Assessment of the Quality Program for the Light Water Reactor Sustainability Program's Materials Aging and Degradation Pathway at the Oak Ridge National Laboratory and the Pacific Northwest National Laboratory

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ORNL Performance Analysis and Quality Organization

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Introduction

This report provides the results of an assessment of the implementation and effectiveness of the Oak Ridge National Laboratory (ORNL) quality assurance (QA) program as it applies to the technical tasks and activities conducted for the Light Water Reactor Sustainability (LWRS) Program's Materials Aging and Degradation (MAaD) Pathway tasks at ORNL and at the Pacific Northwest National Laboratory (PNNL). Specifically, this assessment included a majority of the work packages and milestones undertaken in support of the MAaD Pathway research and development (R&D) principle areas as defined in the *Light Water Reactor Sustainability Program Materials Aging and Degradation Technical Program Plan* (Document #ORNL/LTR-2012/327, Revision 3).

Performed at the request of the MAaD Pathway Lead, the assessment at ORNL included a series of work package-targeted surveillances conducted to determine the level of staff awareness, implementation, and effectiveness of ORNL's QA program in ensuring that quality rigor and associated implementation for each work package is appropriate for the work and for the defined deliverables. For PNNL, a desk-top evaluation of the quality infrastructure was performed. This segment of the assessment was to establish a baseline of knowledge for the MAaD Pathway Lead concerning PNNL's QA program structure at the site level and how it is applied to MAaD work packages and milestones.

No findings were identified during the course of this assessment, but a number of observations are identified for management consideration to address improvements that will be ensure the consistency of the LWRS QA effort across the gamut of MAaD work packages. A copy of the checklists used for this assessment is provided in **Appendix A** of this report.

For the assessment at ORNL, the MAaD Pathway Lead, work package managers, and associated technical staff contacted during the assessment displayed a consistent understanding of the need to apply quality requirements based on:

- the type of work activities under their purview.
- the potential risks or barriers to the success of each work scope.
- the nature of and planned and potential uses for the deliverable(s) for which they are responsible.

- the organizations dependent upon ORNL's LWRS outputs including US nuclear industry participants, the US Nuclear Regulatory Commission (NRC), the Electric Power Research Institute (EPRI), international collaborative partners, and universities.

Information provided by PNNL's technical and quality staff in response to the desk top review indicates that an effective infrastructure is in place and functioning to support meeting the nuclear R&D goals of the MAaD Pathway Lead.

Background

In support of the managing and operating prime contracts at each site, ORNL and PNNL have developed and implemented QA programs that address the requirements contained in DOE Order 414.1D, *Quality Assurance* and in 10 CFR 830, Subpart A, both of which are cited in the prime contracts between the Department of Energy (DOE) and Battelle (UT-Battelle at ORNL), the managing and operating contractor for ORNL and PNNL. More in-depth information concerning PNNL's QA program is found in the last section of this assessment report entitled *Desk-top Assessment of MAaD Pathway Work Package Milestones for Work Managed by and Primarily Conducted at the Pacific Northwest National Laboratory*.

In response to DOE's quality requirements, ORNL adopted ISO 9001:2008 as the Laboratory consensus standard and has been registered to the standard (Certificate Number 2Y251-IS1) by a third party registrar since May 2010. Adoption of ISO 9001:2008 provides the level of rigor and flexibility necessary for the wide range of activities conducted at ORNL.

The ORNL QA Program Description also provides for application of additional QA standards or guidance documents (e.g., ASME NQA-1 and ANSI Z1.13) on a project or process-specific basis based on the usefulness of alternate standards in addressing potential risk factors and customer requirements, expectations, and needs.

For LWRS participant organizations, the DOE Office of Light Water Reactor Technologies (OLWRT) has provided a specific set of QA expectations targeted to the work scopes and outputs from nuclear science and technology activities in its Quality Assurance Program Description Document (INL/MIS-10-19844, currently Revision 1 as of the date of the conduct of this assessment). This document will hereafter be referred to as the LWRS QAPDD.

To address the requirements and unique needs of nuclear R&D sponsors such as DOE-OLWRT, ORNL conducts nuclear science and technology activities under the QA rigor specified in both the ASME NQA-1-2008 standard including the NQA-1a-2009 Addenda (*Quality Assurance Requirements for Nuclear Facility Applications*, hereafter referred to as NQA-1-2008,), and in the NRC's 10CFR50 Appendix B (*Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*). ORNL has developed and implemented a quality program plan specific to nuclear R&D activities entitled *Quality Assurance Plan for Nuclear*

Research and Development Conducted at the Oak Ridge National Laboratory (Document # QAP-ORNL-NR&D-01).

LWRS QA deployment at ORNL also includes implementation of quality-related subject areas and procedures conveyed through the Standards Based Management System (SBMS). The SBMS serves as UT-Battelle's primary site-wide deployment mechanism for the wide range of systems and processes to address sponsor requirements, including QA requirements. The SBMS is a web-based system available to all staff that translates and implements applicable laws, orders, and regulatory requirements through the deployment of subject areas and procedures. References in this report will be made to these various subject areas and procedures to describe how management expectations are conveyed and applicable QA requirements are addressed at ORNL during the conduct of LWRS activities.

Purpose and Scope

The purpose of the assessment was to review the majority of work packages and milestones representing the diverse gamut of activities conducted at or managed by ORNL for the LWRS program and to verify that they are being conducted in accordance with the applicable requirements of the ASME NQA-1-2008 standard and 10 CFR 50 Appendix B.

During the course of the assessment, work packages associated with the following selected MaAD Pathway R&D areas were reviewed:

- management activities.
- reactor metals.
- concrete.
- cabling.
- mitigation technologies.

Appendix B provides a list of each ORNL work package milestone reviewed during the course of the assessment. **Appendix C** provides the list of work package milestones reviewed during the assessment representing work assigned to and primarily managed by PNNL.

Assessment Results

The balance of this report cites each nuclear quality standard element or criteria evaluated (each bolded heading) and the results at ORNL discerned through discussions with personnel, review of technical aspects of each LWRS work scope, review of documentation and records, review of activities conducted and equipment and processes used, and the planned and potential use for each deliverable. The results from PNNL were provided through a thorough response to the assessment checklist targeted to site-level systems and processes and formulated to determine the efficacy of the quality infrastructure used to address LWRS

mandates. The MAaD Pathway Lead will use the information provided in this report to determine the scope and breadth of future assessment activities.

Organization

The MAaD Pathway Lead is an ORNL manager and functions as both a line organization group leader and as the program manager for LWRS activities under his purview at ORNL and at PNNL. A number of emails conveyed to staff funded through MAaD work packages were reviewed that provide substantial evidence of the Pathway Lead's communication of expectations for staff in ensuring the quality of work. Under the program management structure for LWRS, work package managers/principal investigators report functionally to the Pathway Lead for LWRS activities while reporting administratively to their line organization group leaders or division directors.

LWRS Program management interacts with the ORNL Performance Analysis and Quality organization through a Quality Representative (QR) deployed within the line organizations where MAaD activities are conducted. The QR is a support service position that provides nuclear R&D QA expertise, training, assistance, and oversight in ensuring that sponsor needs and quality requirements incumbent upon work are understood and addressed. Examples of Pathway Lead/QR interactions this year:

- at the request Pathway Lead, the QR assisted him in determining the quality rigor levels for each work package based on the sponsor's quality rigor level definitions and requirements, the types of activities to be performed, and the attributes of the milestones and deliverables associated with each work package.
- the Pathway Lead requested that the QR provide nuclear R&D QA training for staff participants in MAaD activities.
- the MAaD Pathway lead requested this assessment and funded its performance.

Quality Assurance Program

The ORNL site-wide quality assurance (QA) program addresses the requirements contained in DOE Order 414.1D, *Quality Assurance,* and in 10 CFR 830, Subpart A and is applied on a graded basis to all work activities at the site. To meet these requirements, ORNL implements its QA Program Description (PD) which serves as the highest tier QA document for the site.

The ORNL QAPD provides the flexibility of addressing sponsor requirements through either the imposition of a QA program based on the ANSI/ISO/ASQ(E) Q9001:2008 standard – for which ORNL is registered - or through an alternate recognized standard. By this approach, the Laboratory's QA program provides the flexibility and authorization to develop activity-specific plans to meet individual national and international quality standards and sponsor needs.

In the case of nuclear R&D at ORNL, the invoked standards are ASME NQA-1-2008 including the NQA-1a-2009 Addendum and the current version of the NRC's 10 CFR 50 Appendix B.

Additionally, the Laboratory implements ASME NQA-1-2008, Part IV, Subpart 4.2, *Guidance on Graded Application of Quality Assurance for Nuclear Related Research and Development* as the guiding document to tailor the application of quality requirements to each nuclear R&D activity, its associated risks, and the nature of both the planned and potential uses of the final deliverables.

DOE QA expectations specific to the LWRS program are described in the *Light Water Reactor Sustainability Program Quality Assurance Program Description Document* (#INL/MIS-10-19844, currently Revision 1). This document provides the QA requirements for organizations performing work for the LWRS program including the expectations for establishing the quality rigor level for each work package.

ORNL has developed and implements a nuclear R&D-targeted quality program plan (Document # QAP-ORNL-NR&D-01) entitled *Quality Assurance Plan for Nuclear Research and Development Conducted at the Oak Ridge National Laboratory* to deploy systems, processes and tools necessary to address the requirements of NQA-1-2008 and 10 CFR 50 Appendix B. This plan applies to both DOE and Work For Others (WFO) nuclear R&D programs and projects not already covered by sponsor-specific QA plans.

Design Control

R&D application of design definition and control requirements contained in nuclear QA standards results in numerous examples of how DOE's mandate for a graded approach to quality based on risk is enacted at the working level using the requirements of the previously-cited nuclear quality standards.

A typical and pervasive example of graded design control in materials research is the use of controlled sketches and drawings for the machining of material test specimens through services provided by external suppliers. Sketches/drawings are included in the procurement documents used to convey specific machining activity controls to suppliers including the applicable quality requirements. In addition to sketches or drawings, design documents to ensure test specimen configuration also include information concerning cleanliness requirements, numbering schemes, cut-up diagrams, and specific identification of desired specimen locations in large material forms to ensure the controlled subdivision of materials necessary for subsequent research.

Other examples of design control at the R&D level include equipment configuration sketches and the use of procedures, use of equipment manufacturers' manuals and recommendations, and other methods to document the correct configuration and calibration of equipment prior to use.

Technical personnel were aware of the need to ensure the efficacy of the design of software used in nuclear R&D activities. Software design control may be as simple as using alternate

calculations and verifying the correctness of outputs from a set of formulae in an Excel spreadsheet used for data manipulation to full verification and validation of the design of a piece of software provided to the sponsor as a deliverable. Staff members displayed a consistent awareness that ORNL maintains design control processes in the SBMS to ensure that software is developed and deployed with a rigor consistent with the planned use of software and the incumbent risks associated with the application and potential impact to LWRS activities and deliverables.

Observation: LWRS program management should remind technical staff of the importance of ensuring that formulae used in spreadsheets to manipulate data must be verified and validated to ensure that calculated results are correct. Even at this level, software is like equipment – it needs to be determined that it performs correctly prior to generating a final data set from which conclusions are drawn and deliverables developed.

Procurement Document Control

Procurement of items, services, hardware, materials, and the subcontracting of R&D activities to other organizations for MaAD Pathway areas is conducted through the processes described in the Laboratory's *Purchasing Supplies and Services* subject area in the SBMS. The subject area requirements have previously been shown to comply with NQA-1-2008 and NRC procurement-focused mandates in prior evaluations for other nuclear R&D programs funded by both DOE and WFO sponsors.

The SBMS subject area provides the Quality Significant Review (QSR) function to facilitate the QR's independent oversight of and input to procurement documents and the inclusion of essential quality requirements necessary to ensure that materials, equipment, and services are appropriate for MAaD use. LWRS requestors/end users of procured materials, equipment, and services were aware of the need for quality review when applicable and their responsibility for mandating that the procurement undergo the QSR prior to release to vendors/suppliers. Numerous examples of the use of the QSR for LWRS procurements were available in the ORNL SAP records.

Observation: LWRS management should remind technical staff of their responsibility to ensure that the procurement of materials, equipment, or services with the potential to impact the quality and success of nuclear R&D activities should include a quality review so that the quality clauses incumbent upon the purchase can be conveyed to the supplier.

Instructions, Procedures, and Drawings/Document Control

Adhering to NQA-1-2008 nuclear R&D guidance, document control activities associated with MAaD-targeted R&D are conducted on a sliding scale of formality and rigor based on risk.

Where needed, the ORNL divisions involved in pathway technical activities maintain internal procedures to address document control and associated considerations for the format and content of instructions, procedures, drawings, and other work controlling documents. The Laboratory's SBMS also imposes site-wide requirements and management expectations for the control of documents that may impact the success of R&D technical activities.

Work package managers, with help from their QR, are responsible for making decisions concerning whether formal work controlling documents are necessary for each activity. In many cases, they may not be necessary. Work controlling document needs may be fulfilled through alternate means such as test plans, reference to use of national or international test standards and methods (e.g., ASME), use of equipment manuals and manufacturer recommendations, entries in log/run forms, and descriptions of work provided in laboratory notebooks and other records. In any case, technical staff and their management are accountable for conducting each activity with the level of control necessary to ensure the repeatability of the results and the efficacy of final deliverables.

Personnel interviewed during the assessment were aware of the need to consider decisions concerning the use of formal controlled documents based on the needs of the work and risk to the success of LWRS outcomes.

Control of Purchased Items and Services

Staff members showed a consistent awareness concerning the need to take the necessary actions to control items, materials, and equipment and to evaluate the performance of purchased services prior to using any delivered commodity in their work activities. Each buy is evaluated using the technical and quality requirements invoked in the procurement document to ensure that each vendor/supplier provides the purchased commodity in conformance to ORNL's requirements. For example, various instances were found where technical personnel conducted subsequent inspection of machined specimens against the requirements of their original sketches or drawings to ensure conformance to the specifications and dimensions contained in each applicable procurement document.

Staff also consistently indicated their awareness of the need to identify problems and other deficiencies found in procured items, materials, equipment, and services promptly so that issues can be appropriately documented and corrective actions taken to address the issues.

Identification and Control of Items

During the assessment, a wide array of materials identification, control, and pedigree maintenance methods and actions were observed across LWRS MAaD activities. Task leads and other technical staff displayed a consistent awareness of the need to track materials from their initial receipt at ORNL and throughout pre-test, testing, and post-test processing including

subdivision of materials, machining of test specimens, materials properties testing, and archiving of materials for future needs. They were also cognizant of the need to ensure that materials to be tested later are provided with certifications and/or chemical analysis to verify pedigree.

Test article control methods observed included:

- use of numbering systems to ensure effective tracking back to the applicable materials certifications when materials are subdivided.
- bagging and tagging of individual materials resulting from subdividing and machining including test specimens.
- use of formal procedures and logbook entries to facilitate tracking during testing or other subsequent processing.
- use of Excel spreadsheet entries tracking each individual test specimen and associated test data traceable to each specimen tested.
- engraving of specimen ID numbers on individual specimens.
- storage of materials with clear ID of the type of material, associated requisition number, or markings that ensure effective pedigree maintenance over long periods of time.
- materials archiving for future reference and use.

Observation: As previously-installed, now-extracted segments of structures, systems, and components from operating reactor environments, historically significant materials critical to the evaluation of degradation and aging (e.g. baffle bolts, electrical cabling segments, reactor pressure vessel segments) are regularly exchanged among national laboratories, industrial partners, EPRI, and other program participants. It is important that care be taken to faithfully capture and convey all associated documentation necessary to maintain the source, pedigree, and traceability of these materials wherever they are sent and however they are subsequently subdivided.

In non-procurement situations involving materials shipped to ORNL, the need for this requirement can be easily missed due to the assumption that the provider of the material is certain of its pedigree. Researchers should be reminded that whether they believe they can trust their source or not, they need to verify pedigree prior to commencing work with materials received from non-supplier sources.

Control of Special Processes

Under NQA-1-2008 and other quality standards, the term *special processes* refers to technical activities used to control or verify the quality of items and materials and the conduct of subsequent processing and testing.

In the case of materials research, control methods for these processes include the use of

national or international test standards and methods, the use of formal procedures, chemical analysis of materials to verify their composition, and others. Special processes may also be controlled through use of calibrated equipment and strict adherence to equipment manufacturers' manuals and recommendations. Many examples of the use of these methods to address special process needs were evident throughout the surveillances and discussions conducted for this assessment.

Inspection

The term *inspection* as it is used in the context of nuclear QA standards typically refers to non-destructive evaluation (NDE) and test procedures, methods, or processes performed in support of materials research. Researchers appeared consistently aware that NDE processes carry expectations of formality and rigor that go beyond many other types of testing activities. They were also aware that ORNL maintains a cadre of NDE personnel who are trained and certified to national standards. Examples of use of these personnel were provided during discussions conducted for this assessment.

Test Control

Various test control approaches and methods used by researchers were observed during the assessment. Because of the wide variety of activities and the associated planned use of the deliverables, test control activities are implemented in many ways.

Use of documents such as laboratory notebooks, test/experimental plans, drawings and sketches, national and international test standards and methods, procedures and guidelines, and equipment manufacturers' manuals and operating recommendations, test logs, and computer-controlled and generated test results were some of the many methods observed to ensure the efficacy and repeatability of test activities.

The breadth of options used to control materials testing is reflective of the many types of testing conducted for the ORNL LWRS MAaD effort, the availability or lack thereof of national/international standards for conduct of certain materials test activities, the nature of each planned final deliverable, and other factors. In any case, researchers' awareness of test control needs consistently reflected the awareness to ensure that:

- test prerequisites and any necessary environmental conditions necessary for the test are in place.
- appropriate instrumentation and equipment were are used in support of ensuring conduct of a valid test method.
- equipment is calibrated to support the accurate recording of test conditions and parameters important to the results.
- test personnel are trained and qualified to conduct planned test activities.

Also included in applied nuclear standards' test control requirements are those associated with the testing, verification, and validation of software used in LWRS activities or software that may be designated in a milestone as a distinct sponsor deliverable. The SBMS subject area entitled *Software Quality Assurance* provides the ORNL processes for developing, grading, and testing software based on the rigor necessary to support the final deliverable and its planned and potential applications. As with other QA subject matter, personnel displayed an awareness of the need to control software based on risk and application, and that QA and information technology expertise is available to them to ensure that software is adequately tested and controlled to the rigor level necessary to support R&D results and the efficacy of deliverables.

Observation: When national or international standards and methods are used to conduct testing, any deviation from the established standard or method needs to be documented and acknowledged. For example, it is a common practice in materials research to test materials specimens that are smaller than those stipulated in test standards or methods. This is typically done to save material or – in the case of specimens destined for irradiation – to save space in the irradiation capsule/target. Such deviation is acceptable, but it must be documented in the records generated for the testing activities and in the resulting publication, report, or other deliverable.

Control of Measuring and Test Equipment

Work package managers and principal investigators appeared to possess a consistently clear understanding concerning what equipment should be calibrated in support of their work. ORNL maintains the SBMS subject area entitled *Calibrations* to provide baseline expectations to staff concerning such issues as the importance of various test parameters to final test results, frequency and accuracy of calibrations, and adherence to national standards and to the specific calibration recommendations described in equipment manuals and other pertinent calibration-related subject matter.

Performance and maintenance of satisfactory calibrations for equipment used in materials testing is provided on a Laboratory-wide basis through the services of the ORNL Metrology organization. For several years, Metrology has been qualified and registered to the international calibration standard, ISO 17025 through bi-annual evaluations by the National Institutes of Standards and Technology's National Voluntary Laboratory Accreditation Program (NAVLAP). Accreditation through the NAVLAP to the ISO 17025 standard has been recognized by the NRC as an appropriate route by which to implement an effective calibration program in support of nuclear R&D.

ORNL Metrology is accredited to perform calibrations in a wide range of expertise including dimensional measurement, electrical/electronic, gas flow and air velocity, laser frequency and wave length measurement, mass, pressure and vacuum, temperature and humidity, and torque.

Researchers interviewed during the assessment displayed a consistent awareness that their QR was available to provide calibration advice for specific technical activities and that the Metrology organization was available for enhanced subject matter expertise related to the wide range of calibration issues for consideration in a nuclear R&D environment.

Control of Nonconforming Items

The requirements associated with nonconforming items or services described in the SBMS subject area entitled *Nonconformance Reporting* are applied to LWRS activities based on the quality level and commensurate expectations of rigor. The following description concerning nonconforming conditions is provided in NQA-1-2008, Part IV, Subpart 4.2 concerning nuclear R&D: "The results of R&D activities are not expected to meet predetermined requirements; therefore, obtaining unexpected results does not constitute a nonconforming condition. The point at which a nonconformance can be identified is the point at which development work has transitioned into design or production of engineered items."

This approach is reflected in the conduct of nuclear R&D at ORNL. The use of nonconformance reporting is most often found in R&D efforts involving material or performance specifications imposed on technical activities, and in cases where the work includes materials irradiation in a reactor environment. Researchers are aware of the need to consult with their QR to identify possible situations where nonconformance reporting is applicable to their activities and to ensure that the process, if used, is completed in accordance with the applicable SBMS subject area. No current LWRS R&D activities have resulted in the need for the use of the subject area requirements thus far.

Problem Reporting and Corrective Action

ORNL management provides staff with problem reporting, corrective action, and continual improvement expectations in the Integrated Performance Management System's subject area entitled *Analysis, Issues Improvement, and Feedback.* In accordance with the subject area requirements, the QR assigned to lead the LWRS QA effort provides subject matter expertise to staff concerning problem reporting, reporting thresholds associated with DOE-defined occurrences, the appropriate use of the non-conformance reporting process, effective preventive/corrective actions, and the use of the Laboratory's Assessment and Commitment Tracking System to ensure completion and maintenance of closure evidence associated with any necessary preventive or corrective actions.

Program management and work package managers, principal investigators, and other technical staff provided feedback that indicated a consistent understanding that, upon discovery of a problem, the QR is to be contacted to ensure that ORNL and LWRS requirements are satisfactorily addressed to document, resolved, and prevent recurrence of issues that may impact work activities and final deliverables.

Quality Assurance Records

Discussions with work package managers and principal investigators concerning the identification, capture, and maintenance of records provided evidence of a consistent understanding of what documentation and archive materials should be kept to support the work they are performing. Staff provided feedback that indicates they understand the salient requirements contained in the SBMS subject area entitled *Records* and are following them. Each researcher reviewed during the assessment had a clear perspective concerning what records should be maintained to substantiate their technical activities and to support the level of quality necessary for each of their deliverables.

Laboratory notebooks are often used as the baseline record-keeping mechanism. In addition to recording research activities, many researchers use their laboratory notebooks to record information concerning where electronic records reside, i.e., identification of the desk top or lap top computer number and the associated files where records are actually stored. Some researchers are also taking advantage of their line organization's automatic computer files back-up systems to implement a redundant records storage mechanism.

Observation: Because the majority of the activities addressed in this report result in electronic and not paper records, LWRS program management should encourage staff to consistently use the computer files back-up services provided by ORNL Information Technology through their line organizations. Electronic storage of records can ensure ready retrievability as long as their preservation is maintained and assured. Computer files back-up enhances the goal of consistent records preservation.

Peer Review

All staff members conducting LWRS activities are required to follow the peer review requirements described in the ORNL SBMS subject area entitled *Publications and Other Scientific Communications* including papers authored for conference proceedings, journal articles, books, ORNL reports, abstracts, and other final deliverables associated with the conduct of nuclear R&D.

Researchers interviewed during the assessment were aware that they are required to use the ORNL Publication Tracking System (PTS) as the peer review vehicle for assuring that research results are properly vetted prior to release. The PTS is used to document completion of the deliverable, identification of the internal and external reviewers, their comments and associated comment resolution, and release for external dissemination.

Desk-top Assessment of MAaD Pathway Work Package Milestones for Work Managed by and Primarily Conducted at the Pacific Northwest National Laboratory

Organization and Quality Program

The PNNL Quality Assurance Program Description (QAPD) provides the basis for a wide gamut of systems, processes and tools used by the Laboratory to ensure the quality of work, including work performed for the LWRS MAaD Pathway. Because PNNL's program is based on the ASME NQA-1 standard – including the Part IV, Subpart 4.2. for nuclear R&D – it aligns very well with the stipulations of the Office of Light Water Reactors Sustainability QAPDD and with ORNL's NQA-1-based program.

Similarly to ORNL, PNNL integrates the quality program into technical programs, projects, and activities through implementation of its standards based management system entitled *How Do I…?* (HDI). The process diagrams and descriptions provided in the HDI form much of the Laboratory infrastructure to assure quality. The HDI also provides the *Quality Controls for Project Work* process for planning technical work and defining applicable rigor levels and quality requirements in a graded approach based on defined risk factors.

In Section 3.5 entitled *Performance/Work Process* of the PNNL QAPD, the discussion section provides the stated approach to R&D planning. "The progression of technology development, commercialization, and retirement flows through phases of basic, applied, and development R&D. The life cycle is characterized by flexible and informal quality assurance activities in basic research, which becomes more structured and formalized through the applied and development R&D stages." This approach mirrors NQA-1, Part IV Subpart 4.2 and should result in deliverables that meet the sponsor's planned use. PNNL has recently established a targeted Nuclear Quality Assurance Program and is in pilot mode for select projects.

Design Control

The current scope of MAaD Pathway activities currently do not include the need for providing design input to any structures, systems, or components associated with a nuclear facility. In the case of R&D activities, the PNNL QAPD indicates that, "Formal design control does not apply to research conducted to expand fundamental knowledge. However, the design of parts and components used in experiments must undergo sufficient design control measures to ensure operational safety (staff, facility, environmental) and desired performance."

Section 3.6 of the PNNL QAPD describes escalating actions to address design control needs as the rigor of an activity increases. Based on the stipulations for risk-based design control implementation, the PNNL quality program appears fully capable of handling any future higher-rigor design needs should they be necessary for LWRS MAaD activities.

Procurement Document Control and Control of Purchased Items

Content in the PNNL QAPD, Section 3.7, *Performance/Procurement,* explicitly addresses how products and services are purchased in relation to the rigor necessary to support each sponsor's needs. Subject matter covers the gamut of considerations from the procurement planning process to verification of received products. This section also provides for QA review of purchases to ensure procured products are appropriate for planned use in R&D activities.

A copy of PNNL's *Acquire Product or Service* was reviewed to determine how procurement QA controls are implemented. It provides a procurement grading process in the *Acquisition Strategy Table* used to "select the appropriate method based on the nature, risk, and dollar value of the procurement."

Instructions, Procedures, Drawings, and Document Control

PNNL technical staff members follow an HDI procedure entitled *Create or Update Procedures and Other Work Instructions* to address the use and control of work-related documents. Project work controlling instructions are maintained in a project share point and include a gamut of documents: organizational internal operating procedures, drawings and specifications, statements of work, laboratory notebooks and other items used for development of intellectual property documentation, inspection and acceptance requirements and documents, and other documents that specify requirements or prescribe work instructions.

Documents are controlled through implementation of the HDI procedure entitled *Manage Controlled Documents*. The PNNL QAPD provides the following statement concerning document control considerations: "*PNNL's document control practices, procedures, requirements and guidelines are maintained in accordance with the source requirement documents referenced in Section 3.4.1 of this document."* Since NQA-1-2000, Part I, Requirement 6 is included in the referenced documents listing, PNNL shows a clear path to meet the document control needs and commitments of the LWRS program.

Identification and Control of Items

Test procedures are used to identify and maintain traceability of test specimens or samples. The records for test activities, including testing conditions, are maintained as a part of the test procedure requirements.

Samples and specimens in LWRS activities are identified at the procurement stage and are tracked throughout execution of tests and experiments. Test item traceability is established through the tracking of each item, and its associated lot, sample, or other unique identifying number for each test activity. Traceability is maintained throughout testing as specimen/sample numbers are recorded in the results for each unique test run. Entries in associated laboratory

notebooks are also used to maintain traceability of materials and the history of their use in test activities.

Inspection and Testing

Work planning documents may include the use of project management plans, work breakdown structure documents, and test plans to scope and document the performance of test activities.

Testing may include the use of measurement equipment and associated software and/or test plans to record results and test parameters. Laboratory notebooks are also used to record results and observations. All project records are subsequently filed with the associated project files according to an established project file plan. PNNL offered several examples concerning how tests in the subject areas of stress corrosion crack initiation, cast stainless steel aging, and cable non-destructive evaluation are planned, controlled, and documented. Evidence of the frequent use of ASTM or other recognized test standards and methods was also provided.

Control of Measuring/Test Equipment

Staff members are required to follow the HDI workflow entitled *Calibrate Measuring and Test Equipment for Use* in situations where calibrated equipment is necessary in the performance of a test activity. Under this procedure, so-called Category 1 calibrations are performed by a qualified external organization. Category 2 calibrations are performed by a staff member in accordance with established project/task plans and the stated workflow. Objective evidence indicates that PNNL meets the calibration requirements of NQA-1 and is fully capable of meeting LWRS needs.

Corrective/Preventive Action

The PNNL TRACS is an on-line system used as the central repository to track project QA issues, deficiencies, non-conformances and related corrective actions. TRACS also facilitates tracking and trending of issues for purposes of identifying emerging site-wide issues and lessons learned. Corrective actions related to external or internal evaluations, corrective actions for issues designated as having a significant negative impact to quality, and non-conforming items are documented and tracked in TRACS.

In addition to TRACS, PNNL has two databases that are used for corrective/preventative actions, ITS and OTS, depending on the severity and reporting requirements associated with each issue. The system designated as ITS is used for DOE reportable issues, while OTS is used for issues below that threshold. Each nonconformance is individually evaluated by project management, staff, and QA subject matter experts to determine which database to use in tracking each issue, its associated risk evaluation, and to document and track the appropriate corrective action to address the issue and prevent recurrence. Corrective actions are given a

due date and assigned to an appropriate individual. Electronic notices are provided to anyone with a role in the resolution of an issue so that the issue receives appropriate attention and the associated corrective actions are tracked to completion.

Quality Assurance Records

PNNL indicates that all projects follow the HDI work controls described in *Quality Controls for Project Work* and in *Manage Project Records* to address records identification, capture, and maintenance requirements. A project file plan is used to specify file categories (where project records will be stored), and their final disposition.

Most records are generated electronically. During project execution, documents, data, records, and related information are managed in accordance with the project file plan structure on a project designated file (server) share. All projects are required to archive records in the PNNL HPRM records management archive system. At the conclusion of a project, any remaining hardcopy records are scanned for archival, or are transferred directly to PNNL Records Management for archival.

Software

Much off-the-shelf software such as Excel, Word and Photoshop is used in the course of validating and presenting work results. For example, a database of cable specimens being used in the cable NDE and aging programs is maintained using MS Excel. More impactful to the actual nuclear R&D activities, MATLAB is used primarily for processing and visualizing measured NDE data, and LabView is used to facilitate measurement system automation on applicable equipment.

PNNL has developed data collection software for various instruments used in materials test activities. This software is used to collect information concerning the test conditions, environmental conditions, material attributes, and to record the test results as raw data. Test data are stored with other project data as described. Software configuration control is managed by the technician/researcher responsible for the hardware.

Examples of how software is used for LWRS activities were provided. For the Stress Corrosion Crack Initiation Project, software has been written to monitor and record test data for long term tests (lasting up to several years). The software documents operating conditions by readings from dedicated commercially available instruments that have built-in digital data output connections. Readings recorded by the software (e.g., temperature, test system load) are verified for accuracy by comparison to visual readouts on the instruments over a range of possible operating conditions.

For the electrical cable NDE activities, software verification is performed through the use of known inputs (such as from waveform generators), and their comparison with results obtained from conduct of testing. For analysis software developed in-house, a similar process is followed with previously vetted results used for verification and validation.

Peer Review

Assessment feedback indicates that all PNNL projects follow the requirements contained in the HDI procedure, *Review and Approve Information Product*. Where it has been determined that a higher level of rigor is required for peer review, the PNNL procedure numbered IP-NQAP-A-TM02 and entitled *Conducting Technical and Peer Review of R&D Project Scientific Information or Deliverable* is used to regulate the peer review process. This escalating rigor approach fits well with the DOE OLWRS peer review requirements and with the approach used at ORNL.

APPENDIX A

Audit Checklist (ORNL)
ORNL Light Water Reactor Sustainability Program

ACTS Number:

Audit Date(s):

Program/Project/Activity: Light Water Reactor Sustainability (LWRS) program

Audit Purpose/Scope: To gauge the current state of compliance with select QA requirements imposed by DOE NE through the LWRS QA Program Description (Doc # INL/MIS10-19844, Revision 1) based on a review of select LWRS work packages classified as either Applied or Development

Audit Team Member(s): M. C. Vance

Audit Contact(s):

Audit Observer(s):

Requirements Document(s): LWRS QA Program Description, Doc # INL/MIS10-19844, Revision 1

Follow-up Audit/Surveillance Required?:

Audit Plan/Strategy: Determine and document current work package compliance with the selected and listed requirements contained in the checklist

Audit Characteristics and Results

Audited Characteristics	**Audit Results**
Design Control Are any design-related actions associated with equipment or other needs necessary for your activities?	
Procurement Document Control Are procurement activities for items or services conducted in accordance with the SBMS subject area for Purchasing Supplies and Services? Are procurement requisitions for items or services that have the potential to impact the quality of LWRS work reviewed to ensure adequate QA requirements are mandated for the vendor/supplier?	

Instructions Procedures and Drawings and Document Control | **Audit Results**

Does your task require the use of written instructions, procedures, or other documented work methods?

If so, how do you control them as work is performed to ensure that only current versions are used in LWRS activities?

If not, what is your method for controlling test activities?

Can specific work/test records be traced back to the documents or methods used to produce the resulting data?

Identification and Control of Items

What processes or methods do you use to maintain control and traceability of test items, materials, and related quality-affecting inputs such as gases during your testing?

Inspection and Testing

Prior to testing activities, where do you describe and document the planned activities?

How do you document the specific characteristics to be tested and test methods to be employed? How do you establish any associated environmental conditions for the test such as the use of gases or other related types of materials that may impact your results?

Do you use nationally-recognized standards or test methods in your activities?

Control of Measuring/Test Equipment

Are any calibrating/operating standards traceable to NIST used in your work?

Do you have equipment calibrated by someone other than technical staff?

Do technical staff perform their own calibrations for test equipment?

Quality Assurance Records **Audit Results**

What are your methods for identifying records you must maintain to support research results, publications, or other deliverables?

In what format are your records generated and maintained?

Software

Do youuse software in your LWRS activities?

Have you developed your own software for any of your LWRS activities?

How do you verify and validate any in-house developed software?

Peer Review

Will the results of your activities be peer reviewed using the ORNL Publication Tracking System?

If not, how do you document the completion of necessary LWRS-mandated peer review requirements?

AUDIT REPORT RESULTS

Overarching Conclusions including Findings, Opportunities for Improvement, and Strengths:

Recommended Actions for Corresponding Audit Results Listed Above:

.

General Conclusions and Comments:

Audit Conducted by:

_____ _____

Date

Audit Checklist (PNNL)
ORNL Light Water Reactor Sustainability Program

ACTS Number:

Audit Date(s):

Program/Project/Activity: Light Water Reactor Sustainability (LWRS) program

Audit Purpose/Scope: To gauge the current state of compliance with select QA requirements imposed by DOE NE through the LWRS QA Program Description (Doc # INL/MIS10-19844, Revision 1). Reviews will be conducted of select LWRS work packages classified as either Applied or Development as described in Part IV Subpart 4.2 of NQA-1-2008 entitled *Guidance on Graded Application of Quality Assurance (QA) for Nuclear-Related Research and Development.*

Audit Team Member(s): M. C. Vance

Audited Organization:

Audit Contact(s):

Audit Observer(s):

Requirements Document(s): LWRS QA Program Description, Doc # INL/MIS10-19844, Revision 1

Applicable and invoked quality assurance program or quality management system at each participant DOE national laboratory or other organization**. A copy of the site's top-level QA document is requested.**

Follow-up Audit/Surveillance Required?: To be determined

Audit Plan/Strategy: Review requested objective evidence pertinent to work package compliance with the selected and listed requirements contained in the checklist.

Audit Characteristics and Results

Audited Characteristics	**Audit Results**
Design Control Are any design-related actions associated with equipment, materials properties specimens, or other needs necessary for your activities? If so, what PNNL procedure describes design control provisions applicable to R&D activities? If applicable, **please provide a copy**.	

Audit Results

Procurement Document Control
Have you made purchases for items, equipment, high-;purity gases, pedigreed materials, or services that could affect the quality and success of your work?

Are procurement requisitions for items or services that have the potential to impact the quality of LWRS work reviewed to ensure adequate QA requirements are mandated for the vendor/supplier including those who may conduct subcontracted R&D activities?

If so, what site procedure describes your procurement QA provisions applicable to R&D activities? **Please provide a copy.**

Instructions Procedures and Drawings and Document Control
Does your task require the use of written instructions, procedures, drawings or other documented work-controlling methods?

If so, how do you control documents as work is performed to ensure that only current versions are used in LWRS activities?

If not, what is your method for controlling test activities?

Can specific work/test records be traced back to the documents or methods used to produce the resulting data?

Please provide a copy of the site-level procedure that provides for the control of documents with the potential to impact the quality and success of your R&D results.

Identification and Control of Items
What processes or methods do you use to maintain control and traceability of test items, materials, and related quality-affecting inputs such as gases during your testing?

Do you include a description of the processes or methods written instructions or in laboratory note-book entries or related records?

Inspection and Testing **Audit Results**

Prior to testing activities, where do you describe and document the planned activities?

If you do perform tests or measurements, How do you document the specific characteristics to be tested and test methods to be employed?

How do you establish any associated environmental conditions for tests such as elevated temperatures, or the use of gases or other related types of materials that may impact your results?

Do you use ANSI or other nationally or internationally-recognized standards or test methods in your activities?

Is training required to perform tests or inspections for your work? Do you use any non-destructive evaluation techniques in conduct of your work? If so, which ones?

Control of Measuring/Test Equipment

Are any calibrating/operating standards used in LWRS R&D traceable to the National Institutes of Standards and Technology?

Do you have equipment calibrated by someone other than technical staff?

Do technical staff perform their own calibrations for test equipment?

Please provide a copy of the site-wide or other procedure that addresses the various routes for conducting and documenting calibrations pertinent to R&D activities.

Corrective/Preventive Action

How does your Laboratory document significant adverse events that may occur during conduct of R&D activities? Is information concerning such events conveyed to LWRS management?

Please provide the procedure used at your site to address corrective or preventive actions to fix problems and prevent occurrence or recurrence.

Audit Results

Quality Assurance Records

What are your methods for identifying records you must maintain to support research results, publications, or other deliverables?

In what formats are your records generated and maintained?

Please provide a copy of your site's records management/control procedure applicable to R&D activities.

Software

What types of software do you use in your LWRS activities?

Have you developed your own software for any of your work ?

How do you verify and validate any in-house developed software?

How do you control software versions that have the potential to impact your deliverables?

Peer Review

What is the process you use to conduct peer review at your site? **Please provide a copy of your site's procedure.**

Do you use your peer review process to conduct and document adherence to the related LWRS requirements described in Section 4.13 (*Peer Review*) of the LWRS Program Quality Assurance Program Description Document (Doc # INL/MIS10-19844, Revision 1)?

AUDIT REPORT RESULTS

Overarching Conclusions including Findings, Opportunities for Improvement, and Strengths:

Recommended Actions for Corresponding Audit Results Listed Above:

General Conclusions and Comments:

Audit Conducted by:_____ _____

Date

APPENDIX B

List of Assessed LWRS MAaD Pathway Work Package Milestones for Work Managed by and Primarily Conducted at the Oak Ridge National Laboratory

M3LW-15OR0401012 Provide input on Materials Aging and Degradation Pathway to LWRS Program Integrated Program Plan.

M2LW-15OR0401013 Complete an update to the Materials Aging and Degradation Pathway Plan.

M3LW-15OR0402012 Complete report detailing the results of fracture toughness test for the round robin test program using mini-disc compact specimens.

M3LW-15OR0402013 Complete report detailing comparative Analysis of Results from High Flux Isotope Reactor and National Institute of Standards and Technology Small-Angle Neutron Scattering Experiments.

M2LW-15OR0402014 Complete report detailing Disassembly and Post-Irradiation Experiments for University of California Santa Barbara Advanced Test Reactor-2 Experiment.

M3LW-15OR0402023 Complete report documenting the results of post-irradiation examination and localized deformation studies on key specimens.

M3LW-15OR0402172 Complete report documenting the thermal aging modeling and validation on the Mo containing Fe-Cr-Ni alloys.

M3LW-15OR0402173 Complete report documenting development of radiation-induced segregation and computational-thermodynamics modeling tool.

M3LW-15OR0402182 Complete report documenting the receipt of the baffle bolts, their inspection and future cutting plan.

M3LW-15OR0402183 Complete report documenting analysis and testing of materials harvested from Ginna baffle bolts.

M3LW-15OR0403012 Complete report documenting prognosis of alkali-silica reactions-affected concrete structures: RILEM State-of-the-Art on residual expansion, numerical strategies, monitoring and large scale testing.

M2LW-15OR0403013 Complete report documenting advanced alkali-silica reactions simulation of nuclear structures.

M3LW-15OR0403032 Complete report documenting fabrication and initial ultrasonic linear array data on new specimen.

M2LW-15OR0403033 Complete report documenting analysis data from the thick specimen using advanced signal processing.

M4LW-15OR0403042 Complete report documenting proposal to perform small and ultra-small angle neutron scattering to characterize the pore structure, including micro fracturing, of irradiated mineral analogues, aggregates, and cementitious materials.

M3LW-15OR0403043 Complete report documenting analysis of structural significance of irradiation on the biological shield: simplified model and statistical analysis.

M3LW-15OR0403044 Complete report documenting Advanced Numerical Model for Irradiated Concrete.

M3LW-15OR0403045 Complete report documenting options to obtain service-irradiated concrete from a nuclear power plant such as Zion, Barseback, Zorita.

M2LW-15OR0403046 Complete report documenting the post irradiation evaluation of the effects of fluence and temperature on swelling of mineral analogues of aggregates.

M3LW-15OR0403052 Complete report documenting guidelines for modeling irradiated concrete structures: physical description, governing equation and recommendation for implementation in Grizzly.

M3LW-15OR0404015 Complete report describing scoping/design study on optimum configuration for combined thermal/radiation of cable samples at High Flux Isotope Reactor Gamma Irradiation Facility.

M3LW-15OR0404016 M3LW-15OR0404016-Complete report documenting baseline irradiation measurements at High Flux Isotope Reactor gamma irradiation facility and start irradiation campaign.

M3LW-15OR0406012 Complete report documenting friction-stir welding process development in welding hot cell environment on un-irradiated stainless steels.

M3LW-15OR0406013 Complete report documenting initiation of installation of the integrated welding hot cell into ORNL's hot cell facility.

M3LW-15OR0406024 Complete report detailing progress, status, and schedule for screening irradiations of candidate advanced alloys.

M3LW-15OR0406022 Complete report documenting tensile and fracture toughness of the procured advanced alloys.

M3LW-15OR0407012 Complete report documenting the Status of Service Harvested Materials Database.

M3LW-15OR0407013 Complete report documenting the harvesting of two segments from the Zion Unit 2 reactor pressure vessel.

M3LW-15OR0407014 Complete report documenting the receipt of cables in radiation, thermal, thermal and radiation, ambient, and submerged environments from the Zion Unit 2 Nuclear Power Plant.

APPENDIX C

List of Assessed LWRS MAaD Pathway Work Package Milestones for Work Managed by and Primarily Conducted at the Pacific Northwest National Laboratory

M3LW-15OR0402032 Complete report documenting presentations and resulting discussion on stress corrosion cracking initiation results for alloy 600 and alloy 690 materials at the Electric Power Research Institute/Nuclear Regulatory Commission Alloy 690 Expert Meeting.

M3LW-15OR0402033 Complete report documenting the presentation and discussion on the mechanisms of precursor formation and stress corrosion cracking initiation in cold-worked alloy 690 at the International Cooperative Group Meeting on Environment-Assisted Cracking.

M2LW-15OR0402034 Complete report summarizing measured stress corrosion cracking initiation response in alloy 600 materials and progress in establishing baseline behavior for comparisons to cold-worked alloy 690 materials.

M3LW-15OR0402152 Report describing activities to reinitiate aging studies at PNNL.

M3LW-15OR0402153 Deliver report describing analysis into the effect of thermal aging on the mechanical behavior and microstructure of cast stainless steels.

M2LW-15OR0404012 Complete report documenting assessment of cable aging equipment, status of acquired materials, and experimental matrix.

M3LW-15OR0404013 Complete report documenting preliminary analysis of inverse temperature effects, submerged cables, diffusion limited oxidation and dose rates.

M3LW-15OR0404018 Complete report documenting mechanical performance testing of treated insulation following rejuvenation treatments.

M3LW-15OR0404022 Complete report documenting assessment of additional key indicators of aging cable insulation.

M4LW-15OR0404023 Complete report documenting purchase and installation of LIRA equipment.

M2LW-15OR0404024 Complete report documenting assessment of state of the art nondestructive examination techniques for cable aging.