

DRAFT Operating Procedures for a Generic Repository Licensing Organization

Fuel Cycle Research & Development

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U.S. Department of Energy
Used Fuel Disposition Campaign
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SUMMARY

This document is milestone M4FT-15SN0826021: Draft Summary of principle operating procedures for a generic repository licensing organization, the result of efforts under work package FT-15SN082602 DOE Managed HLW and SNF Research: Generic Operating Procedures; e.g., Quality Assurance – Sandia National Laboratories (SNL). The objective of this effort was to develop this draft document identifying and summarizing the principle operating procedures for a generic repository licensing organization. The FY16 follow on work package is FT-16SN050303: Develop and Implement Operating Procedures – SNL, having a consistent objective to develop a draft document identifying and summarizing the principle operating procedures for a generic repository licensing organization.

This document identifies and describes the principle operating procedures for a hypothetical and generic organization with the responsibility to site, characterize, design, license, construct and operate a repository for the disposal of high-level radioactive waste (HLW) and spent nuclear fuel (SNF) managed by the Department of Energy. These principle operating procedures reflect practices that facilitate compliance with U.S. Nuclear Regulatory Commission (NRC) expectations and NQA-1 quality standards.

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Acronyms

ADAMS	NRC’s Agencywide Document and Management System
AEA	Atomic Energy Act of 1954, as amended
AFP	Approved Funding Plan
BRC	Blue Ribbon Commission on America’s Nuclear Future
CAP	Corrective Action Program
CBT	Computer Based Training
COTS	Commercial of the Shelf Software
CR	Condition Report
DAS	Data Acquisition System
DOE	U.S. Department of Energy
EA	Environmental Assessment
ECP	Employee Concerns Program
EIS	Environmental Impact Statement
EPA	U.S. Environmental Protection Agency
EVMS	Earned Value Management System
GIS	Geographic Information System
HLW	High-Level Radioactive Waste
HPC	High Performance Computing
IT	Information Technology
ITS	Important to Safety
ITWI	Important to Waste Isolation
LSN	Licensing Support Network
MOW	Members of the Workforce
NEPA	National Environmental Protection Act
NQA-1	American Society of Mechanical Engineers Quality Standard for Nuclear Facilities
NWPA	Nuclear Waste Policy Act of 1982
NWPAA	Nuclear Waste Policy Amendments Act of 1987
NRC	U.S. Nuclear Regulatory Commission

NUREG	NRC Regulatory Guide
PA	Performance Assessment
QA	Quality Assurance
QAPD	Quality Assurance Program Description
QARM	Quality Assurance Requirements Matrix
RAI	Request for Additional Information
RD&D	Research, Development, and Demonstration
SCWE	Safety Conscious Work Environment
SNF	Spent Nuclear Fuel
SNL	Sandia National Laboratories
TBD	To Be Determined
TDMS	Technical Data Management System
UFD	Used Fuel Disposition
WBS	Work Breakdown Structure
YM	Yucca Mountain

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Draft Operating Procedures for a Generic Repository Licensing Organization

1. Introduction

This document is milestone M4FT-15SN0826021: Draft Summary of principle operating procedures for a generic repository licensing organization, the result of efforts under work package FT-15SN082602 DOE Managed HLW and SNF Research: Generic Operating Procedures; e.g., Quality Assurance – Sandia National Laboratories (SNL). The objective of this effort was to develop this draft document identifying and summarizing the principle operating procedures for a generic repository licensing organization. The FY16 follow on work package is FT-16SN050303: Develop and Implement Operating Procedures – SNL, having a consistent objective to develop a draft document identifying and summarizing the principle operating procedures for a generic repository licensing organization.

This document identifies and describes the principle operating procedures for a hypothetical and generic organization with the responsibility to site, characterize, design, license, construct and operate a repository for the disposal of high-level radioactive waste (HLW) and spent nuclear fuel (SNF) managed by the Department of Energy. These principle operating procedures reflect practices that facilitate compliance with U.S. Nuclear Regulatory Commission (NRC) expectations and NQA-1 quality standards.

The context in which the organization's work would be conducted differs substantially from that conducted in the typical research, development and demonstration (RD&D) environment. First, there are work elements that are not customarily included in RD&D work, such as a Corrective Action Program, among other organizational assurance elements. Secondly, the rigor with which the organizational functions need to be applied and practiced is significantly greater than that which is acceptable in the RD&D environment.

2. Background

In January 2012, the final report of the Blue Ribbon Commission on America's Nuclear Future (BRC, 2012) urged the Administration to conduct a review of the current policy to dispose of defense and commercial high level radioactive waste and spent nuclear fuel in a single repository or repositories. Based on that recommendation, in 2013, the administration indicated that the policy would be the subject of analysis moving forward, (DOE, 2013).

In 2014, a report on disposal options for DOE managed High-Level Radioactive Waste and Spent Nuclear Fuel (DOE, 2014) was prepared for the Secretary by a team of federal and contractor personnel led by the Department's Office of Nuclear Energy. The report assesses the technical options for the permanent disposal of HLW and SNF managed by the Department of Energy¹.

¹ DOE-managed HLW and SNF consists of two principal waste streams: (1) HLW, mostly resulting from atomic energy defense activities but also including a small amount of HLW of commercial origin; and (2) SNF, primarily from atomic energy defense activities (weapons plutonium production reactors and naval propulsion reactors), but also including a smaller amount of SNF from DOE research and development activities and some DOE-managed SNF from commercial sources. (DOE, 2014)

Specifically, the report considered whether DOE-managed HLW and SNF should be disposed of with commercial SNF and HLW in one geologic repository or whether there were advantages to developing separate geologic disposal pathways for some DOE-managed HLW and SNF. The report drew heavily on a recently completed DOE report (Sandia, 2014) that summarized the inventory of both commercial and DOE-managed radioactive wastes requiring geologic disposal, organized that inventory into broadly defined waste groups with similar disposal characteristics, and qualitatively evaluated disposal options for each group of waste types. The analyses of alternatives and options related to the treatment and disposal of HLW and SNF presented in Sandia, 2014 are based on technical and programmatic considerations and do not include an evaluation of relevant regulatory and legal considerations.

3. Purpose

The purpose of this report is to identify and describe the principle operating procedures for a hypothetical and generic repository licensing organization and is meant to be agnostic of type of licensee (private, government or combination thereof), geologic media, or the location of the disposal facility. Further elaboration of these procedures will be the subject of follow-on efforts in FY16. These principle operating procedures will provide the foundation for an effective, high quality repository licensing organization.

4. Scope

The scope of responsibility of the organization considered in this report is to site, characterize, design, license, construct and operate a repository for the disposal HLW and SNF managed by the Department of Energy. This scope is extensive, and will undoubtedly take decades to accomplish. Just for perspective, it would not be unrealistic to collectively have more than one thousand policies, plans, and procedures for a fully operational organization engaged in siting, characterization, design, and licensing of a repository site. Recognizing that substantial changes will occur over such a long timeframe, this report focuses on identifying the roles and responsibilities of organizational elements that are needed to initiate the work (i.e., those that will support the scientific and engineering endeavors that will actively accomplish the Siting, Characterization, Design and Licensing of the disposal facility under consideration). These elements are shown in Figure 1 as the 'Management' and 'Support Groups' elements. The nature of these management, administrative, business, and technical support functions are well enough understood to define policy and procedural needs with some detail. The specific configuration and details of the scientific and engineering organizational elements operating procedures is beyond the scope of this report; however, there are some general procedural requirements that will be identified.

All organizational elements reflect a workforce composition and state of practice that facilitates compliance with U.S. Nuclear Regulatory Commission (NRC) expectations and NQA-1 quality standards. One often overlooked component of any licensing endeavor is the importance of having a procedure oriented technical support and business process organization. The unshaded portions of Figure 2 illustrates the professional non-technical (not Science and Engineering) team elements needed to provide support and business process management to ensure success of a geologic repository project. The procedures listed below are organized in this context.

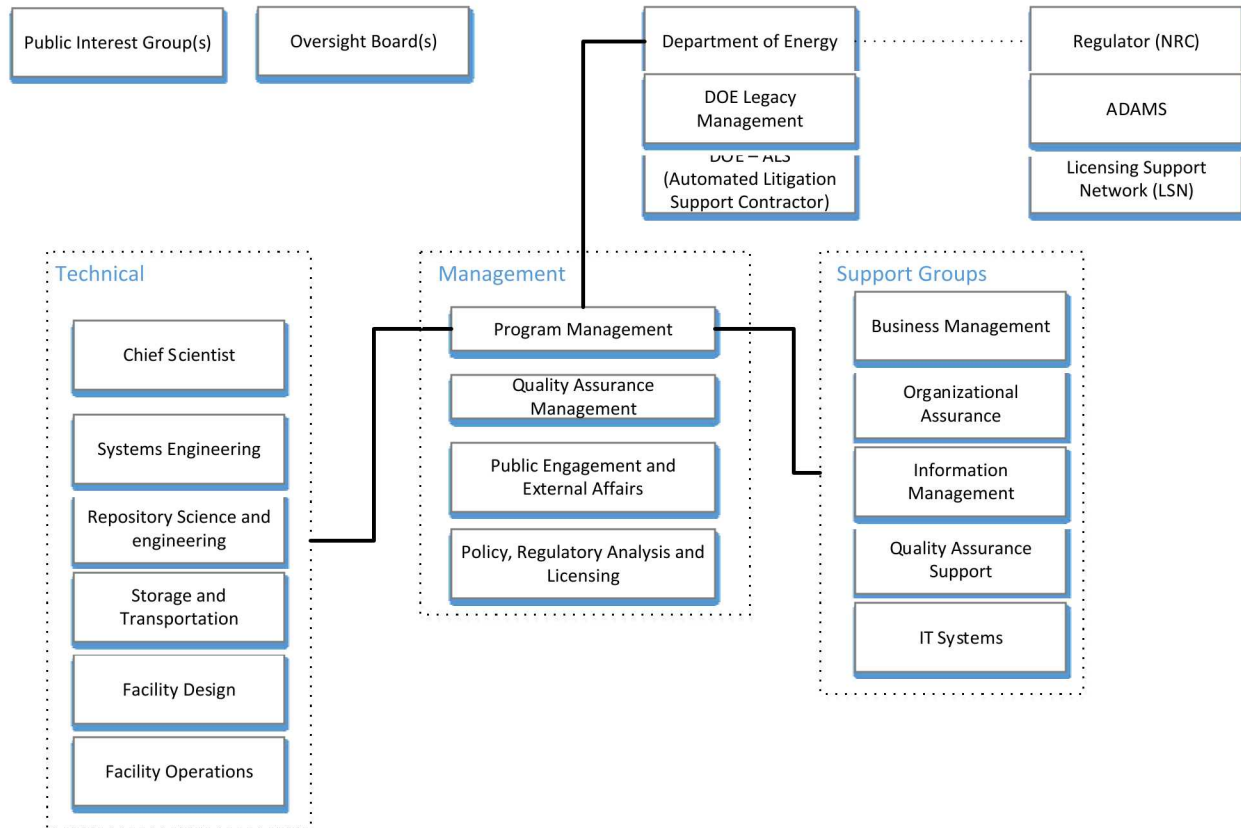


Figure 1 - General Organization

5. Principles, Concepts And Terms

For clarity, several principles, concepts and usage of terms are applied throughout this report. Policies are promulgated by Program Management to provide overall direction to the organization. Organizational elements perform their function(s) in accordance with policy direction. In most cases, organizational elements also perform their function(s) in accordance with a management plan that it has produced and has been approved by Program Management. If necessary, procedural controls are identified in the management plan for activities that require that level of definition. One can anticipate that the procedures listed below will be needed to satisfy the support requirements.

6. Time Frame

The schematic timeline shown in Figure 3 is intended to illustrate the timeframes involved in the activities discussed here and to underscore that the initial focus is on establishing the support infrastructure as opposed to the science and engineering organizational elements.

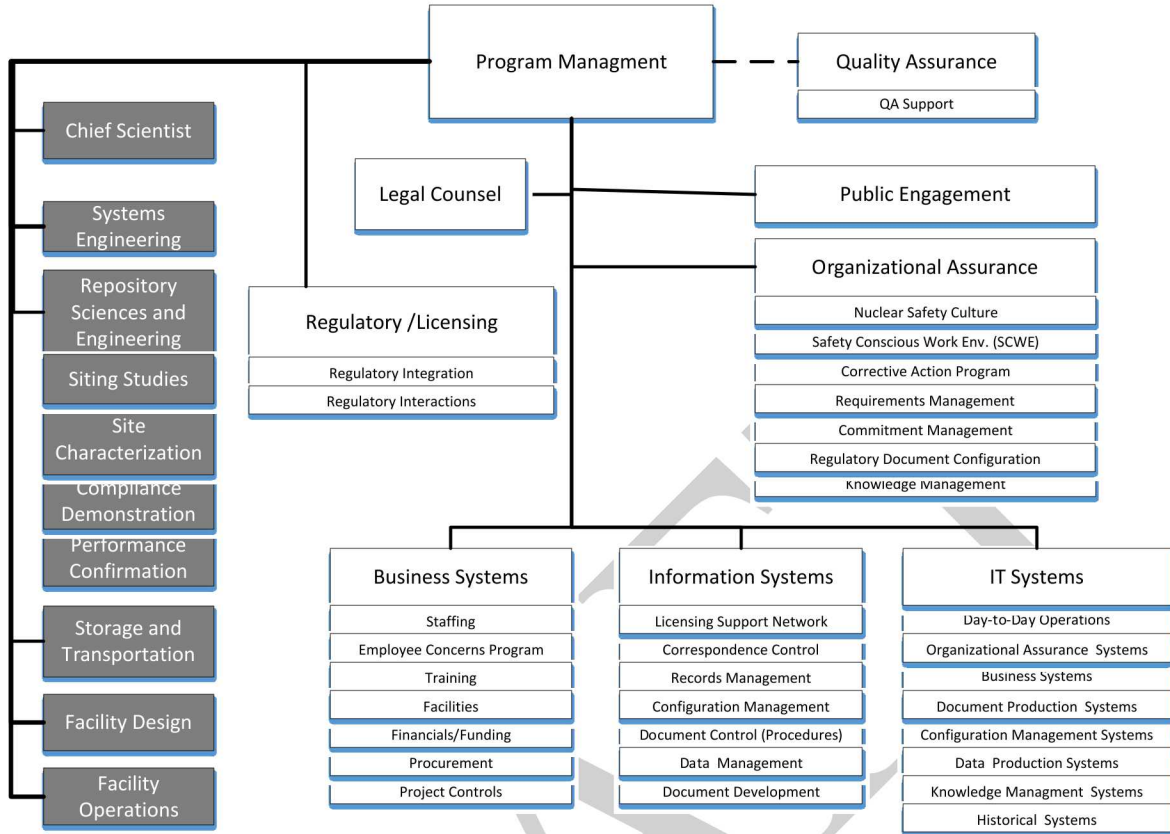


Figure 2 - Organizational Support Elements

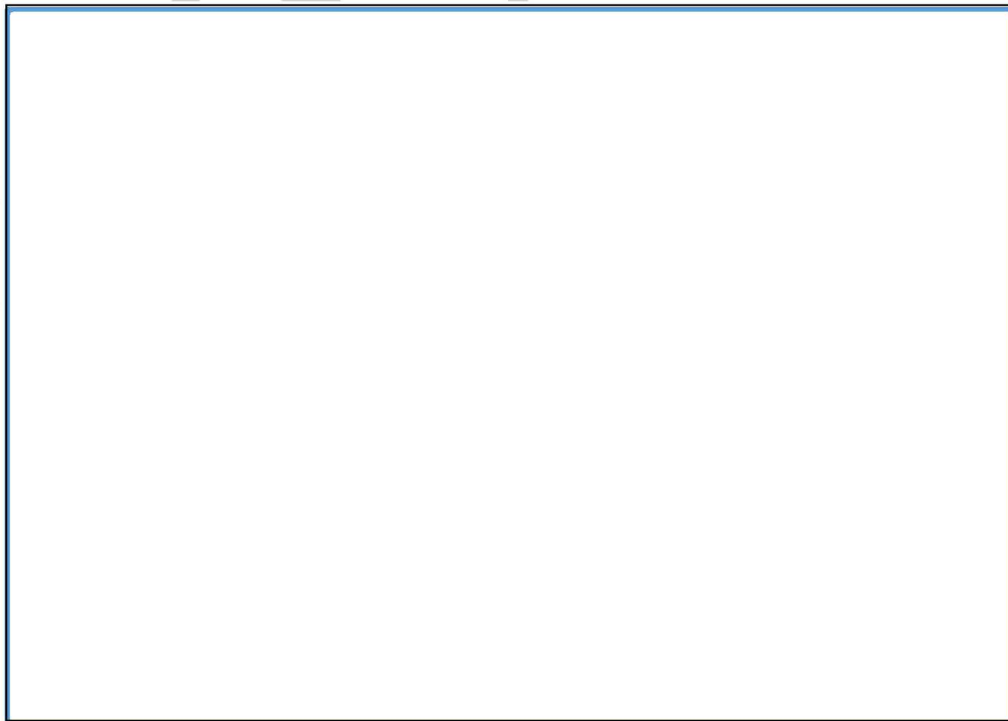


Figure 3 - Schematic Timeline

7. Organizational Element's Policies, Plans and Procedures

7.1 Program Management

This section summarizes the policies and procedures that are established at the highest level in the organization, and are thereby of premier importance, setting the context for all of the organization's activities.

Policy on the Organization's Vision, Mission, and Function

This policy establishes that the organization will demonstrate to the national and international technical and policy community that sound science and regulatory policy together provide for the long-term safe management of HLW and SNF from national defense activities. In addition, establish, explain, defend, and evolve technical and safety bases relative to a repository licensing organizations performance that are credible with the scientific community, defensible with the NRC and other regulators, and respected by all stakeholders. Finally, establish a structure for the licensing organization.

Project Management Plan

This is a top-level plan that describes how the program is structured, identifying its functional elements and their general responsibilities.

Regulatory Compliance Policies, Strategies, Plans, and Activities

A written policy describing how the organization intends to comply with applicable U.S. Nuclear Regulatory Commission (NRC) and U.S. Environmental Protection Agency requirements.

Policy for 10 CFR Part 21 Compliance

A policy that establishes the organization's process for complying with U.S. Nuclear Regulatory Commission (NRC) requirements as described in 10 CFR 21, *Reporting of Defects and Noncompliance*.

Nuclear Safety Culture Policy

This is a policy consistent with NRC's final Safety Culture Policy Statement (NRC, 2011) that clearly communicates to all members of the organization the expected values and behaviors that serve to make nuclear safety the overriding priority.

Timely Condition Report (CR) Submission and CR Completeness Policy

This policy provides guidance to the organization regarding timeliness in the initiation and submission of CRs within the Corrective Action Program.

Policy on Use of and Adherence to Procedures

The policy provides direction on how procedures are to be used and the expectations for using and adhering to them.

Procedure on Preparing and Approving Policies and Programmatic Procedures

This procedure will establish the process and define responsibilities for preparing, reviewing, approving, revising, and cancelling policies and programmatic procedures for the organization.

Self-Assessment Policy

The policy describes the organization's protocols to assess performance and identify areas for improvement, so that efficiencies, errors, oversights, or unintended consequences are identified and corrected at the earliest opportunity.

Quality Assurance Management Assessment Procedure

This procedure establishes the process and responsibilities for planning, performing, and reporting the results of quality assurance management assessments.

Policy for Programmatic Risk Assessment Process

This policy establishes the process and define responsibilities for identifying, tracking, and minimizing risks during the day-to-day activities of the organization.

Readiness Review Procedure

This procedure establishes the process and responsibilities for identifying the need, conducting, and documenting readiness reviews.

Change Management Policy

This policy applies to organizational and/or programmatic changes, to provide a structured approach to transitioning individuals, teams, and organizations to a desired future state.

Procedure for Resolution of Differing Professional Opinions

This procedure establishes a process to disposition differing professional opinions that may arise. This supports a work environment that encourages workers to express their best professional judgement, even though those judgements may differ from the professional opinion of others or a management decision. Implementation of such a procedure is an important element of the Nuclear Safety Culture.

Technical Work Activity Review Procedure

This procedure defines the process and responsibilities for performing initial evaluations of mandatory and discretionary technical activities and final evaluations of technical work activities for potential impacts to the regulatory documents and/or the program technical baseline.

Procedure for Deliverable Acceptance Criteria and Reviewing Deliverables

This procedure describes the process for initiating the review of DOE deliverables, establishing acceptance criteria and resolving comments on DOE deliverables.

7.1.1 Legal Counsel

Legal Counsel customarily does not operate to written program-level procedures.

7.1.2 Quality Assurance**Quality Assurance Policy**

This policy establishes a comprehensive quality assurance program policy and mandates the program for all of the work scope assigned.

Quality Assurance Program Description (QAPD)

A Quality Assurance Program Description describes the approach the organization will utilize to meet applicable quality assurance requirements consistent with NQA-1 (2015).

Quality Assurance Requirements Matrix (QARM)

This matrix illustrates which QA requirements apply to various elements of the work scope.

Procedure for Maintenance of the QA Policy, Program Description, and Requirements Matrix

This procedure establishes the responsibilities and process for maintenance of the organization's Quality Assurance Program Description (QAPD), and Quality Assurance Requirements Matrix (QARM).

QA Grading Procedure

This procedure establishes instructions for implementing a graded approach to Quality Assurance (QA) controls for the organization's activities that are not important to safety or not important to waste isolation.

Quality Assurance Surveillance Procedure

The procedure establishes the process for conducting and documenting quality assurance (QA) surveillances performed by the organization. Surveillance is defined as the act of observing real-time activities and/or reviewing documentation to verify conformance with specified requirements and to evaluate their adequacy and effectiveness.

Audit Personnel Qualification Procedure

This procedure establishes the responsibilities and process for the qualification of Auditors and Lead Auditors; the maintenance of Lead Auditor proficiency; the indoctrination and qualification of Technical Specialists.

Quality Assurance Internal Audit Program Procedure

This procedure establishes the process for scheduling, planning, performing, and documenting the organization's Quality Assurance (QA) internal audits.

Stop Work Procedure

This procedure establishes the responsibilities and process for Quality Assurance (QA) to stop work when warranted by a significant condition adverse to quality, and to authorize the resumption of work that has been stopped, or specifically identified portions thereof, when satisfactory completion of actions required to resolve the significant condition adverse to quality has been verified.

Supplier Evaluation Procedure

This procedure establishes the responsibilities and process for performing supplier evaluations, specifically in the procurement of services and products in support of the organization's activities.

Managing Supplier Condition Reports Procedure

This procedure establishes the responsibilities and process for documenting, evaluating, and resolving conditions adverse to quality, significant conditions adverse to quality, and Stop Work Conditions identified for suppliers to provide products and services to the organization.

Supplier Surveys/Audits Procedure

This procedure defines the responsibilities and process for performing Quality Assurance (QA) supplier surveys/audits for the organization.

Acceptance of Products and Services Procedure

This procedure establishes the responsibilities and methods for determining the acceptability and documenting the acceptance of products and services prior to use by the organization.

7.1.3 Public Engagement

Public engagement activities are necessary to define, design and implement processes for public engagement in organization activities. Consent Based Siting is included in this organizational element. This area includes activities necessary to define, design and implement processes to enable a phased, adaptive, and consent-based approach to siting waste management facilities. Interactions with DOE to formulate project direction will undoubtedly yield the need for assorted policies and procedures.

Public Engagement Plan

This is a management plan that describes how the program's public engagement strategy is structured, identifying its functional elements and their general responsibilities

7.1.4 Regulatory/Licensing

This element addresses activities necessary to manage the regulatory support activities conducted by the organization, regardless of the regulator's identity (e.g. NRC, EPA, or State entities). The strategic response development for regulatory issues as well as the planning for and preparation for regulatory interactions are managed from this element. Working with Program Management, this element will ensure consistency and coordination among other organizational elements during regulatory review proceedings.

Typically there are two functions in this area: regulatory integration; and regulatory interactions. Regulatory integration entails coordination of regulatory activities among the various other organizational elements (e.g., transportation and storage) and with the DOE regulatory affairs. Regulatory interactions provide the interface with and support DOE regulatory affairs, in interactions with regulators and responses to regulatory requests.

Regulatory Management Plan

This is a management plan that describes how the program's regulatory strategy is structured, identifying its functional elements and their general responsibilities.

Regulatory Action Support Plan

This plan describes how DOE and the organization will support regulatory interactions and reviews.

Regulatory Response Development, Review, and Approval Procedure

This procedure establishes the process for responding to requests for additional information (RAIs) from regulators. It provides administrative controls to manage a large number of regulatory questions requiring responses within short time frames, and the steps for developing responses which are complete and accurate in all material respects.

Regulatory Information Validation Process Procedure

Regulatory responses need to be particularly exact and this procedure defines the process and responsibilities for validating material statements being made in regulatory submittals.

NRC Interaction Procedure(s)

This procedure will describe the conduct of interactions with NRC.

EPA Interaction Procedure(s)

This procedure will describe the conduct of interactions with EPA.

7.2 Business Management

Business Management includes the activities that enable a workforce to accomplish its objectives using established work processes, and business management IT systems. The work force and financial controls are supplied via business management processes. There is an understandable debate about the relative benefits of distributed vs. centralized work processes. The organization's approach will provide centralization of function and responsibility. The organization's focus will be on planning, monitoring execution, work performance evaluation and documentation of results including the activities listed below.

Business Management Plan

This is a management plan that describes how the program's business management strategy is structured, identifying its functional elements and their general responsibilities.

7.2.1 Staffing**Separation Checkout**

This procedure assures that the employee separation process is documented ensuring that the departing or transferring employee's records that need to be retained (for example, for derivative discovery are transferred to the organization's Records Management function for retention.

7.2.2 Employee Concerns Program (ECP)**ECP Plan**

This is a management plan that describes how the program's employee concerns program is structured, identifying its functional elements and their general responsibilities.

7.2.3 Training

The training function is integrally tied to the program's operations and Quality Assurance. MOW must be trained to perform certain functions in a high-quality, regulation-aware business and technical team.

Training Plan

This is a management plan that describes how the training program is structured, identifying its functional elements and their general responsibilities.

Training and Qualification Policy

This policy is designed to ensure employees possess the necessary knowledge and skills to effectively perform their jobs. This will include auditable records of employee training, as required, and will implement State and Federally mandated training as well as DOE mandated training.

Training Program Description

The description is mostly a training program plan which outlines the training processes and procedures, and includes a clear definition of program requirements and implementation of a systematic approach to training.

Training Analysis Procedure

This procedure helps ensure the cost-effective use of training by determining what the training response should be to regulatory drivers, management requests for training, and performance issues.

Training Design and Development Procedure

This procedure is designed to provide the basic process to determine the necessity for training material modification. This identifies the sequence of training, objectives for learning and appropriate training settings.

Training Presentation and Evaluation Procedure

This procedure provides the basic process to instruct and perform the evaluation of training materials, students, and instructors (or the presentation in the case of Computer Based Training (CBT)). Training instruction provides the sequence of training objectives for learning and appropriate training settings for a successful presentation.

7.2.4 Procurement

Acquiring material or services is always necessary in performance of any endeavor. There is a very direct connection between QA and procurement when it comes to acquiring quality-affecting items or services.

Procurement Documents Procedure

The procedure establishes the process used to procure services and/or products to support the organization activities.

Procurement of Services from a QSL Laboratory Procedure

The procedure specifies the process used to procure services and/or products to support the organization.

Procurement of Services from a Non-QSL Laboratory Procedure

The procedure specifies the process used to procure services and/or products to support organization from vendors that are not included in the Qualified Suppliers List.

7.2.5 Facilities

Regardless of the nature of the venture property will be necessary to achieve the objectives. Facility functions are directed at all the post-purchase (or rental) management needs for various properties.

Emergency Management Program Description

This description provides guidance for the response to and mitigation of an emergency situation (to include accidents, incidents, or natural phenomena that degrade the safety or security of any off-site building/facility) at any off-site location of the organization through the formation and maintenance of an Emergency Management Program.

Emergency Response Plan

This plan establishes the responsibilities and processes to comply with all requirements found in the organization's safety manual.

Define / Develop Security Plans

These plans establish the security requirements necessary for the organization to be consistent with DOE policies.

7.2.6 Financials/Funding

This function provides for annual budgeting, including cost estimating, and fund management, including receiving and verifying the Approved Funding Program (AFP) to meet government requirements.

7.2.7 Project Controls

This function provides for establishing a work breakdown structure (WBS), which provides a structure for planning, managing, controlling, and monitoring the cost, schedule and performance of a project. Typically this function is responsible for establishing and certifying an Earned Value Management System (EVMS) for the program.

Develop Earned Value Management System

A guide is necessary for establishment and application of an integrated Management system with coordination of work scope, schedule, and cost objectives and application of earned value methods for program or enterprise planning and control.

Plan to Develop Oracle Financials and Primavera Cost Manager Applications

Establishes the process and responsibilities for the development, tracking, and reporting of schedules, resources and budgets within the organization.

7.3 Organizational Assurance

Organizational Assurance includes the activities necessary to oversee the organization's operational and functional fidelity to assure integration and appropriate conduct of operations, including the concepts and activities listed below.

7.3.1 Nuclear Safety Culture

A policy consistent with NRC's final policy statement (NRC, 2011) will be developed as part of Program Management

7.3.2 Safety Conscious Work Environment

A policy will be developed as part of Program Management

7.3.3 Corrective Action Program

The Corrective Action Program (CAP) function develops and implements the organization's corrective action program and system consistent with current regulatory guidance.

Corrective Action Program System Policy and Procedure(s)

These policies and procedures establish the process for the organization to identify issues and to develop and implement a corrective action program and system consistent with current regulatory guidance.

Nonconformance Reporting and Resolution Procedure

The procedure establishes a standard process for the organization to identify, report, control, disposition, and verify correction of nonconforming conditions. This process will also establish the interfaces among organizations or organizational elements to execute this process.

7.3.4 Requirements Management

Requirements Management develops and implements the organization's requirements management effort and process consistent with current organizational policy. It provides a means to identify, record, allocate, implement and track the organization's requirements needs to be developed.

Requirements Management Procedure

The procedure establishes responsibilities and processes for the identification of requirements for work planning, evaluation of risk associated with requirements allocation for implementation of controls, and tracing of requirements to work managed by the organization.

7.3.5 Commitment Management

This function is responsible for the development and implementation of a commitment management process to facilitate the tracking and resolution of the organization's commitments, whether they originate in program policies, administrative directives, or technical or regulatory instruction. It provides a means to record and track resolution of items identified by management. A component of the process could track corrective actions

7.3.6 Regulatory Document Configuration Management

Development and implementation of the organization's regulatory document configuration management process to facilitate the maintenance of rigorous configuration management for formal regulatory documents.

Regulatory Document Configuration Management Policy and Procedure

The purpose of regulatory document configuration management procedure is to manage proposed changes to ensure the information in a particular regulatory document remains complete and accurate in all material respects. It establishes the roles, responsibilities, and processes regulatory document configuration management process for; (1) evaluating proposed changes, initiating change requests, and preparing, reviewing, and approving change packages, (2) preparing, reviewing, approving, and submitting regulatory document updates to the regulator, and (3) implementing the change process.

7.3.7 Knowledge Management

The Knowledge Management function is responsible for development and implementation of the organization's effort directed at compiling, organizing, leveraging, and preserving the organization's knowledge base(s) to support organizational goals and anticipated future needs. Knowledge Management has two principle functions. The first is to provide processes designed to ensure the promulgation of current information to the workforce and the second is to provide long-term historical record of program participant's and developments.

Knowledge Management Plan

This is a management plan that describes how the program is structured, identifying its functional elements and their general responsibilities.

Operation Experience and Lessons Learned

Establishes the process and defines the responsibilities for identifying, documenting, validating, communicating, and identifying actions to be taken on positive and negative experiences originating from within the organization, as well as from the broader nuclear industry.

7.3.8 Self-Assessment

The Self-Assessment function is to develop and implement the organization's process to regularly perform self-assessments consistent with Corporate Procedure: CG100.6.3 Determine, Plan and Perform Assessments, and other Quality Assurance and regulatory requirements. Self-Assessments are integral to most Organizational Assurance functions, as it provides the means by which the program evaluates and documents its conformance with authoritative direction.

Self-Assessments and Management Observations Procedure

This procedure establishes the process for scheduling, preparing, performing, and reporting Self-Assessments (SAs). This is intended to promote a self-critical culture by proactively identifying areas for improvement in processes, practices, behaviors, roles, responsibilities, and organizational expectations.

7.3.9 Risk Management

Risk Management develops and implements the organization's general programmatic risk evaluation and management processes, consistent with CG100.6.1 Manage Risks.

Risk Management Plan

This is a management plan that describes how the program is structured, identifying its functional elements and their general responsibilities.

7.4 Information Management

Information Management includes activities that enable a workforce to accomplish its objectives using program-wide information processes and IT Systems.

Policy for Review and Approval for Release of Products to the Public

The policy explains the process for reviewing products developed by the organization prior to distribution or presentation to the public.

Policy that Final Information Conforms to NRC ADAMS Standards

A procedure will be needed to assure that the organization's documents are initially prepared so as to be acceptable for submittal to NRC.

7.4.1 Records Management

Records Management is the unique process for capturing all information related to the effort, independent of its origin or form.

Records Management Policy

The policy describes the process for identification, creation, maintenance, and disposition of organization records.

Records Management Procedure

The procedure describes the process for the identification, creation, maintenance, disposition, screening, and indexing of the organization's records.

Control and Management of Electronic of Information Procedure

The procedure establishes the responsibilities and provides direction for developing and evaluating the adequacy of process controls on specific uses of electronically stored information.

7.4.1.1 Document Control

Document Control is an element of records management providing for the necessary control of certain documents essential to conduct of operations.

Document Control Procedure

The procedure establishes the process and responsibilities for the identification, submittal, release, distribution, and disposition of controlled and associated change documents. These controls ensure that documents are approved for release and available at the location for use.

7.4.1.2 Correspondence Control

Correspondence Control is an element of records management providing for centralized receipt of official program correspondence coupled with electronic distribution of mail.

Correspondence Control Procedure

A procedure for correspondence control will need to be developed.

7.4.1.3 License Support Network

License Support Network (LSN) is a critical element of records management that provides processes and protocols designed to satisfy the procedural requirements of 10 CFR 2, subpart J of NRC's licensing rules.

LSN Certification Plan

The purpose of this plan is 1) to provide the methodology and schedule to verify that the organization is in compliance with LSN requirements; and 2) to describe the basis for the organization's LSN certification.

Managing Licensing Support Network Relevant Records Procedure

The procedure provides direction for identifying, submitting, and transferring licensing support network (LSN) relevant records and certifying the completion of this activity.

7.4.1.4 Reference Registry

Reference registry processes and systems for documenting (and retaining copies) of all references is critical to assuring the integrity of program documents. Tens (could be hundreds) of thousands of references will be cited in documentation produced on the program, consisting of both public and copyrighted information.

Reference Registry Procedure

This procedure will identify the process and constraints for entering information in the Reference Registry.

7.4.1.5 Email Records

Managing Electronic Mail Records Procedure

The procedure provides direction for creating and dispositioning electronic mail (e-mail) messages generated by members of the organization including e-mail received from outside the organization.

7.4.1.6 Data Management

Data Management is also an element of records management, because all data generated within the program undoubtedly meets the definition of a record. Data management provides a process specifically designed to handle the special needs of data management, which often involves large complicated electronic files.

Data Management Procedure

The procedure establishes the process and responsibilities for management of technical product inputs for the organization's products (e.g., technical reports).

Procedure for Submittals to the Data Management

This procedure establishes the responsibilities and processes for submitting and incorporating Data Packages into the Technical Data Management System (TDMS).

7.5 IT Systems

The IT Systems function includes activities necessary to define, design, implement, and maintain IT systems to support the organization's processes and functions. Systems that are developed to support the business and technical efforts are critically important to the overall success of the project and generally fall into two categories: a) information systems; and b) high performance computing systems.

Network / Collaborative Systems Plan

The plan describes the organization's approach to establish collaborative electronic system(s) to support information access, workflow, approvals, and communication capability with both internal and external entities.

Develop Computer Security Plans

The plan(s) establish computer security requirements necessary for the organization to be consistent with applicable policies.

Software Configuration Management Plan

The plan could provide for a fully automated system that manages and tracks software usage and requests and to facilitate the management of error correction, software retirement, and baseline configuration. This facilitates accurate reporting of software status and provides the architecture for future implementation of an iterative life-cycle process.

Software Management Procedure

The procedure establishes the process, identifies roles, and defines responsibilities for management of software used in support of the organization's scientific and engineering scope, especially important to safety/important to waste isolation (ITS/ITWI) activities. This also specifies the software quality assurance approach for software life cycle management, as well as describes the repository license organizations software management and software configuration (SCM) system.

Software Qualification Procedure

The procedure establishes the responsibilities and processes for those activities (requirement phase, design phase, implementation phase, and testing phase of software life cycle management) that constitute the organization's software qualification process.

7.6 Science / Engineering

Policies and procedures for science and engineering are usually highly specific to the work being undertaken. However, several categories of policies, plans and procedures are generally applicable to science and engineering activities and should be anticipated.

7.6.1 General Science / Engineering Policies and Procedures**Planning for Science Activities Procedure**

The procedure establishes responsibilities and process for preparation, review, approval, revision, cancellation, and distribution of Technical Work Plans (TWPs) for the organization's scientific investigation activities.

Preparing and Approving Technical Procedures

The procedure establishes the process and defines responsibilities for preparing, reviewing, approving, revising, changing, and cancelling technical procedures for science activities.

Technical Reports Procedure

The procedure establishes the responsibilities and process for the preparation, review, approval, change, correction, and revision of technical reports related to the organization's science and engineering activities.

Peer Review Procedure

The procedure establishes the responsibilities and methods for planning, conducting, and documenting peer reviews consistent with the guidance in NUREG-1297, Peer Review for High-Level Nuclear Waste Repositories.

Expert Elicitation Procedure

The procedure establishes the responsibilities and methods for planning, conducting, and documenting expert elicitation projects consistent with the guidance in NUREG-1536, Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program. This procedure also implements Quality Assurance requirements. This procedure presents a consistent and systematic approach that will ensure that the results obtained from an expert elicitation accurately reflect what is known and not known about the topic in question.

Qualification of Unqualified Data Procedure

The procedure establishes the responsibilities and process to be used for the qualification of unqualified data. This does not apply to established fact data or numerical data obtained from an established/authoritative data source.

Document Review Procedure

The procedure provides a process for conducting and documenting reviews of documents (including technical, quality assurance, management, and data submittals) and the preparation and resolution of review comments.

Scientific Analysis and Calculations Procedure

Establishes the responsibilities and the process for the preparation, review, approval, change, correction, and revision of scientific analysis and calculation reports supporting the organization's science and engineering activities.

Models Procedure

The procedure establishes the responsibilities and process for the preparation, review, approval, change, correction, and revision of model reports supporting the organization's science and engineering activities.

Analysis Reports Procedure

The procedure establishes the process and responsibilities for developing analyses that do not change the technical baseline without proper notice. This procedure is intended for use to assess the impact of new scientific information and evaluate or analyze the potential effects of proposed design or requirement changes.

Technical Interface Control Procedure

The procedure establishes the process and responsibilities for controlling design interfaces.

Control of Measuring and Test Equipment Procedure

The procedure establishes the responsibilities and process for the identification, control, calibration, storage, and maintenance of measuring and test equipment.

Scientific Notebooks Procedure

The procedure prescribes requirements for the preparation and use of Scientific Notebooks to document repository scientific investigations, subject to the organization's Quality Assurance Requirements.

Data Acquisition Procedure

The procedure describes the process for collecting electronic data from various Data Acquisition Systems (DAS).

7.6.2 Policies / Procedures Related to Work at a Site Under Evaluation**Work Control Procedure**

The procedure establishes processes necessary to authorize, integrate, and control surveillance and maintenance activities at a site and to provide guidance for developing implementing documents, including maintenance orders (MOs) and Site Work Instructions (SWIs).

Authorization for Site Work Procedure

The procedure establishes the process necessary to authorize work activities to be performed within designated controlled area as designated at a site.

Site Access Training Procedure

The procedure identifies governing requirements and procedures for access to a site.

Borehole Security and Access Procedure

The procedure controls the process for protection of, and access to repository surface boreholes to minimize adverse impacts to repository development data and natural barriers important to waste isolation.

Testing Work Implementation and Control Procedure

The procedure establishes the responsibilities and process for planning, enabling, and controlling the safe conduct of tests related to work activities. This ensures field and applicable laboratory work is authorized, documented, approved, and implemented consistent with applicable quality requirements, technical standards, administrative controls, and hazard controls.

7.6.3 Policies / Procedures Related To General Site Studies / Characterization**Seismic Network Operations Procedure**

The procedure describes the process for seismic monitoring in order to establish a comprehensive and reproducible earthquake catalog for the site region and data suitable for quantitative analysis of ground motions.

Sampling Procedure

The procedure establishes processes and responsibilities for collection, handling, controlling, and disposing samples that have been collected in the field, procured, or produced in laboratory.

Geophysical Analysis Procedure

The procedure establishes the process and responsibilities required for the collection, verification, evaluation, and analysis of borehole geophysical logging data for a site, and for ensuring that the data is traceable, maintained, and verified.

Water Analysis Procedure

The procedure establishes water-sampling methods for a site.

Precipitation Analysis Procedure

The procedure defines the processes for performing routine meteorological site checks including the collection of precipitation quantity data.

8. References

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