FUEL CYCLE TECHNOLOGIES
Quality Assurance Program Document

Revision 2
Effective Date
12/20/2012

U.S. DEPARTMENT OF ENERGY
Nuclear Energy

Fuel Cycle TECHNOLOGIES
safe • secure • sustainable

FCT Quality Assurance Program Document

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12/20/2012

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Revision History

REV.	EFFECTIVE DATE	REVISION DESCRIPTION
0	Date of Approval on Page 1	Initial issuance by the Office of Fuel Cycle Technologies, NE-5 – Reflects the new organization and principles described in the FCT Program Management Plan dated July 13, 2010 – Supersedes and replaces Advanced Fuel Cycle Initiative Quality Assurance Program Document, AFCI-TIO-PMO-QA-PL-2009-000042, dated April 2009.
1	Date of Approval on Page 1	Reflects minor editorials, typographical error corrections, and concurrence/approval changes. Also reflects the new reporting requirement of FCT QA Manager to ADAS. This revision supersedes all previous QAPD's issued.
2	Date of Approval on Page 1	Reflects minor editorials, changes to Table 1 and Appendix E, clarification of the term "N/A" as applied to Lab / Participant QA Program and QAPD requirements, and usage of PICS:NE Deliverable Form. This revision supersedes all previous QAPD's issued.

LIST OF ACRONYMS

AFCI	Advanced Fuel Cycle Initiative
ANSI	American National Standard Institute
ASME	American Society of Mechanical Engineers
CAES	Center for Advanced Energy Studies
DAS	Deputy Assistant Secretary
DOE	U.S. Department of Energy
FCR&D	Fuel Cycle Research and Development
FCT	Fuel Cycle Technologies
HQ	Headquarters
M&TE	Measuring and Test Equipment
NE	DOE Office of Nuclear Energy
NEPA	National Environmental Policy Act
NEUP	Nuclear Energy Universities Program
NQA-1	ASME Document, Quality Assurance Requirements for Nuclear Facility Applications
NRC	Nuclear Regulatory Commission
NTD	National Technical Director
POC	Point of Contact
PMP	Program Management Plan
QA	Quality Assurance
QAPD	Quality Assurance Program Document
QA POC	Quality Assurance Point of Contact
QRL	Quality Rigor Level
R&D	Research and Development
RD&D	Research, Development and Demonstration
TI	Technical Integrator

1.0 INTRODUCTION

The Office of Nuclear Energy (NE) was reorganized effective May 23rd, 2010 and a Program Management Plan (PMP) for the Office of Fuel Cycle Technologies, NE-5, was issued on July 13, 2010[1] .

1.1 Purpose and Applicability

The purpose of this Fuel Cycle Technologies (FCT) Quality Assurance Program Document (QAPD) is to define quality assurance (QA) requirements for the FCT Program. These requirements are applicable to FCT activities and Participants (see definition) to the extent defined herein. In developing these requirements, it is recognized that each Department of Energy (DOE) National Laboratory is required to have a DOE or NNSA-approved QA program which complies with the requirements of DOE Order 414.1 or its equivalent, as well as those specified in 10 CFR 830.1 Subpart A if applicable. The quality requirements specified in this document are to be accomplished in addition to all specific site requirements.

This QAPD is the top-level quality policy and requirements document for the FCT program. The QA requirements specified herein apply to Participants that manage and/or perform work within FCT. Development and implementation of the FCT QAPD is consistent with the DOE Office of Nuclear Energy (NE) Quality Assurance Program Plan Revision 1 (approved April 2008).

The majority of the work for the FCT program is performed at the National Laboratories. Therefore the main focus of this document is on the FCT activities conducted by these laboratories. The QA requirements in this document are specified at three Quality Rigor Levels (QRLs) for work to be performed by National Laboratories, plus another category labeled Lab / Participant QA Program (no additional FCT QA requirements). Generally, procedures and processes established to implement a DOE approved QA Program will be sufficient to meet the Quality Rigor Levels 2 and 3 requirements of this QAPD. Additionally, Participants' procedures and processes that are in place to implement an established NQA-1 Standard should generally be sufficient to meet the Quality Rigor Level 1 requirements. The FCT QAPD provides clarifications to certain existing requirements (such as peer review) and specifies a limited number of discrete requirements for the purpose of ensuring consistent application of QA principles for FCT activities. Some of these requirements may require revisions to existing procedures or issuance of new procedures by Participants to comply with the QAPD requirements and concurrently maintain compliance with site specific quality program requirements.

Each National Laboratory conducting FCT work is required to maintain their interface document describing the application of their QA program (including implementing procedures) to FCT activities. Participants shall review their interface document upon issuance of a FCT QAPD revision to ensure consistency and make appropriate changes to the interface document if required.

This QAPD does not apply to the work conducted by universities under DOE grants. Requirements are specified within this QAPD for other FCT work to be performed by

[1] Fuel Cycle Technologies, Program Management Plan, July 13, 2010

universities. A minimum set of QA requirements for university participants under contract with the Idaho National Laboratory (INL) for the Nuclear Energy Universities Program (NEUP) are provided in Appendix D. Universities performing FCT work as a subcontractor to a National Laboratory follow the requirements of this FCT QAPD as flowed down through contractual documents. National Laboratories may use Appendix D or other means to identify and flow down requirements to universities performing work under contract with them.

NOTE: *This QAPD describes the process for designating Quality Rigor Levels (QRLs) which are not to be confused with milestone levels for milestones / deliverables.*

This QAPD revision is effective immediately upon issuance.

1.2 Background on FCT Technical Mission and Scope

The Office of Nuclear Energy (NE) recently issued a R&D roadmap[2] for its research, development and demonstration (RD&D) activities to ensure nuclear energy remains a compelling and viable energy option for the United States. The roadmap defines NE RD&D activities according to four R&D Objectives that address the challenges to expanding the use of nuclear power. The R&D Objectives are: (1) Develop technologies and other solutions that can improve the reliability, sustain the safety, and extend the life of current reactors; (2) Develop improvements in the affordability of the new reactors to enable nuclear energy to help meet the Administration's energy security and climate change goals; (3) Develop sustainable fuel cycles; and (4) Understand and minimize the risk of nuclear proliferation and terrorism. Within NE, the primary responsibility for achieving Objective 3, Develop Sustainable Fuel Cycles, has been assigned to the Office of Fuel Cycle Technologies, NE-5. Accordingly, the mission of the Office of Fuel Cycle Technologies 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.*

To achieve this mission the following 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; and
- By 2050, demonstrate the selected fuel cycle options at sufficient scale to enable commercialization.

Achieving these objectives will require development of technologies in the following eight major critical technical areas (referred to as R&D pathways or campaigns):

- Fuel Cycle Systems Analysis;
- Fuel Resources;
- Fuels Technology;
- Separations Technology;
- Waste Forms Technology;
- Storage, Transportation and Disposal;
- Transmutation Technology (including advanced reactors); and

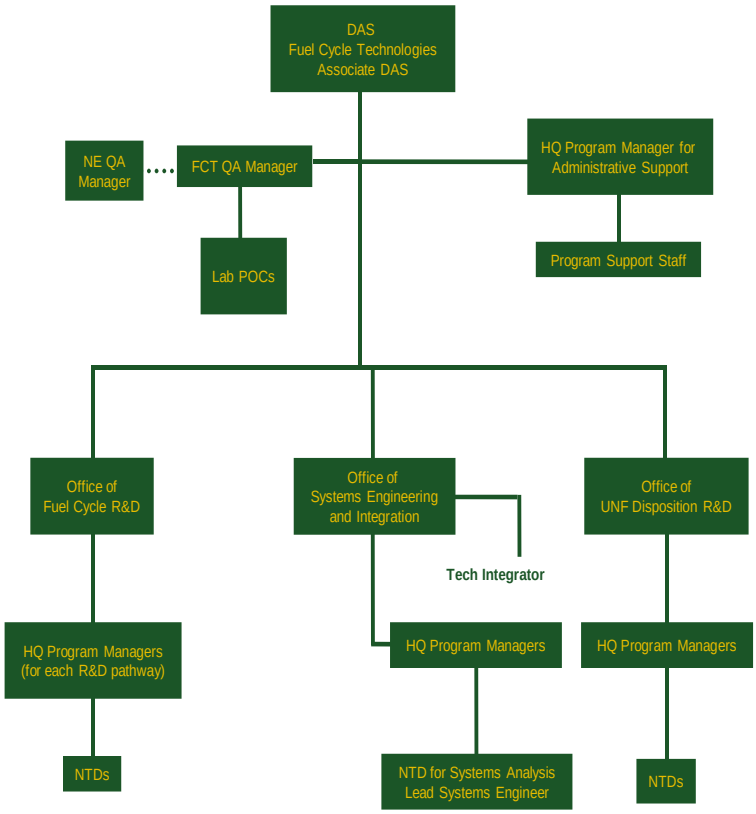
[2] Nuclear Energy Research and Development Roadmap, Report to Congress, April 2010

- Materials, Protection, Accountability and Control Technology.

Each campaign is led by a National Technical Director (NTD) and the program has designated a Technical Integrator (TI) to help integrate all R&D activities conducted under the FCT program.

2.0 FCT ORGANIZATION, ROLES AND RESPONSIBILITIES

The organizational structure for the Office of Fuel Cycle Technologies is depicted below:



NOTES: *(1) DAS has delegated the responsibility of defining FCT QA requirements and overseeing their implementation to the Associate DAS for Fuel Cycle Technologies. (2) The organization chart above does not reflect contractual interfaces between DOE and Laboratory Site Offices.*

The PMP describes roles and responsibilities in the FCT organization. Roles and responsibilities associated with QA for each organizational element are described next:

Deputy Assistant Secretary (DAS) for Fuel Cycle Technologies:

- Provides leadership to define and achieve Fuel Cycle Technologies Program mission, goals and objectives;
- Directs program planning and management and authorizes budgets for program activities;
- Approves FCT program baseline costs and schedules, and approves changes to baseline in accordance with relevant procedures;
- Approves and issues programmatic implementing procedures, through site offices where applicable, for execution of FCT program activities including this QAPD; and
- Ensures appropriate FCT QA resources are allocated to support the program, through site offices where applicable.

NE Quality Assurance Manager:

- Provides advice and assistance to the DAS and the HQ FCT QA Manager in developing program specific QA requirements and overseeing their implementation, and concurs on this QAPD; and
- Coordinates implementation of QA requirements for university-led R&D with other NE programs.

HQ FCT QA Manager

- Prepares FCT Quality Assurance Program Document and coordinates its approval; and
- Defines FCT program specific QA requirements and oversees their implementation including assessing, monitoring, evaluating effectiveness, and reporting results to NE senior management.
    - Coordinates activities with FCT management and staff, TI , NTDs, NE QA Manager as well as with DOE and NNSA Site Offices as appropriate.
    - Conducts formal oversight / assessments (audits / surveillances / reviews) of QAPD activities on as needed basis at his discretion, based on the importance of the tasks, and / or observes FCT QA audits performed by the individual laboratories. (Works through Site Office QA Managers for work performed at NNSA sites).
    - Provides direction to Laboratory QA Points of Contact and approves their work packages.
    - Prepares QAPD training material for FCT program participants. Note that QA POCs can also prepare QAPD training material, in consultation with the FCT QA Manager.
    - Works with Office Directors, NTDs, and the TI for implementation of this QAPD particularly to ensure that applicable QAPD requirements are appropriately reflected in the work packages.
- Provides recommendations and advice to the DAS regarding required resources to effectively implement the QA requirements.

DOE and NNSA Site Offices

The FCT QA Manager is responsible for providing the QAPD to the DOE and NNSA Site Offices on as needed basis. Site Offices make the document available to the Laboratory

(Contractor) QA organization. Site Offices also participate, at their discretion and in consultation with the FCT QA Manager, in FCT QA assessments led by FCT QA Manager. For NNSA sites, audits / surveillances / reviews are conducted through the Site Offices.

National Laboratory QA Organizations

- Designate a QA Point of Contact (POC) for the FCT program at their laboratory;
- Ensure implementation of applicable QAPD requirements; and
- Participate, at their discretion or as directed by their Site Office / FCT QA Manager, in FCT QA audits and surveillances for their laboratory.

HQ Program Managers

- Approve all work packages for their assigned R&D campaign, including designation of appropriate QA Rigor Level in accordance with Section 6.2 of this QAPD; and
- Provide program direction to the cognizant NTD and oversee the technical performance of the work assigned.

Technical Integrator (TI)

- Works closely with the Office Directors, FCT QA Manager, Program Managers and National Technical Directors and provides technical leadership to ensure that program work, including work being performed in cooperation with other DOE programs and Offices, is well-coordinated and integrated, with no gaps or unnecessary duplication within each area and across areas, to achieve the overall objectives of Fuel Cycle Technologies; and
- Helps ensure that work packages appropriately reflect FCT program QA requirements specified in this QAPD, including designation of appropriate QRLs.

National Technical Directors

- Provide technical leadership for their assigned R&D campaigns;
- Approve quality rigor designation for work packages associated with their campaign in accordance with Section 6.2 of this QAPD; and
- Execute approved work plans and monitor progress and quality of R&D for assigned work packages consistent with program quality assurance requirements.

Control Account Managers

- Manage groups of work packages per direction from NTDs;
- Concur with the QRL designation for assigned work packages in accordance with Section 6.2 of this QAPD; and
- Work with the Laboratory QA POC to ensure work package managers and others performing work have a clear understanding of the quality requirements.

Work Package Managers.

- Manage assigned work packages per direction from Control Account Managers and NTDs;
- Develop work package detail including description of scope, milestones and deliverables;
- Designate a QRL for each milestone / deliverable in accordance with Section 6.2 of this QAPD;
- Estimate the resources required to execute the work including those required to implement the requirements of this QAPD; and
- Work with the Laboratory QA POC and others performing the work to ensure that specific QA requirements for the work package are implemented and that objective evidence is maintained of performance to those requirements.

Lead QA Point of Contact (Lead QA POC)

- As described in the approved work packages, supports and assists the FCT QA Manager in assuring that program specific QA requirements are being effectively implemented across the entire FCT program;
- Develops and coordinates issuance of an interface document for his/her laboratory as called for in Section 1.1 of this QAPD;
- Provides and documents indoctrination / training on the FCT QAPD and associated laboratory interface document to laboratory technical staff performing FCT work activities described in approved work packages;
- Provides assistance to laboratory work package managers and others as appropriate in determining Quality Rigor Level(s);
- Coordinates with the Center for Advanced Energy Studies to ensure that the minimum QA requirements for university work specified in Appendix D are incorporated in contracts for the NEUP awards;
- Provides support to laboratory work package managers and other technical staff in determining and implementing applicable QA procedures and policies for their scope of work, and assists with estimating resources for meeting FCT program specific QA requirements;
- Provides assistance to the FCT QA Program Manager in planning, scheduling and conducting QA reviews, including surveillance and assessment activities, across the entire FCT program as directed by the FCT QA Manager;
- Plans, schedules, and coordinates performance of QA surveillance and assessment activities of FCT related work activities at his/her laboratory in consultation with the FCT QA Program Manager;
- Participates in FCT program QA related meetings and represents his/her laboratory at QA POC meetings;
- Participates in R&D campaign Working Group meetings upon approval by the FCT QA Program Manager;
- Provides feedback to his/her laboratory management and the FCT QA Manager on implementation of FCT QA requirements and promptly notifies them and the laboratory Site Office of any performance issues; and

- Assists work package managers in ensuring FCT-related contracts with his/her laboratory appropriately reflect applicable FCT QA requirements.

National Laboratory QA Points of Contact (QA POC)

- As described in the approved work packages, support and assist FCT QA Manager in assuring that program specific QA requirements are being effectively implemented at their laboratory;
- Develop and coordinate issuance of an interface document for their laboratory as called for in Section 1.1 of this QAPD;
- Provide and document indoctrination / training on the FCT QAPD and associated laboratory interface document to laboratory technical staff performing FCT work activities described in approved work packages;
- Provide assistance to laboratory work package managers and others as appropriate in determining Quality Rigor Level(s);
- Provide support to laboratory work package managers and other technical staff in determining and implementing applicable QA procedures and policies for their scope of work, and assist with estimating resources for meeting FCT program specific QA requirements;
- Coordinate performance of QA surveillance, assessment and review activities of FCT related work at their laboratory, in consultation with the FCT QA Program Manager;
- Participate in FCT program QA related meetings and represent their laboratory at QA POC meetings;
- Participate in Working Group meetings held by the National Technical Directors germane to the work packages at their laboratories upon approval by the FCT QA Manager;
- Provides feedback to their laboratory management and to the FCT QA Manager on implementation of FCT QA requirements, and promptly notifies them and their laboratory Site Office of any performance issues; and
- Assists work package managers in ensuring FCT-related contracts with their laboratory appropriately reflect applicable FCT QA requirements.

3.0 QA REQUIREMENTS FOR WORK PERFORMED BY NATIONAL LABORATORIES

This section identifies the quality assurance requirements applicable to the FCT work led by the national laboratories. These are additional requirements and do not replace the laboratory's own QA program.

Quality assurance requirements are specified at three Quality Rigor Levels (QRLs) based on the intended or potential end use of the results of the work being performed. The requirements for each QRL are specified in Sections 3.1 through 3.3 and the process for determining QRLs is described in Section 6.2.

3.1 Quality Rigor Level 1 Requirements

This Quality Rigor Level is generally applied to those activities which directly, indirectly, or potentially support future licensing activities under NRC regulations for potential future facilities. The following table provides examples of these activities and identifies the corresponding quality assurance requirements.

NOTE: *The FCT program will assign lead responsibility for conducting QRL-1 activities only to laboratories having an established NQA-1-2000 (or later version) program. Other laboratories supporting such work are not required to have in place or establish an NQA-1 compliant program in order to meet the requirements of this QAPD. See Section 6.4 for more details.*

Table 1.0 Quality Rigor Level 1

Quality Rigor Level 1	
Examples of Types of Activities	**Quality Rigor Level 1 Requirements**
Activities related to the development of facility safety analysis; experiments, tests, design, and analyses to support regulatory activities as decided by the appropriate Federal Office Manager (NE-5) / NTD. Material code qualification, modeling and simulation (including experimental data to develop the data for modeling and simulation) used for benchmarking of regulatory activities as decided by the appropriate Federal Office Manager (NE-5) / NTD. Development of Nuclear Data.*	Activities shall be conducted in accordance with an established NQA-1-2000 (or later version) quality assurance program. Software design, development, and testing shall meet the requirements of NQA-1-2000 (or later version), Requirement 3, *Design Control*, and Requirement 11, *Test Control*. In addition, a work package may specify that the activities shall meet the requirements of NQA-1 Subpart 2.7 *Quality Assurance Requirements for Computer Software for Nuclear Facility Applications*. The general requirements specified in Section 6 shall also be met. Furthermore, a work package may specify additional QA requirements. The requirements of Appendix A, *Nuclear Data,* shall be met. Furthermore, a work package may specify additional QA requirements.

* *Nuclear Data is included in the above example for completeness; however, it has different and unique requirements from other Quality Rigor Level 1 activities, which are addressed in Appendix A of this FCT QAPD. Laboratories leading or conducting these activities are not required to have an established NQA-1 program.*

3.2 Quality Rigor Level 2 Requirements

This Quality Rigor Level is generally applied to research and development activities which need a higher level of confidence in the results (e.g., proof of principle) relative to that required for Quality Rigor Level 3 activities. These activities usually provide direct input to program decisions and are either more controversial or would receive wide distribution outside the FCT or represent such a high level of resource investment that, in the judgment of those making the

Quality Rigor Level Designation, the work should be designated at a higher Quality Rigor Level. The following table provides examples of these activities and identifies the corresponding quality assurance requirements.

Table 2.0 Quality Rigor Level 2

Quality Rigor Level 2	
Examples of Types of Activities	**Quality Rigor Level 2 Requirements**
Technical analyses to inform policy and key programmatic decisions, reports to Congress and other key stakeholders, supporting analyses for National Environmental Policy Act (NEPA) documents. Certain cost range estimates for DOE O 413.3 Critical Decisions, activities requiring a large expense or addressing controversial issues, trade studies to inform key programmatic decisions, developmental modeling and simulation, etc.	Activities shall be conducted in accordance with the Laboratory's DOE-approved quality assurance program. In addition, milestones/deliverables shall receive a Peer Review in accordance with Appendix C or a procedure that meets the requirements for Peer Review as specified in Appendix C. The general requirements specified in Section 6 shall also be met. Furthermore, a work package may specify additional QA requirements.

3.3 Quality Rigor Level 3 Requirements

This Quality Rigor Level is generally applied to research and development activities that are exploratory, preliminary, or investigative in nature. The following table provides examples of these activities and identifies the corresponding quality assurance requirements.

Table 3.0 Quality Rigor Level 3

Quality Rigor Level 3	
Examples of Types of Activities	**Quality Rigor Level 3 Requirements**
Routine research and development activities such as feasibility studies, pre-conceptual and conceptual designs, exploratory trade studies, conceptual modeling and simulation, etc.	These activities shall be conducted in accordance with the Laboratory's DOE-approved quality assurance program. In addition, milestones / deliverables shall receive a technical review in accordance with Appendix B or a procedure that meets the requirements specified in Appendix B. The general requirements specified in Section 6 shall also be met. Furthermore, a work package may specify additional QA requirements.

4.0 QA REQUIREMENTS FOR WORK PERFORMED BY UNIVERSITIES

Universities conduct work for FCT either by a grant from DOE, a contract through the Nuclear Energy University Program (NEUP) or as a subcontractor to a National Laboratory. Universities

with a grant from DOE shall follow the requirements specified in the grant and this QAPD is not applicable. Universities performing FCT work as a subcontractor to a National Laboratory shall comply with the requirements of the contractual documents. These contractual documents shall flow down the applicable requirements of this QAPD.

Process used for Awards through NEUP: Universities are required to implement QA requirements based on a specific scope of work. Work scopes are reviewed by the sponsoring organizations and NE offices and based on this review, QA requirements are identified on a QA Requirements Form (see Appendix D for minimum requirements for FCT program). Universities under contract with NEUP agree to adhere to the specified QA requirements through use of university procedures or procedures / templates / guidance provided by NEUP.

5.0 QA REQUIREMENT FOR WORK PERFORMED BY OTHERS

In addition to the work performed by the national laboratories and universities, FCT work is conducted under direct DOE contracts. The cognizant Federal Manager considers the requirements of this QAPD to develop QA requirements to be specified in the contract or a Task Order under the contract.

6.0 GENERAL IMPLEMENTATION REQUIREMENTS

This section of the FCT QAPD defines additional general QA requirements for FCT activities performed by national laboratories and describes implementing processes.

6.1 Work Planning

Planning establishes the systematic, sequential progression of actions to meet the defined requirements. All FCT work must be planned and documented, and receive DOE approval using the established electronic work package generator process for the FCT program.

6.2 Quality Rigor Level Designation in a Work Package

This section describes the process for determining the correct QRL associated with milestones / deliverables specified in the work package. Work planning and authorization, including QRL designation, shall be completed prior to the start of work.

The QRL associated with a milestone / deliverable is based on the intended end use of the results of the work performed. Since in the R&D program, it is not possible to predict the actual end use of all work, judgment needs to be made to make sure that only necessary and appropriate QA requirements, above and beyond site specific requirements, are applied. For example, in the case of designating a QRL-1, it may be less expensive to duplicate the work when an actual licensing activity is initiated rather than applying QRL-1 requirements to a large number of activities which may support regulatory activities which may lead to future license activities. An important outcome of the process is that when the results of FCT R&D are used in the future, the user would know the QA pedigree of the information.

The Work Package Manager (utilizing assistance from the QA POC, researchers, NTD, and others as needed) shall designate a QRL for each milestone / deliverable and submit the Work Package to the Control Account Manager for approval.

The QRL level may be designated Lab / Participant QA Program (no additional FCT QA requirements) for certain milestones/deliverables (see Appendix E for additional information). The designation Lab / Participant QA Program means that no additional FCT QA requirements above and beyond the site (Lab) specific requirements apply. Examples of milestones / deliverables which may be designated as Lab / Participant QA Program (no additional FCT QA requirements) in a work package include:

- Deliverables associated with campaign management and other administrative activities;
- Campaign Implementation Plans;
- Presentation packages; and
- Milestones / deliverables which provide input to another final deliverable / milestone which has a QRL-1, 2 or 3 designation, provided the reviews required for the final deliverable will include review of the information in the input deliverables.

Approval of Work Package Quality Rigor Level designation(s) shall occur in the following sequence:

1. The Control Account Manager approves the Work Package and concurs with QRL designations of all milestones / deliverables in the work package;
2. The National Technical Director approves the Work Package and QRL designations of all milestones / deliverables in the work package; and
3. The HQ FCT Federal Program Manager approves the Work Package and QRL designations of all milestones / deliverables in the work package.

6.3 Change Control

QAPD Change Control

The FCT QAPD is a document issued by the DOE Headquarters' FCT Program and will be reviewed at least annually for potential changes. Revisions require the same minimum reviews / approvals as the initial version and shall be summarized by updating the table on Page 5. Participants will have access to and must work to the latest approved version of the FCT QAPD.

Work Package Change Control

The QRL designations in a work package are applicable until changed via the formal work planning and authorization process. Any revision to a work package or creation of a new work package requires compliance with the requirements specified in Section 6.2.

6.4 Flow Down of QA Requirements

QA requirements identified in a work package, including the Quality Rigor Level(s) designated, shall be flowed down to other participants or subcontractors through the appropriate contractual or work control process. Sufficient information shall be provided in the contractual documentation for the contractor to understand the requirements and complete the work in accordance with the FCT QAPD requirements.

Work activities for QRL-1 designated milestones / deliverables shall be (technically) led only by a National Laboratory / Participant having an established NQA-1-2000 (or later version) compliant QA program. The lead lab for the work will develop appropriate QA requirements for the supporting work to be performed at other laboratories or by a sub-contractor not having an

established NQA-1-2000 (or later version) compliant QA program. These requirements shall be included in work packages for supporting laboratories or, in the case of a sub-contract, in the contractual documents.

6.5 FCT QAPD Training

As a minimum, the FCT Federal Technical Staff, TI, NTDs, Work Package Managers, Control Account Managers, and National Laboratory QA POCs shall receive training on the FCT QAPD. Training may be accomplished via classroom presentation or required reading. Completion of FCT QAPD training must be documented.

6.6 Records Management

Records shall be controlled and maintained in accordance with the Records Management Plan defined in Section 7.0.

6.7 Assessment by HQ FCT Management Organizations

All FCT Participants are subject to surveillance (see definition), review (see definition), assessment (see definition), and audit (see definition) of QA requirements implementation for their respective FCT activities by the FCT program. For NNSA sites these assessments are conducted through the Site Office. Participants will be informed of planned surveillances / reviews / assessments or audits at least 30 days in advance of the planned surveillance / review / assessment or audit.

The HQ FCT organization, participant organizations, Technical Integrator, and National Technical Directors shall ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives. They will also implement processes to detect, correct and prevent problems.

6.8 Resolution of Conflict among QA Requirements

In the event of a conflict between the FCT QAPD and other FCT-issued documents, the FCT QAPD takes precedence. In the event of a conflict between the FCT QAPD and regulatory documents, the regulatory documents take precedence. In the event of a conflict between the FCT QAPD and the contractual requirements of participants, the conflict shall be elevated to the FCT QA Manager to facilitate resolution with the contractual entity. Upon discovery of any conflict between the FCT QAPD and any other documents, the affected participant must notify the FCT QA Manager and applicable NTD and QA POC to facilitate an acceptable resolution of the conflict.

6.9 Resource Allocation for Quality Assurance Support

Resources required to implement the applicable QA requirements of this QAPD (beyond those required for implementing the DOE approved QA program in place at the National Laboratory) will be determined for each Work Package and associated costs included in the total budget of the work package. The funding for QA POC support will be provided in separate work packages.

6.10 Marking Deliverables

Each deliverable having a QRL 1, 2, 3 or Lab / Participant QA Program (no additional FCT QA requirements) designation, shall include a standardized Document Cover Sheet (Appendix E). If the PICS:NE system permits, complete information entered into the PICS:NE Deliverable Form,

and listing the names of all reviewers, satisfies the requirement, including the requirement for signatures on the Document Cover Sheet (Appendix E). This recognizes that the PICS:NE electronic system access provisions adequately provide for authentication of the record.

6.11 Submitting Deliverables

The FCT Records Management Plan (Rev 4) says "The DMS is an electronic records management software application that is used to store all milestone deliverables (deliverables includes metadata and files / documents) identified in the Performance Information Collection System – Nuclear Energy (PICS:NE). Milestones / deliverables shall be entered into the FCT Document Management System in accordance with the Records Management Plan defined in Section 7.0 .

7.0 DEFINITIONS

Activity**:** A planned effort that spans duration of time in order to accomplish a specific scope of work or milestone/deliverable.

Assessment: An observation or monitoring to provide confidence that ongoing activities are adequately and effectively performed. Often used interchangeably with surveillance or review.

Audit: A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence, the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation.

Deliverable: A document or product identified in a work package with a due date and work scope.

Milestone: A document, product or deliverable identified in a work package with a due date and work scope.

Participant: Any individual or organization performing work for the FCT Program.

Peer Review: A review performed in accordance with the requirements specified in Appendix C.

Records Management Plan: The Records Management Plan for Fuel Cycle Technologies document.

Review: An observation or monitoring to provide confidence that ongoing activities are adequately and effectively performed. Often used interchangeably with surveillance or assessment.

Surveillance: An assessment technique that uses observation or monitoring to provide confidence that ongoing activities are adequately and effectively performed. Often used interchangeably with review or assessment.

Technical Review: A review to verify compliance to work package requirements, and technical adequacy of the work. Additionally, a review performed in accordance with the requirements specified in Appendix B.

For other definitions refer to the latest version of DOE Order 414.1 “Quality Assurance” and NQA-1-2000 (or later version) “Quality Assurance Requirements for Nuclear Facility Applications.”

APPENDIX A - NUCLEAR DATA

The FCT Nuclear Data activities shall meet the requirements established by the Cross Section Evaluation Working Group (CSEWG) for inclusion in the Evaluated Nuclear Data File as described below.

The QA requirement expressed in this Appendix applies to the Evaluated Nuclear Data File, Version B (ENDF/B), i.e., nuclear data files that have gone through the CSEWG process (to be described below) and released by the National Nuclear Data Center (NNDC) at Brookhaven National Laboratory (BNL). The ENDF/B library is subjected to an extensive and careful validation process, including comparisons to hundreds of experimental benchmarks before the data are released. Application of other nuclear data (i.e., non ENDF/B) in the FCT R&D program is required to demonstrate to the satisfaction of the respective FCT Program Campaign Director that the particular nuclear data has undergone a validation process similar in rigor to the CSEWG process.

The principal use of nuclear data is in the design, and performance and safety evaluation of reactor concepts and other non-reactor systems that operate in a neutron environment. The data that is generally used to describe the interaction of neutrons with the fuel and other materials is contained in the Evaluated Nuclear Data File, Version B (ENDF/B). This library is maintained by the CSEWG an organization established in 1966, and coordinated by the NNDC at Brookhaven National Laboratory (BNL). The library is archived and distributed by the NNDC and is acceptable to the USNRC for applications in licensing calculations.

This data is processed by codes such as NJOY or AMPX to produce nuclear data libraries that are then used in reactor analysis codes such as REBUS-3/ERANOS/MCNP(X) for fast reactors, and CASMO/TRITON/SIMULATE/ PARCS/MCNP(X) for thermal reactors to simulate reactor behavior. This has been accepted by the NRC as the basis for licensing existing and next generation reactors. In order to be acceptable to the NRC, the applicant has to use approved/accepted methods as embodied in the data processing and reactor simulation codes, and demonstrate expertise in their use by simulating experiments or operating reactors that are prototypic of the system being licensed by comparing calculated results to measurements for key parameters such as criticality. These comparisons are the basis for defining biases and uncertainties applicable to the predictions for the system being licensed.

The data in the ENDF/B files for individual isotopes is the result of a comprehensive process, often termed the CSEWG process:

- The measurement of data, followed by the compilation of a data base of measured data for a particular neutron interaction (e.g., capture, fission, etc.) at a particular energy.

- Evaluation of the measured data by professional evaluators (highly experienced scientists) to provide a single “recommended value” with an estimate of uncertainty, and covariance if possible. This effort is complemented by calculations based on theoretical models.
- Validation of data. This is the primary element of the CSEWG QA process and is done in two steps. First, the evaluated data are checked as to whether they meet CSEWG criteria in

terms of formatting compatibility and physics consistency. Then, extensive validation is done against integral benchmark experiments. In general, these experiments are carefully documented, checked and approved by groups of international experts. Included in this is a detailed description of experiments including geometry. Comparison is done of the ability of the evaluated data to simulate the performance of a broad spectrum of measured experimental benchmark configurations. This is usually done with a high fidelity computational methodology that represents the nuclear data and the geometry of the experiments in a minimally approximated way.

- Approval by CSEWG. Only data approved by CSEWG are included in the ENDF/B library. The current version is ENDF/B-VII.0 which was released in December 2007 (there were eight versions of ENDF/B-VI). There is an extensive paper describing the library including its extensive validation against almost one thousand benchmark experiments, [M.B. Chadwick et al, Nuclear Data Sheets 107 (2006) pp. 2931-3060].

APPENDIX B - TECHNICAL REVIEW REQUIREMENTS

- This section establishes the minimum requirements for performing a Technical Review.
- The Technical Reviewer(s) shall be selected by the supervisor, manager, or NTD responsible for the work being performed.
- The Technical Review shall be performed by an individual, or group, other than the originator (a supervisor, manager, or NTD may perform a Technical Review).
- The Technical Reviewer(s) shall have sufficient competence in the subject matter being reviewed as determined by the responsible supervisor, manager, or NTD.
- The Technical Reviewer(s) shall have access to the necessary background information to perform the review.
- The Technical Review shall be documented (hard copy or electronically) using the FCT Document Cover Sheet (Appendix E). If the PICS:NE system permits, complete information entered into the PICS:NE Deliverable Form, and listing the names of all reviewers, satisfies the requirement, including the requirement for signatures on the Document Cover Sheet (Appendix E). This recognizes that the PICS:NE electronic system access provisions adequately provide for the authentication of the record.

APPENDIX C - PEER REVIEW REQUIREMENTS

This section establishes the minimum requirements for performing a Peer Review. The Peer Review is a critical quality assurance mechanism for research activities.

C.1 Purpose for Peer Review

Peer reviews shall include identification of the following:

a) Work to be reviewed.

b) Scope of the peer review.

c) Size and required capabilities of the peer review team (there shall be at least two members on each peer review team).

d) Expected method and reporting schedule.

C.2 Scope of Peer Review

The scope of Peer Review shall include the following considerations as they apply to the work being reviewed:

a) Determine the reasonableness of the assumptions and validity of inputs that were used as the basis for the research and analyses.

b) Verify the adequacy of experimental requirements and criteria (e.g., acceptance criteria from testing) including the use of any applicable national or international standards described.

c) Verify the appropriateness of the methods and implementing documents used to complete the work under review.

d) Determine if the software applications (e.g., simulation, or computer model) used to complete the work under review are appropriate and adequate.

e) Determine the accuracy of the calculations and final documentation.

f) Determine the reasonableness and validity of the conclusions.

g) Verify that the conclusions are clearly stated such that misinterpretation is minimized. Identify any different conclusions that can be drawn from the results presented.

h) Verify that any uncertainty in the results is clearly and adequately discussed.

Additional criteria may be defined by the team and shall be defined in the review criteria documentation.

C.3 Qualification Requirements for Peer Reviewers

Peer reviews shall be conducted by individuals who are independent from the work under review. Independent means that the individual was not involved as a participant, supervisor, or advisor in the work under review and is, to the extent practical, free from other conflicts of interest.

The number of reviewer(s) is commensurate with the complexity of the work to be reviewed, its importance to program objectives, the number of technical disciplines involved, and the degree to which the subject issue is considered controversial by stakeholders and differing viewpoints are strongly held within the applicable technical and scientific community concerning issues under review. The supervisor, manager, or NTD of the performer of the work shall select peer reviewer(s) based on the complexity of the work being reviewed. Peer reviewers are individuals who meet at least one of the following criteria as judged by the responsible manager:

- Have adequate academic education in the same technical discipline in which the work is performed or in a closely related field, or have adequate work experience and technical activity in a related discipline.
- Have demonstrated evidence of proposing and solving engineering, experimental, or theoretical problems that are recognized as valid by the community of technical peers.
- Have contributed to the body of knowledge within a technical discipline such as publishing research results in the proceedings of scientific meetings or in professional journals.

The supervisor, manager, or NTD of the performer of work being peer reviewed must verify that peer reviewer(s) are qualified in accordance with the requirements herein. FCT MOs may require approval of peer reviewers, which should be called out in applicable work packages or otherwise formally requested.

C.4 Documenting Peer Reviews

The Peer Review shall be documented (hard copy or electronically) using the FCT Document Cover Sheet (Appendix E). If the PICS:NE system permits, complete information entered into the PICS:NE Deliverable Form, and listing the names of all reviewers, satisfies the requirement, including the requirement for signatures on the Document Cover Sheet (Appendix E). This recognizes that the PICS:NE electronic system access provisions adequately provide for the authentication of the record.

APPENDIX D – EXAMPLE OF UNIVERSITY QA REQUIREMENTS FORM

NEUP University QA Requirements Worksheet **Proposal No.**

Work Scope Criteria

Perform work to the selected requirements below (those marked with an X) with accepted university documented practices or procedures that demonstrate industry-accepted scientific, engineering, or administrative practices or processes. The funding organization has the right of access to the university facilities and records for surveillance or inspection. Surveillance or inspections will be coordinated with the university researcher.

(A left column box checked with an X means it is applicable to your work scope)

	Requirements
☐	**Test Planning, Implementation, and Documentation (Research Planning)** Test methods and characteristics shall be planned, documented and the approaches and procedures recorded and evaluated. Characteristics to be tested and test methods shall be specified. The test results shall be documented and their conformance to acceptance criteria evaluated.
☐	Documentation shall be developed to ensure replication of the work. The researcher/developer shall document work methods and results in a complete and accurate manner. The level of documentation shall be sufficient to withstand a successful peer review. Protocols on generation and safeguarding of data and process development from research shall be developed for consistency of R&D work.
☐	Laboratory notebooks shall be controlled by a university documented procedure/process. Also, the process for development of intellectual property documentation shall be controlled under university document control procedures/processes.
☐	The university shall develop a Test Plan/Research Plan for the work being performed in the contract. The Test/Research Plan will detail how the QA requirements selected on this QA Requirements Worksheet will be implemented. The university will provide the Test/Research plan to the funding organization for review and concurrence prior to use if requested. (The funding organization will provide a Test Control Plan format to the university if requested.)
	Equipment Calibration and Documentation The researcher shall specify the requirements of accuracy, precision, and repeatability of measuring and test equipment (M&TE). Depending upon the need for accuracy, precision, and repeatability of M&TE used in research, standard university documented procedures shall be implemented. Where university M&TE procedures are not used, effects of the instrument's performance on the uncertainty of the measurements and tests shall be considered and documented in the research. During the process development stage and for all R&D support activities, M&TE shall be controlled. The degree of control shall be dependent on the application of the measurement. The university shall maintain and control calibration records documenting instrument calibration to a national standard. If requested by a funding organization the calibration records will be submitted as a deliverable product.
	Procurement Document Control University documented procurement document control procedures/processes shall be implemented if results of initial research work are expected in the next stage of work, and if the pedigree of materials being used could influence the usefulness of the research work results. Procurement document specifications shall be controlled. For development and support activities, the level of procurement document control shall be applied to support a design basis, i.e., engineering design system criteria. If procurement document control requirements apply, the university shall have a documented procedure/process for control of suspect/counterfeit items (S/CI), and submit material pedigree records as a deliverable product.
	Training and Personnel Qualification Personnel performing research activities shall be trained per university documented requirements to ensure work is being conducted properly to prevent rework or the production of unacceptable data. The university shall maintain and control personnel training records. The university shall submit personnel training records as a deliverable product if requested by the funding organization.

NEUP University QA Requirements Worksheet **Proposal No.**

	Analysis/Modeling Software Verification and Validation The following requirements shall apply: – Software used for modeling development in support of scoping work will have configuration control implemented by a minimum of a baselined copy of software executable file plus a text statement describing chronological changes being made. At a minimum, all changes will be verified to operate correctly by the developer and an independent qualified checker prior to use. – Reports or work summaries for modeling software development shall include: • The software name • Version number • Computer manufacturer name and model • Name and version of operating system • A list of libraries or interfaces/environment required for correct software operation. • Reference to the applicable V&V documentation Modeling shall be performed using codes and/or software packages that have received verification and validation (V&V) in accordance with university documented procedures/processes. The code or software version(s) used to develop results will be identified in the project's final report. Where codes or models have not received V&V, or the V&V documentation is not available, the university shall provide a description of the model or code and the tools and methods used to ensure accuracy of the data generated. The data generated shall be identified as To Be Verified (TBV) and its use tracked until the codes or models have been V&V.
	Records In many cases, the notebook or journal of the researcher is the QA record. These documents shall be maintained and controlled in accordance with university documented procedure/process, e.g., maintain notebook as a controlled document, maintain copies of critical pages or access-controlled filing when not in use to preserve process repeatability and the QA record. Electronic media may be used to record data and shall be subject to documented administrative controls for handling and storage of data. Work activity records shall be maintained by the university. Work activity records shall be provided to the funding organization if requested by the funding organization.
	Data Acquisition/Collection and Analysis When gathering data, the researcher shall ensure that the systems and subsystems of the experiment are operating properly. Software systems used to collect data and operate the experiment requires verification that it meets functional requirements prior to collection of actual data. Data anomalies require investigation. When performing data analysis, define: assumptions and the methods used; the results obtained so that independent qualified experts can evaluate how data was interpreted; methods used to identify and minimize measurement uncertainty; the analytical models used; and whether the R&D results have been documented adequately and can be validated
	Peer Review Peer reviews shall be performed in accordance with journal peer review requirements. The peer reviews shall be documented and maintained by the university. Peer review documentation and results shall be provided to the funding organization if requested.
	Additional items:

Funding Organization QA Representative

QA Representative Name: _____ **Date:** _____

APPENDIX E
FCT DOCUMENT COVER SHEET [1]

Name/Title of Deliverable/Milestone/Revision No. _____

Work Package Title and Number _____

Work Package WBS Number _____

Responsible Work Package Manager _____
(Name/Signature)

Date Submitted

Quality Rigor Level for Deliverable/Milestone[2]	☐ QRL-3	☐ QRL-2	☐ QRL-1 ☐ Nuclear Data	☐ Lab/Participant QA Program (no additional FCT QA requirements)

This deliverable was prepared in accordance with _____
(Participant/National Laboratory Name)

QA program which meets the requirements of
☐ DOE Order 414.1 ☐ NQA-1-2000 ☐ Other

This Deliverable was subjected to:

☐ Technical Review

Technical Review (TR)
Review Documentation Provided
☐ Signed TR Report or,
☐ Signed TR Concurrence Sheet or,
☐ Signature of TR Reviewer(s) below

Name and Signature of Reviewers

_____
_____
_____

☐ Peer Review

Peer Review (PR)
Review Documentation Provided
☐ Signed PR Report or,
☐ Signed PR Concurrence Sheet or,
☐ Signature of PR Reviewer(s) below

_____
_____
_____

NOTE 1: *Appendix E should be filled out and submitted with the deliverable. Or, if the PICS:NE system permits, completely enter all applicable information in the PICS:NE Deliverable Form. The requirement is to ensure that all applicable information is entered either in the PICS:NE system or by using the FCT Document Cover Sheet.*

NOTE 2: *In some cases there may be a milestone where an item is being fabricated, maintenance is being performed on a facility, or a document is being issued through a formal document control process where it specifically calls out a formal review of the document. In these cases, documentation (e.g., inspection report, maintenance request, work planning package documentation or the documented review of the issued document through the document control process) of the completion of the activity, along with the Document Cover Sheet, is sufficient to demonstrate achieving the milestone. If QRL 1, 2, or 3 is not assigned, then the Lab / Participant QA Program (no additional FCT QA requirements) box must be checked, and the work is understood to be performed and any deliverable developed in conformance with the respective National Laboratory / Participant, DOE or NNSA-approved QA Program.*