts are appropriately placed and to assure the level of resources expended are commensurate with the level of risk (either programmatic, operational, or safety) being managed. The QMP provides an integrated approach to quality management and guides continual improvement of BHSO's work processes.

It is the policy of the BHSO to establish, implement and maintain an effective Quality Assurance Program that is consistent with the needs of Brookhaven National Laboratory. Senior BHSO Management is responsible for the scope and implementation of the QA program and each individual is responsible for the quality of his/her work. Each BHSO member shall achieve success in implementing the QA program by promoting a broad knowledge of Quality and Integrated Safety Management (ISM) principles; emphasizing performance based quality principles and promoting an atmosphere of continuous improvement by applying quality management principles.

2.0 Definitions

2.1 **Document:** Documents describe work processes, specify requirements, and/or establish design criteria. Some examples of documents include procedures, plans, operating instructions, standards, directives, and drawings.

2.2 **Graded approach:** Process of ensuring that the level of analysis, documentation, and actions used to comply with requirements are commensurate with:

- the Relative importance to safety, safeguards, and security;
- the Magnitude of any hazards(s) involved;
- the Life cycle stage of a facility;
- the Mission of a facility, project, or activity; and/or
- Any other relevant factor.

2.3 **Product:** Result of activities or processes. A product may be tangible or intangible.

2.4 **Management System:** Management systems are the established and approved processes (e.g., procedures, plans, policies) that are designed to translate requirements into the information that BHSO staff needs to perform work at the required level of quality.

2.5 **Quality:** Condition achieved when an item, service, or process meets or exceeds the user's requirements or expectations.

2.6 **Quality Assurance:** All those actions that provide confidence that quality is achieved.

2.7 **Quality Assurance Program:** Overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

2.8 **Record:** Records describe the results of carrying out the work processes that are described in documents. Some examples of records include reports (bi-weekly, surveillance, assessment, etc), prior procedure revisions, calibration records, and training certificates.

2.9 **Suspect/Counterfeit Items:** An item is suspect when visual inspection or testing indicates that it may not conform to established Government or industry-accepted specifications or national consensus standards or whose documentation, appearance, performance, material, or other characteristics may have been misrepresented by the supplier or manufacturer. A counterfeit item is one that has been copied or substituted without legal right or authority to do so or whose material, performance or characteristics have been misrepresented by the supplier or manufacturer.

3.0 References

3.1 Department of Energy (DOE), *Quality Assurance*, DOE O 414.1C, June 17, 2005.

3.2 Department of Energy (DOE), *Nuclear Safety Management*, 10 CFR 830, 10, 2001.

3.3 Department of Energy (DOE) Quality Assurance Management System Guide for use with 10 CFR 830 Subpart A and DOE Order 414.1, DOE G 414.1-2, June 1999.

3.4 Department of Energy (DOE) Implementation Guide for use with Independent and Management Assessment Requirements of 10 CFR 830 Subpart A and DOE 5700.6C Quality Assurance, DOE G 414.4-4, August 1996.

3.5 SUSPECT/COUNTERFEIT ITEMS GUIDE for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance, DOE G 414.1-3, November 3, 2004

3.6 Department of Energy (DOE) Integrated Oversight and Performance Assurance Program, DOE O 470.2B, October 31, 2002.

3.7 International Organization for Standardization (ISO), *Quality Management Systems Requirements* - ANSI/ISO/ASQQ 9001-2000, December 13, 2000.

3.8 Department of Energy (DOE), *DOE Corporate Operating Experience Program,* DOE O 210.2, June 12, 2006.

3.9 Department Of Energy (DOE), *Implementation of Department of Energy Oversight Policy,* DOE O 226.1, September 15, 2005

3.10 Department of Energy (DOE), *Department of Energy Oversight policy,* DOE P 226.1A, May 25, 2007

3.11 Department of Energy (DOE), *Safety Management System Policy,* DOE P 450.4, December 15, 1996.

3.12 Department of Energy (DOE), Office of Science Quality Assurance Program Description dated August 1, 2006.

4.0 Responsibilities

4.1 Site Manager:

- Responsible for the development and implementation of the QMP.
- Defines the quality management vision, focus, policy, and overall goals and objectives and assigns responsibilities that ensure appropriate supporting programs, plans, and activities are developed and conducted; and
- Consistent with the graded approach, ensures the QMP is integrated into BHSO's work processes.
- Review and approve contractor's Quality Assurance Program Description (QAPD).
- Perform independent assessments of contractor's organization to evaluate the adequacy and QAPD implementation effectiveness.
- Periodically report management assessment results to their organizations Secretarial Offices.

4.2 Division Directors:

- Review, formulate, and recommend to the Site Manager quality management strategies, policies, and programs consistent with the QMP;
- Direct the implementation of the QMP within their divisions and ensure that work processes achieve appropriate levels of quality; and
- Ensure that appropriate resources are available for accomplishing quality management activities and goals.

4.3 Quality Management Coordinator:

- Serve as advisor to BHSO during implementation of the QMP; and
- Provide training to BHSO on the QMP.

- Provide Oversight of contractor's Quality Assurance Program.

4.4 Training Coordinator:

- Develop and implement the BHSO's training and qualification management system, which should meet the objectives and requirements described herein.

4.5 Document Control Coordinator:

- Develop and implement the BHSO's document control management system, which should meet the objectives and requirements described herein.

4.6 Records Management Coordinator:

- Develop and implement the BHSO's records management system, which should meet the objectives and requirements described specified herein.

4.7 Lessons Learned Coordinator:

- Develop and implement the BHSO lessons learned management system, which should meet the objectives and requirements described herein.

4.8 BHSO Staff:

- Implement this plan in accordance with management direction.

5.0 Procedure

5.1 Program

The BHSO's Quality Management Plan (QMP) is based on DOE's quality assurance requirements and expectations by using the graded approach (see References 3.2, 3.3, 3.4, and 3.5). The BHSO Quality Assurance Program is comprised of this plan and the various implementing management systems (e.g., program plans, project plans, policies, procedures, manuals, etc.).

BHSO has to the extent possible integrated the requirements of Integrated Safety Management with the Quality Assurance Criteria. A crosswalk between the QA criteria and the core functions and guiding principles of ISM is provided in Appendix 1.

Each division is responsible for implementing the requirements outlined in this QMP. The BHSO Organization Chart defines the Organizational structure of BHSO. Functional responsibilities are defined in position descriptions, in management plans and procedures.

5.2 Personnel Training and Qualification

BHSO Division Directors are responsible for ensuring that the personnel under their cognizance are trained and qualified as necessary to ensure they are capable of performing their assigned work. Division Directors will determine the resources needed to ensure that employees are adequately prepared to achieve the quality required in their assigned work. Employees shall be provided continuing training to ensure that job proficiency is maintained. BHSO Senior Management will determine the critical and unique job functions and tasks that require highly technical or specialized skills.

An established management system will be used to implement this process. Training and qualification records will be maintained to preserve the basis for management assessment and to serve as evidence of personnel training and qualification and to ensure staff proficiency is achieved, maintained and the training program is effective.

A Training Coordinator, designated by the BHSO Manager, shall develop and implement the BHSO's training and qualification program in accordance with the objectives and requirements described herein.

5.3 Quality Improvement

Processes to detect and prevent quality problems shall be established and implemented. If a deficiency is identified the condition is documented and evaluated. Work processes that do not meet established requirements must be promptly identified, controlled, and corrected according to the importance of the problem and the work process involved. Corrective actions shall include identifying the causes of the problems and other factors that, if corrected, will prevent recurrence. Depending upon the nature of the nonconformance issue, a root cause analysis or other analytical process may be needed to help identify the most appropriate corrective actions. Corrective actions requiring DOE headquarters attention will be managed in accordance with DOE O 414.1C.

Quality improvement processes shall be developed and implemented within all divisions at BHSO to facilitate continual improvement of work processes. Identification of Quality problems may be done during management assessments, independent assessments, surveillances and inspections as well as audits by external organizations. A corrective action program shall be developed for use by all departmental elements within BHSO. Corrective action planning shall be performed in accordance with DOE O 470.2B *Independent Oversight and Performance Assurance Program.*

BHSO personnel as part of continuous improvement should identify and report opportunities for improvement, deficiencies or conditions adverse to quality as they surface during work or during self assessment. This is done by submitting Lessons Learned to the BHSO Lessons Learned/Operating Experience Program Coordinator. The Lessons Learned Coordinator will work with BHSO staff to find resourceful ways in relaying the message to the site office and for outside distribution if applicable. This may be done by using e-mail, staff meetings, all

hands meetings, inclusion in the DOE Corporate Lesson Learned Database or other venues that would enable getting the message out. The BHSO Lesson Learned Coordinator also monitors contractor implementation of its Lesson Learned Program as required by DOE Order 210.2 *DOE Corporate Operating Experience Program.*

5.4 Documents

A document control management system shall be established and implemented to ensure that quality affecting documents are prepared, reviewed, approved, revised, and distributed with appropriate management controls to personnel performing the work. Documents requiring formal control will be identified. Documents may include, but are not limited to, procedures, plans, instructions, purchase orders, drawings/designs, computer codes, assessment/surveillance reports, and other documents important to work processes.

The documentation control management system is designed to assure the following criteria are satisfied: 1) quality affecting documents are prepared, reviewed, approved, and distributed using an established process, and 2) only current approved documents are available for use.

A Document Control Coordinator, designated by the BHSO Manager, shall develop and implement the BHSO's document control management system in accordance with the objectives and requirements described herein.

5.5 Records

Records should be preserved to provide documentary evidence of activities and functions supporting BHSO's mission and to accurately reflect completed work. Procedures will be established, implemented and maintained to ensure that appropriate records are generated, collected, reviewed, approved, properly stored, and legible. Records requiring formal control shall be identified. Retention periods will be identified and records will be indexed for accountability and retrievability. Computer hardware and software used to maintain, index, store or access records will be controlled to ensure accountability, reproducibility, and protection from loss.

A Records Management Coordinator, designated by the BHSO Manager, shall develop and implement the BHSO's records management system in accordance with the objectives and requirements described herein.

5.6 Work Processes

Effective management of work processes provides BHSO management with the assurance that necessary and adequate training, resources, design/acceptance criteria, and management systems are established and used to achieve desired results and that work is performed through effective contract management.

BHSO's Senior Management shall identify work processes (e.g., programs, projects, and activities) that are within the scope of the QMP and ensure that the following criteria are applied:

- work processes are effectively planned,
- work processes are implemented through established and documented instructions, procedures or plans,
- work processes incorporate applicable standards and acceptance criteria (e.g. DOE Orders), and
- all roles and responsibilities are understood during all phases or work processes.

Appropriate levels of BHSO management should be involved in the planning of these work processes. BHSO management should ensure that planning and scheduling consideration for projects and programs do not override safety, health, environmental, quality, or security considerations.

Where determined necessary by BHSO management, the detail of work process procedures and plans should be commensurate with the work being performed. The BHSO's procedures and plans are developed, reviewed, validated, and approved using established management systems.

5.7 Design

While BHSO staff engages in very limited or no design functions, they do manage contracts for the design and construction of facilities for environmental restoration and D&D of excessed facilities, therefore, the following design criteria should be applied to any design functions that may be performed by BHSO staff. As appropriate, design activities will incorporate sound engineering/scientific principals and appropriate standards.

Design work, including changes, must incorporate applicable regulations and design bases. Design interfaces must be controlled and identified. BHSO shall ensure contractors use applicable design regulations and processes through design review, and approval or acceptance of selected items. Oversight of contractor design review, verification, and validation processes is performed through participation in formal design reviews, assessments and deliverable reviews.

Design records, including design steps and sources of input, are maintained to provide evidence that the design was properly executed and to ensure the acceptability of the deliverable. Computer programs used in the design efforts are validated prior to utilization.

All designs are subject to independent design review and verification (i.e., design verification and validation is completed by person(s) other than those who performed the work). The extent of the verifications process depends on complexity, risk, and uniqueness of the design. Verification and validation work should be completed before approval and implementation of the design. Design changes are subject to the same controls as the original design.

5.8 Procurement

Suppliers will be evaluated and selected on the basis of specific criteria. Procured items and services should conform to established criteria and perform as specified.

Dependent upon the nature of the procurement and using the graded approach, the requesting organization is generally responsible for implementing some or all of the following tasks:

- Establish specifications and standards for product or service being requested;
- Prior to awarding contract, ensure supplier(s) is capable of providing item, product, or service at specified quality level;
- Establish and verify the acceptance criteria for procured products or services;
- Deviations from requester's requirements will be documented, controlled, reviewed, and approved;
- Perform periodic reviews to determine the suppliers' continued ability to provide acceptable items and services; and
- Control and document nonconforming items or services to preclude use until conformance with procurement specifications and/or design standards are demonstrated.

Management controls shall be performed through applicable DOE Orders, the DEAR 48 CFR Part 9 and the FAR 48 CFR Parts 1 to 99 and the QA requirements defined in Part 46.

5.9 Inspection and Acceptance Testing

Inspection or testing activities are implemented when required by specification or when assurance is needed that the work will produce the desired outcome. The depth of inspection and testing and the need for independent testing personnel are determined based on the complexity, risk, and past performance of the item, process, or service being tested. The applicability and depth of inspection and acceptance testing will be determined by the owner/requestor of the process, service, or item in question.

BHSO shall comply with FAR Part 46 to formally accept completed work and this constitutes acknowledgement that design and construction activities conform to applicable contract quality and quantity requirements. Inspection and acceptance can be performed in-house, by another agency, or delegated to a subcontractor independent of the contractor performing the work. Inspection processes that involve S/CI shall be performed in accordance with DOE G 414.1-3.

5.10 Management Self-Assessment

Division Directors are responsible for performing and participating in annual, internal assessments (self-assessments) of its work processes. Division

Directors shall develop a schedule or plan for completing the annual self-assessments that have been identified. Results of self-assessment activities shall be documented, with particular emphasis given to identifying opportunities for improvement or corrective actions. Division Directors shall report the results of the assessment through a system for identifying, tracking, and implementing corrective actions to ensure continual improvement of work processes. Management assessments should emphasize issues such as strategic planning, qualification, training, staffing, organizational interfaces, communications, cost control, and mission objectives. Managers are responsible for assigning personnel to ensure tracking, reporting, disposition and closure of corrective actions in their assigned areas.

5.11 Independent Assessment

In collaboration with Senior Management, each Division Director should determine the need for an independent assessment. The need for an independent assessment of a particular work process, service, item, or adequacy of work performance will depend on several factors (e.g., applicable requirements/standards, customer expectations, risk level, complexity, etc). A qualified or knowledgeable person(s), who is not responsible for the work process and/or product being independently assessed, should perform the independent assessments(s). Independent assessments should be performed every three years.

The AM or Division Directors have overall responsibility for ensuring effective independent assessments are conducted. The AM or division director may select qualified teams of independent personnel to conduct crosscutting assessments or assessments involving selected functional areas within BHSO or BHSO contractors. The AM or Division Directors ensure the assessments are scheduled and tracked. The requirements for conducting independent assessments may be satisfied by external team assessments (e.g. HQ Field evaluations). Independent assessments can be performed in-house, by another agency, or delegated to a subcontractor independent of the persons performing the work.

5.12 Suspect/Counterfeit Items

BHSO requires its contractor to have Suspect/Counterfeit Item (S/CI) identification processes that identify and analyze S/CI's, remove them, and prevent them from being used. Their Quality Assurance Program Description includes a description of BHSO's role in these processes. BHSO requires BNL to report discoveries through the DOE Occurance Reporting (ORP's) System. Copies of the S/CI ORP's reports are provided to the Inspector General by BHSO. Disposition of S/CI's is approved through the ORP's process

5.13 Safety Software Quality Requirements
BHSO does not develop or use any computer software for safety applications; therefore these requirements are not applicable.

6.0 Appendices

6.1 Appendix 1 - BHSO Quality Requirements and Related Documents

End

Preparer: _____ Date: _____

Procedure Coordinator: _____ Date: _____

Division Director: _____ Date: _____

Deputy Site Manager: _____ Date: _____

Appendix A
BHSO Quality Requirements and Related Documents

Quality Assurance Criteria	DOE Policy 450.4 Integrated Safety Management	BHSO Implementing Document
Management/Criterion 1 – Program	Guiding Principle (GP) –Line Management Responsibility for Safety GP- Balanced Priorities	BHSO-PPP-04 BHSO Functions, Responsibilities, and Authorities (FRAM) BHSO-PPP-02 BHSO Environment, Safety and Health Management Plan Brookhaven Environmental Management Completion Project Execution Plan Brookhaven National Laboratory Prime Contract BHSO Organization Chart BHSO Position Descriptions BHSO Annual Plan BHSO Procedures
Management/Criterion 2 – Personnel Training and Qualification	GP-Clear Roles and Responsibilities GP-Competence Commensurate with Responsibilities	BHSO-ADM-03 BHSO Training BHSO-OA-13 Facility Representative Qualification BHSO-OA-22 Subject Matter Qualification and Training
Management/Criterion 3 – Quality Improvement	Core Function (CF)-Provide Feedback and Continuous Improvement	BHSO-ADM-10 BHSO Contractor Performance-Based Business Management Procedure BHSO-ADM-14 Self - Assessment BHSO-OA-01 Conduct of

		ESH Assessments BHSO-OA-02 Conduct of Surveillances and Walkthroughs
Management/Criterion 4 – Documents and Records		BHSO-ADM-01 Preparation, Revision and Control of Procedures
Performance/Criterion 5 – Work Processes	GP-Identification of Safety Standards and Requirements GP-Hazard Controls Tailored to Work Being Performed CF- Define the Scope of Work CF-Analyze the Hazards CF-Perform Work within Controls	BHSO-ADM-10 BHSO Contractor Performance-Based Business Management Procedure BHSO-ADM-05 BHSO FEOSH Program BHSO-OA-01 Conduct of ESH Assessments BHSO-OA-02 Conduct of Surveillances and Walkthroughs BHSO-PM-02 Project Management
Performance/Criterion 6 – Design	CF-Develop and Implement Hazard Controls	BHSO-PM-02 Project Management
Performance/Criterion 7 – Procurement		
Performance/Criterion 8 – Inspection and Acceptance	GP-Operations Authorization	NA
Assessment/Criterion 9 – Management Assessment	CF-Provide Feedback and Continuous Improvement	BHSO-ADM-14-Self-Assessment
Assessment/Criterion 10 – Independent Assessment	CF-Provide Feedback and Continuous Improvement	BHSO-OA-01 Conduct of ESH Assessments