



Department of Energy

Washington, DC 20585

December 6, 2005

The Honorable A. J. Eggenberger
Chairman
Defense Nuclear Facilities Safety Board
625 Indiana Avenue, NW, Suite 700
Washington, DC 20004

Dear Mr. Chairman:

Enclosed is the Office of Environment, Safety and Health Management System for Quality and Safety Management (EH MS) that completes Commitment 10A in the Implementation Plan for the Defense Nuclear Facilities Safety Board Recommendation 2004-1.

The deliverable for this commitment also calls for "approved paths forward and schedules for achieving full implementation, including revision and implementation of field element Quality Assurance Programs." The EH MS contains an Implementation Plan (IP) describing actions for full implementation. This IP will be maintained separately from the approved EH MS.

If you have any questions, please contact me (202-586-6151) or have your staff contact Bud Danielson (301-903-2954).

Sincerely,

John Spitaleri Shaw
Assistant Secretary for
Environment, Safety and Health

Enclosure

cc:

Mark B. Whitaker, Jr., DR-1



MANAGEMENT SYSTEM
For
Quality and Safety Management

Office of
Environment, Safety and Health



Department of Energy

November 30, 2005

AGREEMENT

The *EH Management System for Quality and Safety Management* description contained herein is accepted, concurred with, and approved by the signatures below. This agreement can be modified by consent of the approving authority.

John Spitaleri Shaw
Assistant Secretary for
Environment, Safety and Health
Approval Authority

Date _____

C. Russell H. Shearer
Principal Deputy Assistant Secretary for
Environment, Safety and Health
Submitted for approval

Date _____

Prepared by:

(Signature on file) Date 11/28/05

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1. GENERAL

1.1 Introduction

This Management System (MS) is established for the Assistant Secretary for Environment, Safety and Health (EH-1) and is implemented by each Office of Environment, Safety and Health (EH) office. The Department of Energy (DOE) primary quality and safety requirements¹ share a management system² approach to ensuring "all work meets customer expectations," and "do work safely." Consequently, EH uses a single management system to describe how quality and safety is achieved for it's work. EH management is responsible for ensuring that products and services meet all requirements, and that work is conducted efficiently and in a manner that protects workers, the public and the environment.

1.2 EH Mission

The primary mission of EH is to provide corporate leadership, technical assistance, policies, programs and feedback that help enable DOE to excel in mission performance while achieving excellence in safety and environmental stewardship. The primary role for EH is to serve as DOE's corporate resource to assist line programs, particularly field elements, in the conduct or implementation of the following:

- environmental regulations and standards,
- Quality Assurance requirements and programs,
- performance assessment,
- Environment, Safety and Health directives and policies,
- enforcement of compliance with DOE nuclear safety regulations pursuant to the Price-Anderson Amendments Act, and
- conduct of health studies.

1.3 EH Quality and Safety Policy

It is the policy of EH that its work affecting nuclear safety and other high risk activities be clearly defined, planned, performed, assessed and improved in accordance with this MS. The EH Strategic Plan 2003-2006 defines "Quality Focus" as,

"The pursuit of quality, measured performance, and continuous improvement will be an integral part of EH processes, products, and services. EH will conduct its business with measured decision-making, customer focus, technical competence, and teamwork. EH will rely on meaningful performance measures to gauge its success and will be a leader in fostering the use of environment, safety and health performance measures throughout DOE."

Further, EH is committed to the quality and safety principles as defined in DOE O 414.1C and DOE P 450.4 as follows:

1. That quality and safety is assured and maintained through a single, integrated, effective quality management system;
2. That management support for planning, organizing, allocating resources, providing direction and control is essential for assuring quality results are achieved in the work place;

¹ Order O 414.1C, Quality Assurance and Policy P 450.4, Safety Management System Policy

² The management system approach developed by Shewhart & Deming entails four basic steps applied to the system and all underlying processes, "Plan-Do-Check-Act". DOE Quality Assurance policy refers to this approach as the "Plan-Perform-Assess-Improve" model.

3. That performance and quality improvements require a thorough, rigorous assessment to identify appropriate and effective follow up corrective action;
4. That workers are responsible for achieving, maintaining and ensuring quality;
5. That quality achievement is verified by those not directly responsible for performing the work; and
6. That environment, safety and health risks and impacts associated with work processes can be minimized.

1.4 Nuclear Safety and Other High Risk Activities

For the purpose of this document, "Nuclear Safety and Other High Risk Activities" is defined as those EH activities that are related to ensuring safe, reliable, and effective performance of nuclear safety and high risk related work functions. Nuclear safety and other high risk activities are those that in the event of a failure or error, would have significant impact on either the EH Mission, or could result in exceeding published accepted allowable limits (such as radiological exposure of 10 CFR 835) for the protection of the public, workers, and the environment.

1.5 Organization and Responsibilities

EH is headed by an Assistant Secretary (AS) and a Principal Deputy Assistant Secretary (PDAS) who report to the DOE Deputy Secretary. The first level of management reporting to the Assistant Secretary consists of Deputy Assistant Secretaries (DAS) and Office Directors (OD) who are charged with the management of EH's major work functions. These major work functions are further subdivided and managed by Office Directors.

The PDAS is the senior management position responsible for development of this EH MS and ensuring its implementation. The PDAS is supported by the Quality Assurance Policy Manager (QAPM) within the Office of Quality Assurance Programs (EH-31). The QAPM is responsible to the PDAS for: preparing the EH MS; developing its supporting work process (see sections 2 through 9); providing training in its use; conducting independent assessments of its implementation (see section 11); verifying quality achievement of its output (EH products and services); and, reporting on the effectiveness of its implementation. The QAPM has the authority from, and direct access to the PDAS for performing these duties. The QAPM is independent of other EH offices and therefore has the necessary organizational freedom and access to perform assigned responsibilities. Figure 1-1 depicts the EH Program functional management elements and reporting relationships.

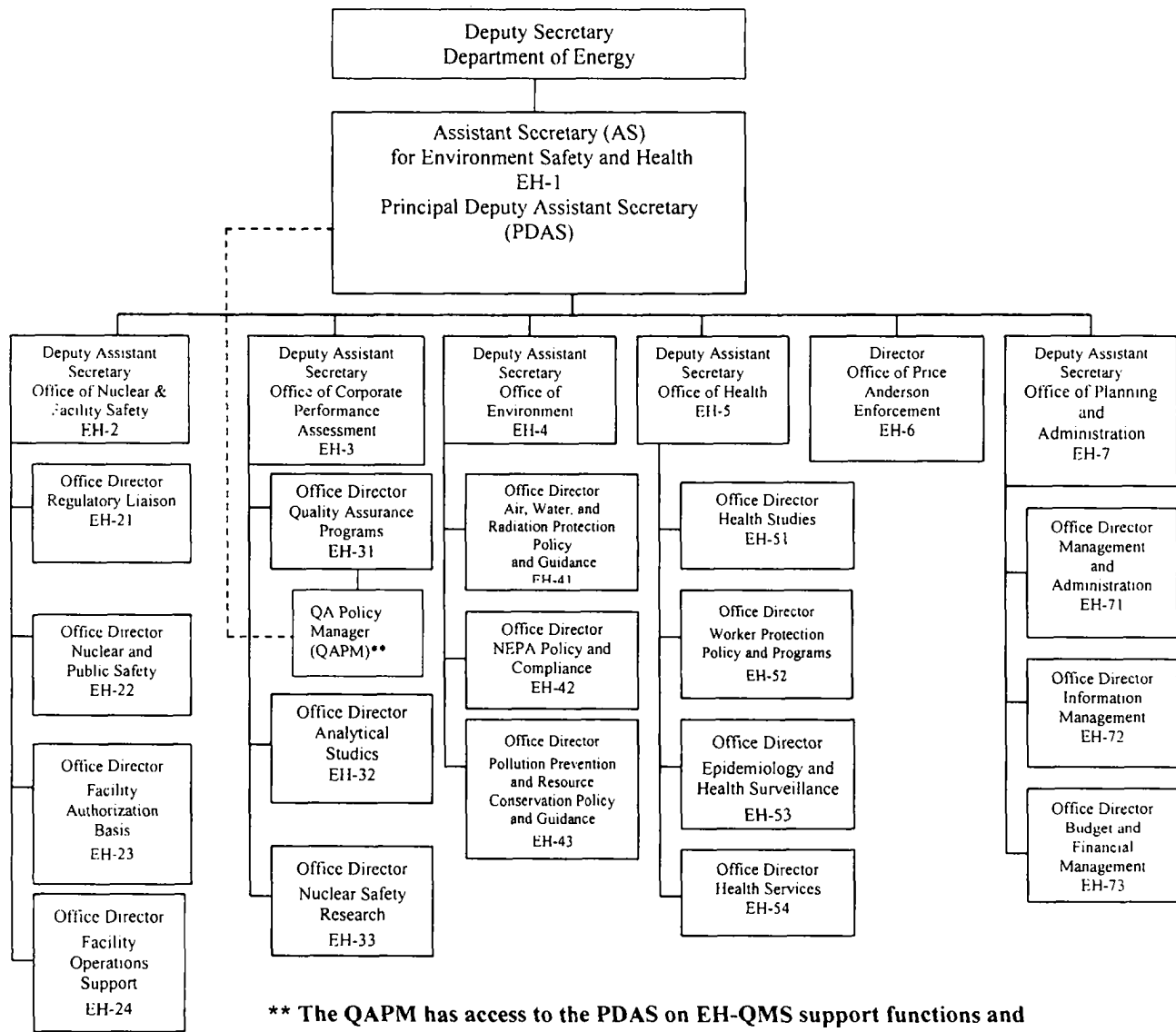


Figure 1-1 - EH Organization Chart

1.5.1 EH-2 Functions and Responsibilities

The primary responsibility of the Office of Facility Safety is to ensure that effective safety policies and procedures are developed and implemented to achieve safe operations of the DOE facilities. The office accomplishes its nuclear safety and high risk responsibilities through the following functions:

1. Establishing, developing and maintaining policies, standards, and guidance for:
 - Nuclear and facility safety;
 - Highly specialized requirement applications for nuclear safety, design, maintenance and operation requirements, health physics; industrial hygiene, fire protection, electrical safety, high explosives, firearms safety, pressure and chemical safety;
 - Protection of Federal and contractor personnel from occupational injury and illness; and
 - Personnel training and conduct of operations.

2. Performing assessments, evaluations and appraisals regarding:
 - The effectiveness of policies and requirements in accomplishing goals,
 - Critical corporate and field management safety issues and accidents,
 - Evaluating corporate issues to determine root cause or to identify systemic problems and,
 - The adequacy of the safety bases of DOE nuclear facilities.
3. Leading and supporting resolution of Department-wide cross-cutting technical issues such as Defense Nuclear Facilities Safety Board (DNFSB) Recommendations.
4. Providing technical support to both Central Technical Authorities and their staff.

1.5.2 EH-3 Functions and Responsibilities

The primary responsibilities of the Office of Corporate Performance Assessment are to: 1) ensure that safety and quality policies, programs, procedures and data are effective for the protection of the public, workers and the environment while performing the missions of DOE, and 2) to identify and assess safety vulnerability trends, and emerging issues. The office accomplishes its nuclear safety and high risk responsibility through the following functions:

1. Assess the effectiveness, vulnerabilities, and performance trends for all DOE missions for protecting the public, workers and environment.
2. Establishes corporate policies and processes for ensuring that quality work is performed in a rigorous and reliable manner.
3. Manage and directs:
 - a. Assessment of the effectiveness of the DOE programs for protection of the public, workers, and environment, ensuring that assessments are meaningful and readily understood;
 - b. Corporate analyses and certification activities that support top management decision-making and increases the awareness of environment, safety and health (ES&H) performance issues;
 - c. Development and improvement of accountability processes that link performance analyses with enhanced accountability of EH Performance through contracts; and
 - d. Development and implementation of Quality Assurance and certification programs to ensure reliability of DOE operations.

1.5.3 EH-4 Functions and Responsibilities

The primary responsibility of the Office of Environment is to ensure corporate policy and guidance meets current and future environmental compliance requirements; assurance that the Department's proposed actions comply with the requirements of the National Environmental Policy Act and related review documents; development of guidance for Departmental environmental stewardship responsibilities; and setting goals to minimize the environmental impacts of DOE operations. The office accomplishes its nuclear safety and high risk responsibility through the following functions:

1. Serves as the central coordinating point for advocating DOE positions on environmental requirements and regulations proposed by other federal agencies.
2. Promotes the implementation of environmental management systems throughout the Department to ensure that consideration of the environmental impacts of DOE operations are integrated into integrated safety management systems.
3. Provides technical support to the Department's program offices and field elements in understanding and implementing environmental requirements.

1.5.4 EH-5 Functions and Responsibilities

The Office of Health promotes the health and safety of DOE's workers and communities surrounding DOE sites; develops comprehensive and effective safety and health policy for DOE workplace hazards, and supports studies and medical screenings to understand the effects of radiation and other potential hazards of DOE operations on humans.

1. Develops, manages and directs programs that provide comprehensive and effective safety and health policy and directives for protecting the safety and health of workers at DOE facilities. Utilize the results of domestic and international studies to improve DOE worker protection policy.
2. Establishes the Department's performance expectations for occupational medicine programs through the publication of policy and directives. Utilize the results of domestic and international studies to improve DOE worker protection policy.
3. Conducts or participates in studies to determine worker and public health effects from exposures to hazardous materials. Utilize the results of domestic and international studies to improve DOE worker protection policy.

1.5.5 EH-6 Functions and Responsibilities

The primary responsibility of the Office of Price-Anderson Enforcement (OE) is to ensure contractor compliance with the Department's nuclear and worker safety requirements. The office accomplishes its nuclear safety and high risk responsibility through the following functions:

1. Investigates potential violations of enforceable requirements, as well as certain nuclear safety and worker safety and health concerns raised by workers.
2. Initiates and resolves enforcement actions in accordance with the process and procedures set forth in 10 CFR Part 820 Issues Notices of Violation.
3. Manages and develops programs and policies that encourage contractor self-identification, reporting, and correction of potential non-compliances through the Noncompliance Tracking System.
4. Conducts Price-Anderson Amendments Act Program Reviews of DOE contactors identification, screening and reporting of non-compliances to ensure consistency with OE expectations and encourage excellence in performance assessment.

1.5.6 EH-7 Functions and Responsibilities

The primary responsibility of the Office for Planning and Administration is to ensure that administrative management functions that support EH mission and responsibilities for procurement, and document and records management processes are effective, fully integrated, and are consistent with Department wide processes. The office accomplishes its nuclear safety and high risk responsibility support functions through the following:

1. Manages the design, development, implementation and operation of management support systems.
2. Develops and administers the EH human resource management programs responsible for high quality training and employee qualification maintenance.
3. Provides a focal point for management and coordination of EH procurement activities.
4. Serves as the focal point for EH management of a customer advocate program to assure an integrated and strategic approach to addressing stakeholder needs to foster continuous improvement, and to provide effective communications within EH on improvement related issues.

1.6 EH Documentation Requirements

EH documents requirements and expectations in federal regulations (rules), in the DOE Directives System through policy documents (designated by "P"), orders (designated by "O"), manuals (designated by "M"), Notices (designated by "N"), Guides (designated by "G") and in internal documents such as the Safety Management Functions, Responsibilities, and Authorities of the Office of Environment, Safety and Health (EH FRA). These documented requirements are utilized to establish management expectations and specify the criteria that must be met to ensure safe and reliable operations. These documents include information regarding industry standards that are acceptable for use in performing work. The primary focus of these documents is on the applicability to work that must be performed

1.6.1 Consensus Standards

In accordance with the DOE O 414.1C Section 4.a and DOE P 450.4, EH uses national or international consensus standards where practicable and consistent with contractual or regulatory requirements. Appropriate standards pertaining to quality include the following:

- (a) ASME NQA-1-2004, Quality Assurance Requirements for Nuclear Facility Applications (for nuclear-related activities) or subsequent revision; and
- (b) ANSI/ISO/ASQ Q 9001-2000, Quality Management System-Requirements for non-nuclear activities.

EH work processes relating to nuclear safety activities are controlled per the requirements of ASME NQA-1-2004. For certain EH-wide work processes, applicable ASME NQA-1-2004 requirements are specified in this EH MS. For other high risk activities the requirements of ASME NQA-1-2004 may be applied as appropriate or other standards with similar rigor may be applied. The specific activities and ASME NQA-1-2004 requirements are described in the documents for that activity. The basis for the selection of the Standard shall be documented and maintained as a record that supports the management decision.

1.6.2 Graded Approach

DOE O 414.1C paragraph 4.a (1) and DOE P 450.4 endorses the use of accepted industry standards that can be tailored for application to DOE specific needs. This technique is defined as the "graded approach." The graded approach is a technique that enables a user of requirement documents to describe and document the level of rigor to be applied in their implementation.

The application of the graded approach process for the purposes of the EH MS is through the development of procedures and guides that document the work processes/steps to be followed for accomplishing work. Guidance is provided in DOE G 414.1-2A, *Quality Assurance Management System Guide*, Section 4.1.3, for the grading process applicable to evaluating hazards or risks. This process is accomplished by deliberate quality planning and is based on facility-specific or activity-specific factors, such as:

- The relative importance to safety, safeguards, and security;
- The magnitude of any hazard or risk involved;
- Impact/consequences on programmatic mission of EH;
- The particular characteristics of an activity;
- The nuclear safety classification or hazard category of the item or activity;
- Adequacy of existing safety documentation;
- Complexity of products or services involved; and
- History of problems within EH.

2. EH MS APPLICATION OF QA CRITERIA

2.1 EH MS Program Requirements

DOE O 414.1C Criterion 1 - *A written Quality Assurance Program (QAP) must be developed, implemented and maintained. The QAP must describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing and assessing the work. The QAP must describe management processes, including planning, scheduling, and resource considerations.*

DOE P 450.4 Principle 1, *Line management is directly responsible for the protection of the public, the workers, and the environment;* **Principle 2**, *Clear and unambiguous lines of authority and responsibility for ensuring safety shall be established and maintained at all organized levels within the Department and its contractors;* **Principle 4**, *Resources shall be effectively allocated to address safety, programmatic, and operational considerations. Protecting the public, the workers, and the environment shall be a priority whenever activities are planned and performed.*

2.2 EH Management System Program

EH quality and safety requirements share a management system approach for achieving their objectives. Criterion 1 of DOE O 414.1C is linked to Integrated Safety Management System (ISMS) through Guiding Principles 1, 2 and 4. EH management has the mission of accomplishing the EH Program that includes the establishment and implementation of the EH MS. This MS covers EH related nuclear safety and high risk management functions and responsibilities of the EH Program Offices.

There are field element groups that perform work requiring EH Program office oversight. These groups are responsible for the development of their specific quality management functions under the direction of the responsible EH Office Director. The quality management systems for these groups are reviewed and recommended by the responsible Office Director, concurred on by the Quality Assurance Policy Manager, and approved by the responsible Deputy Assistant Secretary. This is further discussed in Section 2.1.4 and is graphically depicted in Figure 2.1—*EH Management System Document Hierarchy Relationship*

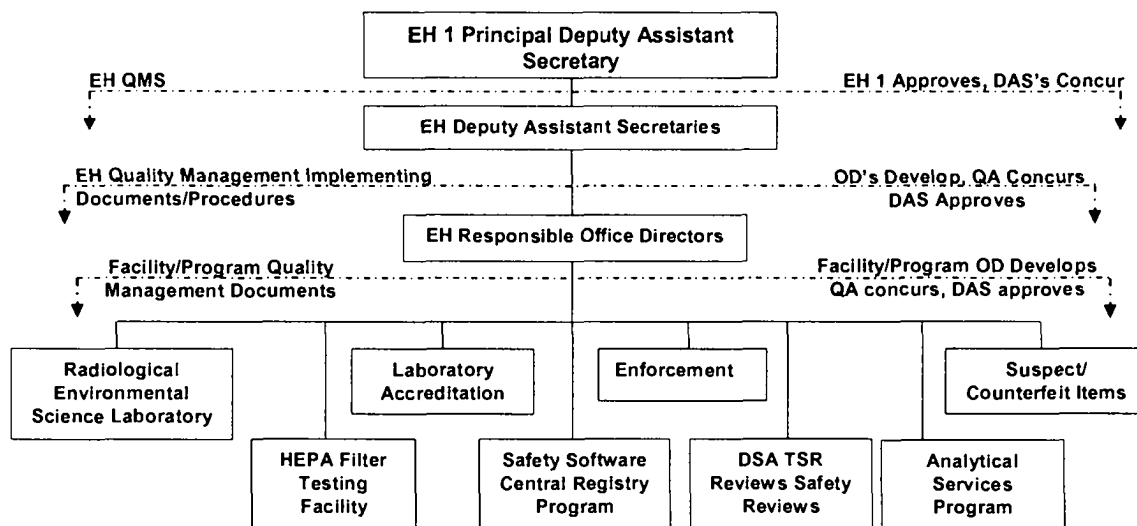


Figure 2.1 - EH Quality Management Document Hierarchy Relationship

The implementation of an effective quality assurance program is to ensure that work is planned, performed and assessed to verify quality and process effectiveness together with a system for quality improvement. The fundamental principles, requirements, and guidance for the EH MS, including the quality assuring programs of participant organizations, are as follows:

- The assurance of quality and safety involves the interaction of many organizational components and is not to be regarded as the sole responsibility of any single group.
- The extent to which management controls are specified and implemented will reflect the anticipated risks of an event that could adversely affect the public, worker's health and safety, the environment, or the EH Mission.
- The achievement of quality and safety is a personal responsibility wherein each manager, supervisor, and individual worker is accountable for the quality of his/her work.
- Quality achievement needs are verified or validated by individuals or groups other than those who performed the work.

The EH MS is the composite of plans and actions that are established and implemented by EH senior managers. Work delegation documents such as Program/Project Execution Plans, Work Authorization Statements (WAS), contracts, specifications, purchase orders, Memoranda of Understanding (MOU), Memoranda of Agreement, Interagency Agreements, and similar work controlling documents specify the scope of delegated work, and the quality and safety requirements to be applied to the work. The process by which work is delegated, including the establishment of management controls, assignment of responsibility, and identification of lines of communication, are defined in work delegation documents.

Some EH program activities may be delegated with the approval of the cognizant Deputy Assistant Secretary or designee. However, EH retains the responsibility for assuring that all activities are performed in accordance with an appropriate system of management controls. These controls are monitored through review and approval of participants' quality management documents (QAPs, procedures, etc.), and performance of overview activities such as assessments, reviews, surveillance, and audits.

2.3 QA Program Requirements – Delegated Work

Participants that perform delegated work shall apply appropriate requirements and guidance in developing and implementing their quality assurance programs. Requirements for quality assurance programs established by EH contractors, subcontractors, and suppliers are passed down through contracts that reference the applicable requirements of DOE Order 414.1C, *Quality Assurance*, and the following DOE guides and standards, and national and international standards:

- DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide for Use with 10 CFR, Part 830, Subpart A, and DOE O 414.1A, Quality Assurance, DOE P 450.4, Safety Management System Policy; and DOE P 450.5, Line ES&H Oversight Policy*, dated May 31, 2001;
- DOE G 414.1-2A, *Quality Assurance Management System Guide For Use with 10 CFR 830 Subpart A and DOE O 414.1C, Quality Assurance*, dated June 17, 2005;
- DOE G 414.1-3, *Suspect/Counterfeit Items Guide For Use with 10 CFR 830 Subpart A, Quality Assurance Requirement, and DOE O 414.1B*, dated November 3, 2004;
- DOE G 414.1-4, *Safety Software Guide for use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*, dated June 17, 2005;
- DOE G 440.1-6, *Implementation Guide For Use With Suspect/Counterfeit Items Requirements of DOE O 440.1, Worker Protection Management; 10 CFR 830.120;*
- DOE –STD-3020-XX, *Specifications for HEPA Filter used by DOE Contractors;*

- ASME NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Applications* (for nuclear-related activities) or subsequent revision; and
- ANSI/ISO/ASQ Q 9001-2000, *Quality Management System Requirements* (for nonnuclear activities).

2.4 EH Implementing Procedures and Guides

The use of implementing procedures and guides is the normal management process for defining specific management control processes and methods necessary to meet commitments for ensuring quality and safety. The graded approach is applied in the development of the amount of rigor contained in the procedures/guides. For example, management controls may vary from simple desk top guidance procedures for the control of routine/repetitive processes to rigorous and methodical procedural guidance to defines steps for staff performance of compliance related, high risk and nuclear safety analysis/reviews. The management philosophy is to ensure that the appropriate level of rigor and consistency is applied in the performance of assigned responsibilities. EH personnel apply the respective management procedures that assure appropriate criteria and interfaces are defined to signify agreement with established obligations.

EH Program procedures that control work for quality and safety related issues are developed by the primary office(s) having responsibility for the work; concurred in by the affected Office Directors and Quality Assurance Policy Manager; and approved by the responsible Deputy Assistant Secretary.

2.5 EH Facility, Program and Supplier Interfaces

EH is responsible for managing the interfaces for certain field facilities, services to Program Secretarial Offices (PSO), and contracted suppliers. These interfaces are controlled by the flow-down of quality requirements specific to the application in contracts, DOE directives, and EH work process documents. EH retains responsibility for the work, regardless of where the work is performed, or if it is delegated to another organization.

- Contracted work - The EH office responsible for the work of contracted suppliers must apply the Procurement Criterion of this EH MS (e.g., HEPA Filter Test Facility). The supplier may work under this EH MS or their own QAP and Integrated Safety Management System Description (ISMSD). Where the supplier is working under their QAP the responsible EH office must define quality requirements in the contract, review and approve the supplier's QA Program, and conduct appropriate supplier oversight. Where the supplier is working under the EH MS, the responsible EH office must define quality requirements in the contract, including a requirement to comply with the EH MS, and conduct supplier oversight.
- Field facilities - The EH office responsible for the work of DOE field facilities that is located on a site managed by another PSO must determine if the work will be conducted under this EH MS, or a QAP and ISMSD prepared by the Field. Such a facility is the Radiological Environmental Science Laboratory, and the Laboratory Accreditation Program. It must be determined if the work is to be performed under this EH MS, or the QAP and ISMSD of the PSO. Where the work is under the PSO's QAP, the responsible EH office must define quality requirements in the work responsibility agreement, and review and approve the PSO's QA Program, and conduct appropriate oversight of the work as it is performed. Where the work is controlled under the EH MS, the responsible EH office must define quality requirements in the work control agreement, including a requirement to comply with the EH MS, and must conduct oversight of the work.
- Other DOE organizations - Where the EH work activity is in support of an outside DOE organization (e.g., Office of Nuclear Energy), the responsible EH Office must describe roles, responsibilities, and quality requirements in the work process documents.

3. PERSONNEL TRAINING AND QUALIFICATION

3.1 Personnel Training and Qualification Requirements

DOE O 414.1C Criterion 2 - *Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained.*

DOE P 450.4, Principle 3, *Personnel shall possess the experience, knowledge, skills, and abilities that are necessary to discharge their responsibilities.*

EH utilizes DOE M 426.1-1A, *Federal Technical Capability Manual*, which provides requirements and responsibilities to ensure recruitment and hiring of technically capable personnel and to retain critical technical capabilities of its technical staff. EH is staffed with senior experienced persons, many of whom are largely considered "Subject Matter Experts" (SMEs) in their respective areas of expertise. When assigned work responsibilities that involve either nuclear safety or other high risk applications involving safety, health or environment applications, EH management is able to draw from within the staff or other DOE organizations, highly qualified persons to address issues. Contractor staff considered SME's may be included to augment the internal staff expertise when addressing high visibility issues.

3.2 Job Descriptions

Qualification requirements for each specific EH staff position category or Senior Manager are principally addressed through the development of position/job descriptions. Job Descriptions establish education and work experience requirements for staff performing the assigned functions. Staff performance is continuously monitored through the establishment of annually evaluated performance elements as required by DOE Order 331.1B change 1, *Employee Performance Management System*, and DOE G 3305.1, *Senior Executive Service Personnel Guide*.

3.3 Individual Development Plans

Individual Development Plans (IDP) are prepared for the continued development of EH personnel in accordance with the requirements of the DOE Order 360.1B, *Federal Employee Training*. The IDP process is used to enable staff to formally identify areas in which expertise augmentation and training is needed to support the EH Mission. Managers coordinate staff participation in developing and updating the IDP.

Upon identifying a need for additional staff training, the manager will arrange for the appropriate training. Formal external training is provided to EH personnel on an "as-needed" basis, contingent on availability of training and funds.

3.4 Technical Qualification Program

EH personnel who perform work affecting nuclear facilities are required to meet the appropriate qualification requirements in the DOE Technical Qualification Program.

3.5 Quality Assurance and Safety Management System (SMS) Training and Qualifications

EH Offices having lead responsibility for specific functions within the EH organization are responsible for developing and providing EH staff training. EH plans, develops, and conducts QA and SMS training for the appropriate EH personnel. Formal training, when needed, may be provided via external resources. In addition to specialized training, the training includes:

- Integrated Safety Management,
- Management Expectations,
- Roles, Responsibilities (in the FRA) and Interfaces,
- EH MS,

- QA Records and Record Keeping,
- Procedures and Guidelines, and
- Quality and safety improvement approaches, methods, and feedback processes.

Managers evaluate the need for training with individual staff. Training may range from individuals completing assigned reading materials, to receiving formal classroom instruction or a combination of both. Training is required when new guidance or instruction documents are issued; or when significant revisions are made to existing documents that are utilized in the performance of work. The need for additional training is based on the importance of the new or revised document and the need to inform the staff.

3.6 Special Qualification Requirements

Persons within the EH Staff are encouraged to qualify as Assessors/Auditors and Lead Assessors/Auditors. Requirements for certification will be established and implemented to enable staff participating in or leading audits. This requirement will apply to all areas for which audits are required to be conducted. Qualification requirements will be in accordance with the procedure to be developed in the implementation phase of the EH MS. As an alternative, EH staff may seek to obtain certification via participation on other DOE audit teams performing audits of programs having similar requirements. Documentation that support EH staff qualification regarding the performance of audits will be developed and maintained as a QA record.

4. QUALITY IMPROVEMENT

4.1 Quality Improvement Requirements

DOE O 414.1C Criterion 3, Quality Improvement – *EH Management shall establish and implement processes to detect and prevent quality problems; identify, control, and correct items, services, and processes that do not meet established requirements; identify causes of problems and include prevention of recurrence as a part of corrective action planning; and review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.*

DOE P 450.4, Core Function 5 - Feedback information on the adequacy of controls is gathered, opportunities for improving the definition and planning of work are identified and implemented, line and independent oversight is conducted, and, if necessary, regulatory enforcement actions occur.

4.2 Quality Improvement Responsibilities

4.2.1 EH Management Commitment

EH management is committed to a process of continuous improvement in performance and quality. EH management is expected to maintain a culture that fosters a “no fault” environment that encourages staff to identify problems without fear of punitive actions.

4.2.2 Performance Goals and Objectives

EH staff members are empowered and encouraged to assume full responsibility for their work, which includes proactively seeking out and identifying areas for improvement, reporting problems and recommending actions that solve them. Performance goals and objectives are developed that enables the determination and development of performance baselines against which changes can be measured and trends analyzed.

4.2.3 Identification of Quality Problems

EH quality management procedures will be developed to provide EH personnel with guidance to enable detecting analyzing and trending quality problems. Self assessments to be performed in compliance with Criterion 9, *Management Assessments*, enable identifying and examining factors that may be used to indicate trends of success or negative progress in the performance of work. Processes that do not meet established requirements will be identified, controlled, and corrected. Corrective actions include identifying the root causes of the problems and taking actions to prevent their recurrence.

The EH Strategic Plan 2003—2006 includes specific objectives and strategies that must be included in EH improvement planning. Process implementation and information derived from oversight activities will be reviewed and the data analyzed to identify processes needing improvement.

5. DOCUMENTS AND RECORDS

5.1 Documents and Records Requirement

DOE O 414.1C Criterion 4, *Document that specify requirements or establish design requirements are to be prepared, reviewed, approved, issued, used, and revised to prescribed processes. Records shall be specified, prepared, reviewed, approved and maintained.*

DOE P 450.4, Principles and Functions, While there is no corresponding parallel Principle and Function that addresses documents and records, Criterion 4 of the QA order is interpreted to apply to the entire set of the ISM Principles and Functions.

5.2 EH Policy

EH shall develop and maintain documents and records so as to effectively manage, perform, and assess EH's work. The preparation, issue, and changes of documents (such as instructions and procedures) that specify or prescribe activities affecting quality/safety requirements shall be controlled to ensure that only correct documents are being employed. Documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

5.3 Document Content Quality

EH organizations are responsible for developing documents that meet established quality requirements. EH document content quality guidelines include those set-forth by the Office of Management and Budget (OMB) policy and procedures developed to ensure and maximize the quality, utility, objectivity, and integrity of information disseminated to members of the public. EH documents shall include requirements provided in DOE guidance that was prepared pursuant to OMB government-wide guidelines under section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Act) (Pub.L. 106-554, 114 Stat.2763). (Details regarding document content quality will be included in implementing procedures to be developed in the implementation phase.)

5.4 Document Control Requirements

The purpose of the document control system is to supply documents necessary for personnel to safely and correctly perform their assigned responsibilities. The EH document control system shall define the management controls to be applied for the preparation, review, approval, issue, control and revision of documents that support nuclear safety and high risk work of the EH organization. Documents included are those that describe work to be done, data to be used at different locations or by different people, or, in changing situations, and data to be controlled from time to time for reference purposes.

The following controls shall be applied to documents and changes thereto:

- Documents for nuclear safety and other high risk applications work shall be identified and prepared;
- Distribution requirements shall be specified;
- Individuals responsible for the preparation, review, approval, and distribution of controlled documents shall be identified;
- Controlled documents shall be reviewed for completeness, technical adequacy, and approval prior to distribution;
- Methods to ensure that correct documents are being used shall be established and followed; and
- A web-based central filing system for all letters and memos going in and out of EH will be considered during the implementation phase.

5.5 Document Changes

Changes to documents, other than those defined as minor changes, are considered major changes and will be reviewed and approved by the same group that performed the original review and approval unless other groups are specifically designated. The reviewing group, if other than the original group, shall have access to pertinent background data or information upon which to base their approval.

Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original document. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision are clearly defined.

5.6 Records Requirements

EH records contain information to be retained for expected future value. Records that support technical requirements and enforcement actions/decisions provide evidence that EH work was correctly performed. Record forms vary to include electronic, written, printed, microfilm, photographs, radiographs and optical disks. Typical records include procedures, plans, and manuals; training and qualification reports; work acceptance documents, technical/enforcement correspondence; operational records, safety basis descriptions, safety review results, revisions to requirements, configuration management information and quality/safety problem resolutions.

Records are to be compiled in a records management system that is consistent with the requirements of: DOE O 200.1, *Information Management Program*, dated 9-30-96; the EH-6 Office of Docketing Clerk procedures as specified in 10 CFR 820.10; and, DOE's Interim Records Management Policy issued by DOE's Chief Information Officer on March 30, 2004³. A records system includes provisions for specifying, preparing, reviewing, approving, disposing, and maintaining records. Records retention, protection, preservation, change, traceability, accountability, and retrievability requirements are established depending on the category of record and importance to the EH mission. However, records must be retained for the length of time identified in the DOE Records Disposition Schedules, which are posted on the DOE Records Management Webpage (<http://cio.doe.gov/RBManagement/Records/records.html>). Records that are uncheduled may not be disposed of until a DOE Records Disposition schedule has been approved by the DOE Records Officer and the National Archives and Records Administration (NARA). The EH Records system will be implemented to meet the requirements of ASME NQA-1-2004 utilizing the graded approach for the application of the requirements. The applicability of existing records systems will be evaluated against the requirements for the function they serve. Those documents/records that meet the criteria as being related to nuclear safety or other high risk activities will be maintained in accordance with the requirements.

Hardware and software tools that are used to create and store records will be maintained to ensure that records can be readily retrieved. The EH approach for maintenance of records, including electronic records management are in accordance with guidance provided in DOE Standard 4001-2000, "*Design Criteria Standard for Electronic Records Management Software applications*" which implements National Archives and Records Administration, 36 CFR Chapter XII.

³ The Interim Records Management Program Policy which can be found at http://cio.doe.gov/RBManagement/Records/PDF/Records_Management_Policy_Program.pdf is in effect until the new Records Management Program Order is issued. In March 2005, draft DOE Order 243.X, *Records Management Program* was issued for comment in the DOE Directives System. The final is expected to be issued soon.

6. WORK PROCESSES

6.1 Requirements

DOE Order 414.1C Criterion 5, -- *Work is to be performed consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.; Items are to be identified and controlled to ensure their proper use, and or maintained to prevent their damage, loss, or deterioration; and Equipment used for process monitoring or data collection shall be calibrated and maintained.*

DOE P 450.4, Principles and Core Function - Principle 5, *Before work is performed, the associated hazards shall be evaluated and an agreed-upon set of safety standards and requirements shall be established which, if properly implemented, will provide adequate assurance that the public, the workers, and the environment are protected from adverse consequences; Principle 6*, *Administrative and engineering controls to prevent and mitigate hazards shall be tailored to the work being performed and associated hazards; Principle 7*, *The conditions and requirements to be satisfied for operations to be initiated and conducted shall be clearly established and agreed-upon; Function 5*, *Feedback information on the adequacy of controls is gathered, opportunities for improving the definition and planning of work are identified and implemented, line and independent oversight is conducted, and, if necessary, regulatory enforcement actions occur.*

6.2 EH Work Processes

EH work processes consist of a series of actions planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls to achieve the desired end result. EH Managers are responsible for ensuring that those under their supervision have the training, skills (including knowledge and understanding of the capabilities of the processes being used), equipment, work process documents, and resources needed to accomplish their work. EH management and staff cooperate to identify processes that can be improved based on feedback prior to and following implementation of the work process.

EH management shall ensure that the following are clearly identified and conveyed to staff before they begin their work:

- Customer and data requirements for the work and final product;
- Hazards associated with the work;
- Safety, administrative, technical, environmental, and quality controls to be applied;
- Technical standards applicable to the work and final product;
- Acceptance criteria applicable to the work and final product; and
- Procedures for verification of the completed work using established criteria.

Procedures, work instructions, or other appropriate means required to define work processes are to be documented and controlled. The scope and detail of documentation shall be commensurate with the complexity and importance of the work, the skills required to perform the work, the hazards and risks or consequences of quality problems in the product, process, or service, and the need to meet regulatory and contract requirements. Control of processes, skills, hazards, and equipment shall be clearly specified, understood, and documented.

EH Staff is responsible for and expected to do its work correctly the first time, in accordance with established procedures and documented work instructions. Since the EH Staff is the best resource for contributing ideas for improving work processes, products, and services, they are expected to be involved in defining and designing work processes, process evaluation, and providing the feedback necessary for improvement.

7. DESIGN

7.1 DOE O 414.1C Requirements

Criterion 6, Design - *Design items and processes use sound engineering/scientific principles and appropriate standards; incorporate applicable requirements and design bases in design work and design changes; identify and control design interfaces; verify/validate the adequacy of design products using individuals or groups other than those who performed the work; and verify/validate work before approval and implementation of the design.*

DOE P 450.4, Principles and Core Functions, - Principle 5, *Before work is performed, the associated hazards shall be evaluated and an agreed-upon set of safety standards and requirements shall be established which, if properly implemented, will provide adequate assurance that the public, the workers, and the environment are protected from adverse consequences; Principle 6,* *Administrative and engineering controls to prevent and mitigate hazards shall be tailored to the work being performed and associated hazards; Function 2,* *Hazards are associated with the work identified, analyzed, and categorized; Function 3* *Applicable standards and requirements are identified and agreed-upon, controls to prevent/mitigate hazards are identified, the safety envelope is established, and controls are implemented.*

7.2 Applicability to EH

In general, EH does not perform original designs. The type of activities that EH anticipates will require design-related skills include oversight of the HEPA filter test facility contractor, and support of technical reviews of DOE Acquisition functions. Design requirements pertaining to the HEPA facility or other similar function will normally be passed down via contractual documents requiring the contractor to do work that is in compliance with the requirements of NQA-1-2004 for the application of intended use.

7.3 Interaction with Field Offices

EH interacts with the DOE field office that is responsible for the Radiological Environmental Science Laboratory facility. EH is responsible for the management of the applications of the facility. Should there be a need for the application of design modifications, requirements particular to the needs of EH will be passed down to the Field Office having design jurisdiction to ensure that nuclear safety and other high risk issues are addressed in accordance with the requirements to be developed as the need is defined and anticipated work controls are established.

7.4 EH Requirements Applicable to Design

The design process shall be established that provides appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces. Design work is expected to be based on justified sound engineering judgment, scientific principles, and applicable codes and standards. For all design related activities including software design, DOE O 414.1C and DOE G 414.1-4 shall be followed. Requirements contained in DOE O 420.1, *Facility Safety*, should be considered in identification of design requirements. DOE G 414.1-2A and DOE G 414.1-4 shall be followed in its entirety when performing design activities that support the EH Mission.

8. PROCUREMENT

8.1 Requirement

DOE O 414.1C Criterion 7 - *Procures items and services that meet established requirements and perform as specified; evaluates and selects prospective suppliers on the basis of specified criteria; establishes and implements processes to ensure that approved suppliers continue to provide acceptable items and services.*

DOE P 450.4, Principles and Functions, - Principle 3, *Personnel shall possess the experience, knowledge, skills, and abilities that are necessary to discharge their responsibilities; Principle 5*, *Before work is performed, the associated hazards shall be evaluated and an agreed-upon set of safety standards and requirements shall be established which, if properly implemented, will provide adequate assurance that the public, the workers, and the environment are protected from adverse consequences; Principle 7*, *The conditions and requirements to be satisfied for operations to be initiated and conducted shall be clearly established and agreed-upon; Function 1*, *Missions are translated into work, expectations are set, tasks are identified and prioritized, and resources are allocated.*

8.2 Implementation

8.2.1 Responsibilities

While procurement functions are normally performed by DOE contractors, EH mainly performs oversight of the procurement functions. Procurement requirements pertaining to the facilities such as the HEPA facility will be passed down via contractual documents requiring the contractor/supplier to do work that is in compliance with the requirements of ASME NQA-1-2004 for the application of intended use. If the procurement function is managed within EH, the work will be considered as nuclear safety related requiring the work to be done under the requirements of this EH MS. The requirements of ASME NQA-1-2004 will be applied utilizing an appropriate graded approach for the procurement activities.

EH procures support contractors to support Mission related work. In general, support contractors are managed by EH headquarters staff and the contractor performs work to the requirements of the EH MS. For highly specialized technical support, the EH contractor may perform the work to the contractor's approved quality assurance and integrated safety programs with oversight provided by the lead EH management group.

8.2.2 Procedures and Guidance

Guidance contained in DOE G 414.1-2A, *Quality Assurance Management System Guide*, shall be followed in its entirety when procuring items that perform a nuclear safety or other high risk function. Guidance provided in DOE G 414.1-4 shall be applied in its entirety for the procurement of safety software. For procurements that are managed within EH, a procedure covering the acquisition activities for nuclear safety procurement applications will be developed under the direction of the Quality Assurance Program Office and approved in accordance with the requirements defined in this MS.

8.2.3 Interactions with Field Offices

EH interacts with a field office in the area of Radiological Environmental Science Laboratory facility applications. Should there be a need for procurement actions, requirements will be passed down to the Field Office having jurisdiction over the facility to ensure that nuclear safety and high risk issues are addressed in accordance with the requirements that will be developed as the need is established.

9. INSPECTION AND ACCEPTANCE TESTING

9.1 Inspection and Acceptance Testing Requirements

DOE O 414.1C Criterion 8, - *Inspects and tests specified items, services, and processes using established acceptance and performance criteria; calibrates and maintains equipment used for inspections and tests.*

DOE P 450.4, Core Functions,-- **Function 1**, *Missions are translated into work, expectations are set, tasks are identified and prioritized, and resources are allocated;* **Function 2**, *Hazards are associated with the work identified, analyzed, and categorized;* **Function 4**, *Readiness is confirmed and work is performed safely.*

9.2 Application of Requirements

EH performance of inspections or acceptance testing as a part of its work is expected to be applied in support of Operational Readiness Reviews (ORRs), Readiness Assessments (RAs), accident investigations, and activities associated with the management of the HEPA Filter Testing Facility and the Radiological Environmental Science Laboratory. The precise requirements will be defined and passed down via contract documents for contractor or memorandum from EH to the responsible PSO organization. Requirements for Inspection and Acceptance Testing will be performed in accordance with guidance provided in DOE G 414.1-2A, *Quality Assurance Management System Guide*, dated 6-17-05.

10. MANAGEMENT ASSESSMENTS

10.1 EH MS Management Assessment Requirements

DOE O 414.1C Criterion 9, - *Ensures that manager's assess their management processes and identifies and corrects problems that hinder the organization from achieving its objectives.*

DOE P 450.4, Core Function 5, - *Feedback information on the adequacy of controls is gathered, opportunities for improving the definition and planning of work are identified and implemented, line and independent oversight is conducted, and, if necessary, regulatory enforcement actions occur.*

Managers at the DAS/OD levels shall periodically assess their organizations and functions to determine how well they are performing against that expected for 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. Management assessments are expected to determine whether an integrated management system exists and whether it is properly focused on meeting performance requirements and strategic goals.

10.2 Purpose of Management Assessments

Management assessments are self-assessments to determine the effectiveness of management leadership. The AS and PDAS are committed to the philosophy of the need to conduct self-assessments of management practices to identify performance issues; evaluate management aspects of performance issues; and make improvements. Strengths and weaknesses affecting the achievement of organizational objectives are identified so that meaningful action can be taken to improve both quality and safety. It is expected that management assessments will focus on the identification of concerns on safety and reliability and not simply the identification of administrative compliance issues or generic symptoms or indications.

10.3 Implementation Responsibilities

EH managers shall conduct an assessment of their organization, at least annually, to measure the effectiveness of the management systems and processes, and the ability of the organization to meet its objective. The assessment is intended to provide a basis for improving management systems; clarifying functions, responsibilities and authorities; and, establishing priorities for work process improvements. These assessments shall be conducted with the direct participation of the responsible Deputy Assistant Secretary (DAS) or Office Director (OD), who may solicit assistance from the EH Quality Assurance Policy Manual (QAPM). Management assessments will not be delegated.

10.4 Assessment Processes

Each DAS and OD will conduct assessments of their key management systems, processes, and procedures. The EH Strategic Plan includes the specific objectives and strategies that must be considered in management assessment planning. The approach for the implementation of management assessments at EH will be as follows (refer to DOE G 414.1-1A for detailed guidance on Management and Independent Assessments):

- Each DAS and OD will develop management expectations for the performance of the respective organizational unit. These expectations will be submitted to the PDAS for concurrence.
- Each DAS and OD will develop annual scope and schedule documents for their management assessments.
- The QAPM will coordinate with the DASs on this scope and schedule process.
- Each DAS will submit their schedule and scoping documents to the PDAS for approval.
- Management assessments will be conducted by the respective DAS or OD.
- Results of the assessment will be documented and the QAPM will analyze the results of all assessments to establish EH organization trends, performance results and lessons learned.

- Corrective actions for findings will be developed by the respective DAS or OD and gauged against the established set of expectations.
- The cognizant DAS or OD will assign responsible individual(s) to follow through and ensure that corrective actions are implemented.

Management assessment results will be used as feedback for internal lessons learned and corrective action plans will be developed to implement improvements to the management systems, processes, and procedures. These corrective actions may be incorporated in training to enhance EH personnel's understanding of missions and functions of their organization, knowledge of the work processes, and proper use of the procedures.

11. INDEPENDENT ASSESSMENTS

11.1 Quality and Safety Requirement

DOE O 414.1C Criterion 10, Independent Assessments, will be planned and conducted to measure item and service quality, the adequacy of work performance, and to promote management process improvements; teams will be established with sufficient authority and freedom from line management; and persons conducting independent assessments will be technically qualified and knowledgeable in the areas to be assessed.

DOE P 450.4, Core Function 5, Feedback information on the adequacy of controls is gathered, opportunities for improving the definition and planning of work are identified and implemented, line and independent oversight is conducted, and, if necessary, regulatory enforcement actions occur.

11.2 Applicability to EH

Independent assessments are necessary to provide the AS with an unbiased evaluation of organizational performance to ensure successful mission performance. Results of the independent assessments are a critical source of input for improvement of the management system and EH products. The Office of Quality Assurance Programs provides for the conduct of independent assessments under the direction of the PDAS.

11.3 Assessment Approach

Independent assessments will be planned, scheduled and coordinated by the QAPM and approved by the PDAS. Independent assessments will be conducted annually in accordance with DOE G 414.1-1A. The PDAS may waive the annual independent assessment based on a comprehensive external assessment (e.g., General Accounting Office or DOE Inspector General) being completed in a particular year. The QAPM is responsible for working with the DAS's and OD's to define the scope and develop the plan for each assessment. The assessment plan will be reviewed and approved by the PDAS and concurred in by the QAPM. Once the plan is approved, support for the assessment will be solicited and scheduled.

11.4 Conduct of an Assessment

A pre-assessment conference will be conducted with the management of the organization to be assessed. The purpose of the conference will be to confirm the scope and schedule designate interfaces, discuss the sequence and duration of the assessment, set the time for the post-assessment conference, and establishes channels of communication. During the conference, an agenda for the assessment shall be agreed upon.

It is expected that the QAPM or other approved and qualified individuals may lead and conduct the assessments. Independent subject matter experts (SME) and technically qualified individuals may be recommended from sources that are not connected to the organization being assessed. The QAPM will work closely with the assessment team leader on the detailed plans of the assessment to ensure that appropriate team staff are selected and oriented for the task, and the objectives of the assessment are defined.

11.5 Results and Follow-up

Assessment results shall be documented and reported by the assessment team to the responsible management for review. The report shall be distributed to responsible management of the assessed organizations. All assessment reports of EH activities shall be approved and issued by EH-1. Assessment reports of Field elements shall be approved and issued by the cognizant DAS of the work that was assessed. Follow-up actions including corrective actions will be developed by the assessed organization. This will be verified by the QAPM.

11.6 Procedures and Guidance (to be developed during the implementation phase)

11.7 Assessment and Oversight Interaction with Field and Contractor Organizations

EH will schedule and conduct independent assessments of its field elements (e.g., RESL) and contractors performing mission critical work for EH. The responsible EH DAS/OD will schedule these assessments, notify the organizations, and conduct these assessments using EH personnel, external technical experts, and support from EH-31.

12. SOFTWARE QUALITY ASSURANCE

12.1 DOE O 414.1C Requirements

The general requirements of DOE O 414.1C apply to all software developed, acquired, or used for EH work activities, including work performed by others for EH. Safety software, as defined in DOE O 414.1C, shall meet the specific requirements in DOE O 414.1C.

12.2 Applicability to EH

EH organizations perform work through the development or acquisition of software, including safety software. This work includes the analyses of issues pertaining to facility safety design, worker protection, and public health requirements; and the management and operation of facilities, including the HEPA filter test facility, Radiological Environmental Science Laboratory facilities, and DOE's safety software Central Registry. This work will be done under the requirements of DOE O 414.1C, including, where applicable, the safety software requirements.

12.3 Implementation

12.3.1 Responsibilities

The Office Director responsible for implementation of safety software application shall ensure the requirements in DOE O 414.1C applicable to software are implemented.

12.3.2 Procedures and Guidelines

The guidance provided in DOE G 414.1-4 shall be followed in its entirety for safety software applications. For other software applications, an appropriate consensus standard to implement the general requirements in DOE O 414.1C shall be selected and the basis for its selection documented.

13. SUSPECT/COUNTERFEIT ITEMS PREVENTION

13.1 EH Requirements

The Assistant Secretary for the Office of Environment, Safety and Health, is responsible for ensuring that Department crosscutting ES&H issues are addressed and resolved in a timely manner. This includes suspect/counterfeit items (S/CI) or defective items that could potentially impact operations at DOE facilities. The guidance provided in DOE O 414.1C, *Quality Assurance* and DOE G 414.1-3, *Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements*, shall be followed in its entirety when addressing provisions for the elimination of S/CI or defective items.

EH manages the DOE-wide S/CI prevention process as a service to the Department and its contractors. The process includes:

- a. Screening data sources to identify potential S/CI or defective items,
- b. Preparing and distributing Operating Experience Summaries, ES&H Alerts, Bulletins, and Special Operational Reports for potential S/CI or defective items,
- c. Drafting memoranda from EH-1 and developing, in cooperation with subject matter experts, GC and IG lines of inquiry for crosscutting or high-priority S/CI or defective items, requesting that Program Secretarial Officers (PSO) direct field element investigations and interface with other DOE offices as necessary,
- d. Evaluating the completeness of information provided to PSOs on the results of field element investigations of crosscutting or high-priority S/CI or defective items,
- e. Conducting trending and analysis for actions taken on S/CI or defective items,
- f. Preparing the annual S/CI Report to disseminate information regarding S/CI trends, analysis, and related quality assurance/procurement issues,
- g. Providing feedback and recommendations to EH-1 on S/CI process improvements,
- h. Providing training on the identification and disposition of S/CI or defective items.

13.2 Work Process Controls

EH shall develop work process controls that use available guidance and information to identify, prevent, and remove S/CI materials or items and defective items from being used in nuclear safety or high risk activities. Guidance in compliance for meeting requirements is provided in DOE G 414.1-3, *Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements*, and DOE O 414.1B, dated 11-03-04.

14. ACRONYMS

CAP	Corrective Action Plan
CFR	Code of Federal Regulations
CIO	Department of Energy Chief Information Officer
CRD	Contractor Requirements Document
DAS	Deputy Assistant Secretary
DEAR	Department of Energy Acquisition Regulation
DNFSB	Defense Nuclear Facilities Safety Board
EA	Environmental Assessment
EH-1	Office of Environment, Safety and Health
EH-2	Office of Facility Safety
EH-3	Office of Corporate Performance Assessment
EH-4	Office of Environment
EH-5	Office of Health
EH-6	Office of Price-Anderson Enforcement
EH-7	Office of Planning and Administration
ES&H	Environment, Safety, and Health
FAQS	Functional Area Qualification Standard
FRA	Functions, Responsibilities, and Authorities
FRAM	Functions, Responsibilities, and Authorities Manual
GC	Department of Energy Office of General Counsel
MFS	Mission and Functions Statement
MOU	Memorandum of Understanding
NNSA	National Nuclear Security Administration
NOV	Notice of Violation
NRC	Nuclear Regulatory Commission
ORPS	Occurrence Reporting and Processing System
ORR	Operational Readiness Review
OSH	Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
POC	Point of Contact
PSO	Program Secretarial Office(r)
QAP	Quality Assurance Program
QAPP	Quality Assurance Program Plan
RPP	Radiation Protection Program
SAR	Safety Analysis Report
S/CI	Suspect/Counterfeit Item
SME	Subject Matter Expert
SO	Secretarial Office(r)
S/RID	Standards/Requirements Identification Document
SSCs	Structures, Systems, Components
TSP	Technical Standards Program
USQ	Unreviewed Safety Question

15. LIST OF REFERENCES

Department of Energy Directives

- EH Strategic Plan 2003 – 2006
- EH FRA
- DOE 360.1B, Federal Employee Training
- DOE O 414.1C, Quality Assurance
- DOE P 450.4, Safety Management System Policy
- DOE G 414.1-2A, Quality Assurance Management System Guide
- DOE G 414.1-3, Suspect/Counterfeit Items Guide for use with 10 CFR 830 Subpart A, Quality Assurance Requirements
- DOE G 414.1-4, Safety Software Guide for use with 10 CFR 830 Subpart A, Quality Assurance Requirements and DOE O 414.1C, Quality Assurance
- DOE P 226.1, DOE Oversight Policy
- DOE O 226.1, Implementation of DOE Oversight Policy
- DOE O 420.1A, Facility Safety
- DOE-STD-3020-XX, Specification for HEPA Filter used by DOE Contractors
- DOE-STD-3022-XX, DOE HEPA Filter Test Program
- DOE-STD-3025-XX, Quality Assurance Inspection and Testing of HEPA Filters
- DOE-STD-3026-XX, Filter Test Facility Quality Program Plan

Consensus Standards

- ASME NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Applications*
- ANSI/ISO/ASQ Q 9001-2000, *Quality Management System-Requirements (for non-nuclear activities)*

16. GLOSSARY

Graded Approach: The adaptation of a DOE accepted industry standard or management practice to a specific EH management application.

High Risk Activity: An EH provided service that is necessary for achieving and ensuring safe, reliable, and effective performance of work functions that could result, in the event of a failure, to have significant impact on either the EH Mission or could result in exceeding published accepted limits for the protection of workers, public, and the environment.

Management System: A description or a documented set of the work controls that describes responsibilities for work and their application pertaining to the operation of an organization.

Nuclear Safety: An EH provided service that is necessary to achieve and ensure safe, reliable, and effective performance of work functions that control nuclear related actions whose failure could result in significant impact on either the EH Mission, or could result in exceeding published accepted limits for the protection of workers, public, and the environment.

Quality: The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations. [10 CFR 830]

Quality Assurance: All those actions that provide confidence that quality is achieved. [10 CFR 830]

Quality Assurance Program: A 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 an item, service, or process. [10 CFR 830]

System: An integrated composite of people, products, and processes that provide a capability to satisfy a stated need or objective. [DoD 882E]

Implementation Plan⁴

For the

EH Quality/Safety Management System

INTRODUCTION

The implementation process will focus on four major areas; namely 1) EH Documents and Records, 2) EH Management Assessments, 3) EH Independent Assessments, and 4) EH Work Process Controls.

1. EH Documents and Records (work to commence second quarter 2006)

There are issues that require EH Management to address in order to establish a quality document and records management system. Once the issues are resolved, work will commence to implement the management decisions. Document issues include the following:

- What documents will be placed under quality assurance control?
- Responsibilities defined for the development, review, and issuance of controlled documents
- Controls for document logging, distribution, and storage to be applied
- Document maintenance and change process controls to be applied

Records issues include the following:

- Identification of documents that will be designated as EH records
- Definition of requirements for the control and storage for the various types of records
- Identification of responsibilities for logging, filing, and storing of records
- Definition of the process for revising and maintaining records

2. EH Management Assessments (expected to commence during fourth quarter FY 2006)

Each EH Manager is responsible for conducting assessments of selected management processes being implemented for work within the group. Office Directors will conduct management assessments in accordance with a procedure to be developed. Responsibility for development of the procedure along with the schedule for its implementation is shown in Table 1.

3. EH Independent Assessments (expected to commence during second quarter FY 2007)

The goal of independent assessments is to achieve an authoritative independent appraisal of the adequacy of work processes being implemented for producing quality products (are we meeting customer requirements and expectations?).

Independent Assessments will be conducted in accordance with a procedure to be developed that will define processes and requirements to include technical and expertise requirements for team members. Responsibility for development of the procedure along with the schedule for its implementation is shown in Table 1. Independent Assessments would be scheduled after completion of at least one Management Assessment cycle for all EH offices.

4. EH Work Process Controls (EH work in process; balance will largely be completed in FY 2006)

Applicable criterion elements of Order 414.1C will require management guidance in the form of work control procedures for EH Staff use. Several procedures have been identified and some are under preparation that is expected to address requirements for the management of work governing EH functions. There may be others yet to be defined. The status of identified documents to be or being developed, along with the schedule for completion, is provided in Table 1.

⁴ The Implementation Plan is not a part of the EH Quality/Safety Management System document. As the Implementation Plan is completed, the EH Quality/Safety Management System document will be revised to reflect added information that results during the implementation process.

Table 1 - EH Management System Work Process Control Documents

No.	DOCUMENT TITLE or Action	Applicable DOE Order 414.1C Criterion	Responsible Lead Group	Supporting Group(s)	Document or Action Schedule (Issue date)	Implementation Schedule (60 days following document issue)
1	Office of Oversight Procedure	1, 3	EH-1	EH-31		
2	Correspondence Review and Approval Process	1	EH-1, EH-7	EH-71		
3	Differing Professional Opinions	1	EH-1			
4	Emergency Response EH Management Succession Plan and DOOP Teams	1	EH-1			
5	EH Tracking System	1	EH-1	EH-71		
6	Policy and Standard Procedure Development	1	EH-1	EH-7, EH-31		
7	Budget and Accounting Procedures	1	EH-1	EH-73		
8	Department Readiness Review Process	1	EH-1, EH-3	EH-31		
9	Preparation of Periodic Reports	1	EH-1	EH-7		
10	Defense Nuclear Facilities Safety Board Commitment Management	1	EH-1	EH-7		
11	Development and Processing Safety Alerts, Safety Bulletins, and Special Operations Reports	3	EH-1	EH-31		
12	Coordination and Approval of EH Program Element Activities	3, 5	EH-1	EH-31		
13	Procedure for Field Interaction Operating Experience Summary	5	EH-1	EH-32		
14	Staff Indoctrination, Training and Qualification	2	EH-3	EH-31	March 2006	May 2006
15	Document Process Control	4	EH-3, EH-7	EH-31 EH-72	EH-31, April 2006 EH-72, _____	60 days following issuance of procedure
16	Records Management	4	EH-7	EH-31		
17	Management Assessments	9	EH-3	EH-2 thru EH-7	April 2006	May 2006
18	Independent Assessments	10	EH-3	EH-2 thru EH-7	July 2006	September 2006
19	Quality Improvement	3	EH-3	EH-31	March 2006	May 2006
20	Procurement Quality Control Processes	5	EH-3, EH-7	EH-31, EH-71	June 2006	June 2006
21	Review initial Management and Independent Assessments results to define critical barriers to full implementation	3	EH-3		October 2006	June 2007

No.	DOCUMENT TITLE or Action	Applicable DOE Order 414.1C Criterion	Responsible Lead Group	Supporting Group(s)	Document or Action Schedule (Issue date)	Implementation Schedule (60 days following document issue)
22	Review 2 nd cycle of assessments to confirm implementation	3	EH-3		October 2007	June 2007

13. SUSPECT/COUNTERFEIT ITEMS PREVENTION

13.1 EH Requirements

The Assistant Secretary for the Office of Environment, Safety and Health, is responsible for ensuring that Department crosscutting ES&H issues are addressed and resolved in a timely manner. This includes suspect/counterfeit items (S/CI) or defective items that could potentially impact operations at DOE facilities. The guidance provided in DOE O 414.1C, *Quality Assurance* and DOE G 414.1-3, *Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements*, shall be followed in its entirety when addressing provisions for the elimination of S/CI or defective items.

EH manages the DOE-wide S/CI prevention process as a service to the Department and its contractors. The process includes:

- a. Screening data sources to identify potential S/CI or defective items,
- b. Preparing and distributing Operating Experience Summaries, ES&H Alerts, Bulletins, and Special Operational Reports for potential S/CI or defective items,
- c. Drafting memoranda from EH-1 and developing, in cooperation with subject matter experts, GC and IG lines of inquiry for crosscutting or high-priority S/CI or defective items, requesting that Program Secretarial Officers (PSO) direct field element investigations and interface with other DOE offices as necessary,
- d. Evaluating the completeness of information provided to PSOs on the results of field element investigations of crosscutting or high-priority S/CI or defective items,
- e. Conducting trending and analysis for actions taken on S/CI or defective items,
- f. Preparing the annual S/CI Report to disseminate information regarding S/CI trends, analysis, and related quality assurance/procurement issues,
- g. Providing feedback and recommendations to EH-1 on S/CI process improvements,
- h. Providing training on the identification and disposition of S/CI or defective items.

13.2 Work Process Controls

EH shall develop work process controls that use available guidance and information to identify, prevent, and remove S/CI materials or items and defective items from being used in nuclear safety or high risk activities. Guidance in compliance for meeting requirements is provided in DOE G 414.1-3, *Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements*, and DOE O 414.1B, dated 11-03-04.

14. ACRONYMS

CAP	Corrective Action Plan
CFR	Code of Federal Regulations
CIO	Department of Energy Chief Information Officer
CRD	Contractor Requirements Document
DAS	Deputy Assistant Secretary
DEAR	Department of Energy Acquisition Regulation
DNFSB	Defense Nuclear Facilities Safety Board
EA	Environmental Assessment
EH-1	Office of Environment, Safety and Health
EH-2	Office of Facility Safety
EH-3	Office of Corporate Performance Assessment
EH-4	Office of Environment
EH-5	Office of Health
EH-6	Office of Price-Anderson Enforcement
EH-7	Office of Planning and Administration
ES&H	Environment, Safety, and Health
FAQS	Functional Area Qualification Standard
FRA	Functions, Responsibilities, and Authorities
FRAM	Functions, Responsibilities, and Authorities Manual
GC	Department of Energy Office of General Counsel
MFS	Mission and Functions Statement
MOU	Memorandum of Understanding
NNSA	National Nuclear Security Administration
NOV	Notice of Violation
NRC	Nuclear Regulatory Commission
ORPS	Occurrence Reporting and Processing System
ORR	Operational Readiness Review
OSH	Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
POC	Point of Contact
PSO	Program Secretarial Office(r)
QAP	Quality Assurance Program
QAPP	Quality Assurance Program Plan
RPP	Radiation Protection Program
SAR	Safety Analysis Report
S/CI	Suspect/Counterfeit Item
SME	Subject Matter Expert
SO	Secretarial Office(r)
S/RID	Standards/Requirements Identification Document
SSCs	Structures, Systems, Components
TSP	Technical Standards Program
USQ	Unreviewed Safety Question

15. LIST OF REFERENCES

Department of Energy Directives

- EH Strategic Plan 2003 – 2006
- EH FRA
- DOE 360.1B, Federal Employee Training
- DOE O 414.1C, Quality Assurance
- DOE P 450.4, Safety Management System Policy
- DOE G 414.1-2A, Quality Assurance Management System Guide
- DOE G 414.1-3, Suspect/Counterfeit Items Guide for use with 10 CFR 830 Subpart A, Quality Assurance Requirements
- DOE G 414.1-4, Safety Software Guide for use with 10 CFR 830 Subpart A, Quality Assurance Requirements and DOE O 414.1C, Quality Assurance
- DOE P 226.1, DOE Oversight Policy
- DOE O 226.1, Implementation of DOE Oversight Policy
- DOE O 420.1A, Facility Safety
- DOE-STD-3020-XX, Specification for HEPA Filter used by DOE Contractors
- DOE-STD-3022-XX, DOE HEPA Filter Test Program
- DOE-STD-3025-XX, Quality Assurance Inspection and Testing of HEPA Filters
- DOE-STD-3026-XX, Filter Test Facility Quality Program Plan

Consensus Standards

- ASME NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Applications*
- ANSI/ISO/ASQ Q 9001-2000, *Quality Management System-Requirements (for non-nuclear activities)*

16. GLOSSARY

Graded Approach: The adaptation of a DOE accepted industry standard or management practice to a specific EH management application.

High Risk Activity: An EH provided service that is necessary for achieving and ensuring safe, reliable, and effective performance of work functions that could result, in the event of a failure, to have significant impact on either the EH Mission or could result in exceeding published accepted limits for the protection of workers, public, and the environment.

Management System: A description or a documented set of the work controls that describes responsibilities for work and their application pertaining to the operation of an organization.

Nuclear Safety: An EH provided service that is necessary to achieve and ensure safe, reliable, and effective performance of work functions that control nuclear related actions whose failure could result in significant impact on either the EH Mission, or could result in exceeding published accepted limits for the protection of workers, public, and the environment.

Quality: The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations. [10 CFR 830]

Quality Assurance: All those actions that provide confidence that quality is achieved. [10 CFR 830]

Quality Assurance Program: A 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 an item, service, or process. [10 CFR 830]

System: An integrated composite of people, products, and processes that provide a capability to satisfy a stated need or objective. [DoD 882E]

Implementation Plan⁴

For the

EH Quality/Safety Management System

INTRODUCTION

The implementation process will focus on four major areas; namely 1) EH Documents and Records, 2) EH Management Assessments, 3) EH Independent Assessments, and 4) EH Work Process Controls.

1. EH Documents and Records (work to commence second quarter 2006)

There are issues that require EH Management to address in order to establish a quality document and records management system. Once the issues are resolved, work will commence to implement the management decisions. Document issues include the following:

- What documents will be placed under quality assurance control?
- Responsibilities defined for the development, review, and issuance of controlled documents
- Controls for document logging, distribution, and storage to be applied
- Document maintenance and change process controls to be applied

Records issues include the following:

- Identification of documents that will be designated as EH records
- Definition of requirements for the control and storage for the various types of records
- Identification of responsibilities for logging, filing, and storing of records
- Definition of the process for revising and maintaining records

2. EH Management Assessments (expected to commence during fourth quarter FY 2006)

Each EH Manager is responsible for conducting assessments of selected management processes being implemented for work within the group. Office Directors will conduct management assessments in accordance with a procedure to be developed. Responsibility for development of the procedure along with the schedule for its implementation is shown in Table 1.

3. EH Independent Assessments (expected to commence during second quarter FY 2007)

The goal of independent assessments is to achieve an authoritative independent appraisal of the adequacy of work processes being implemented for producing quality products (are we meeting customer requirements and expectations?).

Independent Assessments will be conducted in accordance with a procedure to be developed that will define processes and requirements to include technical and expertise requirements for team members. Responsibility for development of the procedure along with the schedule for its implementation is shown in Table 1. Independent Assessments would be scheduled after completion of at least one Management Assessment cycle for all EH offices.

4. EH Work Process Controls (EH work in process; balance will largely be completed in FY 2006)

Applicable criterion elements of Order 414.1C will require management guidance in the form of work control procedures for EH Staff use. Several procedures have been identified and some are under preparation that is expected to address requirements for the management of work governing EH functions. There may be others yet to be defined. The status of identified documents to be or being developed, along with the schedule for completion, is provided in Table 1.

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