

Quality Assurance Program Description for the U.S. Department of Energy Pacific Northwest Site Office

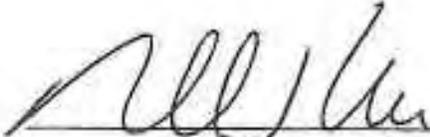


U.S. DEPARTMENT OF
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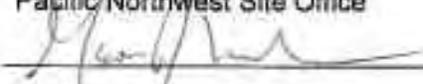
Pacific Northwest Site Office

June 2009

 _____ 7/10/09

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 _____ 8/6/09

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INTRODUCTION

DOE O 414.1C, *Quality Assurance*, is applicable to DOE Site Office activities. This Pacific Northwest Site Office (PNSO) Quality Assurance Program Description (QAPD) describes the method by which Quality Assurance (QA) will be implemented and quality achieved within PNSO. At a high level, the Office of Science ensures that its mission is executed properly and efficiently by utilizing a web-based management tool called the Science Management System (SCMS). SCMS and its supporting documentation and procedures serve the organization by providing a comprehensive, high-level description of SC's responsibilities, the associated authorities it operates within, and its management approaches designed specifically to deliver the above mission. Where appropriate, this QAPD will reference SCMS.

The PNSO Quality Assurance Program incorporates the principles of NQA-1:2000, which is one of a family of quality management standards. NQA-1-2000 "American Society of Mechanical Engineers, Quality Assurance Requirements for Nuclear Facility Applications" will be applied to specific work activities. Performance associated with NQA-1-2000 for some office work will not be applicable.

A graded approach, based on the relative importance of the activity to safety, safeguards and security, and other pertinent areas of management consideration is used in applying the requirements of this document as described in the Appendix A.

Appendix B contains a PNSO crosswalk between O 414.1C/10CFR830 /NQA-1 to show how PNSO Guides/Plans/Procedures are linked to QA requirements in relation to federal requirements and orders as well as quality standards.

For reference, Appendix C lists the basic (100 level) text of the NQA-1 requirements, which are, in essence, the objectives of each of the 18 requirements that make up the NQA-1 Standard.

This QAPD describes the federal role for each of the ten QA criteria outlined in the DOE O 414.1C and shown in this QAPD. For each section, the specific requirements associated with that criterion are identified and outlined inside a heavy line, followed by a General Information sub-section and an Implementation sub-section. The General Information sub-section identifies PNSO Management Expectations required to comply with this program, along with a discussion that amplifies the expectations and/or provides necessary background. This information is directed toward the application of the criterion to the federal employees' role. The Implementation sub-section provides a link to PNSO/SCMS documents and processes that implement the applicable requirements at PNSO. Contract management, including contractor oversight, is addressed under the procurement criterion. One of the criteria, Inspection and Acceptance Testing Requirements, does not apply to the work performed by PNSO, and is addressed accordingly in this QAPD.

This QAPD incorporates the DOE Pacific Northwest Site Office (PNSO) NEPA activities including the approval of Environmental Assessments (EAs), Findings Of No Significant Impact (FONSIs), and Categorical Exclusions (CXs). However, Appendix D provides a NEPA specific description as to how each NEPA requirement is addressed. The

plan satisfies the NEPA quality requirements contained in US Code of Federal Regulations.10 CFR 1021, US Department of Energy, *National Environmental Policy Act; Implementing Procedures*.

Quality Assurance is defined as those actions that provide confidence that quality is achieved and is the responsibility of each PNSO employee. Specifically, the responsibility for quality resides with those individuals performing tasks, as well as those checking or verifying a task is properly performed. However, the PNSO Manager retains the overall responsibility and accountability for the scope and implementation of the PNSO QAPD. The PNSO Manager has delegated the responsibility for development and maintenance of the QAPD to the QAP POC. Quality Assurance will be applied with a graded approach such that the level of control and verification appropriate for a task will be dependent upon the consequences of the task not being performed properly.

PNSO employees typically perform two functions: 1) performing work that is inherently a government responsibility and 2) managing contracts where the primary responsibility for achieving quality results resides with the contractor. The overall role of the federal employee includes the following:

- Understanding and helping to shape the expectations of customers (DOE-HQ, stakeholders, regulators, contractors, and those internal to PNSO).
- Defining and prioritizing the work of PNSO contractor, including setting aggressive, but realistic performance expectations.
- Establishing the right contracts and requirements to complete the work.
- Requesting adequate funding to meet DOE obligations.
- Authorizing work and providing government-furnished items and services necessary to complete the work.
- Maintaining an honest and accurate view of the current state of affairs, through monitoring, assessments, knowledge, analysis, and open communication using an assortment of channels.
- Ensuring the government receives value for work performed, consistent with its cost.
- Ensuring corrective actions resulting from assessments are, in fact, effective and the feedback and lessons learned are captured and result in continuous improvement for PNSO staff and contractor.

When employees comply with PSNO processes, procedures, and other documents, they are implementing this QAPD. PNSO will ensure that all staff members understand their responsibility in meeting the requirements outlined in this QAPD.

1.0 PROGRAM REQUIREMENTS

The following are the program requirements from Criterion 1, DOE O 414.1C:

- (a) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.
- (b) Establish management processes, including planning, scheduling, and providing resources for work.

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:
PNSO senior management and staff shall be familiar with and facilitate achievement of the management expectations included in this document.
PNSO senior management and staff shall be familiar with and utilize SCMS in implementing the expectations of this document.
This QAPD shall be maintained current.
The PNSO Manager is responsible to assure adequate resources are provided to implement the QAPD.

The QAPD is implemented by: (1) incorporating the commitments of this document into PNSO products, and (2) following PSNO procedures to perform work. The QA POC is responsible to the PNSO Manager for review and revision of this document when: (1) DOE O 414.1C is revised, (2) PNSO management actions render it obsolete, or (3) annually to ensure it remains consistent with PNSO management expectations. The QA POC will also perform an annual assessment against the QAPD to identify any issues or gaps relative to implementation.

The Pacific Northwest Site Office is organized into two primary Divisions (see Figure 1).

The Laboratory Stewardship Division contains two teams. The Capability Stewardship Team is responsible for oversight of mission-related programs (i.e., Fundamental Science, Energy Science & Technology, Environmental Technology, National Security, and Computational and Information Sciences) and the Capability Replacement (CRL) Project, which includes the Physical Sciences Facility (PSF) as well as 2 alternatively financed facilities. The Business &

Organizational Systems Team is responsible for Contract Administration and Business Management including Human Resources, Financial, Legal and Information Technology.

The Operations Division is also comprised of two teams. The first is the ESSH&Q team which is responsible for oversight of Environment, Safety and Health, Quality Assurance, Nuclear Safety, Safeguards & Security, Radiological Protection, Worker Health & Safety, Emergency Management, Project Management and Training and Qualification. The second is the Facilities & Operations Team which has oversight responsibilities for Facility Management, Facility Safety, and day-to-day oversight (via 3 Facility Representatives).

Through this management structure, PNSO uses a systems based approach for oversight where it provides *direction*, conducts *oversight*, and *approves* contract deliverable products to accomplish its roles and responsibilities. PNSO staff members are aligned by PNNL management systems (i.e., safety, environmental, quality, acquisition etc.) The PNSO oversight processes are described in PNSO documents and procedures (e.g., Contract Management Plan, Performance Evaluation and Measurement Plan, Performance Assurance Program, Proposal and Work Authorization Procedure, etc.)

The PNSO organizational structure creates an environment in which staff works interdependently in managing and performing the federal functions of the PNSO office. Functional responsibilities and levels of authority for PNSO employees are addressed in PNSO processes, procedures, and program documents. The PNSO Functions, Responsibilities and Authorities (FRA) Document identifies the responsibilities and authorities for PNSO. The PNSO Manager has created a framework in its Performance Assurance Program that assist in the planning, scheduling, and allocation of resources to accomplish the federal work performed by PNSO staff and for the Laboratory contractor. Where necessary, PNSO coordinates and integrates activities with DOE's Richland Operations Office (RL). An Operational Agreement documents the relationship between the DOE Manager of RL and the DOE Manager of PNSO.

IMPLEMENTATION

- (a) This document describes the PNSO Quality Assurance program, and is referred to herewith as the Quality Assurance Program Description (QAPD). This QAPD complies with DOE O 414.1C, *Quality Assurance* and 10 CFR 830 Subpart A (and implements the National Environmental Policy Act (NEPA) requirement for a quality assurance plan).
- (b) The approved PNSO Organizational Chart (figure 1), which is posted on the PNSO website, reflects the levels of authority in the organization with Division Directors being the first level of supervision, who report directly to the Site Office Manager. Roles, responsibilities, authorities, and accountabilities are described in the PNSO R2A2 document.
- (c) A Contract Management Plan and FRA (Functions, Responsibilities and Authorities) Document shall be developed and maintained for PNSO.

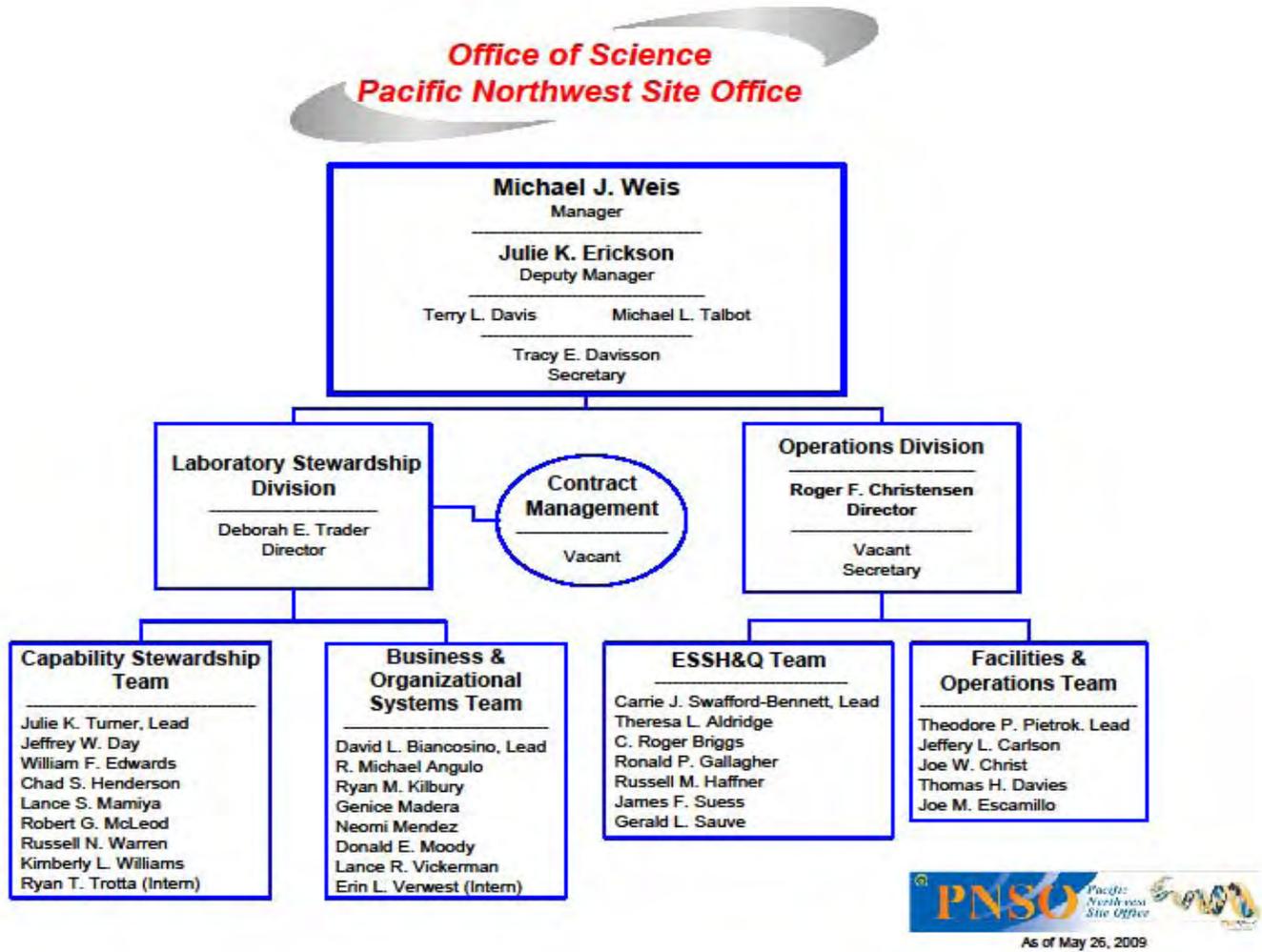


Figure 1

2.0 PERSONNEL TRAINING AND QUALIFICATION

The following are the requirements from DOE O 414.1C:

- (a) Train and qualify personnel to be capable of performing assigned work.
- (b) Provide continuing training to personnel to maintain job proficiency.

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:
Individual Development Plans (IDPs) are developed and maintained for employees.
Personnel training and qualifications shall be consistent with PNSO Annual Performance Plan objectives.

The success of any organization requires members of the organization be skilled in the work processes they perform. Training is provided to PNSO employees to maintain job proficiency, enhance existing skills, and develop new skills. PNSO Managers are responsible for ensuring personnel are qualified for their positions before being placed in those positions. Training includes education in principles, enhancement of skills and practices, and on the job training. Methods of training include reading assignments, observation and performance of activities, feedback from co-workers and managers, briefings, and formal training classes, among others. The extent of training is commensurate with the scope, complexity, and nature of the respective task. Education, experience, and formal training comprise the basis for qualification.

PNSO currently relies on an internal qualification program for facility representatives that include testing and an oral board examination. For other positions managers rely on the initial human resources screening, interviews, and observation on the job. PNSO Human Resources Support at the Oak Ridge Service Center assists in these efforts by screening applicants against the education, skills, and experience requirements for the position and ensuring only qualified personnel are considered.

IDPs provide the structure of an effective training and development program and provide activities that are carried out in an organized, systematic manner, with established goals clearly defined and sequenced. IDPs are designed for initial training and qualification, as well as maintenance of proficiency and progressive improvement. IDPs are designed to stimulate

professional development and may include managerial, communication, and interpersonal skills. Initial training prepares personnel to perform the job. Continuing training specified in the IDP maintains and promotes improvement in the incumbent's job performance, and/or prepares personnel for new responsibilities.

Qualifications for specific job categories are based on requirements established by DOE Directives, other requirement documents, or management. PNSO management reviews job categories to determine:

- If critical and/or unique job functions or tasks require highly technical, specialized skills
- Whether competency must be demonstrated before performance
- Whether a specialized certification may be required

Based on the review, qualification requirements that provide evidence of employee proficiency through a practical and/or written examination process may be established.

The DOE directives related to this criterion are DOE Order 360.1B, *Federal Employee Training*, its associated Manual, DOE Manual 360.1-1B, *Federal Employee Training Manual*, and DOE Manual 426.1-1, *Federal Technical Capability Manual*.

Relative to NEPA Compliance, PNSO ensures that staff involved in the NEPA review process shall be qualified professionals by background, experience, and/or training. These personnel shall be adequately trained in the laws, regulations, policies, requirements and guidance identified in Appendix D of this Plan.

IMPLEMENTATION

- (a) The methods for ensuring personnel are trained and qualified, capable of performing their assigned work, are identified in the IDPs, Individual Performance Plans, Appraisals, and Position Descriptions.
- (b) The methods for ensuring personnel requiring technical qualification are trained and qualified, capable of performing their assigned work, are identified in the SC Technical Qualification Program which can be found in the Human Resources Services Management System in SCMS in the Employee Development Subject Area. See "Procedure 5. Implementing Technical Qualification Program".
- (c) The methods for ensuring personnel are provided continuing training and job proficiency are identified through the Oakridge Operations Integrated Support Center Human Resources processes. Organization specific personnel development is treated in associated documents such as PNSO-GUID-12: DOE-PNSO Facility Representative Qualification Standard for PNNL.

3.0 QUALITY IMPROVEMENT

The following are the requirements from DOE O 414.1C:

- (a) Establish and implement processes to detect and prevent quality problems.
- (b) Identify, control, and correct items, services, and processes that do not meet established requirements.
- (c) Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.
- (d) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:
PNSO management shall set measurable Site Office performance goals and standards in the PNSO Annual Performance Plan.
PNSO management shall establish Site Office metrics that measure performance.
Corrective action plans shall be developed for findings, approved by the assessing organization, and implemented according to the plan.
Completed corrective actions shall be verified by the assessing organization.

In order for quality improvement to be obtained, measurable performance goals and standards must be set as a baseline. This is accomplished with the development of the PNSO Annual Performance Plan. Once this baseline is established, it can be measured against and improved upon. Then, systems must be in place that identify problems. Problem identification can occur as a result of self-assessments, independent or external assessments, anomalous behavior of some measured quantity against a predefined metric, benchmarking, failure to achieve performance goals or accomplish improvement plans, or as a result of the occurrence of an event. Problem identification can also result from unfulfilled expectations of customers served by the organization. In most cases, problems are associated with deviations or inconsistencies with a requirement, or failures to meet customer, or management expectation. Items, services, or processes that conform to requirements and meet known customer or management expectation

but still need improvement generally require such improvement because the activity could have been performed more effectively or efficiently.

Responses to findings identified by the Office of Health, Safety and Security (HSS), Judgments of Need for Type A accident investigations, and for other sources as directed by the Secretary or Deputy Secretary are subject to the requirements of DOE O 414.1C, Attachment 4, "Corrective Action Management Program [CAMP]." This includes the requirement to prepare a comprehensive Corrective Action Plan (CAP) and to track and report CAP data in the DOE Corrective Action Tracking System (CATS) database (see SCMS Quality Assurance and Oversight MS, Issues Management Subject Area). Responses to findings by OA are also subject to DOE O 470.2B, "Independent Oversight and Performance Assurance Program" requirements. Problems resulting from inadequacies in management systems are candidates for the Lessons Learned.

Quality improvement of the PNSO NEPA review and approval process is achieved through the auditing program and lessons-learned program. The PNSO Deputy/Assistant NEPA Compliance Officer (NCO) oversees the implementation of these programs and participates in DOE Office of Science NEPA teleconferences to benefit from lessons learned and headquarters guidance. PNSO staff will also utilize the NEPA workshops at the regular ES&H Coordination Meetings to focus on continuous NEPA improvement, successes, problem solving, and issue resolution. As needed, the PNSO Deputy/Assistant NCO will obtain reviews by individuals and organizations with the proper expertise to ensure document quality. Corrective actions are documented and tracked in the ONESC Issue Tracking System (SITS) and/or the Headquarters Corrective Action Tracking System (CATS), as applicable.

The PNSO Corrective Action Management Program POC is required to manage compliance with the CAMP. Once accepted, CAP actions are entered and maintained in the Headquarters CATS. The designated POC is responsible for coordinating responses, transmitting the CAP, and preparing closeout documentation in accordance with DOE O 414.1C, Attachment 4, "Corrective Action Management Program [CAMP]."

Corrective action for significant conditions adverse to quality should include an analysis of causal factors. Formal root cause analysis should be considered based on the complexity of the identified issue. Root cause should be performed using some authoritative methodology for root cause identification, such as the DOE Guideline DOE-NE-STD-1004-92, *Root Cause Analysis Document*.

PNSO has established processes to detect and prevent quality problems and to ensure quality improvement. A corrective action system is used to identify and control needed improvements. The PNSO corrective action system is described in the Performance Assurance Program. The corrective action process requires that identified problems are analyzed, causal factors determined, and cost-effective corrective actions identified and implemented. Corrections are directed towards preventing reoccurrence.

PNSO conducts corrective action verification/validation and effectiveness reviews using a graded approach (Appendix A). Lower-level corrective actions may be verified by PNSO staff, program owners, or facility representatives and documented in the PNSO Capture Tool. For higher-level corrective actions (e.g., from HSS reviews, project reviews, Type B accident

investigations, etc), PNSO conducts or leads a formal validation review and subsequent effectiveness review, which is documented in a formal report.

IMPLEMENTATION

- (a) Processes to detect and prevent quality problems include Self-Assessment, Independent Oversight, Benchmarking, and measuring established metrics.
- (b) Services and processes that do not meet established requirements must be controlled and corrected in accordance with PNSO Corrective Actions management process as described in the Performance Assurance Program.
- (c) Correction, identification of the causes of problems, and steps to prevent recurrence shall be taken in accordance with PNSO Corrective Actions management process as described in the Performance Assurance Program.
- (d) Process improvement at PNSO is achieved through Self-Assessment as described in the PNSO Performance Assurance Program and through the Corporate Operating Experience/Lessons Learned program as described in SCMS in the QA & Oversight MS.
- (e) Quality improvement is measured against PNSO Annual Performance Plan.

4.0 DOCUMENTS AND RECORDS REQUIREMENTS

The following are the requirements from DOE O 414.1C:

- (a) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
- (b) Specify, prepare, review, approve, and maintain records.

GENERAL INFORMATION

Documents

MANAGEMENT EXPECTATIONS:
PNSO staff shall identify or develop documents based on governing requirements, SCMS guidelines, applicable technical standards, and this QAPD, that define how the work will be performed by federal employees.
New or revised requirements shall be analyzed to determine impact on implementing procedures and/or contracts.
PNSO documents shall be development in accordance with SCMS, reviewed by affected organizations and approved by PNSO staff.
PNSO documents shall be deployed in a manner that makes the documents readily available to the users.

Documents establish requirements and/or define how work is to be performed. PNSO documents that establish policy, prescribe work, or specify requirements shall be prepared, reviewed, approved, issued, implemented, and revised. Requirements typically originate from laws, regulations, and/or DOE Directives. New or revised requirements documents are analyzed to determine impact on PNSO implementing documents and/or PNSO contracts. PNSO has processes and procedures for preparing, reviewing, approving, issuing, revising, and using documents. Documents controlled by PNSO include program descriptions, processes, procedures, organization specific procedures, and other work documents. Users of PNSO documents are responsible for implementing the latest revision of documents. Major changes to documents are subject to the same level of review and approval as was the original document.

All PNSO NEPA documents and determinations will be prepared, reviewed, approved, issued, used, and revised according to DOE and PNSO policies and requirements. Hard copies of all PNSO NEPA documents and

determinations, guidance and procedures will be maintained by the PNSO NCO and/or NEPA Document Manager in accordance with *DOE Records Schedule for Environmental Records*. Documents will include the following:

- Approved NEPA documents and supporting data used as a basis for the decision
- Review comments and resolution
- Subject matter expert concurrences
- Other NEPA documentation demonstrating that DOE followed the proper process in complying with NEPA.

Records

MANAGEMENT EXPECTATIONS:
PNSO products shall identify records that need to be created and maintained.
PNSO records shall be maintained in accordance with SCMS Management System Description: <i>Records Management</i> .
Records shall be transferred to permanent storage in a timely manner when they are no longer needed by the organization.

Records are typically the outcome of creating documents that reflect what was done. Records include but are not limited to formal correspondence, plans, study results, permits, financial records, assessment reports, contract related documents, etc. Staff performs work, prepares, collects, protects, and retains records in a manner that makes the record retrievable, useable, and auditable. Written procedures govern records required to support ongoing activities (active records) as well as records transferred to records retention areas (inactive records). Records requirements are communicated to PNSO personnel using ‘records capture statements’ in procedures. Records must accurately reflect the work performed, be legible and traceable to the applicable work and the responsible personnel.

Completed records are collected by the organizations performing the work, except the record copies of formal correspondence, which are maintained by PNSO correspondence control. PNSO documents are entered into the Document Control System and controlled on the PNSO internal SharePoint website. The correspondence control and responsible staff are responsible for maintaining these records before transferring them to the Records Holding Area (RHA) for long-term, secured storage of the records. Completed records are maintained in active files until they are no longer required to support ongoing activities at which time the responsible organization transfers them to the RHA. While in the custody of the responsible organizations, these records are protected from loss or damage by employing filing equipment suitable for the level of protection required.

IMPLEMENTATION

- (a) PNSO Correspondence Manual (PNSO-PCDR-12) describes Site Office document control.

5.0 WORK PROCESS REQUIREMENTS

The following are the requirements from DOE O 414.1C:

Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.

- (a) Identify and control items to ensure their proper use.
- (b) Maintain items to prevent their damage, loss, or deterioration.
- (c) Calibrate and maintain equipment used for process monitoring or data collection.

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:
Common SC-wide processes for conducting work are documented in SCMS. Refer to the SC Management System Description: <i>Office of Science Management System</i> .
Processes that are routinely performed shall be incorporated into PNSO documents.
PNSO documents shall clearly establish the roles and responsibilities for federal employees.
Employees shall follow applicable PNSO documents when performing assigned tasks.
Employees shall identify and assist in making changes that improve PNSO processes.

Work performed by PNSO employees focuses on facilitating contractor work to complete the PNSO mission through effective contract management. SCMS describes how federal work will be accomplished. Requirements originating from laws, regulations, and DOE Directives, including revisions, are analyzed, documented, and translated by PNSO employees (with support from subject matter experts) into crosscutting processes, procedures, program descriptions, and/or organization specific procedures. Processes and procedures delineate the roles and responsibilities of federal staff and describe the steps necessary to fulfill the federal work in an efficient and effective manner. Processes carried out by a single organization are defined in

organization specific procedures. The level of detail in these documents is commensurate with the complexity of the work activity and the risk associated with performing the work.

The primary steps in the PNSO Environmental Assessment (EA) process are summarized in Appendix D Section "Work Processes". Other procedures are available to provide additional direction and guidance, including the *PNSO Internal Scoping Procedure* and the *PNSO Public Participation Plan*, contained in the Science Integrated Safety Management System (SCISMS) Environmental Protection Management System.

Note: PNSO/PNNL actions that involve Hanford facilities or property will follow the NEPA procedures developed by the Hanford NEPA Compliance Officer (NCO); in such cases, the Hanford NCO will be responsible for many of the activities identified below, including forming the internal scoping team, providing external notifications, providing a recommendation regarding the final threshold determination and maintaining appropriate records.

Since PNSO does not possess any items or equipment within the context of this criterion, requirements (a), (b), and (c) are not applicable.

IMPLEMENTATION

- a) PNSO's established standards and controls for performing work are contained at PNSO's internal SharePoint website and are in accordance with the SCMS Management System Description.

6.0 DESIGN REQUIREMENTS

The following are the requirements from DOE Order 414.1C:

- (a) Design items and processes using sound engineering/scientific principles and appropriate standards.
- (b) Incorporate applicable requirements and design bases in design work and design changes.
- (c) Identify and control design interfaces.
- (d) Verify and validate the adequacy of design products using individuals or groups other than those who perform the work.
- (e) Verify and validate work before approval and implementation of the design.

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:
PNSO Management expects to have management systems/processes and controls in place.
The establishment or design of such products provides the management tools needed to measure the Site Office’s performance against the PNSO Annual Performance Plan.

IMPLEMENTATION

- (a) PNSO does not perform any design functions from an engineering perspective but the Site Office does design management approaches and controls via its management systems and performance management processes. The Site Office Annual Performance Plan document helps to establish goals and measures relative to Site Office performance and is an example of design from a management control/management approach systems perspective.

7.0 PROCUREMENT REQUIREMENTS

The following are the requirements from DOE O 414.1C:

- (a) Procure items and services that meet established requirements and perform as specified.
- (b) Evaluate and select prospective suppliers on the basis of specified criteria.
- (c) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:
Develop and maintain an integrated acquisition strategy for sequencing PNSO work.
Oversight shall focus on verifying contractor performance in meeting expectations in an effective and efficient manner, providing the best value to the government. It shall emphasize contractor, business management, environmental, safety, health, and security performance in accordance with contract requirements.
Government Furnished Services/Items (GFS/I) shall be provided according to contract provisions.

PNSO procurement functions are predominantly related to the award and administration of the prime contract for the management and operations of the PNNL Site, Facilities on the Hanford Sited, and Sequim. PNSO does not procure items that require suspect/counterfeit item (S/CI) controls. However, PNSO is responsible for monitoring implementation of the contractors' S/CI programs which implement DOE S/CI requirements in their contracts. Consistent with Attachment 3 of DOE O 414.1C, PNSO uses the DOE-wide S/CI Prevention Process in its oversight programs.

PNSO administers and oversees SC/I issues with its contractors as a normal contract management process. Contractors have access to, and review, the HQ SC/I web site. Special HQ requests are transmitted to contractors with appropriate instructions on a case by case basis. PNSO oversees contractor SC/I programs through its normal oversight process, as described in this QAPD.

The procurement process begins with PNSO staff determining and approving the scope of work to be performed, how the work is to be “packaged” (i.e., the type of contract that is most beneficial to the government), duration of the contract, special requirements unique to the scope of work, etc. PNSO places and administers one prime contract for the management and operations of PNNL. PNSO also places some grants. The procurement process includes the following:

1. Developing program and acquisition strategies and plans,
2. Establishing requirements,
3. Selecting qualified contractors,
4. Providing direction to the contractor,
5. Reviewing and approving deliverables,
6. Evaluating work performed to ensure it meets contract requirements,
7. Performing oversight to ensure work is completed in a cost effective, safe, and quality manner, and
8. Furnishing GFS/I in a timely manner.

Because of the lead-time required to place a contract, acquisition planning must be performed sufficiently early to enable evaluation of proposed strategies against ongoing trends and current events. Two years or more may be required from the time of constitution of a Source Evaluation Board (SEB) until a contract is placed. The standard timeframe was ten months. An acquisition strategy and acquisition plan will normally be required before constituting the SEB and significant interaction between the procurement specialists and site management will need to occur.

To ensure contractor/supplier qualifications are thoroughly evaluated, a Source Selection Official is appointed by the Procurement Executive (usually in consultation with the Lead Principal Secretarial Officer), who in turn appoints a SEB. The composition of the SEB is based on the nature of services being requested. The SEB establishes a specific set of evaluation criteria, including quality requirements and the technical requirements established for the services. The individual elements of the criteria are weighted by the SEB to reflect their relative importance. Qualified technical support personnel serve on SEBs. When QA plans or program documents are required as part of an offeror’s response to procurement documents, they are reviewed by qualified personnel during the evaluation process.

Contractor performance is monitored on an ongoing basis. PNSO’s monitoring includes facility walkthroughs, observations of contractor activities, reviewing contractor work products or reports, and formal assessments/surveillances that are planned, performed, and documented, with corrective actions verified. PNSO may vary its level of oversight depending on 1) relative importance of the work to the site mission, 2) past performance of contractor, and 3) relative risk of current and future work. PNSO monitoring is focused primarily on verification of costs, work progress, implementation of environmental agreements and permits, verifying quality, and verifying/evaluating completion of work in accordance with applicable contract requirements. Special oversight activities are performed as needed to respond to circumstances that cannot be foreseen e.g., events/incidents, employee concerns, degrading performance, etc. Monitoring is also conducted to verify the contractor’s integrated safety and security management systems are effective. PNSO reviews performance data and other relevant information quarterly and

provides timely GFS/I. PNSO, with support from the Integrated Support Center (ISC) NCO as requested, will provide sufficient oversight and assessments to ensure that the contractor is qualified to perform the required services and have sufficient resources to implement and complete the tasks. PNSO provides the contractor the necessary guidance, procedures, rules, and requirements to adequately prepare and /or review NEPA documentation. Contractor performance is monitored periodically by the PNSO Deputy/Assistant NCO to ensure quality services and acceptable deliverables are supplied.

PNSO is responsible for verifying work units that the contractor claims to have completed are actually completed satisfactorily in accordance with contract provisions. A conditional payment of fee (CPOF) clause allows the government to withhold fee, if the contractor does not perform in accordance with certain contractual requirements. The contractual requirements exposed to action under the CPOF clause vary from contract to contract. Contractor performance against CPOF criteria is evaluated at least annually with the HCA (SC-3) making the final decision as to the amount of fee, if any, to be withheld.

The Federal Acquisition Regulations (FAR), Department of Energy Acquisition Regulations (DEAR), and DOE Acquisition Letters are the primary requirements with which PNSO must comply in the planning, preparation, selection, and award of contracts. Most of the DOE Directives are applicable to some aspect of the overall procurement process, but the directives particularly or uniquely applicable to procurement are, *Business Instrument Numbering System*, *Appointment of Contracting Officers and Contracting Officer's Representatives*, *Unsolicited Proposals*, and the 480 series, which deal with work for others, reimbursable work, technology partnering programs, and cooperative research and development agreements.

PNSO does not maintain an approved suppliers list since it does not procure pieces and parts under open purchase orders nor procure vehicles. However, as a part of the acquisition process, FAR Part 10 requires market research to be conducted that, among other things, identifies the capabilities of prospective suppliers for meeting the requirements of the agency. In addition, as a part of the acquisition process, past performance of offerors is evaluated. In particular, FAR 15.304 requires "the quality of the product or service shall be addressed in every source selection through consideration of one or more non-cost evaluation factors such as past performance..." This part goes on to require "...past performance shall be evaluated in all source selections for negotiated competitive acquisitions expected to exceed \$1,000,000."

IMPLEMENTATION

- (a) The methods for ensuring procured services meet established requirements are identified in the Contract Management crosscutting process. Contractor specific Quality Assurance Surveillance Plans (QASP) provide details on acceptance of contract work, as well as frequency of oversight activities. The annual Performance Evaluation and Measurement Plan defines the requirements for planning, performing, and evaluating contractor performance. The PNSO Performance Assurance Program identifies minimum oversight activities and QA oversight responsibilities.

8.0 INSPECTION AND ACCEPTANCE TESTING REQUIREMENTS

The following are the requirements from DOE O 414.1C:

- | |
|--|
| <ul style="list-style-type: none">(a) Inspection and testing of specified items, services and processes must be conducted using established acceptance and performance criteria.(b) Calibrate and maintain equipment used for inspection and tests. |
|--|

GENERAL INFORMATION

Since PNSO does not perform inspection and testing functions, this criterion is not applicable.

9.0 MANAGEMENT ASSESSMENTS

The following are the requirements from DOE 414.1C:

- (a) Managers must assess their management processes.
- (b) Problems that hinder the organization from achieving its objectives must be identified and corrected.

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:
Management assessments shall be the primary means for identifying areas needing correction and/or improvement.
Management assessments shall be utilized as a method of measuring site office performance against current Site Office Annual Performance Plan.
Results of management assessments shall be documented and deficiencies identified, and tracked, with corrective actions taken.

Management assessment, also known as “self-assessment”, is a method used by PNSO to achieve continuous improvement and/or to identify barriers that hinder improved performance. PNSO managers must periodically evaluate the performance of their organizations in comparison with their mission, responsibilities, and priorities. Management assessments are performed by each level of management and include verifying roles and responsibilities are known and understood, processes and procedures are effective, appropriate measurement systems are in place and functional, evidence of continuous improvement is readily available, procedures are being complied with, organizational activities are consistent with the mission, and customer requirements and expectations are satisfied. The assessments include evaluating available quality performance data such as the results of independent or external assessments and data from PNSO’s issue tracking and corrective action systems. Areas that present the greatest consequences of failure and the greatest benefit from improvements, if implemented, should receive particular emphasis.

Management assessments include an introspective evaluation to determine if the Site Office effectively focuses on meeting strategic goals. Therefore, participation by the manager in the assessment is an essential element and expectation of PNSO management assessment. Management assessments also identify opportunities for improving cost, schedule, and/or quality

of performance. Assessment results shall be documented. Assessments requiring corrective actions shall be tracked per the PNSO Corrective Actions process described in the Performance Assurance Program until corrective actions have been completed and verified.

In regards to NEPA, the ISC NCO supported by the PNSO Deputy/Assistant NCO will perform management assessments on the adequacy and quality of the PNSO NEPA program and its effective implementation. This will include assessments on PNSO Program Office and contractor conformance to requirements and procedures. The assessments will be conducted in accordance with the requirements in the Office of Science Integrated Safety Management System (SCISMS) Environmental Protection Management System and will identify problems, propose and monitor corrective actions. Corrective actions will be documented and tracked in the SC Issue Tracking System and/or the Headquarters Corrective Action Tracking System, as applicable. Specific areas for assessment include: the performance of the PNSO NEPA program, the performance of line management in implementing the NEPA process, and opportunities for improving the quality, cost effectiveness, and timeliness of the PNSO NEPA program.

IMPLEMENTATION

- (a) Managers must assess their management processes in accordance with Self-Assessment, which is included in the PNSO Performance Assurance Program.
- (b) Problems that hinder the organization from achieving its objectives must be identified and corrected in accordance with PNSO Corrective Actions processes established in the Performance Assurance Program.
- (c) Monthly Program Reviews are held by management to assess current status of site office performance as measured against the PNSO Annual Performance Plan.

10.0 INDEPENDENT ASSESSMENT REQUIREMENTS

The following are the requirements from DOE O 414.1C:

- (a) Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance, and to promote improvement.
- (b) Establish sufficient authority and freedom from line management for independent assessment teams.
- (c) Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:

Results of independent assessments shall be documented; deficiencies tracked, corrective action plans reviewed and corrective actions verified.

PNSO currently relies upon external reviews such as the DOE Office of Health, Safety and Security (HSS), GAO audits, HSS-lead Voluntary Protection Program reviews, Gallup, Lehman, and many other external assessments to evaluate the extent to which PNSO organizations perform consistent with requirements and management expectations. The benefit of these types of assessments is that they contribute to the effectiveness of PNSO through identification of issues that detract or potentially detract from the effectiveness of the Site Office. These assessors are trained and qualified to perform independent assessments of Federal activities. Reviews such as the HSS review meet the intent to review each applicable QA criterion.

Independent assessment of the PNSO NEPA Program will be conducted by DOE and/or coordinated by the ISC NCO. In addition, the PNSO Deputy/Assistant NCO's performance in determining approval of CXs and recommending approval of EAs will be periodically assessed by reviewing the NEPA documents forwarded to DOE and/or the Integrated Support Center Chicago (CH) NCO. Deficiencies will be tracked to closure by using SITS.

IMPLEMENTATION

- (a) Periodic reviews are conducted to assess the need for an Independent Assessment. PNSO validates its self assessment results against these Independent Assessments. QA audits required by NQA-1 will be conducted as appropriate.

APPENDIX A - GRADED APPROACH OF PNSO ACTIVITIES

In accordance to SC-wide Quality Assurance Program Description in SCMS, all of the criteria in the PNSO QAPD are applied to situations based on the “graded approach” concept, as defined in the DOE Quality Assurance Directive. The application of quality, safety, or security requirements is commensurate with the risk involved. Risk is a function of probability of occurrence and consequence of occurrence. For example, the risk involved by not applying strict product inspection procedures to office supplies is that of having to take time to exchange defective products for new ones should a defect be encountered. The risk involved in making an error in the data quality of an environmental assessment dealing with drinking water can have much more profound consequences and thus deserves much more attention.

A graded approach is used to determine the applicability of the QAPD requirements to any activity and the extent of rigor in applying them. The level of control and verification appropriate for a task is dependent upon the consequences of the task not being performed properly. This is defined as applying a graded approach to quality assurance.

Each DOE QA criterion is stated as an expectation for management of work, performance of work, and assessment of work. As such, rigorous quality assurance controls for any high risk activity at PNSO might include: establishing a work plan to prescribe work, approving work plans, assigning responsibilities, specifying personnel qualification & training provisions, developing & implementing work control processes/procedures including configuration control, implementing procurement process control, instituting verification and validation of items/services performed or procured, and/or performing assessments to verify adequacy of performance and to identify & implement improvement opportunities when performance is unsatisfactory.

Rigorous QA controls should be considered for activities that: (1) involve compliance with laws, regulations, agreements, or directives, (2) could result in failure to achieve enforceable milestones, (3) could have a significant adverse impact on the safety and health of the public, the workers or the environment, (4) could result in incorrect data or information being released externally, or (5) could result in significant financial loss because of failure to perform an activity correctly or in a timely manner.

Routine QA controls should be considered for activities such as: (1) application of PNSO policies and implementation of PNSO procedures, (2) providing program/acquisition direction, (3) review of contractor prepared documents such as those related to safety, regulatory, design, etc, (4) evaluation of contractor performance, (5) investigation of employee concerns, (6) interfacing where commitments or agreements are established with DOE-HQ or regulating agencies, (7) definition, preparation, and control of records, (8) review or conduct of evaluations or investigations of safety-related events, (9) implementation and evaluation of corrective actions, (10) obtaining safety and environmental related services or activities, and (11) conduct of PNSO assessments.

Minimal QA controls should be considered for activities such as the procurement of office supplies or internal correspondence that does not impact any of the above.

Software Quality Assurance

PNSO apply a graded approach to software quality assurance depending upon the risk and safety application of the software. This graded approach is typically defined in the Contractor's QAP or software QA procedure. QA requirements for non-safety software are consistent with applicable criteria for the QA program in general (e.g., design software must meet criterion 6 requirements.)

PNSO make limited use of safety software for the design of or review of the safety bases for nuclear facilities, other safety analysis purposes, or supervisory control and data acquisition systems (SCADA) or programmable logic controllers (PLC) software. Any software intended for such use would first be reviewed by persons competent in the field of software quality assurance and nuclear safety engineering to ensure that all the current DOE software quality assurance requirements are met. PNSO periodically assess the effectiveness of their contractor's safety software QA processes.

Management of Suspect or Counterfeit Items (SCI)

PNSO maintains awareness of SCI found at SC Sites through the Occurrence Reporting and Processing System and communications from the SC Site Offices. Any significant issues are brought to the attention of the Site Office Manager. PNSO ensures that our contractor has an appropriate SCI program in place and assesses the adequacy of these programs.

APPENDIX B – FEDERAL REQUIREMENTS – NQA-1 REQUIREMENTS - PNSO PROCEDURES AND DOCUMENTS CROSSWALK

	10CFR830.122 / DOE O 414.1C Criteria	NQA-1-2000 Requirements	PNSO QAPD	Procedures / Documents
Management	Criterion 1 Program	1. Organization 2. Quality Assurance Program	QAPD Section 1	PNSO Plan-01-Rev2.PNSO FY 2009 Annual Performance Plan (APP)
	Criterion 2 Personnel Training and Qualification	2. Quality Assurance Program	QAPD Section 2	PNSO-GUID-05. FRA Document.Rev2 PNSO-PCDR-28. Training & Qualification PNSO-GUID-07.Federal Employee Occupational Safety and Health Program
	Criterion 3 Quality Improvement	2. Quality Assurance Program 15. Control of Nonconforming Items 16. Corrective Action	QAPD Section 3	PNSO-GUID-04. Contract Management Plan PNSO-GUID-08.PNSO ISM Program Description.Rev0.updated FY09 App A PNSO PCDR-02.Performance Assurance Program – April 2009
	Criterion 4 Documents and Records	5. Instructions, Procedures, and Drawings 6. Document Control 17. Quality Assurance Records	QAPD Section 4	PNSO-PCDR-12.PNSO Correspondence Manual
Performance	Criterion 5 Work Processes	5. Instructions, Procedures and Drawings 8. Identification and Control of Items 12. Control of Measuring and Test Equipment 13. Handling, Storage and Shipping 14. Inspection, Test and Operating Status Part 1 Introduction	QAPD Section 5	PNSO-GUID-04. Contract Management Plan PNSO-GUID-08.PNSO ISM Program Description.Rev0.updated FY09 App A PNSO-PCDR-02.Performance Assurance Program – April 2009 PNSO-PCDR-03. Proposal-Work Authorization Procedure PNSO-PCDR-12.PNSO Correspondence Manual

Performance	Criterion 6 Design	3. Design Control	QAPD Section 6*	PNSO Plan-01.Rev2.PNSO FY 2009 Annual Performance Plan (APP)
	Criterion 7 Procurement	4. Procurement Document Control 7. Control of Purchased Items and Services	QAPD Section 7	PNSO-PCDR-03. Proposal-Work Authorization Procedure
	Criterion 8 Inspection & Acceptance Testing	10. Inspections 11. Test Control 12. Control of Measuring and Test Equipment	QAPD Section 8	PNSO does not perform inspection and testing functions
Assessment	Criterion 9 Management Assessment	2. Quality Assurance Program	QAPD Section 9	PNSO-PCDR-02. Performance Assurance Program – April 2009 PNSO-PCDR-24. Facility Rep Oversight
	Criterion 10 Independent Assessment	18. Audits	QAPD Section 10	PNSO-PCDR-02. Performance Assurance Program – April 2009 PNSO-PCDR-24. Facility Rep Oversight

* *PNSO does not perform any design functions from an engineering perspective, but the Site Office does design management approaches and controls via Annual Performance Plan.*

APPENDIX C – NQA-1-2000 REQUIREMENTS - BASIC TEXT

NQA-1-2000 REQUIREMENT	NQA-1-2000 TEXT (BASIC – 100)
1. Organization	Responsibilities for the establishment and implementation of the quality assurance program shall be defined. The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality shall be documented.
2. Quality Assurance Program	<p>a) A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Part (Part I), or portions thereof. The program shall identify the activities and items to which it applies. The program shall provide control over activities affecting quality to an extent consistent with their importance. The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily. The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.</p> <p>The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality. The organization shall establish and implement processes to detect and correct quality problems.</p> <p>b) The program shall provide for indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality to assure that suitable proficiency is achieved and maintained.</p> <p>c) Management shall regularly assess the adequacy and effective implementation of the quality assurance program.</p>
3. Design Control	The design shall be defined, controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by persons other than those who designed the item. Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design.
4. Procurement Document Control	Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require Suppliers to have a quality assurance program consistent with the applicable requirements of this

	Standard.
5. Instructions, Procedures, and Drawings	Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed results have been satisfactorily attained. The activity shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results. The need for and level of detail in written procedures or instructions shall be determined based upon complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience).
6. Document Control	The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.
7. Control of Purchased Items and Services	The procurement of items and services shall be controlled to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion
8. Identification and Control of Items and Services	Controls shall be established to assure that only correct and accepted items are used or installed. Identification shall be maintained on the items or in documents traceable to the items, or in a manner that assures that identification is established and maintained.
9. Control of Special Processes	Special processes that control or verify quality, such as those used in welding, heat treating, and non-destructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.
10. Inspection	Inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service shall be planned and executed. Characteristics subject to inspection and inspection methods shall be specified. Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.
11. Test Control	Tests required to collect data such as for siting or design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated.

12. Control of Measuring and Test Equipment	Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specified periods, adjusted, and maintained to required accuracy limits.
13. Handling, Storage, and Shipping	Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. These activities shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.
14. Inspection, Test, and Operating Status	The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items which have not passed the required inspections and tests are not inadvertently installed, used or operated. Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means. The authority for application and removal of tags, markings, labels, and stamps shall be specified. Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.
15. Control of Nonconforming Items	Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.
16. Corrective Action	Conditions adverse to quality shall be identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Completion of corrective actions shall be verified.
17. Quality Assurance Records	Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements. Quality assurance records shall be identified, generated, authenticated, and maintained, and their final disposition specified. Requirements and responsibilities for these activities shall be documented. The term <i>records</i> , used throughout this section, is to be interpreted as <i>quality assurance records</i> .
18. Audits	Audits shall be performed to verify that performance criteria are met and to determine the effectiveness of the program. These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to and reviewed by responsible management. Follow-up action shall be taken where indicated.

APPENDIX D – PNSO NEPA QUALITY ASSURANCE PLAN FOR ENVIRONMENTAL ASSESSMENTS

INTRODUCTION

The National Environmental Policy Act (NEPA) was enacted in 1970 to assure that potential environmental impacts as well as technical factors and costs are considered during federal agency decision making. This section gives a brief background of NEPA and the Federal requirement for a quality assurance plan. The PNSO Manager serves as the NEPA Compliance Officer (NCO) and relies on staffing to comply with the Federal requirements. The SC Integrated Service Center (ISC) provides support as requested to PNSO and maintains DOE-SC NEPA procedures.

The NEPA Law

The *National Environmental Policy Act* of 1969 (42 USC 4321, et seq.) was enacted by Congress as Public Law 91-190 and signed into law on January 1, 1970. NEPA declares a national environmental policy and promotes consideration of environmental concerns by federal agencies. Title 1, Section 102 of NEPA requires all agencies of the federal government to "utilize a systematic, interdisciplinary approach which shall insure the integrated use of the natural and social sciences and the environmental design arts in planning and in decision-making which may have an impact on man's environment ..." This section of NEPA also requires that a federal agency prepare a "detailed statement" for all federal actions significantly affecting the quality of the human environment. This "detailed statement" is interpreted to be an environmental impact statement (EIS). Title II of NEPA established the Council on Environmental Quality (CEQ) and directed it to prepare the "Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act" (40 CFR 1500-1508).

Council on Environmental Quality NEPA Regulations

The CEQ regulations for the implementation of NEPA (found in 40 CFR 1500-1508) provide procedures that federal agencies are required to follow and are applicable to contractor projects funded by federal agencies. In all cases the responsibility for NEPA compliance rests with the federal agency. According to the CEQ regulations, the NEPA process is intended to help public officials make decisions that are based on an understanding of potential environmental consequences and to take actions that protect, restore, and enhance the environment. NEPA review of activities is mandatory for federal agencies. As guided by CEQ regulations, federal agencies must consider the real or potential environmental consequences of all of their proposed actions and subsequent decisions. CEQ regulations also require that federal agencies adopt their own procedures to supplement the CEQ regulations.

1.3 US Department of Energy NEPA Regulations and Guidance

10 CFR 1021 contains the US Department of Energy (DOE) NEPA Implementing Procedures, which apply to any DOE action affecting the quality of the environment of the United States, its territories, or possessions. The DOE NEPA implementing procedures tier from and augment the CEQ regulations. The implementing procedures are updated periodically to reflect the changing situations at the field offices and to reflect updated regulatory requirements. The ISC follows the SC Integrated Management System and procedures for implementation of DOE Directives.

SCOPE AND APPLICABILITY

This Quality Assurance Plan (QA Plan) applies to the DOE Pacific Northwest Site Office (PNSO) for NEPA activities including the approval of Environmental Assessments (EAs), Findings Of No Significant Impact (FONSI), and Categorical Exclusions (CXs). The QA Plan meets the requirements specified in the Federal rules and regulations for a quality assurance plan for PNSO and follows the format of DOE 414.1C, *Quality Assurance Requirements*, and 10 CFR 830, *Energy/Nuclear Safety Management, Subpart A, Quality Assurance Requirements*. The requirements in DOE 414.1C and 10 CFR 830, Subpart A are identical and correspond with the quality fundamentals given in Section 5. 10 CFR 830, Subpart A and the Price Anderson Amendment Act (PAAA) apply to all work activities within a nuclear facility and/or work activities that have the "potential to cause radiological harm," and DOE 414.1C applies to all other work. These procedures comply with the requirements in DOE Order 226.1 Implementation of DOE Oversight Policy, and DOE Policy 226.1 DOE Oversight Policy.

REQUIREMENTS AND GUIDANCE

The following laws, and regulations, can be used in addressing particular NEPA issues. Many of these citations can be accessed from [DOE Office of Environment, Safety and Health NEPA](#) website or the [Office of Science NEPA](#) website.

Applicable Federal Regulations and Guidance

10 CFR 1021, US Department of Energy, *National Environmental Policy Act; Implementing Procedures*. US Code of Federal Regulations.

10 CFR 1022, US Department of Energy, *Compliance with Floodplain/Wetlands Environmental Review Requirements*, US Code of Federal Regulations.

40 CFR 1500-1508, *Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act*, Council on Environmental Quality, US Code of Federal Regulations.

46 FR 18026-18038, March 1981, *Forty Most-Asked Questions Concerning CEQ's National Environmental Policy Act Regulations*, Council on Environmental Quality, Federal Register.

National Environmental Policy Act of 1970, Public Law 91-190, as amended (also recognized as the National Environmental Policy Act of 1969. 42 USC 4321-4347 et seq., as amended).

10 CFR 830, Subpart A, *Quality Assurance*

DOE O 451.1B, Change 1 NEPA Compliance Program

Applicable PNSO Regulations and Guidance

- ONESC Environmental Protection Management System
- ISC NEPA (process/procedure)
- PNSO NEPA Public Participation Plan
- PNSO NEPA Internal Scoping Procedure

- Records Management
- Self-Assessments
- Training

ORGANIZATIONAL ROLES AND RESPONSIBILITIES

The implementation of the NEPA review and approval process is accomplished by individuals at various levels of DOE. The organizational roles and responsibilities of these individuals are described below. Figure 4.1 depicts the PNSO organizational structure and interfaces for those managing, performing, and assessing the work. The ISC NEPA NCO provides support to PNSO as requested.

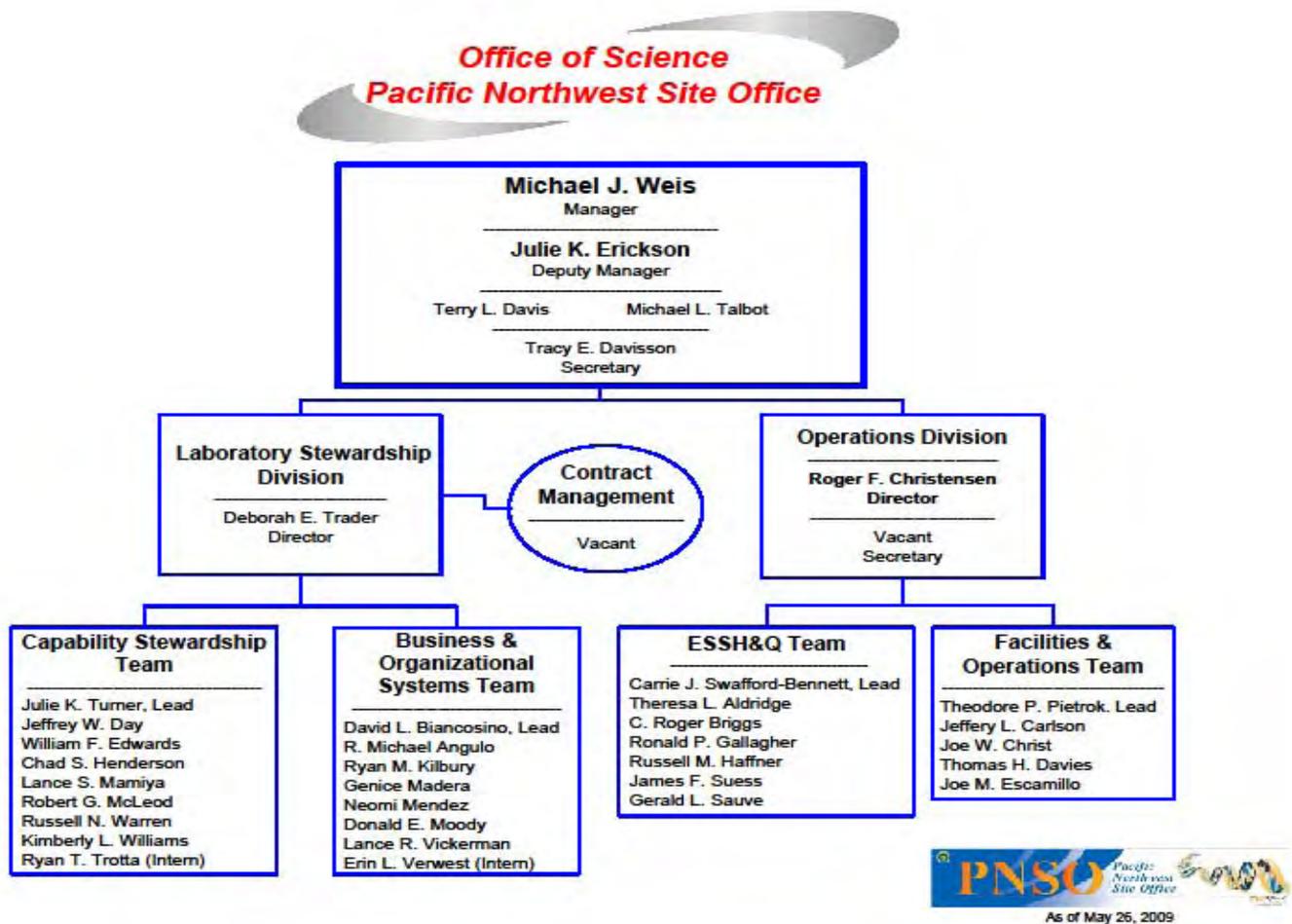


Figure 4.1

ISC NEPA Compliance Officer (CH NCO)

- Supports PNSO in NEPA policy issues as requested
- Performs periodic assessments of the PNSO NEPA review and approval process as requested.
- Supports PNSO relative to implementation of the NEPA requirements contained in DOE Directives and guidance.

PNSO Manager

- Provides adequate resources to implement the NEPA review process
- Appoints the PNSO Deputy/Assistant NCO
- Determines that an EA or EIS is appropriate and required
- Approves CXs, EAs and issues FONSIs (or Determinations of Significance)

PNSO Operations and/or Program Managers

- Assumes role of NEPA Document Manager for project/proposal as appropriate
- Integrates the NEPA review process into project planning and scheduling.

PNSO Deputy/Assistant NCO

- Responsible for the overall quality of the NEPA review and approval process at PNSO
- Assists PNSO and contractor implementation of the NEPA process as well as compliance with the requirements, regulations, policies, procedures, and guidance identified in this QA Plan,
- Coordinates the review of NEPA documents, including the identification and involvement of an interdisciplinary team of subject matter experts as appropriate (including ISC NCO)
- Recommends to the PNSO Manager whether EAs, FONSIs, and Determinations of Significance are appropriate or required
- Recommends to PNSO NCO approval for CX determinations, including associated floodplain and wetland documents
- Coordinates and integrates the review of NEPA documentation with the Hanford NCO for projects involving Hanford facilities or property
- Performs assessments of the contractor NEPA review process
- Coordinated with the NEPA Document Manager, assures the quality of any NEPA documents required
- Assists the maintenance of NEPA document records under PNSO responsibility.

PNSO Legal Office (OR)

- Provides review and input regarding all PNSO NEPA documents
- Provides additional NEPA input and support upon request.

Pacific Northwest National Laboratory (PNNL) Contractor

- Reviews projects and coordinates with PNSO Deputy/Assistant NCO
- Initiates preliminary NEPA documentation
- Maintains records as needed to verify compliance with NEPA requirements.

NEPA Document Manager

- Establish a team, representing all necessary DOE Elements to plan assist in preparing, and concurrently review documents.
- Conduct an early internal scoping process

- Maintain tracking systems to monitor cost of and adherence to the schedule for the NEPA process
- Manage the document preparation process including reviewing internal drafts for technical adequacy controlling cost, and maintaining schedule.
- Encourage and facilitate public participation through the NEPA process.
- Evaluate upon completion of the environmental impact statement of environmental assessment, any support contractor's performance for timeliness, quality, cost-effectiveness, responsiveness, and application requirement and guidance.
- Report to the Office of NEPA Policy and Compliance on lessons learned after completing the environmental impact statement or environmental assessment.

QUALITY ASSURANCE CRITERIA

The following sections describe the applicability of the quality assurance criteria of DOE Order 414.1C and 10 CFR 830 Subpart A to the PNSO NEPA review process.

Program

A written QA Plan must be developed, implemented, and maintained. The QA Plan must describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. The QA Plan must describe management processes, including planning, scheduling, and resource considerations.

This QA Plan documents the quality assurance activities used by PNSO for the NEPA review and approval process. The organizational roles and responsibilities are described in Section 4 of the NEPA QA plan. The PNSO Manager, project/program managers, and PNSO NCO manage, perform, and assess the adequacy of work and the quality of NEPA documents that support the PNSO project and program decision-making.

Personnel Training and Qualification

Personnel must be trained and qualified to ensure they are capable of performing their assigned work. Personnel must be provided continuing training to ensure that job proficiency is maintained.

PNSO ensures that staff involved in the NEPA review process shall be qualified professionals by background, experience, and/or training. These personnel shall be adequately trained in the laws, regulations, policies, requirements and guidance identified in this QA Plan.

The PNSO Deputy/Assistant NCO will be a qualified NEPA professional by background and experience. The PNSO Deputy/Assistant NCO will attend and actively participate in NCO meetings sponsored by the Office of NEPA Oversight or other NCOs in order to obtain current information and training on the DOE NEPA Compliance Program. The PNSO Deputy/Assistant NCO will distribute relevant information to PNSO and PNNL contractor staff as appropriate using vehicles such as periodic NEPA Councils. Other NEPA-related and environmental training opportunities are available to the NCO and other PNSO staff through DOE and non-DOE training programs.

PNSO and PNNL contractor staff will be trained using the DOE SC Integrated Service Center Chicago CH training or the Hanford NEPA Process Training Course as available. Topics include: use of NEPA as an integrated environmental planning process, folding NEPA into project and baseline planning to avoid project delays, and the role of other environmental regulations in the NEPA process.

The PNNL contractor ensures that staff involved in the NEPA review process shall have completed the appropriate NEPA training course identified in the PNNL NEPA Compliance subject area within a short time of employment of assuming the NEPA review position.

Quality Improvement

Processes to detect and prevent quality problems must be established and implemented. Items, services, and processes that do not meet established requirements must be identified, controlled, and corrected according to the importance of the problem and work affected. Correction must include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information must be reviewed and the data analyzed to identify items, services, and processes needing improvement.

Quality improvement of the PNSO NEPA review and approval process is achieved through the auditing program and lessons-learned program. The PNSO Deputy/Assistant NCO oversees the implementation of these programs. The PNSO Deputy/Assistant NCO will participate in DOE Office of Science NEPA teleconferences to benefit from lessons learned and headquarters guidance. PNSO staff will also utilize the NEPA workshops at the regular ES&H Coordination Meetings to focus on continuous NEPA improvement, successes, problem solving, and issue resolution.

As needed, the PNSO Deputy/Assistant NCO will obtain reviews by individuals and organizations with the proper expertise to ensure document quality.

Corrective actions are documented and tracked in the ONESC Issue Tracking System (SITS) and/or the Headquarters Corrective Action Tracking System (CATS), as applicable.

The PNNL contractor implements an annually updated NEPA self-assessment plan which focuses on various aspects of NEPA compliance at PNNL. Self-assessments and corrective actions are tracked in the PNNL Assessment Tracking System (ATS).

Documents and Records

Documents must be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records must be specified, prepared, reviewed, approved, and maintained.

All PNSO NEPA documents and determinations will be prepared, reviewed, approved, issued, used, and revised according to DOE and PNSO policies and requirements. Hard copies of all PNSO NEPA documents and determinations, guidance and procedures will be maintained by the PNSO NCO and/or NEPA Document Manager in accordance with *DOE Records Schedule for Environmental Records*.

Documents will include the following:

- Approved NEPA documents and supporting data used as a basis for the decision

- Review comments and resolution
- Subject matter expert concurrences
- Other NEPA documentation demonstrating that DOE followed the proper process in complying with NEPA.

PNNL Contractor NEPA records are primarily maintained in electronic format as Electronic Prep & Risk records and Facility Modification Permits. These records allow the contractor and PNSO to 1) verify the nature and basis of the recommended decision; 2) verify for audit and appraisal purposes that the project has been reviewed in a manner consistent with DOE policy; 3) support DOE audits and assessments of NEPA compliance; and 4) generate reports on the NEPA program.

Work Processes

Work must be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means. Items must be identified and controlled to ensure their proper use. Items must be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection must be calibrated and maintained.

The primary steps in the PNSO EA process are summarized below. Other procedures are available to provide additional direction and guidance, including the *PNSO Internal Scoping Procedure* and the *PNSO Public Participation Plan*, contained in the Science Integrated Safety Management System (SCISMS) Environmental Protection Management System.

Note: PNSO/PNNL actions that involve Hanford facilities or property will follow the NEPA procedures developed by the Hanford NCO; in such cases, the Hanford NCO will be responsible for many of the activities identified below, including forming the internal scoping team, providing external notifications, providing a recommendation regarding the final threshold determination and maintaining appropriate records.

Initiation – The PNNL contractor initiates the review process through the development of an Electronic Prep & Risk form for funded projects. Electronic Prep & Risk forms for projects involving laboratory or field work are reviewed by contractor NEPA and environmental compliance reviewers.

Internal scoping – The PNSO Deputy/Assistant NCO and NEPA Document Manager collectively form an interdisciplinary team of subject matter experts, to assure a thorough review of the potential environmental impacts, establish the Purpose and Need and preliminary schedule. Additional direction and guidance is found in the *PNSO NEPA Internal Scoping Procedure*.

Determinations – After internal scoping, timely coordination of formal determination requests to initiate an EA will be prepared by the NEPA Document Manager in consultation with the PNSO Deputy/Assistant NCO, for written approval by the PNSO Manager. Actions that are determined to be appropriately addressed under a CX will be tracked and recommended for approval by the PNSO Deputy/Assistant NCO to the PNSO Manager.

Notification - Notification of the host states/tribes of DOE's intent to prepare an EA will be made in a timely manner following the NEPA determination, usually within two weeks. Notification is usually made by the PNSO Deputy/Assistant NEPA Compliance Officer or PNSO Manager.

Internal Review - Concurrent internal DOE reviews of EAs should occur to the maximum extent possible, to promote efficiency, save time, reduce delays, and enhance quality.

Document Quality - The quality and adequacy of each EA will be assured by preparing, reviewing, and approving them against existing CEQ and DOE guidance and standards.

Internal Concurrence and Approval – Concurrence will be obtained from the PNSO Deputy/Assistant NEPA Compliance Officer, NEPA Document Manager, PNSO program office, legal counsel, and internal scoping team, as appropriate. The PNSO Manager approves the EA.

External Review – After a notice is placed in the local newspaper, the EA will be provided to the public for an opportunity for review. The review will be conducted in accordance with the EA public participation plan developed through the internal scoping process and the *PNSO NEPA Public Participation Plan*.

Final Approval and Threshold Determination – After external review, comment response, and EA revision, and after concurrence of the interdisciplinary review team, the PNSO Deputy/Assistant NCO recommends to the PNSO Manager approval of the EA and makes a determination of whether there will be significant impacts. Depending upon the determination, a FONSI is issued by the PNSO Manager or a Determination of Significance is issued.

Distribution and Records - The PNSO Deputy/Assistant NCO distributes copies as appropriate to the ISC NCO, Hanford NCO, SC NCO, PNSO Manager, applicable project or program managers, and PNNL contractor. The EA should also be provided in electronic format suitable for posting on the DOE NEPA web site. The PNSO Deputy/Assistant NCO and/or NEPA Document Manager maintain records as described in Section 5.4 of this NEPA QA Plan.

Design

Items and processes must be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, must incorporate applicable requirements and design bases. Design interfaces must be identified and controlled. The adequacy of design products must be verified or validated by individuals or groups other than those who performed the work. Verification and validation work must be completed before approval and implementation of the design.

This criterion does not apply to the NEPA review process.

Procurement

Procured items and services must meet established requirements and perform as specified. Prospective suppliers must be evaluated and selected on the basis of the specified criteria. Processes to ensure that approved suppliers continue to provide acceptable items and services must be established.

PNSO, with support from the ISC NCO as requested, will provide sufficient oversight and assessments to ensure that the contractor is qualified to perform the required services and have sufficient resources to implement and complete the tasks. PNSO provides the contractor the necessary guidance, procedures, rules, and requirements to adequately prepare and /or review NEPA documentation. Contractor performance is monitored periodically by the PNSO Deputy/Assistant NCO to ensure quality services and acceptable deliverables are supplied.

Inspection and Acceptance Testing

Inspection and acceptance testing of specified items and processes must be conducted using established acceptance and performance criteria. Equipment used for inspections and tests must be calibrated and maintained.

Inspection and testing do not apply to the NEPA review process.

Management Assessment

Managers must assess their management processes. Problems that hinder the organization from achieving its objectives must be identified and corrected.

The ISC NCO supported by the PNSO Deputy/Assistant NCO will perform management assessments on the adequacy and quality of the PNSO NEPA program and its effective implementation. This will include assessments on PNSO Program Office and contractor conformance to requirements and procedures. The assessments will be conducted in accordance with the requirements in the Office of Science Integrated Safety Management System (SCISMS) Environmental Protection Management System (under development) and will identify problems and propose and monitor corrective actions. Corrective actions will be documented and tracked in the SC Issue Tracking System (SITS) and/or the Headquarters Corrective Action Tracking System, as applicable. Specific areas for assessment include: the performance of the PNSO NEPA program, the performance of line management in implementing the NEPA process, and opportunities for improving the quality, cost effectiveness, and timeliness of the PNSO NEPA program.

Independent Assessment

Independent assessments must be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. The group performing independent assessments must have sufficient authority and freedom from the line to carry out its responsibilities. Persons conducting independent assessments must be technically qualified and knowledgeable in the areas assessed.

Independent assessment of the PNSO NEPA Program will be conducted by DOE and/or coordinated by the ISC NCO. In addition, the PNSO Deputy/Assistant NCO's performance in determining approval of CXs and recommending approval of EAs will be periodically assessed by review of NEPA documents forwarded to DOE and/or the CH NCO. Deficiencies will be tracked to closure by using SITS.

In 2002, the PNNL contractor gained registration with ISO 14001, which provides an internationally recognized voluntary approach for an environmental management system (EMS). An EMS is a systematic methodology for managing the environmental impacts of an organization's operations and integrates

environmental performance into daily business decisions. The PNNL NEPA program is an integral part of the EMS. An external review of the EMS is performed on an annual basis.

Acronyms

CATS – DOE Corrective Action Tracking System
 CEQ – Council on Environmental Quality
 CFR – Code of Federal Regulations
 CH – DOE-SC Integrated Service Center Chicago
 CX – Categorical Exclusion
 CAMP- Corrective Action Management Plan
 CAP- Corrective Action Plan
 CATS- Corrective Action Tracking System
 CX- Categorical Exclusions
 DEAR- Department of Energy Acquisition Regulations
 DOE – US Department of Energy
 EA – Environmental Assessment
 EIS – Environmental Impact Statement
 ER – Energy Research (now designated DOE Office of Science)
 FAR- Federal Acquisition Regulation
 FONSI- Finding of No Significant Impact
 FR – Federal Register
 GFS/I- Government Furnished Services/Items
 ISC – Integrated Support Center
 ISMS- Integrated Safety Management System
 IDP- Individual Development Plan
 MOA- Memorandum of Agreement
 MS- Management System
 NCO – NEPA Compliance Officer
 NEPA – National Environmental Policy Act
 OA- Office of Independent Oversight and Performance Assurance
 OR-Oak Ridge
 PAAA – Price Anderson Amendments Act
 PNNL – Pacific Northwest National Laboratory
 PNSO – DOE Pacific Northwest Site Office
 PNSO Manager – Designated NCO by Position
 PNSO Deputy/Assistant NCO
 QA- Quality Assurance
 QA Plan – Quality Assurance Plan
 QAPD- Quality Assurance Program Description
 QASP- Quality Assurance Surveillance Plan
 R2A2s- Roles, Responsibilities, Accountabilities, and Authority
 RHA- Records Holding Area
 RL – DOE Richland Operations Office
 SBMS- Standards Base Management System
 SCMS-office of SCience Management System
 SEB- Source Evaluation Board

SC – DOE Office of Science

S/CI- Suspect Counterfeit Items

SCISMS – Office of Science (SC) Integrated Safety Management System

SITS – DOE Office of Science (ONESC) Information Tracking System

Quality Assurance Program Description for the U.S. Department of Energy Pacific Northwest Site Office

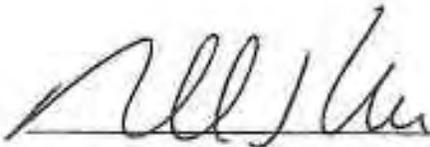


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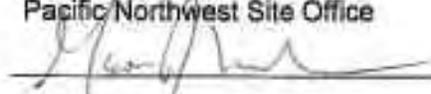
Pacific Northwest Site Office

June 2009

 _____ 7/10/09

Submitted by: Michael J. Weis, Manager
Pacific Northwest Site Office

Date

 _____ 8/10/09

Approved by: George J. Malosh
Deputy Director for Field Operations
Office of Science

Date

Further dissemination authorized to U.S. Government agencies and their contractors; other requests shall be approved by the originating facility or higher DOE programmatic authority.

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INTRODUCTION

DOE O 414.1C, *Quality Assurance*, is applicable to DOE Site Office activities. This Pacific Northwest Site Office (PNSO) Quality Assurance Program Description (QAPD) describes the method by which Quality Assurance (QA) will be implemented and quality achieved within PNSO. At a high level, the Office of Science ensures that its mission is executed properly and efficiently by utilizing a web-based management tool called the SCience Management System (SCMS). SCMS and its supporting documentation and procedures serve the organization by providing a comprehensive, high-level description of SC's responsibilities, the associated authorities it operates within, and its management approaches designed specifically to deliver the above mission. Where appropriate, this QAPD will reference SCMS.

The PNSO Quality Assurance Program incorporates the principles of NQA-1:2000, which is one of a family of quality management standards. NQA-1-2000 "American Society of Mechanical Engineers, Quality Assurance Requirements for Nuclear Facility Applications" will be applied to specific work activities. Performance associated with NQA-1-2000 for some office work will not be applicable.

A graded approach, based on the relative importance of the activity to safety, safeguards and security, and other pertinent areas of management consideration is used in applying the requirements of this document as described in the Appendix A.

Appendix B contains a PNSO crosswalk between O 414.1C/10CFR830 /NQA-1 to show how PNSO Guides/Plans/Procedures are linked to QA requirements in relation to federal requirements and orders as well as quality standards.

For reference, Appendix C lists the basic (100 level) text of the NQA-1 requirements, which are, in essence, the objectives of each of the 18 requirements that make up the NQA-1 Standard.

This QAPD describes the federal role for each of the ten QA criteria outlined in the DOE O 414.1C and shown in this QAPD. For each section, the specific requirements associated with that criterion are identified and outlined inside a heavy line, followed by a General Information sub-section and an Implementation sub-section. The General Information sub-section identifies PNSO Management Expectations required to comply with this program, along with a discussion that amplifies the expectations and/or provides necessary background. This information is directed toward the application of the criterion to the federal employees' role. The Implementation sub-section provides a link to PNSO/SCMS documents and processes that implement the applicable requirements at PNSO. Contract management, including contractor oversight, is addressed under the procurement criterion. One of the criteria, Inspection and Acceptance Testing Requirements, does not apply to the work performed by PNSO, and is addressed accordingly in this QAPD.

This QAPD incorporates the DOE Pacific Northwest Site Office (PNSO) NEPA activities including the approval of Environmental Assessments (EAs), Findings Of No Significant Impact (FONSI), and Categorical Exclusions (CXs). However, Appendix D provides a NEPA specific description as to how each NEPA requirement is addressed. The

plan satisfies the NEPA quality requirements contained in US Code of Federal Regulations, 10 CFR 1021, US Department of Energy, *National Environmental Policy Act; Implementing Procedures*.

Quality Assurance is defined as those actions that provide confidence that quality is achieved and is the responsibility of each PNSO employee. Specifically, the responsibility for quality resides with those individuals performing tasks, as well as those checking or verifying a task is properly performed. However, the PNSO Manager retains the overall responsibility and accountability for the scope and implementation of the PNSO QAPD. The PNSO Manager has delegated the responsibility for development and maintenance of the QAPD to the QAP POC. Quality Assurance will be applied with a graded approach such that the level of control and verification appropriate for a task will be dependent upon the consequences of the task not being performed properly.

PNSO employees typically perform two functions: 1) performing work that is inherently a government responsibility and 2) managing contracts where the primary responsibility for achieving quality results resides with the contractor. The overall role of the federal employee includes the following:

- Understanding and helping to shape the expectations of customers (DOE-HQ, stakeholders, regulators, contractors, and those internal to PNSO).
- Defining and prioritizing the work of PNSO contractor, including setting aggressive, but realistic performance expectations.
- Establishing the right contracts and requirements to complete the work.
- Requesting adequate funding to meet DOE obligations.
- Authorizing work and providing government-furnished items and services necessary to complete the work.
- Maintaining an honest and accurate view of the current state of affairs, through monitoring, assessments, knowledge, analysis, and open communication using an assortment of channels.
- Ensuring the government receives value for work performed, consistent with its cost.
- Ensuring corrective actions resulting from assessments are, in fact, effective and the feedback and lessons learned are captured and result in continuous improvement for PNSO staff and contractor.

When employees comply with PSNO processes, procedures, and other documents, they are implementing this QAPD. PNSO will ensure that all staff members understand their responsibility in meeting the requirements outlined in this QAPD.

1.0 PROGRAM REQUIREMENTS

The following are the program requirements from Criterion 1, DOE O 414.1C:

- (a) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.
- (b) Establish management processes, including planning, scheduling, and providing resources for work.

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:
PNSO senior management and staff shall be familiar with and facilitate achievement of the management expectations included in this document.
PNSO senior management and staff shall be familiar with and utilize SCMS in implementing the expectations of this document.
This QAPD shall be maintained current.
The PNSO Manager is responsible to assure adequate resources are provided to implement the QAPD.

The QAPD is implemented by: (1) incorporating the commitments of this document into PNSO products, and (2) following PSNO procedures to perform work. The QA POC is responsible to the PNSO Manager for review and revision of this document when: (1) DOE O 414.1C is revised, (2) PNSO management actions render it obsolete, or (3) annually to ensure it remains consistent with PNSO management expectations. The QA POC will also perform an annual assessment against the QAPD to identify any issues or gaps relative to implementation.

The Pacific Northwest Site Office is organized into two primary Divisions (see Figure 1).

The Laboratory Stewardship Division contains two teams. The Capability Stewardship Team is responsible for oversight of mission-related programs (i.e., Fundamental Science, Energy Science & Technology, Environmental Technology, National Security, and Computational and Information Sciences) and the Capability Replacement (CRL) Project, which includes the Physical Sciences Facility (PSF) as well as 2 alternatively financed facilities. The Business &

Organizational Systems Team is responsible for contract administration and business management (including financial/legal/information/technology).

The Operations Division is also comprised of two teams. The first is the ESSH&Q team which is responsible for oversight of Environment, Safety and Health, Quality Assurance, Safeguards & Security, Emergency Management, Project Management and Training and Qualification. The second is the Facilities & Operations Team which has oversight responsibilities for Facility Management, Facility Safety, and day-to-day oversight (via 3 Facility Representatives).

Through this management structure, PNSO uses a systems based approach for oversight where it provides *direction*, conducts *oversight*, and *approves* contract deliverable products to accomplish its roles and responsibilities. PNSO staff members are aligned by PNNL management systems (i.e., safety, environmental, quality, acquisition etc.) The PNSO oversight processes are described in PNSO documents and procedures (e.g., Contract Management Plan, Performance Evaluation and Measurement Plan, Performance Assurance Program, Proposal and Work Authorization Procedure, etc.)

The PNSO organizational structure creates an environment in which staff works interdependently in managing and performing the federal functions of the PNSO office. Functional responsibilities and levels of authority for PNSO employees are addressed in PNSO processes, procedures, and program documents. The PNSO Functions, Responsibilities and Authorities (FRA) Document identifies the responsibilities and authorities for PNSO. The PNSO Manager has created a framework in its Performance Assurance Program that assist in the planning, scheduling, and allocation of resources to accomplish the federal work performed by PNSO staff and for the Laboratory contractor. Where necessary, PNSO coordinates and integrates activities with DOE's Richland Operations Office (RL). An Operational Agreement documents the relationship between the DOE Manager of RL and the DOE Manager of PNSO.

IMPLEMENTATION

- (a) This document describes the PNSO Quality Assurance program, and is referred to herewith as the Quality Assurance Program Description (QAPD). This QAPD complies with DOE O 414.1C, *Quality Assurance* and 10 CFR 830 Subpart A (and implements the National Environmental Policy Act (NEPA) requirement for a quality assurance plan).
- (b) The approved PNSO Organizational Chart (figure 1), which is posted on the PNSO website, reflects the levels of authority in the organization with Division Directors being the first level of supervision, who report directly to the Site Office Manager. Roles, responsibilities, authorities, and accountabilities are described in the PNSO R2A2 document.
- (c) A Contract Management Plan and FRA (Functions, Responsibilities and Authorities) Document shall be developed and maintained for PNSO.

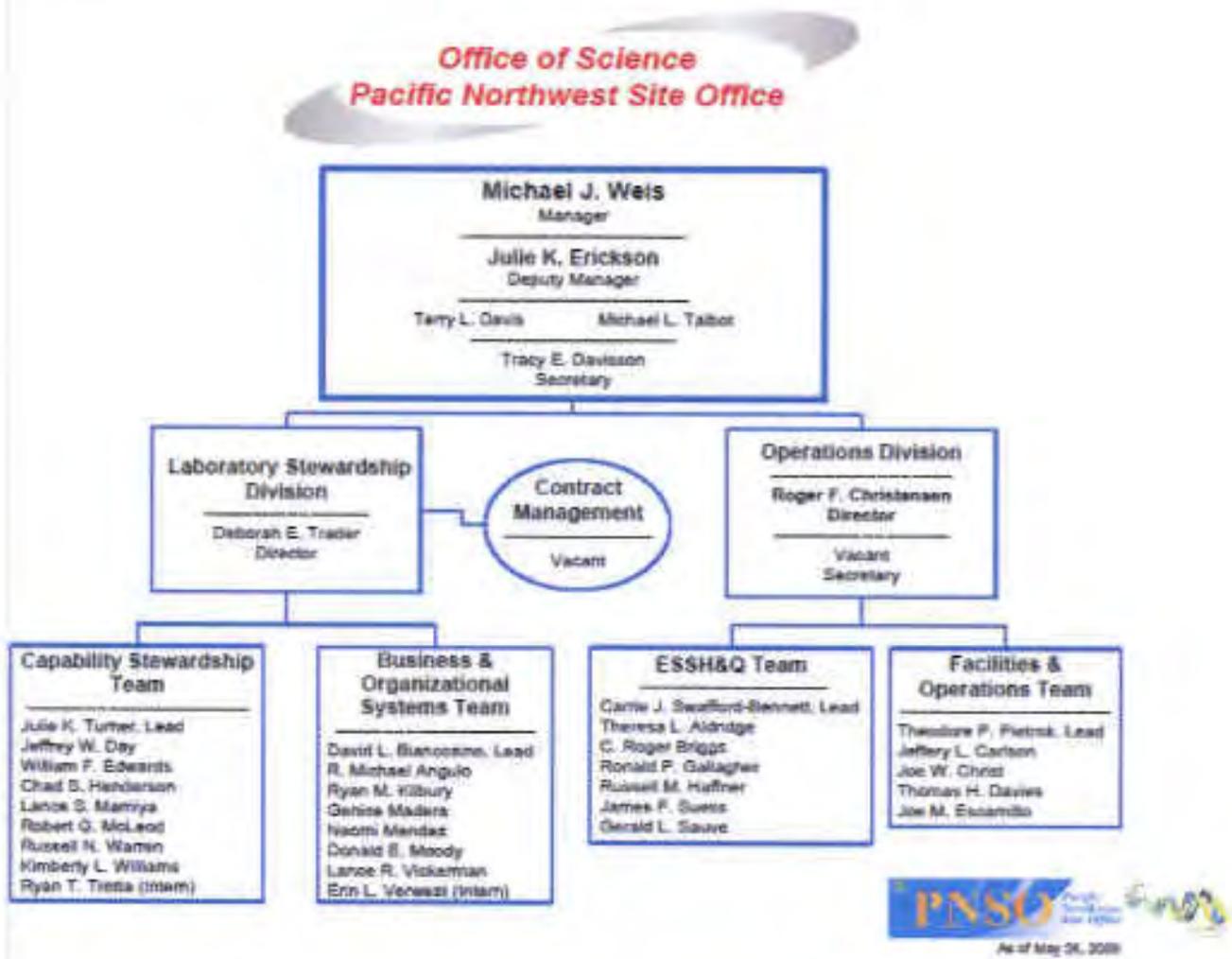


Figure 1

2.0 PERSONNEL TRAINING AND QUALIFICATION

The following are the requirements from DOE O 414.IC:

- | |
|--|
| <p>(a) Train and qualify personnel to be capable of performing assigned work.
 (b) Provide continuing training to personnel to maintain job proficiency.</p> |
|--|

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:
<p>Individual Development Plans (IDPs) are developed and maintained for employees.</p>
<p>Personnel training and qualifications shall be consistent with PNSO Annual Performance Plan objectives.</p>

The success of any organization requires members of the organization be skilled in the work processes they perform. Training is provided to PNSO employees to maintain job proficiency, enhance existing skills, and develop new skills. PNSO Managers are responsible for ensuring personnel are qualified for their positions before being placed in those positions. Training includes education in principles, enhancement of skills and practices, and on the job training. Methods of training include reading assignments, observation and performance of activities, feedback from co-workers and managers, briefings, and formal training classes, among others. The extent of training is commensurate with the scope, complexity, and nature of the respective task. Education, experience, and formal training comprise the basis for qualification.

PNSO currently relies on an internal qualification program for facility representatives that include testing and an oral board examination. For other positions managers rely on the initial human resources screening, interviews, and observation on the job. PNSO Human Resources Support at the Oak Ridge Service Center assists in these efforts by screening applicants against the education, skills, and experience requirements for the position and ensuring only qualified personnel are considered.

IDPs provide the structure of an effective training and development program and provide activities that are carried out in an organized, systematic manner, with established goals clearly defined and sequenced. IDPs are designed for initial training and qualification, as well as maintenance of proficiency and progressive improvement. IDPs are designed to stimulate

professional development and may include managerial, communication, and interpersonal skills. Initial training prepares personnel to perform the job. Continuing training specified in the IDP maintains and promotes improvement in the incumbent's job performance, and/or prepares personnel for new responsibilities.

Qualifications for specific job categories are based on requirements established by DOE Directives, other requirement documents, or management. PNSO management reviews job categories to determine:

- If critical and/or unique job functions or tasks require highly technical, specialized skills
- Whether competency must be demonstrated before performance
- Whether a specialized certification may be required

Based on the review, qualification requirements that provide evidence of employee proficiency through a practical and/or written examination process may be established.

The DOE directives related to this criterion are DOE Order 360.1B, *Federal Employee Training*, its associated Manual, DOE Manual 360.1-1B, *Federal Employee Training Manual*, and DOE Manual 426.1-1, *Federal Technical Capability Manual*.

Relative to NEPA Compliance, PNSO ensures that staff involved in the NEPA review process shall be qualified professionals by background, experience, and/or training. These personnel shall be adequately trained in the laws, regulations, policies, requirements and guidance identified in Appendix D of this Plan.

IMPLEMENTATION

- (a) The methods for ensuring personnel are trained and qualified, capable of performing their assigned work, are identified in the IDPs, Individual Performance Plans, Appraisals, and Position Descriptions.
- (b) The methods for ensuring personnel requiring technical qualification are trained and qualified, capable of performing their assigned work, are identified in the SC Technical Qualification Program which can be found in the Human Resources Services Management System in SCMS in the Employee Development Subject Area. See "Procedure 5. Implementing Technical Qualification Program".
- (c) The methods for ensuring personnel are provided continuing training and job proficiency are identified through the Oakridge Operations Integrated Support Center Human Resources processes. Organization specific personnel development is treated in associated documents such as PNSO-GUID-12: DOE-PNSO Facility Representative Qualification Standard for PNNL.

3.0 QUALITY IMPROVEMENT

The following are the requirements from DOE O 414.1C:

- (a) Establish and implement processes to detect and prevent quality problems.
- (b) Identify, control, and correct items, services, and processes that do not meet established requirements.
- (c) Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.
- (d) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:
PNSO management shall set measurable Site Office performance goals and standards in the PNSO Annual Performance Plan.
PNSO management shall establish Site Office metrics that measure performance.
Corrective action plans shall be developed for findings, approved by the assessing organization, and implemented according to the plan.
Completed corrective actions shall be verified by the assessing organization.

In order for quality improvement to be obtained, measurable performance goals and standards must be set as a baseline. This is accomplished with the development of the PNSO Annual Performance Plan. Once this baseline is established, it can be measured against and improved upon. Then, systems must be in place that identify problems. Problem identification can occur as a result of self-assessments, independent or external assessments, anomalous behavior of some measured quantity against a predefined metric, benchmarking, failure to achieve performance goals or accomplish improvement plans, or as a result of the occurrence of an event. Problem identification can also result from unfulfilled expectations of customers served by the organization. In most cases, problems are associated with deviations or inconsistencies with a requirement, or failures to meet customer, or management expectation. Items, services, or processes that conform to requirements and meet known customer or management expectation

but still need improvement generally require such improvement because the activity could have been performed more effectively or efficiently.

Responses to findings identified by the Office of Health, Safety and Security (HSS), Judgments of Need for Type A accident investigations, and for other sources as directed by the Secretary or Deputy Secretary are subject to the requirements of DOE O 414.1C, Attachment 4, "Corrective Action Management Program [CAMP]." This includes the requirement to prepare a comprehensive Corrective Action Plan (CAP) and to track and report CAP data in the DOE Corrective Action Tracking System (CATS) database (see SCMS Quality Assurance and Oversight MS, Issues Management Subject Area). Responses to findings by OA are also subject to DOE O 470.2B, "Independent Oversight and Performance Assurance Program" requirements. Problems resulting from inadequacies in management systems are candidates for the Lessons Learned.

Quality improvement of the PNSO NEPA review and approval process is achieved through the auditing program and lessons-learned program. The PNSO Deputy/Assistant NEPA Compliance Officer (NCO) oversees the implementation of these programs and participates in DOE Office of Science NEPA teleconferences to benefit from lessons learned and headquarters guidance. PNSO staff will also utilize the NEPA workshops at the regular ES&H Coordination Meetings to focus on continuous NEPA improvement, successes, problem solving, and issue resolution. As needed, the PNSO Deputy/Assistant NCO will obtain reviews by individuals and organizations with the proper expertise to ensure document quality. Corrective actions are documented and tracked in the ONESC Issue Tracking System (SITS) and/or the Headquarters Corrective Action Tracking System (CATS), as applicable.

The PNSO Corrective Action Management Program POC is required to manage compliance with the CAMP. Once accepted, CAP actions are entered and maintained in the Headquarters CATS. The designated POC is responsible for coordinating responses, transmitting the CAP, and preparing closeout documentation in accordance with DOE O 414.1C, Attachment 4, "Corrective Action Management Program [CAMP]."

Corrective action for significant conditions adverse to quality should include an analysis of causal factors. Formal root cause analysis should be considered based on the complexity of the identified issue. Root cause should be performed using some authoritative methodology for root cause identification, such as the DOE Guideline DOE-NE-STD-1004-92, *Root Cause Analysis Document*.

PNSO has established processes to detect and prevent quality problems and to ensure quality improvement. A corrective action system is used to identify and control needed improvements. The PNSO corrective action system is described in the Performance Assurance Program. The corrective action process requires that identified problems are analyzed, causal factors determined, and cost-effective corrective actions identified and implemented. Corrections are directed towards preventing reoccurrence.

PNSO conducts corrective action verification/validation and effectiveness reviews using a graded approach (Appendix A). Lower-level corrective actions may be verified by PNSO staff, program owners, or facility representatives and documented in the PNSO Capture Tool. For higher-level corrective actions (e.g., from HSS reviews, project reviews, Type B accident

investigations, etc), PNSO conducts or leads a formal validation review and subsequent effectiveness review, which is documented in a formal report.

IMPLEMENTATION

- (a) Processes to detect and prevent quality problems include Self-Assessment, Independent Oversight, Benchmarking, and measuring established metrics.
- (b) Services and processes that do not meet established requirements must be controlled and corrected in accordance with PNSO Corrective Actions management process as described in the Performance Assurance Program.
- (c) Correction, identification of the causes of problems, and steps to prevent recurrence shall be taken in accordance with PNSO Corrective Actions management process as described in the Performance Assurance Program.
- (d) Process improvement at PNSO is achieved through Self-Assessment as described in the PNSO Performance Assurance Program and through the Corporate Operating Experience/Lessons Learned program as described in SCMS in the QA & Oversight MS.
- (e) Quality improvement is measured against PNSO Annual Performance Plan.

4.0

4.0 DOCUMENTS AND RECORDS REQUIREMENTS

The following are the requirements from DOE O 414.1C:

- (a) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
- (b) Specify, prepare, review, approve, and maintain records.

GENERAL INFORMATION

Documents

MANAGEMENT EXPECTATIONS:
PNSO staff shall identify or develop documents based on governing requirements, SCMS guidelines, applicable technical standards, and this QAPD, that define how the work will be performed by federal employees.
New or revised requirements shall be analyzed to determine impact on implementing procedures and/or contracts.
PNSO documents shall be development in accordance with SCMS, reviewed by affected organizations and approved by PNSO staff.
PNSO documents shall be deployed in a manner that makes the documents readily available to the users.

Documents establish requirements and/or define how work is to be performed. PNSO documents that establish policy, prescribe work, or specify requirements shall be prepared, reviewed, approved, issued, implemented, and revised. Requirements typically originate from laws, regulations, and/or DOE Directives. New or revised requirements documents are analyzed to determine impact on PNSO implementing documents and/or PNSO contracts. PNSO has processes and procedures for preparing, reviewing, approving, issuing, revising, and using documents. Documents controlled by PNSO include program descriptions, processes, procedures, organization specific procedures, and other work documents. Users of PNSO

documents are responsible for implementing the latest revision of documents. Major changes to documents are subject to the same level of review and approval as was the original document.

All PNSO NEPA documents and determinations will be prepared, reviewed, approved, issued, used, and revised according to DOE and PNSO policies and requirements. Hard copies of all PNSO NEPA documents and determinations, guidance and procedures will be maintained by the PNSO NCO and/or NEPA Document Manager in accordance with *DOE Records Schedule for Environmental Records*. Documents will include the following:

- Approved NEPA documents and supporting data used as a basis for the decision
- Review comments and resolution
- Subject matter expert concurrences
- Other NEPA documentation demonstrating that DOE followed the proper process in complying with NEPA.

Records

MANAGEMENT EXPECTATIONS:
PNSO products shall identify records that need to be created and maintained.
PNSO records shall be maintained in accordance with SCMS Management System Description: <i>Records Management</i> .
Records shall be transferred to permanent storage in a timely manner when they are no longer needed by the organization.

Records are typically the outcome of creating documents that reflect what was done. Records include but are not limited to formal correspondence, plans, study results, permits, financial records, assessment reports, contract related documents, etc. Staff performs work, prepares, collects, protects, and retains records in a manner that makes the record retrievable, useable, and auditable. Written procedures govern records required to support ongoing activities (active records) as well as records transferred to records retention areas (inactive records). Records requirements are communicated to PNSO personnel using 'records capture statements' in procedures. Records must accurately reflect the work performed, be legible and traceable to the applicable work and the responsible personnel.

Completed records are collected by the organizations performing the work, except the record copies of formal correspondence, which are maintained by PNSO correspondence control. PNSO documents are entered into the Document Control System and controlled on the PNSO internal SharePoint website. The correspondence control and responsible staff are responsible for maintaining these records before transferring them to the Records Holding Area (RHA) for long-term, secured storage of the records. Completed records are maintained in active files until they are no longer required to support ongoing activities at which time the responsible organization transfers them to the RHA. While in the custody of the responsible organizations, these records are protected from loss or damage by employing filing equipment suitable for the level of protection required.

IMPLEMENTATION

- (a) PNSO Correspondence Manual (PNSO-PCDR-12) describes Site Office document control.

5.0 WORK PROCESS REQUIREMENTS

The following are the requirements from DOE O 414.1C:

Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.

- (a) Identify and control items to ensure their proper use.
- (b) Maintain items to prevent their damage, loss, or deterioration.
- (c) Calibrate and maintain equipment used for process monitoring or data collection.

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:
Common SC-wide processes for conducting work are documented in SCMS. Refer to the SC Management System Description: <i>Office of Science Management System</i> .
Processes that are routinely performed shall be incorporated into PNSO documents.
PNSO documents shall clearly establish the roles and responsibilities for federal employees.
Employees shall follow applicable PNSO documents when performing assigned tasks.
Employees shall identify and assist in making changes that improve PNSO processes.

Work performed by PNSO employees focuses on facilitating contractor work to complete the PNSO mission through effective contract management. SCMS describes how federal work will be accomplished. Requirements originating from laws, regulations, and DOE Directives, including revisions, are analyzed, documented, and translated by PNSO employees (with support from subject matter experts) into crosscutting processes, procedures, program descriptions, and/or organization specific procedures. Processes and procedures delineate the roles and responsibilities of federal staff and describe the steps necessary to fulfill the federal work in an efficient and effective manner. Processes carried out by a single organization are defined in

organization specific procedures. The level of detail in these documents is commensurate with the complexity of the work activity and the risk associated with performing the work.

The primary steps in the PNSO Environmental Assessment (EA) process are summarized in Appendix D Section "Work Processes". Other procedures are available to provide additional direction and guidance, including the *PNSO Internal Scoping Procedure* and the *PNSO Public Participation Plan*, contained in the Science Integrated Safety Management System (SCISMS) Environmental Protection Management System.

Note: PNSO/PNNL actions that involve Hanford facilities or property will follow the NEPA procedures developed by the Hanford NEPA Compliance Officer (NCO); in such cases, the Hanford NCO will be responsible for many of the activities identified below, including forming the internal scoping team, providing external notifications, providing a recommendation regarding the final threshold determination and maintaining appropriate records.

Since PNSO does not possess any items or equipment within the context of this criterion, requirements (a), (b), and (c) are not applicable.

IMPLEMENTATION

- a) PNSO's established standards and controls for performing work are contained at PNSO's internal SharePoint website and are in accordance with the SCMS Management System Description.

6.0 DESIGN REQUIREMENTS

The following are the requirements from DOE Order 414.1C:

- (a) Design items and processes using sound engineering/scientific principles and appropriate standards.
- (b) Incorporate applicable requirements and design bases in design work and design changes.
- (c) Identify and control design interfaces.
- (d) Verify and validate the adequacy of design products using individuals or groups other than those who perform the work.
- (e) Verify and validate work before approval and implementation of the design.

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:
PNSO Management expects to have management systems/processes and controls in place.
The establishment or design of such products provides the management tools needed to measure the Site Office's performance against the PNSO Annual Performance Plan.

IMPLEMENTATION

- (a) PNSO does not perform any design functions from an engineering perspective but the Site Office does design management approaches and controls via its management systems and performance management processes. The Site Office Annual Performance Plan document helps to establish goals and measures relative to Site Office performance and is an example of design from a management control/management approach systems perspective.

7.0 PROCUREMENT REQUIREMENTS

The following are the requirements from DOE O 414.1C:

- (a) Procure items and services that meet established requirements and perform as specified.
- (b) Evaluate and select prospective suppliers on the basis of specified criteria.
- (c) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:
Develop and maintain an integrated acquisition strategy for sequencing PNSO work.
Oversight shall focus on verifying contractor performance in meeting expectations in an effective and efficient manner, providing the best value to the government. It shall emphasize contractor, business management, environmental, safety, health, and security performance in accordance with contract requirements.
Government Furnished Services/Items (GFS/I) shall be provided according to contract provisions.

PNSO procurement functions are predominantly related to the award and administration of the prime contract for the management and operations of the PNNL Site, Facilities on the Hanford Sited, and Sequim. PNSO does not procure items that require suspect/counterfeit item (S/CI) controls. However, PNSO is responsible for monitoring implementation of the contractors' S/CI programs which implement DOE S/CI requirements in their contracts. Consistent with Attachment 3 of DOE O 414.1C, PNSO uses the DOE-wide S/CI Prevention Process in its oversight programs.

PNSO administers and oversees SC/I issues with its contractors as a normal contract management process. Contractors have access to, and review, the HQ SC/I web site. Special HQ requests are transmitted to contractors with appropriate instructions on a case by case basis. PNSO oversees contractor SC/I programs through its normal oversight process, as described in this QAPD.

The procurement process begins with PNSO staff determining and approving the scope of work to be performed, how the work is to be “packaged” (i.e., the type of contract that is most beneficial to the government), duration of the contract, special requirements unique to the scope of work, etc. PNSO places and administers one prime contract for the management and operations of PNNL. PNSO also places some grants. The procurement process includes the following:

1. Developing program and acquisition strategies and plans,
2. Establishing requirements,
3. Selecting qualified contractors,
4. Providing direction to the contractor,
5. Reviewing and approving deliverables,
6. Evaluating work performed to ensure it meets contract requirements,
7. Performing oversight to ensure work is completed in a cost effective, safe, and quality manner, and
8. Furnishing GFS/I in a timely manner.

Because of the lead-time required to place a contract, acquisition planning must be performed sufficiently early to enable evaluation of proposed strategies against ongoing trends and current events. Two years or more may be required from the time of constitution of a Source Evaluation Board (SEB) until a contract is placed. The standard timeframe was ten months. An acquisition strategy and acquisition plan will normally be required before constituting the SEB and significant interaction between the procurement specialists and site management will need to occur.

To ensure contractor/supplier qualifications are thoroughly evaluated, a Source Selection Official is appointed by the Procurement Executive (usually in consultation with the Lead Principal Secretarial Officer), who in turn appoints a SEB. The composition of the SEB is based on the nature of services being requested. The SEB establishes a specific set of evaluation criteria, including quality requirements and the technical requirements established for the services. The individual elements of the criteria are weighted by the SEB to reflect their relative importance. Qualified technical support personnel serve on SEBs. When QA plans or program documents are required as part of an offeror’s response to procurement documents, they are reviewed by qualified personnel during the evaluation process.

Contractor performance is monitored on an ongoing basis. PNSO’s monitoring includes facility walkthroughs, observations of contractor activities, reviewing contractor work products or reports, and formal assessments/surveillances that are planned, performed, and documented, with corrective actions verified. PNSO may vary its level of oversight depending on 1) relative importance of the work to the site mission, 2) past performance of contractor, and 3) relative risk of current and future work. PNSO monitoring is focused primarily on verification of costs, work progress, implementation of environmental agreements and permits, verifying quality, and verifying/evaluating completion of work in accordance with applicable contract requirements. Special oversight activities are performed as needed to respond to circumstances that cannot be foreseen e.g., events/incidents, employee concerns, degrading performance, etc. Monitoring is also conducted to verify the contractor’s integrated safety and security management systems are effective. PNSO reviews performance data and other relevant information quarterly and

provides timely GFS/I. PNSO, with support from the Integrated Support Center (ISC) NCO as requested, will provide sufficient oversight and assessments to ensure that the contractor is qualified to perform the required services and have sufficient resources to implement and complete the tasks. PNSO provides the contractor the necessary guidance, procedures, rules, and requirements to adequately prepare and /or review NEPA documentation. Contractor performance is monitored periodically by the PNSO Deputy/Assistant NCO to ensure quality services and acceptable deliverables are supplied.

PNSO is responsible for verifying work units that the contractor claims to have completed are actually completed satisfactorily in accordance with contract provisions. A conditional payment of fee (CPOF) clause allows the government to withhold fee, if the contractor does not perform in accordance with certain contractual requirements. The contractual requirements exposed to action under the CPOF clause vary from contract to contract. Contractor performance against CPOF criteria is evaluated at least annually with the HCA (SC-3) making the final decision as to the amount of fee, if any, to be withheld.

The Federal Acquisition Regulations (FAR), Department of Energy Acquisition Regulations (DEAR), and DOE Acquisition Letters are the primary requirements with which PNSO must comply in the planning, preparation, selection, and award of contracts. Most of the DOE Directives are applicable to some aspect of the overall procurement process, but the directives particularly or uniquely applicable to procurement are, *Business Instrument Numbering System*, *Appointment of Contracting Officers and Contracting Officer's Representatives*, *Unsolicited Proposals*, and the 480 series, which deal with work for others, reimbursable work, technology partnering programs, and cooperative research and development agreements.

PNSO does not maintain an approved suppliers list since it does not procure pieces and parts under open purchase orders nor procure vehicles. However, as a part of the acquisition process, FAR Part 10 requires market research to be conducted that, among other things, identifies the capabilities of prospective suppliers for meeting the requirements of the agency. In addition, as a part of the acquisition process, past performance of offerors is evaluated. In particular, FAR 15.304 requires "the quality of the product or service shall be addressed in every source selection through consideration of one or more non-cost evaluation factors such as past performance..." This part goes on to require "...past performance shall be evaluated in all source selections for negotiated competitive acquisitions expected to exceed \$1,000,000."

IMPLEMENTATION

- (a) The methods for ensuring procured services meet established requirements are identified in the Contract Management crosscutting process. Contractor specific Quality Assurance Surveillance Plans (QASP) provide details on acceptance of contract work, as well as frequency of oversight activities. The annual Performance Evaluation and Measurement Plan defines the requirements for planning, performing, and evaluating contractor performance. The PNSO Performance Assurance Program identifies minimum oversight activities and QA oversight responsibilities.

8.0 INSPECTION AND ACCEPTANCE TESTING REQUIREMENTS

The following are the requirements from DOE O 414.1C:

- (a) Inspection and testing of specified items, services and processes must be conducted using established acceptance and performance criteria.
- (b) Calibrate and maintain equipment used for inspection and tests.

GENERAL INFORMATION

Since PNSO does not perform inspection and testing functions, this criterion is not applicable.

9.0 MANAGEMENT ASSESSMENTS

The following are the requirements from DOE 414.1C:

- (a) Managers must assess their management processes.
- (b) Problems that hinder the organization from achieving its objectives must be identified and corrected.

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:
Management assessments shall be the primary means for identifying areas needing correction and/or improvement.
Management assessments shall be utilized as a method of measuring site office performance against current Site Office Annual Performance Plan.
Results of management assessments shall be documented and deficiencies identified, and tracked, with corrective actions taken.

Management assessment, also known as “self-assessment”, is a method used by PNSO to achieve continuous improvement and/or to identify barriers that hinder improved performance. PNSO managers must periodically evaluate the performance of their organizations in comparison with their mission, responsibilities, and priorities. Management assessments are performed by each level of management and include verifying roles and responsibilities are known and understood, processes and procedures are effective, appropriate measurement systems are in place and functional, evidence of continuous improvement is readily available, procedures are being complied with, organizational activities are consistent with the mission, and customer requirements and expectations are satisfied. The assessments include evaluating available quality performance data such as the results of independent or external assessments and data from PNSO’s issue tracking and corrective action systems. Areas that present the greatest consequences of failure and the greatest benefit from improvements, if implemented, should receive particular emphasis.

Management assessments include an introspective evaluation to determine if the Site Office effectively focuses on meeting strategic goals. Therefore, participation by the manager in the assessment is an essential element and expectation of PNSO management assessment. Management assessments also identify opportunities for improving cost, schedule, and/or quality.

of performance. Assessment results shall be documented. Assessments requiring corrective actions shall be tracked per the PNSO Corrective Actions process described in the Performance Assurance Program until corrective actions have been completed and verified.

In regards to NEPA, the ISC NCO supported by the PNSO Deputy/Assistant NCO will perform management assessments on the adequacy and quality of the PNSO NEPA program and its effective implementation. This will include assessments on PNSO Program Office and contractor conformance to requirements and procedures. The assessments will be conducted in accordance with the requirements in the Office of Science Integrated Safety Management System (SCISMS) Environmental Protection Management System and will identify problems, propose and monitor corrective actions. Corrective actions will be documented and tracked in the SC Issue Tracking System and/or the Headquarters Corrective Action Tracking System, as applicable. Specific areas for assessment include: the performance of the PNSO NEPA program, the performance of line management in implementing the NEPA process, and opportunities for improving the quality, cost effectiveness, and timeliness of the PNSO NEPA program.

IMPLEMENTATION

- (a) Managers must assess their management processes in accordance with Self-Assessment, which is included in the PNSO Performance Assurance Program.
- (b) Problems that hinder the organization from achieving its objectives must be identified and corrected in accordance with PNSO Corrective Actions processes established in the Performance Assurance Program.
- (c) Monthly Program Reviews are held by management to assess current status of site office performance as measured against the PNSO Annual Performance Plan.

10.0 INDEPENDENT ASSESSMENT REQUIREMENTS

The following are the requirements from DOE O 414.1C:

- (a) Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance, and to promote improvement.
- (b) Establish sufficient authority and freedom from line management for independent assessment teams.
- (c) Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

GENERAL INFORMATION

MANAGEMENT EXPECTATIONS:

Results of independent assessments shall be documented; deficiencies tracked, corrective action plans reviewed and corrective actions verified.

PNSO currently relies upon external reviews such as the DOE Office of Health, Safety and Security (HSS), GAO audits, HSS-lead Voluntary Protection Program reviews, Gallup, Lehman, and many other external assessments to evaluate the extent to which PNSO organizations perform consistent with requirements and management expectations. The benefit of these types of assessments is that they contribute to the effectiveness of PNSO through identification of issues that detract or potentially detract from the effectiveness of the Site Office. These assessors are trained and qualified to perform independent assessments of Federal activities. Reviews such as the HSS review meet the intent to review each applicable QA criterion.

Independent assessment of the PNSO NEPA Program will be conducted by DOE and/or coordinated by the ISC NCO. In addition, the PNSO Deputy/Assistant NCO's performance in determining approval of CXs and recommending approval of EAs will be periodically assessed by reviewing the NEPA documents forwarded to DOE and/or the Integrated Support Center Chicago (CH) NCO. Deficiencies will be tracked to closure by using SITS.

IMPLEMENTATION

- (a) Periodic reviews are conducted to assess the need for an Independent Assessment. PNSO validates its self assessment results against these Independent Assessments. QA audits required by NQA-1 will be conducted as appropriate.

APPENDIX A - GRADED APPROACH OF PNSO ACTIVITIES

In accordance to SC-wide Quality Assurance Program Description in SCMS, all of the criteria in the PNSO QAPD are applied to situations based on the "graded approach" concept, as defined in the DOE Quality Assurance Directive. The application of quality, safety, or security requirements is commensurate with the risk involved. Risk is a function of probability of occurrence and consequence of occurrence. For example, the risk involved by not applying strict product inspection procedures to office supplies is that of having to take time to exchange defective products for new ones should a defect be encountered. The risk involved in making an error in the data quality of an environmental assessment dealing with drinking water can have much more profound consequences and thus deserves much more attention.

A graded approach is used to determine the applicability of the QAPD requirements to any activity and the extent of rigor in applying them. The level of control and verification appropriate for a task is dependent upon the consequences of the task not being performed properly. This is defined as applying a graded approach to quality assurance.

Each DOE QA criterion is stated as an expectation for management of work, performance of work, and assessment of work. As such, rigorous quality assurance controls for any high risk activity at PNSO might include: establishing a work plan to prescribe work, approving work plans, assigning responsibilities, specifying personnel qualification & training provisions, developing & implementing work control processes/procedures including configuration control, implementing procurement process control, instituting verification and validation of items/services performed or procured, and/or performing assessments to verify adequacy of performance and to identify & implement improvement opportunities when performance is unsatisfactory.

Rigorous QA controls should be considered for activities that: (1) involve compliance with laws, regulations, agreements, or directives, (2) could result in failure to achieve enforceable milestones, (3) could have a significant adverse impact on the safety and health of the public, the workers or the environment, (4) could result in incorrect data or information being released externally, or (5) could result in significant financial loss because of failure to perform an activity correctly or in a timely manner.

Routine QA controls should be considered for activities such as: (1) application of PNSO policies and implementation of PNSO procedures, (2) providing program/acquisition direction, (3) review of contractor prepared documents such as those related to safety, regulatory, design, etc, (4) evaluation of contractor performance, (5) investigation of employee concerns, (6) interfacing where commitments or agreements are established with DOE-HQ or regulating agencies, (7) definition, preparation, and control of records, (8) review or conduct of evaluations or investigations of safety-related events, (9) implementation and evaluation of corrective actions, (10) obtaining safety and environmental related services or activities, and (11) conduct of PNSO assessments.

Minimal QA controls should be considered for activities such as the procurement of office supplies or internal correspondence that does not impact any of the above.

Software Quality Assurance

PNSO apply a graded approach to software quality assurance depending upon the risk and safety application of the software. This graded approach is typically defined in the Contractor's QAP or software QA procedure. QA requirements for non-safety software are consistent with applicable criteria for the QA program in general (e.g., design software must meet criterion 6 requirements.)

PNSO make limited use of safety software for the design of or review of the safety bases for nuclear facilities, other safety analysis purposes, or supervisory control and data acquisition systems (SCADA) or programmable logic controllers (PLC) software. Any software intended for such use would first be reviewed by persons competent in the field of software quality assurance and nuclear safety engineering to ensure that all the current DOE software quality assurance requirements are met. PNSO periodically assess the effectiveness of their contractor's safety software QA processes.

Management of Suspect or Counterfeit Items (SCI)

PNSO maintains awareness of SCI found at SC Sites through the Occurrence Reporting and Processing System and communications from the SC Site Offices. Any significant issues are brought to the attention of the Site Office Manager. PNSO ensures that our contractor has an appropriate SCI program in place and assesses the adequacy of these programs.

APPENDIX B – FEDERAL REQUIREMENTS – NQA-1 REQUIREMENTS - PNSO PROCEDURES AND DOCUMENTS CROSSWALK

	10CFR830.122 / DOE O 414.1C Criteria	NQA-1-2000 Requirements	PNSO QAPD	Procedures / Documents
Management	Criterion 1 <i>Program</i>	1. Organization 2. Quality Assurance Program	QAPD Section 1	PNSO Plan-01-Rev2.PNSO FY 2009 Annual Performance Plan (APP)
	Criterion 2 <i>Personnel Training and Qualification</i>	2. Quality Assurance Program	QAPD Section 2	PNSO-GUID-05. FRA Document.Rev2 PNSO-PCDR-28. Training & Qualification PNSO-GUID-07.Federal Employee Occupational Safety and Health Program
	Criterion 3 <i>Quality Improvement</i>	2. Quality Assurance Program 15. Control of Nonconforming Items 16. Corrective Action	QAPD Section 3	PNSO-GUID-04. Contract Management Plan PNSO-GUID-06.PNSO ISM Program Description.Rev0.updated FY09 App A PNSO PCDR-02.Performance Assurance Program – April 2009
	Criterion 4 <i>Documents and Records</i>	5. Instructions, Procedures, and Drawings 6. Document Control 17. Quality Assurance Records	QAPD Section 4	PNSO-PCDR-12.PNSO Correspondence Manual

Performance	Criterion 5 <i>Work Processes</i>	5. Instructions, Procedures and Drawings 8. Identification and Control of Items 12. Control of Measuring and Test Equipment 13. Handling, Storage and Shipping 14. Inspection, Test and Operating Status Part I Introduction	QAPD Section 5	PNSO-GUID-04. Contract Management Plan PNSO-GUID-08. PNSO ISM Program Description. Rev0. updated FY09 App A PNSO-PCDR-02. Performance Assurance Program – April 2009 PNSO-PCDR-03. Proposal-Work Authorization Procedure PNSO-PCDR-12. PNSO Correspondence Manual
Performance	Criterion 6 <i>Design</i>	3. Design Control	QAPD Section 6*	PNSO Plan-01. Rev2. PNSO FY 2009 Annual Performance Plan (APP)
	Criterion 7 <i>Procurement</i>	4. Procurement Document Control 7. Control of Purchased Items and Services	QAPD Section 7	PNSO-PCDR-03. Proposal-Work Authorization Procedure
	Criterion 8 <i>Inspection & Acceptance Testing</i>	10. Inspections 11. Test Control 12. Control of Measuring and Test Equipment	QAPD Section 8	PNSO does not perform inspection and testing functions
Assessment	Criterion 9 <i>Management Assessment</i>	2. Quality Assurance Program	QAPD Section 9	PNSO-PCDR-02. Performance Assurance Program – April 2009 PNSO-PCDR-24. Facility Rep Oversight
	Criterion 10 <i>Independent Assessment</i>	18. Audits	QAPD Section 10	PNSO-PCDR-02. Performance Assurance Program – April 2009 PNSO-PCDR-24. Facility Rep Oversight

* PNSO does not perform any design functions from an engineering perspective, but the Site Office does design management approaches and controls via Annual Performance Plan.

APPENDIX C – NQA-1-2000 REQUIREMENTS - BASIC TEXT

NQA-1-2000 REQUIREMENT	NQA-1-2000 TEXT (BASIC – 100)
1. Organization	Responsibilities for the establishment and implementation of the quality assurance program shall be defined. The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality shall be documented.
2. Quality Assurance Program	<p>a) A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Part (Part I), or portions thereof. The program shall identify the activities and items to which it applies. The program shall provide control over activities affecting quality to an extent consistent with their importance. The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily. The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.</p> <p>The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality. The organization shall establish and implement processes to detect and correct quality problems.</p> <p>b) The program shall provide for indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality to assure that suitable proficiency is achieved and maintained.</p> <p>c) Management shall regularly assess the adequacy and effective implementation of the quality assurance program.</p>
3. Design Control	The design shall be defined, controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by persons other than those who designed the item. Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design.
4. Procurement Document Control	Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require Suppliers to have a quality assurance program consistent with the applicable requirements of this

	Standard.
5. Instructions, Procedures, and Drawings	Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed results have been satisfactorily attained. The activity shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results. The need for and level of detail in written procedures or instructions shall be determined based upon complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience).
6. Document Control	The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.
7. Control of Purchased Items and Services	The procurement of items and services shall be controlled to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.
8. Identification and Control of Items and Services	Controls shall be established to assure that only correct and accepted items are used or installed. Identification shall be maintained on the items or in documents traceable to the items, or in a manner that assures that identification is established and maintained.
9. Control of Special Processes	Special processes that control or verify quality, such as those used in welding, heat treating, and non-destructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.
10. Inspection	Inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service shall be planned and executed. Characteristics subject to inspection and inspection methods shall be specified. Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.
11. Test Control	Tests required to collect data such as for siting or design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated.

12. Control of Measuring and Test Equipment	Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specified periods, adjusted, and maintained to required accuracy limits.
13. Handling, Storage, and Shipping	Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. These activities shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.
14. Inspection, Test, and Operating Status	The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items which have not passed the required inspections and tests are not inadvertently installed, used or operated. Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means. The authority for application and removal of tags, markings, labels, and stamps shall be specified. Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.
15. Control of Nonconforming Items	Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.
16. Corrective Action	Conditions adverse to quality shall be identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Completion of corrective actions shall be verified.
17. Quality Assurance Records	Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements. Quality assurance records shall be identified, generated, authenticated, and maintained, and their final disposition specified. Requirements and responsibilities for these activities shall be documented. The term <i>records</i> , used throughout this section, is to be interpreted as <i>quality assurance records</i> .
18. Audits	Audits shall be performed to verify that performance criteria are met and to determine the effectiveness of the program. These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to and reviewed by responsible management. Follow-up action shall be taken where indicated.

APPENDIX D – PNSO NEPA QUALITY ASSURANCE PLAN FOR ENVIRONMENTAL ASSESSMENTS

INTRODUCTION

The National Environmental Policy Act (NEPA) was enacted in 1970 to assure that potential environmental impacts as well as technical factors and costs are considered during federal agency decision making. This section gives a brief background of NEPA and the Federal requirement for a quality assurance plan. The PNSO Manager serves as the NEPA Compliance Officer (NCO) and relies on staffing to comply with the Federal requirements. The SC Integrated Service Center (ISC) provides support as requested to PNSO and maintains DOE-SC NEPA procedures.

The NEPA Law

The *National Environmental Policy Act* of 1969 (42 USC 4321, et seq.) was enacted by Congress as Public Law 91-190 and signed into law on January 1, 1970. NEPA declares a national environmental policy and promotes consideration of environmental concerns by federal agencies. Title 1, Section 102 of NEPA requires all agencies of the federal government to "utilize a systematic, interdisciplinary approach which shall insure the integrated use of the natural and social sciences and the environmental design arts in planning and in decision-making which may have an impact on man's environment ..." This section of NEPA also requires that a federal agency prepare a "detailed statement" for all federal actions significantly affecting the quality of the human environment. This "detailed statement" is interpreted to be an environmental impact statement (EIS). Title II of NEPA established the Council on Environmental Quality (CEQ) and directed it to prepare the "Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act" (40 CFR 1500-1508).

Council on Environmental Quality NEPA Regulations

The CEQ regulations for the implementation of NEPA (found in 40 CFR 1500-1508) provide procedures that federal agencies are required to follow and are applicable to contractor projects funded by federal agencies. In all cases the responsibility for NEPA compliance rests with the federal agency. According to the CEQ regulations, the NEPA process is intended to help public officials make decisions that are based on an understanding of potential environmental consequences and to take actions that protect, restore, and enhance the environment. NEPA review of activities is mandatory for federal agencies. As guided by CEQ regulations, federal agencies must consider the real or potential environmental consequences of all of their proposed actions and subsequent decisions. CEQ regulations also require that federal agencies adopt their own procedures to supplement the CEQ regulations.

1.3 US Department of Energy NEPA Regulations and Guidance

10 CFR 1021 contains the US Department of Energy (DOE) NEPA Implementing Procedures, which apply to any DOE action affecting the quality of the environment of the United States, its territories, or possessions. The DOE NEPA implementing procedures tier from and augment the CEQ regulations. The implementing procedures are updated periodically to reflect the changing situations at the field offices and to reflect updated regulatory requirements. The ISC follows the SC Integrated Management System and procedures for implementation of DOE Directives.

SCOPE AND APPLICABILITY

This Quality Assurance Plan (QA Plan) applies to the DOE Pacific Northwest Site Office (PNSO) for NEPA activities including the approval of Environmental Assessments (EAs), Findings Of No Significant Impact (FONSI)s, and Categorical Exclusions (CXs). The QA Plan meets the requirements specified in the Federal rules and regulations for a quality assurance plan for PNSO and follows the format of DOE 414.1C, *Quality Assurance Requirements*, and 10 CFR 830, *Energy/Nuclear Safety Management, Subpart A, Quality Assurance Requirements*. The requirements in DOE 414.1C and 10 CFR 830, Subpart A are identical and correspond with the quality fundamentals given in Section 5. 10 CFR 830, Subpart A and the Price Anderson Amendment Act (PAAA) apply to all work activities within a nuclear facility and/or work activities that have the "potential to cause radiological harm," and DOE 414.1C applies to all other work. These procedures comply with the requirements in DOE Order 226.1 Implementation of DOE Oversight Policy, and DOE Policy 226.1 DOE Oversight Policy.

REQUIREMENTS AND GUIDANCE

The following laws, and regulations, can be used in addressing particular NEPA issues. Many of these citations can be accessed from [DOE Office of Environment, Safety and Health NEPA](#) website or the [Office of Science NEPA](#) website.

Applicable Federal Regulations and Guidance

10 CFR 1021, US Department of Energy, *National Environmental Policy Act; Implementing Procedures*, US Code of Federal Regulations.

10 CFR 1022, US Department of Energy, *Compliance with Floodplain/Wetlands Environmental Review Requirements*, US Code of Federal Regulations.

40 CFR 1500-1508, *Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act*, Council on Environmental Quality, US Code of Federal Regulations.

46 FR 18026-18038, March 1981, *Forty Most-Asked Questions Concerning CEQ's National Environmental Policy Act Regulations*, Council on Environmental Quality, Federal Register.

National Environmental Policy Act of 1970, Public Law 91-190, as amended (also recognized as the National Environmental Policy Act of 1969. 42 USC 4321-4347 et seq., as amended).

10 CFR 830, Subpart A, *Quality Assurance*

DOE O 451.1B, Change 1 NEPA Compliance Program

Applicable PNSO Regulations and Guidance

- ONESC Environmental Protection Management System
- ISC NEPA (process/procedure)
- PNSO NEPA Public Participation Plan
- PNSO NEPA Internal Scoping Procedure

- Records Management
- Self-Assessments
- Training

ORGANIZATIONAL ROLES AND RESPONSIBILITIES

The implementation of the NEPA review and approval process is accomplished by individuals at various levels of DOE. The organizational roles and responsibilities of these individuals are described below. Figure 4.1 depicts the PNSO organizational structure and interfaces for those managing, performing, and assessing the work. The ISC NEPA NCO provides support to PNSO as requested.

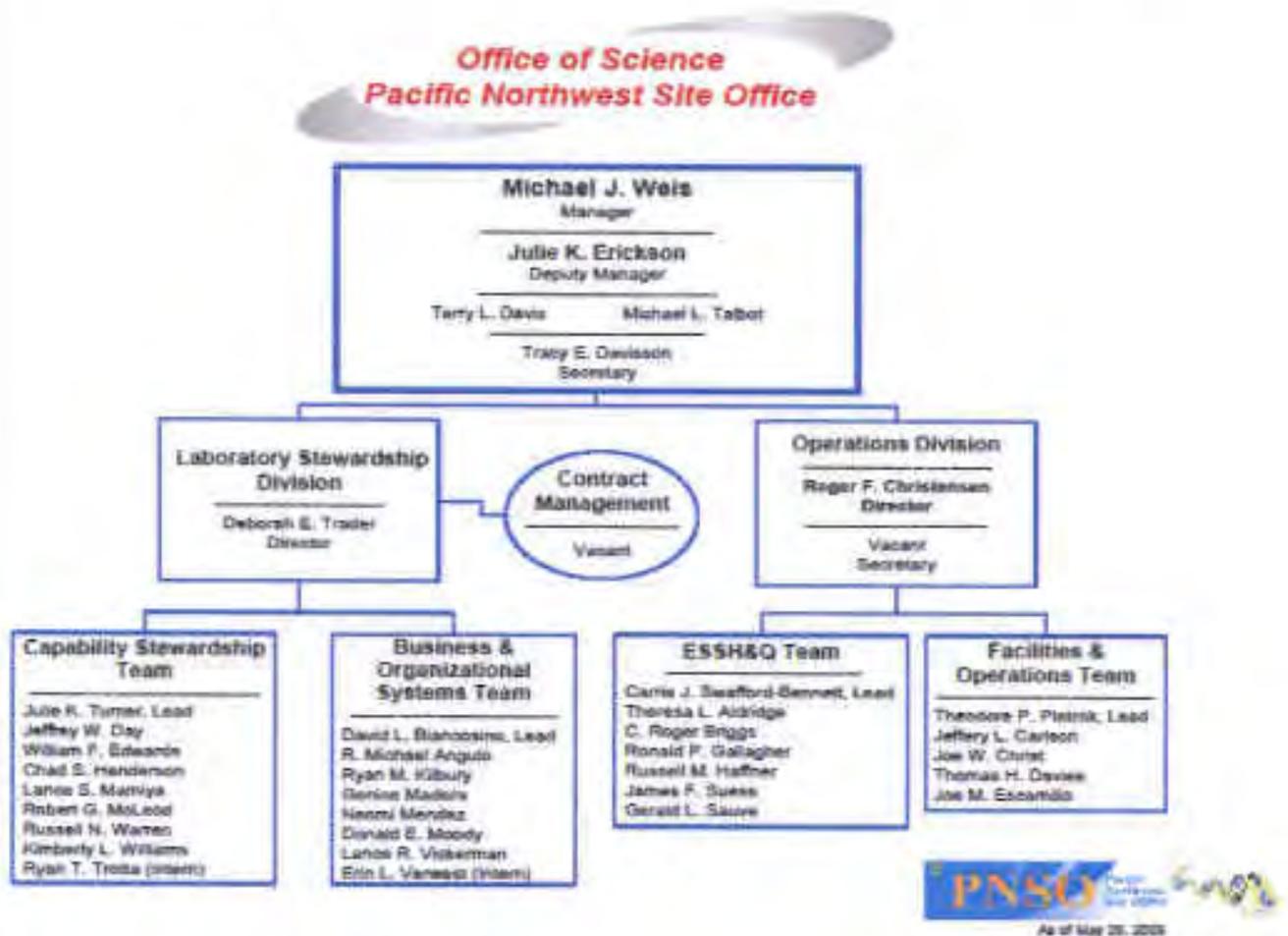


Figure 4.1

ISC NEPA Compliance Officer (CH NCO)

- Supports PNSO in NEPA policy issues as requested
- Performs periodic assessments of the PNSO NEPA review and approval process as requested
- Supports PNSO relative to implementation of the NEPA requirements contained in DOE Directives and guidance.

PNSO Manager

- Provides adequate resources to implement the NEPA review process
- Appoints the PNSO Deputy/Assistant NCO
- Determines that an EA or EIS is appropriate and required
- Approves CXs, EAs and issues FONSI (or Determinations of Significance)

PNSO Operations and/or Program Managers

- Assumes role of NEPA Document Manager for project/proposal as appropriate
- Integrates the NEPA review process into project planning and scheduling.

PNSO Deputy/Assistant NCO

- Responsible for the overall quality of the NEPA review and approval process at PNSO
- Assists PNSO and contractor implementation of the NEPA process as well as compliance with the requirements, regulations, policies, procedures, and guidance identified in this QA Plan.
- Coordinates the review of NEPA documents, including the identification and involvement of an interdisciplinary team of subject matter experts as appropriate (including ISC NCO)
- Recommends to the PNSO Manager whether EAs, FONSI, and Determinations of Significance are appropriate or required
- Recommends to PNSO NCO approval for CX determinations, including associated floodplain and wetland documents
- Coordinates and integrates the review of NEPA documentation with the Hanford NCO for projects involving Hanford facilities or property
- Performs assessments of the contractor NEPA review process
- Coordinated with the NEPA Document Manager, assures the quality of any NEPA documents required
- Assists the maintenance of NEPA document records under PNSO responsibility.

PNSO Legal Office (OR)

- Provides review and input regarding all PNSO NEPA documents
- Provides additional NEPA input and support upon request.

Pacific Northwest National Laboratory (PNNL) Contractor

- Reviews projects and coordinates with PNSO Deputy/Assistant NCO
- Initiates preliminary NEPA documentation
- Maintains records as needed to verify compliance with NEPA requirements.

NEPA Document Manager

- Establish a team, representing all necessary DOE Elements to plan assist in preparing, and concurrently review documents.
- Conduct an early internal scoping process

- Maintain tracking systems to monitor cost of and adherence to the schedule for the NEPA process
- Manage the document preparation process including reviewing internal drafts for technical adequacy controlling cost, and maintaining schedule.
- Encourage and facilitate public participation through the NEPA process.
- Evaluate upon completion of the environmental impact statement of environmental assessment, any support contractor's performance for timeliness, quality, cost-effectiveness, responsiveness, and application requirement and guidance.
- Report to the Office of NEPA Policy and Compliance on lessons learned after completing the environmental impact statement or environmental assessment.

QUALITY ASSURANCE CRITERIA

The following sections describe the applicability of the quality assurance criteria of DOE Order 414.1C and 10 CFR 830 Subpart A to the PNSO NEPA review process.

Program

A written QA Plan must be developed, implemented, and maintained. The QA Plan must describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. The QA Plan must describe management processes, including planning, scheduling, and resource considerations.

This QA Plan documents the quality assurance activities used by PNSO for the NEPA review and approval process. The organizational roles and responsibilities are described in Section 4 of the NEPA QA plan. The PNSO Manager, project/program managers, and PNSO NCO manage, perform, and assess the adequacy of work and the quality of NEPA documents that support the PNSO project and program decision-making.

Personnel Training and Qualification

Personnel must be trained and qualified to ensure they are capable of performing their assigned work. Personnel must be provided continuing training to ensure that job proficiency is maintained.

PNSO ensures that staff involved in the NEPA review process shall be qualified professionals by background, experience, and/or training. These personnel shall be adequately trained in the laws, regulations, policies, requirements and guidance identified in this QA Plan.

The PNSO Deputy/Assistant NCO will be a qualified NEPA professional by background and experience. The PNSO Deputy/Assistant NCO will attend and actively participate in NCO meetings sponsored by the Office of NEPA Oversight or other NCOs in order to obtain current information and training on the DOE NEPA Compliance Program. The PNSO Deputy/Assistant NCO will distribute relevant information to PNSO and PNNL contractor staff as appropriate using vehicles such as periodic NEPA Councils. Other NEPA-related and environmental training opportunities are available to the NCO and other PNSO staff through DOE and non-DOE training programs.

PNSO and PNNL contractor staff will be trained using the DOE SC Integrated Service Center Chicago CH training or the Hanford NEPA Process Training Course as available. Topics include: use of NEPA as an integrated environmental planning process, folding NEPA into project and baseline planning to avoid project delays, and the role of other environmental regulations in the NEPA process.

The PNNL contractor ensures that staff involved in the NEPA review process shall have completed the appropriate NEPA training course identified in the PNNL NEPA Compliance subject area within a short time of employment of assuming the NEPA review position.

Quality Improvement

Processes to detect and prevent quality problems must be established and implemented. Items, services, and processes that do not meet established requirements must be identified, controlled, and corrected according to the importance of the problem and work affected. Correction must include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information must be reviewed and the data analyzed to identify items, services, and processes needing improvement.

Quality improvement of the PNSO NEPA review and approval process is achieved through the auditing program and lessons-learned program. The PNSO Deputy/Assistant NCO oversees the implementation of these programs. The PNSO Deputy/Assistant NCO will participate in DOE Office of Science NEPA teleconferences to benefit from lessons learned and headquarters guidance. PNSO staff will also utilize the NEPA workshops at the regular ES&H Coordination Meetings to focus on continuous NEPA improvement, successes, problem solving, and issue resolution.

As needed, the PNSO Deputy/Assistant NCO will obtain reviews by individuals and organizations with the proper expertise to ensure document quality.

Corrective actions are documented and tracked in the ONESC issue Tracking System (SITS) and/or the Headquarters Corrective Action Tracking System (CATS), as applicable.

The PNNL contractor implements an annually updated NEPA self-assessment plan which focuses on various aspects of NEPA compliance at PNNL. Self-assessments and corrective actions are tracked in the PNNL Assessment Tracking System (ATS).

Documents and Records

Documents must be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records must be specified, prepared, reviewed, approved, and maintained.

All PNSO NEPA documents and determinations will be prepared, reviewed, approved, issued, used, and revised according to DOE and PNSO policies and requirements. Hard copies of all PNSO NEPA documents and determinations, guidance and procedures will be maintained by the PNSO NCO and/or NEPA Document Manager in accordance with *DOE Records Schedule for Environmental Records*.

Documents will include the following:

- Approved NEPA documents and supporting data used as a basis for the decision

- Review comments and resolution
- Subject matter expert concurrences
- Other NEPA documentation demonstrating that DOE followed the proper process in complying with NEPA.

PNNL Contractor NEPA records are primarily maintained in electronic format as Electronic Prep & Risk records and Facility Modification Permits. These records allow the contractor and PNSO to 1) verify the nature and basis of the recommended decision; 2) verify for audit and appraisal purposes that the project has been reviewed in a manner consistent with DOE policy; 3) support DOE audits and assessments of NEPA compliance; and 4) generate reports on the NEPA program.

Work Processes

Work must be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means. Items must be identified and controlled to ensure their proper use. Items must be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection must be calibrated and maintained.

The primary steps in the PNSO EA process are summarized below. Other procedures are available to provide additional direction and guidance, including the *PNSO Internal Scoping Procedure* and the *PNSO Public Participation Plan*, contained in the Science Integrated Safety Management System (SCISMS) Environmental Protection Management System.

Note: PNSO/PNNL actions that involve Hanford facilities or property will follow the NEPA procedures developed by the Hanford NCO; in such cases, the Hanford NCO will be responsible for many of the activities identified below, including forming the internal scoping team, providing external notifications, providing a recommendation regarding the final threshold determination and maintaining appropriate records.

Initiation – The PNNL contractor initiates the review process through the development of an Electronic Prep & Risk form for funded projects. Electronic Prep & Risk forms for projects involving laboratory or field work are reviewed by contractor NEPA and environmental compliance reviewers.

Internal scoping – The PNSO Deputy/Assistant NCO and NEPA Document Manager collectively form an interdisciplinary team of subject matter experts, to assure a thorough review of the potential environmental impacts, establish the Purpose and Need and preliminary schedule. Additional direction and guidance is found in the *PNSO NEPA Internal Scoping Procedure*.

Determinations – After internal scoping, timely coordination of formal determination requests to initiate an EA will be prepared by the NEPA Document Manager in consultation with the PNSO Deputy/Assistant NCO, for written approval by the PNSO Manager. Actions that are determined to be appropriately addressed under a CX will be tracked and recommended for approval by the PNSO Deputy/Assistant NCO to the PNSO Manager.

Notification - Notification of the host states/tribes of DOE's intent to prepare an EA will be made in a timely manner following the NEPA determination, usually within two weeks. Notification is usually made by the PNSO Deputy/Assistant NEPA Compliance Officer or PNSO Manager.

Internal Review - Concurrent internal DOE reviews of EAs should occur to the maximum extent possible, to promote efficiency, save time, reduce delays, and enhance quality.

Document Quality - The quality and adequacy of each EA will be assured by preparing, reviewing, and approving them against existing CEQ and DOE guidance and standards.

Internal Concurrence and Approval - Concurrence will be obtained from the PNSO Deputy/Assistant NEPA Compliance Officer, NEPA Document Manager, PNSO program office, legal counsel, and internal scoping team, as appropriate. The PNSO Manager approves the EA.

External Review - After a notice is placed in the local newspaper, the EA will be provided to the public for an opportunity for review. The review will be conducted in accordance with the EA public participation plan developed through the internal scoping process and the *PNSO NEPA Public Participation Plan*.

Final Approval and Threshold Determination - After external review, comment response, and EA revision, and after concurrence of the interdisciplinary review team, the PNSO Deputy/Assistant NCO recommends to the PNSO Manager approval of the EA and makes a determination of whether there will be significant impacts. Depending upon the determination, a FONSI is issued by the PNSO Manager or a Determination of Significance is issued.

Distribution and Records - The PNSO Deputy/Assistant NCO distributes copies as appropriate to the ISC NCO, Hanford NCO, SC NCO, PNSO Manager, applicable project or program managers, and PNNL contractor. The EA should also be provided in electronic format suitable for posting on the DOE NEPA web site. The PNSO Deputy/Assistant NCO and/or NEPA Document Manager maintain records as described in Section 5.4 of this NEPA QA Plan.

Design

Items and processes must be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, must incorporate applicable requirements and design bases. Design interfaces must be identified and controlled. The adequacy of design products must be verified or validated by individuals or groups other than those who performed the work. Verification and validation work must be completed before approval and implementation of the design.

This criterion does not apply to the NEPA review process.

Procurement

Procured items and services must meet established requirements and perform as specified. Prospective suppliers must be evaluated and selected on the basis of the specified criteria. Processes to ensure that approved suppliers continue to provide acceptable items and services must be established.

PNSO, with support from the ISC NCO as requested, will provide sufficient oversight and assessments to ensure that the contractor is qualified to perform the required services and have sufficient resources to implement and complete the tasks. PNSO provides the contractor the necessary guidance, procedures, rules, and requirements to adequately prepare and /or review NEPA documentation. Contractor performance is monitored periodically by the PNSO Deputy/Assistant NCO to ensure quality services and acceptable deliverables are supplied.

Inspection and Acceptance Testing

Inspection and acceptance testing of specified items and processes must be conducted using established acceptance and performance criteria. Equipment used for inspections and tests must be calibrated and maintained.

Inspection and testing do not apply to the NEPA review process.

Management Assessment

Managers must assess their management processes. Problems that hinder the organization from achieving its objectives must be identified and corrected.

The ISC NCO supported by the PNSO Deputy/Assistant NCO will perform management assessments on the adequacy and quality of the PNSO NEPA program and its effective implementation. This will include assessments on PNSO Program Office and contractor conformance to requirements and procedures. The assessments will be conducted in accordance with the requirements in the Office of Science Integrated Safety Management System (SCISMS) Environmental Protection Management System (under development) and will identify problems and propose and monitor corrective actions. Corrective actions will be documented and tracked in the SC Issue Tracking System (SITS) and/or the Headquarters Corrective Action Tracking System, as applicable. Specific areas for assessment include: the performance of the PNSO NEPA program, the performance of line management in implementing the NEPA process, and opportunities for improving the quality, cost effectiveness, and timeliness of the PNSO NEPA program.

Independent Assessment

Independent assessments must be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. The group performing independent assessments must have sufficient authority and freedom from the line to carry out its responsibilities. Persons conducting independent assessments must be technically qualified and knowledgeable in the areas assessed.

Independent assessment of the PNSO NEPA Program will be conducted by DOE and/or coordinated by the ISC NCO. In addition, the PNSO Deputy/Assistant NCO's performance in determining approval of CXs and recommending approval of EAs will be periodically assessed by review of NEPA documents forwarded to DOE and/or the CH NCO. Deficiencies will be tracked to closure by using SITS.

In 2002, the PNNL contractor gained registration with ISO 14001, which provides an internationally recognized voluntary approach for an environmental management system (EMS). An EMS is a systematic methodology for managing the environmental impacts of an organization's operations and integrates

environmental performance into daily business decisions. The PNNL NEPA program is an integral part of the EMS. An external review of the EMS is performed on an annual basis.

Acronyms

CATS – DOE Corrective Action Tracking System
 CEQ – Council on Environmental Quality
 CFR – Code of Federal Regulations
 CH – DOE-SC Integrated Service Center Chicago
 CX – Categorical Exclusion
 CAMP- Corrective Action Management Plan
 CAP- Corrective Action Plan
 CATS- Corrective Action Tracking System
 CX- Categorical Exclusions
 DEAR- Department of Energy Acquisition Regulations
 DOE – US Department of Energy
 EA – Environmental Assessment
 EIS – Environmental Impact Statement
 ER – Energy Research (now designated DOE Office of Science)
 FAR- Federal Acquisition Regulation
 FONSI- Finding of No Significant Impact
 FR – Federal Register
 GFS/I- Government Furnished Services/Items
 ISC – Integrated Support Center
 ISMS- Integrated Safety Management System
 IDP- Individual Development Plan
 MOA- Memorandum of Agreement
 MS- Management System
 NCO – NEPA Compliance Officer
 NEPA – National Environmental Policy Act
 OA- Office of Independent Oversight and Performance Assurance
 OR-Oak Ridge
 PAAA – Price Anderson Amendments Act
 PNNL – Pacific Northwest National Laboratory
 PNSO – DOE Pacific Northwest Site Office
 PNSO Manager – Designated NCO by Position
 PNSO Deputy/Assistant NCO
 QA- Quality Assurance
 QA Plan – Quality Assurance Plan
 QAPD- Quality Assurance Program Description
 QASP- Quality Assurance Surveillance Plan
 R2A2s- Roles, Responsibilities, Accountabilities, and Authority
 RHA- Records Holding Area
 RL – DOE Richland Operations Office
 SBMS- Standards Base Management System
 SCMS-office of Science Management System
 SEB- Source Evaluation Board

SC – DOE Office of Science

S/CI- Suspect Counterfeit Items

SCISMS – Office of Science (SC) Integrated Safety Management System

SITS – DOE Office of Science (ONESC) Information Tracking System



Department of Energy
Washington, DC 20585

AUG 06 2009

MEMORANDUM FOR MICHAEL J. WEIS
MANAGER, PACIFIC NORTHWEST SITE OFFICE
OFFICE OF SCIENCE

FROM: GEORGE J. MALOSH
DEPUTY DIRECTOR FOR FIELD OPERATIONS
OFFICE OF SCIENCE

SUBJECT: Approval of the Pacific Northwest Site Office Quality Assurance
Program Description, June 2009 Version

The Pacific Northwest Site Office Quality Assurance Program Description, dated June 2009, is approved.

If you have any questions or need further information, please contact Matt Cole of my staff at 301-903-8388 or via email at matt.cole@science.doe.gov.

Attachment

cc w/o attachment:
P. Dehmer, SC-2