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**SANDIA NATIONAL LABORATORIES
QUALITY ASSURANCE PROGRAM
for the
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT**

QUALITY ASSURANCE PROGRAM PLAN

Revision 1

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0	Initial Document	05/04/2004
1	Administrative changes resulting from audit OQA FS-04-07	05/20/2004

Quality Assurance Policy Statement

The United States Department of Energy (DOE) has authorized the Office of Civilian Radioactive Waste Management (OCRWM) through the Office of Science & Technology and International (OSTI) Program to research, develop, test and analyze materials and methods for use in enhancing their potential industry applications. Sandia National Laboratories (SNL), under Cooperative Agreement "Guidance and funds to Sandia National Laboratories from the Office of Civilian Radioactive Waste Management", shall maintain and implement the SNL OSTI Quality Assurance Program and administer and conduct scientific and engineering studies.

The governing documents for the SNL OSTI QA Program are the DOE/OCRWM Quality Assurance Requirements Description (QARD) document and Attachment 1 "QA Requirements" of the above referenced. Cooperative Agreement Requirements from these documents shall be integrated into the SNL OSTI QA implementing documents. If work cannot be completed as directed in the implementing documents, the work shall be suspended. Work shall not resume until appropriate modifications are approved and issued, or other documented resolution is obtained.

SNL shall implement the SNL OSTI QA Program from the planning stage through completion of work activities subject to the requirements of the DOE OCRWM QARD and the Funding Guidance Memorandum. Compliance with the SNL OSTI QA Program is mandatory when work is identified as applicable to QARD requirements.

Introduction

Sandia National Laboratories (SNL) is responsible for performing work sponsored by the Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM), Office of Science & Technology and International (OSTI). This work shall be conducted in accordance with the Quality Assurance (QA) guidelines outlined in this Quality Assurance Program Plan (QAPP) and shall satisfy the requirements of the OCRWM Quality Assurance Requirements and Description (QARD) document for the Yucca Mountain Project (YMP). The QAPP also satisfies the quality assurance guidelines set forth in the document entitled "Quality Assurance Requirements for Work Authorized by OCRWM Program and Funding Guidance Memorandum". The following table provides a roadmap from the SNL OSTI QA Program to this QAPP, the QARD, and the Funding Guidance Memorandum.

QA Element	SNL OSTI QAPP Section	YMP QARD Section	OSTI Funding Memorandum
Organization	1.0	1.0	•
Quality Assurance Program	2.0	2.0	•
Design Control	N/A	3.0	N/A
Procurement Document Control	4.0	4.0	•
Implementing Documents	5.0	5.0	•
Document Control	6.0	6.0	•
Control of Purchased Items and Services	7.0	7.0	•
Identification and Control of Items	8.0	8.0	N/A
Control of Special Processes	N/A	9.0	N/A
Inspection	N/A	10.0	N/A
Test Control	11.0	11.0	•
Control of Measuring and Test Equipment	12.0	12.0	•
Handling, Storage and Shipping	13.0	13.0	N/A
Inspection, Test and Operating Status	N/A	14.0	N/A
Nonconformances	15.0	15.0	•
Corrective Action	16.0	16.0	•
Quality Assurance Records	17.0	17.0	•
Audit	18.0	18.0	•
Software	Sup I	Sup I	•
Sample Control	Sup II	Sup II	•
Scientific Investigation	Sup III	Sup III	•
Field Surveying	N/A	Sup IV	N/A
Modeling	Sup III	Sup III	•
Control of the Electronic Management of Data	Sup V	Sup V	•
High Level Waste Form Production	N/A	App A	N/A
Storage and Transportation	N/A	App B	N/A
Monitored Geologic Repository	N/A	App C	•

Scope

This QAPP has been developed to encompass the work activities that are the responsibility of SNL in support of the OSTI Program. This work includes procurement of pertinent materials and equipment and preparation of documentation. All SNL personnel assigned to support SNL OSTI work shall conform to the applicable section of this QAPP.

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1.0 Organization

SNL shall establish an organizational structure to manage and accomplish the technical and quality objectives established by OSTI for the planning, performance, completion and reporting of advanced material science studies.

An organizational structure has been established and is located on the SNL OSTI On-line Documents web site. This structure identifies the line and Quality Assurance (QA) organizations involved in performing OSTI work scope. Quality shall be achieved by those assigned the responsibility for performing work. Verification of quality achievement shall be performed by personnel or organizations not directly responsible for performing the work.

- SNL OSTI Project Lead

The SNL OSTI Project Lead (OPL) is a SNL Line Manager who reports to the OCRWM OSTI Program Deputy Director and is responsible for completion of OSTI work assigned to SNL in accordance with established implementing documents. The OPL is responsible for execution of the SNL OSTI QA Program, resolving any difficulties and differences of opinion regarding the development and implementation of the QA Program, and interfacing with Responsible Managers and Principal Investigators to assure that technical and QA matters are properly addressed.

- Responsible Manager

A Responsible Manager is a SNL Line Manager (or designee) who is accountable for the planning, performance, and completion of a unique scientific activity. Managers may delegate any of the functions assigned to them by this QAPP to another qualified individual. This delegation shall be documented and management shall retain ultimate responsibility for accomplishment of the functions in accordance with the provisions of this QAPP.

- Quality Assurance Lead

The SNL Quality Assurance Lead is responsible for ensuring compliance with the requirements of the QA Program. The QA Lead reports to the OPL and shall be sufficiently independent from cost and schedule considerations, have the organizational freedom to effectively communicate with other management positions, shall be responsible for interpreting and approving QA Program requirements, shall verify adequate establishment and execution of the QA Program, and shall have the authority to stop work. In addition, a reporting relationship will be established between the QA Lead and the OCRWM Office of Quality Assurance (OQA) to assure an independent line of communication on matters related to the adequacy and effectiveness of the SNL OSTI QA Program.

- Principal Investigators

Principal Investigators (PIs) are responsible for managing the performance of scientific investigations within their area of expertise. The PIs are responsible for the performance and

reporting of these investigations and for performing such work in accordance with the requirements of the QA Program.

2.0 Quality Assurance Program

SNL shall establish, implement and maintain a Quality Assurance Program to control work activities that affect the quality of this work conducted under the SNL OSTI Program. The QA Program shall provide control over activities to the extent consistent with their importance. QA Program requirements shall be implemented through Quality Assurance Procedures (QAPs), Test Plans (TPs), and Experimental Implementing Procedures (EIPs) developed to control the performance of scientific investigation, calibration, and other activities that affect the quality of tasks performed under the SNL OSTI Program.

The use of expert elicitation may be considered to provide a systematic process for its conduct and is implemented to assure the results of the elicitation accurately reflect data, process and model uncertainty. New data will be reviewed to determine relevance with respect to the expert's assessment, including the need for reassessment. Software that has not been qualified in accordance with the requirements of *Supplement I, Software*, and unqualified data may be used in the expert elicitation process, and the results of the expert solicitation process will be considered qualified. However, the expert elicitation process will not be used to qualify software or unqualified data used as input.

Documents developed to implement the QA Program shall be reviewed and approved at a minimum by the manager responsible for the work, a qualified technical individual, and the QA Lead. Prior to performing activities that affect the quality of tasks conducted for the SNL OSTI Program, personnel shall be: 1) qualified to appropriate education and experience, 2) trained to the appropriate implementing documents, and 3) indoctrinated in the requirements of the QA Program. Verification of education and experience (VOEE) and training shall be documented.

The SNL QA Lead shall request that the OCRWM Office of Quality Assurance (OQA) perform or direct the performance of surveillances, audits and/or management assessments of the SNL QA Program, and shall be responsible for planning, performing, and evaluating the effectiveness of the QA Program and reporting results to appropriate management.

The following QAPs, as a minimum, shall be developed to implement this QAPP. Additional implementing documents may be issued as needed to support changes in the OSTI work scope.

QAP No.	Title	QAP No.	Title
QAP 1-1	Organization and Quality Assurance	QAP 16-1	Corrective Action and Nonconformance
QAP 2-1	Qualification and Training	QAP 17-1	Records Management
QAP 4-1	Procurement Document Control	QAP 18-1	Audits
QAP 5-1	Implementing Documents	QAP 19-1	Software Development & Qualification
QAP 6-1	Document Review	QAP 20-1	Test and Analysis Plans
QAP 6-2	Document Control	QAP 20-2	Scientific Notebooks
QAP 12-1	Control of Measuring & Test Equipment	QAP 20-5	Control of Electronic Management of Data
QAP 13-1	Sample Control		

At the writing of this QAPP, peer review activities are not a part of the SNL OSTI Program. If peer review activities become a responsibility of the SNL OSTI Program at a later date, then SNL shall develop the appropriate implementing document to ensure compliance with the QARD.

3.0 Design Control

At the writing of this QAPP, design activities are not a part of the SNL OSTI Program. If design activities become a responsibility of the SNL OSTI Program at a later date, then SNL shall develop the appropriate implementing document to ensure compliance with the QARD.

4.0 Procurement Document Control

SNL shall establish measures to assure procurement documents, and any changes thereto, for items or services that affect the quality of SNL OSTI Program activities include appropriate technical and quality requirements. These shall conform to SNL procurement requirements and to SNL Price-Anderson Amendments Act processes for procurement.

Procurement documents shall include the following as a minimum when applicable: 1) a statement of work for service; 2) applicable technical requirements such as part of the codes, standards, specifications, procedures, instructions, and/or drawings; 3) applicable quality requirements such as reference to the suppliers documented QA Program or, as an alternative, allowance to perform some or all of the work scope under the SNL OSTI QA Program (provided the applicable controls from the QA Program are included in the procurement documents, such as the procedures to be followed, calibrated measuring and test equipment to be provided, oversight established to assure material traceability and/or compliance with procedures, etc.); 4) right of access to the supplier's facilities and records for inspection or audit by SNL and/or OCRWM; 5) documentation to be provided to SNL for information, review, or acceptance; and 6) reporting of nonconformances and approval of their disposition by the SNL QA Lead (or designee).

The procurement of analytical services may be done through the SNL Sample Management office. The measurement of properties or other characterization of samples in support of scientific investigations may not require the supplier to have a documented QA program approved by SNL, provided such services are controlled in accordance with the requirements of Section 7.0.

Procurement documents and any changes thereto, shall be reviewed and approved by the Responsible Manager and by the SNL QA Lead to assure adequacy of quality and technical requirements.

5.0 Implementing Documents

SNL shall establish measures to assure work is prescribed by, and performed in accordance with, written implementing documents: TP, QAP, and EIP. Implementing documents shall include appropriate guidance to control the performance of work including, but not limited to, a description of the work/activity to be performed; the responsibilities and organizational interfaces affected by the document; technical and quality requirements; qualitative or quantitative acceptance criteria; prerequisites, limits, precautions, and environmental conditions; and

required records. Implementing documents shall be reviewed, approved and controlled in accordance with the requirements of Section 6.0.

SNL personnel shall comply with approved implementing documents; however, when work cannot be accomplished as prescribed in the implementing document, work shall be stopped and shall not resume until the document is revised to reflect the correct work guidance.

6.0 Document Control

SNL shall establish measures to assure documents, including changes thereto, are reviewed for adequacy, approved for release, and distributed to and used at the location where work is being performed. Individuals, other than the preparer of the document, who are technically competent shall review project documents, including changes thereto, for applicability, correctness, completeness, and accuracy. Documents shall be reviewed by SNL OSTI QA to verify that they include appropriate quality requirements and are in compliance with the requirements of the SNL QA OSTI Program, and shall be approved by SNL OSTI management for release. This review and approval shall be documented.

Documents, including changes thereto, (either in hardcopy or electronic media) used to perform work shall be distributed to, or made available, and used at the work location. Documents shall be identified with effective dates, and electronic database files shall be available to determine the current status of documents used to perform work. Obsolete or superseded documents shall be controlled to assure they are not inadvertently used.

7.0 Control of Purchased Items and Services

SNL shall control the procurement of items and services that affect the quality of SNL OSTI Program activities to assure conformance with requirements specified by procurement documents. SNL shall use only suppliers who have been evaluated and accepted by OCRWM and who have been placed on the OCRWM Qualified Suppliers List (QSL). SNL shall require that suppliers on the OCRWM QSL perform work in accordance with Section 4.0.

SNL shall establish the process to accept items and services by verifying suppliers have complied with procurement document requirements. Verification activities include, but are not limited to, review of objective evidence (such as certificates, test or calibration reports, certifications, personnel qualifications, conduct of source surveillances or audits at the supplier's facilities, or any combination of these activities). The performance of verification activities and the acceptance of items and services shall be documented. Acceptance activities shall include the review and acceptance of the disposition of any nonconformances identified by the supplier.

Analytical services in support of scientific investigations may be obtained from suppliers not listed on the QSL provided the supplier is required to participate in a quality control sample plan. The quality control sample plan shall be developed prior to issue of the procurement document to the supplier and shall address the number and approach of quality control samples to be submitted, the preparation and analysis of the quality control samples, acceptance criteria, and how the quality control samples, the approach and acceptance criteria provide confidence in the accuracy/precision of the data. The quality control sample analytical results shall be received

and evaluated against the acceptance criteria prior to using the suppliers' data developed as a result of the analytical service. Analytical data produced, the quality control sample plan, and the quality control sample analytical results and evaluation documentation shall be submitted as QA records.

8.0 Identification and Control of Items

SNL shall establish measures to assure that only correct and accepted items are used during the performance of tests and experiments. Identification shall be maintained on the item or documents traceable to the item or in a manner that assures that identification will be established and maintained. Physical marking, when used, shall be applied using methods and materials that provide a clear and legible identification, shall not be detrimental to the function or service of the item, and shall be transferred to each part of an identified item when the item is subdivided.

9.0 Control of Special Processes

At the writing of this QAPP, special process activities are not a part of the SNL OSTI Program. If special process activities become a responsibility of the SNL OSTI Program at a later date, then SNL shall develop the appropriate implementing document to ensure compliance with the QARD. Any special processes performed by SNL suppliers shall be controlled in accordance with Section 4.0 and Section 7.0.

10.0 Inspection

At the writing of this QAPP, performance inspection activities are not an element of the SNL OSTI Program. If design activities become a responsibility of the SNL OSTI Program at a later date, then SNL shall develop the appropriate implementing document to ensure compliance with the QARD. As needed, specific test may be included in activities such as those for the acceptance of procurement items and for determining operational status.

11.0 Test Control

SNL measures for controlling tests shall be addressed by the SNL controls established for the performance of scientific investigations in accordance with Supplement III Scientific Investigation of this QAPP. If test control activities under this section become a responsibility of the SNL OSTI Program at a later date, then SNL shall develop the appropriate implementing document to ensure compliance with the QARD.

12.0 Control of Measuring and Test Equipment

SNL shall establish measures to assure measuring and test equipment (M&TE) is properly controlled, calibrated, and maintained. M&TE shall be calibrated at prescribed intervals or prior to use against reference standards having traceability to nationally recognized standards. If no

nationally recognized standards or physical constants exist, the basis of the calibration shall be documented. Calibration standards shall have a greater accuracy than the required accuracy of the M&TE being calibrated, unless they do not exist or are unavailable. The use of calibration standards with accuracy equal to the required calibration accuracy shall be authorized if they can be shown to be adequate for the requirements and the basis for the use is documented and approved by the SNL QA Lead.

Calibrated M&TE shall be labeled, tagged, or otherwise marked or documented to indicated due date or interval of the next calibration and shall be uniquely identified to provide traceability to its calibration data. Calibration documentation shall include identification of the M&TE calibrated, reference standards used for the calibration, identification of the procedure used to conduct the calibration and resulting calibration data, name of the individual performing the calibration, date of calibration and recalibration due date or interval, a statement of the acceptability of the calibration, and reference to any action taken in connection with out-of-calibration or other nonconforming conditions noted during the calibration. M&TE shall be properly handled and stored to maintain accuracy.

The use M&TE shall be documented. M&TE found to be out-of-calibration, producing erroneous results, or exceeding its calibration due date, shall be tagged, segregated, or otherwise controlled to prevent use until they have been recalibrated. M&TE found out-of-calibration during the recalibration process shall be evaluated to determine the validity of results obtained using the M&TE since its last valid calibration, and the evaluation shall be documented.

The procurement and acceptance of supplier calibration services shall be controlled in accordance with Section 4.0 and Section 7.0.

13.0 Handling, Storage, and Shipping

SNL shall establish measures for the handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. These measures shall be conducted in accordance with work implementing documents, shipping instructions or other specified documents. SNL shall develop specific implementing documents for critical, sensitive, perishable, or high-value articles that may require special handling tools and equipment or protective environments. Such articles shall be marked and/or labeled to identify any special controls.

14.0 Inspection, Test and Operating Status

SNL measures for performance of inspection and operating activities shall be addressed by the SNL controls established for the performance of scientific investigations in accordance with Supplement III, Scientific Investigation, of this QAPP. If performance of inspection and operating activities under this section become a responsibility of the SNL OSTI Program at a later date, then SNL shall develop the appropriate implementing document to ensure compliance with the QARD.

15.0 Nonconformances

SNL shall establish measures to control items that do not conform to requirements in order to prevent their inadvertent use of installation. Measures shall provide for the documentation, identification, evaluation, and disposition of nonconforming items. Nonconformances shall be documented to clearly identify and describe the characteristics that do not conform to specified criteria. Nonconformance documentation shall be reviewed and recommended dispositions shall be proposed. Recommended dispositions shall be reviewed, evaluated and approved by the PI and the SNL QA Lead.

Nonconforming items shall be identified by marking, tagging, or other methods that do not adversely affect their use in order to control further processing, delivery, installation, or use pending the evaluation and approval of the disposition. If identification of the item is not practical, then the container, package, or storage area shall be identified. Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until proper disposition. If segregation is impractical or impossible due to physical conditions, then other precautions shall be employed to preclude inadvertent use.

The disposition of items such as “use-as-is” or “reject” for nonconforming items shall be identified and documented. The technical justification for dispositions of “use-as-is” shall be documented. The PI shall verify implementation of the disposition and shall complete the nonconformance documentation.

16.0 Corrective Action

SNL shall establish measures to assure that conditions adverse to quality are promptly identified and corrected as soon and as efficiently as possible. Conditions adverse to quality shall be identified when a requirement from this QAPP or an implementing document is not met. Conditions adverse to quality shall be classified in regard to their significance as either 1) Conditions Adverse to Quality (CAQ) or 2) Significant Conditions Adverse to Quality (SCAQ). CAQs shall be documented and reported to the PI responsible for the condition and to the QA Lead for tracking. The PI shall determine the extent of the condition and complete remedial corrective action as soon as practical. The QA Lead shall concur with the proposed remedial action to assure that the QA Program requirements are satisfied.

The PI and the QA Lead shall evaluate CAQs to determine their significance. Significant conditions adverse to quality shall be documented and reported to responsible management, and shall be evaluated to determine if stopping work is warranted. Responsible management shall determine the extent and impact of the condition, document the results, and complete any remedial action as soon as practical. In addition, responsible management shall determine the root cause of the condition and take appropriate corrective action to prevent recurrence. The QA Lead shall periodically review documentation produced by the corrective action and nonconformance processes to identify trends.

17.0 Quality Assurance Records

SNL shall establish measures for the specification, preparation, protection, storage, retention, and maintenance of quality assurance records. Implementing documents based on this QAPP shall identify the documents that are generated as QA records. Records shall be legible, accurate and complete, appropriate for the work, and identifiable to the item or activity to which they apply. Documents shall be considered records when they are complete and verified. Records may be originals or copies and shall be protected from damage, deterioration or loss until they are submitted to the Records Management system.

Records shall be classified as lifetime or nonpermanent. Lifetime records shall be transferred to the Yucca Mountain Project (YMP) Records Processing Center (RPC) for permanent storage. QA records shall be classified as lifetime. Nonpermanent records shall be retained by SNL for the length of the SNL OSTI Program or a minimum of 3 years. A receipt control system shall be established to control the receipt and retrieval of records.

18.0 Audits

Internal surveillances shall be scheduled and performed by the SNL OSTI QA Program to verify compliance and effectiveness of the QA Program. The OCRWM Office of Quality Assurance (OQA) is responsible for performing external audit and surveillance activities of SNL OSTI Program work. SNL shall be responsible for coordinating and supporting OQA audits and surveillances.

SNL personnel who are assigned to perform internal surveillance activities shall be appropriately trained and qualified as per the requirements of the QARD, Section 18.0. Audits and surveillances shall be planned, performed and reported to the appropriate levels of SNL OSTI management.

Supplement I, Software

SNL shall establish measures to ensure appropriate control of the acquisition, development, modification, use and qualification of OSTI Program software. Software that is integral to the operations, maintenance, or calibration of M&TE, and has not been developed or modified by SNL, is controlled by Section 12.0 Control of Measuring and Test Equipment of this QAPP and is exempt from the requirements of this supplement.

The following types of software are exempt from the requirements of this supplement: operating systems, word processors, spreadsheets, database managers, e-mail, and other types of automated office support systems. Any applications, other than software routines and macros, developed using these types of commercially available software shall meet the requirements of this supplement.

Software routines or macros that are documented in each product in which they are used and independently verified by visual inspection or hand calculations without recourse to the

originator shall have limited requirements applied (i.e., identification of software routine or macro, including version; documentation that includes input, computer program generated results for the specified input, and verified results; identification of the commercially available software used to develop the routine and macro, including version).

Software acquisition, development, modification, and maintenance shall proceed in a planned, traceable, and orderly manner utilizing a defined software life cycle methodology. The methodology shall address the following phases: requirements, design, implementation, testing, installation and checkout, operations and maintenance, and retirement.

Software verification and validation activities shall be planned, documented, and performed for each software code, for software changes, and for those system configurations that are determined to impact the software. Individuals not associated with development of the software shall perform software verification and validation actions, unless such level of independence cannot be achieved. When such level of independence cannot be achieved, an individual associated with the development of the software may perform these activities, provided use of the individual is approved by the Responsible Manager and justification is documented.

A software configuration management (SCM) system shall be established to include identification, change control, and status accounting. Software shall be placed under SCM control as each baseline is approved. Software shall not be used in work subject to this QAPP until the SCM system is established.

A software defect and resolution process shall be implemented to promptly report and formally resolve software errors and failures, and shall be integrated with the SCM process. If a defect is identified in software that adversely impacts previous applications, the condition shall be documented and controlled in accordance with Section 16.0 Corrective Action of this QAPP. Software procurement shall be controlled in accordance with Section 4.0 Procurement Document Control and Section 7.0 Control of Purchased Items and Services. Software suppliers shall be required to have policies and procedures in place that meet applicable requirements of Supplement I. Procurement documents shall require the submittal of required documentation and shall require notification of software errors and failures identified by the supplier.

Software that is not developed in accordance with the requirements of this supplement shall be placed under SCM control prior to use. The user organization shall perform, document and provide an independent review and evaluation of the software to determine its adequacy to support software operation and maintenance, and to identify activities to be performed and documents required in order for the software to be placed under SCM. Upon completion of the review and approval of these activities, the software shall be placed under SCM control. The use of software shall be controlled and documented, and the release of software shall be such that comparable results can be obtained through independent replication of the process. Use of software shall be independently reviewed and approved to assure the software selected is suitable to the application. If the intended use of the software falls outside the range of validation as baselined, changes shall be made and approved prior to continuing use. Documentation of receipt of software obtained from SCM shall be provided and maintained for all software in operation or use.

Model development and approaches to validation shall be planned, controlled, and documented. Planning for model validation shall identify the validation methods and validation criteria used. Model validation may be completed after documentation of the model provided this sequence is described by the planning document. Documentation of models shall include a definition of the objective or intended use of the model, a description of the conceptual model and scientific basis, results of literature searches and other background information, identification of inputs and their sources, identification of and rationale for assumptions used to develop or apply the model, discussion of the mathematical and numerical methods used in the model, identification of any associated software used or computer calculations performed, discussion of initial and/or boundary conditions, discussions of model limitations and uncertainties, and identification of the originator, reviewer, and approver.

The intended use and importance of the model for assessing system/experiments performance shall determine the appropriate level of confidence for the model (i.e., highest levels of confidence). Criteria for model validation shall be established to reduce the uncertainties in the model and to demonstrate the phenomenon, process, or system being represented by the model is sufficiently well understood to support the model's intended use. Model validation criteria shall address criteria used to establish the adequacy of the scientific basis for the model, shall be consistent with the model application and justified in the model documentation, shall demonstrate that the model is sufficiently accurate for its intended use, shall be consistent with parameter uncertainties and justified in the model documentation, shall define the importance of the model for assessing system/experiment performance, shall describe the level of confidence for the model, and shall define the supporting information needed to substantiate validation.

Model progression, usually from conceptual model to mathematical model to process model to abstraction model to system model, shall exist. A conceptual model is validated when its implementation as a mathematical process, abstraction, or system-level model is validated. Technical review through publication in a referenced professional journal or review by an external agency may be used to corroborate model validation when used in conjunction with one or more of the following:

- Corroboration of model results with data acquired from field experiments, analogue studies, laboratory experiments, or subsequent relevant observations. Data used to develop and calibrate a model shall not be used to validate a model.
- Peer review and independent technical review,
- Performance confirmation studies using validation-test model predictions prior to comparison with field or laboratory data,
- Comparison of model results with other model results obtained from implementation of an alternative model,
- Calibration with experimental data sets, including the review of model calibrations parameters for reasonableness and consistency in explanation of all relevant data.

Supplement II, Sample Control

SNL shall establish measures to receive, identify, handle, analyze, track, store, preserve, ship, and transfer physical samples consistent with their intended use. Sample identification shall assure that traceability is established and maintained from the sample to applicable implementing or specifying documents, and the sample shall be traceable at all times from its

initial collection through final use. Sample identification shall be documented and checked before release for use. Identification shall be maintained on the sample, or if physical marking is either impractical or insufficient, other appropriate means shall be employed, such as physical separation, labels or tags attached to containers, or procedural controls. Physical marking, when used, shall be applied using materials and methods that provide clear and legible identification, shall not be detrimental to the sample content or form, shall be transferred to each sample part when the sample is subdivided, and shall not be obliterated or hidden by surface treatments or sample preparations unless other identification means are substituted.

Handling, storage, cleaning, packaging, shipping and preservation of samples shall be conducted in accordance with implementing documents or other specified requirements. These controls shall address any requirements for shelf life, protective or preservative environments, handling tools and equipment, replacement of identification tags or marking, etc., required to maintain the integrity of the samples. Samples that do not meet the requirements specified in controlling work documents shall be processed as nonconforming items in accordance with Section 15.0 Nonconformances.

Supplement III, Scientific Investigation

SNL shall establish measures to control the conduct of scientific investigations, including data identification, data reduction, model development and use, and data submittal. Scientific investigations shall be planned and coordinated with the organizations providing input to or using the results of the investigation. Scientific investigations shall be performed using implementing document, scientific notebooks, or a combination of both. When scientific notebooks are used, they will contain a reference to the planning document, identification of samples, and measuring and test equipment, and a description of the work, including identification of procurements, methods, computer software and hardware, individuals performing the work, and a list of individuals authorized to make entries in the notebook, and a summary of the results. Independent qualified individuals shall review scientific notebooks to verify there is sufficient detail to retrace the investigation and confirm the results or repeat the investigation and achieve comparable results without recourse to the original investigator.

Data shall be identified in a manner that facilitates traceability to samples, to associated documentation and to its qualification status, and this identification and traceability shall be maintained throughout the lifetime of the data. Data reduction shall be described to permit independent reproducibility by another qualified individual. Qualified individuals other than those who collected or reduced the data shall review data reduction to assure technical correctness. Unqualified data (i.e., data not developed in accordance with the requirements of this QAPP) may be qualified provided the qualification process is planned and documented and by completing one or more of the following methods:

- Verification that the controls under which the data were generated are similar in scope, requirements, and implementation to the QAPP;
- Evaluation of corroborating data; the basis for selection of the corroborating data is clearly explained and justified;
- Confirmatory testing;
- Peer reviews;
- Technical assessment to independently evaluate data.

Supplement IV, Field Surveying

At the writing of this QAPP, field surveying activities are not a part of the SNL OSTI Program. If field surveying activities become a responsibility of the SNL OSTI Program at a later date, then SNL shall develop the appropriate implementing document to ensure compliance with the QARD.

Supplement V, Control of the Electronic Management of Data

SNL shall establish measures to control the management of data that either exist or are used in an electronic format. This includes data developed as an output of scientific investigation or performance assessment modeling and analysis. Data shall be suitably protected from damage and destruction during their prescribed lifetime and shall be readily retrievable. Descriptions shall be prepared to identify how data shall be stored with respect to media, conditions, location, retention time, security and access. Storage and transfer media shall be properly identified as to source, physical and logical format, and relevant date. The completeness and accuracy of data input and any subsequent changes to the data, as well as the security and integrity of the data, shall be maintained. Data transfers shall be error free, or within a defined permissible error rate, to assure no information is lost in transfer and that the input is recoverable from the output.