

Used Fuel Disposition Campaign

Preliminary Quality Assurance Implementation Plan

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- **Fuel Cycle Technologies (FCT) QA program overview**
- **QA Considerations for UFD Campaign work activities**
- **Is the QAPD sufficient for UFD work activities?**
- **Implementing QA for UFD...path forward**
- **Selected WIPP NQA-1 procedures → FCT NQA-1 procedures**

FCT QA Program Overview

The approach is based on the following 4 principles:

■ **QA requirements must be end-use driven**

- *Quality Assurance is a set of planned and systematic actions taken to provide confidence that the end result of an activity meets its intended objectives*
 - *The QA requirements which apply to a task must be derived from the end-use of the product/information generated*
 - *QA requirements cannot be determined by the PI alone. HQ program Manager must make the determination consistent with the HQ policy guidance and input from the National Technical Director, PI and the regulatory cross-cut manager (potentially with input from industry participants).*

■ **Must have buy-in**

- *The QA requirements must be understood by each participant*

■ **Must provide funding**

- *Appropriate budget must be allocated for implementing the QA requirements*

■ **Don't reinvent the wheel**

- *The approach should minimize the impact on established QA programs and practices.*

Key considerations include:

- ***Each laboratory has a QA program which complies with DOE Order 414.1 or equivalent***
 - *Safeguards, security, worker safety and environmental safety are covered under existing programs*
- ***Some labs have NQA-1 compliant programs in place (different versions).***
- ***Each laboratory has processes in place to protect intellectual property and export control***
- ***Each laboratory has procedures for peer-review of work to be published.***

- ***UFD work is likely to include experimental or developmental work that:***
 - 1. Is of long duration;***
 - 2. May be difficult to repeat;***
 - 3. Is expensive to conduct; or,***
 - 4. Includes software (code) development***
AND has a potential of being used to directly or indirectly support licensing activities in the future.
- ***Early examples include:***
 - ***Salt Disposal Investigations (salt mechanics at elevated temperatures)***
 - ***Storage and Transportation R&D associated with storage-system material degradation issues***

Is the QAPD sufficient for UFD work activities?

- ***Meetings/workshops held June and November, 2010.***
- ***QA Points of Contact (POCS) from each FCT participating lab participated***
- ***Consensus reached during November 2010 meeting that***
“... there need be no specific changes to the FCT QAPD for QA implementation when conducting UFDC R&D activities. The FCT QAPD provides a sound and useable foundation for the implementation of QA for UFDC R&D activities, including the application of QA in a graded approach...”

When work activities are determined to have a reasonable likelihood that results may be used in future licensing...and additional QA requirements are to be implemented...

- 1. A test/activity plan is included as a milestone in each work package.*
- 2. The plan identifies and describes the test(s) being performed and identification of additional NQA-1 QA elements as requirements for the work package*
- 3. Specific associated NQA-1 procedures necessary to implement these additional requirements included.*
- 4. Graded application of these NQA-1 requirements are in addition to existing base Lab QA at the performing national lab*

Details available in milestone #M21UF010201, “UFDC Preliminary Quality Assurance Implementation Plan,” FCR&D-USED-2011-000019

SDI is being used to begin SNL FCT QA Program...

SNL has an existing, operational NQA-1 based QA program in our Carlsbad Program Offices for WIPP based on NQA-1 1989

These existing WIPP procedures are being used as templates to develop FCT NQA-1 procedures based on NQA-1 2008

The FCT procedures are being developed “as needed” for Salt Disposal Investigations (SDI) for now...

Review of SDI SOW and technical test plans resulted in identification of “applicable NQA-1” QA elements

These elements are being documented and QA procedures are being developed from WIPP procedures

The FCT NQA-1 procedures are being developed to reference NQA-1 2008 with the 2009 addendum (NRC “blessed” versions of NQA-1)

Sample of QA Matrix in SDI Test Plan...

Sample excerpt for first 3 NQA-1 QA elements from SDI "Test Plan" QA section...

NQA-1 (2008) Requirement Excerpt	Summary of Grading	Procedures as Appropriate
<p>Organization - Responsibilities for the establishment and implementation of the quality assurance program shall be defined. The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality shall be documented.</p>	<p>A description of performing organizations placement within laboratory organization, including interfaces, is provided above. Rely on CPS procedures, including those listed in adjacent column, as appropriate.</p>	<p>CG 100.1 - Establish the Decision-Making Framework CG 100.1.1 - Create and Maintain the Mgmt. Structure CG 100.1.2 - Create or Change a Policy - Process - or Procedure ...</p>
<p>Quality Assurance Program - The program shall identify the activities and items to which it applies. The program shall provide control over activities affecting quality to an extent consistent with their importance.</p>	<p>A description of the Quality Assurance Program, requirements flow down, relationships between FCT QA, NNSA/SSO QA and laboratory QA organizations, is provided. Rely on CPS procedures, including those listed in adjacent column, as appropriate. Specific qualifications and training required of MOW involved in the activity are addressed by the specific QAP identified.</p>	<p>Multiple CPS procedures in HR100.2. QAP 2-1 Qualification and Training</p>
<p>Design Control - The design shall be defined, controlled, and verified. Design inputs shall be specified on a timely basis and translated into design documents. Design interfaces shall be identified and controlled. (Note: Includes provisions applicable to use of computer programs.)</p>	<p>Rely on CPS procedures, including those listed in adjacent column, as appropriate. Related controls are addressed by the specific QAP identified. Note: Requirements specifically identified for software determined to be N/A, because no software is designed as part of this activity.</p>	<p>ME100.3.1 - Perform Work ME100.3.2 – Manage Projects Throughout Their Lifecycle ME100.3.3 - Apply Configuration Management Principles to Documents and Physical Items QAP 20-1 Test Plans</p>