



Initial SNL WIPP QA Program Training





Objectives

- **Understand the Source of the SNL WIPP QA Requirements.**
- **Define Basic QA Requirements.**
- **Define QA Roles and Responsibilities for Managers, Staff, and the QA Team.**
- **Review NPs.**





First – What is Quality?

Quality - The condition achieved when an item, service or process meets or exceeds the user's requirements and expectations.

Quality Assurance - All those actions that provide confidence that quality is achieved or exists.



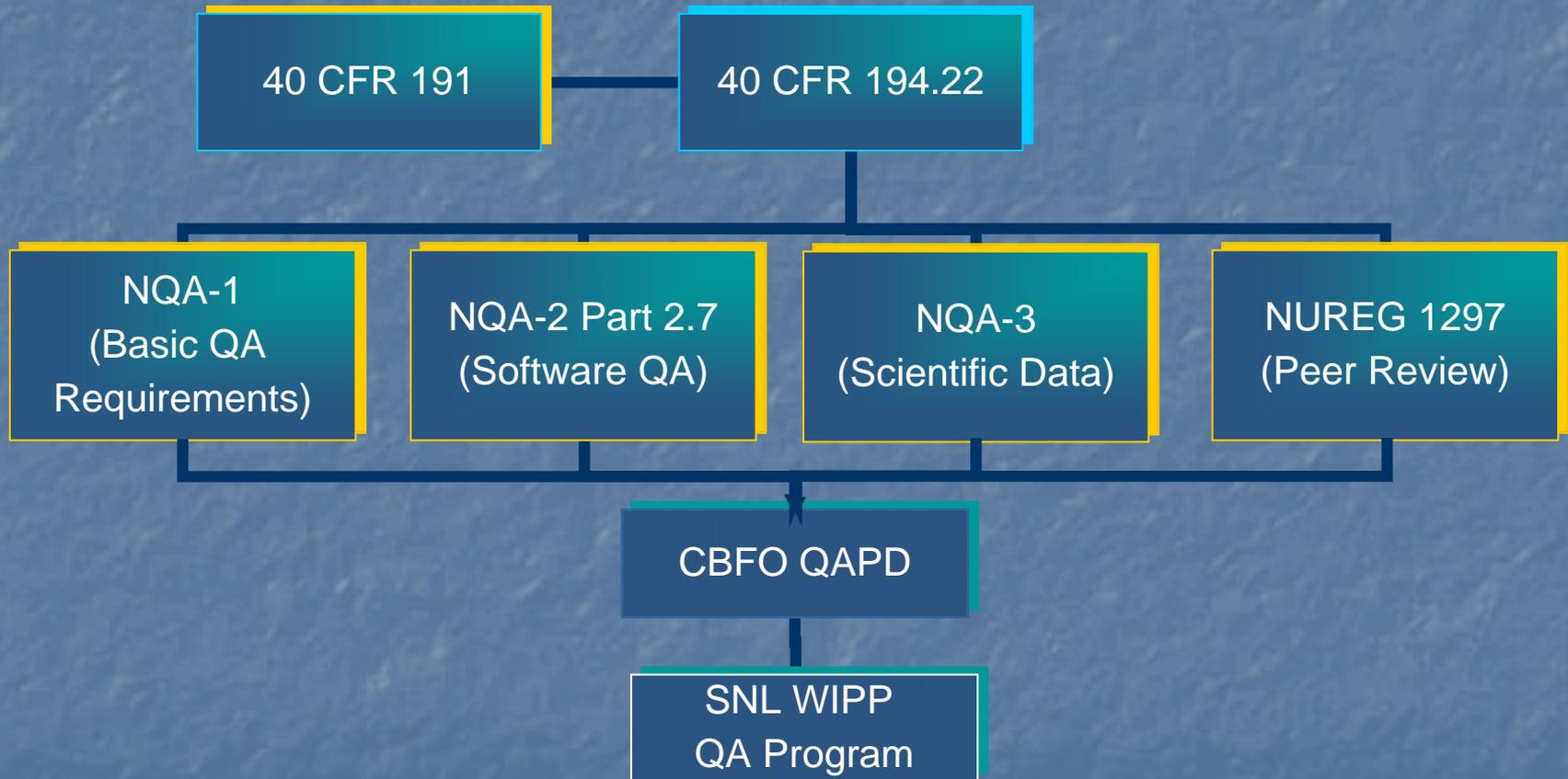


Source of QA Requirements





Quality Assurance Requirements



Other Regulatory Requirement Documents Include: 10 CFR 830.120, 10 CFR Part 71 and 21, NM 48901 39088, and NRC Certificates 9212, 9218, 9279, 9204.





Where do our QA Requirements come from?

- **Code of Federal Regulations (CFR)**
 - 40 CFR Part 191 – EPA 1985, 1993 amended requires that all WIPP participants have a QA program.
 - 40 CFR Part 194 – EPA 1996, 1998 amended describes the QA requirements needed to comply with 40 CFR 191 and incorporates by reference the requirements of NQA-1, NQA-2 Part 2.7 and NQA-3.





Quality Assurance Requirement Flow Down

- **Carlsbad Field Office (CBFO) Quality Assurance Program Document (QAPD) establishes and describes a QA program that meets the requirements of 40 CFR 191 and 194.**
- **CBFO QAPD applies to all WIPP program participants. SNL serves as the Science Advisor for the WIPP program.**





NQA-1 Basic QA Requirements





Quality Assurance Basic Principles

- **Quality is everyone's responsibility.**
- **Work will be planned, documented and performed under controlled conditions.**
- **Work will be periodically assessed to establish work items quality and process effectiveness.**
- **Process improvement is continuous.**





Benefits of QA

The objective of the SNL WIPP QA Program is to effectively satisfy QA requirements imposed by the CBFO QAPD.

By implementing QA, we are able to provide objective evidence that our program is rigorously implementing sound scientific practices, with qualified staff, and producing defensible results.





Basic QA Requirements

- NQA-1 includes eighteen basic requirements (BR).
- Sixteen of the eighteen apply to the work SNL performs for the WIPP Project.

BR	Title	BR	Title
1	Organization	10	Inspection
2	Quality Assurance Program	11	Test Control
3	<i>Design Control</i>	12	Control of Measuring and Test Equipment
4	Procurement Document Control	13	Handling, Storage, and Shipping
5	Instructions, Procedures and Drawings	14	<i>Inspection, Test and Operating Status</i>
6	Document Control	15	Control of Nonconforming Items
7	Control of Purchased Items and Services	16	Corrective Action
8	Identification and Control of Items	17	Quality Assurance Records
9	Control of Processes	18	Audits





Basic QA Requirements

**NQA-1
BR 1
Organization**

Management:

- Defines policies and objectives.
- Establishes and communicates expectations for quality and continual improvement.
- Identifies and allocates resources to achieve expectation.
- Specifies roles, responsibilities and authorities.
- Ensures NQA principles are understood, accepted and followed.

Quality of work is:

- Achieved and maintained by those performing the work.
- Verified by those not directly responsible for performing the work.

Relates to:

NP 1-1, Organization and QA Program





Basic QA Requirements

NQA-1

BR 2

QA Program

- Ensures activities affecting quality are controlled.
- Ensures people are competent to perform their assigned quality-affecting work.
- Ensures training is provided to achieve and maintain worker proficiency and qualifications.
- Assess the QA program to ensure effective implementation.

Relates to:

NP 1-1, Organization and QA Program

NP 2-1, Qualification and Training





Basic QA Requirements

**NQA-1
BR 4 & 7
Procurement**

- Items and services are purchased, accepted and controlled to specified requirements.
- Items are inspected to verify conformance to specified requirements.

**Relates to:
NP 4-1, Procurement**

**NQA-1
BR 5
Instructions,
procedures and
drawings**

- Activities affecting quality are planned and controlled.
- Activities are performed in accordance with prescribed procedures.

**Relates to:
NP 5-1, Implementing Procedures**





Basic QA Requirements

**NQA-1
BR 6
Document
Control**

- Documents that specify quality requirements are developed, identified and controlled in accordance with specified requirements.
- Documents, including changes to documents, are reviewed for adequacy, and approved for release.

Relates to:

NP 6-1, Document Review Process

NP 6-2, Document Control Process





Basic QA Requirements

NQA-1

BR 8

**Identification
and Control of
Items**

- **Items will be identified to assure only correct and accepted items are used or installed.**
- **Identification will be maintained on the items or in documents traceable to the items, or in a manner that assures identification is maintained.**

Relates to:

NP 4-1, Procurement

NP 12-1, Control of Measuring and Test Equipment

NP 13-1, Control of Samples and Standards

NP 20-2, Scientific Notebooks





Basic QA Requirements

NQA-1

BR 9

**Control of
Processes**

- **Processes affecting quality of items or services will be controlled.**

Relates to:

NP 4-1, Procurement

NP 9-1, Analyses

NP 9-2, Parameters





Basic QA Requirements

NQA-1

BR 11

Test Control

- Tests to verify conformance of an item or computer program to specified requirements, and to show satisfactory performance for service will be planned and executed.
- Characteristics to be tested and the methods used to test will be specified.
- Test results will be documented, and conformance to acceptance criteria will be evaluated.

Relates to:

NP 19-1, Software Requirements





Basic QA Requirements

NQA-1

BR 12

**Control of
Measuring and
Test Equipment**

- Measuring and test equipment (M&TE) used for activities affecting quality are controlled to specified accuracy requirements.
- M&TE are calibrated or adjusted, at prescribed intervals, to maintain accuracy.
- M&TE are properly handled and stored to maintain accuracy.
- Items are suitably marked to indicate calibration status.

Relates to:

NP 12-1, Control of Measuring and Test Equipment





Basic QA Requirements

**NQA-1
BR 13
Handling,
Storage and
Shipping**

- Items are identified and controlled during shipping, handling, installation or use to assure their quality and prevent damage, loss or deterioration.
- Items will be marked or labeled to indicate the need for special environments or special controls.

Relates to:

NP 13-1, Control of Sample and Standards





Basic QA Requirements

**NQA-1
BR 15
Control of
Nonconforming
Items**

- Items that do not conform to specified requirements will be controlled to prevent inadvertent use or installation.
- Controls will provide for identification, documentation, evaluation, segregation (when practical) and disposition.

**Relates to:
NP 16-1, Corrective Action**





Basic QA Requirements

NQA-1

BR 16

**Corrective
Action**

- **Conditions adverse to quality are promptly identified.**
- **Conditions adverse to quality are controlled and corrected to prevent recurrence and reviewed for lessons learned.**

Definitions:

Condition Adverse to Quality – an all inclusive term used in reference to failures, malfunctions, deficiencies, defective items, and non-conformances.

Corrective Action – measures taken to rectify conditions adverse to quality.

Relates to:

NP 16-1, Corrective Action





Basic QA Requirements

NQA-1 BR 17 Records

- QA Records are those records that furnish evidence of quality.
- QA Records are specified, prepared and maintained.
- QA Records must be legible, identifiable, and retrievable.
- QA Records are protected against damage, deterioration or loss.

**Relates to:
NP 17-1, Records**





Basic QA Requirements

**NQA-1
BR 18
Audits**

- Assessments will be performed to verify compliance with all aspects of the QA Program.
- Assessments will determine QA Program effectiveness.
- Assessments are performed by qualified personnel, in accordance with procedures or checklists.
- Assessment results are reported to Management.

Relates to:

NP 18-1, Audits and Surveillances





NQA-2.7





Basic QA Requirements

NQA-2 Part 2.7

- **Software development shall proceed in a traceable, planned and orderly manner.**
- **The software life-cycle phases are:**
 - **Requirements Phase – during this phase the requirements the software must satisfy are specified, and a plan for verification and validation is created.**
 - **Design Phase – during this phase a design, based on the requirements, is developed, documented and reviewed.**
 - **Implementation Phase – during this phase the design is translated into a programming language, and is analyzed to identify and correct errors.**
 - **Testing Phase – during this phase the design as implemented is exercised using test cases. The testing phase will assure the software produces correct results for the test cases.**
 - **Installation and Checkout Phase – during this phase the software becomes part of a system and will undergo testing to verify the software performs correctly on the system.**





Basic QA Requirements

NQA-2

Part 2.7

Continued

- **Operations and Maintenance Phase – during this phase the activities include correction of latent errors (change control), response to new or revised requirements, and response to changes in the operating environment. All modifications will be documented, approved, verified and validated, and controlled.**
- **Retirement Phase – during this phase the support for the software is terminated and use of the software is prevented.**
- **Software Verification and Validation (V&V) ensure the software adequately and correctly performs all intended functions and does not perform any unintended functions.**
- **Software V&V activities must be planned and documented.**
- **Software V&V activities must be performed by persons other than those who designed the software.**





Basic QA Requirements

NQA-2

Part 2.7

Continued

- Changes to software must be documented, evaluated, and approved. Changes must be appropriately reflected in the software documentation.
- A formal system for reporting and correcting software problems must be established.

Relates to:

NP 19-1, Software Requirements





NQA-3





Basic QA Requirements

NQA-3

BR 1 - 18

NQA-3

BR 2

- Basic requirements of NQA-1 apply.
- The following additions, amplifications, and modifications apply.

- Activities to collect scientific and technical information must be planned, including:
 - identification of the data to be collected and analyzed.
 - identification of technical and quality standards/criteria.
 - identification of field and laboratory testing equipment.
 - identification of methods/procedures for sampling, testing and analysis activities.
 - identification of quality assurance records.

Relates to:

**NP 9-1, Analyses; NP 20-1, Test Plans; and
NP 20-2, Scientific Notebooks**





Basic QA Requirements

NQA-3

BR 3

- Scientific investigations must be defined, controlled, verified and documented.
- Variables affecting scientific investigations must be measured and controlled.
- Development activities to establish new methods or procedures must be documented, and the results reviewed for adequacy, and approved prior to implementation.
- Data that were not collected under a QA program must be qualified before use.
- Peer reviews must be performed when the adequacy of information or methods cannot otherwise be established.

Relates to:

NP 9-1, Analyses; NP 20-1, Test Plans; and
NP 20-2, Scientific Notebooks





Basic QA Requirements

NQA-3

BR 8

- Samples shall be identified and controlled in a manner consistent with their intended use.
- Identification systems must assure documented traceability of samples from the initial source, through final disposition.
- Archive samples must be maintained from difficult to repeat sample collection activities, such as principal boreholes.

Relates to:

NP 13-1, Control of Samples and Standards





Basic QA Requirements

NQA-3

BR 16

- Trend analysis will be conducted to identify, evaluate and correct trends significant to quality.
- Significant quality problems shall be identified, the root cause determined, reported and corrected. Impact to completed work must also be determined.
- Quality problems that are recurring must be evaluated to develop an understanding of the event leading to the occurrence, the technical and work activities associated with the problem, its implications, and the effectiveness of corrective actions taken.

Relates to:

NP 16-1, Corrective Action





Basic QA Requirements

NQA-3

BR 18

- The audit program must include audits of a technical nature.
- Auditor must have the appropriate technical expertise or experience in the work being audited.

Relates to:

NP 18-1, Audits and Surveillances





Roles and Responsibilities





Fundamentals

Effective implementation of the SNL QA program is dependent on the efforts at all levels of the organization. Therefore, those organizations or individuals that have been assigned responsibility for performing the work are responsible for achieving and maintaining quality.

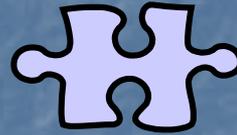




Basic Responsibilities

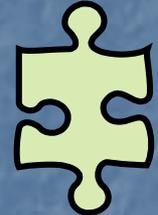
MANAGERS

RESPONSIBLE AND ACCOUNTABLE FOR ALL ASPECTS OF QUALITY OF PERFORMANCE, INCLUDING PLANNING, ORGANIZATION, DIRECTION, CONTROL, AND SUPPORT



STAFF

RESPONSIBLE FOR ACHIEVING QUALITY OF PERFORMANCE SO AS TO ENSURE SAFETY AND RELIABILITY



QA TEAM

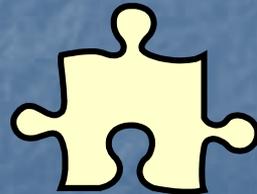
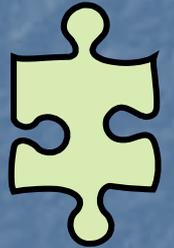
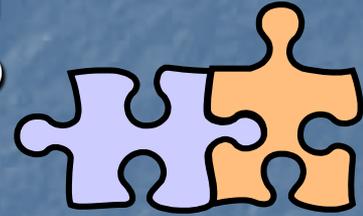
RESPONSIBLE FOR EVALUATING EFFECTIVENESS TO ACHIEVE QUALITY OF PERFORMANCE, IDENTIFY DEFICIENCIES, AND ENSURE CORRECTIONS





Management

- Management is responsible for defining quality, developing appropriate plans to attain quality, and supporting the staff in pursuit of quality.
- Accomplish activities in accordance with the SNL WIPP QA procedures.
- Ensure staff are adequately trained (technical and QA) to perform activities in accordance with the SNL WIPP QA procedures.
- Foster an environment that encourages continuous improvement.





Staff

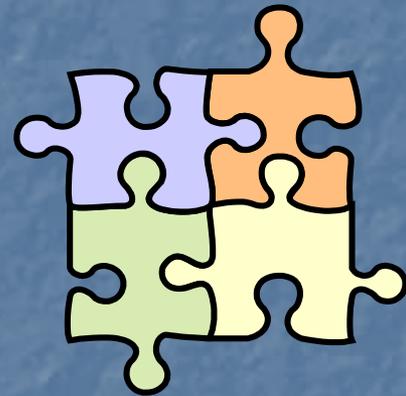
- **Quality achievement is the responsibility of those performing the work.**
- **Adhere to SNL WIPP QA procedures for work performed.**
- **Promptly report all existing, developing or potential conditions adverse to quality to management.**
- **Exercise the authority to stop unsatisfactory work.**





Quality Assurance Team

- Responsible for verifying the achievement of quality in the implementation of the SNL WIPP QA program.
- Assist management and staff with quality planning, documentation, and problem identification and resolution.
- Conduct QA assessments.
- Ensure the SNL WIPP QA procedures implement the provisions of the CBFO QAPD.





SNL WIPP Quality Assurance Program





Quality Program Organization

- There are two types of procedures in the SNL WIPP QA Program. Nuclear Waste Management Procedures (NPs) and Activity/Project Specific Procedures (SPs). Both are controlled documents.
- Both are grouped by NQA element.
- NPs are the highest level procedure, and apply to all SNL WIPP activities.
- SPs are the lowest level procedure, and apply to a specific activity.





Quality Program Organization

- **Analysis Plans (APs) and Test Plans (TPs) – Describe particular analytical and scientific activities in greater detail, describe corresponding quality requirements, and appropriate methods for producing objective evidence. APs and TPs are controlled documents.**





Quality Program Organization

- **Analysis Plans are written under NP 9-1.**
 - Describe and ensure documentation of specific analysis.
 - Organize analysis – calculations into manageable, logical components.
- **Test Plans are written under NP 20-1.**
 - Describe and ensure documentation of laboratory and field activities.
 - Organize laboratory and field work into manageable, logical components.





NP OVERVIEW





General Programmatic Procedures

- **NP 1-1, Organization and QA Program**
 - Establishes a process for appropriate management and quality control throughout our program:
 - either built into individual procedures or
 - quality levels called out specifically in SP 1-1 as applied to procurement grading.
 - Identifies roles and responsibilities of Management, Staff and QA team.
 - Establishes principle that everyone is responsible for:
 - Achieving quality in their work.
 - Identifying potential/existing conditions adverse to quality.
 - Addresses dispute resolution process.





General Programmatic Procedures

- NP 2-1, Qualification and Training
 - Establishes a process for documenting staff qualification (Form NP 2-1-1 Qualification and Training).
 - Establishes a process for the manager to assign appropriate training to staff PRIOR to performing quality affecting activities.
 - Management is responsible for ensuring staff have completed all assigned training PRIOR to performing quality affecting activities.
 - Establishes a process for documenting internal QA-related training (Form NP 2-1-2, Training Record).
 - Everyone is responsible to ensure:
 - Training called out in a TP and/or AP is completed PRIOR to beginning work.
 - Form NP 2-1-1 is updated when there is a change in job scope and different qualifications and skills are required .





General Programmatic Procedures

- **NP 4-1, Procurement and SP 1-1, QA Grading**
 - Applies to the purchase and acceptance of quality affecting items and services.
 - Establishes a process for determining the level of quality needed in accordance with the definitions in SP 1-1.
 - Establishes a process for the application of quality requirements in procurement documents.
 - Provides a method for documenting receipt inspection of items and services to ensure required quality is present.
 - Establishes a system to track performance of suppliers.





General Programmatic Procedures

■ SP 1-1, QA Grading

- Establishes two Quality Levels for WIPP activities: QL-1 and QL-2.
- QL-1 applies to those SNL WIPP activities (including materials and services) which are critical to the quality of data which directly supports the WIPP project (e.g., computer codes used for Performance Assessment and repository modeling, field and laboratory data collection used in support of regulatory compliance).
- QL-2 is assigned to SNL WIPP activities (including materials and services) which are important to the quality of data which directly supports the WIPP project (e.g., calibration services, testing support services, field and laboratory standards and chemicals, analytical services, measuring and test equipment).





General Programmatic Procedures

- **NP 5-1, Implementing Procedures**
 - Applies to the development, preparation, review, and approval of QA implementing procedures (NPs and SPs).
 - Establishes a format for NPs and SPs.
 - Establishes the reviews and approvals necessary for issuance.
 - Establishes a three year review cycle for NPs and SPs.
 - Author is responsible for:
 - preparing new/revised procedure, and coordinates review and approval.
 - determining training needs, if any, and completes a Form NP 5-1-1.





General Programmatic Procedures

- **NP 6-1, Document Review Process**
 - Establishes the review process for SNL WIPP QA procedures, plans, reports, and other documents.
 - Establishes requirements for reviews, including technical, management, and QA reviews.
 - Establishes requirements of “independent” reviewer.
 - To qualify as independent, a technical reviewer must not have performed, contributed or directed the work being reviewed and must not stand to either gain or be adversely affected by the results of the work or the success of the reviewed document.
 - Addresses resolution of review comments using the Document Review and Comment (DRC) form, Form NP 6-1-1.





General Programmatic Procedures

- **NP 6-1, Document Review Process (Continued)**
 - **Use of DRC.**
 - DRCs are optional if the reviewer has no comments AND if the reviewer's signature is incorporated into the document.
 - DRCs must be used if the reviewer has comments. Comments may be conveyed by listing each comment on the DRC or by attaching a markup of the document to the DRC.





General Programmatic Procedures

- **NP 6-2, Document Control Process**
 - Establishes a process to ensure that correct versions of documents controlling quality affecting work are available for use where work is being performed.
 - Everyone is responsible for using the correct and active document in performing activities.
 - All SNL WIPP Controlled Documents are available on-line at:



Bookmark this web address for future reference!

<https://nwmp.sandia.gov/onlinedocuments>





General Programmatic Procedures

- **NP 9-1, Analyses**
 - Describes the requirements for defining, investigating, validating, reviewing, and documenting the study of a system or component of a system.
 - Umbrella procedure that ensures defensible results.
 - Describes the requirements for writing an Analysis Plan (AP). An approved AP must be online prior to start of calculations.
 - Does not describe how to conduct laboratory or field activities or how to qualify either data or software.





General Programmatic Procedures

- **NP 9-1, Analyses (Continued)**
 - The purpose of an Analysis Plan is to define the technical scope, approach, methodology and requirements for conduct of a calculation or computational investigation.
 - Analysis Plans must be designated as either programmatic or compliance decision.
 - Analysis Plans must be reviewed and placed under document control prior to the start of work.
 - Details for package requirements found in Appendix B.
 - For analysis not executed on CMS, how run control was maintained must be explained. Electronic copies of all files needed to reproduce calculations must be provided (NQ).





General Programmatic Procedures

- **NP 9-2, Parameters**
 - Applies to the development, documentation, control, and changes of quantities and distributions used in the WIPP Parameter Database (the PAPDB).
 - Control of parameter values serves to manage the interface between data generation and analysis activities.
 - Justification and a traceable source is required for each parameter approval.
 - Examples of acceptable justifications include an Analysis Package, Routine Calculation, Reviewed Memo.





General Programmatic Procedures

- **NP 9-2, Parameters (Continued)**
 - **Parameter Approval Process.**
 - The Requester determines parameter values per NP 9-1, NP 20-1, or NP 20-2, determines the parameter distribution (NP 9-2), and completes the Parameter Data Entry form (NP 9-2-1).
 - Review of Parameter Data Entry Form, for correctness. Values must be from a traceable source (i.e., approved justification).
 - Upon approval, the Database Administrator (DBA) enters the values into the parameter database (PAPDB). Parameter values can then be accessed by PA codes.





General Programmatic Procedures

- **NP 9-2, Parameters (Continued)**
 - **Parameter Problem Reports (PPR) are issued to document a problem with the parameter value or the data entry form.**
 - **The initiator and QA will review the problem report to determine if a Condition Adverse to Quality or an Significant Condition Adverse to Quality exists. If so, a Corrective Action Request will be initiated as per NP 16-1, Corrective Action.**





General Programmatic Procedures

- **NP 12-1, Control of Measuring and Test Equipment**
 - Applies to the purchase/receipt and use and control of measuring devices to ensure data is always collected with M&TE that is in calibration.
 - M&TE accuracy must equal or exceed the accuracy requirements of the data collection effort.
 - Purchased M&TE must meet specified requirements, and calibration must be documented.
 - Labeling M&TE with calibration status stickers are required.
 - Impact of out-of-tolerance conditions is investigated to determine validity of previously collected data.





General Programmatic Procedures

- **NP 13-1, Sample Control**
 - Addresses handling, preservation, cleaning, shipping, transfer, analysis, storage, archiving and final disposition of samples collected or created by anyone working on WIPP.
 - Staff are responsible for following NP 13-1 when transferring samples from one sample custodian to another.
 - Ensures appropriate traceability of chemical standards.
 - Samples must be uniquely labeled.
 - Samples must be controlled from time of collection until disposition - as stated in the Test Plan, SP, or Scientific Notebook.





General Programmatic Procedures

- **NP 16-1, Corrective Action**
 - Describes the process for identifying, documenting, evaluating, controlling, and correcting conditions adverse to quality, and for ensuring continuous improvement.
 - Tracks quality issues from identification to resolution.
 - Requires the collection and analysis of data relating to the performance of specific processes, in order to monitor positive or negative trends within a program or system (Trend Analysis).





General Programmatic Procedures

- **NP 16-1, Corrective Action (Continued)**
 - **Corrective Action Request (CAR) (Form NP 16-1-1) is the document used to identify a Condition Adverse to Quality (CAQ) or Significant Condition Adverse to Quality (SCAQ).**
 - **CARs are used to document the following actions:**
 - **the deficiencies (deviations from requirements).**
 - **the reason the deficiencies have occurred.**
 - **the actions taken to correct the deviations found (remedial).**
 - **the investigative actions taken to determine if other deviations exist in the population.**
 - **the identification and preventative actions taken to keep related or similar deficiencies from happening in the future.**
 - **communication of deficiencies to management and the organization.**

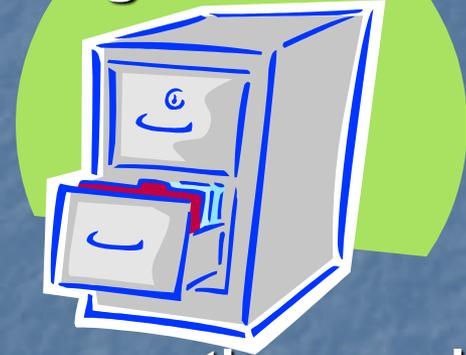




General Programmatic Procedures

■ NP 17-1, Records

- Describes the process for identifying, creating, protecting, submitting, and retrieving records from the SNL WIPP Records Center.
- QA records must be:
 - Legible, accurate, and complete.
 - Authenticated (see below).
 - Submitted to the records center as soon as the record is complete and authenticated.
- QA Records may be originals (preferred) or copies.





General Programmatic Procedures

- **NP 17-1, Records (Continued)**
 - Authentication is the act of attesting that the information contained within a record is accurate, complete, legible, and appropriate to the work accomplished.
 - The normal method of authentication is for the author or cognizant individual to sign or initial, and date the document.
 - Electronic records (CDs, etc.) can be submitted but will be designated Non-Quality (NQ) (Use Form NP 17-1-1, Machine Readable Media).
 - Areas or pages left blank shall have a line drawn diagonally through the blank area with the individual's initials and date.





General Programmatic Procedures

- NP 17-1, Records (Continued)
 - QA Records Dos and Don'ts
 - Do make corrections by drawing a single line-through the change, and initial and date.
 - Do put a file code on all records (except forms).
 - Do note the total number of pages on the first page.
 - Do submit two copies of all QA records.
 - Do not use whiteout, highlighter, red ink, gel ink pens or pencil on records.





General Programmatic Procedures



■ NP 18-1, Audits and Surveillances

- Applies to the planning, performing, and reporting of audits and surveillances, including follow-up activities.
- Describes the process used to qualify auditors and technical specialists and the certification process for lead auditors.
- Identifies activities associated with: preparation, conducting, reporting and follow-up of audits and surveillances.
- Assessment results are reported to management of assessed organizations and other affected organizations.





General Programmatic Procedures

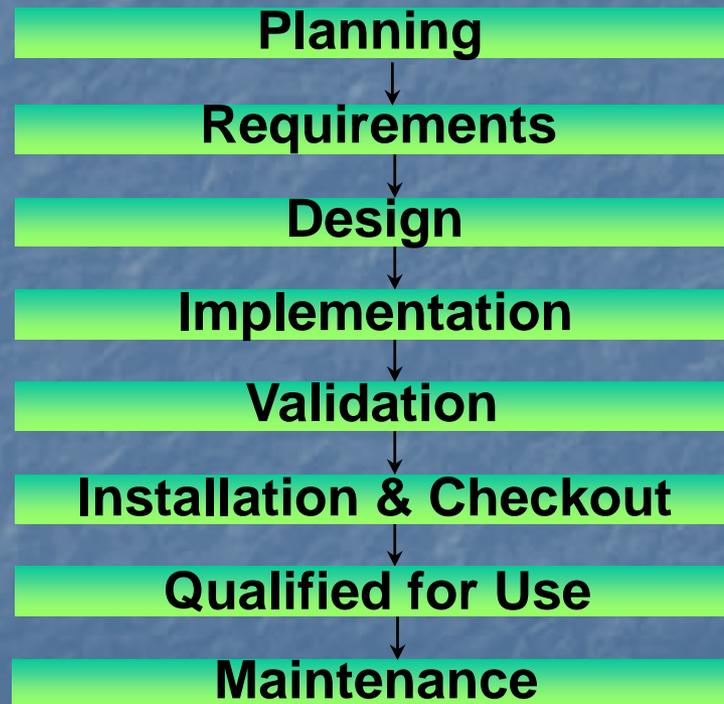
- **NP 19-1, Software Requirements**
 - Applies to all technical software codes used within the SNL WIPP program to assure they perform as designed.
 - SNL software QA process is based on the “waterfall” life-cycle method.
 - Each phase of the life-cycle requires verification. Verification is the process of determining whether or not the product of a given phase of the software development cycle fulfills the requirements imposed by the previous phase(s).
 - *Key Point:* Software needs to be “QUALIFIED” in accordance with NP 19-1 prior to use.





General Programmatic Procedures

Waterfall Life-Cycle





General Programmatic Procedures

- **NP 19-1, Software Requirements (Continued)**
 - **Planning Phase is accomplished through the Software QA Plan (SQAP).**
 - SQAP provides the big picture view of what and why we are qualifying a software baseline.
 - The evaluation of acquired software against the NP 19-1 Operation and Maintenance requirements are documented in the SQAP.
 - Exceptions to the “waterfall” lifecycle process are documented in the SQAP.
 - **Verification is accomplished through the Software QA Plan Criteria Form (NP 19-1-1).**





General Programmatic Procedures

- **NP 19-1, Software Requirements (Continued)**
 - Requirements Phase is accomplished through creation of the Requirements Document and the Verification and Validation Plan.
 - Requirements Document (RD)
 - The functions the software is to perform are specified in the RD. Specify those functions that will be tested and not-tested.
 - Verification accomplished through the Requirements Document Criteria form (NP 19-1-2).
 - Verification and Validation Plan (VVP)
 - Test Cases for testing the functionality that will be used are developed and documented in the VVP. These test cases will be executed and documented in the Validation Phase in the Validation Document (VD).
 - Verification accomplished through the Verification and Validation Plan Criteria form (NP 19-1-3).





General Programmatic Procedures

- **NP 19-1, Software Requirements (Continued)**
 - The Design Phase is the reduction of the requirements into physical solutions, developing the structure of the software.
 - A Design Document (DD) is produced during this phase. It will provide the following information:
 - Theoretical basis (physical process represented).
 - Mathematical model (numerical model).
 - Input and Output Ranges.
 - Control Logic.
 - Data Structures.
 - Major Software Components.
 - Verification accomplished through the Design Document Criteria form (NP 19-1-4).





General Programmatic Procedures

- **NP 19-1, Software Requirements (Continued)**
 - The Implementation phase is the phase in which the code is written and analyzed to identify and correct errors.
 - Code is created to implement the functional requirements identified in the RD, and as described in the DD.
 - Implementation Document (ID) is produced during this phase. It will include the code listing, and description of executable generation process.
 - User's Manual (UM) is also created during this phase. The UM provides information to assist users understanding of and interaction with the software.
 - Verification accomplished through the Implementation Document Criteria form (NP 19-1-5) and the User's Manual Criteria form (NP 19-1-6).





General Programmatic Procedures

- **NP 19-1, Software Requirements (Continued)**
 - Validation Phase consists of executing and reviewing the test cases identified in the VVP to demonstrate that the developed software meets the requirements defined for it in the RD.
 - A Validation Document (VD) is produced in this phase. The VD will document the test case input and output files, and the evaluation of the results verses the acceptance criteria identified in the VVP for each test case.
 - Verification accomplished through the Validation Document Criteria form (NP 19-1-7).





General Programmatic Procedures

- **NP 19-1, Software Requirements (Continued)**
 - The Installation and Checkout Phase involves integrating the software into a system.
 - The following documents are produced during this phase:
 - Installation and Checkout (I&C) form (NP 19-1-8). The I&C documents the execution of test case on the system, installation of the software and all components on the system, and approval for production use.
 - Access Control Memorandum establishes control to permit authorized and prevent unauthorized access for a particular code.
 - Approved Users Memorandum identifies users for a particular code.
 - Software is “Qualified for Use” once the I&C Phase is complete.





General Programmatic Procedures

- **NP 19-1, Software Requirements (Continued)**
 - The Maintenance Phase activities consist of modifying software to respond to new requirements, or to remove errors.
 - Change requests are controlled using the Change Control form (NP 19-1-9). The Change Control form:
 - Documents the request for a change/modification.
 - Documents the evaluation and approval of requested changes.
 - Ensures changes are reflected in the life-cycle documentation, as required.
 - The Installation and Checkout process must be completed prior to becoming “Qualified for Use”.





General Programmatic Procedures

- **NP 20-1, Test Plans**
 - Applies to both lab and field data collection activities, to ensure the scientific activity is accomplished under suitable, controlled conditions.
 - PI or designee is responsible for writing the test plan according to NP 20-1.
 - PI and staff are responsible for following the plan.
 - Requires Technical, QA, and Management approval, as a minimum.
 - Depending on the nature of the work a Safety approval may be required.
 - CBFO counterpart requires concurrence.





General Programmatic Procedures

- **NP 20-2, Scientific Notebooks**
 - **Describes the method for documenting data collection for a specific investigation to ensure traceability and transparency.**
 - **PI or designee will determine the need for Scientific Notebook (SN).**
 - **PI and staff follow NP 20-2 when documenting field or lab activities in an SN.**
 - **All personnel must complete NP 20-2 Scientific Notebook Training (on-line PowerPoint presentation) PRIOR to making entries into a scientific notebook.**





General Programmatic Procedures

- **NP 20-2, Scientific Notebooks (Continued)**
 - **Entries will include sufficient detail to allow a qualified individual to:**
 - repeat the investigation and achieve comparable results; or
 - retrace the investigation and confirm the results.
 - **Information recorded in a SN will relate to a single research project.**
 - **Entries should be made in a bound notebook with consecutively numbered pages.**
 - **All entries shall be permanent, black or dark blue ink.**
 - **If corrections are substantial (e.g. a paragraph or larger), an explanation shall be provided.**





General Programmatic Procedures

- **NP 20-2, Scientific Notebooks (Continued)**
 - **Entries should be recorded on the day the work is performed in order to prevent loss of data.**
 - **Supporting documents (computer outputs, photographs, etc.) may be captured in a SN supplement.**
 - **The PI is responsible for the security of the SN until it is entered into the SNL WIPP Records Center.**



