

QAP-ORNL-FCT-01, Revision 1

**QUALITY ASSURANCE PLAN AND INTERFACE DOCUMENT
FOR FUEL CYCLE TECHNOLOGY RESEARCH AND DEVELOPMENT
ACTIVITIES CONDUCTED AT OAK RIDGE NATIONAL LABORATORY**

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**Quality Assurance Plan and Interface Document for Fuel Cycle Technology Research
and Development Activities Conducted at Oak Ridge National Laboratory**

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ACRONYM LIST

ACTS	Assessment and Commitments Tracking System
AFCF	Advanced Fuel Cycle Facility
DOE	Department of Energy
ES&H	Environmental, Safety, and Health
FCT	Fuel Cycle Technology
M&TE	Measuring and Test Equipment
NDE	Non-destructive examination
NE	DOE-Office of Nuclear Energy
NQA	Nuclear Quality Assurance
OFCT	Office of Fuel Cycle Technology
ORNL	Oak Ridge National Laboratory
PI	Principal Investigator
PM	Program Manager
POC	Point of contact
QA	Quality Assurance
QAM	Quality Assurance Manual
QAP	Quality Assurance Plan
QAPD	Quality Assurance Program Description (ORNL) or Quality Assurance Program Document (OFCT)
QMS	Quality Management System
QR	Quality Representative
QRL	Quality Rigor Level
QSSD	Quality Systems and Services Division
R&D	Research and development
RD&D	Research, development, and demonstration
SBMS	Standards Based Management System

1.0 INTRODUCTION

The Department of Energy's (DOE) Office of Nuclear Energy (NE) has issued what is termed a research and development (R&D) road map for its research, development and demonstration (RD&D) activities. This road map is intended to chart the course necessary to position and promote nuclear energy as a compelling and viable energy option for the United States. The road map defines DOE-NE's RD&D activities according to four objectives that address the challenges to expanding the use of nuclear power. The objectives are:

- develop technologies and other solutions that can improve the reliability, sustain the safety, and extend the life of current reactors.
- develop improvements in the affordability of the new reactors to enable nuclear energy to help meet the current and future Administrations' energy security and climate change goals.
- develop sustainable fuel cycles.
- understand and minimize the risks of nuclear proliferation and terrorism.

Within NE, the primary responsibility for achieving the third objective - develop sustainable fuel cycles - has been assigned to the Office of Fuel Cycle Technologies (OFCT). Accordingly, the mission of the OFCT is to research, develop and demonstrate options to the current U.S commercial fuel cycle to enable the safe, secure, economic, and sustainable expansion of nuclear energy while minimizing proliferation and terrorism risks.

Sustainable fuel cycle options are intended to improve uranium resource availability and use, minimize waste generation, and provide adequate capability and capacity to manage all wastes produced by the fuel cycle. The key challenge for the U.S. government is to develop a set of options that will enable future decision-makers in making informed choices concerning how best to manage the used fuel from reactors. The current overall goal is to demonstrate, by 2050, the technologies necessary to allow commercial deployment of technical solutions for the sustainable management of used nuclear fuel that are safe, economical, secure and widely acceptable to the American public. To achieve this mission, the following sequentially-planned OFCT objectives have been established:

- In the near term, define and analyze fuel cycle technologies to develop options that increase the sustainability of nuclear energy.
- In the medium term, select the preferred fuel cycle option(s) for further development.
- By 2050, demonstrate the selected fuel cycle options at sufficient scale to enable commercialization.

This Quality Assurance Plan (QAP) describes the Quality Management System (QMS) implemented to assure the appropriate level of quality of the work performed and deliverables produced associated with FCT activities at ORNL. The range of work scopes – as described in work package information contained in the FCT work breakdown structure and in FCT milestone descriptions - cover three primary areas: fuels, materials, and modeling/simulation efforts.

1.2 Products and Deliverables

Principal products and deliverables from the range of OFCT-sponsored activities at ORNL include the following:

- **Strategic Plans/White Papers/Road Maps** – overarching documents providing subject matter expertise concerning future plans and direction in various program technical pursuits.
- **Technical Data/Information** —raw and processed data from experimental activities.
- **Computer Models/Code Inputs** – development information, input and output verification and validation information concerning computer models and codes necessary for future FCT needs.
- **Technical Reports** – reports documenting and analyzing fuel cycle scientific and technical data and knowledge.
- **Process Descriptions** – captured detailed process descriptions, work flow information, and process parameters.
- **Capabilities** – operational capabilities represented by physical systems, facilities, hardware, equipment, software, and human skills, knowledge, and experience.

1.3 ORNL's FCT Quality Assurance Program Approach

This QAP is established, maintained, and executed in accordance with the applicable criteria of the ORNL Quality Assurance Program Description, and is an enabling document for quality-related work associated with FCT activities to be conducted at ORNL or for ORNL by any subcontracted organizations. The ORNL quality assurance program implements the quality assurance (QA) requirements contained in DOE Order 414.1D and in 10 CFR 830, Subpart A and is applied on a graded basis to all work activities at the site. ORNL's QA program also provides the flexibility and authorization to develop activity-specific programs to meet national and international quality standards and sponsor needs.

ORNL management recognizes that – though FCT activities are conducted as part of an ongoing R&D effort – successful outcomes represent potential inputs to future design and licensing decisions. Therefore all activities shall be conducted 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 10CFR50 Appendix B (*Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*). Management's intent is to ensure that this targeted quality program is satisfactory in addressing all work package milestones assigned to ORNL including those designated Quality Rigor Level 1.

The requirements of these standards shall be imposed on a graded basis using the guidance contained in NQA-1-2008, Part IV, Subpart 4.2 (*Guidance on Graded Application of Quality Assurance for Nuclear-Related Research and Development*). Further, this plan is intended to meld the requirements contained in these national standards with those described in the OFCT-issued *Quality Assurance Program Document* (no document number or revision indicator - latest version last approved on December 20, 2012). The Quality Assurance Program Document (QAPD) represents the highest- tier QA document specific to the FCT mission and applicable to the various work scopes, activities, and tasks funded at national laboratories including ORNL.

ORNL's QA approach allows management and staff the capability and flexibility to tailor QA systems, processes, and tools to meet the needs of each technical task or process based upon the types of activities conducted and the intended use of the final deliverables resulting from each task,

Requirements stated in this plan are implemented through a combination of the ORNL FCT QAP, associated subordinate QA procedures, and the ORNL Standards Based Management System (SBMS) by line and program management. The SBMS is ORNL's web-based system for the translation and implementation of applicable laws, orders, and regulatory requirements through the deployment of Laboratory-wide subject areas and procedures. FCT-specific requirements will be further implemented through the use of laboratory notebooks, national standards and test methods, and – where deemed necessary - approved internal work controlling documents including technical procedures, guidelines, drawings, sketches, or other documents that may be used to control and ensure the quality of work. Decisions concerning the level of documentation necessary to control work activities and ensure the quality of the associated outcomes are under the purview of each Principal Investigator (PI) in consultation with the Program Manager (PM) and Quality Representative (QR).

The QAP provides the framework for establishing and maintaining a QA program to fulfill the applicable requirements described in the NQA-1 standard and in 10CFR50 Appendix B as they are applied to FCT activities. This plan – plus any additional referenced QA implementing procedures and SBMS documents necessary for conduct of the described work activities – shall constitute the ORNL FCT QA manual (QAM).

Appendix A provides a matrix of the higher-level Laboratory and program documents implemented to meet the requirements of the elements or criteria of the NQA-1 standard and of 10 CFR 50 Appendix B.

2.0 QUALITY ASSURANCE REQUIREMENTS AND GUIDELINES

The QAP specifies the relevant and applicable requirements imposed from internal and external sources.

2.1 Internal Requirements Source

- *ORNL Quality Assurance Program Description* (based on DOE Order 414.1D, 10 CFR 830, Subpart A, and ISO 9001:2008)

2.2 External Requirements Sources

- *Office of Fuel Cycle Technologies Quality Assurance Program Document*
- ASME NQA-1-2008 including the NQA-1a-2009 Addenda, *Quality Assurance Requirements for Nuclear Facility Applications*
- 10CFR50 Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*

2.3 External Requirements Application Guidance

- ASME NQA-1-2008 including the NQA-1a-2009 Addenda , Part IV, Subpart 4.2, *Guidance on Graded Application of Quality Assurance (QA) for Nuclear Related Research and Development*"

3.0 QUALITY ASSURANCE PLAN DESCRIPTION

3.1 Organization

The requirements of NQA-1, Part 1, Requirement 1.0 and 10CFR50, Appendix B, Criterion I, both entitled *Organization*, will be implemented and applied in accordance with this section of the QAP.

ORNL FCT program management implements an effective quality program by appropriately balancing QA considerations with cost and schedule in operations and related activities. The ORNL FCT PM is the primary interface with the DOE program sponsor and other external FCT participants. The PM delegates responsibilities for executing program-associated activities performed by or subcontracted by ORNL and is responsible for the establishment, approval, and implementation of the QAP. He will also obtain the concurrence of a management representative of the ORNL Quality Systems and Services Division. A Quality Representative (QR) is assigned as an independent resource to the FCT effort and interfaces with the PM on issues related to QA. The QR also serves as the QA point of contact (POC) described in the sponsor-imposed FCT QAPD. The Quality Programs Group Leader coordinates the resources necessary to support the effective implementation and oversight of the QA program. **Figure 1** and this section provide information concerning the responsibilities, internal and external interfaces, and authorities of each organization involved in the ORNL FCT effort.

FCT program management resides within the ORNL Fuel Cycle and Isotopes Division. Sponsor funding is distributed through this organization by way of the Research Lead for Nuclear Fuels and Materials, who is the primary management lead for FCT activities conducted at ORNL. Funding is distributed to work groups within various technical divisions to perform the R&D and related activities that contribute to the completion of program milestones. Program milestones are contained in FCT work packages. Pls are the task/project leads assigned responsibility for each work package and the quality of the activities that conducted to successfully complete the associated milestones. They oversee the staff personnel who conduct the technical activities necessary to fulfill the work package milestones. The ORNL SBMS contains a description of the roles, responsibilities, accountabilities, and authorities (R2A2s) for program management, Pls, and staff.

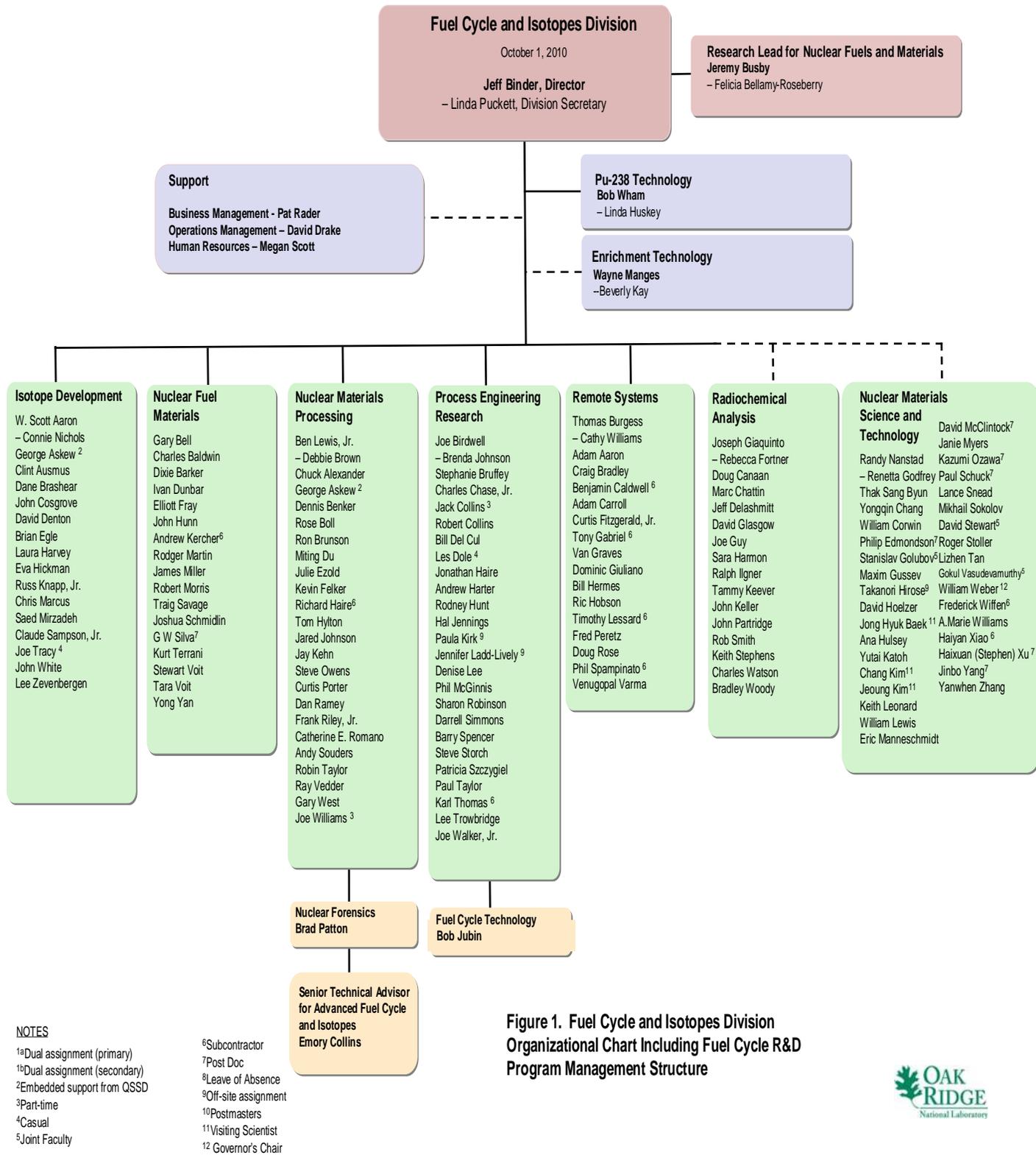


Figure 1. Fuel Cycle and Isotopes Division Organizational Chart Including Fuel Cycle R&D Program Management Structure



3.1.1 ORNL QA Point of Contact/Quality Representative (QR)

The QR assigned to the ORNL FCT Program reports to the ORNL Quality Systems and Services Division (QSSD) and is matrixed to the FCT PM. The QR is responsible for ensuring that the QAP has been established and implemented in compliance to the ORNL Quality Management System (QMS) and the FCT QAPD, and for verifying that activities affecting quality have been satisfactorily performed. The QR shall act as the QA Point of Contact (POC) for FCT Program activities as described in the OFCT QAPD. The QR has sufficient authority, access to work areas, direct access to management, independence from cost and schedule considerations, and the organizational freedom to:

- assist the line organization in planning, developing, and implementing quality programs(s).
- interpret quality assurance program requirements.
- assess the implementation of quality program(s).
- identify quality-related problems and their impacts.
- initiate, recommend, or provide solutions to quality-related problems through designated channels.
- verify implementation of solutions.
- initiate stop work orders in consultation with the affected line organization management when a condition adverse to quality cannot be satisfactorily resolved.
- assure that further deliverable-related activities such as transmittal, processing, delivery, installation, or use is controlled until proper disposition of any related nonconformance, deficiency, or unsatisfactory condition has occurred.
- support coordination of internal and external assessments and responses to assessments.
- assist the organization in assuring that program work is properly documented and reviewed.

3.1.2 Responsibilities for Quality

Program management and technical staff associated with the FCT Program are responsible for the achievement of quality and for continuous improvement. Quality is achieved and maintained by those who have been assigned responsibility for performing work. As the position not directly responsible for performing program work, the QR coordinates the activities to verify achievement of program quality commitments. Each PI is the focal point for the achievement of quality within an activity or task and is the work-level contact for the QR.

In response to FCT program management expectations, each PI develops the overall structure for the work activities or tasks through work planning and control documents and any other documentation considered necessary to satisfactorily define FCT technical workflow. The PI also implements any necessary improvements concerning the work structure based on feedback from participants including sponsors, and is responsible for obtaining desired program results.

3.2 Quality Assurance Program

This section of the QAP defines the processes and actions to meet the requirements of NQA-1-2008, Part 1, Requirement 2.0, and 10CFR50 Appendix B, Criterion II, both entitled *Quality Assurance Program*. Applying these requirements in a judicious fashion based on the activities and deliverables associated with each activity or task, the QAP provides for planning and

accomplishing activities affecting quality under suitably controlled conditions. Decisions concerning applicability of the requirements of the referenced standards to ORNL's current scope of work are documented in this plan and in the QA implementing procedures. The resulting QAP has been designed to ensure that appropriate planning is established and implemented commensurate with ORNL's responsibilities for the:

- health and safety of workers and the public.
- environmental protection.
- reliability and continuity of operations.
- successful accomplishment of the program's mission and objectives.
- acquisition of valid results and completion of program deliverables.

This QAP is prepared and shall be reviewed, approved, issued, implemented, and maintained for ORNL organizations and staff responsible for performing quality-related activities governed by requirements imposed by DOE and its representatives. Before FCT activities are closed out, open or incomplete quality-related action items shall be resolved, records shall be completed and transmitted as required, and leftover or archival materials shall be shipped or disposed of in accordance with applicable regulations and agreements between the program and DOE or any entities designated by DOE.

The ORNL Quality Assurance Program is implemented by line management. This QAP identifies applicable requirements referenced in Section 2.0 to be implemented for ORNL FCT activities. The controls required by this QAP will be administered on a graded basis with the importance of activities and consequence of failure as the grading criteria. The previously-referenced NQA-1-2008, Part 1, Subpart 4.2 guidance applicable to nuclear-related R&D will be the basis for applying the needed level of rigor with emphasis upon the deliverables resulting from each activity. Decisions concerning applicability will then be used to assign the FCT QAPD-mandated quality levels for assigned work package milestones.

Identifying the primary deliverables based on work package and milestone descriptions and prior to the commencement of work promotes the application of the appropriate work controls to the degree necessary to ensure that applicable requirements are met. In summary, the degree of requirements application is based upon (1) the work activities performed and the controls necessary to ensure the quality of results, (2) the consequence of failure of work activities to program success, and 3) the final deliverables and their intended use.

3.2.1 Activities Grading and Work Planning, Control, and Documentation Considerations

The management controls described in this plan and in the associated implementing documents provide systems, processes, and tools that enable the ORNL FCT Program to deliver products that effectively address the needs and requirements of the program sponsor. Quality controls shall be applied to the degree commensurate with the:

- function or end use of the publication, report, data/information set, item, service, or other final deliverable.
- consequence of failure (risk) associated with the publication, report, data/information set, item, service, or other final deliverable..
- importance of the data or information being collected or analyzed.

- complexity of the equipment/software required to produce each deliverable.
- uniqueness of the deliverable or degree of standardization.
- degree to which functional compliance can be demonstrated through inspection or testing.

Activities that have the potential to impact the quality of the deliverables for which ORNL is responsible are defined as quality-affecting activities. As previously stated, the program shall provide control over quality-affecting activities to an extent consistent with their importance to results associated with the project deliverables and implementing the grading guidance provided in NQA-1-2008, Part IV, Subpart 4.2. For any future planned activities, the PM and PIs, with the support of the QR, shall determine whether work controlling documents are needed prior to the commencement of the associated activity.

Implementing documents applicable to the program scope of work shall translate the QAP requirements into work processes where the QAP does not do so directly. The ORNL FCT PM directs the activities and resources required to develop, proceduralize, and implement this QAP and is responsible to ensure that each PI and staff members under their work consider the following elements during work planning activities:

- definition of the work scope, objectives, and a listing of the primary activities involved.
- identification and intended subsequent use of each associated deliverable.
- appropriate application of the quality assurance requirements.
- definition of the necessary activities and how they are to be accomplished.
- identification or development of appropriate implementing documents.
- identification of equipment and software to be used.
- identification of prerequisites, special controls, environmental conditions, processes, or skills needed to complete planned work successfully..
- identification of applicable technical and management controls, required records, and verification activities.
- assignment of responsibilities.
- training and qualification.
- program closeout activities.

The technical activities undertaken to produce program deliverables are identified by program management and staff and are documented in documents such as experimental/test plans, and other technical planning documents, or in the associated work breakdown structure including work package and milestone descriptions. These documents are expected to be modified to reflect changes in priorities and the course of work activities and are updated by new revisions of the original documents.

Because different work activities conducted in support of the FCT Program may have larger or smaller effects on the overall quality, the rigor of the application of the quality control requirements may vary depending on the needs and impacts of a particular set of work activities.

Laboratory notebooks or alternate records capture and maintenance processes and methods such as computer acquisition and storage of results shall be used as the baseline method of control of technical activities. Alternate records capture and maintenance methods are an

acceptable alternative to the use of a laboratory notebook for the development of processing and testing methods, recording of results, and for the compilation of the records that provide objective evidence of the work performed.

In addition to the use of laboratory notebooks or alternate records capture and maintenance methods, procedures, guidelines, drawings, sketches and similar work controlling documents shall also be used to control the conduct of the work. Other work controlling methods include job specific training, qualification for specific activities by demonstrated competence, and the direct supervision of staff by PIs or other designated personnel. Conduct of processing and testing activities may also be supplemented using recognized, proven methods described in national or international consensus standards or methods, in manufacturers' equipment instructions, and log sheets or other data-recording methods.. In all cases, work control mechanisms shall include a clear description of the controlled conditions necessary for conduct of each activity including the use of appropriate equipment, maintenance of the environmental conditions suitable for accomplishing the activity if any are required, and the processes and methods for assuring that prerequisites for the activity have been satisfied.

Because the ORNL FCT Program includes a number of R&D pursuits, the documentation necessary to accomplish these goals may, in many cases, be produced after-the-fact in research records in an iterative fashion as a result of the initial processing or testing activities. These records will then be used to develop a consistent approach to the conduct of future processing and testing activities.

Work controlling documents, when necessary, are modified during the course of program activities and are updated using processes to ensure change control as described or referenced in Section 3.5 and 3.6 of this plan. Work control for purposes of identifying and mitigating any associated hazards is implemented using the facility-based or laboratory-based systems and processes developed in accordance with ORNL SBMS work control requirements.

Program personnel are responsible to ensure that any documents used are of the latest revision prior to use. Documents with the potential to affect the quality of FCT activities shall be controlled in accordance with Section 3.6 of this plan and shall be prepared, reviewed, and approved in accordance with the requirements described in Section 3.5 of this plan. In addition to documents generated by program participants, pre-work verification that any non-program documents are appropriate for use and of the latest revision is the responsibility of each PI and associated staff members.

This QAP and the associated QA implementing procedures shall be issued through ORNL's web-based Integrated Document Management System and made available to all program personnel.

3.2.2 FCT QAPD-Mandated Quality Rigor Levels

The FCT QAPD requirements for Quality Rigor Level (QRL) designations for each milestone in each FCT work package shall be implemented using the previous section's grading process and in compliance to Section 6.2 of the FCT QAPD. Review and approval of ORNL QRL designations shall follow the stated requirements specified in Section 6.2.

3.2.3 Qualification of Existing Data

Data inputs developed/generated prior to imposition of the QAP shall – in a graded fashion – be reviewed pertinent to the QA rigor under which they were originally generated. Where necessary, these data inputs shall be qualified in support of future FCT work activities based on the guidance contained in NQA-1-2008, Part III, Non-mandatory Appendix 3.1, *Guidance on Qualification of Existing Data*.

3.2.4 Peer/Technical Review of Research and Development Results

R&D activities conducted for the FCT Program at ORNL are primarily documented through periodic reports published by ORNL. Additionally, the research and results may be documented in open literature reports, including scientific journals, technical publications, and conference proceedings. In all cases, the publications and the associated research results are subject to peer review.

All ORNL FCT Program technical reports are internally reviewed according to the publication and clearance process for the Laboratory including review, comment, and modifications - when necessary - from two or more Laboratory staff members not directly involved in the described work but who are qualified to review the documents for scientific merit. Documentation of the peer review process is maintained in the ORNL Publication Tracking System.

When applicable, external publications, reports, and other deliverables receive the same type of Laboratory internal peer review as described above as well as the additional requirements mandated by the OFCT QAPD in Appendix B entitled *Technical Review Requirements and Appendix C entitled Peer Review Requirements*. Post-technical/peer review milestones shall be released by ORNL and submitted to the appropriate external FCT-mandated entities using Appendix E entitled *FCT Document Cover Sheet*.

3.2.5 Evaluation Activities - Independent Audits, Surveillances, and Management Assessment

Evaluation activities commensurate with each scope of work and the potential importance to FCT Program results and deliverables shall be conducted by ORNL to ensure appropriate oversight of activities. FCT program management and the QR are responsible for ensuring that QA audits are conducted by auditing personnel with the competencies required in NQA-1-2008. These competencies and the other NQA-1-2008 stipulations associated with QA auditing processes are addressed through implementation of - including the ORNL documents referenced in - implementing procedure FCT-QA-18.

Surveillance activities shall be conducted on a frequency basis commensurate with the importance of ongoing activities and their potential impact on program results and deliverables. Surveillances shall be scheduled, planned, performed, and documented to ensure effective implementation of program quality requirements in accordance with the requirements of procedure QSSD-QMS-004.

3.2.5 Personnel Training, Qualification, and Certification

Each organization participating in FCT activities is responsible for planning, coordinating, and conducting the necessary performance-based training, and retraining to ensure that suitable proficiency is achieved, maintained, and documented for program activities. The program's goal is to ensure that the satisfactory training, qualification, and certification of personnel performing or managing activities affecting quality to a suitable proficiency is achieved and maintained. Training activities shall be planned, accomplished, and documented in compliance to ORNL SBMS subject area, *Training and Qualification of Staff* and its subordinate procedures. The systems and processes described in these documents are intended to ensure the satisfactory knowledge and performance of personnel, that all necessary training and qualification/certification activities are completed prior to the commencement of the associated work activities, and to ensure that only the personnel who meet the explicit training and related requirements are permitted to perform each activity.

Each organization shall train personnel on a case-by-case basis for the particular program activities to be performed, and is responsible to designate those activities that require qualification of personnel and establishing the minimum requirements for each person. Considerations associated with training, qualification/certification, and associated documentation will include the previous education, training, experience, and proficiency of each individual and the scope, complexity, and importance of each technical activity. Decisions concerning the level of formality of training, qualification/certification, and associated documentation for personnel performing or managing technical activities with the potential to affect the quality of FCT deliverables shall be the responsibility of each PI, with help from the QR and training subject matter experts. Subject matter expertise to ensure that the referenced Training and Qualification SBMS subject area is properly implemented is available from each line organization's Training Officer.

Any required training records shall be identified in work controlling documents or in related documentation and shall be maintained to document technical training. Training or qualification necessary to ensure the quality of FCT results shall be documented where required and include the specific review of reading requirements, specific hands-on training requirements, and the specific requirements necessary to demonstrate satisfactory proficiency.

PIs shall ensure that training planned for each activity establishes the initial necessary proficiency, maintains the proficiency on a timely basis, and promotes the skills and knowledge to adapt to changes in technology, methods, or job responsibilities that may be associated with each activity.

PIs have the option to train the staff on the general conduct of the work or for only specific technical activities associated with the work segment at their discretion. Direct supervision for infrequently conducted activities may be used when extensive training is not practical.

The program participant's line manager shall be responsible for the review of qualification and training needs of program personnel outside of those needed for FCT activities. Examples include site-wide (e.g. new employee) or activity-mandated (e.g. radiation worker) training requirements. Qualification of program personnel may be through a review of each person's previous education and experience, examination of credentials, and/or observation of work performance.

Records maintained by the FCT Program and by associated line organizations of the

implementation for training may take the form of attendance sheets, training logs, personnel training records, records of academic attainment, or acknowledgement of the completion of required reading through emails.

Program personnel will be trained concerning the program quality assurance requirements contained in this plan and in the previously referenced SBMS training and qualification subject area. The training shall be planned and documented and shall include, as a minimum, the required reading of this plan.

Records of training, qualification, and certification including re-qualification/re-certification pertinent to auditors, lead auditors, and inspection and test personnel shall be established and maintained by the program, associated line management, or the ORNL Training organization.

Some work scopes may utilize the services of personnel assigned non-destructive examination (NDE) program responsibilities at ORNL. These personnel shall be qualified in accordance with the ORNL Fabrication, Hoisting, and Rigging Division procedure FD-ADM-ACP-11 entitled *Qualification/Certification Requirements for NDE Examiners* which implements the NQA-1-2008-referenced non-destructive examination standard ASNT-TC-1A and its supplements.

When applicable, the cognizant PI is responsible for assuring the identification of any special physical characteristics or attributes needed by personnel to perform an activity, including the need for initial and subsequent physical and vision examinations.

3.2.6 Quality Problem Detection and Prevention

The ORNL FCT Program participates in the quality improvement initiatives mandated through ORNL's QA program. Participants in the program prepare and report results through line and staff organization mechanisms as required by plans, procedures, and ORNL requirements that are used as input to management decisions affecting the success of the program.

Processes to monitor performance, identify weaknesses and deficiencies, share lessons learned, and establish and implement corrective actions are part of the quality improvement process. These processes shall be defined in select evaluations – including audits, surveillances, and assessments - which are scheduled, planned, performed, and documented to ensure effective implementation of program quality requirements. The identification of weaknesses and deficiencies resulting from conduct of surveillances shall include a determination of whether issues discovered during the course of technical activities represent an issue adverse or significantly adverse to quality. The criterion for this determination is defined in SBMS subject area, *Analysis, Issues Improvement, and Feedback*

Quality improvements in day-to-day program operations are identified and implemented when needed. Changes in processes are controlled and captured through the document revision process or through documentation on equipment run sheets or logs, and in laboratory notebooks or alternate records compilations. Problems that transcend a particular program segment shall be communicated to all program participants and to other ORNL staff. Assessments, including surveillances and audits, are used as sources of information concerning scientific, business, and operational performance by management, staff, and clients and provide mechanisms for continuous improvement. Corrective actions from evaluations and other

sources are tracked to completion through the ORNL Assessment and Commitment Tracking System (ACTS).

3.2.7 Resolution of Quality Disputes

Information concerning problems noted at the working level will be conveyed to the PI. The PI and QR will work to define the problem, its cause, and recommended resolution. The problem will then be documented and resolution implemented. Any differences of opinion or continuing concerns resulting from problem identification and involving QAP requirements are brought to the attention of the ORNL FCT PM. The PM and the QR will work with the appropriate representative of the affected organization to effect resolution. If this approach does not resolve the problem, it will be elevated to incrementally higher levels of ORNL management until resolved or until DOE management is involved and resolves the dispute.

3.2.8 Stop-Work Authority

Any ORNL staff member shall stop work if the following conditions exist:

- an obvious, serious condition, hazard or near miss.
- a condition viewed as an imminent danger situation.
- no immediate known options to correct the situation and allow the activity to continue safely.
- a situation that could seriously affect the quality of test articles or the associated collected data or program deliverables, especially in the case of test articles that will undergo destructive testing.

A stop-work action under these conditions is conducted according to ORNL SBMS subject area, *Stop Work*.

Health, safety, or environmental issues associated with the stop-work condition must be addressed prior to resumption of operations and approval obtained from the relevant facility and laboratory entities. For any suspension of operations, actions prerequisite to resumption will be identified and verified as complete prior to resumption in accordance with the referenced subject area. Reporting of FCT-related stop work actions shall be based upon the previously-referenced SBMS subject area. The ORNL FCT PM shall determine the extent of external reporting coverage including notification to the work sponsor.

3.3 Design Control

The requirements of ASME NQA-1-2008 Requirement 3.0 and 10 CFR 50 Appendix B Section III, both entitled *Design Control*, are implemented and applied in accordance with this section of the QAP. Any design activities shall include the identification, documentation, and review and approval of the applicable appropriate quality standards to be applied to the design. The baseline design requirements are those contained in the NQA-1-2008 standard. Design review shall include the verification of critical characteristics which are defined as those that provide reasonable assurance that the item or equipment performs its intended function.

The primary design documents for nuclear R&D activities are:

- test plans or product specifications often jointly developed between the sponsor and ORNL based on any sponsor-mandated test requirements (owning ORNL organization – task manager’s technical division).
- software control plans and other documentation related to the design/development of software.
- configuration drawings or sketches for each type of test specimens (owning ORNL organization – task manager’s technical division).
- irradiation capsule and associated design drawings (owning ORNL organization – Reactor and Nuclear Systems Division/RNSD) .

The task manager shall act as the responsible design authority of software developed for nuclear R&D activities. He/she shall identify and document the particular design verification process used. The results of design verification shall be documented with the identification of the task manager or his/her designee clearly indicated. Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. Whether for test article, other designed items, or software, verification may be performed by the originator’s group leader, provided:

- the group leader did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design.
- the supervisor is the only individual in the organization competent to perform the verification.

Any type of cursory design review by the group leader will not satisfy the requirement for verification.

If qualification tests are necessary for a design, testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions shall be considered in determining the most adverse conditions.

Interface controls among design participants shall include assignment of responsibility and establishment of procedures among participating design organizations for review, approval, release, distribution, and revision of documents involving design interfaces. Design information transmitted across interfaces shall identify the status of the subject design information or document and identify incomplete items which that require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

The complete set of requirements mandated by the sponsor and addressed by ORNL to implement the necessary test requirements are contained in QA implementing procedure NR&D-QA-08. Test specimen configuration drawings or sketches produced by ORNL shall be controlled documents, shall have a unique drawing number and revision number assigned to them, and shall be issued prior to performing the work for which the drawing or sketch is produced. Each drawing or sketch shall be developed and signed by an individual with the appropriate background for developing the candidate drawing or sketch. The QR shall also review and sign indicating approval to ensure that the drawing or sketch is reflective of the

original design and contains the QA requirements necessary to ensure that test articles are produced and controlled in compliance to program requirements. Any additional external review requirements imposed by the sponsor shall be identified and implemented.

No laboratory-based testing or processing equipment currently utilized for nuclear R&D activities at ORNL is anticipated to be regulated under a configuration management process. The R&D equipment used for these activities shall be satisfactorily controlled through test control and pre-operational qualification requirements described in QA implementing procedure NR&D-QA-08. Control of associated calibration activities shall be established and maintained through implementation of the ORNL SBMS subject area entitled *Calibration*. In-house, unique, one-of-a-kind equipment shall be documented in drawings or sketches to a detail level necessary to address any future needs for research repeatability.

3.3.1 Software Design

ORNL research activities covered under this QAP shall primarily utilize off-the-shelf software. Any additional software including software-based models developed in-house shall be evaluated against the applicable SBMS requirements contained in the Information Technology Management System under the subject area entitled *Software Quality Assurance for Software Owners and Users* and implementation shall address applicable NQA-1-2008 software design and development requirements. In-house developed software inputs and outputs shall be verified and validated using alternate calculation methods, testing with materials providing a known and verified result, or through peer review. In-house developed software shall also be configuration controlled.

Software design verification shall be performed by competent individuals or group other than those who developed and documented the original design, but who may be from the same organization.

RNSD activities associated with the design, fabrication, assembly, and pre-irradiation testing of test capsules is controlled in accordance with ORNL High Flux Isotope Reactor Procedure EG-1, latest revision entitled *Review and Approval Process for HFIR In-Vessel and Gamma Irradiation Experiments* and any additional procedures generated by the RNSD to address EG-1 requirements.

On the basis of the previously-described activities associated with design and development, ORNL applies the associated quality requirements on a graded basis as described in the site QA Program Description in the section entitled *Graded Approach*. Controlled test article configurations – most often defined in national or international standards and agreed to with the sponsor - shall be used in the machining of test articles.

Based on the previous information, the most stringent rigor in application of quality requirements associated with nuclear R&D shall primarily apply to irradiation capsule design and development activities. Design and development stages for irradiation capsules are well defined through RNSD procedures. Capsule design review, verification, and validation requirements including the formulation of appropriate calculations for each development stage and the applicable responsibilities and authorities are governed by these procedures and by the requirements of RRD procedure EG-1. The interfaces among R&D divisions, RNSD, and RRD are clearly defined in both RNSD and RRD procedures to facilitate effective communication and clear

assignment of responsibility. RNSD - as the capsule design authority – updates and finalizes the capsule designs as development progresses.

The inputs applicable to capsule design are defined in both RNSD and RRD procedures. These inputs include:

- irradiation functional and performance requirements and associated performance calculations.
- applicable statutory and regulatory requirements governed through RRD as the reactor owner/operator organization.
- previous and often similar capsule designs. Most capsules currently planned or under irradiation have been verified for their adequacy over years of experience and through numerous cycles in the reactor.
- any other unique technical requirements that may be essential for effective design and development.

The RNSD and RRD procedures provide for the review for adequacy, and verification that requirements incumbent upon each capsule design are complete, unambiguous, and non-conflicting.

Outputs associated with capsule design and development are approved prior to release after verification against the design inputs. These outputs are explicitly verified to:

- meet the input requirements as defined by RNSD and verified by RRD for capsule design and development.
- provide appropriate information for the purchase of materials, sub-assembly production, capsule assembly and loading, and for any associated pre-irradiation inspections mandated by the design documents.
- define or reference capsule inspection points and acceptance criteria.
- specify the characteristics of each capsule design that are essential for its safe and compliant use in conformance to technical specifications and reactor operating requirements.

Any substantive design changes shall be approved by the same affected groups or organizations that reviewed and approved the original design documents. Any change in organization causing a related change in ownership of the design shall include the designation of the new responsible organization.

The stages for systematic review of capsules designs are defined in RNSD and RRD governing procedures. These procedures explicitly require that design and development results be evaluated – first by RNSD personnel, and then by RRD as the reactor owner/operator – to ensure that the applicable technical and quality requirements are met prior to acceptance by RRD for subsequent irradiation. This evaluation also ensures that any associated problems are clearly identified and documented through the ORNL nonconformance control process. This process requires that applicable corrective or preventive actions be defined and addressed. The governing procedures clearly define the technical, management, and quality reviews required for this process, and each review is documented including any resulting actions. All final capsule data packages require two documented QA reviews prior to release for installation and irradiation.

3.4 Procurement Document Control

The requirements of NQA-1-2008, Part 1, Requirement 4.0 and 10CFR50, Appendix B, Criterion IV, both entitled *Procurement Document Control*, will be implemented and applied in accordance with ORNL SBMS subject area, *Purchasing Supplies and Services*.

3.5 Instructions, Procedures, and Drawings

The requirements of NQA-1-2008, Part 1, Requirement 5.0 and 10CFR50, Appendix B, Criterion V, both entitled *Instructions, Procedures, and Drawings*, will be implemented and applied in accordance with this section of the QAP, individual document development and implementation requirements of each participant division, and the SBMS subject area, *Internal Operating Procedures*.

Each PI is authorized and responsible for making decisions concerning when and for what activities procedures, guidelines, or work instructions (collectively referred to as work controlling documents) shall be used. Because of the nature of the scope of work that constitutes the FCT activities at ORNL, laboratory notebooks and alternate records capture and maintenance processes and methods may be used to control work activities. National consensus standards and manufacturer's operating manuals may also be used in place of work controlling documents. In any case, measures will be taken to ensure that processes are defined and repeatable in pursuit of consistency of FCT results. Because of the iterative and developmental nature of many of the work scopes constituting the ORNL FCT Program, the development of test plans and associated methods for operation will become more formal as progress is made in defining and conducting technical activities. This progress will be reflected in the establishment of work controlling documents necessary to conduct future work in a repeatable fashion.

Established documents that affect the performance of the work such as procedures, guidelines, work instructions, drawings, sketches, and procurement specifications will be controlled to ensure that the proper version of the document is supplied to the personnel performing associated activities. Each document used in performance of the work shall be identified using a unique number and revision number. Where applicable, the document will contain appropriate acceptance criteria. The PI, line manager, or a designee shall approve these documents and any subsequent changes that may become necessary as activities progress. The PI or line management – with input from the QR – shall determine which documents are controlled. The latest revisions of the QAP, subordinate implementing procedures, and applicable SBMS document revisions are available on the Laboratory's web-based system for use by staff.

3.6 Document Control

The requirements of NQA-1-2008, Part 1, Requirement 6.0 and 10CFR50, Appendix B, Criterion VI, both entitled *Document Control*, shall be addressed through the requirements described in

this section, implementation of individual document development and implementation requirements of each participant division, and the SBMS subject area, *Internal Operating Procedures*.

3.6.1 Use of Laboratory Notebooks

Each PI is responsible to determine the need for the use of technical procedures or other formal work controlling documents in conduct of activities under their purview. Laboratory notebooks or alternate records capture and maintenance processes and methods may be used in many cases in place of technical procedures and other work controlling documents. They are used to record original research data and will contain:

- original description of ideas, concepts, data, calculations, notes, and sketches pertinent to the research.
- identification of individuals performing the research and making the entry.
- identification of samples or test articles.
- any unusual measuring and test equipment calibration requirements.
- a description of the planned work, methods used to perform the work, any changes to the described methods, and the results obtained.
- any references to pertinent research data not located in the notebook.

The ORNL SBMS Records Management System contains the exhibit procedure entitled *Instructions For Use Of This Research And Technical Notebook*, which provides guidelines for use and preparation. The following practices are to be followed in the preparation and use of scientific/laboratory notebooks:

- entries shall be independently reviewed on a quarterly basis and the review documented by signature and date.
- a statement of purpose shall be included in the front of each laboratory notebook or alternate test record notebook.
- the persons authorized to make entries in the notebook shall be identified in the front of the notebook.
- unused space on each page of the notebook shall be lined out, to prevent reuse.
- a table of contents shall be included in the completed notebook.

In-process and completed project laboratory notebooks and alternate records types shall be protected to prevent unauthorized entries, damage, loss, and deterioration. When appropriate, the critical data and process descriptions in notebooks are collected and documented in topical or progress reports and other formats sanctioned under applicable ORNL SBMS subject areas.

Technical notebooks and alternate records shall be maintained as back-up data to technical reports or data packages. Large amounts of data may also be stored in an electronic form. These shall be periodically backed up to prevent loss.

Controls for scientific and technical information are described in the ORNL SBMS subject area, *Scientific and Technical Information*.

3.7 Control of Purchased Items and Services/Control of Purchased Material, Equipment, and Services

The requirements of NQA-1-2008, Part 1, Requirement 7.0, *Control of Purchased Items and Services* and of 10CFR50 Appendix B, Criterion VII, *Control of Material, Equipment, and Services*, will be implemented and applied in accordance with ORNL SBMS subject area, *Purchasing Supplies and Services*.

3.8 Identification and Control of Items/Identification and Control of Materials, Parts, and Components

The requirements of NQA-1-2008, Part 1, Requirement 8.0, *Identification and Control of Items* and 10CFR50 Appendix B, Criterion VIII, *Identification and Control of Materials, Parts, and Components*, will be implemented and applied in accordance with ORNL FCT QA implementing procedure, FCT-QA-08, *Processing/Testing Items and Materials Identification and Control, Processing, Inspection, Testing, Handling, and Status Requirements*, Section 1.0.

3.9 Control of Special Processes

The requirements of NQA-1-2008, Part 1, Requirement 9.0, and 10CFR50 Appendix B, Criterion IX, both entitled *Control of Special Processes* will be implemented and applied in accordance with ORNL FCT QA implementing procedure, FCT-QA-08, *Processing/Testing Items and Materials Identification and Control, Processing, Inspection, Testing, Handling, and Status Requirements*, Section 2.0..

3.10 Inspections

The requirements of NQA-1-2008, Part 1, Requirement 10.0 and 10CFR50 Appendix B, Criterion X, both entitled *Inspection*, will be implemented and applied in accordance with ORNL FCT QA implementing procedure, FCT-QA-08, *Processing/Testing Items and Materials Identification and Control, Processing, Inspection, Testing, Handling, and Status Requirements*, Section 3.0.

3.11 Test Control

The requirements of NQA-1-2008, Part 1, Requirement 11.0 and 10CFR50 Appendix B, Criterion XI, both entitled *Test Control*, will be implemented and applied in accordance with ORNL FCT QA implementing procedure, FCT-QA-08, *Processing/Testing Items and Materials Identification and Control, Processing, Inspection, Testing, Handling, and Status Requirements*, Section 4.0.

3.12 Control of Measuring and Test Equipment

The requirements of NQA-1-2008, Part 1, Requirement 12.0 and 10CFR50 Appendix B, Criterion XII both entitled *Control of Measuring and Test Equipment*, will be implemented and applied in accordance with this section of the QAP and through implementation of the ORNL SBMS subject area entitled *Calibration*.

Providers of calibration services will be required to document traceability of calibration standards to nationally-recognized standards. Calibration procedures shall identify or reference the required accuracy for each instrument. Methods and frequency of checking the accuracy of calibrated measuring and test equipment (M&TE) shall follow established ORNL calibration procedures or the associated manufacturers' recommendations provided with the equipment.

Where specified, tests will be conducted to determine if the equipment performs as specified before it is put into service. M&TE shall be properly handled and stored to maintain accuracy and instrumentation consistently found to be out of calibration shall be repaired or replaced. M&TE shall be stored, used, and calibrated in accordance with manufacturers' recommendations as described in operating and maintenance documentation such as equipment manuals.

In situations involving M&TE found to be out of calibration, an evaluation regarding the validity of the data previously taken with the M&TE item will be conducted and documented.

3.13 Handling, Storage, and Shipping

The requirements of NQA-1-2008, Part 1, Requirement 13.0, and 10CFR50 Appendix B, Criterion XIII, both entitled *Handling, Storage, and Shipping*, will be implemented and applied in accordance with ORNL FCT QA implementing procedure, FCT-QA-08, *Processing/Testing Items and Materials Identification and Control, Processing, Inspection, Testing, Handling, and Status Requirements*, Section 5.0.

3.14 Inspection, Test, and Operating Status

The requirements of NQA-1-2008, Part 1, Requirement 14.0, and 10CFR50 Appendix B, Criterion XIV, both entitled *Inspection, Test, and Operating Status* will be implemented and applied in accordance with ORNL FCT QA implementing procedure, FCT-QA-08, *Processing/Testing Items and Materials Identification and Control, Processing, Inspection, Testing, Handling, and Status Requirements*, Section 6.0.

3.15 Control of Nonconforming Items

The requirements of NQA-1-2008, Part 1, Requirement 15.0, *Control of Nonconforming Items*, and 10CFR50 Appendix B, Criterion XV, *Nonconforming Materials, Parts, or Components* are implemented through the ORNL SBMS subject area, *Nonconformance Control*.

In addition to those imposed through implementation of the SBMS subject area, the following additional requirements apply to the control of nonconforming items associated with FCT test articles.

The QR shall manage the nonconformance identification, control, and disposition process in accordance with the SBMS subject area. The PI has the responsibility and authority for the control of further testing, delivery, installation, or use of nonconforming items. Each PI is designated to perform evaluations to determine a disposition for a nonconforming condition associated with FCT activities and shall have demonstrated competence in the specific area they are evaluating, have adequate understanding of the applicable requirements, and have

access to pertinent background information. Demonstrated competence is based upon previous education and experience.

Nonconformances associated with applicable design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. Required drawings, test article or other fabrication documentation, and other associated records shall reflect the use-as-is or repair condition of the associated FCT item, test article, or any other type of deliverable. Reworked or repaired items shall be re-examined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria. All nonconformance reports shall be reviewed and approved by the FCT PM, PI, and QR. Other subject matter expertise may be added to the review when needed.

3.16 Corrective Action

The requirements of NQA-1-2008, Part 1, Requirement 16.0 and 10CFR50 Appendix B, Criterion XVI, both entitled *Corrective Action*, are implemented through FCT QA implementing procedure, FCT-QA-16. ORNL activities in response to Nuclear Regulatory Commission defect and non-compliance requirements imposed through 10CFR21 are also addressed in FCT-QA-16.

3.17 Quality Assurance Records

The requirements of NQA-1-2008, Part 1, Requirement 17.0 and 10CFR50 B, Criterion XVII, both entitled *Quality Assurance Records*, are addressed in this section of the QAP and through implementation of the SBMS subject area entitled *Records*.

The FCT Program shall capture and maintain quality assurance records that furnish documentary evidence that items or activities meet 1) specified quality requirements and 2) customer's expectations for final deliverables. These records shall be documented in various forms including laboratory notebooks, alternate records types, other associated equipment-related documentation such as logs or run sheets, and in electronic formats that allow for efficient retrieval. PIs and their designees are responsible to ensure that records are:

- identified.
- generated to provide objective evidence of work performed.
- authenticated by periodic review by someone other than the person responsible for generation.
- maintained in a way that ensures their retrieval.
- specified as to final disposition.

3.17.1 QA Records Requirements and Responsibilities

Each PI is responsible to ensure that QA records are identified and maintained in a legible form, are traceable to associated items and activities, accurately reflect the work accomplished or information required for each item or activity, and stored to prevent damage, loss, or degradation. A listing of candidate QA records is provided in Appendix B of this QAP. The PI shall ensure that laboratory notebooks are validated and authenticated by periodic signing and

dating of entries by persons other than those directly responsible for generating the records. Validation and authentication actions may also include independent review of any needed data package information prior to transmittal to external entities.

Based on the QA records definitions for permanent and non-permanent records contained in the NQA-1 standard, all ORNL records generated for FCT activities are classified as non-permanent. Non-permanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained by ORNL for the life of the item because they do not meet the criteria for lifetime records.

Based on the non-permanent classification, records generated for the program shall be maintained for a minimum period of five years. After that time, no records shall be disposed of, shipped off-site, or destroyed until DOE is consulted and permission obtained in writing.

Records pertinent to materials and associated items received from other organizations shall be maintained by the PI or his designee as a subset of the work scope QA records set and stored in the applicable laboratory notebook or through alternate records capture/maintenance processes and methods. Examples include procurement records for calibrated equipment and materials certifications provided by external program participants or suppliers.

FCT records shall be stored so that they are protected from damage or loss. Methods to be used include the following:

- records stored in metal file cabinets in offices locked during off-hours and in buildings restricted to those with appropriate electronic entry credentials.
- In-process records such as laboratory notebooks kept in laboratories under access control requirements during working hours.
- protection of electronic records media.
- room temperature maintenance by standard thermostat controls.
- maintenance of records in designated no-smoking areas and protection by sprinkler systems.

No situations associated with FCT activities have been identified that would require dual storage facilities or containers.

Each PI is responsible to ensure that records under his/her purview are maintained for the minimum five-year retention period and that no actions are taken to dispose of records at the end of the five-year period unless authorized through the FCT PM. The QR shall coordinate final disposition of records after consultation with the appropriate DOE or DOE-designated entity. The PI is responsible to ensure that records are protected from damage or loss and maintained in a retrievable form.

Corrections to QA records shall include the dated initials or signature of the person authorized to make the change. Persons authorized to correct QA records include the originator of the record, the PI, and the PM. The only approved method for correcting a QA record is to draw a single line through the information to be replaced, and hand-write the new information into the record. The new entry shall be initialed and dated by the authorized person. Use of White Out™ or any other method of correction is not permitted.

Records shall be reviewed for any special storage needs. Examples include considerations associated with radiographs, photographs, negatives, microfilm, and magnetic and optical media to prevent damage from excessive light, stacking, electromagnetic fields, temperature and humidity. Archival material specimens shall be stored to prevent damage or deterioration, and to ensure maintenance of material pedigree and traceability.

3.18 Audits

The requirements of NQA-1-2008, Part 1, Requirement 18.0 and 10CFR50 Appendix B, Criterion XVIII, both entitled *Audits*, will be implemented and applied in accordance with ORNL FCT QA implementing procedure, FCT-QA-18, *Independent Assessment*.

APPENDIX A - REQUIREMENTS APPLICABILITY AND IMPLEMENTING DOCUMENT MATRIX

Note: The 19 requirements sections contained in QAP Sections 3.1-3.19 are applicable to ORNL's scope of work as described in the QAP and as implemented through the documents referenced in this matrix. The application of the requirements to each FCT work scope shall be based on the OFCT-mandated quality-level determination (1-3) and the stipulations contained in QAP Section 3.2.1.

NQA-1-2008/ 10CFR50 Appendix B	ORNL IMPLEMENTING DOCUMENTS
1. Organization	QAP-ORNL-FCT-01, Quality Assurance Plan and Interface Document for Fuel Cycle Technology Research and Development Activities Conducted at the Oak Ridge National Laboratory , Section 3.1, Organization
2. QA Program	QAP-ORNL-FCT-01, Quality Assurance Plan and Interface Document for Fuel Cycle Technology Research and Development Activities Conducted at the Oak Ridge National Laboratory , Section 3.2, Quality Assurance Program ORNL Standards Based Management System, Quality Management System: Quality Assurance Program Description Note: ORNL's web-based SBMS documents are not numbered, only titled. Revision control is managed through issue dates and on-line document history summaries.
Evaluation Activities-Independent. Audits, Surveillances & Management Assessments	QSSD-QMS-004, Independent Assessments
Training and Qualification	QAP-ORNL-FCT-01, Quality Assurance Plan and Interface Document for Fuel Cycle Technology Research and Development Activities Conducted at the Oak Ridge National Laboratory , Section 3.2.4, Quality Assurance Program ORNL Standards Based Management System Subject Area: Training and Qualification of Staff
Stop-Work Authority	ORNL Standards Based Management System Subject Area: Stop/Suspend Work
3. Design Control	QAP-ORNL-FCT-01, Quality Assurance Plan and Interface Document for Fuel Cycle Technology Research and Development Activities Conducted at the Oak Ridge National Laboratory , Section 3.3, Design Control
4. Procurement Document Control	ORNL Standards Based Management System Subject Area: Purchasing Supplies and Services

NQA-1-2008/ 10CFR50 Appendix B	ORNL IMPLEMENTING DOCUMENTS
5. Instructions, Procedures, and Drawings	ORNL Standards Based Management System Subject Area: Internal Operating Procedures QAP-ORNL-FCT-01, Quality Assurance Plan and Interface Document for Fuel Cycle Technology Research and Development Activities Conducted at the Oak Ridge National Laboratory , Section 3.5, Instructions, Procedures, and Drawings
6. Document Control	ORNL Standards Based Management System Subject Area: Internal Operating Procedures ORNL Standards Based Management System Procedure: Instructions for Use of This Research and Technical Notebook
7. Control of Purchased Items and Services/ Control of Purchased Materials, Equipment, and Services	ORNL Standards Based Management System Subject Area: Purchasing Supplies and Services
8. Identification and Control of Items/Identification of Materials, Parts, and Components	FCT-QA-8, Processing/Testing Items and Materials Identification and Control, Processing, Inspection, Testing, Handling, and Status Requirements , Section 1.0
9. Control of Special Processes	FCT-QA-8, Processing/Testing Items and Materials Identification and Control, Processing, Inspection, Testing, Handling, and Status Requirements , Section 2.0
10. Inspection	FCT-QA-8, Processing/Testing Items and Materials Identification and Control, Processing, Inspection, Testing, Handling, and Status Requirements , Section 3.0
11. Test Control	FCT-QA-8, Processing/Testing Items and Materials Identification and Control, Processing, Inspection, Testing, Handling, and Status Requirements , Section 4.0
12. Control of Measuring and Test Equipment	ORNL Standards Based Management System Subject Area: Calibrations
13. Handling Storage and Shipping	FCT-QA-8, Processing/Testing Items and Materials Identification and Control, Processing, Inspection, Testing, Handling, and Status Requirements , Section 5.0

NQA-1-2008/ 10CFR50 Appendix B	ORNL IMPLEMENTING DOCUMENTS
14. Inspection, Test and Operating Status	FCT-QA-8, Processing/Testing Items and Materials Identification and Control, Processing, Inspection, Testing, Handling, and Status Requirements , Section 6.0
15. Control of Nonconforming Items/ Nonconforming Materials, Parts, and Components	ORNL Standards Based Management System Subject Area: Nonconformance Control FCT-QA-16, Corrective Actions Associated with FCT Program Activities
16. Corrective Action	ORNL Standards Based Management System subject area: Analysis, Issues Improvement, and Feedback ORNL Standards Based Management System Subject Area: Stop Work
17. Quality Assurance Records	QAP-ORNL-FCT-01, Quality Assurance Plan and Interface Document for Fuel Cycle Technology Research and Development Activities Conducted at the Oak Ridge National Laboratory , Section 3.17, Records Management
18. Audits	ORNL SBMS subject area: Audits and Assessments Nuclear R&D QA implementing procedure: NR&D-QA-18, Audits and Independent Assessments QSSD-QMS-001, Qualifying Auditors and Certifying Lead Auditors
19. Software	ORNL Standards Based Management System Subject Area: Software Quality Assurance

APPENDIX B - LIST OF CANDIDATE FCT RECORDS*

Laboratory notebooks
Technical reports (If the content meets the definition of a QA record)
Material certifications
Procurement records
Test/analysis/inspection results
Personnel qualification records
Surveillance and audit reports
Measuring and test equipment calibration procedures and records
Equipment as-built design drawings
Equipment operating records
Design review results
Completed processing information/data/log sheets
Inspection and test reports
Receiving inspection reports
Corrective action tracking closeout/validation records
Peer reviewed publications and associated records
Audit reports
Surveillance reports
Nonconformance reports
Corrective actions and associated objective evidence of closure in ACTS
Product/deliverables-related data/information

* **Note:** In many cases, records may be in electronic as well as paper format