NNPP-SNF-YMSA-19

NNPP QUALITY ASSURANCE PROGRAM

BACKGROUND, EVALUATION, AND ANALYSIS REPORT (BEAR) 19

Revision 1

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Change Summary

Revision Number	Description of Change
1	Updated the BEAR to accurately describe the basis for demonstration of compliance with the quality attributes of NUREG 1804. This was accomplished by correcting the title of Reference 19-4 and by inserting a new Reference 19-5. Insertion of the new Reference 19-5 also forced renumbering of subsequent References in the document.

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19.1 INTRODUCTION

The Naval Nuclear Propulsion Program (NNPP) Quality Assurance (QA) Program is applied to all aspects of NNPP work. This report describes the implementation of the NNPP QA Program as it pertains to the disposal of naval spent nuclear fuel (SNF) in the geologic repository at Yucca Mountain, Nevada. Included in this report are descriptions of:

1. Naval Nuclear Propulsion Program

   The NNPP is comprised of military and civilian personnel, who design, procure, build, maintain, operate, and manage the naval nuclear-powered fleet and facilities that support the fleet, and prepare naval SNF for ultimate disposal. Section 19.2 provides an overview of the NNPP structure, organization, responsibilities, and management philosophy.

2. Memorandum of Agreement for Acceptance of Naval SNF

   Section 19.3 describes the memorandum of agreement (MOA) for acceptance of naval SNF between the Director, NNPP, and the Director, Department of Energy Office of Civilian Radioactive Waste Management (DOE-RW). The MOA provides:

   a. Terms and conditions under which DOE-RW will make available disposal services to NNPP for naval SNF;
   b. Coordination and implementation of QA activities associated with preparation of naval SNF for acceptance in a DOE-RW-managed, Nuclear Regulatory Commission (NRC)-licensed disposal facility; and
   c. Roles and responsibilities of NNPP and DOE-RW in coordinating and implementing the NNPP QA program.

3. Memorandum of Agreement for Naval SNF Return from Idaho Nuclear Technology and Engineering Center

   Section 19.4 describes the MOA between the Department of Energy Idaho Operations Office (DOE-ID) and the Naval Reactors Laboratory Field Office Idaho Branch Office (NRLFO-IBO) for naval SNF return to NNPP from the Idaho Nuclear Technology and Engineering Center (INTEC) located at the Idaho National Laboratory (INL). The MOA defines the relationships and responsibilities between INTEC and NNPP. The MOA lays the groundwork for the exchange of information and provision of equipment necessary to ensure that regulatory and NNPP requirements are met for the work performed at INTEC involving naval SNF. The execution of the MOA provides assurance that naval SNF, prepared for disposal at INTEC, can be certified for shipment to and disposal in the geologic repository, and that the applicable regulatory and NNPP requirements have been incorporated into INTEC hardware designs and work procedures.

4. Naval Nuclear Propulsion Program Quality Assurance Program

   The NNPP QA Program ensures that work performed and product delivered meet technical specifications and regulatory requirements for all aspects of NNPP work. Section 19.5 describes the NNPP QA program structure, organization, fundamental principles, and requirements that are important to the successful execution of NNPP objectives.

   The NNPP part of the Yucca Mountain License Application (LA) is documented in classified Technical Support Document (TSD) sections and Background, Evaluation, and Analysis Reports

(BEARs). The TSD sections describe the safety case for naval SNF. The BEARs provide detailed descriptions of NNPP work that support statements made in TSD sections. The QA plan developed for NNPP work associated with the TSD part of the Yucca Mountain LA summarized in Appendix A describes actions that ensure TSD sections and BEARs achieve a high level of quality.

Computer program verification and engineering model qualification are conducted for NNPP work in accordance with NNPP QA program requirements. Verification is the process of ensuring that the computer program properly executes the mathematical or logical processes intended and produces a result that is mathematically and logically correct. Qualification ensures that the analytical procedures, such as mathematical models, methods, assumptions, correlations, limits, data input, numerical technique, and computer programs, solve the specific problem of interest, to a level of accuracy acceptable to the design organization. Qualification includes comparison of results of an analytical procedure to empirical data, comparison to results from a previously qualified procedure, completion of a detailed peer review, or use of other technically justified approaches. Appendix B summarizes the methods used by NNPP for computer program verification and engineering model qualification.

19.2 NAVAL NUCLEAR PROPULSION PROGRAM

Presidential Executive Order 12344 and Public Laws 98-525 and 106-65 set forth the responsibility and authority of the NNPP for all aspects of the Navy's nuclear propulsion program.

Executive Order 12344 requires NNPP to operate as an integrated program carried out by two organizational units, one in the Department of Energy and the other in the Department of the Navy. The NNPP organizational units are Naval Reactors (NR) and Naval Sea Systems Command Code 08, within the Department of Energy and Department of the Navy respectively. The Executive Order requires that the same Director head both organizations, "...so that the activities of each may continue in practice under common management." With presidential approval, the Secretary of the Navy (through the Secretary of Defense) and the Secretary of Energy appoint the Director of NNPP.

The NNPP has a broad reach, maintaining responsibility for naval nuclear propulsion from cradle to grave. NNPP responsibilities include:

1. Design and procurement of naval nuclear reactor and propulsion plant components;
2. Defueling and refueling of reactors for naval nuclear surface ships, submarines, and prototypes;
3. Safety of naval nuclear reactors and propulsion plants;
4. Control of radiation and radioactivity associated with naval nuclear propulsion activities;
5. Ultimate disposition of naval nuclear reactors and propulsion plants; and
6. Training of naval nuclear reactor operators.

NNPP responsibilities for disposal of naval SNF in the geologic repository include:

1. Analysis of naval SNF performance at the geologic repository in support of licensing;
2. Design, certification, and fabrication of transportation and storage systems;
3. Naval SNF preparation and characterization;
4. Loading and transportation operations outside of and before acceptance at the geologic repository boundary; and
5. Documentation required for acceptance of naval SNF at the geologic repository.

As shown on Figure 19-1, the NNPP organization is comprised of military and civilian personnel, who design, procure, build, maintain, operate, and manage the naval nuclear-powered fleet and facilities that support the fleet, and prepare naval SNF for ultimate disposal. As shown on Figure 19-2, the NNPP QA organization includes:

1. Naval Reactors Headquarters

   NR Headquarters exercises control over all aspects of NNPP work. A dedicated professional staff, expert in nuclear technology, makes all major decisions. Engineers at NR Headquarters undergo rigorous classroom training and on-the-job training assignments covering the fundamentals of reactor and propulsion plant design and operation, including training at a prototype reactor and nuclear shipyard.

   NR Headquarters responsibilities include:

   a. Issuance of top-level documents for all NNPP work;
   b. Setting of standards and specifications for all NNPP work;
   c. Oversight and direction of all elements of NNPP work;
   d. Establishment and control of NNPP policy, including design bases, assumptions, requirements, nature of regulatory action required, and disposition of instances of nonconformance;
   e. Approval of design and procurement documents and changes to these documents;
   f. Approval of design and equipment specification requirements for test programs;
   g. Approval of operating procedures (e.g., technical manuals), which provide detailed, component-specific instructions;
   h. Assessment of NNPP practices, through periodic visits to facilities and review of reports;
   i. Special nuclear material shipment compliance with all Federal and State regulations and guidelines;
   j. Approval of SARs and Safety Analysis Reports for Packaging (SARPs); and
   k. Approval of NNPP input into SAR sections, TSD sections, and BEARs.

2. Naval Reactors Laboratory Field Office

   Naval Reactors Laboratory Field Office (NRLFO) personnel provide on-site oversight and surveillance of operations, to verify compliance with the standards and specifications set by NR Headquarters for NNPP work.

3. Defense Contract Management Agency

   Defense Contract Management Agency (DCMA) is a government agency that provides oversight and inspection services for government funded purchase orders.

NAVAL NUCLEAR PROPULSION PROGRAM

OPERATIONS FACILITY
- Naval Reactors Facility (NRF) located in Idaho

NRLFO

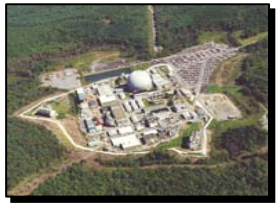
NUCLEAR POWERED FLEET

NR HEADQUARTERS
Located in Washington, DC

DESIGN AGENCIES
- Bettis Atomic Power Laboratory (Bettis) located in Pittsburgh, Pennsylvania
- Knolls Atomic Power Laboratory (KAPL) located in Schenectady, New York

SHIPYARDS

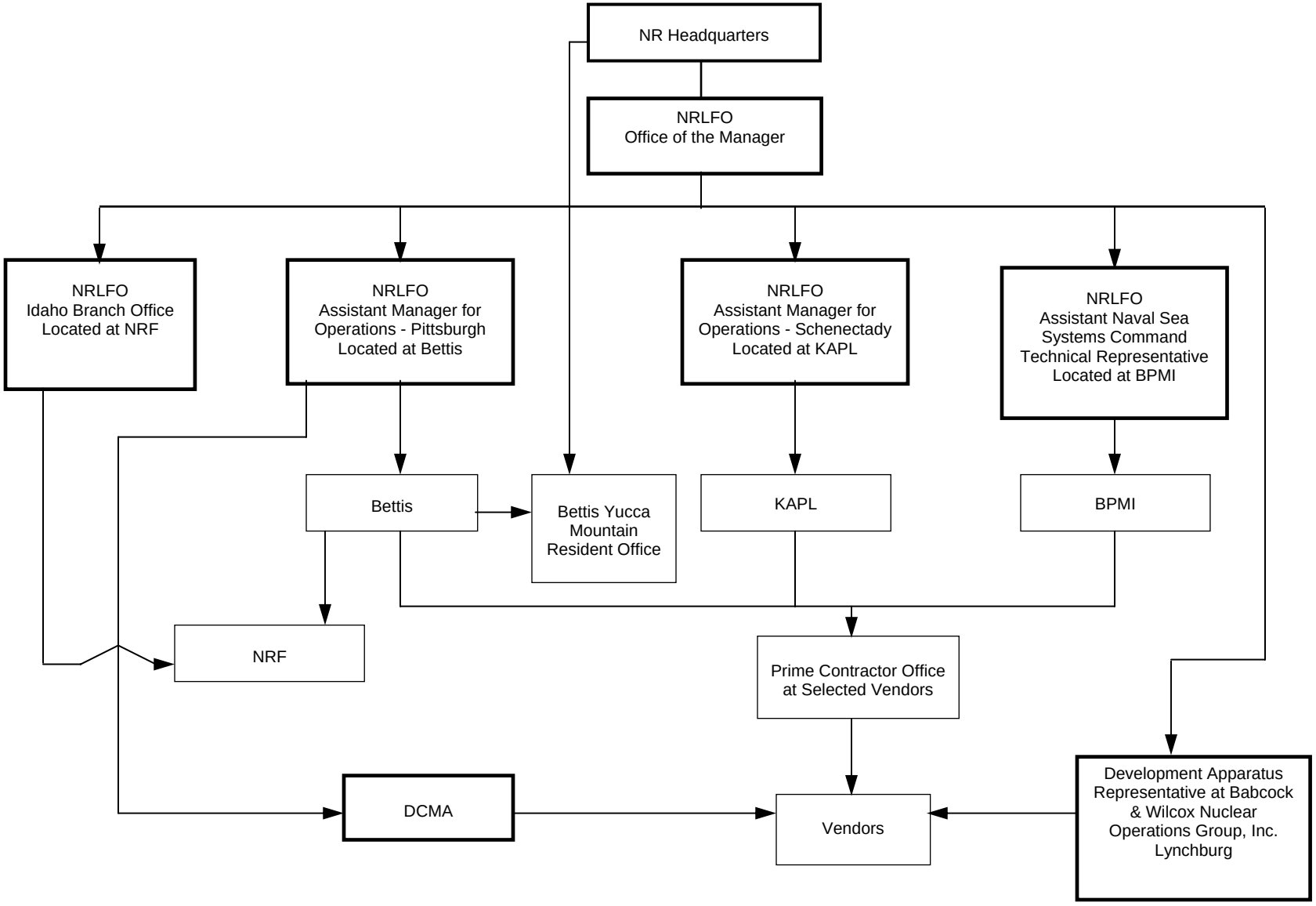
PROCUREMENT AGENCY
- Bechtel Plant Machinery, Inc. (BPMI) located in Pittsburgh, Pennsylvania and Schenectady, New York



R&D/TRAINING REACTORS

SCHOOLS
Nuclear Power School
Nuclear Field “A” School

Figure 19-1 NNPP Organization



Notes:
1. Government organizations are identified by heavy border

Figure 19-2 NNPP Quality Assurance Organization

4. Prime Contractors

   Prime Contractors are the organizations, under contract with the government, which function as the Design and Procurement Agencies and Operations Facility for NNPP.

   a. Design Agencies

      The Design Agencies provide research and development to support naval nuclear propulsion. The responsibilities of the Design Agencies for the disposal of naval SNF in the geologic repository include:

      1) Design and certification of transportation and storage systems;
      2) Naval SNF characterization;
      3) Support preparation of SAR sections;
      4) Issuance of TSD sections, BEARs, and SARPs;
      5) Issuance of operating procedures (e.g., technical manuals); and
      6) Issuance of a Technical Information Package (TIP) for each loaded naval SNF canister.

   b. Procurement Agency

      The Procurement Agency provides procurement and technical manual preparation support for NNPP.

   c. Operations Facility – Naval Reactors Facility (NRF)

      NRF provides operational support for NNPP. The responsibilities of NRF for the disposal of naval SNF in the geologic repository include:

      1) Naval SNF preparation and characterization; and
      2) Loading and transportation operations outside of and before acceptance at the geologic repository boundary.

   The Prime Contractors have on-site representatives at selected manufacturing facilities that audit and provide oversight for technical and quality operations.

5. Bettis Yucca Mountain Resident Office

   The Bettis Yucca Mountain Resident Office is the liaison between NNPP and DOE-RW operations in Las Vegas.

The NNPP has an engineering design and technical management philosophy that embraces the following key elements:

1. Central technical control of all aspects of NNPP work, including research, design, development, manufacture, testing, operation, maintenance, environmental controls, waste disposal, radiological controls, training, and personnel.
2. NR Headquarters involvement in direction and oversight of all aspects of NNPP work.
3. An organizational structure with internal checks and balances, to ensure that all aspects of a technical issue are scrutinized thoroughly.
4. Prompt reporting, evaluation, and correction of incidents or problems. Critical emphasis is placed on detecting and reporting problems or deficiencies to prevent recurrence.
5. Rigorous theoretical and practical training at all levels of NNPP.

6. Conservative designs to provide ample safety margins. Simplicity, redundancy, standardization, and ruggedness for combat conditions are emphasized in plant and equipment design and manufacture. Thorough design reviews are performed.
7. Thorough testing of equipment prior to use.
8. Clearly defined line responsibility for technical results, safety, radiological controls, environmental controls, and self assessment emphasizing individual accountability.
9. Formality, discipline, and precision in all aspects of NNPP work.
10. Rigorous QA validation of design, procurement, construction, testing, maintenance, operation, and preparation for disposal using technical surveillance, oversight, and inspections.
11. Skepticism, frankness, self-criticism, personal integrity, attention to detail, and appreciation for differing professional opinions.
12. Documentation of work (including dissenting opinions) and compliance with requirements.

Application of these key elements of NNPP philosophy is emphasized at every level of the organization and implemented by the Prime Contractors.

19.3 MEMORANDUM OF AGREEMENT FOR ACCEPTANCE OF NAVAL SPENT NUCLEAR FUEL

To cooperatively achieve disposal of naval SNF in a safe, secure, timely, and cost-effective manner, the Director of NNPP and the Director of DOE-RW established an MOA (Reference 19-1) consistent with their individual missions. The MOA provides:

1. Terms and conditions under which DOE-RW will make available disposal services to NNPP for naval SNF;
2. Coordination and implementation of QA activities associated with preparation of naval SNF for acceptance in a DOE-RW-managed, NRC-licensed disposal facility; and
3. Roles and responsibilities of NNPP and DOE-RW in coordinating and implementing the NNPP QA program.

The NNPP QA program is defined and administered solely by NNPP. DOE-RW assesses the NNPP QA program to confirm that its implementation effectively supports the acceptance of naval SNF. NNPP and DOE-RW reviewed the elements of the NNPP QA program relevant to disposal of naval SNF and determined that these elements comply with the requirements of 10 CFR 63.142, *Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada*, Subpart G, *Quality Assurance Criteria*. Additionally, NNPP and DOE-RW determined that the NNPP QA program is compatible with the key quality objectives of the Quality Assurance Requirements and Description (QARD) (Reference 19-2).

The *Justification Documents to Demonstrate Acceptability of Naval Nuclear Propulsion Program Quality Assurance Program Requirements for Disposal of Naval Spent Nuclear Fuel in a Geologic Repository* (Reference 19-3) describe the NNPP QA program implementation of 10 CFR 63.142 requirements and the key quality objectives of the QARD.

The *Naval Nuclear Propulsion Program NRC Review Plan Compliance Matrix* (Reference 19-4) and the *NUREG-1804 versus NRC Review Plan, Rev. 2, 1989 Quality Assurance Program Requirements Gap Analysis* (Reference 19-5) combine to demonstrate that the NNPP QA program addresses the key quality objectives of the *Yucca Mountain Review Plan* (Reference 19-6).

The MOA acknowledges that DOE-RW reviewed the NNPP QA program and found it to be acceptable for work conducted by, or under the direction of, NNPP, in support of DOE-RW acceptance of naval

SNF. This acceptance of the NNPP QA program is documented in Reference 19-7 and is validated by continuing assessments and annual reviews.

Among the provisions of the MOA are actions to provide DOE-RW with the information necessary to conclude that naval SNF shipped to the geologic repository for disposal continues to meet established DOE-RW technical requirements for waste acceptance in a DOE-RW-managed, NRC-licensed, disposal facility. Accordingly, the provisions of the MOA include:

1. Conduct of periodic reviews and information exchanges;
2. Opportunity for DOE-RW to observe NNPP QA activities related to acceptance of naval SNF; and
3. Annual NNPP/DOE-RW review of NNPP QA program activities.

Both agencies have fulfilled these provisions, since the establishment of the MOA, and this fulfillment has resulted in documented, continued DOE-RW acceptance of the NNPP QA program for disposal of naval SNF.

19.4 MEMORANDUM OF AGREEMENT FOR NAVAL SPENT NUCLEAR FUEL RETURN FROM INTEC

Naval SNF stored in water pools at INTEC is transferred to NRF for packaging and shipment to the geologic repository. DOE-ID and NRLFO-IBO signed an MOA (Reference 19-8) to define the relationships and responsibilities between INTEC and NNPP. The MOA is consistent with existing agreements and the long standing independent but cooperative relationship between DOE-ID and NRLFO-IBO. The MOA lays the groundwork for the exchange of information and provision of equipment necessary to ensure that regulatory and NNPP requirements are met for the work performed at INTEC involving naval SNF. The work performed at INTEC involving naval SNF is described in Reference 19-9. The execution of the MOA provides assurance that naval SNF prepared at INTEC for disposal can be certified for shipment to and disposal in the geologic repository, and that the applicable regulatory and NNPP requirements have been incorporated into INTEC hardware designs and work procedures.

The MOA identifies that NNPP is responsible for the provision of technical requirements and instructions; design requirements for specified INTEC supplied hardware; NNPP Government Furnished Equipment (GFE); NNPP GFE operating procedures (e.g., technical manuals); and NNPP GFE history, for use in the development and execution of INTEC work procedures. The NNPP is also responsible for ensuring that NNPP GFE satisfies design criteria prior to delivery to INTEC. The MOA also provides, for NNPP validation, that technical requirements are met for work performed by INTEC through design reviews, work procedure reviews, project readiness assessments and reviews, and observation of work.

The MOA acknowledges that the INTEC QA Program has been reviewed and accepted by DOE-RW. As identified in the MOA, the work performed on naval SNF at INTEC is required to meet the QA provisions of a separate MOA for Acceptance of Spent Nuclear Fuel and High Level Radioactive Waste between DOE-RW and the Department of Energy Environmental Management (DOE-EM). The NNPP reviewed INTEC QA Plan PLN-533, which governs the work involved in the handling of naval SNF. NNPP QA oversight of INTEC work on naval SNF includes participation in INTEC or external evaluations and audits and performance of independent audits. NNPP also reviews results of audits applicable to naval SNF that are conducted by DOE-RW, DOE-EM, or INTEC.

As identified in the MOA, the physical transfer of a loaded Large Cell Cask (LCC) (i.e., a NNPP transportation cask) from INTEC to NRF is conducted under the NNPP LCC transport plan. The NNPP takes physical custody of a loaded LCC upon arrival at the boundary of the NRF secure area.

NNPP review and oversight of INTEC work ensures that hardware designs, work procedures, and records are generated and retained, to show that all technical requirements are met. In addition, NNPP review and oversight ensures that INTEC generated certification data packages are equivalent to those generated at NRF.

19.5 NAVAL NUCLEAR PROPULSION PROGRAM QUALITY ASSURANCE PROGRAM

The aforementioned prime contractor organizations, including the Design and Procurement Agencies and NRF, conduct NNPP work associated with disposal of naval SNF.

The *Prime Contractor Quality Specification* (PCQS, Reference 19-10) establishes the QA program requirements for all work activities conducted by the Design and Procurement Agencies for NNPP. For naval SNF, this work consists of the analysis work in support of the LA and the design and procurement of hardware used for packaging and handling naval SNF in sealed canisters. The Design and Procurement Agencies have established QA programs in compliance with the requirements of PCQS.

NAVSEA 0989-062-4000 (Naval Nuclear Quality Assurance Manual for Shipyards and the Naval Reactors Facility, Reference 19-11) establishes the QA program requirements for all work activities conducted by NRF for NNPP, including preparation, characterization, loading, handling, and transportation of naval SNF. NRF has established a QA program in compliance with the requirements of NAVSEA 0989-062-4000.

The requirements of PCQS (Reference 19-10) and NAVSEA 0989-062-4000 (Naval Nuclear Quality Assurance Manual for Shipyards and the Naval Reactors Facility, Reference 19-11) comply with the criteria specified in 10 CFR 63.142. The following subsections (19.5.1 through 19.5.18) identify NNPP quality assurance requirements and the corresponding criteria specified in 10 CFR 63.142 for Design Agency, Procurement Agency, and NRF work conducted in support of naval SNF disposal. The *Justification Documents to Demonstrate Acceptability of Naval Nuclear Propulsion Program Quality Assurance Program Requirements for Disposal of Naval Spent Nuclear Fuel in a Geologic Repository* (Reference 19-3) provide additional details regarding the NNPP QA program implementation of 10 CFR 63.142 requirements.

19.5.1 Organization
10 CFR 63.142(b)

The NNPP QA program is established and overseen by NR Headquarters. NR Headquarters directs QA programs for Prime Contractors via issuance of policy documents and approval of quality specifications. The organizational responsibilities and structures are similar at each Prime Contractor. All organizational structures have been reviewed, concurred with, or formally approved by NR Headquarters or NRLFO. Key management personnel at the Prime Contractors are approved by NR Headquarters. Additionally, NR Headquarters establishes and staffs the NRLFO, which provides oversight of the QA program execution at each site.

The organizational structures, functional responsibilities, levels of authority, and lines of communication for activities affecting quality are documented. The persons or organizations

responsible for activities affecting quality or for evaluating activities affecting quality have sufficient authority, access to work areas, direct access to responsible management at a level where appropriate actions can be effected, and organizational freedom to:

1. Verify that activities have been correctly performed by checking, auditing, and inspecting;
2. Identify quality problems;
3. Initiate, recommend, and provide solutions to correct and prevent quality problems;
4. Verify implementation of solutions; and
5. Ensure that further processing, delivery, installation, or use of a nonconforming product is controlled.

The QA organizations are responsible for establishing and evaluating the implementation of the QA programs at each site. Organizational interfaces are identified and controlled by the QA organizations.

Each QA organization is organized into departments under the direction of a General Manager. The managers of the departments communicate directly with each other, NR Headquarters, and NRLFO. The responsibilities of the managers are:

1. General Managers

   The General Managers have overall responsibility for executing the NNPP QA Program. The General Managers establish the organizational structure, define the responsibilities of management, and allocate resources.

2. Managers of Quality Assurance

   The Managers of Quality Assurance are responsible for establishing and administering the QA programs at each site. In addition, the Procurement Agency includes line-level managers responsible for overseeing both supplier and internal quality programs. The line-level managers independently establish and execute QA programs in their respective areas of responsibility without any direct product engineering or manufacturing responsibilities.

3. Department Managers

   The responsibility of the department managers within the Design Agencies include: a) the analysis of naval SNF performance at the repository, b) the design, analysis, and testing of components, c) preparation of operating procedures, and d) documentation of technical data. The responsibility of the department managers within the Procurement Agency include: a) the development of technical requirements packages, b) the origination, placement, and technical follow of purchase orders, and c) preparation of technical manuals. The department managers are responsible for the quality of their products.

4. Managers at NRF

   Management at NRF is responsible for the receipt, processing, examination, storage, and shipment of naval SNF. Management is responsible for the quality of the work performed.

19.5.2 Quality Assurance Program
10 CFR 63.142(c)

NR Headquarters directs QA programs for Prime Contractors via issuance of policy documents (e.g., PCQS) and approval of quality specifications. NR Headquarters and NRLFO oversee and audit the implementation of the QA program for each NNPP organization and conduct regular quality management meetings to ensure quality requirements are being executed effectively.

Each Prime Contractor prepares quality program documents (e.g., forms, instructions, manuals, procedures, specifications, and work documents) that implement QA program requirements. Each program ensures that NNPP policies, objectives, and requirements are met for all aspects of NNPP work. The QA programs provide for:

1. Control of activities affecting quality to an extent consistent with their importance;
2. Planning and accomplishment of activities affecting quality under suitably controlled conditions;
3. Performance of work using written procedures, instructions, and drawings, where appropriate;
4. Special controls, processes, equipment, tools, and skills to attain the required quality and for verification of quality;
5. Indoctrination and training (i.e., initial and continuing) for personnel performing activities affecting quality;
6. Clear, candid, accurate, and open communications; and
7. Continuous improvement and preventive action activities leading to higher quality, improved customer satisfaction (i.e., internal and external), and more efficient processes.

The QA programs utilize a graded approach for all work activities. The work activities are controlled based on the risks (i.e., probability and consequence) associated with the work to be conducted. Some work activities carry a high consequence of failure and, therefore, require a high level of control. Reduced levels of control are appropriate for work activities with less consequence of failure. The assessment of risks and associated degrees of control invoked for work activities consider:

1. Probability of failing to perform as predicted due to:

    a. Design complexity or uniqueness,
    b. Need for special fabrication techniques, processes, and equipment, and
    c. Quality history of a process, product, service, or organization.

2. Consequence of failing to perform, with respect to:

    a. Potential for personnel injury or injury to the environment,
    b. Impact on NNPP mission, and
    c. Cost of rework and/or corrective action.

3. Degree of difficulty in detecting an error.

The responsible organizations develop work plans consistent with the degrees of control invoked for the work activities, including the minimum review and concurrence controls necessary to ensure that work is accomplished under suitable controlled conditions. The management establishes the processes to periodically assess organizational performance and effectiveness, document the assessment, and use the assessment to improve the QA program. The QA organizations verify proper implementation of the QA programs and periodically report on the performance of the QA programs. Measurable quality metrics are established and monitored. Results from internal and external audits, technical and administrative appraisals, organizational self-assessments, quality

program assessments, and feedback from NR Headquarters and NRLFO are indicators of the effectiveness of the QA programs. Corrective actions are implemented when required.

19.5.3 Design Control
10 CFR 63.142(d)

The Design Agencies utilize a comprehensive system of controls to ensure that all designs are defined, controlled, documented, and verified. The comprehensive system of controls identify the fundamental principles, guidelines, and general requirements for designing safe, reliable, high quality products that meet NR Headquarters and NNPP QA program requirements. A cognizant design organization is assigned responsibility for each system or component design from inception throughout operational life of the design and disposal. In addition, design interfaces are identified and controlled, and a clear division of responsibilities is defined. The comprehensive system of controls provides for the review, approval, release, distribution, and revision of documents involving design interfaces. Design interface controls include, but are not limited to:

1. Documentation of design information transmitted by cognizant organizations;
2. Identification of changes to information transmitted by cognizant organizations;
3. Provision of proper revisions of specifications, drawings, procedures, and instructions by cognizant design organization used for interfacing systems and components;
4. Establishment of compatibility of materials with interfacing materials through reviews by cognizant organizations and, if required, through testing; and
5. Elimination or minimization of hazardous materials in component(s).

Design work is planned and executed using a process that provides for:

1. Correct and timely specification of design inputs, such as design features, design bases, underlying design assumptions, supporting test data, functional requirements, constraints, performance requirements, regulatory requirements, codes, and standards;
2. Correct translation of design inputs into specifications, drawings, procedures, and instructions. The specifications, drawings, procedures, and instructions are reviewed and approved by the cognizant organizations;
3. Specification and incorporation of appropriate quality standards into design documents and measures to control deviations from such standards;
4. Methods to select materials, parts, equipment, and processes and review them for suitability of application;
5. Review and use of documentation of design problems and experience such as Lessons Learned Bulletins and Design Notes;
6. Verification of documented design outputs against design input requirements to ensure that design outputs meet requirements and to verify design adequacy. Verification of design outputs is performed prior to release for use. The analysis or test considers the most adverse design conditions when analytical verification of all possible design conditions is not practical or testing alone is used to verify design adequacy;
7. Adequate documentation of the rationale for design decisions; and
8. Independent verification of documented design results and/or testing that verifies the design adequacy. Design adequacy is verified by personnel other than those who performed the work. Where appropriate, review by a committee of experts is used in addition to other design verification methods. Design verification methods and results are documented.

Methods to review and over-check design work include:

1. Management review of the methods and assumptions used in the design work;
2. Peer review of the calculations, assumptions, and methods used in the design work;
3. Reviews conducted by committees of experts in the appropriate disciplines at intervals in the design process. Reviews conducted during the conceptual design phase evaluate the overall adequacy of the design approach and the direction of future work efforts. Reviews conducted during the final design phase assess the design and its ability to meet the functional requirements throughout operational life;
4. Interface organization review of design documents;
5. Qualification tests to demonstrate the performance capabilities of component design features; and
6. Independent evaluation of an analysis performed by another analyst or Prime Contractor organization working from the same set of design inputs and requirements.

Design changes are incorporated via a process as rigorous as that which generated the design, adjusted as necessary to reflect the nature of the change. NR Headquarters approves the design documents and changes to these documents. Upon receipt of NR Headquarters approval and incorporation of any comments, the design documents are released and distributed for use.

The Design Agencies have established configuration management systems which provide accurate and systematic approaches to planning, identifying, and controlling design configurations from inception throughout life. The cognizant design organization identifies the design configurations to be controlled. Configuration control is provided to ensure that the approved and documented design specification is maintained and available. Configuration control also ensures proper fit-up of mating parts and enables after-life servicing (e.g., disassembly, shipping, storage, and disposal).

Computer programs used in design, analysis, equipment or system control, testing, monitoring and/or operation, or other similar activities are demonstrated to meet specified requirements and to be acceptable for use in the intended application(s). The process used to demonstrate computer program acceptability is commensurate with the complexity of the program and the importance of the application, and includes use of a program QA plan. Sufficient documentation is maintained to allow independent reproducibility of the process and results of the specified demonstrations. Changes to the program or, where appropriate, to the environment in which the program is operated, are incorporated using a process as rigorous as that which generated the program, adjusted as necessary to reflect the nature of the change. Computer program verification and engineering model qualification methods are discussed in Appendix B.

A QA plan has been developed to ensure that the NNPP work associated with the TSD part of the Yucca Mountain LA SAR meets PCQS requirements, which, in turn, comply with applicable elements of 10 CFR 63.142. The QA plan is discussed in Appendix A.

19.5.4 Procurement Document Control
10 CFR 63.142(e)

The Prime Contractors prepare procurement documents, which consist of the purchase order, technical requirements, quality assurance requirements, and administrative requirements.

Technical requirements are developed in a technical requirements package. The technical requirements package establishes the scope of the work and identifies the technical requirements, regulatory requirements, design bases (for supplier-design purchase orders), and other requirements necessary to ensure adequate quality is included or referenced in the purchase order. The technical requirements package specifies that the suppliers have a QA program consistent with the value,

importance and complexity of the product or service. The Prime Contractors review the QA program for aspects of fabrication and inspection, prior to initiation of procurement activities. The technical requirements package identifies the documents that are prepared and submitted by the supplier for approval and the documents that are available for review at the supplier. The technical requirements package requires the supplier to furnish certifications that the components are manufactured, assembled, and operationally tested to the requirements specified in the purchase order.

Administrative specifications in the technical requirements package include or invoke instructions for the preparation and submittal of documents to the Prime Contractors including approval requests, change requests, and nonconformance reports. The specifications instruct suppliers to pass down appropriate requirements to subcontractors. The specifications provide QA, audit, and oversight requirements for procurements from subcontractors. The specifications provide for access by the Prime Contractor QA and DCMA personnel to supplier records and facilities for source inspections and audits. Documents are required to be available at suppliers for review by DCMA (when requested by NNPP) and Prime Contractor personnel.

The Prime Contractors have a comprehensive system of controls for the preparation, review, approval and revision of procurement documents to assure that applicable regulatory requirements, design bases, and other requirements necessary to assure adequate quality are included or referenced. Reviews are performed to ensure that the procurement documents are adequate for their intended purpose. The level of review is commensurate with the importance of the work. Concurrence is obtained from interface organizations (e.g., Design Agencies and QA organizations) to ensure that the procurement documents are correct.

Changes are incorporated via a process as rigorous as that which generated the procurement document, adjusted as necessary to reflect the nature of the change.

19.5.5 Instructions, Procedures, and Drawings
10 CFR 63.142(f)

The Prime Contractor activities are prescribed by and performed in accordance with documented instructions, procedures, and drawings. The range and level of detail of such documents is dependent on the complexity of the work activities, the methods used, and the skills and training required to perform the work activities. The documents include or reference the appropriate quantitative (e.g., dimensions, tolerances, and operating limits) or qualitative (e.g., workmanship samples) acceptance criteria for determining that the work activities have been satisfactorily accomplished. The documents include, but are not limited to:

1. Design Agency Quality Program Manuals

   Design Agency quality program manuals provide documented instructions, procedures, and drawings that govern performance of analysis and design work.

2. Technical Requirements Packages

   The technical requirements package is a compilation of the drawings, specifications, and requirements which provide the necessary technical requirements to fully define contract deliverables. The technical requirements package establishes the technical requirements for fabrication, inspection, and testing to which the supplier must contractually conform. The technical requirements package identifies the requirements for the preparation, review, approval, use, and control of instructions, procedures, and drawings. Quantitative and qualitative acceptance criteria are included in the instructions, procedures, and drawings. The technical requirements package

details the documentation (e.g., welding procedures, testing procedures, inspection operations, assembly procedures, and special process procedures) that the supplier is required to submit or make available to the Prime Contactors. By review of the documentation, the Prime Contractors ensure that equipment and environmental conditions for processing and inspection are used, applicable drawings, codes and standards are invoked, and proper work instructions are employed.

3. Operating procedures (e.g., technical manuals) which contain:

   a. Information necessary to understand the functions and principles of operation of the component parts, subassemblies, and assemblies;
   b. Instructions, procedures and drawings for loading, unloading, maintaining, repairing, storing, packing or packaging, inspecting, shipping, installing, and removing component parts, subassemblies, and assemblies; and
   c. Appropriate quantitative and qualitative acceptance criteria.

4. Work Procedures

   Work procedures for the component parts, subassemblies, and assemblies incorporate the requirements from the operating procedures and administrative control documents (e.g., radiological control manuals). The procedures identify specific requirements for the work activities (e.g., inspections, measurements, lifting and handling, and radiological control surveys) to be performed.

If the work activity cannot be accomplished as described in the applicable documents, or if complying with the documents would result in an undesirable situation, the personnel performing the work activity and appropriate management agree on and document the actions to be taken. Such deficiencies are reported to and corrected by the document owners in a timely manner.

19.5.6 Document Control
10 CFR 63.142(g)

The Prime Contractors have a comprehensive document control system for the documents that specify quality requirements and ensure that correct practices are employed. The document control system ensures that documents affecting quality, and changes thereto, are reviewed for adequacy and approved for release by authorized personnel. Document control procedures are as follows:

1. Identify the documents to be controlled;
2. Establish responsibilities for preparation, review, approval, and issue of controlled documents, including changes;
3. Define the extent of review for adequacy and accuracy;
4. Ensure that correct documents are available in the work areas;
5. Include appropriate methods to preclude inadvertent use of invalid or obsolete documents;
6. Establish requirements and responsibilities for maintenance, storage, and disposition of quality related documents;
7. Ensure that documentation that provides an appropriate historical record of the rationale for changes is maintained; and
8. Ensure that the documentation allows re-creation and validation of work that a) forms design basis, b) establishes policy, c) commits significant resources, or d) presents a potential risk to personal or public safety.

Document controls are imposed on suppliers through quality specifications provided in technical requirements packages. The quality specifications require that the suppliers prepare and maintain a document control system for drawings and associated work instructions. At a minimum, the supplier controls manufacturing and installation drawings, and manufacturing, inspection, assembly and testing instructions. DCMA (when requested by NNPP) and/or the Prime Contractor personnel review and verify supplier conformance with this system as part of routine surveillance programs.

19.5.7 Control of Purchased Material, Equipment, and Services
10 CFR 63.142(h)

The Prime Contractors have documented systems to control procurements. Procurement is controlled to ensure conformance with specified requirements. Such control provides for the following:

1. Source (i.e., at supplier's facility) evaluation and selection, based on a review of the supplier's capability to provide products or services that meet the specified requirements;
2. Evaluation of objective quality evidence, furnished by the supplier;
3. Source inspection;
4. Audit; and
5. Examination and acceptance of products and services, upon delivery or completion.

The Prime Contractors also ensure:

1. Verification of supplier and subcontractor performance, based on review of submittals, inspections, or surveillance of work activities. The extent of verification is based on:

    a. Importance of the products or services to safety and reliability;
    b. Complexity and quality of the products or services;
    c. Consequences of the supplier failing to perform; and
    d. Supplier's history of providing quality products.

2. Records of supplier evaluations, verification of supplier performance, and acceptance of products or services, which provide evidence of conformance to requirements, are maintained consistent with the life cycle of the product.

3. The organization with authority to release components for shipment is defined. Documented evidence of acceptance is provided to the receiving destination.

The procurement process, prior to order placement, includes selection of suppliers, bid preparation, and bid evaluation. Suppliers are reviewed to determine if a pre-award quality system survey is required, and to identify any quality control deficiencies that will require supplier agreement for correction. Prime Contractor technical specialist reviews may be held to evaluate the technical capability of suppliers in specific processing or inspection areas (e.g., welding and non-destructive testing (NDT)).

The technical requirements packages require suppliers to submit specified drawings and procedures for Prime Contractor approval. The technical requirements packages also require the supplier to provide DCMA and/or Prime Contractor personnel access to the supplier's facilities utilized in the fabrication of the components, and to permit DCMA and/or Prime Contractor personnel to examine and inspect the suppliers, witness the performance of manufacture, and perform quality program and inspection system audits. This includes Prime Contractor technical specialist surveillance of specific processes and inspections.

The supplier may be required to perform quality control or inspection system evaluations at important subcontractors' plants. In addition, the supplier must arrange for DCMA and/or Prime Contractor personnel participation in these evaluations.

Bids are evaluated to ensure that the technical, quality, and production capabilities are adequate and to assure complete supplier understanding of the order requirements.

The procurement process, after order placement, includes the evaluation of the supplier and selected subcontractors for technical, quality, and delivery performance. Formal periodic evaluations of selected supplier QA systems are conducted to ensure continuing effectiveness. Acceptance of the procured items or services at the supplier's facility prior to shipment is generally performed by DCMA personnel. Prime Contractor personnel also may perform source verification and surveillance, in support of acceptance of items and services, prior to their shipment from supplier facilities, as well as verification upon receipt of the items at their delivery destination.

DCMA and/or Prime Contractor quality surveillance and verification plans may be used to ensure that requirements (e.g., welding, NDT, dimensional characteristics, cleanliness, material identification and certification, and packaging) are met. This review action is supplemented by the quality program evaluations and special product and process audits at supplier facilities. Product and process surveillance at suppliers often use a team approach, including the Prime Contractor technical specialists in specific processing or inspection areas, QA personnel, and personnel cognizant in the disciplines (e.g., materials, design, testing, and manufacturing) being evaluated.

Supplier records, procedures, and drawings, demonstrating conformance to requirements, including formal certifications, are defined and required to be submitted, as outlined in the technical requirements package. These records are retained for defined periods, in accordance with established procedures, and are made available with the delivered product as required.

Upon receipt at their destination, the components are inspected for shipping damage or other obvious areas of concern.

19.5.8 Identification and Control of Materials, Parts, and Components
10 CFR 63.142(i)

The Prime Contractors use comprehensive measures to ensure that materials, parts, and components are properly identified and controlled. Identification is maintained on the materials, parts, or components, in documents traceable to the materials, parts, or components, or in a manner that ensures identification is established and maintained. Where required, traceability to past history is provided (e.g., manufacturing history, test history, and maintenance history). These measures ensure that, where required, materials, parts, and components can be identified, controlled, and traced through fabrication, testing, shipment, storage, installation, use, and disposal. Documents containing these measures include, but are not limited to:

1. Technical Requirements Package

   The technical requirements package contains:

   a. Material identification requirements, to confirm that correct material is used for component part fabrication;
   b. Records retention requirements, to ensure traceability and identification of material and component parts, subassemblies, and assemblies;

c. Identification marking requirements for component parts, subassemblies, and assemblies to permit trace-back to material and any special processing; and
d. Supplier control measure requirements, to prevent use of incorrect or deficient materials and component parts, subassemblies and assemblies.

2. Operating Procedures

   The operating procedures (e.g., technical manuals) contain:

   a. Identification marking requirements for component parts, subassemblies, and assemblies to permit trace-back to material and any special processing; and
   b. Controls to prevent use of incorrect or deficient materials and component parts, subassemblies and assemblies.

3. Work Procedures

   Work procedures provide for the identification and control of the materials and component parts, subassemblies, and assemblies used to perform work activities.

19.5.9 Control of Special Processes
10 CFR 63.142(j)

The Prime Contractors have established measures to ensure that special processes that affect or verify the quality of products or services (e.g., welding, heat treating, and NDT) are appropriately defined, qualified, controlled, and accomplished by trained or qualified personnel using qualified work procedures, in accordance with applicable specifications, codes, or standards. The control of special processes includes:

1. Documentation defining the special process, where absence of such documentation would adversely affect quality;
2. Use of suitable equipment;
3. Compliance with applicable requirements;
4. Monitoring and control of processes and work products;
5. Prediction of expected results and establishment of actions, to be taken if actual results deviate from predictions;
6. Approval of special processes and equipment;
7. Identification of minimum acceptable requirements; and
8. Suitable maintenance of equipment.

The Prime Contractors designate the special processes that must be performed or witnessed and accepted by qualified personnel, using qualified work procedures and equipment, and/or subject to continuous monitoring and control of process parameters. Special processes include those for which verification of the process cannot be performed by direct examination of the product or where the consequences of improper action would be severe. Minimum requirements for qualification, including requirements for maintenance of qualification and periodic recertification, are established. Records of qualifications are maintained and periodically audited.

Documents containing the controls of special processes include, but are not limited to:

1. Technical Requirements Package

   The technical requirements package provides the supplier with the special process requirements for fabrication of the component parts, subassemblies, and assemblies. Personnel performing special process operations are trained and qualified. Qualification records are maintained in accordance with the supplier's quality program and technical requirements package requirements.

2. Operating Procedures

   Operating procedures (e.g., technical manuals) specify the special process requirements for the fabrication, installation, removal, maintenance, and repair of component parts, subassemblies, and assemblies.

3. Work Procedures

   Work procedures specify the special process requirements for the work activities to be performed. Personnel performing special process operations are trained and qualified. Qualification records are maintained in accordance with approved written work procedures.

19.5.10 Inspection
10 CFR 63.142(k)

The Prime Contractors have documented requirements to control inspection. The Prime Contractors are required to:

1. Plan and execute inspections and reviews to verify conformance of a product, service, or activity to specified requirements;
2. Specify characteristics to be inspected and reviewed and methods to be employed; and
3. Document inspection and review results.

Quality specifications also require:

1. Identification of the personnel responsible for performing the inspection operation;
2. Acceptance and rejection criteria; and
3. Recorded evidence of completion and verification of manufacturing, inspection, or test operations.

Inspection requirements ensure materials and services conform to requirements in accordance with documented technical and administrative instructions, procedures, drawings, and specifications.

Inspection for acceptance or review for correctness is performed by inspectors in the QA organizations or by other personnel trained or qualified to perform inspections. Inspection is performed by qualified personnel who did not perform or directly supervise the work being inspected and/or reviewed. Qualification programs are established and maintained to certify personnel for specific inspection functions.

Inspection is consistent with the relative importance of the item. Written procedures, checklists, or work instructions identify proper sequencing of inspection and acceptance criteria. Critical in-process operations and final inspections may be designated as mandatory inspection hold points and release points. Mandatory inspection hold points require witness or inspection by qualified Prime Contractor personnel and are points beyond which work may not proceed without the consent of the Prime

Contractor. The cognizant Prime Contractor organization determines whether indirect controls (e.g., process monitoring) are needed to ensure quality when physical methods of inspection are impossible or impractical and specifies the controls in the work documents. Both inspection and indirect controls are required when control is inadequate without both. When appropriate, sampling is specified or approved and used for product acceptance.

Controls governing product inspection for acceptance are passed down to suppliers in the technical requirements package. The supplier QA program includes receipt inspection with attendant measures to ensure that subcontractors provide materials that meet the requirements specified in the purchase order. A formal inspection program is maintained for performance of inspections at suppliers as an audit function of the supplier's inspection system. Records of the inspections are maintained, distributed, or made available to NNPP personnel.

NRF and INTEC perform receipt, in-process, and final inspections required by the operating procedures. Receipt inspections are performed to ensure that no shipping damage occurred, to re-verify correct assembly, and may include trial insertion of mock-ups into storage or shipping components. In-process inspections include mandatory prerequisites that must be satisfied prior to storage or loading of radioactive material. Final inspections are performed to ensure proper loading of materials from transfer equipment, to ensure proper packaging conditions are established, and to ensure compliance with shipping regulations.

19.5.11 Test Control
10 CFR 63.142(l)

The Prime Contractors use tests to critically examine the conditions and operations of products and services to demonstrate conformance to specified requirements. Experiments are performed to determine operating characteristics or performance criteria, to qualify design procedures, to generate/evaluate fundamental material properties, or to determine if products will perform satisfactorily in service. Controls on tests apply equally to experiments.

The Prime Contractors plan and execute tests to demonstrate conformance to specified requirements. Appropriately trained and qualified personnel perform tests in a controlled manner, in accordance with approved written test procedures, which contain the requirements and acceptance criteria of the applicable implementing documents. Tests include fundamental model development qualification and structural integrity tests (e.g., proof, pre-operational, and operational).

The Prime Contractors ensure that written test procedures are thorough and capable of demonstrating that applicable requirements (e.g., functional requirements) are met. The test procedures specify the prerequisite requirements, instrumentation requirements, control of the test environment, characteristics to be tested, and test methods to be employed. For complex tests, both independent review of the test methods and independent verification of test results are performed. When appropriate, expected test results are predicted and future actions are established should the actual test results deviate from predictions. Test results are documented and evaluated to ensure conformance with established acceptance limits.

Documents requiring the performance of tests include, but are not limited to:

1. Technical Requirements Package

   The technical requirements package specifies the tests to be performed by the supplier and provides the requirements and acceptance criteria for incorporation into the test procedures. The

technical requirements package also specifies the test procedures and reports to be submitted by the supplier for Prime Contractor approval.

2. Operating Procedures

   Operating procedures (e.g., technical manuals) specify the tests to be performed and provides the requirements for incorporation into test procedures. The procedures specify the data to be recorded, evaluation techniques to be used, and applicable acceptance criteria.

3. Work Procedures

   Tests are performed in accordance with approved written work procedures. The work procedure specifies the data to be recorded, evaluation techniques to be used, and applicable acceptance criteria. Results are published in a test report.

19.5.12 Control of Measuring and Test Equipment
10 CFR 63.142(m)

Tools, gauges, instruments, other measuring and test equipment, and measurement standards used by the Prime Contractors in evaluating conformance to requirements are controlled, to ensure accurate measurements are obtained. Controlled measuring equipment is identified, maintained, adjusted, and calibrated at established intervals, in accordance with documented instructions and procedures. Measuring equipment and reference standards are calibrated based upon inherent stability, purpose, accuracy, experience, and degree of usage.

The calibration program for equipment used by the Prime Contractors to evaluate conformance with requirements is conducted in accordance with a nationally recognized specification. The calibration program for other equipment is established and performed in accordance with approved written instructions and procedures. Where no calibration standard exists, the basis for calibration is documented.

The technical requirements package specifies the requirements for control of measuring and test equipment used by a supplier in support of work for the Prime Contractors. The Prime Contractors and DCMA personnel monitor the system of calibration used by the supplier, for compliance to technical requirements package requirements.

19.5.13 Handling, Storage, and Shipping
10 CFR 63.142(n)

The handling, storage, cleaning, packaging, packing, shipping, and preservation of materials, parts and components are controlled by the Prime Contractors, to prevent damage or loss and minimize deterioration. The controls ensure that the materials, parts, and components are not released for shipment until required inspections and tests have been satisfactorily completed; quality records required prior to shipment have been completed, reviewed, and accepted by appropriate personnel; and authorized personnel have granted a documented shipping release.

The technical requirements package specifies the requirements for handling, storage, cleaning, packaging, packing, shipping, and preservation of the material, parts, and components, during fabrication at the supplier’s facilities.

Work procedures provide for the handling, storage, cleaning, and preservation of the delivered components. The operating procedures (e.g., technical manuals) specify the handling, storage, cleaning, and preservation requirements for the components.

19.5.14 Inspection, Test, and Operating Status
10 CFR 63.142(o)

The Prime Contractors have controls in place to ensure that components released for installation, use, or operation passed required inspections and tests. These controls require that the status of inspection or tests be identified, to ensure that required inspections and tests are performed. Status is maintained through indicators (e.g., physical location and tags, markings, stamps, inspection records, or other suitable means). The authority for application and removal of tags, markings, labels, and stamps is specified. Status indicators provide for identification of the status of systems and components to prevent inadvertent operation.

Operating procedures provide the Prime Contractors with the controls for inspection, test, and operating status of the components. The technical requirements package specifies the requirements for inspection, test, and operating status of the components being fabricated by the supplier.

19.5.15 Nonconforming Materials, Parts, or Components
10 CFR 63.142(p)

The Prime Contractors have established measures to control products, which do not conform to specified requirements, to prevent inadvertent installation, use, or dissemination. The controls provide for the identification, documentation, evaluation, marking and/or segregation, re-inspection of reworked products, documented disposition, and notification to affected organizations of nonconforming products.

The technical requirements package specifies the requirements for control of nonconforming product to the supplier. The requirements specify that the supplier establish and maintain an effective, documented system for controlling nonconforming product, including procedures for identification, segregation, and disposition by the appropriate Prime Contractor personnel. The Prime Contractor technical review and disposition of the supplier nonconformance reports are documented. NR Headquarters concurrence or approval with the disposition of any supplier nonconformance is obtained in accordance with the established measures for control of nonconforming product.

A system of Trouble Records is used by the Prime Contractors, to identify defects, damage, or need for repairs to components. Prime Contractor personnel review and disposition Trouble Records in accordance with established measures for the control of nonconforming product.

The Prime Contractor and NR Headquarters personnel evaluating the disposition of a nonconformance have demonstrated competence in the area being evaluated, an understanding of the requirements, and access to pertinent background information. The rationale behind decisions to accept nonconforming conditions is documented.

QA organization responsibilities related to nonconformance control include analyzing nonconformance reports to show quality trends and identify root causes of nonconformance.

The NNPP has a three-Prime Contractor procedure for reporting potential defects and failures to comply associated with substantial safety hazards in accordance with 10 CFR 21, *Reporting of Defects and Noncompliance*. This procedure provides additional administrative instructions for reports made to NR Headquarters related to component deviations. This procedure does not

supersede other NNPP instructions. NNPP instructions governing identifying, evaluating, or reporting problems to NR Headquarters are used in support of actions taken in accordance with this procedure.

19.5.16 Corrective Action
10 CFR 63.142(q)

The Prime Contractors investigate any conditions determined to be adverse to quality (e.g., unplanned events such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and instances of nonconformance). The conditions adverse to quality are identified and corrected as soon as practical. A critique process has been established to identify the root cause of unplanned events. An unplanned event is an occurrence that is not normal behavior or is an unexpected outcome for a work process, which resulted in or, if not found and corrected, could have resulted in significant recovery time and cost. The requirements for the critique process, causal analysis, corrective and preventive action identification, and reporting of problems associated with an unplanned event are contained in written procedures and operating instructions. The goal is to learn from problems or near misses, as well as positive outcomes, to institutionalize the learning, and to make available concise and reliable information to prevent recurrence of similar problems or to provide insight from positive outcomes. The use of the critique process to identify root cause and the level of corrective, preventive and follow-up actions taken is commensurate with the significance of the condition. The condition, circumstances, cause, and corrective action are documented and reported to appropriate levels of management. Follow-up action is taken to verify implementation and effectiveness of the corrective action.

Isolated deficiencies with minimal overall impact and no significant consequences are normally corrected on the spot and documented in a deficiency report issued by management. Formal evaluation of trends associated with deficiencies enables implementation of needed changes in requirements, training, or behaviors before significant problems occur.

Comparable processes exist to address supplier corrective actions to conditions adverse to quality. The requirements governing corrective actions for product nonconformance or conditions adverse to quality at supplier facilities are passed down to suppliers in the technical requirements package. Suppliers are required to determine the cause of nonconformance, to implement corrective actions to fix the condition that caused the problem, and to document the process. The Prime Contractors and DCMA (when requested by NNPP) personnel confirm compliance to and effectiveness of the corrective action(s).

Product deficiencies that are reported in Trouble Records by the Prime Contractors, and are considered to be the supplier's responsibility, are reported to the supplier for corrective action.

Significant quality problems and Lessons Learned Bulletins are reported to benefit future NNPP work efforts.

19.5.17 Quality Assurance Records
10 CFR 63.142(r)

The Prime Contractors have a records management system that complies with DOE and National Archives and Records Administration (NARA) requirements. The requirements and responsibilities for records transmittal, distribution, retention, maintenance, and disposition are documented. Records that document evidence of quality, including pertinent subcontractor records, are specified, prepared, and maintained. The records are to be legible, identifiable, readily retrievable, and protected against damage, deterioration, and loss. The records include technical, material, manufacturing, inspection,

test, and QA operations that demonstrate the completion of required operations and compliance with program and component requirements.

The records are identified on a Records Inventory and Disposition Schedule (RIDS). Each schedule contains the name of the responsible individual, title, description, location of the records, disposition authority, and authorized disposition instructions, including transfer instructions. The RIDS is verified annually and selected records are reviewed biennially to ensure they are not deteriorating and are retrievable. The records are stored at the Federal Archives Records Center, on-site records centers, or corporate records storage sites.

The technical requirements package identifies the records to be retained, controlled, maintained by the supplier, and delivered to the Prime Contractors. Prime Contractor personnel review the supplier's maintenance of records and monitor the supplier's compliance with the requirements. The supplier is required to provide storage facilities with a suitable environment to protect the records from damage. The records are retained by the supplier for the warranty period and filed in a manner that allows quick access to the information. The supplier must obtain Prime Contractor agreement to dispose of the records at the end of the contract retention period. The Prime Contractors may take custody of the records and maintain them indefinitely.

Reference 19-12 describes the records management system employed by NNPP to provide assurance of addressing the records control requirements and objectives of 10 CFR 63, applicable DOE and NRC documents, and current and future geologic repository licensing activities.

19.5.18 Audits
10 CFR 63.142(s)

The Prime Contractors maintain a comprehensive system of internal and external auditing, oversight, and assessments, to verify compliance with NNPP QA program requirements, to determine the effectiveness of the NNPP QA program, and to identify areas for improvement. Each element of the NNPP QA program is considered for an audit at least triennially. An independent management decision is made about the need for and value of an audit considering available inputs. An audit of an element of the NNPP QA program need not cover all requirements for that element. More frequent audits of specific elements or selected requirements within an element are considered based upon the importance of the activity and past performance history.

Internal audit programs exist at the Prime Contractors to perform audits at planned frequencies, to assess organizational performance, and to address specific problem areas. Audit personnel are selected based upon qualifications, experience, technical specialties, and familiarity with the area being audited. Audit personnel have the authority, independence, and organizational freedom to ensure meaningful results. Audit personnel do not have direct responsibility for performance of the activity being audited. Audit team leaders are either appropriately trained management personnel or experienced personnel. Audits are performed in accordance with written procedures and plans that identify the scope and content of the audit. Audit results are documented and reported to responsible management for review, assessment, and appropriate corrective action. Corrective actions, taken or planned, are documented and follow-up actions are taken where indicated. Follow-up actions include an evaluation of the adequacy of the response and verification that corrective action is accomplished in a timely manner and effective.

Audits are supplemented by documented, organizational self-assessments. Internal evaluations conducted by organizations provide insights not identified by external auditors. The self-assessment program is a tool for managers and leaders to develop and maintain comprehensive day-to-day understanding of problems faced by an organization. Self-assessment enables an organization to

identify trends and problems without external intervention, address areas needing improvement before they become significant problems, and identify operational improvements to safety, quality, schedule, and cost. Effective self-assessment will lead to an organization that efficiently produces quality results and continuously improves without external intervention. Audit results are used by management in their periodic assessments of the effectiveness of the NNPP QA Program.

NNPP specifications and policies provide the instructions and requirements for audit and surveillance of suppliers, including instructions for conducting Process Sponsor reviews, pre-audit and post-audit conferences, time constraints for issuing audit reports and receiving responses, acceptance criteria for audit responses, and instructions for conducting follow-up evaluations. Process Sponsor reviews are in-depth evaluations of supplier processing or inspection, including the identification of any contractual non-compliance; identification of and suggestions for improvement of poor supplier practices; and identification of "best practices" for dissemination to appropriate organizations. NNPP specifications and policy require Prime Contractor audits of suppliers using formally qualified leaders and team members and includes the same level of performance addressed above. External programs include documented plans generated in accordance with formal guidelines and audit frequency based upon the complexity, nature of the work scope, supplier quality history, and the results of other quality surveillance efforts. External audits are also planned and carried out to ensure compliance at multiple levels of subcontracted effort. Audits are planned and conducted and include pre-award surveys of new suppliers, more frequent and more in-depth audits at developing suppliers, and continuing surveillance at established suppliers. Prime Contractors and DCMA (when requested by NNPP) personnel also participate in selected self-audits performed by suppliers.

Contract quality specifications require selected suppliers to maintain effective internal self-audit programs for their facilities and for supplier audit of selected subcontractors in accordance with the contractually invoked quality system standards.

19.6 SUMMARY

NNPP responsibilities for disposal of naval SNF in the geologic repository include:

1. Analysis of naval SNF performance at the geologic repository in support of licensing;
2. Design, certification, and fabrication of transportation and storage systems;
3. Naval SNF preparation and characterization;
4. Loading and transportation operations outside of and before acceptance at the geologic repository boundary; and
5. Documentation required for acceptance of naval SNF at the geologic repository.

NNPP organizational structure includes:

1. NR Headquarters, which exercises control over all aspects of NNPP work;
2. NRLFO, which provides on-site oversight and surveillance of operations, to verify compliance with the standards and specifications set by NR Headquarters for NNPP work;
3. DCMA, which provides oversight and inspection services for government funded purchase orders;
4. Prime Contractors, who function as the Design and Procurement Agencies and NRF for NNPP. The Design Agencies (Bettis, KAPL) provide research and development to support naval nuclear propulsion. The Procurement Agency (BPMI) provides procurement and technical manual preparation support for NNPP. NRF provides operational support for NNPP; and
5. Bettis Yucca Mountain Resident Office, which is the liaison between NNPP and DOE-RW.

The NNPP QA program is defined and administered solely by NNPP. NR Headquarters directs QA programs for Prime Contractors via issuance of policy documents (e.g., PCQS) and approval of quality specifications. NR Headquarters and NRLFO oversee and audit the implementation of the QA program for each NNPP organization and conduct regular quality management meetings to ensure quality requirements are being executed effectively. Each Prime Contractor prepares quality program documents (e.g., forms, instructions, manuals, procedures, specifications, work documents) which implement QA program requirements. Each program ensures that NNPP policies, objectives, and requirements are met for all aspects of NNPP work. The Design and Procurement Agencies have established QA programs in compliance with the requirements of PCQS. NRF has established a QA program in compliance with the requirements of NAVSEA 0989-062-4000. NNPP and DOE-RW reviewed the elements of the NNPP QA program relevant to disposal of naval SNF and determined that these elements comply with the requirements of 10 CFR 63.142.

The MOA for acceptance of naval SNF acknowledges that DOE-RW reviewed the NNPP QA program and found it to be acceptable for work conducted by, or under the direction of, NNPP, in support of DOE-RW acceptance of naval SNF. Among the provisions of the MOA are actions to provide DOE-RW with the information necessary to conclude that naval SNF shipped to the geologic repository for disposal will meet established technical requirements for waste acceptance. The provisions of the MOA include:

1. Conduct of periodic reviews and information exchanges;
2. Opportunity for DOE-RW to observe NNPP QA activities related to acceptance of naval SNF; and
3. Annual NNPP/DOE-RW review of NNPP QA program activities.

Both agencies have fulfilled these provisions, since the establishment of the MOA, and this fulfillment has resulted in documented, continued DOE-RW acceptance of the NNPP QA program for disposal of naval SNF.

Naval SNF stored in water pools at INTEC is transferred to NRF for packaging and shipment to the geologic repository. The MOA for naval SNF return from INTEC is consistent with existing agreements and the long standing independent but cooperative relationship between DOE-ID and NRLFO-IBO. The MOA lays the groundwork for the exchange of information and provision of equipment necessary to ensure that regulatory and NNPP requirements are met for the work performed at INTEC involving naval SNF.

The MOA acknowledges that the INTEC QA Program has been reviewed and accepted by DOE-RW and that the work performed on naval SNF at INTEC is required to meet the QA provisions of a separate MOA for Acceptance of Spent Nuclear Fuel and High Level Radioactive Waste between DOE-RW and DOE-EM. The NNPP reviewed INTEC QA Plan PLN-533, which governs the work involved in the handling of naval SNF. The physical transfer of a loaded LCC from INTEC to NRF is conducted under the NNPP LCC transport plan.

NNPP review and oversight of INTEC work ensures that hardware designs, work procedures, and records are generated and retained to show that all technical requirements are met. In addition, NNPP review and oversight ensures that INTEC generated certification data packages are equivalent to those generated at NRF.

The QA plan developed for NNPP work associated with the TSD part of the Yucca Mountain LA SAR is described in Appendix A. The QA plan has been developed to ensure that the NNPP work associated with the Yucca Mountain LA SAR meets PCQS requirements, which, in turn, comply with applicable elements of 10 CFR 63.142, and provides a product that is clear, concise, consistent, and accurate.

The implementation of PCQS requirements for computer program verification and engineering model qualification are described in Appendix B.

19.7 REFERENCES

19-1 Memorandum of Agreement for Acceptance of Naval Spent Nuclear Fuel between Director, Naval Nuclear Propulsion Program (NNPP), and Director, Office of Civilian Radioactive Waste Management (RW), Revision 1, April 11, 2000

19-2 DOE/RW-0333P, Quality Assurance Requirements and Description

19-3 NNPP-SNF-QA-1, Justification Documents to Demonstrate Acceptability of Naval Nuclear Propulsion Program Quality Assurance Program Requirements for Disposal of Naval Spent Nuclear Fuel in a Geologic Repository

19-4 NNPP-SNF-QA-2, Naval Nuclear Propulsion Program NRC Review Plan Compliance Matrix

19-5 NUREG-1804 versus NRC Review Plan, Rev. 2, 1989 Quality Assurance Program Requirements Gap Analysis, Revision Original, September 2003

19-6 NUREG-1804, Yucca Mountain Review Plan

19-7 Letter from Dwight E Shelor (DOE) to J.T Greeves (NRC) dated March 8, 1999, OCRWM Review and Acceptance of the NNPP QA Program

19-8 Memorandum of Agreement for Naval Spent Nuclear Fuel Transfer Project, Revision 1, December 2006

19-9 NNPP-SNF-YMSA-16, “Disposal Component Manufacturing and Operation (U),” Revision Original, Background, Evaluation and Analysis Report (BEAR) 16. [This is a classified document.]

19-10 NAVSEA PCQS, Naval Nuclear Propulsion Program Prime Contractor Quality Specification (PCQS)

19-11 NAVSEA 0989-062-4000, Naval Nuclear Quality Assurance Manual for Shipyards and the Naval Reactors Facility

19-12 NNPP-SNF-YMSA-20, “Control of Naval Nuclear Propulsion Program Records Related to the Yucca Mountain Repository,” Revision Original, Background, Evaluation and Analysis Report (BEAR) 20

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SUMMARY OF QUALITY ASSURANCE PLAN FOR NNPP WORK ASSOCIATED WITH YUCCA MOUNTAIN LICENSE APPLICATION SAFETY ANALYSIS REPORT

Appendix A

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1.0 INTRODUCTION

This appendix describes the Quality Assurance (QA) plan (Reference A-1) for the Naval Nuclear Propulsion Program (NNPP) work associated with the Yucca Mountain License Application (LA) Safety Analysis Report (SAR). NNPP work, documented in classified Technical Support Document (TSD) sections and Background, Evaluation, and Analysis Reports (BEARs), must be consistent with the information presented in the Yucca Mountain LA SAR, prepared for the Department of Energy (DOE) by Bechtel SAIC Company (BSC) and Sandia National Laboratory (SNL). Unclassified SAR sections and classified TSD sections are limited to the essential, high level descriptions of the work performed in support of the Yucca Mountain LA SAR. The BEARs provide detailed descriptions of the NNPP work that support statements made in SAR and TSD sections.

The QA plan for NNPP work associated with the TSD part of the Yucca Mountain LA SAR describes actions that ensure NNPP input to SAR sections, TSD sections, and BEARs achieve the appropriate level of quality prior to their submittal to DOE and Nuclear Regulatory Commission (NRC).

2.0 OBJECTIVES

The QA plan has been developed to ensure that the NNPP work associated with the TSD part of the Yucca Mountain LA SAR meets the Prime Contractor Quality Specification (PCQS, Reference A-2) requirements, which, in turn, comply with applicable elements of 10 CFR 63.142, *Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada, Subpart G, Quality Assurance Criteria*, and provides a product that is clear, concise, consistent, accurate, and complete.

The QA plan ensures that TSD sections and BEARs meet the following objectives:

1. Configuration or operation being analyzed must be clearly defined. A specific definition of the configuration or operation must be presented in each analysis performed. The definition must include sufficient detail to allow the analysis to be reproduced;
2. Software used during the analysis must be verified. A description of the verification or reference to a verification document must be included;
3. Engineering models and assumptions used during the analysis must be defined. A description of the engineering model qualification must be included;
4. Specific data used during analysis or modeling must be defined and traceable;
5. Each analysis must be reviewed by a knowledgeable Bettis Atomic Power Laboratory (Bettis)/Knolls Atomic Power Laboratory (KAPL) peer who checks the work of the original analyst. Review comments are reviewed by cognizant management and resolved;
6. An individual not involved in the creation or performance of the original analysis, outside of the work groups performing analysis for TSD sections and BEARs, must perform a summary review of each analysis for appropriate technical content;
7. An individual with relevant experience from the other Design Agency must review the analysis;
8. A Yucca Mountain specialist must review each analysis to ensure the analysis meets the specific requirements of the Yucca Mountain Review Plan (Reference A-3) applicable to that part of the LA.
9. A Yucca Mountain technical specialist must review each analysis to ensure NNPP analysis technically interfaces with the rest of the LA;
10. Each analysis must be reviewed by a joint Bettis/KAPL Fuel Handling Safety Committee (FHSC). The Chairman of the Bettis FHSC chairs the joint committee. All comments generated in the safety committee reviews must be resolved by formal letter;
11. All analysis and documentation must be maintained in a retrievable location; and

12. Each section of the TSD must be written to be consistent with and must integrate into the Yucca Mountain LA SAR.

A supplemental concurrence record sheet (CRS) is used to formally document that these objectives have been met and is part of the TSD section or BEAR submittal to NR Headquarters for technical review and approval.

3.0 VULNERABILTY ASSESSMENT

Vulnerability assessments are used to determine the technical and administrative areas of highest risk and to focus program resources. To ensure that technical vulnerabilities have been addressed, the QA plan requires certification that all open items have been resolved. Formal documentation that a vulnerability assessment was performed and all open items were resolved is provided in the supplemental CRS.

4.0 TRAINING

The QA plan addresses the personnel training needs in two stages to support preparation and review of TSD sections and BEARs. These stages include the training of engineers and managers responsible for writing and preparing the documents, as well as training for personnel responsible for reviewing the documents.

5.0 PERFORMANCE OF TECHNICAL WORK

Within each area of expertise, cognizant management develops a plan for completing the necessary analyses or evaluations, assigns cognizant personnel to perform the work, ensures that the work is performed using qualified engineering models and verified computer programs, reviews the on-going analysis efforts to determine if revisions to the plan are necessary, and assigns an engineer to perform a technical review. In addition, the cognizant manager reviews the completed work to ensure consistency and adequacy.

The cognizant professionals review the analysis assignment, establish the analytical method(s) to be used, ensure the engineering model is qualified, verify that the input data is consistent with the intended use, perform the analysis, and review the results for consistency and adequacy. Any uncertainties or restrictions are identified.

Formal requirements are invoked for development and use of computer programs, including documentation, configuration control, verification, qualification, change control, and user responsibilities. Computer program verification and engineering model qualification is discussed in Appendix B. Each user must understand the level of verification and qualification required and the scope of application, including any limits of the computer program on the applicable use.

6.0 DOCUMENTATION OF WORK

Documentation of analysis method must be complete; a knowledgeable independent reviewer should be able to repeat the work and arrive at similar conclusions. All documentation is maintained in a retrievable location.

7.0 PERFORMANCE AND DOCUMENTATION OF REVIEWS

The Design Agencies conduct various levels of review to ensure that documents are of appropriately high quality before the documents are submitted to NR Headquarters for approval.

The level and type of reviews for a particular document are chosen based on content, with the lowest level of review being applied to documents containing descriptive information and analysis descriptions containing no calculations, and the highest level of review established for documents containing original analysis methodology and calculations. Technical management responsible for the document prepares a supplemental CRS to document the reviews completed for the document. The completed supplemental CRS is included with the document submittal to NR Headquarters for approval.

The most common types of reviews performed are:

1. Technical Reviews

   Cognizant management assigns technical reviewers to check the document using the expertise of the reviewer. The technical review includes instances where the adequacy of the information or the suitability of implementing documents and methods essential to meet specified objectives cannot be established through testing, alternate calculations, or reference to previously established standards and practices. Detailed and summary technical reviews are planned and conducted for each TSD section and BEAR submittal. Technical reviews are also performed by experts in the Design Agency that was not responsible for the work. Technical review comments are evaluated with cognizant management and resolved. Resolution of comments is indicated by a concurrence signature.

2. Management Reviews

   Management reviews must be performed for all submittals. First level management review indicates management agreement with the technical content of the submittal and signifies that internal group reviews have been completed for the document. Second level management review indicates that all of the appropriate reviews have been performed and signifies that the correspondence is ready to be issued. Resolution of comments is indicated by a concurrence signature.

3. Committee Reviews

   A joint Bettis/KAPL FHSC review is performed for each TSD section and BEAR submittal which contains analysis. The number of committee members is commensurate with the complexity of work being reviewed, its importance to TSD section and BEAR objectives, and the number of technical disciplines involved.

   Resolution of FHSC comments is documented by formal correspondence. The concurrence signature of the FHSC Chairman indicates adequate resolution of all comments. In addition to the final FHSC reviews, cognizant management considers, on a case-by-case basis, if formal intermediate FHSC reviews for scope and content of lengthy and complex sections should be considered.

4. Quality Assurance Review

   The quality of each analysis is the responsibility of the cognizant technical organization. Independent surveillance and oversight is completed by the Design Agency QA organization. The Design Agency QA organization surveillance and oversight process consists of reviews performed as required by the applicable QA program documents, reviews performed as requested by the cognizant technical organization, reviews performed as deemed appropriate by the QA organization, or validation of selected QA program elements through independent audits. The supplemental CRS documents independent validation performed by the Design Agency QA organization requested by management.

8.0 REFERENCES

A-1 Quality Assurance Plan for the Naval Nuclear Propulsion Program Technical Support Document for the Yucca Mountain License Application, Revision 1
A-2 NAVSEA PCQS, Naval Nuclear Propulsion Program Prime Contractor Quality Specification (PCQS)
A-3 NUREG-1804, Yucca Mountain Review Plan

COMPUTER PROGRAM VERIFICATION AND ENGINEERING MODEL QUALIFICATION

Appendix B

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1.0 INTRODUCTION

This appendix describes the implementation of the Prime Contractor Quality Specification (PCQS, Reference B-1) requirements that relate to design computer programs (DCP). DCPs are computer programs that are used in technical design and analysis applications. A computer program refers to a set of predetermined calculations or operations, which use input that is defined by the user and provide output to the user based on the calculations or operations. A computer program may be in various forms (e.g., spreadsheets, series of linked subroutines or scripts, and commercial-off-the-shelf (COTS)).

The principles upon which these requirements are based are:

1. The Quality Assurance (QA) process for DCPs must be completed in a high quality and timely fashion, be visible, and last the life of the analysis and/or design they support; and
2. The user must accept ownership and responsibility for the application of computer programs and associated engineering models, including understanding the functions and limitations of the programs.

2.0 VALIDATION OF COMPUTER PROGRAMS

Validation is the act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements. Validation of computer programs is a combination of program verification and engineering model qualification.

The level of formality for computer program related QA efforts is determined by:

1. Consequences and/or impacts of design products failing to perform as predicted (e.g., impact on design or performance, potential for personnel injury, and cost and/or schedule impact of rework or corrective action);
2. Breadth of use throughout an organization or across organizations;
3. Degree of difficulty detecting an error;
4. Sophistication of technical algorithms; and
5. Duration of use.

Users and their management, working together with cognizant computer program developers, have the prime responsibility to determine the level of formality to be followed for the programs they use.

2.1 COMPUTER PROGRAM VERIFICATION

Computer programs must be verified and the verification must be documented before the programs can be used to support design recommendations. Computer program verification is the process of ensuring that the program properly executes the mathematical and logical processes intended and produces a result that is mathematically and logically correct. Verification provides assurance that the computer program does what it is supposed to do in a predicable fashion.

The computer program verification policy applies to programs developed by the Naval Nuclear Propulsion Program (NNPP) and to programs obtained from external sources (e.g., COTS programs). For externally developed computer programs, confirmation and documentation of existing verification is required; additional NNPP-performed verification and related documentation is also performed when necessary to ensure the computer program performs correctly on NNPP specific platforms and

for NNPP specific applications. Computer programs must be verified on all platforms (i.e., microcomputers, workstations, and mainframe computers) on which they will be executed. The verification process involves execution of the computer program over a wide range of input parameters to gain confidence that the program performs as specified. The verification report documents quality control elements associated with the computer program to permit evaluation by a potential user.

It is the responsibility of the computer program developer to ensure that the program is verified.

Verification is accomplished by the computer program developer using at least one of the following techniques:

1. Comparison with results obtained from a previously verified version of the same computer program;
2. Comparison with solutions obtained from other independently developed computer programs;
3. Comparison with hand calculations;
4. Comparison with known analytical solutions;
5. Comparison with standard benchmark calculations;
6. Comparison with confirmed published data; and
7. Comparison with the results of alternate verified calculation methods.

A suite of customized verification tests is created and maintained by the computer program developer for the computer program being verified. The tests span the range of applications of the computer program and exercise the major calculation paths. Although it is impractical to cover all possible combinations of paths through a computer program that contains a multitude of branches, the verification test suite provides reasonable assurance of overall program quality.

Revisions to a computer program are re-verified in the same manner as a new program. Special tests are executed that specifically address the computer program revisions that have been made; the tests are added to the verification test suite. Computer program developers do not make revisions to the production version; instead, new versions are created, verified, and placed into production. Computer programs are also re-verified in the same manner as a new program following alterations to the platform(s) on which they are executed.

When verification is complete, the computer program developer documents the verification of the program and writes the user manual. Following verification but prior to documentation of the verification and issuance of the user manual, the computer program is released for preproduction use in design studies. For preproduction use, separate documentation is required (e.g., in a technical work record (TWR)) to utilize computer program results for production work to ensure the program verification is adequate for the intended application. Any changes to the preproduction version of a computer program must be verified before the program is allowed to continue in preproduction use. It is expected that a preproduction version will last no longer than six months.

The documentation of a computer program is an integral part of the program's development and modification work. Documentation serves as the main communication link between the computer program developer and the users. Documentation contains the important details of the computer program from the standpoint of the analyst, the user, the maintenance programmer, and the installation programmer at another computing facility who may adapt the program to his or her computing environment. The documentation clearly describes the capability, limitations, method, reliability, and input-output data formats for the computer program in sufficient detail to enable a user to evaluate the limitations and the applicability of the program. Explicit instructions are required to ensure correct preparation of input data and correct interpretations of output data. Sufficient

documentation is maintained to allow independent reproducibility of the process and results of the specified demonstration. In general, as the computer program complexity increases so does the need for more extensive documentation.

All verification work is documented, generally in a verification report. At a minimum, the verification report provides a permanent record of the verification process performed for the computer program.

The initial verification report for a computer program includes:

1. A general statement of objectives for the computer program, the specifications for all calculation and/or logic processes performed, and an overview of any special mathematical techniques employed;
2. A description of the verification test suite developed for the computer program; and
3. A careful discussion of the output from the verification test suite. The discussion includes a clear statement of the standard against which the output was compared and the degree to which the output matched the standard.

The verification report for a computer program modification includes:

1. The purpose of the modification and a specification of any calculation and/or logical processes associated with it;
2. A statement that the entire computer program verification suite has been executed, either with no change in output from the original execution or with changes that are justified in the report; and
3. A description of any tests developed specifically from this modification, together with an analysis of the output obtained.

The verification report includes a description of all QA measures used during specification, development, and testing of the computer program. The QA measures include, but are not limited to:

1. Use of formalized computer program specifications;
2. Independent review of the computer program specifications for model accuracy;
3. Design review of the computer program specifications;
4. Independent review of the computer program design;
5. Independent review of adherence to programming standards;
6. Independent inspection comparing code to specifications;
7. Use of standard computer program libraries;
8. Independent review of module interfaces;
9. Use of standard numerical computational methods;
10. Detailed independent code review;
11. Pre-verification of the computer program by users;
12. Independent review of option coverage by the verification test suite;
13. Independent review of test output;
14. Test of multiple-case jobs;
15. Test of interfaces between the computer program and any other program(s) that provides its input or processes its output; and
16. Test that out-of-range input is properly rejected by the computer program.

After the verification documentation and users' manual have been issued, the computer program is placed into production status. The users' manual explains how to use the computer program. A users' manual includes:

1. Brief description of the computer program and its range of application;
2. Detailed description of input requirements, formats, file assignments, all options, and possible paths;
3. Detailed output description (e.g., files, formats, and options); and
4. Samples of typical input and output.

2.2 ENGINEERING MODEL QUALIFICATION

The users must confirm that the versions of any computer program they use have been properly verified and that the associated engineering models are qualified. The engineering model is the specific application of a computer program in a design application. The engineering model includes the computer program, physical data collections, methods, modeling techniques, assumptions, and boundary conditions. The users must understand the level of verification and qualification and the scope of application, including any limits on the applicability, for all computer programs they use.

Once verification work is complete and provides evidence that the computer program computes results consistent with those expected from one or more of the verification methods, the user must show that the computer program is applicable to the set of conditions in the engineering model of the specific problem. This action is called qualification of the engineering model. If necessary, verification and qualification work may be performed in parallel. Qualification is the process of ensuring that the analytical procedures such as mathematical models, methods, assumptions, correlations, limits, data input, numerical technique, and computer programs solve the specific problem of interest to a level of accuracy considered acceptable by the design organization. Qualification includes comparison of results of an analytical procedure to empirical data, comparison to results from a previously qualified procedure, completion of a detailed peer review, or use of other technically justified approaches.

Because the computer program is an integral part of the engineering model and overall design procedure, the computer program cannot be qualified independently from the model and procedure. All aspects (e.g., physical data, methods, modeling techniques, assumptions, and boundary conditions) of the engineering model are important in determining the adequacy of the analytical results obtained.

Documented experience with the computer program in uses related to and complexity of the intended application are considered in defining the qualification effort. Qualification tests are the primary means used to qualify computer programs for specific engineering models. Qualification testing provides the empirical data needed to demonstrate the accuracy of the specific engineering model. When empirical data obtained from qualification testing is not available, other approaches for qualification are needed. For example, the specific engineering model can be compared to a previously qualified model or to a more fundamental model. Qualification of the specific engineering model is integrated into the design assurance process described in Section 19.5.3 of this BEAR. The design assurance process includes the performance of a detailed peer review of the design work.

Qualification of engineering models is documented in the same manner as other engineering work (e.g., Bettis TWR and KAPL technical work book (TWB)).

2.3 LIMITED USE SOFTWARE

Limited use software is a computer program that is used as a simple calculational tool (e.g., a spreadsheet) for repetitive calculations. Such software is generally used only within a small working

group at a single Prime Contractor site. Once such an application is used across working groups or across Prime Contractor sites, it is considered for production status.
Due to its limited scope, documentation of limited use software is completed by the user who ensures that the software is suitable for the tasks, references any documentation supplied with the software, and documents the verification in a TWR, TWB, or in formal documentation. Limited use software is approved by management.

3.0 REFERENCES

B-1 NAVSEA PCQS, Naval Nuclear Propulsion Program Prime Contractor Quality Specification (PCQS)

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