Department of Energy
Richland Operations Office
P.O. Box 550
Richland, Washington 99352

04-SED-0102

AUG 23 2004

Dr. L. K. Peters, Director
Pacific Northwest National Laboratory
Richland, Washington 99352

Dear Dr. Peters:

CONTRACT NO. DE-AC06-76RL01830 – SAFETY SOFTWARE QUALITY ASSURANCE ASSESSMENT OF PACIFIC NORTHWEST NATIONAL LABORATORY

An assessment of PNNL's safety software quality assurance processes were conducted during June 1-9, 2004. The assessment was undertaken to fulfill commitments in the DOE's Implementation Plan, Quality Assurance for Safety Software at DOE Defense Nuclear Facilities, for Defense Nuclear Facilities Safety Board Recommendation 2002-1. The assessment revealed weaknesses in PNNL's implementation of software quality assurance requirements as evidenced by the seven findings and seven observations described in the enclosed assessment report. Please respond to Findings F-1 through F-7 and Observations O-2 through O-7 within 60 days of receipt of this letter. Your response to the findings should address extent of condition, causes, and corrective actions to prevent recurrence. The response to the observations should indicate how they will be dispositioned. DOE will retain closure authority for these findings and observations.

The Government considers this action to be within the scope of the existing contract and therefore, the action does not involve or authorize any delay in delivery or additional cost to the Government, either direct or indirect.

If you have any questions, please contact me, or your staff may contact Roger F. Christensen, Director, Pacific Northwest Site Office Operations Division, on (509) 372-4900.

Sincerely,

Keith A. Klein
Manager

ESD:CAA

Attachment

cc w/attach:
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DEPARTMENT OF ENERGY
RICHLAND OPERATIONS OFFICE

ASSESSMENT OF PACIFIC NORTHWEST NALTIONAL LABORATORY SAFETY SOFTWARE QUALITY ASSURANCE
June 1 – 9, 2004

A-04-SED-PNNL-017

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June 2004

U. S. Department of Energy
Richland Operations Office (RL)
Assessment of Pacific Northwest National Laboratory Safety Software Quality Assurance

Report Approval

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U.S. Department of Energy
Richland Operations Office (RL)
Assessment of Pacific Northwest National Laboratory Safety Software Quality Assurance

EXECUTIVE SUMMARY

The DOE Richland Operations Office (RL) conducted an assessment of software quality assurance (SQA) processes of the Pacific Northwest National Laboratory (PNNL) during the period June 1 – 9, 2004. PNNL is managed by the Battelle Memorial Institute under a contract with RL. The assessment was undertaken to fulfill field office commitments in the DOE's Implementation Plan, *Quality Assurance for Safety Software at Department of Energy Defense Nuclear Facilities,* for Defense Nuclear Facilities Safety Board Recommendation 2002-1.

PNNL is responsible for a single nuclear facility, the Radiochemical Processing Laboratory, requiring a documented safety analysis (DSA). However, PNNL provides support to other Hanford contractors in the development of their required DSAs and with extensive radiological support services.

The overall objective of the assessment was to determine the adequacy of SQA processes for safety analysis and design software of nuclear facilities, including review of supporting databases and calculation software. The assessment focused on a sample of software that the assessment team judged had "the potential to cause radiological harm." As stated in the PNNL Quality Assurance Program Description (QAPD), items classified this way are regulated under 10 CFR 830.120, Subpart A (QA Rule). The assessment team used this criterion in order to limit the scope of the assessment to software with a role in safety.

The assessment was based on the criteria and approach documents developed by the DOE Office of Assistant Secretary for Environment, Safety, and Health (EH). This included but was not limited to the CRAD 4.2.4.1 guideline that "safety analysis and design software includes database programs and associated user files used to maintain control of information that has nuclear safety implications." The scope of this assessment was broader then CRAD 4.2.4.1 so that RL could assure it had a complete understanding of the adequacy of software quality assurance in PNNL. The following were the eight areas of SQA assessment:

- Software Requirements Description
- Software Design Description
- Software User Documentation
- Software Verification and Validation (V&V)
- Software Configuration Management
- Software Quality Assurance
- Software Procurement

- Software Reporting and Corrective Action

The assessment team identified several noteworthy practices.

- Some PNNL software applications have evolved over a number of years and have gained considerable maturity.Most mature software applications have generally adequate model descriptions, have generally adequate user's manuals, and are relatively stable.Available documentation in the form of technical bases, theoretical models, and user manuals for most codes provided information on code architecture and has generally provided sufficient basis for training, operating, and maintaining the software. Most of the PNNL designated principal users of safety software have excellent qualifications and experience.

The assessment team also found deficiencies in the PNNL QA program that represent non-compliances with requirements. The assessment team categorized these deficiencies as either a finding (non-compliance with specific requirements), or an observation (area recommended for improvement). The assessment team identified seven findings and seven observations, which are listed below.

Findings:

F-1: *Consensus standards were not always applied to PNNL activities affecting quality, including the development and maintenance of software.*

F-2: *Required documentation and control processes did not exist for some software.*

F-3: *Software requirements were not always adequately defined, and some software applications did not have any design description documentation.*

F-4: *For most software applications, there were no criteria to determine the appropriate level of rigor (based upon a graded approach), independence, and documentation of V&V for software changes.*

F-5: *PNNL did not always document evaluations of suppliers prior to awarding contracts.*

F-6: *PNNL did not protect software quality records from loss or damage.*

F-7: *Some "Electronic Prep and Risk" forms (key work planning documents) did not properly reflect the requirements for projects.*

Observations:

O-1: *Resolution of anomalies in the V&V documentation for CINDY, Version 1.4, for test data not meeting the V&V acceptance criteria were not documented.*

O-2: *PNNL lacked an appropriate system for managing legacy software.*

O-3: *Appropriate users' lists were not maintained for several applications.*

O-4: *There were no established procedures for training and qualification of users of APGEMS, GENII, and STOMP.*

O-5: *The PNNL SBMS system lacked formal direction on software problem reporting.*

O-6: *PNNL did not adequately identify software for which the requirements of the QA Rule apply.*

O-7: *PNNL did not adequately assess their software quality assurance program.*

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LIST OF ACRONYMS

COTS	Commercial-Off-The-Shelf
CFR	Code of Federal Regulations
CH2M HILL	CH2M Hill Hanford Group, Inc.
CRAD	Criteria, Review, and Approach Document
DSA	Documented Safety Analysis
DNFSB	Defense Nuclear Facilities Safety Board
EOC	Emergency Operations Center
FHI	Fluor Hanford, Inc.
HIDP	Hanford Internal Dosimetry Program
NFPA	National Fire Protection Association
NQA	Nuclear Quality Assurance
PNNL	Pacific Northwest National Laboratory
RL	DOE Richland Operations Office
RIDS	Records Inventory and Disposition System
RPL	Radiochemical Processing Laboratory (Building 325)
SBMS	Standards Based Management System
SDD	Software Design Description
SQA	Software Quality Assurance
SRD	Software Requirements Description
UDAC	Unified Dose Assessment Center
V&V	Verification and Validation
QA	Quality Assurance
QAPD	Quality Assurance Program Description

U. S. Department of Energy
Richland Operations Office (RL)
Assessment of Pacific Northwest National Laboratory Safety Software Quality Assurance

1.0 INTRODUCTION

This report presents the results of a Richland Operations Office (RL) assessment of safety software quality assurance (SQA) processes of the Pacific Northwest National Laboratory (PNNL). PNNL is managed by Battelle Memorial Institute under a contract with RL. The assessment was conducted during the period June 1 – 9, 2004. The background and objectives of the assessment are discussed below.

1.1 Background

The DOE Implementation Plan [1] for Defense Nuclear Facilities Safety Board (DNFSB) Recommendation 2002-1, *Quality Assurance for Safety-Related Software,* September 2002, defines the actions DOE is taking to ensure the quality of safety software at defense nuclear facilities. Safety software includes safety analysis and design software. Commitment 4.2.4.3 of this plan required assessments of the processes in place to ensure that safety software currently used to support the analysis and design of defense nuclear facilities is adequate. The present assessment was undertaken to fulfill this commitment relative to safety software currently used by PNNL.

PNNL is responsible for providing radiological support services to other prime contractors at the Hanford Site, which involves the use of many software applications. In addition, one of PNNL's software applications is used to support the generation of the documented safety analysis (DSA) of the Radiochemical Processing Laboratory (RPL), which is a nuclear facility.

1.2 Objectives and Criteria

The overall objective of the assessment was to determine the adequacy of SQA processes for safety analysis and design software of nuclear facilities, including review of supporting databases and calculation software. The assessment focused on a sample of software that the assessment team judged had "the potential to cause radiological harm." As stated in the PNNL Quality Assurance Program Description (QAPD), [2] items classified this way are regulated under 10 CFR 830.120, Subpart A (QA Rule) [3]. The assessment team used this criterion in order to limit the scope of the assessment to software with a role in safety.

The assessment was based on the criteria and review approach documents (CRADs) [4] developed by the DOE Office of Assistant Secretary for Environment, Safety, and Health (EH). This includes, but is not limited to, the CRAD 4.2.4.1 guideline that "safety analysis and design software includes database programs and associated user files used to maintain control of information that has nuclear safety implications." The scope of this assessment was broader than CRAD 4.2.4.1 so that RL could assure it had a reasonable understanding of the adequacy of software quality assurance in PNNL.

The QAPD is PNNL's top-level document for establishing quality assurance requirements. It implements 10 CFR 830, Subpart A and DOE Order 414.1A *Quality Assurance,* Attachment 2, "Contractor Requirements Document on Quality Assurance." Compliance with the QAPD is mandatory for all of PNNL's DOE-related activities. Implementation of the QAPD is supported by PNNL procedures [5,6] contained in PNNL's Standards Based Management System (SBMS) system. The results of this SQA assessment, therefore, were keyed to PNNL's specific requirements in the QAPD and the SBMS.

1.3 Report Organization

Sections 2 and 3 discuss the scope and approach of the assessment. Table 1 in Section 3 identifies the specific computer codes and applications reviewed. Section 4 presents the results of the assessment in terms of findings and observations. The findings represent conditions that do not conform to requirements. Section 5 provides brief summaries of assessment areas described in the DOE CRAD, including whether the specified criteria were met. These summaries cross-reference the concern, findings, and observations in Section 4 to identify issues described in the specific assessment areas.

Appendices A-1 and A-2 are lists of documents reviewed and personnel interviewed, respectively, in support of this assessment. Appendix B provides brief biographies of assessment team members.

2.0 SCOPE OF ASSESSMENT

PNNL is responsible for a single nuclear facility, the Radiochemical Processing Laboratory, requiring a DSA. However, PNNL provides support to other Hanford contractors (including those responsible to RL) in the development of their required DSAs. The assessment team reviewed SQA processes associated with safety software used by PNNL for development of these DSAs. The assessment of SQA processes also included review of supporting database and calculation software.

The assessment team also reviewed a sample of other software that they judged had "the potential to cause radiological harm," including database programs and other safety management software that have nuclear safety implications Software applications of this type are used by PNNL for DOE contractor-operated facilities across the Hanford Site through services agreements with PNNL. Such applications include radiological dose assessment and radiation exposure monitoring. This software still must be developed and maintained in accordance with the requirements of QA Rule. The assessment was based on the CRAD developed by DOE-EH. Some software evaluated by the assessment team was outside the scope of the EH CRAD, although it was within the scope of the QA Rule. This software was included to assure RL had a reasonable understanding of the adequacy of the control of software with a role in safety.

3.0 ASSESSMENT APPROACH AND TAILORING

3.1 Software Identification and Selection

An initial step in this assessment, undertaken with PNNL's assistance, was the development and review of PNNL's inventory of software that could be classified as safety software using the definitions in DOE CRAD[4], as well as other software that is subject to the requirements of the QA Rule. This enabled the assessment team to select computer codes for assessment of SQA processes. It also enabled PNNL to identify and provide, or to keep ready for review at the facility, a significant portion of the requested documents for the team's review; and to develop a preliminary schedule for interviews with key personnel.

A starting point for identifying the safety analysis and design codes was the results of surveys of such codes completed as part of previous commitments in the DOE Implementation Plan for DNFSB Recommendation 2002-1. A careful selection of computer codes was necessary because several factors affect the applicable SQA processes. These factors included: (a) the type of software (COTS, government agency sponsored, or custom); (b) model complexity (affecting user understanding, interaction, documentation, and code validation method); (c) age (affecting the nature of available life cycle documentation and how "legacy" software is brought into compliance); and (d) whether the software is "currently used". The consideration of these factors resulted in a sample set of safety software used by staff from three different PNNL organizations. The list of selected safety analysis and design software is shown in Table 1.

3.2 Software Assessment

The DOE CRAD for SQA assessment identifies eight broad areas covering the typical software life cycle:

- Software Requirements Description
- Software Design Description
- Software User Documentation
- Software Verification and Validation (V&V)
- Software Configuration Management
- Software Quality Assurance
- Software Procurement
- Software Reporting and Corrective Action

The assessment team evaluated each of these areas to the extent it deemed appropriate. The assessment team's review for each area followed the approach described in the CRAD for that area.

TABLE 1
List of Selected Safety Analysis and Design Software Used by Pacific Northwest National Laboratory (PNNL)

Name, Owner and Version	*Type of Application*	*Application/Function*
GENII	Safety analysis of nuclear facilities	Atmospheric dispersion modeling and analysis
STOMP	Analysis of contaminated water	Groundwater analysis
DSA Development (Paradox) Data Base	Safety analysis of nuclear facilities	Hazard Analysis documentation, risk bin determination, control identification, DSA development, and USQ support
DSA Development (Access) Data Base	Safety analysis of nuclear facilities	Hazard Analysis documentation, risk bin determination, control identification, DSA development, and USQ support
ED	External Dosimetry	External dosimetry data management system for dose calculation and dosimeter tracking
CINDY	Internal Dosimetry	Occupational dose calculations for internally-deposited radioactivity
ABACOS	IVVRF	VMS operating system for data acquisition and analysis from whole body counting and other measurements
REX	Field Dosimetry	Radiological Records
APGEMS	Air Pollutant Graphical Environmental Monitoring System	Emergency response application to radioactive plume incidents.

The criteria and approach in the CRAD in certain areas required tailoring. For example, software requirements description and software design description areas do not fully apply to procured COTS software. Similarly, V&V applies differently to COTS, where the assessment focused on installation V&V and proper validation using test problems and cases appropriately matched to the intended software application.

The qualification and training of software users was an important element in this assessment, especially for relatively complex safety analysis and design codes where significant technical expertise is needed for proper code validation, problem modeling, and correct use of the software for diverse applications. The assessment criteria provided in the DOE CRAD do not address this aspect explicitly, although they refer to user training as part of one item in describing the approach for software user documentation assessment area. The assessment team augmented its lines of inquiry in this assessment area to address software user qualifications and training in greater detail.

The assessment team made field visits, reviewed documents, and interviewed personnel to gather data and information for the assessment. During the field review of a particular software application, the team ensured that appropriate PNNL staff were involved. The following provides examples of the types of general and software-specific documents that were reviewed, depending on their applicability to SQA processes and activities; and the types of personnel who were interviewed. The full lists of documents reviewed and personnel interviewed are provided in Appendices A-1 and A-2, respectively.

The following are examples of types of requirements and background documents reviewed:

- DOE and PNNL SQA assurance requirements documents
- Project-specific SQA requirements and procedures
- Self-assessments, audits, and independent assessments
- List of databases that may have safety implications
- List of evaluated suppliers of software and technical services
- Occurrence reports and corrective action requests/reports

The following are examples of types of software-specific documents reviewed:

- Description of current work related to the software, including changes
- Software functional and requirements and descriptions
- Software design description
- Software development and management plans covering the entire lifecycle
- Products during and following software development
- Program description manuals, user manuals, guides, and instructions
- Audit reports; problem/resolution and corrective action reports
- List of individuals that performed V&V and their qualifications
- List of authorized users
- Sample input and output files

The following are examples of key personnel interviewed:

- Principal user
- Users of software
- Managers
- Individuals responsible for developing and implementing software modifications
- Individuals responsible for software V&V
- Nuclear safety (authorization basis) staff
- Quality assurance manager and staff

PNNL staff members accompanied the assessment team throughout its fieldwork to facilitate the reviews, provide assistance in obtaining the necessary additional documents, and understand the issues identified. In addition, daily exit meetings with PNNL staff were held. At the completion of its fieldwork, the assessment team provided a comprehensive out-brief to DOE and PNNL organizations, which presented all the preliminary results of the assessment.

Additional document reviews and discussions with PNNL personnel were conducted as necessary to bring closure to open issues and finalize the results. A draft of this report was provided to PNNL for a review of factual accuracy. The assessment team considered all review comments before finalizing the report.

4.0 ASSESSMENT RESULTS

The following is a discussion of the results of the team's assessment of the safety software quality assurance processes of PNNL. Deficiencies were categorized as either a finding (non-compliance with specific requirements) or an observation (area recommended for improvement). Most of these deficiencies cut across several assessment areas, therefore all the essential information from relevant assessment areas which supports a given deficiency is included with each deficiency. Brief summaries of the assessment areas with references to the results discussed below are provided in section 5.

The assessment team identified a few noteworthy practices.

- Some PNNL software applications have evolved over a number of years and have gained considerable maturity.
- Most mature software applications have generally adequate model descriptions, have generally adequate user's manuals, and are relatively stable.
- Available documentation in the form of technical bases, theoretical models, and user manuals for most codes provides information on code architecture and has generally provided a sufficient basis for training, operating, and maintaining the software.
- Most of the PNNL designated principal users of safety software have excellent qualifications and experience.

However, the assessment found several deficiencies in PNNL's implementation of software quality assurance requirements.

The findings and observations, presented in Sections 4.1 and 4.2, respectively, are assigned identification numbers and trending categories (shown in parenthesis), in accordance with RL procedures.

4.1 Findings

(F-1) Finding A-04-SED-PNNL-017-F01

Consensus standards were not always applied to PNNL activities affecting quality, including the development and maintenance of software. **[QA-QAPROG, QA-WORKPR, ISMS-IDHAZ]**

Requirements:

1. PNNL QAPD, Section "Applicability" states, "PNWD has established that 10 CFR 830, Subpart A applies to all work to which the Nuclear Hazard Indemnity Clause also applies and that has the 'potential to cause radiological harm ..."

2. PNNL QAPD, Section "Applicability" states, "If a customer identifies special quality requirements for a project ...that are necessary to meet some other quality standards beyond those listed above, those requirements will be considered supplemental and applied to the extent that they do not violate any quality requirements of the PNNL...."

3. PNNL QAPD, Section "Quality Assurance Program General Requirements – Discussion and Implementation, Implementation Approach for DOE O 414.1A (1a4) and 10 CFR 830.121(c3)" states, "PNNL uses a Requirements Management process to identify all applicable requirements and self-adopted standards. Specifically, each element of DOE O 414.1A and 10 CFR 830, Subpart A is supported by RODs that document the driver requirement or self-adopted industry standard and identifies how that requirement is flowed down to management and staff."

4. PNNL "External Requirement Document Records of Decision (RODs)", for example, 10CFR830.122(f) and 10CFR830(h)(1) states, "Information Resources Management System (IRMS) provides to the laboratory standards and processes intended to achieve quality in computer software and databases in the areas of research and operations. For example, through the SBMS subject area Computer Software and Database Control, IRMS provides the requirements for software quality assurance and related activities associated with the development and acquisition of software and databases at the laboratory."

5. The PNNL Quality Assurance Program Description (QAPD) states, "Projects or activities will identify their use and implementation of a graded approach to quality and customer specific quality requirements (including any specific consensus standards) in appropriate project or activity specific record document(s) (e.g., project management plan,

administrative procedure, technical and operating procedure, facility modification permit, RODs, quality assurance plan, RPL Operations Manual, etc.)."

6. Memorandum of Agreement (MOA), Number 012904-01, Revision 0, *Memorandum of Agreement Between Pacific Northwest National Laboratory and Fluor Hanford, Inc.* Under "Performance of Work," the MOA states, "Each contractor will perform work in accordance with the provisions of its prime contract with DOE, its internal procedures and requirements, quality assurance provisions (including safety), ..." Under "Flowdown of Requirements," the MOA stated, "Requirements such as 10 CFR 830 ... are identified in each prime contract and covered by the MOA ... Additional requirements over and above the Performing (Prime) Contractor's Prime Contract requirements or special task requirements will be explicitly identified in the individual statements of work ..."

7. 10 CFR 830.121(c) states in part, "The QAP must ...use voluntary consensus standards in its development and implementation, where practicable and consistent with contractual and regulatory requirements, and identify the standards used."

Discussion:

PNNL quality assurance procedures and projects did not always identify and implement consensus standards to be applied to activities affecting quality, such as software engineering. PNNL relies on the SMBS "Software" subject area for compliance with the quality assurance requirements of DOE O 414.A and 10 CFR 830, Subpart A, as they apply to software. However, the most recent revision to the "Software" subject area did not effectively implement any specific software engineering standard. The assessment team believes that weak commitment to consensus standards has inhibited PNNL from consistently satisfying the requirement for implementation of consensus standards in areas such as software engineering and records management. The following are conditions that led the assessment team to its conclusion:

- The SBMS system "Software" subject area procedure set, dated February 2004, did not identify consensus standards for implementation. The PNNL QAPD and the supporting RODs that implement the QA rule commit to applying self-adopted standards intended to achieve quality in computer software. For software engineering activities, the SBMS system should have specified it was implementing an appropriate SQA standard set, such as NQA-1 Subpart 2.7[7] or a suite of IEEE software engineering standards. These standards should have been used to define the software life cycle and to specify the required SQA documentation and practices. As a result; the SBMS procedures failed to address some software engineering topics described in consensus standards, such as regression testing of software changes.

- SBMS procedures from the May 2000 version of the "Computer Software and Database Control" subject area cited an appropriate set of IEEE software engineering standards. However, this SBMS procedure was superseded by the February 2004 version.

- PNNL staff responsible for the SBMS Software subject area said they removed references to standards from procedures because they expected customers to specify quality assurance and consensus standards requirements in project contracts for implementation in project-specific procedures. However, the PNNL QAPD states that the SBMS procedures are required for performance of work to which the QA Rule applies. Its implementation approach calls for identifying all applicable requirements and self-adopted standards. This indicates that the SBMS procedures should meet the minimum requirements of the QA Rule, including the requirement to implement QA Rule requirements through consensus standards.

- The Electronic Prep and Risk evaluation process did not always identify quality assurance as being applicable to project work that involved the use of software applications considered in this assessment. This is further discussed under Finding 7.

- Fluor Hanford, Inc., (FHI) and CH2M Hill Hanford Group, Inc., (CH2M HILL) managers interviewed by the assessment team said they relied on PNNL's procedures to assure that the correct consensus standard were implemented for work regulated under the QA Rule. They cited recently executed memoranda of agreement (MOA), such as Number 012904-01, Revision 0, *Memorandum of Agreement Between Pacific Northwest National Laboratory and Fluor Hanford, Inc.* Under "Flowdown of Requirements," the MOU stated, "Requirements such as 10 CFR 830 ... are identified in each prime contract and covered by the MOA ... Additional requirements over and above the Performing (Prime) Contractor's Prime Contract requirements or special task requirements will be explicitly identified in the individual statements of work ..." Managers from the other contractors said they interpreted this to mean that they did not need to specify quality assurance requirements, such as implementation of consensus standards, for work regulated under the QA Rule because they would be adequately addressed in PNNL's procedures. The exception would only be unique and special requirements for a specific project.

- Procedures cited by PNNL as implementing software engineering standards did not unambiguously implement a specific quality assurance standard or standards, were not mandatory, and were not widely used. These were contained in the Software Systems Engineering Process (SSEP) Guide which was developed, maintained, and used by the Information Sciences and Engineering (IS&E) organization. The procedures appeared to be useful, were used by IS&E, and were available to personnel developing and maintaining software in other parts of the Laboratory. However, the assessment team saw no evidence the SSEP was actually used outside of the IS&E organization. While the SSEP Guide addressed topics defined in NQA-1 and IEEE software engineering standards, it did not identify a standard and provide explicit implementation of the standard. (The Carnegie-Mellon Capability Maturity Model, reference by the SSEP Guide, is not a consensus standard within the intent of DOE O 414.1A or the QA Rule.)

- PNNL computer codes, such as the PGEMS component of APGEMS, used in the Hanford Emergency Center's Unified Dose Assessment Center, lacked conventional

quality assurance documentation described in NQA-1 and IEEE consensus standards, such as for validation testing.

- For several computer codes, such as CINDY, ABACOS, and REX, there was no formal process for determining the significance of software changes and applying an appropriate level of consensus standards as it relates to, for example, the rigor in planning, testing, and validating software modifications. It should be noted that PNNL had recently identified this deficiency for REX.

- Records of software quality maintained in Building 318 were not protected from loss due to fire in accordance with any consensus standard. The SBMS system did not identify and implement a standard for protection of records, such as those in NQA-1 or the NFPA *National Fire Code.*

RL Closure Required: YES [X] NO [ ]

(F-2) Finding A-04-SED-PNNL-017-F02

Required documentation and control processes did not exist for some software. **[QA-QAPROG, QA-DOC, ENG-CM, QA-INSP, ISMS-WORK]**

Requirements:

1. PNNL SBMS, February 2004, Subject Area, – *Software*, Section 6, Step 8 states "Project Team: Maintain documentation, including requirements and design, current with the state of the software."

2. PNNL SBMS, May 2000, Subject Area, *Computer Software and Database Control*, Section 3, Step 2 states in part, "Maintain the software under configuration management (for more information, see the Software Configuration Management exhibit)."

3. PNNL SBMS, May 2000, Subject Area, *Computer Software and Database Control*, Section 1, Step 4 states in part, "Complete a software documentation plan and maintain the plan in the project files."

4. PNNL SBMS, May 2000, Subject Area, *Computer Software and Database Control*, Section 2, Step 5 states in part, "Document configuration management in compliance with the software documentation plan."

Discussion:

The assessment team found examples of weaknesses and inadequacies in the software configuration management process. The following examples illustrate this problem:

- There is no formal software management and control for the applications of GENII at Hanford as required by PNNL SBMS. For example, there does not exist a documentation, quality or configuration plan, a list of authorized users, or documented training and qualification requirements for use of the code. Since the development and configuration management of GENII, Version 1.485, has been separately reviewed and judged to be adequate (DOE-EH-4.2.1.3-GENII-Gap Analysis), the focus of this assessment was on the configuration management aspects of the executable version of the code for Hanford applications. The custodian for GENII application interviewed by the assessment team said that any PNNL staff member could download and use the code without any custodian control, version validation, or verification of user qualifications.

- For APGEMS and for Hanford applications of STOMP, there are no software documentation plans, as required by PNNL SBMS. They also do not have a configuration management plan or a quality assurance plan, which for some other codes have served to address many of the requirements of the software documentation plan.

- For DSA database applications, PNNL does not prepare or maintain adequate documentation describing the detailed database configurations (schemes) that are used in different applications, as required by PNNL SBMS.

RL Closure Required: YES [X] NO [ ]

(F-3) Finding A-04-SED-PNNL-017-F3

Software requirements were not always adequately defined, and some software applications did not have any design description documentation.
[QA-PROG, QA-DESIGN, ENG-RQMNTS, ISMS-DEFINE]

Requirements:

1. PNNL SBMS, February 2004, Subject Area – *Software*, Section 6. *Maintaining Software*, Step 8, "Project Team: Maintain documentation, including requirements and design, current with the state of the software." Also a note to this section states, "Significant changes should be treated as new projects."

2. PNNL SBMS, May 2000, Subject Area, *Computer Software and Database Control*, Section 2, Step 1 states in part, "Define software requirements:"

3. PNNL SBMS, May 2000, Subject Area, *Computer Software and Database Control*, Section 2, Step 6 states in part, "Record information about the software design in

compliance with the software documentation plan. Design documentation defines how the implementation will satisfy the software requirements."

4. The PNNL QAPD states: "Projects or activities regulated by 10 CFR 830, Subpart A quality requirements are required to implement basic SBMS requirements."

Discussion:

The assessment team reviewed a sample of requirements documents and design descriptions. It found that some design requirements and design descriptions were inadequately documented. The following are examples that led the assessment team to this conclusion:

- For APGEMS, there is no software design description document or software requirements specification.
- For ABACOS, there is no design description of the interface software developed by PNNL.
- Requirements and design were not maintained current with the state of the software for the database applications used for development of DSAs.

RL Closure Required: YES [X] NO [ ]

(F-4) Finding A-04-SED-PNNL-017-F4

For most software applications, there were no criteria to determine the appropriate level of rigor (based upon a graded approach), independence, and documentation of V&V for software changes. **[QA-INSP, ENG-CHANGE, ISMS-DEFINE, ISMS-FEEDBK]**

Requirements:

1. 10 CFR 830.122(f)(4) states: "Verify or validate the adequacy of design products using individuals or groups other than those who performed the work."
2. The PNNL QAPD states:
   - "Projects or activities regulated by 10 CFR 830, Subpart A quality requirements are required to implement basic SBMS requirements."
   - "Projects or activities will identify their use and implementation of a graded approach ... in appropriate project or activity specific record documents."
3. PNNL SBMS, February 2004, Subject Area, *Software*, Section 6, Step 8, states: "Step 8 - Project Team: Maintain documentation, including requirements and design, current with the state of the software." Also, section 7, "Using Software to Conduct Analyses," states: "Step 4 - Project Manager and Team: Designate reviewers and schedule reviews.

Reviewers should be selected to collectively provide domain and software engineering knowledge. Reviewers should be independent in that they are not directly involved in the work that they are reviewing, although they may be involved in other facets of the work."

4. PNNL SBMS, May 2000, Subject Area, *Computer Software and Database Control*, Section 2, Step 7 states in part, "Determine the approach and assign responsibilities for testing and develop a testing and evaluation plan, then record the test plan information in compliance with the software documentation plan, and conduct testing in accordance with the testing and evaluation plan."

5. The PNNL SBMS, May 2000, Subject Area, *Computer Software and Database Control, Form: Software Testing and Review*, states in part, "It is strongly recommended that the Software Requirements Specification, Design Description, and the program source code be subject to an Independent Technical Review."

Discussion:

For CINDY, ABACOS, and REX, there are no criteria for determining the significance of software changes to be implemented and for applying a higher degree of rigor to software change control when errors in making software changes could have significant unintended impacts. This is not in compliance with the PNNL QAPD. Examples of additional rigor for significant changes include the development of appropriate test cases, test plan, regression testing, and independent V&V. It should be noted that PNNL had recently identified this deficiency for REX.

Approximately 50 modifications have been made to ED algorithms, both to enhance the models and capabilities, as well as to correct errors. An important recent modification corrected an identified error in a neutron dosimetry algorithm where the range for applying a correction factor was incorrectly programmed. The VAX change control procedures recognize that code modifications generally fall into two categories for the purpose of V&V, depending on whether there is or is not a "significant potential to impact the calculation of doses." Based on this category determination, a higher level of testing is required for the significant changes. The change procedure also provides a checklist for completing the V&V. However, there is no procedure for conducting the V&V. Such a procedure could include the development of a test plan, documentation of test results, the level and nature of review, selective retesting and other pertinent considerations as described in IEEE and ASME consensus standards. Due to lack of a procedure, for example, there was no V&V documentation for the upgrade of the ED code in 1996 to incorporate functionality for extremity monitoring.

Modifications to the ABACOS system were made and tested by the same programmer/analyst, contrary to the requirements of 10 CFR 830 and PNNL SBMS.

Extensive V&V testing was conducted for the PGEMS component of APGEMS during its development, however, PNNL said they did not retain the electronic records of this V&V testing. V&V testing of the PGEMS component of the APGEMS code was not formally documented for PNNL's use of APGEMS. As a result, PNNL does not have the documentation expected of software used for safety purposes.

Although the results of Hanford applications of STOMP were independently reviewed, no formal V&V documentation or approval of modifications was maintained in project files.

RL Closure Required: YES [X] NO [ ]

(F-5) Finding A-04-SED-PNNL-017-F05

PNNL did not always document evaluations of suppliers prior to awarding contracts. **[QA-PRO, ISMS-ANLYZE]**

Requirements:

1. 10 CFR 830.122(g), section 7, paragraph (2) states, "Evaluate and select prospective suppliers on the basis of specified criteria."

2. PNNL QA Plan No. LSC-022, Revision 7, "Hanford External Dosimetry Program," section 7.3 states, "Prospective suppliers shall be evaluated to ensure that only qualified suppliers are selected in accordance with PNNL procedures."

Discussion:

The assessment team reviewed procurement documents for several suppliers who provided computer software. The assessment team compared source selection information with DOE requirements and clarifying information in DOE G 414.1-2, *Quality Management System Guide for use with 10 CFR 830.120 and DOE O 414.1.* Section 4.7.3 of DOE G 414.1-2 states, "Prospective suppliers should be evaluated to verify their capability to meet performance and schedule requirements... The method or combination of methods chosen should provide adequate confidence that the supplied item or service will meet requirements."

Contrary to the above requirements, PNNL did not have objective evidence that some suppliers were evaluated prior to award of contract. These were:

- PNNL did not have objective evidence that Canberra Industries had been evaluated as a supplier for both hardware and software for the In Vivo Radioassay facility. PNNL management said an evaluation was conducted but it was not documented.

- PNNL did not have documentation demonstrating they had evaluated the Oracle Corporation as the supplier for the REX database engine. PNNL management said an evaluation was conducted but it was not documented.

RL Closure Required: YES [X] NO [ ]

(F-6) Finding A-04-SED-PNNL-017-F06

PNNL did not protect software quality records from loss or damage.
[QA-PROG, QA-DOC, ISMS-IDHAZ]

Requirements:

1. The PNNL QAPD, Element 4 states, "PNWD maintains a record system documenting evidence of activities performed. This system provides for the protection against loss, damage, or deterioration of records, hard copy or electronic. It also provides for the identification, storage, retrieval, and final disposition of these records. In-process requirements are established for record generators and custodians for maintaining records in working files."

Discussion:

Some quality records attesting to the quality of computer software were not adequately protected from loss or damage. In some cases records had been lost.

- Records of software quality maintained at Building 318 were not stored in accordance with any consensus standard, such as the NFPA *National Fire Code* or NQA-1. For example, records maintained in single-storage were not kept in fire-rated containers.

- Records were not dispositioned within a reasonable time frame. The file room in Building 318 contained records attesting to the quality of some software from 1995. An example was Program Change Request, Verification, and Validation Form 95-500-01 for the software application ED, dated February 6, 1995. The applicable RIDS designated this as a permanent record and the associated instruction stated, "Retire records in the DOE Records Holding Area annually or as volume warrants." The assessment team saw no justification for retaining this record in Building 318 since the record was approximately nine years old. In the unlikely event that the form was actually required for reference, a copy could still have been retained at Building 318.

- A log of computer program change requests maintained at Building 318 identified 118 change requests, but PNNL personnel could not locate 12 of these. The change requests were designated as permanent records and applied to computer codes used in the Hanford External Dosimetry Program.

RL Closure Required: YES [X] NO [ ]

(F-7) Finding A-04-SED-PNNL-017-F07
Some "Electronic Prep and Risk" forms (key work planning documents) did not properly reflect the requirements for projects. **[QA-PROG, QA-DESIGN, ENG-RQMNTS, ISMS-DEFINE]**

Requirements:

1. The SBMS Project Management subject area, procedure 1, "Documenting Project Planning Information," states, "Project managers must demonstrate to their PLMs that they have effectively planned the project prior to the start of work by ... completing the funded-stage section of the Electronic Prep & Risk (EPR) and submitting the EPR Risk Mitigation Permit for PLM approval."

Discussion:

While the EPR process provided an important vehicle for identifying risks associated with projects, some EPRs did not accurately identify risks. This occurred in part because contracts did not always accurately identify all requirements. Some customers did not accurately identify Price Anderson Act Amendment (PAAA) requirements and did not identify quality assurance requirements. The EPR process sometimes did and sometimes did not compensate for these weaknesses. The following are examples of conditions that led the assessment team to its conclusions:

- The EPR for "UDAC/EOC FY04 Meteorology and Modeling and Support" was incorrectly marked "No" for both "PAAA" and "Quality Assurance." This work included upgrading software applications in the UDAC that were to be used in emergency management. While these responses accurately reflected specifications of the FHI statement of work in their contract with PNNL, the EPR process did not recognize these as errors. Despite what the contract specified, the work was still enforceable under PAAA and quality assurance controls were required.

- The EPR for the Hanford Tank Farm Vadose Zone Project was incorrectly marked "No" for "Quality Assurance." The work involved several contracts with CH2M HILL for modeling the influence of groundwater movement on the transport of tank waste leaked into the soil. The product was to be used to satisfy regulatory commitments to both the state and the Environmental Protection Agency. A contract for groundwater modeling for waste tank C-106 was marked "N/A" for both quality assurance and application of standards. While the EPR accurately reflected contract specifications, the process failed to compensate for errors in the contract.

RL Closure Required: YES [X] NO [ ]

4.2 Observations

(O-1) Observation A-04-SED-PNNL-017-O01

Resolution of anomalies in the V&V documentation for CINDY, Version 1.4, for test data not meeting the V&V acceptance criteria were not documented. **[QA-INSP, ENG-CHANGE, ISMS-FEEDBK]**

Discussion:

There is extensive documentation of the V&V performed for the initial development of CINDY, however the results of V&V testing in 1995 indicated discrepancies with the V&V acceptance criteria for uranium-238. This V&V was a comprehensive testing of all aspects of CINDY. A major upgrade to CINDY (Version 1.4) was performed in 1995. The V&V testing for this upgrade was performed by technical staff of the Hanford Internal Dosimetry Program (HIDP) since there is very limited technical staff at Hanford capable of performing and interpreting the results of such V&V testing outside the HIDP. Based on discussions with the HIDP Manager, the V&V acceptance criteria had been based on benchmarking against results from the GENMOD code. The HIDP technical staff made the professional decision that the CINDY code provided more reliable results for uranium-238 than the GENMOD code, and therefore, implemented Version 1.4 of CINDY. However, this decision and its rationale were not documented in the V&V documentation.

RL Closure Required: YES [ ] NO [X]

(O-2) Observation A-04-SED-PNNL-017-O02

PNNL lacked an appropriate system for managing legacy software. **[QA-QAPROG, QA-DOC, ENG-CM, ISMS-DEFINE]**

Discussion:

Many of the codes evaluated by the assessment team were developed before consensus standards on SQA had matured. Standards like NQA-1 subpart 2.7 and the IEEE software engineering standards now describe processes for managing software not developed using contemporary standards and for identifying requirements that allow the continuing use of this software. PNNL had not established a process for managing older software not developed using contemporary standards (legacy software).

As an example, the application APGEMS was deployed in the Hanford Emergency Operations Center to provide information to decision-makers on potential exposures to off-site personnel in the event of an emergency, but the important PGEMS component of the software lacked standard SQA documentation. For example, there was no record of validation testing for PGEMS. PNNL had no process for evaluating the existing documentation and identifying necessary actions to qualify the software for continued use in safety applications.

The consensus standard requirement is based on an expectation that standards have been specified and the legacy management process will bring software into reasonable alignment with the specified standards.

RL Closure Required: YES [X] NO [ ]

(O-3) Observation A-04-SED-PNNL-017-O03

Appropriate users' lists were not maintained for several applications. **[CONOPS-LOGS, QA-DOC, QA-WORKPR, ISMS-WORK]**

Discussion

Lists of qualified users are maintained for the ABACOS, CINDY, ED, and REX applications, but not for the database applications used for development of DSAs, or Hanford users of GENII, STOMP, or APGEMS. An authorized current list of properly qualified users is necessary to ensure that the desired correct version of the code is adequately validated on the specific computer utilized and that the user is adequately qualified.

RL Closure Required: YES [X] NO [ ]

(O-4) Observation A-04-SED-PNNL-017-O04

There were no established procedures for training and qualification of users of APGEMS, GENII, and STOMP. **[QA-DOC, QA-WORKPR, ISMS-WORK]**

Discussion:

Detailed procedures for training and qualification of users of ABACOS, CINDY, ED, and REX have been established. However, while PNNL has prepared training materials and provided training for APGEMS and STOMP, there are no established procedures for training and qualification of users of these applications. Instructions on use are provided by the Radiation Safety Information Computational Center with GENII, but there are no established procedures or training provided for use of this application at Hanford.

RL Closure Required: YES [X] NO [ ]

(O-5) Observation A-04-SED-PNNL-017-O05

The PNNL SBMS system lacked formal direction on software problem reporting. **[QA-DOC, QA-WORKPR, ISMS-WORK]**

Discussion:

While some projects had formalized processes for reporting and resolving software problems/errors, this feature of software engineering was not addressed by the SBMS system. In

the view of the assessment team, this weakness is related to the lack of implemented software engineering and quality assurance standards discussed elsewhere in this report. (Reference CRAD 4.2.4.1, Section 4.8. entitled Software Problem Reporting and Corrective Action)

RL Closure Required: YES [X] NO [ ]

(O-6) Observation A-04-SED-PNNL-017-O06

PNNL did not adequately identify software for which the requirements of the QA Rule apply. **[QA-QAPROG, QA-DOC, ISMS-DEFINE]**

Discussion

The assessment team judged that all of the PNNL software applications reviewed during this assessment (reference Table 1) have "the potential to cause radiological harm" and are subject to the requirements of 10 CFR 830 Subpart A (QA Rule), as required by the PNNL QAPD. However, PNNL has not formally identified which computer software applications are subject to the requirements of the QA Rule.

By not adequately identifying software applications that should be covered by the QA Rule, PNNL staff may not complete the Electronic Prep and Risk evaluation correctly, and thus, may not apply the appropriate QA during the development, testing, maintenance and deployment of these applications. This could be an issue if, for example, radiological plume dispersion resulting from an accident was not accurately described by the code APGEMS. Similarly the spread/movement of radionuclides in ground water could be predicted incorrectly if a significant error is made in making modifications to the models in the STOMP code.

Identifying the software subject to the QA rule is an important step for ensuring that appropriately graded SQA standards are applied. This assessment focused on a selected sample of software applications that should be subject to the appropriately graded application of consensus standards as required by the QA rule. However, there could be other PNNL software applications for which SQA requirements and standards may not have been invoked and implemented adequately.

RL Closure Required: YES [X] NO [ ]

(O-7) Observation A-04-SED-PNNL-017-O07

PNNL did not adequately assess their software quality assurance program. **[QA-ASSMNT]**

Discussion:

PNNL was not performing either management or independent assessments focused programmatically on SQA. While projects chartered appropriate independent assessments of their local activities, an independent oversight organization had not conducted any assessments

focused specifically on the Laboratory's overall SQA program. The Information Resources management system owner had reorganized and was still in the process of developing a management assessment process. DNFSB Tech 25 and DNFSB Recommendation 2002-1 put DOE and PNNL on notice that SQA was an important issue, so SQA should already have been a focus of broad assessment attention. The assessment team considers PNNL should schedule and perform periodic independent programmatic assessments that address software quality assurance across the laboratory.

5.0 SUMMARY OF ASSESSMENT AREAS

The following provides a summary of assessment areas by the eight software quality assurance topics covered in the DOE CRAD. The lists of documents reviewed and personnel interviewed were organized according to the software application selected for assessment. These lists are provided in Appendix A-1 and A-2, respectively.

5.1 Software Requirements Description

Objective:

Software functions, requirements, and their bases are defined and documented.

Criteria:

1 The functional and performance requirements for the software are complete, correct, consistent, clear, testable, and feasible.
2. The software requirements are documented and consistent with the safety basis.
3. The software requirements description is reviewed, controlled and maintained.
4. Each requirement should be uniquely identified and defined such that it can be objectively verified and validated.

Summary:

The criteria were partially met considering the nature, experience, and stability of the software applications.

Most of the software applications have evolved over the years, have generally adequate model descriptions and user's manuals, and are relatively stable. The available documents have served as the basis for user training as well as making the necessary changes to the software. In many radiological applications, the changes required to the functionality of the codes are minor. Specific issues were noted in a finding.

Related Findings and Observations:

Finding: (F-3)

5.2 Software Design Description

Objective:

The software design description (SDD) depicting the logical structure, information flow, logical processing steps, and data structures are defined and documented.

Criteria:

1. All software related requirements are implemented in the design.
2. All design elements are traceable to the requirements.
3. The design is correct, consistent, clearly presented and feasible.

Summary:

The criteria were partially met considering the nature, experience, and stability of the software applications.

The available documentation in the form of technical basis, theoretical models, and user manuals for most codes provides information on code architecture and has generally provided sufficient basis for using, operating and maintaining the software. There is significant historical experience with the codes and anticipated modifications for the selected codes are generally minor. Specific issues were noted in a finding.

Related Finding and Observation:

Finding: (F-3)

5.3 Software User Documentation

Objective:

Software documentation is available to guide the user in installing, operating, managing, and maintaining the software.

Criteria:

1. The system requirements and constraints, installation procedures, and maintenance procedures such as database fine-tuning are clearly and accurately documented.
2. Any operational data system requirements and limitations are clearly and accurately documented.
3. Documentation exists to aid the users in correct operation of the software and to provide assistance for error conditions.
4. Appropriate software design and coding documentation to assist in future software modifications is defined and documented.

Summary:

The criteria were generally met.

The assessment team noted that the current principal users for all of the software applications reviewed by the assessment team are highly experienced and very well-versed in the use of these applications. In many instances these users were involved in the initial development of these applications and include several nationally and internationally recognized experts in the disciplines upon which their software applications are based.

Observations in this subject area concern the lack of authorized user lists and formal training and qualification procedures for software applications.

Related Findings and Observations:

Observations: (O-3), (O-4)

5.4 Software Verification and Validation (V&V)

Objective:

The software V&V process is defined and performed, and related documentation is maintained to ensure that (a) the software adequately and correctly performs all intended functions, and (b) the software does not perform any unintended function.

Criteria:

1. All analysis and design software requirements and software design have been verified and validated for correct operation using testing, observation, or inspection techniques.
2. Relevant abnormal conditions have been evaluated for mitigating unintended functions through testing, observation, or inspection techniques.

Summary:

The criteria were partially met.

Adequate V&V testing has been performed for the software applications reviewed by the assessment. Database applications for the development of DSA's were subject to independent review as part of the DSA review process. However, adequate procedures for and documentation of V&V testing are not maintained for the applications: APGEMS, and STOMP. Additionally, the procedures for V&V testing for ABACOS, CINDY, and REX do not provide definitions or protocols to differentiate "significant" modifications to these codes. The reviewers of changes to ABACOS, REX, and APGEMS were not always independent of the work being reviewed.

Related Findings and Observations:

Findings: (F-1), (F-2), (F-4)
Observations: (O-1), (O-2)

5.5 Software Configuration Management

Objective:

Software components, products, and related documentation are identified and maintained; and changes to those items are controlled.

Criteria:

1. All software components and products to be managed are identified.
2. For those components and products, procedures exist to manage the modification and installation of new versions.
3. Procedures for modifications to those components and products are followed.

Summary:

The criteria were not met.

While several PNNL codes have evolved over a number of years and have gained considerable maturity, the software change process generally lacks adequate planning and formality. Even when changes to a software application are minor, a small error introduced in the software, however mature, could be deleterious. Different specific issues have been identified with most of the software evaluated during this assessment.

As an example, for CINDY, ABACOS, and REX, there are no criteria for determining the significance of software changes to be implemented and for applying a higher degree of rigor to software change control when errors in making software changes could have significant unintended impacts. This was not in compliance with the PNNL QAPD.

Related Findings and Observations:

Findings: (F-1), (F-2), (F-4)
Observations: (O-2), (O-3), (O-6)

5.6 Software Quality Assurance

Objective:

SQA activities are evaluated for applicability to the analysis and design software, defined to the appropriate level of rigor, and implemented.

Criteria:

1. SQA activities and software practices for requirements management, software design, software configuration management, procurement controls, V&V (including reviews and testing), and documentation have been evaluated and established at the appropriate level for proper applicability to the software under assessment.
2. SQA activities have been effectively implemented.

Summary:

The criteria were not met.

While PNNL had procedures in the SBMS system governing the PNNL's software life-cycle, the procedures were not based on any specific consensus standards as required by both 10 CFR 830 Subpart A and DOE O 414.1. An earlier version of the "Software" subject area was based on IEEE standards, but that level of rigor had been removed. Also, the procedures were so sketchy that they did not address important features of SQA such as regression testing for software changes. Some project-level procedures did implement consensus standards, but some software development and maintenance activities were not covered by project-level procedures.

Software quality records were not being managed in accordance with 10 CFR 830 Subpart A and DOE O 414.1. Records in at least one location were not protected from loss or damage in accordance with any standard, and some records had been lost. Also, a formal record of validation testing of some codes used in the UDAC did not exist. These records were never formally established.

PNNL was not performing either management or independent assessments focused programmatically on SQA. Projects did charter appropriate independent assessments of their activities. However, an independent oversight organization had not conducted any assessments focused specifically on the Laboratory's SQA program. The Information Resources management system owner had reorganized and was still in the process of developing a management assessment process. DNFSB Tech 25 and DNFSB Recommendation 2002-1 put DOE and PNNL on notice that SQA was an important issue, so SQA should already have been a focus of broad assessment attention.

PNNL codes like HUDU and APGEMS used in the UDAC to support emergency evacuation decisions lacked the required SQA documentation. This condition should be remedied promptly. While PNNL shares responsibility for management of the UDAC codes with FHI, problems caused by poor SQA in the UDAC have the potential to harm the PNNL's reputation.

Related Findings and Observations:

Findings: (F-1), (F-6), (F-7)
Observation: (O-2) , (O-6), (O-7)

5.7 Software Procurement

Objective:

Vendor-supplied software, either COTS software, custom-developed or modified, requires the appropriate levels of QA commensurate with the level of risk introduced by their use.

Criteria:

1. Procurement documents for acquisition of software programs identify the quality requirements appropriate for the level of risk introduced by their use.
2. Acquired software is verified to meet the identified quality requirements.

Summary:

The criteria were partially met.

The acquired software evaluated by the assessment team was evaluated to assure it met the quality needs of PNNL. However, this was done through functional testing of the software rather than verifying quality requirements. In fact, quality requirements were not explicitly identified in the contracts reviewed by the assessment team. PNNL did not document evaluations of suppliers for some bioassay and database software. Licenses for were acquired from Oracle Corporation and Canberra Industries. Oracle Corporation and Canberra Industries are reputable companies, so the assessment team did not doubt the quality of the software. However, 10 CFR 830.122 and DOE O 414.1B still require PNNL to specify requirements and evaluate suppliers of computer software prior to awarding contracts.

Related Findings and Observations:

Finding: (F-5)

5.8 Software Problem Reporting and Corrective Action

Objective:

Formal procedures for software problem reporting and corrective action for software errors and failures are established, maintained, and controlled.

Criteria:

1. Practices and procedures for reporting, tracking, and resolving problems or issues identified in both software items and software development and maintenance processes are defined, documented and implemented.
2. Organizational responsibilities for reporting issues, approving changes, and performing corrective actions are identified and effective.

Summary:

The assessment criteria were partially met in that some projects had processes for identifying and resolving software errors. However, there was no PNNL requirement for projects to have formal error reporting processes, and some did not. In the view of the assessment team, this weakness stems from the lack of standards applied to PNNL software engineering, particularly for work regulated under 10 CFR 830.

Related Findings and Observations:

Observation: (O-5)

6.0 Lessons Learned

The following summarizes the lessons learned for improving safety SQA assessment process and approach:

- Complete and accurate software inventory. Assembling and obtaining a correct inventory of all the software that should be considered for the assessment was a far more difficult task than was anticipated. Perhaps a major factor that made this task difficult was the lack of PNNL requirement and organization to identify and control all software subject to requirements of the QA rule.

- Selected sample of software applications. The selection of safety analysis and design codes properly considered several factors, such as software type, complexity, age, current use, and safety significance (e.g., for spreadsheet and database applications with safety implications). However, some modifications were made to the sample during the assessment. Additional discussions during the planning would have avoided the changes.

7.0 References

1. *Quality Assurance for Safety Software at Department of Energy Defense Nuclear Facilities,* Implementation Plan for Defense Nuclear Facilities Safety Board Recommendation 2002-1, U.S. Department of Energy, March 13, 2003.

2. Quality Assurance Program Description, transmitted to DOE-RL on December 2, 2003 via PNNL letter 2003-QMS-06-RTS.

3. 10 CFR 830 (1-1-03 Edition) *Nuclear Safety Management*

4. *Assessment Criteria and Guidelines for Determining the Adequacy of Software Used in the Safety Analysis and Design of Defense Nuclear Facilities,* CRAD – 4.2.4.1, Revision 3, U.S. Department of Energy, October 24, 2003.

5. *PNNL Standards-Based Management System (SBMS), Computer Software and Database Control* Subject Area, *May 2000*

6. *PNNL Standards-Based Management System (SBMS), Software* Subject Area,, *February 2004*

7. *Quality Assurance Requirements for Computer Software for Nuclear Facility Applications,* ASME NQA-1, Subpart 2.7, The American Society of Mechanical Engineers.

Appendix A-1

Documents Reviewed

PACIFIC NORTHWEST NATIONAL LABORATORY (PNNL) Documents (GENERAL)

PNNL Quality Assurance Program Description, February 2004

PNNL Software Systems Engineering Process Guide, April 2004

PNNL Standards-Based Management System (SBMS), Computer Software and Database Control, May 2000

ERC Work Order Number P40001 and P40002, *FY 2004 Statement of Work for Radiological Dosimetery Services Provided By Pacific Northwest National Laboratory, dated May 29, 2003*

PNNL SBMS, Standards-Based Management System, April 2002

PNNL SBMS, Computer Software and Database Control, May 2000

FUA-318-R3, Facility Use Agreement for Radiological Calibrations Laboratory Building, 318, 300 Area, October 2003

FUA-325-R5, Facility Use Agreement for Radiochemical Processing Laboratory (RPL), 325 Building, 300 Area, October 2003

PNNL Integrated Environment, Safety, Health, and Quality Vocabulary, April 2002

EPR Summary View, Scope Numbers 30267, 42058, 43849, 43850, 46469. 46749, 46992, and 46997

Memorandum of Agreement (Number 012904-01), Rev. 0, Between Pacific Northwest National Laboratory and Fluor Hanford, Inc. March 2004

External requirement document Record of Decision for 10 CFR 830, Subpart A, January 1, 2001.

PNNL Software Applications

GENII

DOE-EH-4.2.1.3-GENII-Gap Analysis, May 2004, *Software Quality Assurance Improvement Plan: GENII Gap Analysis*, Final Report

PNNL-DSA-RPL, *Radiochemical Processing Laboratory Documented Safety Analysis*, Rev. 1, 2003

RPL-SA-R4, Rev. 0, May 1999, *Radiation Dose Analysis for the Radiochemical Processing Laboratory SAR and Implementing Procedures*

PNL-6584, Vol. 1, GENII – *The Hanford Environmental Radiation Dosimetry Software System, Conceptual Representation*, Napier, B. A, R. A. Peloquin, D. L. Strenge, and J. V. Ramsdell, Pacific Northwest Laboratory, Richland, Washington, 1988

PNL-6584, Vol. 2, GENII – *The Hanford Environmental Radiation Dosimetry Software System, Users' Manual*, Napier, B. A, R. A. Peloquin, D. L. Strenge, and J. V. Ramsdell, Pacific Northwest Laboratory, Richland, Washington, 1988

PNL-6584, Vol. 3, GENII – *The Hanford Environmental Radiation Dosimetry Software System, Code Maintenance Manual*, Napier, B. A, R. A. Peloquin, D. L. Strenge, and J. V. Ramsdell, Pacific Northwest Laboratory, Richland, Washington, 1988

GENII 1.485 DOE Radiation Safety Information Computational Center (RSICC) Electronic Distribution Package, CCC-601 Oak Ridge National Laboratory

STOMP

STOMP Configuration Management Plan, Version 1, Rev. 0, June 1997

PNNL-11216 (UC-2010), STOMP Subsurface Transport over Multiple Phases: Theory Guide

PNNL-14286 (UC-2010), STOMP Subsurface Transport Over Multiple Phases, Version 3.0: User Guide

PNNL-11216 (UC-2010), STOMP Subsurface Transport over Multiple Phases: Application Guide

Statement of Work (Requisition #94464), *Vadose and Groundwater Long Term Modeling to Support Risk Assessment for Tank C-106*, Rev. 0, October 23, 2002 (PNNL support to CH2M HILL, re: STOMP)

Contract 7857, Release 2, February 5, 2001 (PNNL support to CH2M HILL, re: STOMP)

DSA DEVELOPMENT DATA BASES (ACCESS and PARADOX)

RPP-15188, Rev. 2, October 2003, Hazard Evaluation Database (prepared for CH2M HILL

RPP-14286, Rev. 1, Facility Worker Technical Basis Document, August 2003

HNF-12652, Rev. 0, April 16, 2003, Hazard Evaluation for 222-s Laboratory Complex (prepared for Fluor Hanford Inc.)

Memorandum of Agreement, Number 012904-01, Rev. 0 , Signed March 29, 2004 (PNNL to provide FHI software support for ACCESS database)

Memorandum of Agreement, Number CH2M-PNNL-2112004, Signed February 23, 2004 (PNNL to provide CH2M HILL software support for PARADOX database)

ED

ED Change No. 03-500-03, Program Change Request V&V Form, November 10, 2003

Program Change Request, Verification, and Validation Log – FY98 (HEDP)

Hanford External Dosimetry Project Thermoluminescent Dosimetry Processing and Data Base System Functional Requirements/Conceptual Design, B. A. Rathbone, August 1994

PNL-MA-841, 500.1.50, Rev. 6, January 2004, VAX Change Control Hanford External Dosimetry Procedures

PNL-MA-859, Hanford External Dosimetry Program Quality Manual, November 2002

Source Code Error in 8816 PFP Neutron Dose Algorithm, B. A. Rathbone, November 20, 2003

PNL-MA-859, Hanford External Dosimetry Program Quality Manual, November 2002

PNL-MA-844, Hanford External Dosimetry Project Data Management Manual, December 2003

ED Vax-Cluster User List

Quality Assurance Plan for Hanford External Dosimetry Program, QA Plan No. LSC-022, Rev. 7, January 2003

Verification Testing of the Hanford External Dosimetry Data Management System, Bruce Rathbone, July 7, 1995

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PNL-MA-552, Hanford Internal Dosimetry Project Manual

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Software Testing Plan – CINDY: Code for Internal Dosimetry, Version 1.000, February 1991

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ABACOS

PNL-MA-554, IVMP300.B.10, Revision 2, Software Configuration Management (for ABACOS), November 2003

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ABACOS Users' List

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Model 480726, Genie-ESP System User's Manual, September 2000

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Request for Technical Equivalence, T. P. Lynch, September 28, 1999

Software Verification and Validation Plan (SVVP) for Abacos Plus, 48-0686, AP-P00 Rev 1.0, November 11, 1992

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REX

REX-002, Version 3, March 2002, Radiological Exposure System (REX) Software Design Description

REX-001, Revision 3, REX Software Configuration Management Plan

REX Software Change Request, May 24, 2004

REX System Users

REX Software Change Requests, Nos. 144-150.

PNL-MA-553, Rev. 2, February 2002, Hanford Radiation Records Program Manual, Radiation and Health Technology

HRRP-01, Hanford Radiation Records Program Procedures

HRRP-02, Radiation & Health Technology/Radiation Records Program, Dosimetry Operations Procedures Manual

Quality Assurance Plan for Hanford Radiological Records Project, QA Plan No. LSC-025, Rev. 3, March 2001

Radiological Exposure System (REX) Version 3 Acceptance

APGEMS/UDAC

PNNL-14043, September 2002, User's Guide for APGEMS

Instructions for Installing APGEMS, May 31, 2002

Acceptance Test Procedure for APGEMS, July 27, 1999

Statement of Work, *Emergency Operation Center Consequence Assessment Support Fiscal Year 2000*, October 20, 1999

Statement of Work, *Prepare Meteorological Data and Modify Meteorological Workstation Software to Support UDAC Exercises*, Rev. 1, July 19, 1999

Appendix A-2

Personnel Interviewed/Contacted

PACIFIC NORTHWEST NATIONAL LABABORY (PNNL)

Jerry Johnson, Associate Director for Information Resources Management
Rebecca Kennedy, Information Resources Management
Larry Kimmel, Environment, Safety, Health & Quality Manager
Tonya Graham, Facility Safety Manager
Taffy Almeida, Environment Safety, Health, and Quality
Rick Steele, Quality & Integrated Safety
Paul Korstad, Internal Auditing
Jay McLellan, Records Manager
Ron Schrotke, Technical Project QA Support

PNNL SAFETY ANALYSIS AND DESIGN AND OTHER SOFTWARE

GENII
Kathy Rhoades, GENII Custodian and Lead

STOMP
Mark White, STOMP Custodian
Will Nichols, STOMP User

DSA Development (Paradox and Access) Data Base
John Young, Project Manager (DSA development using Microsoft ACCESS and COREL PARADOX), Environmental Technology Division

ED and ATLAS
Bruce Rathbone, ED Technical Manager and Principal User
Alan Endres, ED Programmer/Analyst
Scott Huneycutt ED Program Manager

CINDY
Dennis Strenge, CINDY Custodian
Eugene Carbaugh, Hanford Internal Dosimetry Program Manager

ABACOS
John Berecca, ABACOS custodian/programmer
Tim Lynch, In Vivo Monitoring Program Manager

REX

Eric Talbott, REX Custodian
Michelle Johnson, Radiation Dosimetry Program Manager

APGEMS/UDAC
Clifford Glantz, APGEMS Project Manager and Lead Meteorologist
Mitch Pelton, APGEMS Programmer

Appendix B

Assessment Team Qualifications and Experience

Clifford A. Ashley, Team Leader – Mr. Ashley has been leading and participating in quality assurance assessments and surveillances during the last 13 years for the US DOE. This includes nine years experience as a DOE Facility Representative, as well as service as subject matter expert and various quality assurance positions with the New Production Reactor Project and the Tank Waste Remediation System Project. Several assessments included or were focused on computer software quality assurance. From February 2004 to May 2004, Mr. Ashley actively participated as an assessor in a software quality assurance assessment of BNI Design and Analysis Software; FHI I&C, Design and Analysis Software; and CH2M HILL Design and Analysis Software.

During 1979 to 1981, Mr. Ashley's primary responsibility was to program a HP-1000 computer to record and extract critical test data from DOD sidewinder missile servomechanisms.

Mr. Ashley holds a baccalaureate degree in electrical engineering from Washington State University (1975), and a Master of Science degree in Electrical Engineering from North Dakota State University (1976).

Dr. Shivaji S. (Shiv) Seth, Deputy Team Leader – Dr. Seth is Senior Technical Advisor for Nuclear Safety at the DOE Richland Operations Office. He has reviewed the nuclear safety authorization basis and operational safety of several nuclear facilities at the Hanford site, including those where safety software is deployed both in safety systems and in analyzing facility safety. As a member of a DOE team responding to DNFSB Recommendation 2002-1, Dr. Seth was a contributor to the development of the DOE qualification standard for software engineers and the CRADs for safety software assessments. Since February 2004, he has served as the lead or the deputy lead for DOE's comprehensive assessments of software quality assurance programs of various prime contractors at the Hanford site; namely, Bechtel National for the Waste Treatment Plant under design and construction at Hanford, CH2M Hill for the Tank Farms, Fluor Hanford for the rest of the Hanford site, and Battelle for the Pacific Northwest National Laboratory.

Prior to joining DOE in 1996, Dr. Seth managed and guided several safety and systems engineering projects at the MITRE Corporation in support of the USNRC and DNFSB. He was the principal investigator of a major project for the USNRC for developing the guidelines, technical basis, and research needs for high-integrity (safety) software in nuclear power plant safety systems. This work (NUREG/CR-6263) has been cited as a resource in various USNRC Regulatory Guides.

Dr. Seth's 35 years of work in the nuclear field also includes nuclear reactor core design and analysis, optimization of the reactor fuel cycle, and safety and probabilistic risk analyses. These involved considerable programming and use of computers. His experience at a national laboratory includes planning and analyzing reactor critical experiments for investigating the

design and safety of fast reactors and supervising reactor operations. These involved the use of digital instrumentation and control systems.

Dr. Seth holds Master's and Doctor's degrees in Nuclear Engineering from the Massachusetts Institute of Technology, Cambridge, Massachusetts, and has authored over 80 technical publications.

David H. Brown – Mr. Brown has been leading and participating in quality assurance assessments for 17 years. Several of these have included or been focused on computer software quality assurance. He has been certified as a Lead Auditor in accordance with the requirements of NQA-1, *Quality Assurance Program Requirements for Nuclear Facilities*, since June, 1987. Mr. Brown holds a baccalaureate degree in nuclear science from the State University of New York, Maritime College (1971). During 15 years of civilian employment with the U.S. Navy he served as reactor plant Chief Test Engineer for nuclear submarine refuelings and overhauls. He received formal training in computer software quality assurance from the Pacific Northwest National Laboratory in May, 1992. He participated in development of the following DOE directives and documents:

- The DOE response to DNFSB Recommendation 2002-1, *Quality Assurance for Safety Software at Department of Energy Defense Nuclear Facilities.*
- CRAD 4.2.3.1, *Criteria and Guidelines for the Assessment of Safety System Software and Firmware at Defense Nuclear Facilities*
- CRAD 4.2.4.1, *Assessment Criteria and Guidelines for Determining the Adequacy of Software Used in the Safety Analysis and Design of Defense Nuclear Facilities*
- DOE-STD-1172-2003, *Safety Software Quality Assurance Functional Area Qualification Standard*

Wayne M. Glines, Assessor - Mr. Glines has been a Senior Technical Radiological Controls Advisor (STA) for the Department of Energy, Richland Operations Office since January 1997. Mr. Glines is currently the technical lead for the radiological release of property from the Hanford Site, and also the Program Manager for Hanford Radiological Site Services, including Hanford external and internal dosimetry, radiation exposure records, and radiological instrumentation programs.

At the Hanford Site Mr. Glines has conducted numerous technical reviews and evaluations of radiological program elements, and safety basis and environmental compliance documents. As a member of the RL NEPA Review Panel he has provided technical comments on numerous DOE and Hanford NEPA documents. He has also provided technical review and evaluation for programmatic documents such as the 300 Area Accelerated Closure Plan, and has participated in several Operations Readiness Reviews and Readiness Assessments.

Prior to working at the Hanford Site, from 1993 through 1996, Mr. Glines worked at the Nevada Test Site (NTS) where he managed the Environmental Surveillance Program for the NTS including the design, implementation, data analysis and assessment, and reporting of data for

several comprehensive monitoring networks. Mr. Glines also served on several working groups associated with environmental monitoring, dosimetry usage, and waste management at the NTS.

From 1979 to 1993 Mr. Glines held several positions in the Radiation Health Division of Puget Sound Naval Shipyard (PSNS) covering areas such as external and internal dosimetry, NRC-licensed activities, environmental monitoring, regulatory compliance, emergency response, and radiation litigation. From 1986 through 1993, Mr. Glines held dual positions as the Head, Environmental Monitoring Branch, and Senior Health Physics Advisor, and was responsible for managing the Environmental Monitoring and Radioassay Programs, and providing technical advice to senior PSNS and Department of Navy management on radiological protection issues.

Mr. Glines graduated with a Bachelor of Science in physics from the University of New Hampshire, and a Master of Science degree in Radiological Sciences from the University of Washington. He was certified by the American Board of Health Physics in Comprehensive Health Physics in 1985. Mr. Glines has over 25 years of professional experience in a broad range of radiation protection areas, and is currently a member of the Health Physics Society Standards Committee.

E-STARS™ Report
Task Detail Report
08/23/2004 0147

TASK INFORMATION			
Task#	DOE-SED-C-2004-0102		
Subject	CONTRACT NO. DE-AC06-76RL01830 – SAFETY SOFTWARE QUALITY ASSURANCE ASSESSMENT OF PACIFIC NORTHWEST NATIONAL LABORATORY		
Parent Task#		**Status**	Open
Reference		**Due**	
Originator	Mercado, Sally C	**Priority**	High
Originator Phone	(509) 376-7597	**Category**	None
Origination Date	07/21/2004 1050	**Generic1**	
Remote Task#		**Generic2**	
Deliverable	None	**Generic3**	
Class	None	**View Permissions**	Normal
Instructions	bcc: SED OFF FILE SED RDG FILE bcc w/attach: C. Ashley, SED R. Christensen, PNSO T. Davis, PNSO R. DAwson, PNSO S. S. Seth, PMD Record Note: This letter formally transmits the subject assessment report to PNNL. The DOE-Office of Science and PNNL management were provided a briefing on the issues June 9, 2004. Also, PNNL management and staff were provided a draft copy of the assessment report on June 25, 2004 and their formal and informal (verbal) comments (received July 9, 2004) were addressed in the report. The Assessment Team and RL Management had a meeting with the DOE Office of Science staff and management on July 20, 2004, where they were provided the teams written response to each PNNL comment (46 pages), and the revised PNNL SQA Assessment report (attachment to this letter).		

ROUTING LISTS		
1	List 1	Inactive
	• Ashley, Clifford A - Approve - Approved - 07/26/2004 0728	
	• Hill, Burt E - Approve - Approved with comments - 07/26/2004 1141	
	• Garcia, Pete J - Approve - Approved with comments - 08/04/2004 0939	
2	Final List	Active
	• Weis, Michael J - Approve - Approved with comments - 08/20/2004 1126	
	• Klein, Keith A - Approve - Approved - 08/23/2004 0746	
3	List 2	Inactive
	• Christensen, Roger - Approve - Approved with comments - 08/18/2004 1032	
	• Davis, Terry - Approve - Approved - 08/18/2004 1241	
	• Kruger, Paul - Approve - Approved - 08/20/2004 0804	
	• Shoop, Doug S - Approve - Approved with comments - 08/18/2004 1613	

ATTACHMENTS

Attachments	1. 04-SED-0102 Report (Final!).CAA.doc 2. 04-SED-0102.software quality assurance of pnnl.doc

COMMENTS

Poster	Hill, Burt E (Hill, Burt E) - 07/26/2004 1107
	Approve
	The words used, align them selves with the PNNL contract lanuage.
Poster	Garcia, Pete J (Mercado, Sally C) - 08/04/2004 0908
	Approve
	Approve per P. Garcia scm 8/4/04
Poster	Christensen, Roger (Christensen, Roger) - 08/18/2004 1008
	Approve
	Please clarify the response expectation for the observations in the transmittal letter by including the following sentence near the end of the first paragraph: Your response to the findings should address extent of condition, causes, and corrective actions to prevent recurrence. "The response to the observations should indicate how they will be dispositioned." RL will retain closure authority for these findings and observations. The additional sentence was agree to by Cliff Ashley via telecon.
Poster	Shoop, Doug S (Spargur, J Jill) - 08/18/2004 0408
	Approve
	Concur DSS 8/18/04
Poster	Weis, Michael J (Henrich, Dianne L) - 08/20/2004 1108
	Approve
	N/A

TASK DUE DATE HISTORY

No Due Date History

SUB TASK HISTORY

No Subtasks

-- end of report --