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**SNL WIPP QA
Procedures Matrix**

Revision 0

Effective Date: 05/30/03

**Based on the
CBFO Quality Assurance Program Document
Document Number DOE-CBFO-94-1012
Revision 4**

WIPP Matrix Coordinator:	<u>Steve Davis</u> (printed name)	<u>Original signed by Steve Davis</u> (signature)	<u>5-30-03</u> (date)
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Note: On-line format of Matrix introduces lines when page breaks occur. See previous or next page for mapping information if page break creates inadvertent empty blocks.

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**SNL QA PROCEDURES MATRIX
CAO QAPD (DOE-CBFO-94-1012, Revision 4), Effective 01/01/03**

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>1.1 ORGANIZATION AND QUALITY ASSURANCE PROGRAM</p> <p>This section describes the requirement for the organizational structure, primary interfaces, functional responsibilities, and levels of authority required to implement the CBFO QA program. In addition, this section describes the basic elements of the QA program and their applicability.</p>	√			NP 1-1	
<p>1.1.1 Organization</p> <p>Effective implementation of the CBFO QA program is dependent on the efforts at all levels of the program participants. The organization is structured such that the individual performing the work is responsible for achieving and maintaining quality. Management is responsible for defining quality, developing appropriate plans to attain quality, supporting the workers in pursuit of quality, and evaluating quality achievement. QA managers of the program participants are responsible for defining, integrating, and ensuring effective implementation of the CBFO QA program. CBFO organizational and individual responsibilities are addressed in appendices C and D. Organizational and individual responsibilities for TRU waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility are addressed in Appendix E.</p>				NP 1-1, Section 2.1, 2.2.1.1 and 2.2.1.4	
<p>1.1.1.1 Management</p> <p>A. Management has overall responsibility for successfully accomplishing activities subject to this QAPD. Management provides the necessary planning, organization, direction, control, resources, and support to achieve their defined objectives. Management is responsible for planning, performing, assessing, and improving the work.</p> <p>B. Management is responsible for establishing and implementing policies, plans, and procedures that control the quality of work, consistent with the provisions of this QAPD.</p> <p>C. Management QA responsibilities include:</p> <p>1. Ensuring that adequate technical and QA training is provided for personnel performing activities subject to this QAPD</p> <p>2. Ensuring compliance with all applicable regulations, DOE orders and requirements, and applicable federal,</p>	√			NP 1-1, Section 2.2.1.1	
	√			NP 1-1, Section 2.2.1	
	√			(C) NP 1-1, Section 2.2.1	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>state, and local laws</p> <p>3. Ensuring that personnel adhere to procedures for the generation, identification, control, and protection of QA records</p> <p>4. Exercising the authority and responsibility to stop unsatisfactory work such that cost and schedule do not override environmental, safety, or health considerations</p> <p>5. Developing, implementing, and maintaining plans, policies, and procedures that implement this QAPD</p> <p>6. Identifying, investigating, reporting, and correcting quality problems</p> <p>D. Quality achievement is the responsibility of those performing the work. Members of management are responsible for achieving and evaluating quality in their areas.</p> <p>E. Management empowers employees by delegating authority and decision making to the lowest appropriate level in the organization.</p>	<p>√</p> <p>√</p> <p>√</p>			<p>NP 16-1, Section 2.3</p> <p>NP 1-1, Section 2.2.1</p> <p>NP 1-1, Section 2.2.1.1</p>	
<p>1.1.1.2 Employees</p> <p>Each program participant employee is responsible for the quality of his or her work and for promptly reporting all existing, developing, or potential conditions adverse to quality to the responsible management for evaluation and action.</p>	<p>√</p>			<p>NP 1-1, Section 2.2.1.1 and 2.2.1.4</p>	
<p>1.1.1.3 QA Management</p> <p>An organization's QA management has the authority and overall responsibility to independently assess the organization's effective implementation of the QA program.</p> <p>A. QA management shall:</p> <ol style="list-style-type: none"> 1. Schedule and conduct QA assessments 2. Maintain liaison with participant QA organizations and other affected organizations 3. Ensure preparation, review, and issuance of QA plans and procedures that implement the provisions of this QAPD 4. Review and approve supplier and subcontractor QA plans 5. Track or perform trend analysis of quality problems, and report quality problem areas 6. Provide for the administrative processing of 	<p>√</p>			<p>NP 1-1, Section 2.2.1.1 and 2.2.1.3</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
documentation concerning conditions adverse to quality 7. Have direct access to responsible management at a level where appropriate action can be effected 8. Be sufficiently independent from cost and schedule considerations 9. Have the organizational freedom to communicate with management 10. Have no assigned responsibilities unrelated to the quality assurance program that would prevent appropriate attention to QA matters 11. Develop, establish, and interpret QA policy and ensure effective implementation 12. Interface, as appropriate, with the CBFO staff, participants, and other stakeholders on QA matters 13. Assist subordinate organizations with quality planning, documentation, quality measurement, and problem identification and resolution 14. Provide guidance to all applicable subordinate organizations concerning identification, control, and protection of QA records					
B. The QA organization shall have sufficient authority, access to work areas, and organizational freedom to:	√			NP 2.2.1.2	
1. Identify quality problems					
2. Recommend solutions	√			NP 1-1, Section 2.2.1.2	
3. Verify implementation of solutions					
4. Ensure that unsatisfactory conditions are controlled until proper disposition has occurred					
1.1.1.4 Communication and Interface Responsibilities A. Communication Responsibilities Participating organizations at all management levels shall establish communication channels that provide timely and wide dissemination of information pertinent to quality performance, such as:	√			NP 1-1, Section 2.2.2	
1. The status of development and implementation of the QA program					
2. The status and resolution of significant quality problems					

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
3. The lessons learned from significant quality problems and adverse conditions 4. Quality management practices and improvements 5. Trend analysis results B. Interface Responsibilities					
1. Where more than one organization is involved in the execution of activities covered by this QAPD, the responsibility and authority of each organization shall be clearly established, defined, and documented. The external interfaces between organizations, the internal interfaces between organizational units, and interface changes shall be documented. Interface responsibilities shall be defined and documented and shall include the requirements for management, performance, and assessment.	√			NP 1-1, Section 2.	
2. CBFO-sponsored activities, performed by organizations external to the CBFO, include, but are not limited to, compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility. Responsible CBFO organizations shall ensure the effective implementation of the CBFO QA program.	√			SNL WIPP QA Procedure Matrix, Rev. 8	This matrix demonstrates compliance with the CBFO QAPD
1.1.1.5 Delegation of Work Individuals or organizations responsible for establishing, planning, accomplishing, and assessing the work may delegate work to other individuals or organizations. However, the individuals or organizations making the delegation shall retain overall responsibility for the delegated work.	√			NP 1-1, Section 2.2.1.3	
1.1.1.6 Resolution of Disputes Differences of opinion involving the definition and implementation of QA program requirements will be brought to the attention of the appropriate QA manager and the responsible manager. If not resolved, the issues will be elevated progressively to successively higher levels of management as necessary.	√			NP 1-1, Section 2.2.4	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>1.1.2 Implementation of the CBFO QA Program</p> <p>1.1.2.1 Quality Assurance Program Documents</p> <p>Program participants shall develop and follow plans and procedures that effectively implement the requirements described in this QAPD along with those requirements contained within the RCRA Permit Waste Analysis Plan (WAP), Quality Assurance Project Plans (QAPjPs), Certification QA Plans, Waste Acceptance Criteria (WAC), and TRUPACT-II Certification of Compliance, including TRUPACT-II Authorized Methods for Payload Control (TRAMPAC), as applicable.</p>	√			NP 1-1, Section 2.2.1.1	
<p>1.1.2.2 Procedures Matrix</p> <p>A. Each organization that directly supports CBFO activities shall prepare and maintain a procedures matrix that identifies applicable documents of each organization or project that implements each applicable requirement of this QAPD. The matrix shall specifically reference the applicable portion of the procedure or document. The matrix shall be updated semi-annually.</p> <p>B. When this QAPD is revised, subtier documents such as site QAPjPs, Certification QA Plans, and implementing procedures shall be evaluated and appropriately revised to ensure that the QA program of each organization meets the applicable requirements of the CBFO QA program.</p>	√			NP 5-1, Section 2.1.1 and 2.1.2	This matrix is maintained on the SNL WIPP on-line documents Web page
<p>1.1.2.3 Applicability of QAPD Requirements</p> <p>The terminology “items or activities important to compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility” is used generically throughout this QAPD to refer to the following:</p> <p>A. WIPP site activities or operations that process or store radioactive liquid or solid waste, perform waste management activities involving radioactive materials, or design, manufacture, or assemble items for use with radioactive materials in such a form and quantity that a nuclear hazard exists</p> <p>B. Waste characterization activities</p> <p>C. Environmental monitoring, monitoring the performance of the disposal system, and sampling and analysis activities</p> <p>D. Field measurements of geological factors, ground water, meteorology, and topography</p> <p>E. Computations, codes, models, and methods used to</p>	√		√ √	NP 9-1, Section 1.0; NP 12-1, Section 1.1; NP 20-1, Section 1.0; NP 20-2, Section 1.0 NP 19-1, Section	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
demonstrate compliance with disposal regulations	√			1.0	
F. Expert judgement elicitation to support applications for re-certification or determination of compliance	√			NP 9-1, Section 1.0; NP 9-2, Section 1.0	
G. Design of the disposal system and actions taken to ensure compliance with design specifications			√		
H. The collection of data and information used to support compliance application(s) and/or any modifications to the compliance application	√			NP 9-2, Section 1.0; NP 20-1, Section 1.0; NP 20-2, Section 1.0	
I. Other systems, structures, components, and activities important to the isolation of waste in the disposal system			√		
J. Those items and activities related to Nuclear Regulatory Commission (NRC) licensed packaging (e.g., Transuranic Package Transporter Model II [TRUPACT-II]), design, purchase, fabrication, handling, shipping, storage, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification or components of packaging that are important to safety			√ √		Transportation and packaging are not in the scope of SNL WIPP activities.
1.1.2.4 Grading Items and Activities and Applying Management Controls					
A. The graded approach is the process by which the level of analysis, documentation, verification, and other controls necessary to comply with QA program requirements are developed commensurate with the following factors:	√			NP 1-1, Section 1.2 SP 1-1, Section 2.1 and Appendix A NP 4-1, Section 2.1.1	
1. The importance of an item or activity with respect to safety, waste isolation, and regulatory compliance					
2. The importance of the data to be generated					
3. The need to demonstrate compliance with specific regulatory design and QA requirements					
4. The impact on the results of performance assessments and engineering analyses					
5. The magnitude of a hazard or the consequences of failure					
6. The life-cycle stage of a facility or item					
7. The programmatic mission of a facility					
8. The particular characteristics of a facility, item, or activity (e.g., complexity, uniqueness, history, or the necessity for special controls or processes)					
9. The relative importance of radiological and non-					

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>radiological hazards</p> <p>B. The extent of management and QA controls applied to an item or activity will vary as a function of the degree of confidence needed to achieve the desired quality of the item or activity. The grading process provides the flexibility to design and implement controls that best suit the facility or activity. Each organization should develop their own method to determine that the defined grading process is effective. The use of the graded approach shall determine the appropriate level of controls necessary to manage the items, systems, and activities necessary to ship TRU waste to WIPP.</p> <p>C. Grading methods for each organization shall provide for:</p> <ol style="list-style-type: none"> 1. The assignment of management and QA control levels 2. The definitive criteria used in selecting those levels 3. Detailed descriptions of the management and QA control provisions corresponding to those levels, based on the above requirements <p>D. Program participant procedures that establish and implement a graded approach for items and activities under the cognizance of the CBFO shall be submitted to the CBFO QA Manager for approval for use in CBFO programs.</p>				<p>NP 1-1, Section 1.2 SP 1-1, Section 2</p> <p>NP 1-1, Section 1.2 SP 1-1, Section 2.2 and 2.3</p> <p>NP 1-1, Section 1.2.1</p>	<p>SP 1-1 was submitted to CAO for review on 1/4/99</p>
<p>1.1.2.5 Planning Work</p> <p>Planning shall be performed and documented to ensure that work is accomplished under suitably controlled conditions. As appropriate, planning elements shall include:</p> <ol style="list-style-type: none"> A. Definition of work scope, objectives, and a listing of the primary tasks involved B. Identification of scientific approaches or technical methods used to collect, analyze, or study results of applicable work C. Identification of field and laboratory testing standards and quality criteria D. Identification of applicable implementation documents (appropriate nationally recognized standards shall be used whenever possible) E. Identification of field and laboratory testing equipment or other equipment F. Identification of, or provisions for the identification of, 	√			<p>NP 20-1, Appendix A</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>required records and the recording of objective evidence of the results of the work performed</p> <p>G. Identification of prerequisites, special controls, specific environmental conditions, processes, or skills</p> <p>H. Identification of computer software</p>					
<p>1.1.2.6 Peer Reviews</p> <p>Peer reviews performed in support of WIPP compliance activities shall be documented, as shall all peer review processes. Peer reviews of the following activities shall be conducted in a manner consistent with NUREG-1297, <i>Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories</i>:</p> <p>A. Conceptual models selected and developed by the DOE</p> <p>B. Waste characterization analysis as required in 40 CFR § 194.24(b)</p> <p>C. Engineered barrier evaluation as required in 40 CFR § 194.44</p>	√			See Comment	CBFO Procedure 10.5 is used for Peer Reviews on the WIPP.
<p>1.2 PERSONNEL QUALIFICATION AND TRAINING</p> <p>Personnel shall be trained and qualified to ensure they are capable of performing their assigned tasks and to ensure that job proficiency is maintained.</p>	√			NP 2-1	
<p>1.2.1 Qualification Requirements</p> <p>Qualification requirements for CBFO and participant positions or job functions shall be established for activities important to compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility. The evaluation shall be documented. At a minimum, these positions include managers, designers, scientists, independent assessment personnel, operators, maintenance personnel, technicians, and inspectors.</p> <p>The responsible organization shall:</p> <p>A. Analyze each job position to determine the task responsibilities of the position subject to the QAPD. The analysis shall identify minimum education, experience, and training prerequisites for each position involved in the planning, performance, or verification of activities subject to the QAPD, commensurate with the scope, complexity, and nature of the work.</p> <p>B. Ensure that personnel selected to perform or verify activities subject to the QAPD shall have education, experience, and training commensurate with the minimum requirements specified. The qualification of</p>	√			NP 2-1, Section 2-1, Appendix A, Form NP 2-1-1, Section II; Section III, and Section V	
	√			NP 2-1, Sections 2.1 and 2.2	
	√			NP 2-1, Section 2.2	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
an individual shall be based upon evaluation of education and experience, which is compared to the established requirements for the position.					
<p>1.2.2 Training Requirements</p> <p>CBFO and participant personnel performing activities important to compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility shall receive related training in accordance with the following requirements. Training shall emphasize the correct performance of work, describe why the applicable quality and nuclear safety requirements exist, and describe the fundamentals of the work and the context. Training shall be subject to ongoing review to determine instruction and training program effectiveness and shall be upgraded whenever needed improvements or enhancements are identified. Management shall</p> <p>A. Ensure that personnel receive indoctrination and training, including on-the-job and hands-on training, as needed, to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, job responsibilities, and quality assurance implementing procedures, prior to performing any tasks subject to the QAPD</p> <p>B. Ensure that personnel receive indoctrination in the following</p> <ol style="list-style-type: none"> 1. General criteria, including applicable QA plans, codes, regulations, and standards 2. Specific criteria, including applicable QAPjPs and implementing procedures <p>C. Ensure that records generated during qualification, general indoctrination and training, or specific skill training activities are collected and maintained as QA records.</p>	√			NP 2-1, Section 2.2	
<p>1.3 QUALITY IMPROVEMENT</p> <p>Quality improvement is a management process, carried out to improve items, services, products, or processes. All aspects of work that affect quality and the management system are subject to continuous improvement through assessment and feedback processes.</p> <p>1.3.1 Quality-Affecting Problems</p> <p>Quality-affecting problems and items, services, and processes that do not meet established requirements shall be identified, documented, reported, controlled, and corrected. Quality problems may be identified by the</p>	√			NP 16-1, Section 1.0, 2.1 and 2.2	
	√			NP 16-1, Section 1.0	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
organization or by an external source.					
<p>1.3.1.1 Problem Identification</p> <p>All personnel shall be responsible for identifying quality problems and shall be encouraged by management to suggest improvements. CBFO and participant organizations foster a “no-fault” attitude for quality problems and prioritize and focus resources on preventive actions and on those quality problems that have the greatest potential for</p> <p>A. Posing adverse risks to the environment and human health</p> <p>B. Adversely impacting the quality, safety, and reliability of waste operations</p> <p>C. Affecting the ability to meet quality requirements</p>	√			NP 16-1, Section 1.0, 2.2.1	
<p>1.3.1.2 Problem Types</p> <p>Quality-affecting problems may involve</p> <p>A. Noncompliance with a QA program requirement. A noncompliance is classified as a Condition Adverse to Quality (CAQ) or Significant Condition Adverse to Quality (SCAQ)</p> <p>B. Nonconforming items, including suspect/counterfeit items or data, that do not conform to specified requirements.</p>	√			NP 16-1, Section 2.1	
<p>1.3.2 Nonconformances</p> <p>Items or data that do not conform to established requirements shall be controlled to prevent inadvertent installation or use.</p> <p>1.3.2.1 Documenting and Evaluating Nonconforming Items</p> <p>The documentation and evaluation of nonconforming items shall be accomplished by</p> <p>A. Clearly identifying and describing the characteristics that do not conform to specified criteria</p> <p>B. Reviewing nonconformance documentation and proposed recommended disposition of the nonconforming item or data. The review shall include a determination of the need for corrective action in accordance with the requirements of Section 1.3.3 <i>Corrective Action</i>. In addition, organizations affected by the nonconformance shall be notified.</p> <p>C. Evaluating and approving of recommended dispositions</p>	√			NP 16-1, Section 2.2.1	
	√			(A-E) NP 16-1, Section 2.2.1 and 2.2.2	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
D. Ensuring that personnel performing evaluation or recommending disposition have demonstrated competence in the specific area they are evaluating or dispositioning, and have an adequate understanding of the requirements					
E. Implementing procedures that specify the responsibility and authority for reviewing, evaluating, approving the disposition, and closure of the nonconformance					
1.3.2.2 Identifying Nonconforming Items or Data					
A. Nonconforming items shall be physically identified by marking, tagging, segregation, or other methods that do not adversely affect the end use. The identification shall be legible and easily recognizable, and shall be traceable to the reporting documentation.	√			NP 16-1, Section 2.2.1	SNL work scope does not specifically involve "items," therefore "nonconforming items" in this section are not applicable.
B. If physical identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be physically identified as in A above.					
1.3.2.3 Reporting Nonconformances			√		This requirement applies to TRU waste generator sites.
Organizations affected by a nonconformance shall be notified. The QA Manager and the National TRU Programs Assistant Manager, CBFO shall be notified in writing within 5 calendar days of identification of any non-administrative nonconformance related to applicable requirements specified in the WIPP Hazardous Waste Facility Permit (HWFP) Waste Analysis Plan (WAP), which are first identified at the site project manager's signature release level (i.e., a failure to meet a data quality objective [DQO]). Notification is also required if the results of the confirmatory analytical techniques specified in the Permit Attachment B are inconsistent with acceptable knowledge documentation. The nonconformance report shall be submitted to CBFO within 30 calendar days of identification of the deficiency.					
1.3.2.4 Segregating Nonconforming Items	√			NP 16-1, Section 2.2.1	
A. Further processing, delivery, installation, or use of nonconforming items shall be controlled pending the evaluation and approval of the disposition.					
B. Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.					
If segregation is impractical or impossible due to physical condition, other precautions shall be employed to preclude inadvertent use.					
1.3.2.5 Disposition of Nonconforming Items or Data	√			(A)NP 16-1, Section 2.2.2	Any condition adverse to quality or significant condition adverse to quality
The disposition of nonconforming characteristics shall be accomplished as follows					

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>A. The nonconformance characteristics shall be reviewed, and recommended dispositions of nonconforming items or data shall be proposed and approved in accordance with documented procedures. Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have adequate understanding of the requirements, and have access to pertinent background information.</p> <p>B. The dispositions “use-as-is,” “reject,” “repair,” or “rework” for nonconforming items or data shall be identified and documented.</p> <p>C. The technical justification for the acceptability of a nonconforming item or data that has been dispositioned “use-as-is” or “repair” shall be documented.</p> <p>D. Items that do not meet original design requirements that are dispositioned “use-as-is” or “repair” shall be subject to design control measures commensurate with those applied to the original design, and</p> <p>1. If changes to the specifying document are required to reflect the as-built condition, then the disposition shall require action to change the specifying document to reflect the accepted nonconformance.</p> <p>2. Any document or QA record change required by the disposition of the nonconformance shall be identified in the nonconformance documentation and, when a document or record is changed, the justification for the change shall identify the nonconformance documentation.</p> <p>E. The disposition of an item to be reworked or repaired shall contain a requirement to re-examine (inspect, test, or examine by nondestructive examination) the item to verify acceptability. Repaired or reworked items shall be re-examined using the original process and acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.</p>	<p>√</p> <p>√</p> <p>√</p> <p>√</p> <p>√</p> <p>√</p> <p>√</p>	<p>√</p> <p>√</p> <p>√</p> <p>√</p>	<p>√</p> <p>√</p> <p>√</p> <p>√</p>	<p>NP 16-1, Section 2.2.2</p>	<p>identified for data will be processes in accordance with NP 16-1 and the applicable procedure for that activity.</p> <p>The terms “use-as-is”, “reject” and “repair” are not used. All CAQ and SCAQ conditions are evaluated for impact on the work process or product and associated documentation or records. Management or their delegate are involved in resolution of all CAQ and SCAQ conditions.</p>
<p>1.3.2.6 Quality Trending of Nonconformances</p> <p>Nonconformance documentation shall be periodically analyzed by the QA organization to identify quality trends in accordance with section</p>	<p>√</p>			<p>NP 16-1, Section 2.5</p>	<p>Quality Trending applies to all CAQ and SCAQ conditions, now this includes CDA/CDS.</p>
<p>1.3.3 Corrective Action</p> <p>1.3.3.1 Identifying Conditions Adverse to Quality (CAQ)</p> <p>A CAQ occurs when a QA requirement has not been met.</p>	<p>√</p>			<p>NP 16-1, Section 2.1</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>D. Actions to Preclude Recurrence: actions necessary to prevent recurrence of the SCAQ</p> <p>E. Schedule: milestones for completion of the CAP, including expected completion dates and identification of responsible individuals</p> <p>1.3.3.6 Work Suspension</p> <p>If a work suspension condition has been identified, responsible management shall take appropriate action to lift and close the work suspension, based on the resolution of the related SCAQ. The QA organization shall verify and document the completion of applicable corrective actions prior to any management action releasing the work suspension.</p> <p>1.3.3.7 Corrective Action Follow-up</p> <p>A system shall be established to verify the effective implementation of scheduled corrective actions and to complete corrective actions in a timely manner. The QA organization shall evaluate the adequacy of corrective actions planned, assign responsibility for follow-up verification, and perform and document verification results. If results of verification are unsatisfactory, the CAP shall be revised appropriately, and corrective actions and verification performed.</p> <p>1.3.3.8 Recurring Conditions Adverse to Quality</p> <p>For recurring CAQs, management shall</p> <p>A. Determine the events leading up to the occurrences</p> <p>B. Develop an understanding of the technical and work activities associated with the CAQ</p> <p>C. Ascertain and identify any generic implications and impacts on completed work</p> <p>D. Determine the extent to which similar quality problems, or precursors to the problem, have been identified</p> <p>E. Determine the effectiveness of corrective actions that have been taken</p> <p>F. Consider suspending work associated with the applicable activity, as appropriate</p> <p>G. Suggest actions that can be taken by the responsible organization to preclude recurrence, as appropriate</p> <p>1.3.3.9 Quality Trending</p> <p>The need for quality improvement is accomplished through</p>	<p>√</p> <p>√</p> <p>√</p> <p>√</p>			<p>NP 16-1, Section 2.3</p> <p>NP 16-1, Section 2.2.3</p> <p>(A-G)NP 16-1, Section 2.4</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>C. The requesting organization shall identify the applicable criteria for the review. These criteria shall consider technical adequacy, accuracy, completeness, and compliance with established requirements.</p> <p>D. Pertinent background information or data shall be made available by the organization requesting the review if the information is not readily available to the reviewer</p> <p>E. The review will be performed by individuals other than the originator.</p> <p>F. Reviewers will be technically competent in the subject area being reviewed.</p> <p>G. The organization or technical discipline affected by the document shall review the document according to the established review criteria.</p> <p>H. The appropriate quality assurance organization shall review documents that translate CBFO QAPD or other CBFO requirements.</p> <p>I. Review comment documentation shall be resolved in accordance with approved procedures. Evidence of review comment resolution shall be maintained by the originating organization.</p> <p>J. Documents shall be approved for release by authorities designated in accordance with approved procedures.</p> <p>K. Documents shall be issued by designated individuals or organizations in accordance with approved procedures.</p>	√			<p>C. NP 6-1, Section 2.3 Form NP 6-1-1, Sections 4 & 5</p> <p>D. NP 6-1, Section 2.3</p> <p>E-I. NP 6-1, Sections 2.2, 2.4, and 2.5</p> <p>E-I. NP 6-1, Sections 2.2, 2.4, and 2.5</p> <p>J. NPs 3-1, 5-1, 9-1, 20-1, and SP 5-1</p> <p>K. NP 6-2, Section 2.0</p>	
<p>1.4.2 Document Distribution and Use</p> <p>The distribution and use of controlled documents and forms that document or prescribe work, including changes and editorial corrections to documents, shall be controlled to meet the following requirements:</p> <p>A. Documents shall be distributed to affected personnel and used at the work location.</p> <p>B. Effective dates shall be established and identified on the approved documents.</p> <p>C. The disposition of obsolete or superseded documents and forms shall be controlled to avoid their inadvertent use.</p> <p>D. Controls shall be established and maintained to identify the current status or revision of controlled documents and forms.</p>	√			<p>NP 6-2, Sections 2.1 to 2.2</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
E. Controls shall provide for identification of documents to be controlled and their distribution.					
<p>1.4.3 Document Changes</p> <p>A. Changes to documents, other than those defined below as editorial changes, shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated in accordance with approved procedures.</p> <p>B. Document changes shall be:</p> <ol style="list-style-type: none"> 1. Reviewed by the organizations or technical disciplines affected 2. Clearly indicated in the changed document <p>C. Editorial or minor changes may be made without the same level of review and approval as the original or otherwise changed document. The following items are considered editorial or minor changes:</p> <ol style="list-style-type: none"> 1. Correcting grammar or spelling (the meaning has not changed) 2. Renumbering sections or attachments 3. Updating organizational titles 4. Changes to nonquality affecting schedules 5. Revising or reformatting forms, providing the original intent of the form has not been altered 6. Attachments marked "Example," or "Sample," or exhibits that are clearly intended to be representative only 7. Clarification changes that don't affect the purpose of the document <p>D. A change in an organizational title accompanied by a change in responsibilities is not considered an editorial change.</p> <p>E. The organization responsible for preparing the document shall identify and approve editorial changes.</p>	√			<p>A. NP 6-1, Section 2.2 NP 6-2, Section 2.1</p> <p>B. NP 6-1, Section 2.2 NP 6-2, Section 2.1</p> <p>C. NP 6-2, Section 2.1 NWMP Glossary under "Editorial Changes"</p> <p>D. NWMP Glossary under "Editorial Changes"</p> <p>E. NP 6-1, Section 2.1 NP 6-2, Section 2.1</p>	<p>A. "Functional areas" is a synonymous term for "same organization"</p>

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>1.5 RECORDS</p> <p>A. Records shall be specified, prepared, reviewed, approved, and maintained.</p> <p>B. A "QA record" is an authenticated record that provides objective evidence of the quality of items or activities. QA records shall be controlled in accordance with the following requirements.</p>	√			<p>NP 17-1, Section 2.1</p> <p>NP 17-1, Section 2.1</p>	
<p>1.5.1 Records System</p> <p>A. A QA records system shall be established by the responsible organization at the earliest practical time, consistent with the schedule for accomplishing work activities. The QA records system shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.</p> <p>B. This does not prohibit the management of QA records within a general records system, nor does this require a separate records system for QA records, as long as the applicable provisions of this section are satisfied for the control of QA records.</p>	√			<p>NP 17-1, Section 2.1</p>	
<p>1.5.2 Generating QA Records</p> <p>A. Prior to conducting a work activity, the responsible organization shall:</p> <p>Identify those documents that shall become QA records</p> <p>Identify the organization responsible for submitting the QA records to the records system</p> <p>B. QA records shall be legible, accurate, and completed appropriate to the work accomplished.</p> <p>C. Individuals handling documents intended to become QA records shall provide reasonable protection for the records from damage or loss until the records are submitted to the records system (this includes documents generated during field operations).</p> <p>D. Documents shall be considered valid QA records only if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated. If the nature of the record (such as magnetic or optical media) precludes stamping or signing, then other means of authentication by authorized personnel are required. This authentication represents a certification as to the content of the record by those individuals with knowledge of the related facts, whether by direct personal knowledge or through the direct reports of others. The authentication should not be confused with any subsequent reviews of the content.</p>	√			<p>A. NP 17-1, Section 2.1</p> <p>B. NP 17-1, Section 2.1</p> <p>C. NP 17-1, Section 2.2</p> <p>D. NP 17-1, Sections 2.1, 2.3.1</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>E. Once authenticated, QA records shall be submitted to the records system as prescribed by approved procedures. Upon completion of a project or other discrete task or activity, responsible management shall verify that the contents of the applicable QA records package are stored in the records system.</p> <p>F. QA records may be originals or reproducible copies unless otherwise required.</p> <p>G. Documents referenced by final reports, except readily available references such as encyclopedias, dictionaries, engineering handbooks, and national codes and standards shall be retrievable from records files. Preparers of such records shall ensure that the documents are entered into the records system.</p>				<p>E. NP 17-1, Section 2.2</p> <p>F. NP 17-1, Section 2.1</p> <p>G. NP 17-1, Section 2.3</p>	<p>E. Because projects are directly tied to milestones, the responsibility of verifying storage of these records is delegated to the Record Source and ASTL per SP 6-2. Verification can be accomplished through returned submittal forms.</p>
<p>1.5.3 Indexing QA Records</p> <p>The records system shall provide for the indexing of QA records according to the following requirements:</p> <p>A. An individual or organization shall be assigned the responsibility of indexing and maintaining QA records.</p> <p>B. The indexing system shall include, at a minimum, record retention times and the location of the record within the records system. These and other features of the records system shall facilitate the disposition of scheduled QA records and ensure the retrievability of any QA records entered.</p>	√			<p>A. SP 17-1, Section 1.0</p> <p>B. SP 17-1, Sections 2.1.5, 2.1.6</p>	
<p>1.5.4 Classifying QA Records</p> <p>A. QA records shall be classified as either "post-closure," "lifetime," or "nonpermanent." Post-closure QA records may be required to be maintained for periods of several hundred years and in a manner that will permit future generations to maintain them longer, if desired, using reasonably available technology. Records that fall into one or more of the following categories shall be classified as "post-closure" QA records:</p> <ol style="list-style-type: none"> 1. Records assisting prevention of actions that could impair the long-term isolation of the waste 2. Records preserving information that would prevent inadvertent human intrusion, such as the nature and hazard of the waste and the locations of the geologic repository operations area, the underground facility, boreholes and shafts, and boundaries of the controlled area 3. Records providing information relevant to post-closure monitoring and assessment of performance of the repository system 	√			<p>NP 17-1, Section 2.1</p> <p>SP 17-1, Sections 2.1.6, 2.2</p>	<p>All QA Records are classified as "Lifetime"</p>

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>4. Records preserving for future generations information regarding the geologic setting relevant to mitigation of releases of radioactive materials</p> <p>5. Records of significant value in exercising the retrieval option for waste packages after decommissioning and closure of the repository</p> <p>B. Records not falling into the categories listed above, but falling into one or more of the following categories, shall be classified as "lifetime" QA records:</p> <p>1. Records used for repository permitting or certification</p> <p>2. Records used to identify and assess the performance capabilities of those engineered and natural barriers important to waste isolation</p> <p>3. Records of computer programs and mathematical models needed to perform ongoing correlations between performance assessment predictions and actual tests and data analyses</p> <p>4. Records of significant value in demonstrating the capability for safe operation of or in determining the cause of an accident or a malfunction of an item in the WIPP repository</p> <p>5. Records of significant value in maintaining, reworking, repairing, replacing, or modifying WIPP repository systems, components, or structures</p> <p>6. Records that would be needed during decommissioning and closure of the repository</p> <p>7. Records relating to site characterization samples and data</p> <p>8. Records relating to data used in performance assessment of the WIPP facility</p> <p>9. Records relating to the mixed transuranic waste form characterization and acceptance of the mixed transuranic waste form</p> <p>10. Records documenting regulatory compliance</p> <p>11. Records which provide required baseline data for in-service inspections</p> <p>C. Lifetime QA records are required to be retained and preserved in an acceptable condition for the operating life of the repository (i.e., until termination of the repository permit). Prior to destruction of any lifetime</p>				<p>NP 17-1, Section 2.1</p> <p>SP 17-1, Sections 2.1.6, 2.2</p>	<p>All QA Records are classified as "Lifetime"</p>

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>record, it shall be evaluated for upgrade to a post-closure record</p> <p>D. Records that provide objective evidence that the QA program has been properly implemented, but do not meet the above criteria for post-closure or lifetime records shall be classified as “nonpermanent” QA records. The retention period for nonpermanent records shall be established in writing.</p>					
<p>1.5.5 Receiving QA Records</p> <p>Each organization responsible for the receipt of QA records shall designate the person or organization responsible for receiving QA records. The designee shall be responsible for organizing and implementing a system of controls for the receipt of QA records for permanent and temporary storage. At a minimum, the receipt control system shall include:</p> <p>A. Provisions to permit a current and accurate assessment of the status of QA records</p> <p>B. A method for identifying the records required to be included in the records system</p> <p>C. A method for identifying the records that have been received</p> <p>D. Procedures for the receipt and inspection of incoming records, including verification that the QA records received are in agreement with the transmittal document and that the records are legible</p> <p>E. Provisions to control and protect the records from damage or loss during the receiving processes</p> <p>F. A method for submittal of completed records to the storage facility without unnecessary delay</p>	√			<p>A. SP 17-1, Sections 2.1.1, 2.1.7</p> <p>B. NP 17-1, Section 2.1</p> <p>C. SP 17-1, Section 2.1.1</p> <p>D. SP 17-1, Section 2.1</p> <p>E. SP 17-1, Sections 2.2.1, 2.2.2</p> <p>F. SP 17-1, Section 2.1.7 NP 17-1, Sections 2.1, 2.2, 2.3</p>	
<p>1.5.6 Storage, Preservation, Safekeeping, and Disposition of QA Records</p> <p>A. QA records shall be stored and preserved in predetermined storage facilities in accordance with approved QA implementing procedures that provide a</p> <ol style="list-style-type: none"> 1. Description of the storage facility 2. Description of the filing and indexing systems that are used 3. A method for verifying that a receipt acknowledgment is returned to the sender 4. Description of controls governing QA records access, retrieval, and removal 	√			<p>A. SP 17-1, Sections 2.1.1, 2.1.5, 2.1.6, 2.1.8, 2.2 NP 17-1, Section 2.4</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>5. A method for filing supplemental information and documenting the authorization for corrections</p> <p>B. The records storage arrangements shall provide adequate protection of records, including special processed records (such as radiographs, photographs, negatives, microfilm, and magnetic media) to preclude damage from moisture, temperature, rodent infestation, excessive light, electromagnetic fields, or stacking, as appropriate for the type of record being stored.</p> <p>C. Records that require special processing and control, such as software and related documentation or information on high density media or optical disks, or hardware and software required to maintain and access records, shall be controlled to ensure that the records are useable.</p>				<p>B. SP 17-1, Section 2.2.4</p> <p>C. NP 17-1, Sections 2.3.1, 2.3.3 SP 17-1, Section 2.2.4</p>	
<p>1.5.6.1 Records Disposition</p> <p>A. Lifetime QA records shall be retained and preserved in an acceptable condition for the operating life of the WIPP repository (i.e., until termination of the operating permits), or for the particular item while it is installed in the repository or is being stored for future use. Lifetime records shall be evaluated for the need to be upgraded to post-closure records prior to their destruction.</p> <p>B. Waste characterization data and related QA/QC records in the generator/storage site project files for TRU waste to be shipped to the WIPP facility are designated as either lifetime records or non-permanent records as specified in Attachment B of the WIPP Hazardous Waste Facility Permit. Records that are designated as lifetime records shall be maintained for the life of the waste characterization program at a participating generator/storage site plus six years, then offered to CBFO for permanent archiving, or transferred to the appropriate Federal Records Center (FRC). Waste characterization records designated as non-permanent records shall be maintained for ten years from the date of (record) generation and then dispositioned according to their approved records inventory and disposition schedule (RIDS). If a generator/storage site ceases to operate, records shall be transferred before closeout.</p> <p>C. Records relevant to an enforcement action under the WIPP Hazardous Waste Permit, regardless of assigned dispositions, shall be maintained at the TRU waste site until the NMED determines that they are no longer needed for enforcement actions, and then dispositioned as required.</p> <p>D. Waste characterization data for each TRU mixed waste container transmitted to WIPP shall be maintained by CBFO for the active life of the WIPP facility plus two</p>	<p>√ (A)</p>		<p>√ B-G</p>	<p>A. SP 17-1, Section 2.2</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>years. The active life of the WIPP facility is defined as the period from the initial receipt of TRU mixed waste at the facility until NMED receives certification of final closure of the facility. After their active life, records shall be retired to the FRC and maintained for 30 years.</p> <p>E. Design and construction of a single records storage facility shall meet the applicable requirements of NQA-1-1989, NQA-3-1989, 10 CFR 71, and current requirements of NARA.</p> <p>F. The construction details shall be reviewed by a person who is competent in the technical field of fire protection and fire extinguishing to determine the adequacy of protection of contents. If the facility is located within a building or structure, the environments and construction of that building can provide a portion or all of these criteria.</p> <p>G. The following criteria are acceptable alternatives to the current National Archives and Records Administration requirements and NQA-1-1989 criteria for a single storage facility:</p> <ol style="list-style-type: none"> 1. Two-hour fire-rated vault meeting the National Fire Protection Association (NFPA) 232-1986, <i>Standards for the Protection of Records</i>, or NFPA 232AM-1986, or both 2. Two-hour fire-rated Class B file containers meeting the requirements of NFPA 232-1986, or NFPA 232AM-1986, or both 3. Two-hour fire-rated file room meeting the requirements of NFPA 232-1986, or NFPA 232AM-1986, or both, with the following additional provisions: <ol style="list-style-type: none"> a. Early warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended central station b. Records storage in fully enclosed metal cabinets c. Adequate access and aisle ways d. Prohibition in the room of work not directly associated with record storage or retrieval e. Prohibition of smoking, eating, or drinking f. Two-hour fire-rated dampers or doors in all boundary penetrations 					E-G SNL does not have a "single" record storage facility. SNL maintains duplicate storage.

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>boundary penetrations</p> <p>H. If storage at dual facilities for each record is provided, the facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Each facility is not required to satisfy the requirements of either sections E or F above, but shall meet all other records storage requirements prescribed in this QAPD.</p> <p>I. When temporary storage of records (such as for processing, review, or use) is required by an organization's procedures, the records shall be stored in a 1-hour fire-rated container. The procedures shall specify the maximum allowable time limit for temporary storage. The container shall bear a UL label (or equivalent) certifying one-hour fire protection, or be certified by a person competent in fire protection.</p> <p>J. Access to storage facilities shall be controlled. A list designating personnel who are permitted access to the QA records shall be maintained and posted. Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against theft and vandalism.</p> <p>K. Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records.</p> <p>L. QA records shall not be destroyed until the following conditions are met:</p> <ol style="list-style-type: none"> 1. The appropriately assigned National Archives and Records Administration (NARA) authorized disposition specifies destruction 2. Regulatory requirements are satisfied 3. Operational status permits the disposal of such records 4. The related contractual requirements have been satisfied 	<p>√</p> <p>H-L</p>			<p>H. SP 17-1, Section 2.2</p> <p>I. SP 17-1, Section 2.2; 2.2.1; 2.2.2</p> <p>J. SP 17-1, Section 2.2.5; 2.2.6</p> <p>K. SP 17-1, Section 2.1.8</p> <p>L. SP 17-1, Section 2.2</p> <p>SP 17-1, Section 2.2</p>	
<p>1.5.7 Correcting Information in QA Records</p> <p>A. Corrections to records will include the initials or signature of the authorized person making the correction and the date the correction was made.</p> <p>B. Corrections to QA records shall be authorized by the originating organization.</p> <p>C. Corrections to QA records should be made using a single line through and shall not obliterate the prior entry. QA records shall not be corrected with correction fluids or tapes.</p>	<p>√</p>			<p>NP 17-1, Section 2.4</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
2.1 WORK PROCESSES					
A. Work shall be performed in accordance with established technical standards and administrative controls. Work shall be performed under controlled conditions using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained.	√			NPs 3-1, 9-1, 20-1, NP 5-1, and 6-2 ("Items" are not applicable to SNL scope of work.) NP 12-1	Design work activities shall be performed IAW Design Plans (3-1), data collection work IAW Test Plans (20-1), and analysis work IAW Analysis Plans (9-1). NP 5-1 governs QA implementing procedures. NP 6-2 governs issuance of approved plans and procedures. NP 12-1 governs calibration and maintenance.
B. The intent of this section is to establish the policy that each person who performs work is responsible for the quality of his or her work, and he or she will have the goal of doing work correctly the first time. To ensure that the person doing the work achieves that goal, management is responsible for establishing processes and procedures to ensure that all work is planned and performed under controlled conditions by personnel who are knowledgeable of the work requirements, and that these individuals are capable of accomplishing the work in accordance with the requirements of this QAPD.	√			NP 1-1, Section 2.2.1.4 and 2.2.1.1	
C. This section further establishes management involvement in the work processes through their interactions with personnel performing the work and through their review and verification of ongoing and completed work. This helps to ensure that the definition of "acceptable work performance" is clearly communicated and that personnel are provided the necessary training, resources, and administrative controls to properly accomplish their tasks.	√			NP 1-1, Section 2.2.1.1	
2.1.1 Work	√			NP 1-1, 2.2.1.4	
A. Personnel performing work are responsible for the quality of their work. Because the individual worker is the first line in ensuring quality, personnel will be knowledgeable of requirements for work they perform and the capability of the tools and processes they use.					
B. Line managers will ensure that personnel working under their supervision are qualified and are provided the necessary training, resources, and administrative controls to accomplish assigned tasks. Criteria describing acceptable work performance shall be defined for the worker.	√			NP 1-1, Section 2.2.1.1	
C. Line managers will review work and related information to ensure that the desired quality is achieved and to identify areas needing improvement.	√			NP 1-1, Section 2.2.1.1	
D. Work shall be planned, authorized, and accomplished under controlled conditions using technical standards, QA requirements, and implementing procedures	√			NP 1-1, Section 2.2.1.1	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
commensurate with applicable control levels.					
2.1.2 Implementing Procedures					
A. Implementing procedures shall be developed, reviewed, and approved by technically competent personnel.	√			NP 1-1, Section 2.2.1.1; NP 5-1, Section 2.3	
B. Implementing procedures shall include the following information, as appropriate to the work to be performed:	√			NP 5-1, Appendix A	
1. Responsibilities of the organizations affected by the document					
2. Technical, regulatory, quality assurance, or other program requirements					
3. Sequential description of the work to be performed, including any allowance for out-of-sequence processing					
4. Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished					
C. Individuals performing work shall comply with implementing procedures; however, when work cannot be accomplished as described in the implementing procedure or accomplishment of such work would result in an undesirable situation, a condition adverse to quality, or an unacceptable safety risk, the work shall be suspended until the appropriate procedure change provisions are implemented.	√			NP 5-1, Section 2.6	
2.1.3 Item Identification and Control					
A. Processes shall be established and maintained to identify, control, and maintain items to prevent their damage, loss, or deterioration. The identification of items shall be maintained to ensure appropriate traceability. Traceability requirements shall be specified in design documents or implementing procedures. Processes shall be established and implemented to control consumables and items with limited operating or shelf life and to prevent the use of incorrect or defective items.			√	See Comment	SNL work scope does not include "items"; sample identification and control is covered by NP 13-1, M&TE is covered by NP 12-1. Therefore, this section is not applicable. N/A applies to all of Section 2.1.3
B. The following controls shall be established to ensure that only correct and accepted items are used or installed:			√		
1. Items shall be identified and traced from the time of receipt, up to and including installation or end use. Records shall be maintained to ensure that the item can be traced at all times, from its source through installation or end use.					
2. Item identification methods shall include physical			√		

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>markings. If physical markings are either impractical or insufficient, other appropriate means shall be employed (such as physical separation, labels or tags attached to containers, or procedural control). When used, physical markings shall</p> <ol style="list-style-type: none"> a. Be applied using materials and methods that provide a clear, permanent, and legible identification b. Not be detrimental to the function or service life of the item c. Be transferred to each part of an identified item when the item is subdivided d. Not be obliterated or hidden by surface treatments, coatings, or installation unless other means of identification are substituted <p>3. If codes, standards, or specifications include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification or grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other record(s), then identification and traceability methods shall be implemented to ensure meeting the special requirements.</p> <p>4. Item identification control system records shall provide the inspection, test, and operating status of items. Items that have satisfactorily passed the required inspections and tests shall be identified. The identification methods shall preclude the inadvertent installation, use, or operation of items that have not passed required inspections and tests.</p> <p>5. The status of inspections and tests shall be identified either on the items or in documents traceable to the items. Status shall be maintained through the use of status indicators (such as tags, markings, labels, and stamps) or other means (such as inspection or test records), and the authority for applying and removing status indicators shall be specified.</p>			<p>√</p> <p>√</p> <p>√</p> <p>√</p>		
<p>2.1.4 Special Processes</p> <p>A. Special Processes shall be considered as special processes if they meet any one or a combination of the following criteria:</p> <ol style="list-style-type: none"> 1. The results are highly dependent on the control of the process 			√	See Comment	SNL work scope does not involve "Special Processes," therefore this section is not applicable

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>2. The results are highly dependent on the skill of the operator</p> <p>3. The quality of the results cannot be readily determined by inspection or test of the product</p> <p>B. Implementing procedures shall be developed and implemented to ensure that special process parameters are controlled and specified environmental conditions are maintained. In addition to the requirements provided in section 2.1.2, special process implementing procedures shall include or reference:</p> <p>1. The requirements for training/qualification of personnel and quality processes/equipment</p> <p>2. The conditions necessary for completion of the special process, including equipment, statistical process control, controlled parameters of the process, and calibration requirements</p>			√		
<p>2.1.5 Handling, Storage, and Shipping</p> <p>A. Handling, storage, cleaning, shipping, and other means of preserving, transporting, and packaging of items shall be conducted in accordance with established work and inspection procedures, shipping instructions, or other specified documents.</p> <p>B. If required for critical, sensitive, perishable, or high-value articles, specific implementing procedures for handling, storage, cleaning, packaging, shipping, and other preservation shall be prepared and used.</p> <p>C. Measures shall be established and implemented for the marking and labeling of items for packaging, shipping, handling, and storage as necessary to adequately identify, maintain, and preserve the item. Markings and labels shall indicate the presence of special environments or the need for special controls, as necessary, and shall be applied and removed by authorized personnel.</p> <p>D. If required for protection or maintenance of particular items, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas and specific moisture and temperature levels) shall be specified, planned for, and provided.</p> <p>1. If special protective equipment and environments are used, provisions shall be made for verifying their adequacy.</p> <p>2. Special handling tools and equipment shall be used</p>			√ √ √		<p>SNL work scope does not include "items"; sample identification and control is covered by NP 13-1, M&TE is covered by NP 12-1. Therefore, this section is not applicable.</p> <p>See Comment to QAPD Section 2.1.5</p> <p>See Comment to QAPD Section 2.1.5</p> <p>See Comment to QAPD Section 2.1.5</p>

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>and controlled, as necessary, to ensure safe and adequate handling.</p> <p>3. Special handling tools and equipment shall be inspected and tested at specified intervals and in accordance with implementing procedures to verify that the tools and equipment are adequately maintained.</p> <p>4. Operators of special handling and lifting equipment shall be sufficiently experienced and trained to use the equipment.</p> <p>E. If storage of items is required, methods shall be established for the control of item identification records that are commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:</p> <p>1. Maintenance or replacement of markings and identification tags damaged during handling or aging</p> <p>2. Protection of identification markings that are subject to excessive deterioration resulting from environmental exposure</p> <p>3. Update of related identification records and documentation</p> <p>F. Status indicators, such as tags or valves and switches to prevent inadvertent operation, shall be used to indicate the operating status of items. Status indicators, such as lockout tagging, shall also be used where appropriate and shall be applied and removed by authorized personnel.</p>			<p>√</p> <p>√</p>		<p>See Comment to QAPD Section 2.1.5</p> <p>See Comment to QAPD Section 2.1.5</p>
<p>2.2 DESIGN CONTROL</p> <p>A. Items and processes shall be designed using sound engineering and scientific principles and appropriate standards. Design work, including changes, shall incorporate appropriate requirements, such as general design criteria and design bases. Design interfaces shall be identified and controlled.</p> <p>B. The adequacy of design products shall be verified by individuals or groups other than those who performed the design work. Required verification and validation shall be completed before approval and implementation of the design.</p> <p>C. Designs (from conceptual through final) shall be defined, controlled, and verified. In establishing design controls, management is responsible for ensuring that design inputs are technically correct; that design</p>	<p>√</p> <p>√</p> <p>√</p>			<p>NP 3-1, Appendix A</p> <p>NP 3-1, Appendix A</p> <p>NP 3-1, Appendix B</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
interfaces are identified; that authorities, responsibilities, and lines of communication are clearly defined; and that the design processes clearly define the acceptance criteria for the product.					
<p>2.2.1 Design Input</p> <p>Applicable design inputs such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes, and standards shall be controlled by those responsible for the design in accordance with the following requirements:</p> <p>A. Design inputs shall be identified and documented and their selection reviewed and approved by those responsible for the design.</p> <p>B. Design inputs shall be specified and approved on a timely basis to the level of detail necessary to permit the design work to be carried out correctly in a manner that provides a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.</p> <p>C. Changes from approved design inputs and reasons for the changes shall be identified, approved, documented, and controlled.</p> <p>D. Design inputs based on assumptions that require reverification shall be identified and controlled.</p>	√			NP 3-1, Appendix A	
<p>2.2.2 Design Process</p> <p>The design process shall be controlled according to the following requirements:</p> <p>A. Appropriate standards shall be identified and documented and their selection reviewed and approved. Changes from specified standards, including the reasons for the change, shall be identified, approved, documented, and controlled.</p> <p>B. Design work shall be prescribed and documented on a timely basis and to the level of detail necessary to permit the design process to be carried out correctly.</p> <p>C. Design documents shall be adequate to support design, fabrication, construction, and operation.</p> <p>D. Design documents shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can understand the documents and verify their adequacy without recourse to the originator.</p> <p>E. Controls for identifying assemblies or components that</p>	√			NP 3-1, Appendix A and B	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>are part of the item being designed shall be established. If a commercial grade assembly or component is modified or selected by special inspection or testing to meet requirements that are more restrictive than the supplier's published product description, then the assembly or component shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.</p> <p>F. Controls for selecting and reviewing design methods, materials, parts, equipment, and processes essential to the function of an item shall be established.</p> <p>G. Drawings, specifications, and other design output documents shall contain appropriate inspection and testing acceptance criteria.</p>	√			NP 3-1, Appendix A and B	
<p>2.2.3 Design Analyses</p> <p>A. Design analyses shall be planned, controlled, and documented.</p> <p>B. Documentation of design analyses shall include</p> <ol style="list-style-type: none"> 1. Definition of the objective of the analyses 2. Definition of design inputs and their sources 3. Results of literature searches or other applicable background data 4. Identification of assumptions and designation of those assumptions that shall be verified as the design proceeds 5. Identification of any computer calculations, including computer type, computer software name, revision identification, inputs, outputs, and the bases (or reference thereto) supporting application of the software to the specific physical problem. 6. Identification of the reviewer and the approver <p>C. Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date, or by other designator such that the calculations are traceable.</p> <p>D. Computer software used to perform design analyses shall be developed, qualified, and used according to the requirements of Section 6.</p>	√			NP 3-1, Section 2.2; Appendix A and B	
<p>2.2.4 Design Interface</p> <p>A. Design interfaces shall be identified, documented, and controlled so that efforts are coordinated among</p>	√			NP 3-1, Appendix A	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>participating organizations.</p> <p>B. Design interface controls shall including the assignment of responsibility and the establishment of implementing procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces</p> <p>C. Design information transmitted across interfaces shall be documented and controlled.</p> <p>D. The status of the design information or issued design documents shall be identified in transmittals. Where necessary, incomplete designs that require further evaluation, review, or approval shall be identified.</p>					
<p>2.2.5 Design Verification</p> <p>The acceptability of design work and documents, including design inputs, processes, outputs, and changes, shall be verified. The following design control requirements shall be applied to verify the adequacy of design:</p> <p>A. Design verification shall be performed using one or a combination of the following methods:</p> <ol style="list-style-type: none"> 1. Design review 2. Alternate calculations 3. Qualification testing <p>B. The particular design verification method shall be identified and its use justified.</p> <p>C. The results of design verification shall be clearly documented, including the identification of the verifier.</p> <p>D. Design verification shall be performed by competent individuals or groups other than those who performed the original design (but they may be from the same organization). If necessary, this design verification may be performed by the originator's supervisor, provided that:</p> <ol style="list-style-type: none"> 1. The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design. 2. The supervisor is the only individual in the organization competent to perform the verification. 3. The determination to use the supervisor is documented and approved in advance. 	<p>√</p> <p>√</p> <p>√</p> <p>√</p>		<p>NP 3-1, Section 2.3</p> <p>NP 3-1, Section 2.3</p> <p>NP 3-1, Section 2.3</p> <p>NP 3-1, Section 2.3, Part C</p> <p>See Comment</p>	<p>SNL does not use qualification testing on WIPP design activities.</p> <p>SNL QA Program does not allow supervisors to perform design verification.</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>E. Design verification shall be performed at appropriate times during the design process.</p> <ol style="list-style-type: none"> 1. Verification shall be performed before release for procurement, manufacture, construction, or release to another organization for use in other design work. 2. Design verification shall be completed before relying on an item to perform its function. 	√			NP 3-1, Section 2.3	
<p>F. The extent of the design verification required shall be based on the complexity, risk, uniqueness of design, complexity of design, degree of standardization, state of the art, and similarity previously proven designs. When the design has been subjected to a verification process in accordance with this QAPD, the verification process need not be duplicated for identical designs.</p>	√			NP 3-1, Section 2.1.2	
<p>G. Use of previously proven designs shall be controlled according to the following requirements:</p> <ol style="list-style-type: none"> 1. The applicability of standardized or previously proven designs shall be verified with respect to meeting pertinent design inputs for each application. 2. Known problems affecting standard or previously proven designs and their effects on other features shall be considered. 3. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design. 4. Changes in previously verified designs shall require reverification. Such reverifications shall include the evaluation of the effects of those changes on the overall previously verified design and on any design analyses upon which the design is based. 	√			NP 3-1, Section 2.3, Part D	
<p>2.2.6 Design Reviews</p> <p>A. Design reviews shall be controlled, documented, and performed, and shall consider the following:</p> <ol style="list-style-type: none"> 1. Design inputs were correctly selected and incorporated. 2. Assumptions necessary to perform the design work were adequately described, reasonable, and reverified as necessary. 3. Appropriate design methods were used. 	√			NP 3-1, Appendix C	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>4. Design output is reasonable compared to design inputs.</p> <p>5. The necessary design input and verification requirements for interfacing organizations were specified in the design documents or in supporting implementing procedures.</p> <p>B. Disposition of design review comments shall be documented.</p>					
<p>2.2.7 Alternative Calculations</p> <p>These are calculations or analyses that are made using alternate methods to verify correctness of the original calculations or analyses. The appropriateness of any assumptions, the input data used, any computer programs, or other calculation methods used, shall be evaluated.</p>	√			NP 3-1, Appendix C	
<p>2.2.8 Qualification Testing</p> <p>If design adequacy is to be verified by qualification tests, the tests shall be pre-identified. When qualification testing is used, the following requirements shall apply:</p> <p>A. The test configuration shall be defined and documented.</p> <p>B. Testing shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item shall perform satisfactorily shall be considered in determining the most adverse conditions.</p> <p>C. If the tests verify only specific design features, then the other features of the design shall be verified by other means.</p> <p>D. Test results shall be documented and evaluated by the responsible design organization to ensure that test requirements have been met.</p> <p>E. If qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, then the modification shall be documented and the modified item retested or otherwise verified to ensure satisfactory performance.</p> <p>F. Scaling laws shall be established and verified when tests are being performed on models or mockups.</p> <p>G. The results of model test work shall be subject to error analysis, where applicable, before the results are used in final design work.</p>			√	See Comment	SNL does not use this form of testing on WIPP design activities.
<p>2.2.9 Design Change</p>	√			See Comment	SNL does not use this form of testing on WIPP design activities.
				NP 3-1, Section 2.5	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>Design changes shall be controlled in accordance with the following requirements:</p> <p>A. Changes to final designs, field changes, and nonconforming items dispositioned "use as is" or "repair" shall be justified and shall be subject to design control measures commensurate with those applied to the original design.</p> <p>B. Design control measures for changes shall include provisions to ensure that the design analyses for the item are still valid.</p> <p>C. Changes shall be approved by the same groups or organizations that reviewed and approved the original design documents, with the following considerations:</p> <ol style="list-style-type: none"> 1. If an organization that originally was responsible for approving a particular design document is no longer responsible, the new responsible organization shall be designated. 2. The cognizant design organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design. <p>D. When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate.</p> <p>E. If a significant design change becomes necessary because of an incorrect original design, the design process and design verification methods and implementing procedures shall be reviewed and modified as appropriate. These design deficiencies shall be documented according to the requirements provided in section 1.3.2.</p> <p>F. Field changes shall be incorporated into the applicable design documents.</p> <p>G. Design changes that affect related implementing procedures or training programs shall be communicated to the appropriate organizations.</p>					
<p>2.3 PROCUREMENT</p> <p>CBFO and participant organizations shall ensure that participant organizations comply with applicable Federal Acquisition Regulations (FARs) that procured items and services meet established technical and QA requirements, and that they perform as specified. Prospective suppliers</p>	v			NP 4-1: Sections 2.1.1, 2.1.2, 2.1.3, 2.4, 2.5, and 2.6	The FAR is implemented based on a combination of DOE and SNL corporate guidance.

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
shall be evaluated and selected on the basis of documented criteria. The responsible organization shall verify that approved suppliers continue to provide acceptable items and services.					
<p>2.3.1 Procurement Planning Requirements</p> <p>Procurement activities shall be planned as early as possible and documented to ensure a systematic approach to the procurement process. Procurement planning shall</p> <p>A. Identify procurement methods and organizational responsibilities, including the appropriate QA organization</p> <p>B. Identify and document the sequence of actions and milestones needed to effectively complete the procurement.</p> <p>C. Provide for the integration of the following activities:</p> <ol style="list-style-type: none"> 1. Procurement document preparation, review, and change control 2. Selection of procurement sources 3. Proposal or bid evaluation and award 4. Purchaser evaluation of supplier performance 5. Purchaser verifications including any hold-point and witness-point notifications 6. Control of nonconformance's 7. Corrective action 8. Acceptance of the item or service 9. Identification of QA records 	v			<p>NP 4-1: Appendix B, Section 2.0 (for 1-6), Section 2.5.3 (for 7), Section 2.5 and 2.6 (for 8) and Section 3.0 (for 9).</p> <p>NP 4-1: Appendix B, Section 2.0 (for 1-6), Section 2.5.3 (for 7), Section 2.5 and 2.6 (for 8) and Section 3.0 (for 9).</p> <p>NP 4-1, Section 2.2; 2.4; 2.5 and 2.6</p>	
<p>2.3.2 Supplier Selection</p> <p>A. Supplier selection shall be based on evaluation of the supplier's capability to provide items or services in accordance with procurement document requirements</p> <p>B. Organizations responsible for supplier source selection shall be identified and shall include the appropriate QA organization.</p> <p>C. Measures for selecting procurement sources shall include one or more of the following elements:</p> <ol style="list-style-type: none"> 1. An evaluation of the supplier's history for providing an identical or similar product that performs 	v			(A- D)NP 4-1: Section 2.1.3, Section 2.4, Section 2.5, and Section 2.6	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>instructions) that describe the technical requirements of the items or services to be furnished shall be identified. The revision level or change status of these documents shall also be identified.</p> <p>3. Tests, inspections, hold points, or acceptance criteria that the purchaser shall use to monitor and evaluate the performance of the supplier shall be specified.</p> <p>C. QA provisions specified by the purchaser QA organization shall include</p> <p>1. The requisite QA and documentation requirements, depending on the control level of the item or service being procured</p> <p>2. The pass-down requirements that the supplier shall incorporate into any sub-tier procurement document</p> <p>3. When deemed appropriate, the purchaser may permit some or all supplier work to be performed under the purchaser QA program, provided that the requirements are adequately implemented. In these cases, procurement documents shall specify that the purchaser's QA implementing procedures are applicable to the supplier and that the purchaser shall provide these applicable documents to the supplier.</p> <p>4. Right of access to supplier facilities and records for inspection and audit by the purchaser, CBFO, or other designee authorized by the purchaser</p> <p>5. The requirements of section 1.5 and provisions for disposition, if the supplier is required to maintain QA records</p> <p>6. Requirements for the supplier to report nonconformance's and obtain purchaser approval of supplier-recommended dispositions</p> <p>7. Spare and replacement parts or assemblies and the appropriate technical and QA requirements for ordering</p> <p>8. Requirements for the use, control, and calibration of measuring and test equipment in conformance to the requirements of ANSI/NCSL Z540-1, <i>Calibration Laboratories and Measuring and Testing Equipment - General Requirements</i></p>				<p>NP 4-1, Section 2.1.3</p> <p>NP 4-1: Section 2.4, Section 2.5, and Section 2.6</p> <p>NP 4-1: Section 2.1.3</p>	<p>Suppliers are required to adhere to either the QAPD (incl. QA records requirements) or SNL NP 17-1. All suppliers are required to forward QA records to SNL for disposition.</p> <p>Suppliers are required to adhere to either the QAPD (incl. M&TE control requirements) or SNL NP 12-1, which includes this rqmt</p>

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>2.3.5 Procurement Document Review and Approval</p> <p>A. A review of the procurement documents and any changes thereto shall be made to verify that documents include appropriate provisions to ensure that items or services meet the prescribed requirements. Procurement document changes shall be subject to the same degree of control as the original documents.</p> <p>B. Procurement document reviews shall be performed and documented prior to the document being issued to the supplier.</p> <p>C. Reviews shall be performed by personnel who have access to pertinent information and who have adequate understanding of the requirements and scope of the procurement.</p> <p>D. Procurement document reviews shall include representatives from the technical and QA organizations and shall be approved by responsible management.</p>	v			(A-D) NP 4-1, Section 2.1.4 and 2.1.5	
<p>2.3.6 Supplier Performance Evaluation</p> <p>The purchaser of items and services shall establish measures to interface with the supplier and to verify supplier performance, as deemed necessary by the purchaser. The measures shall include:</p> <p>A. Establishing an understanding between the purchaser and supplier of the requirements and specifications identified in the procurement documents</p> <p>B. Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements</p> <p>C. Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement requirements</p> <p>D. Identifying and processing necessary change information</p> <p>E. Establishing the method to be used to document information exchanges between purchaser and supplier</p> <p>F. Establishing the extent of assessment activities and inspection</p>	v			<p>NP 4-1, All</p> <p>NP ,4-1, Section 2.1.3</p> <p>NP 6-1, Section 1.0</p> <p>NP 4-1, Section 2.4 and 2.6</p>	documents and the process of placing a procurement accomplish this
<p>2.3.7 Acceptance of Items or Services</p> <p>2.3.7.1 Source Verification</p> <p>A. The purchaser may accept an item or service by monitoring, auditing, surveilling, witnessing, or</p>	v			(A-B) NP 4-1, Section 2.4	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>observing activities performed by the supplier. This method of acceptance is called source verification.</p> <p>B. The extent of source verification shall be a function of the relative importance, complexity, and quantity of items or services being procured, as well as the supplier's quality of performance. Source verifications shall be accomplished as early as possible, but prior to the start of those activities that are required to be controlled, and shall include the active involvement of the purchaser's QA organization. In addition:</p> <ol style="list-style-type: none"> 1. Source verification shall be accomplished consistent with the supplier's planned inspections, examinations, or tests and performed at intervals consistent with the importance and complexity of the item. 2. Documented evidence of acceptance of source verified items or services shall be furnished to the party receiving the item, to the purchaser, and to the supplier. 3. Source verification shall be performed by qualified personnel. <p>C. For procurement of services only (such as third party inspection, engineering and consulting services), and installation, repair, overhead, or maintenance work, the purchaser shall accept the service by any or all of the following methods:</p> <ol style="list-style-type: none"> 1. Technical verification of data produced 2. Surveillance and/or audit of the activity 3. Review of objective evidence for conformance to the procurement document requirements such as certifications or test reports 	v			NP 4-1, Section 2.4	
<p>2.3.7.2 Receiving Inspection</p> <p>When a receiving inspection is used to accept an item:</p> <ol style="list-style-type: none"> 1. The inspection shall include consideration of source assessments, verifications and audits and the demonstrated quality performance of the supplier. 2. The inspection shall be performed in accordance with established inspection procedures or instructions. 3. The inspection shall verify, as applicable, proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. 	v			NP 4-1: Section 2.4, Section 2.5, Section 2.6, and SP 1-1, Appendix A (Form SP 1-1-1)	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>4. The inspection shall be planned and executed in accordance with the applicable requirements of Section 2.4.</p> <p>5. Receiving inspection shall include a review of the adequacy and completeness of any required supplier documentation.</p>					
<p>2.3.7.3 Post-Installation Testing</p> <p>When post-installation testing is used as a method of acceptance, then post-installation test requirements and acceptance documentation shall be mutually established and agreed upon by the purchaser and supplier.</p>	v			NP 4-1, Section 2.4	
<p>2.3.7.4 Supplier Certificate of Conformance</p> <p>When a certificate of conformance is used, the following, at a minimum, shall be met:</p> <p>A. The certificate shall identify the purchased material or equipment, including the purchase order and item number or other identification that is traceable to the requirements of the procurement document.</p> <p>B. The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.</p> <p>C. The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances.</p> <p>D. The certificate shall be signed or otherwise authenticated by an official of the supplier organization, whose function and position are described in the supplier's QA program.</p> <p>E. The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificate, shall be described in the purchaser or supplier QA program.</p> <p>F. Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier or independent inspection or test of the items. Such verification shall be conducted by the purchaser at intervals commensurate with the supplier's past quality performance.</p>	v			<p>NP 4-1, Section 2.4</p> <p>NP 4-1, Section 2.5</p> <p>NP 4-1, Section 2.5.2</p> <p>NP 4-1, Section 2.5, 2.5.2, and 2.5.3</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>2.3.8 Control of Supplier Nonconformances</p> <p>The purchaser and supplier shall establish and document the process for dispositioning items and services that do not meet procurement document requirements in accordance with the following:</p> <p>A. The supplier shall submit a report of nonconformance to the purchaser that includes supplier-recommended disposition (for example, "use as is" or "repair") and provide technical justification for such disposition.</p> <p>B. Reports of nonconformances to procurement document requirements or documents approved by the purchaser shall be submitted to the purchaser for approval. Examples of conditions requiring a report of nonconformance include:</p> <ol style="list-style-type: none"> 1. Failure to meet technical or material requirements 2. Failure to meet a requirement in supplier documents that have been approved by the purchaser 3. The nonconformance cannot be corrected by continuation of the original manufacturing process or by rework 4. The item does not conform to the original requirement even though the item can be restored to a condition such that the its capability to function is unimpaired <p>C. The purchaser shall evaluate the supplier-recommended disposition.</p> <p>D. The purchaser shall verify implementation of the disposition.</p>	V			NP 4-1, Section 2.5.2, .2.5.3, and 2.5.4	
<p>2.3.9 Commercial Grade Items</p> <p>Where the design specifies the use of commercial grade items, the following requirements are an acceptable alternative to other requirements of this section.</p> <p>A. The commercial grade item shall be identified in an approved design output document, such as drawing, specification, or other document translated from a design input document. An alternative commercial grade item may be applied as long as the responsible design organization provides verification that the alternative commercial grade item performs the intended function and meets design requirements that are applicable to both the replaced item and its</p>	V			NP 4-1, Section 2.5; SP 1-1, Appendix A	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>2.4.1 Qualification of Inspection and Test Personnel</p> <p>This section provides amplified requirements for the qualification of personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptability. The requirements of this section do not apply to the qualification of personnel for performance of nondestructive examination. Qualification of personnel for nondestructive examination is addressed in section 2.4.2.2.</p>	v			NP 4-1, Section 2.5 and 2.5.1	This applies to Receipt Inspection Personnel only.
<p>A. The responsible organization shall designate those activities that require qualified inspection and test personnel and the minimum requirements for such personnel. Further, the responsible organization shall establish written procedures for the qualification of inspection and test personnel and for the assurance that only those personnel who meet the requirements of this section are permitted to perform applicable inspection and test activities.</p> <p>B. When a single inspection or test requires implementation by a team or a group, personnel not meeting the requirements of this section may be used in data-taking assignments or in plant or equipment operation, provided they are supervised or overseen by a qualified individual.</p> <p>C. Personnel selected for performing inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities.</p> <p>D. Provisions shall be made for the indoctrination of personnel to the technical objectives and requirements of the applicable codes and standards and the QA program controls that are to be employed.</p> <p>E. The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel that perform such inspections and tests. On-the-job training shall also be included in the program, as appropriate, with emphasis on first-hand experience gained through actual performance of inspections and tests.</p> <p>F. The capabilities of a candidate for certification shall be initially determined by a suitable evaluation of the candidate's previous education, experience, training, and either test results or capability demonstration.</p>	v			(A-G) NP 4-1, Section 2.5 and 2.6	
<p>G. The job performance of inspection and test personnel shall be reevaluated for capability at periodic intervals, not to exceed three years. Reevaluation shall be by</p>	v			NP 4-1, Section 2.5.1	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>evidence of continued satisfactory performance or redetermination of capability in accordance with the above requirements. If, during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in their qualified area for a period of one year shall be reevaluated for the required capability in accordance with the above requirements.</p> <p>H. The qualification of personnel shall be certified in writing in an appropriate form and shall include the following information:</p> <ol style="list-style-type: none"> 1. Employer's name 2. Identification of person being certified 3. Activities certified to perform 4. Basis used for certification, including such factors as: (1) education, experience, indoctrination, and training; (2) test results, where applicable; and (3) results of capability demonstration 5. Results of periodic evaluation 6. Results of physical examinations, when required 7. Signature of the employer's designated representative responsible for such certification 8. The date of certification and date of certification expiration <p>I. The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination.</p> <p>J. Records of personnel qualification shall be established and maintained by the employer. These records shall include the information required above for certification.</p>	v			NP 4-1, Section 2.5.1	
<p>6. Results of physical examinations, when required</p> <p>7. Signature of the employer's designated representative responsible for such certification</p> <p>8. The date of certification and date of certification expiration</p>	v			NP 4-1, Section 2.5.1	
<p>2.4.2 Qualification of Nondestructive Examination Personnel</p> <p>This section identifies the requirements for the qualification of personnel who perform nondestructive examination (NDE) (radiographic, magnetic particle, ultrasonic, liquid penetrant, eddy current, neutron radiographic, leak testing, and visual testing) to verify conformance to specified requirements, for nondestructive examination activities</p>			v	See Comment	This requirement does not apply to SNL.

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>performed at the WIPP site.</p> <p>A. The American Society of Nondestructive Testing (ASNT) Recommended Practice No. SNT-TC-1A, June 1980 Edition, and its applicable supplements, shall apply as requirements for personnel performing the above methods of NDE.</p> <p>B. The responsible organization shall establish written procedures for the control and administration of the training, examination, and certification of NDE personnel.</p> <p>C. Records of personnel qualification shall be established and maintained by the employer.</p>					
<p>2.4.3 Inspection</p> <p>2.4.3.1. Inspection Planning</p> <p>A. Inspection planning shall be performed and documented and shall include the</p> <ol style="list-style-type: none"> 1. Identification of work operations where inspections are necessary 2. Identification of the characteristics to be inspected and the identification of when during the work process inspections are to be performed 3. Identification of inspection or process monitoring methods to be employed 4. Identification of acceptance criteria 5. Identification of sampling requirements 6. Methods to record inspection results 7. Selection and identification of the measuring and test equipment (M&TE) to be used to perform the inspection 8. Process used to ensure that the equipment being utilized for inspection or testing is calibrated and is of the proper type, range, accuracy, and tolerance to accomplish the intended function <p>B. When statistical sampling is to be used to verify the acceptability of a group of items, the sampling method shall be based on recognized standard practices.</p>	v			(A-B) NP 4-1, Section 2.5 and SP 1-1, Appendix A	This applies to receiving inspections only at SNL.
<p>2.4.3.2. Inspection Hold Points</p> <p>Hold points are used to control work that is not to proceed without the specific consent of the organization placing the hold point. The specific hold points shall be indicated in</p>	v			NP 4-1, Section 2.1.4	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
appropriate documents. Only the organization responsible for the hold point may waive the hold point. Approval to waive specified hold points shall be documented before continuing work beyond the designated hold point.					
2.4.3.3. In-Process Inspections and Monitoring					
A. Items in process shall be inspected as necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be conducted when control is deemed inadequate, using only one of these methods.	V			NP 4-1, Section 2.1.4	
B. When a combination of inspection and process monitoring methods is used, monitoring shall be performed systematically to ensure that the specified requirements for control of the process and the quality of the item are met throughout the duration of the process.	V			NP 4-1, Section 2.1.4 and NP 18-1, Section 2.3	
C. Controls shall be established and documented for the coordination and sequencing of the work at established inspection points during successive stages of the process.	V			NP 4-1, Section 2.1.4 and NP 18-1, Section 2.3	
2.4.3.4. Final Inspections					
A. Final inspections shall include a review of the results and the verification of the resolution of all nonconformance's identified by earlier inspections.	V			(A-D)NP 4-1, Section 2.1.4 and NP 18-1, Section 2.3	This would be accomplished by SNL through Monitoring in a Surveillances.
B. Finished items shall be inspected for completeness, markings, calibration, protection from damage, or other characteristics, as required to verify the quality and conformance of the item to the applicable requirements.					
C. Records review shall be performed to ensure adequacy and completeness.					
D. Item modifications, repairs, or replacements that are performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.					
2.4.3.5. Inservice Inspections			V		This requirement does not apply to SNL.
A. Required inservice inspection or surveillance of structures, systems, or components shall be planned and executed by or for the organization responsible for their operation.					
B. Inspection methods shall be established and executed to verify that the characteristics of an item continue to remain within specified limits.					
C. Inspection methods shall include evaluations of					

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.					
<p>2.4.3.6. Inspection Documentation</p> <p>Inspection documentation shall identify:</p> <p>A. The item inspected and the date of the inspection</p> <p>B. The name or unique identifier of the inspector who documented, evaluated, and determined acceptability</p> <p>C. The method of inspection</p> <p>D. The inspection criteria, sampling plan, or reference documents (including revision designation) used to determine acceptance</p> <p>E. The results</p> <p>F. The M&TE used during the inspection, including the identification number and the calibration due date</p> <p>G. Reference to any information on actions taken in connection with nonconformance's, as applicable</p>	v			NP 4-1, Section 2.5 and SP 1-1, Appendix A	
<p>2.4.4 Test Requirements</p> <p>Testing shall be used to determine the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions. Examples of such tests include prototype qualification tests, production tests, proof tests prior to installation, construction tests, and pre-operational tests.</p>			v	See Comment	This requirement does not apply to SNL. Qualification and production testing is covered under SQA in NP 19-1 for software controls.
<p>2.4.4.1. Test Planning</p> <p>Test planning shall include:</p> <p>A. The identification of the implementing procedures to be developed to control and perform the test. In lieu of specially prepared written test procedures appropriate sections of related documents such as American Society for Testing and Materials (ASTM) methods may be used. If used, they shall incorporate the information directly into the approved test implementing procedure, or shall be incorporated by reference.</p> <p>B. The identification of the item to be tested and the test requirements and acceptance limit, including the required levels of precision and accuracy.</p> <p>C. The identification of the M&TE to be used to perform the test to ensure that the equipment being utilized is calibrated and is of the proper type, range, accuracy, and tolerance to accomplish the intended function</p>			v	See Comment	This requirement does not apply to SNL. Qualification and production testing is covered under SQA in NP 19-1 for software controls.

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>D. Any test prerequisites, including test equipment, instrumentation and software needs, personnel training and qualification, and suitably controlled environmental conditions.</p> <p>E. Any mandatory hold points</p> <p>F. The methods to be used to record data and results</p> <p>G. The provisions for ensuring that prerequisites for the given test have been met</p>					
<p>2.4.4.2. Test Documentation</p> <p>Test documentation shall identify:</p> <p>A. The applicable test requirements, plans, and procedures, including revisions</p> <p>B. The item or work product tested</p> <p>C. The date of the test</p> <p>D. The name of the tester and data recorders</p> <p>E. The type of observation and method of testing</p> <p>F. The identification of test criteria or reference documents used to determine acceptance</p> <p>G. The results and acceptability of the test</p> <p>H. The actions taken in connection with any noted nonconformance's</p> <p>I. The name of the person evaluating the test results</p> <p>J. The identification of the M&TE used during the test (including the identification number and calibration due date)</p>			<p>▼</p> <p>▼</p>		<p>This requirement does not apply to SNL. Qualification and production testing is covered under SQA in NP 19-1 for software controls.</p> <p>This requirement does not apply to SNL. Qualification and production testing is covered under SQA in NP 19-1 for software controls.</p>
<p>2.4.4.3. Test Results</p> <p>Test results shall be documented and their conformance with acceptance criteria shall be evaluated by a qualified individual within the responsible organization to ensure that all test requirements have been satisfied.</p>			<p>▼</p>		<p>This requirement does not apply to SNL. Qualification and production testing is covered under SQA in NP 19-1 for software controls.</p>
<p>2.4.5 Monitoring, Measuring, Testing, and Data Collection Equipment</p> <p>The following sections establish requirements to ensure that equipment used for inspection and testing is properly controlled, calibrated, and maintained. Equipment discussed in the following sections includes inspection and</p>	<p>▼</p>			<p>NP 12-1, Section 1.0</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>(When it is impractical to apply a label directly to an item, the label may be affixed to the instrument container or some other suitable means may be used to reflect calibration status.)</p> <p>F. Evaluate the validity of previous inspection and test results and the acceptability of related items, data collected, and processes monitored, when M&TE is found to be out-of-calibration</p> <p>G. Handle, store, and transport M&TE in a manner that does not adversely affect the accuracy of the equipment</p> <p>H. Give due consideration to temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference, and any other factors affecting the results of measurements. Where pertinent, these factors shall be monitored and recorded and, when appropriate, correcting compensations shall be applied to measurement results.</p>				Section 2.4.2	
<p>2.4.7 Calibration</p> <p>A. M&TE requiring calibration shall be calibrated at periodic intervals established and maintained to ensure acceptable reliability, where reliability is described as the probability that M&TE will remain in tolerance throughout the interval.</p> <p>B. Intervals shall be established for all M&TE requiring calibration unless the equipment is regularly monitored through the use of check standards in a documented measurement assurance process. Check standards must closely represent the item parameters normally tested in the process, and the check standard must be verified periodically.</p> <p>C. Where intervals are used to ensure reliability, the interval setting system must be systematically applied and shall have stated reliability goals and a method of verifying that the goals are being attained.</p> <p>D. Intervals may be based on usage or time since last calibration.</p> <p>E. All exemptions from periodic calibration shall be approved and documented.</p> <p>F. The recall system may provide for the temporary extension of the calibration due date for limited periods of time under specified conditions that do not unreasonably impair the satisfaction of task objectives.</p> <p>G. Calibration services shall conform to the requirements of ANSI/NCSS Z540-1, <i>Calibration Laboratories and Measuring and Testing Equipment - General</i></p>	<p>v</p> <p>v</p>			<p>NP 12-1, Section 2.3</p> <p>(B-H) NP 12-1, Section 2.1 through Section 2.4.2</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p><i>Requirements.</i></p> <p>H. If any M&TE is found to be significantly out-of-tolerance during the calibration process, the cognizant organization shall provide for the notification to the user and cognizant QA management of the out-of-tolerance condition, with the associated measurement data, so that appropriate action can be taken.</p>				NP 12-1, Section 2.1	
<p>3.1 MANAGEMENT ASSESSMENT</p> <p>Managers at every level shall periodically assess the performance of their organization to determine the effectiveness of QA program provisions that enable the organization to meet customer requirements and expectations. This assessment shall emphasize the use of human and material resources to achieve organizational goals and objectives.</p> <p>A. The management assessment should include an introspective evaluation to determine if the entire integrated management system effectively focuses on meeting strategic goals.</p> <p>B. Managers shall retain overall responsibility for management assessments. Direct participation by senior management is essential to the success of the process because management is in the position to view the organization as a total system.</p> <p>C. Management assessments should focus on the identification and resolution of both systemic and management issues and problems. Strengths and weaknesses affecting the achievement of organizational objectives should be identified so that meaningful action can be taken to improve quality.</p> <p>D. Processes being assessed should also include strategic planning, organizational interfaces, cost control, use of performance indicators, staff training and qualifications, and supervisory oversight and support. Effective management assessments should evaluate such conditions as the state of employee knowledge, motivation, and morale; the amount of mutual trust and communication among workers and organizations; the existence of an atmosphere of creativity and improvement; and the adequacy of human and material resources.</p> <p>E. Management assessments of the QA program shall be conducted regularly and reported at least annually to an identified senior management level with sufficient authority to effect corrective measures, as necessary.</p> <p>F. Management assessment results should be used as input to the organizational continuous improvement</p>	v			NP 1-1, Section 2.2.3 (A-F) NP 1-1, Section 2.2.3.1	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
process.					
<p>3.2 INDEPENDENT ASSESSMENT</p> <p>A. Planned and periodic independent assessments shall be conducted to measure item and service quality, process effectiveness, and promote improvement. The organization performing assessments shall have sufficient authority and freedom from the activities being assessed to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable of the items and activities being assessed.</p> <p>B. The types and frequencies of independent assessments shall be based upon the relevant control levels assigned to the items and activities under the cognizance of the organization.</p> <p>C. The CBFO and participant organizations responsible for the performance of activities important to compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP site shall implement a program of surveillance and audits. The program shall be planned and documented and shall include both routine surveillance of those activities and audits to verify compliance with all aspects of the quality assurance program and to determine its adequacy and effectiveness.</p>	√			<p>NP 18-1, Section 2.1.2</p> <p>NP 18-1, Section 2.1.2</p> <p>NP 18-1, Section 1.0</p> <p>NP 18-1, Section 1.0</p>	
<p>3.2.1 Surveillances</p> <p>A. A program of surveillance of the activities referenced above shall be planned, performed, documented, and reported to appropriate management personnel. The surveillance process consists of monitoring or observing to verify whether an item, activity, system, or process conforms to specified requirements.</p> <p>B. Surveillances shall accomplish the following:</p> <ol style="list-style-type: none"> 1. Monitor work in progress 2. Document compliance or noncompliance with established requirements and procedures 3. Identify actual and potential conditions adverse to quality 4. Obtain timely corrective action commitment from cognizant managers for identified conditions adverse to quality 5. Provide notification to responsible managers of the status and performance of work under surveillance 	√			<p>NP 18-1, Section 2.3</p> <p>NP 18-1, Section 2.3</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>6. Verify timely implementation of corrective actions</p> <p>D. Audits or other independent assessments of the subject activities, conducted by the responsible organization, may be counted as satisfying the requirement to do surveillances of related activities in the corresponding surveillance schedule period.</p>	√			NP 18-1, Section 2.3	
<p>3.2.2 Audits</p> <p>The following describe the audit process requirements.</p> <p>3.2.2.1 Scheduling Audits</p> <p>A. Audits shall be scheduled to begin as early in the life of a project or activity as practicable and continue at intervals consistent with the schedule for accomplishing the work and commensurate with assigned control level.</p> <p>B. Periodically scheduled QA program audits shall be supplemented by, or integrated with, either audits or surveillances of a technical nature (e.g., performance-based audits) which assess the quality of selected work products and work processes.</p>	√			NP 18-1, Section 2.2.1	
<p>3.2.2.2 Planning and Preparation for Audits</p> <p>The organization performing the audit shall develop and document a plan for each audit.</p> <p>A. The plan shall include the scope, requirements, purpose, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists to be used.</p> <p>B. Audit planning shall include a review of past assessment results to determine the nature of problems that have occurred. When recurring problems are found, the audit team shall review corrective actions that have been taken and attempt to determine whether the corrective actions were effective in preventing recurrence.</p> <p>C. Audit preparation shall include review of pertinent background information, procedures, and technical documents so that audit team members are familiar with the work being audited.</p> <p>D. Audits shall include technical evaluations of the applicable procedures, instructions, activities, and items, as appropriate.</p> <p>E. The scope shall include related corrective actions taken since the previous assessment.</p>	√			<p>NP 18-1, Section 2.2.2</p> <p>NP 18-1, Section 2.2.2</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>3.2.2.3 Audit Team Selection</p> <p>A. Audit team members shall be identified prior to the start of the audit activity. The team members shall be selected on the basis of technical qualifications and knowledge of the item or process being audited and shall be independent from the items or processes being audited. Audit team members shall have sufficient authority and organizational freedom to carry out their assigned responsibilities. In the case of internal audits, personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team.</p> <p>B. An audit team leader shall be appointed to provide indoctrination and supervision of the team, organize and direct the audit, and coordinate the preparation and issuance of the audit report.</p> <p>C. Before starting the audit, the audit team leader shall ensure that the assigned personnel collectively have experience and training commensurate with the scope, complexity, or special nature of the work to be audited.</p> <p>D. Technical specialists, with appropriate technical expertise or experience in the work being audited, shall be used when auditing the adequacy of technical processes.</p>	√			<p>NP 18-1, Section 2.1.2 and 2.2.2</p> <p>NP18-1, Section 2.1.2, 2.1.3.2, 2.1.3.3 and 2.2.2</p> <p>NP 18-1, Section 2.1.3.2 and 2.2.2</p> <p>NP 18-1, Section 2.1.3.2</p>	
<p>3.2.2.4 Auditor Qualification</p> <p>Auditors shall be technically qualified in their assigned roles. In addition, they shall have appropriate training or orientation to develop their competence for performing audits. Competence of personnel performing various audit functions shall be developed by one or more of the following methods:</p> <p>A. Orientation to provide a working knowledge and understanding of the QA program requirements and the auditing organization's implementing procedures used to perform audits and report audit results</p> <p>B. Training programs that provide general and specialized training in audit performance, including fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of evaluating the effectiveness of corrective actions for conditions adverse to quality.</p> <p>C. On-the-job training, guidance, and counseling under the direct supervision of a lead auditor. Such training shall include audit planning, performing, reporting, and follow-up actions.</p>	√			<p>NP 18-1, Section 2.1.3.1</p>	

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	Y	N	N/A		
<p>3.2.2.5 Technical Specialist Qualification</p> <p>Technical specialists selected for audit assignments shall receive indoctrination commensurate with the scope, complexity, or special nature of the work being audited. In addition, they shall be trained to the requirements of the audit process associated with their duties.</p>	√			NP 18-1, Section 2.1.3.2	
<p>3.2.2.6 Lead Auditor Qualification</p> <p>A lead auditor shall be capable of organizing and directing audits, reporting audit results, and evaluating planned and implemented corrective action. A lead auditor also shall be certified as meeting the requirements provided in this section for education and experience, communication skills, training, audit participation, and the successful completion of a lead auditor examination.</p> <p>A. Lead Auditor Education and Experience: The prospective lead auditor shall have verifiable evidence that a minimum of 10 credits have been accumulated under the following scoring system:</p> <p>1. Education (four credits maximum)</p> <p>a. An associate's degree from an accredited institution scores one credit. If the degree is in engineering, physical sciences, mathematics, or QA, it scores two credits.</p> <p>b. A bachelor's degree from an accredited institution scores two credits. If the degree is in engineering, physical sciences, mathematics, or QA, it scores three credits. In addition, score one more credit for a master's degree (or higher) in engineering, physical sciences, business management, or QA from an accredited institution.</p> <p>2. Experience (nine credits maximum)</p> <p>a. The prospective lead auditor shall have participated in a minimum of 5 QA audits or equivalent verifications (such as management assessments, pre-award surveys, or comprehensive surveillance, as long as the parameters of the audit process are met) within three years prior to the date of certification, one of which shall be a nuclear QA audit within the year prior to qualification. In addition, for technical experience in such areas as scientific investigation, site characterization, nuclear waste management, production, transportation, engineering, manufacturing, construction, operation, or maintenance, or experience</p>	√			<p>NP 18-1, Section 2.1.3.3</p> <p>NP 18-1, Section 2.1.3.3 and Appendix B</p> <p>NP 18-1, Section 2.1.3.3 and Appendix B</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>applicable to the auditing organization's area of responsibility, score one credit for each full year, with a maximum of five credits.</p> <p>b. If two years of this experience have been in a nuclear field, score one additional credit; or</p> <p>c. If two years of this experience have been in QA, score two additional credits; or</p> <p>d. If two years of this experience have been in auditing or assessment, score three additional credits; or</p> <p>e. If two years of this experience have been in nuclear-related QA, score three additional credits; or</p> <p>f. If two years of this experience have been in nuclear-related QA auditing or assessment, score four additional credits.</p> <p>3. Professional Competence (two credits maximum)</p> <p>For certification of competency in engineering, science, or QA specialties, issued and approved by a state agency or national professional or technical society, score two credits.</p> <p>4. Rights of Management (two credits maximum)</p> <p>When determined appropriate, the organization performing the qualification may grant up to two credits for other performance factors applicable to auditing that are not explicitly called out in this section (such as leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and completed QA training courses).</p> <p>B. Lead Auditor Communication Skills</p> <p>The prospective lead auditor shall have the capability to communicate effectively both in writing and orally. These skills shall be attested to in writing by the candidate's supervisor.</p> <p>C. Lead Auditor Training</p> <p>Prospective lead auditors shall be trained to the extent necessary to ensure their competence in skills as established by the organization responsible for performing audits. Training in the following areas shall be accomplished and its completion verified based upon a management evaluation of the particular needs of each prospective lead auditor:</p>	√			NP 18-1, Section 2.1.3.4 and Appendix B	
	√			NP 18-1, Section 2.1.3.3 and Appendix B	
	√			NP 18-1, Section 2.1.3.3 and Appendix B	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
1. Knowledge and understanding of the participant organization's QA program and other program-related procedures, codes, standards, regulations, DOE orders, and regulatory guides, as applicable 2. General structure of QA plans and implementation procedures as a whole 3. Auditing techniques of examining, questioning, evaluating, reporting, and methods of identifying, following up, and closing corrective actions 4. Audit planning in functional areas of nuclear QA	√			NP 18-1, Section 2.1.3.3	
D. Lead Auditor Examination 1. The prospective lead auditor shall pass an examination that evaluates his or her comprehension of, and ability to apply, the audit knowledge described in this section. The examination may be oral, written, practical, or any combination thereof. 2. The development and administration of the examination for a lead auditor is the responsibility of the organization responsible for the auditing program. This organization shall: <ul style="list-style-type: none"> a. Maintain the integrity of the examination through confidentiality of files and, where applicable, proctor examinations b. Develop and maintain objective evidence regarding the type and content of the examination 	√			NP 18-1, Section 2.1.3.3 and Appendix B	
E. Lead Auditor Certification Lead auditors shall be certified by the organization responsible for the auditing program as being qualified to lead audits. This certification will document the <ul style="list-style-type: none"> 1. Name of the organization performing the certification 2. Name of the lead auditor 3. Date of certification or recertification 4. Basis of certification (such as education, experience, communication skills, and training) 5. Signature of the designated representative of the organization responsible for the certification 	√			NP 18-1, Section 2.1.3.4	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>F. Lead Auditor Proficiency Maintenance</p> <p>1. Lead auditors shall maintain their proficiency through one or a combination of the following:</p> <p>a. Regular and active participation in the audit process</p> <p>b. Review and study of codes, standards, QA implementation procedures, instructions, and other documents related to QA program auditing</p> <p>c. Participation in training programs</p> <p>d. Management of the auditing organization shall evaluate the proficiency of lead auditors annually. Based on the evaluation, management shall choose to extend the qualification, require retraining, or require requalification. Management evaluations shall be documented.</p> <p>2. Lead auditors who fail to maintain their proficiency for a two-year period shall require requalification to the requirements of this section of the QAPD. However, participation in only one nuclear audit is required.</p> <p>3.2.2.7 Performing Audits</p> <p>A. Audits shall be performed using the written procedures related to the activity being audited or checklists.</p> <p>B. Elements that have been selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if those elements are being implemented effectively.</p> <p>C. Audit results shall be documented by audit personnel and reported to and reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.</p> <p>D. Conditions adverse to quality shall be documented and corrected according to the requirements of section 1.3.2.</p>	√			<p>NP 18-1, Section 2.1.3.5 and Appendix C</p> <p>NP 18-1, Section 2.1.3.5 and Appendix C</p> <p>NP 18-1, Section 2.2.2</p>	
<p>3.2.2.8 Reporting Audit Results</p> <p>A. The audit report shall be prepared and signed by the audit team leader and issued to the management of the</p>	√			<p>NP 18-1, Section 2.2.2</p> <p>NP 18-1, Section 2.2.2</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>audited organization and any affected organizations. The audit report shall include the following, as appropriate:</p> <ol style="list-style-type: none"> 1. A description of the audit scope 2. The identification of the auditors 3. The identification of persons contacted during the audit 4. A summary of the documents reviewed, persons interviewed, and the specific results of the reviews and interviews (i.e., a summary of the checklist contents) 5. A summary of audit results, including a statement of the QA program adequacy, implementation, and effectiveness, as appropriate to the scope 6. A description of each reported condition adverse to quality in sufficient detail to enable corrective action to be taken by the audited organization 7. A description of commendable quality practices <p>B. Additionally, common audit findings shall be grouped in the report whenever possible so that related or systematic breakdowns in the QA program are identified. Findings or deficiencies shall be categorized based on their relative importance to indicate their degree of impact on compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, or management and operation of the WIPP facility.</p>					
<p>3.2.2.9 Audit Response and Follow Up</p> <p>Management of the audited organization will investigate conditions adverse to quality; determine and schedule corrective actions, including measures to preclude recurrence; and notify the auditing organization in writing of the actions planned or taken. The adequacy of audit responses shall be evaluated by or for the auditing organization. Follow-up action shall be taken to verify that corrective action is accomplished as scheduled.</p>	√			NP 18-1, Section 2.2.2	
<p>3.2.2.10 Audit Records</p> <p>The following documents, when developed in fulfillment of the audit requirements of this QAPD, shall be controlled as QA records in accordance with section 1.5 of this QAPD: audit plans, audit reports, audit checklists, audit responses, and documentation of corrective action completion and follow-up.</p>	√			NP 18-1, Section 3.0	
<p>4.1 SAMPLE CONTROL</p>					

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>A. Samples shall be controlled and identified in a manner consistent with their intended use.</p> <p>B. Implementing procedures shall define responsibilities, including organizational interfaces, related to documenting and tracking sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final disposition.</p> <p>C. Sample control measures shall include provisions for the identification of the in situ orientation of samples, where appropriate.</p> <p>D. A chain of custody record form shall be maintained. The chain of custody record shall provide a document trail of all persons who have custody of a given sample, including the date and time of its transfer.</p> <p>E. Sample control measures, including identification and documentation, shall ensure that samples can be traced at all times, from collection through final disposition.</p> <p>F. Where samples have a maximum life expectancy or expiration date, methods shall be employed that preclude the use of the sample beyond its specified life.</p> <p>G. Representative archival samples from difficult-to-repeat sample collection activities, such as principal bore holes, shall be maintained.</p> <p>H. Implementing procedures shall specify the representative samples to be archived if the need to archive samples is identified.</p>	<p>v</p> <p>v</p> <p>v</p>			<p>(A-C) NP 13-1, Section 1.0</p> <p>NP 13-1, Section 1.0, 2.2, and 2.3</p> <p>(E-H) NP 13-1, Section 2.2</p>	
<p>4.2 SAMPLE IDENTIFICATION</p> <p>A. Each sample shall be uniquely identified from its initial collection through the final disposition of the sample.</p> <p>B. Sample identification shall be verified and documented before each transfer or release for testing, analysis, or disposition.</p> <p>C. Identification shall be maintained by placing the identification directly on the samples wherever possible or in a manner that ensures identification is maintained. If direct physical markings are either impractical or insufficient, other appropriate means shall be employed (e.g., physical separation, labels or tags attached to containers, or procedural control). When used, physical markings shall</p> <p>1. Be applied using materials and methods that provide clear and legible identification</p>	<p>v</p>			<p>(A-C) NP 13-1, Section 2.2</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>2. Not effect the sample content or form</p> <p>3. Be transferable to each identified sample part when the sample is subdivided</p> <p>4. Not be obliterated or hidden by surface treatments or sample preparation unless other means of identification are substituted</p> <p>D. If sample storage is required, then methods shall be established for the control of sample identification that are commensurate with the planned duration and storage conditions. These methods shall provide for, as applicable:</p> <p>1. The maintenance or replacement of markings and identification tags that have been damaged because of age or during handling</p> <p>2. The protection of identification markings from excessive deterioration due to environmental exposure</p>	v			NP 13-1, Section 2.4	
<p>4.3 HANDLING, STORING, AND SHIPPING SAMPLES</p> <p>A. Handling, storing, cleaning, packaging, shipping, and preserving samples shall be conducted in accordance with established work and inspection implementing procedures. Controls shall provide for the maintenance of sample characteristics, sample integrity, and sample identification during storage.</p> <p>B. The controls shall be consistent with the planned duration and storage conditions and shall describe actions to be taken where maximum sample life expectancy limits are identified.</p> <p>C. Storage methodology shall be developed and implemented to ensure that samples are maintained in predetermined environmental conditions commensurate with their intended use and purpose.</p> <p>D. Samples shall be controlled to preclude the mixing of like samples.</p> <p>E. Samples on which analysis or tests have been performed shall be identified and maintained in a separate part of the storage area.</p> <p>F. If required for critical, sensitive, perishable, or high-value samples, specific measures for the handling, storage, cleaning, packaging, shipping, and sample preservation shall be identified and used.</p>	v	v	v	<p>NP 13-1, Section 2.4</p> <p>NP 13-1, Section 2.4</p> <p>(C-D) NP 13-1, Section 2.5</p> <p>NP 13-1, Section 2.4</p> <p>NP 13-1, Section 2.2</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
G. Measures shall be established for sample marking and labeling for packaging, shipping, handling, and storage as necessary to adequately identify, maintain, and preserve the sample. Markings and labels shall indicate the need for and the presence of special environments or the need for other special controls, if necessary.	V			NP 13-1, Section 2.2 and 2.4	
H. Samples requiring special protective equipment (such as containers) and special protective environments (such as inert gas or limits on moisture and temperature) shall be specified, employed, verified, and documented.	V			NP 13-1, Section 2.4	
4.4 DISPOSITION OF NONCONFORMING SAMPLES	V			NP 13-1, Section 2.3	
A. Samples that do not conform to requirements specified in work controlling documents (such as job packages, travelers, or work requests) shall be identified, documented, evaluated, and segregated in accordance with section 1.3.					
B. The disposition for nonconforming samples shall be identified and documented and shall be limited to "use-as-is," "limited use," or "discard."					
C. Samples that have lost their identity shall be documented as nonconforming and shall not be used.					
5.1 PLANNING SCIENTIFIC INVESTIGATIONS					
A. Variables that affect interrelated scientific investigations shall be identified and controlled appropriately in each related investigation.	V			(A-D) NP 20-1, Section 2.1 and Appendix A	
B. The intended use of the data shall be documented before collection as part of the planning for data processing. Any alternate use of the data shall be evaluated for appropriateness and the justification for use shall be documented.					
C. Planning shall consider the compatibility of data processing with any conceptual or mathematical models used at each applicable stage.					
D. The technical adequacy of procedures for conducting scientific investigations and their implementation shall be reviewed and approved by qualified persons other than those who prepared the procedures. Changes to procedures for conducting scientific investigations shall be reviewed and approved in a manner commensurate with the original procedure.					
E. Development activities used to establish new methods or procedures for conducting scientific investigations shall be documented. The results of developmental testing shall be reviewed for adequacy and approved by	V			NP 20-1,	"New methodologies conducted in laboratory or field activities" is the SNL terminology for developmental testing

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>be controlled and measured to ensure that tests are valid</p> <p>D. Scientific results shall be periodically reviewed by an independent qualified individual to verify that there is sufficient detail to retrace the investigation and confirm the results, if feasible, or repeat the investigation and achieve comparable results without recourse to the original investigator.</p> <p>E. Practices, techniques, equipment, and manual or computerized methods used to obtain and analyze data shall be verified to ensure that they are technically sound and have been properly selected. Controls shall be established for these processes to ensure that they are properly implemented, including controls to prevent tampering.</p> <p>F. Data collection and analysis shall be controlled by procedures of sufficient detail to allow the processes to be repeated. Where appropriate, quality control checks shall be performed using recognized methods such as replicate, spike, and split samples; control charts; blanks; reagent checks; replication of the methods used to obtain the results; or alternate analysis methods.</p> <p>G. Test media (e.g., fluids), when used, shall be characterized and controlled in accordance with test procedures.</p> <p>H. Scientific notebooks and technical implementation documents shall be maintained as QA records.</p>	<p>v</p> <p>v</p> <p>v</p> <p>v</p> <p>v</p>			<p>NP 20-2, Section 2.3</p> <p>NP 20-1, Appendix A</p> <p>NP 20-1, Appendix A</p> <p>NP 20-1, Appendix A</p> <p>NP 20-1, Appendix A, NP 20-2, Section 2.2</p>	<p>“practices”=primary tasks & conduct. “techniques”=sample/ data quality control “equipment”=M&TE “obtain & analyze data”=DAS, data identification and use.</p>
<p>5.3 DATA DOCUMENTATION, CONTROL, AND VALIDATION</p> <p>5.3.1 Data Identification and Usage</p> <p>A. All data shall be recorded so that they are clearly identifiable and traceable to the test, experiment, study, or other source from which they were generated. Identification and traceability of the data shall be maintained for the lifetime of the WIPP.</p> <p>B. The method of data recording (e.g., scientific notebooks, log books, data sheets, or computerized instrumentation systems) shall be controlled to avoid data loss and permit data retrievability. Controls shall be established to ensure that data integrity and security are maintained wherever data are stored. Controls shall prescribe how specific types of data will be stored with respect to media, conditions, location, retention time, security, and access. Data shall be suitably protected from damage and destruction during their prescribed lifetime and shall be readily retrievable.</p>	<p>v</p> <p>v</p>			<p>NP 9-2 Appendix A for data entry NP 20-1 Appendix A and Section 2.6</p> <p>NP 9-2 Appendix A for data entry NP 20-1 Appendix A NP 17-1, SP 17-1, SP 9-5 for data maintenance</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>prescribed lifetime and shall be readily retrievable.</p> <p>C. Data transfer and reduction controls shall be established to ensure that data transfer is error free (or within a prescribed permissible error rate), that no information is lost in transfer, and that the input is completely recoverable. Data transfer and reduction will be controlled to permit independent reproducibility by another qualified individual. Examples of data transfer include copying raw data from a notebook into computerized data form, or copying from computer tape to disk.</p> <p>D. Data that are determined to be erroneous, rejected, superseded, or otherwise unsuited for their intended use shall be controlled to prevent their inadvertent use. Controls shall include the identification, segregation, and disposition of inadequate data. The basis for the disposition of erroneous data shall be justified and documented.</p> <p>E. All processes which change either the form of expression or quantity of data, values, or number of data items (data reduction) shall be controlled by prescribed methods that allow for the validation of the conversion process.</p> <p>F. Data collection and analysis shall be critically reviewed and questions resolved before the results are either used or reported. Uncertainty limits shall be assigned to the data prior to their use.</p>	<p>V</p> <p>V</p> <p>V</p>			<p>NP 9-2 Appendix A for data entry NP 20-1 Appendix A SP 9-5 for data maintenance</p> <p>NP 9-2, Section 2.2, 2.3, 2.4 and Appendix B, and NP 20-1, Appendix A</p> <p>(E-F) NP 20-1, Section 2.6, Appendix A NP 9-1; Routine Calcs NP 9-2 Section 2.3 for changes Appendix A for data entry</p>	
<p>5.3.2 Data Validation</p> <p>Data validation is a systematic process used to review data to ensure that the required data quality characteristics have been obtained. Results of the review may require that qualifiers be placed on the use of the data.</p> <p>A. Validation methods shall be planned and documented. The documentation shall include the acceptance criteria used to determine if the data are valid.</p> <p>B. All applicable data collected shall be validated. Validation shall include the following:</p> <ol style="list-style-type: none"> The relevant documentation is reviewed to evaluate the technical adequacy, the suitability for the intended use, and the adequacy of the QA record. The results of the data review shall be documented. The reviewer shall be independent of the collection activities. <p>C. Data validation shall be controlled to permit</p>	<p>√</p>			<p>(A-D) The entire QA program contributes to data validation for Section 5.3.2 by way of technical reviews, NP 6-1, in both planning (NP 20-1 Test Plans, NP 9-1 Analysis Plans), implementation [NP 20-2 Scientific Notebooks, Activity/Project Specific Procedures (SPs)] and NP 9-2, Section 7.1.2 and Appendix A.</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>independent reproducibility by another qualified individual.</p> <p>D. Data considered as established fact by the scientific and engineering community, such as engineering handbook data or critical tables, do not require validation.</p>					
<p>5.4 QUALIFICATION OF EXISTING DATA</p> <p>A. This section contains requirements unique to the post-qualification of data and information that are relied upon to support the WIPP compliance application and were collected prior to the implementation of this QAPD. While the qualification process shall be conducted in accordance with the program control requirements of the CBFO QAPD, it is not intended that the QAPD identify the data that are subject to this process or the technical requirements of the qualification process. The qualification process shall be conducted in accordance with approved procedures that provide for documentation of the decision process, the factors used in arriving at the choice of the qualification method, and the decision that the data are qualified for their intended use.</p> <p>B. Existing data shall be qualified using one or a combination of the following methods:</p> <ol style="list-style-type: none"> 1. Determination that the data were collected under a QA program that is equivalent in effect to ASME NQA-1-1989 edition; ASME NQA-2a-1990 addenda, Part 2.7, to ASME NQA-2-1989 edition; and NQA-3-1989. Factors to be considered include: <ol style="list-style-type: none"> a. Qualifications of personnel or organizations generating the data. b. Technical adequacy of the equipment and procedures used to collect and analyze the data. c. Environmental conditions under which the data were obtained (if germane) d. Quality and reliability of the measurement control program under which the data were generated e. Extent to which data demonstrate properties of interest (e.g., physical, chemical, geologic, or mechanical) f. Extent to which conditions generating the data may partially meet requirements of this QAPD 			√	See comment	<p>This activity for Section 5.4 was completed when the CCA was submitted in 10/96. SNL has no intentions of using this process in the future. All data used is collected under an approved QA program.</p>
			√	See comment	<p>This activity for Section 5.4 was completed when the CCA was submitted in 10/96. SNL has no intentions of using this process in the future. All data used</p>

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>g. Prior uses of the data and the associated verification processes</p> <p>h. Prior peer or other professional reviews of data and their results</p> <p>i. Extent and reliability of the documentation associated with the data</p> <p>j. Extent and quality of corroborating data or confirmatory testing results</p> <p>k. Degree to which data generating processes were independently audited</p> <p>l. The importance of the data in showing that the repository design meets the performance objectives</p> <p>2. The use of corroborating data, with the data relationships and inferences clearly identified and justified</p> <p>3. Confirmatory testing that is performed and documented</p> <p>4. Peer review conducted in a manner that is compatible with NUREG-1297, <i>Peer Review for High-Level Nuclear Waste Repositories</i></p> <p>a. Peer reviews shall be performed when the adequacy of information or the suitability of procedures and methods essential to showing that a repository system meets its performance requirements with respect to safety and calculations, or reference to previously established standards and practices.</p> <p>b. Peer reviews performed in support of WIPP compliance activities shall be documented, as shall all peer review processes.</p> <p>5. Peer reviews are used for the following activities:</p> <p>a. Conceptual models selected and developed by DOE</p> <p>b. Waste characterization analysis as required in 40 CFR 194.24(b)</p> <p>c. Engineered barrier evaluation as required in 40 CFR 194.44</p>					is collected under an approved QA program.
5.5 QUALITY ASSURANCE COMPLIANCE APPLICATION DATA				See Comment	This section is taken from 40 CFR §

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>Any compliance application shall provide, to the extent practical, information that describes how all data used to support the compliance application has been assessed for quality characteristics, including:</p> <p>A. Data accuracy: the degree to which data agree with an accepted reference or true value</p> <p>B. Data precision: a measure of the mutual agreement between comparable data gathered or developed under similar conditions, expressed in terms of standards deviation</p> <p>C. Data representativeness: the degree to which data accuracy and precision represent a characteristic of a population, a parameter, variations at a sampling point, or environmental conditions</p> <p>D. Data completeness: a measure of the amount of valid data obtained compared to the amount that was expected</p> <p>E. Data comparability: a measure of the confidence with which one data set can be compared to another</p>					194.22(c). This section of 194 describes requirements to be applied to a compliance application. As such, these requirements will be addressed, to the extent practical, in the compliance application.
<p>6.1 APPLICABILITY</p> <p>A. The requirements in this section apply to computer software used in the manipulation or production of data that are, in turn, used in the processing, gathering, or generation of information whose output is relied upon to make design, analytical, operational, or compliance-related decisions with respect to the performance of the waste confinement, waste characterization, waste transportation, or waste acceptance processes. The application of these requirements shall be prescribed in written plan(s), policies, procedures, or instructions.</p> <p>B. The basic requirements defined in this section apply to those activities involved in the processing, control, or measurement of the hazardous, radioactive, and waste matrix materials of the TRU or mixed TRU waste. Waste matrix materials include but are not limited to metals, cellulose, chelating agents, water, and other liquids, plastics, and rubber.</p> <p>C. The NQA-2 Part 2.7 requirements defined in this section apply to software used in the processing, control, or measurement of the radioactive and waste matrix materials of the TRU waste. These requirements also apply to software used to model the performance of the WIPP for purposes of compliance application and/or reapplication.</p> <p>D. Exempt from the requirements of this section of the</p>	√			NP 19-1	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>QAPD is software that is considered to be "systems software," (e.g., operating systems, administrative and management systems, system utilities, compilers, assemblers, translators, interpreters, query languages, word processing programs, spreadsheets, database managers, and graphing programs) or other software that does not generate data that are used in the formulation of conclusions. Software utilized in conjunction with the documents prepared to comply with the NEPA is also excluded from the requirements of this section except to the extent that the results of the NEPA analysis are used as the basis for establishing how activities related to the items listed in Table I-1 are performed. These activities include those related to compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility. Specific applications supporting section 6.2A., written for use within these types of software (e.g., detailed formulas or macros) that can be verified by hand calculations or other means shall meet the following requirements of this section:</p> <ol style="list-style-type: none"> 1. A listing of the version of the software used shall be developed and maintained. 2. Documentation shall be prepared to indicate that the specific application provides the correct results for the specified range of input parameters. 				NP 19-1	
<p>6.2 Basic Requirements for Inventory and Classification of Software</p> <p>A. An inventory of all applicable software shall be maintained that identifies the software name, version, classification, exemption status, operating environment, and the person and organization responsible for the software.</p>	√			(A-B) NP 19-1, Sections 2.3.7.2, 2.3.7.4, and Appendix J	NP 19-1 Sections 2.3.7.2, 2.3.7.4, and Appendix J
<p>B. Software governed by this section of the QAPD shall be categorized. The criteria for classification shall be documented in the inventory and shall address the purpose of the software relative to its use in engineering, scientific, testing, data collection, design, analysis, and operations activities, as well as its importance to safety or its significance in managing information or augmenting mission-essential decisions.</p>					
<p>6.3 Software Quality Assurance</p> <p>6.3.1 Basic Requirements for Software Quality Assurance</p> <p>Controls governing applicable software development projects shall be identified in controlled and documented plans. The plans shall be formally reviewed and approved. Controls governing the configuration and use of the software shall be identified in plans or procedures appropriate to the organizations using the software. The</p>	√			NP 9-1, Appendix A,D NP 19-1, Section 2.1	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>following activities shall be addressed in plans or procedures:</p> <p>A. Software development</p> <p>B. Software verification and validation</p> <p>C. Software configuration control</p> <p>D. Software operation and maintenance</p> <p>Plans may be issued separately or as a single, composite plan, depending on the nature and complexity of the project. The software control plans may be a section of the overall project plan, provided that each software item is addressed and the software control portion of the plan prescribes the documentation, reviews, and controls required by this section.</p>	√			<p>Appendix B, C,D</p> <p>NP 19-1, Section 2.3.1</p>	
<p>6.3.2 NQA-2 Part 2.7 Requirements for Software Quality Assurance</p> <p>Plan(s) for ensuring software quality shall be prepared for each new software project at the start of the software life cycle. For acquired software, the software quality plan shall be prepared before the software enters the purchaser organization. Plan(s) may be prepared individually for each software project, may exist as a generic document to be applied to software prepared within or procured by an organization, or may be incorporated into the overall QA program. The plan shall identify:</p> <p>A. The software products governed by the plan</p> <p>B. The types of documentation to be prepared, reviewed, and maintained during the software design, development, implementation, test, and use</p> <p>C. The organizations responsible for performing the work and achieving software quality, and their tasks and responsibilities</p> <p>D. The process for reporting and documenting software discrepancies, evaluating the impact of discrepancies on previous calculations, and determining the appropriate corrective action(s)</p> <p>E. The standards, conventions, techniques, or methodologies that guide the software development, as well as the methods used to ensure implementation of requirements</p> <p>F. The procedure(s) used for establishing and maintaining the integrity of data, embodied mathematical models, and output files</p>	√			<p>NP 19-1, Section 2.2.1</p> <p>NP 19-1, Section 2.2 and 2.3.1</p> <p>NP 19-1, Section 2.3.1</p> <p>NP 19-1, Section 2.3.7.3</p> <p>NP 19-1, Section 2.3.1</p> <p>NP 19-1, Table 1 and Section 2.3.1</p>	<p>F. Integrity of data is governed by NP 9-1, Appendix B.</p>
<p>6.4 SOFTWARE PROCUREMENT</p>	√			<p>NP 19-1, Section 2.2.1</p>	<p>'Procured' software falls under the category</p>

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>6.4.1 Basic Requirements for Software Procurement</p> <p>This section of the QAPD identifies responsibilities of the sponsoring organization for acquired software upon receipt of the software.</p> <p>All procured software governed by this section shall be tested in accordance with documented and approved test procedures using approved test-case specifications to ensure that the acquired software will perform satisfactorily in its operating environment. The installation tests (including the test procedures), the test case specifications, and the results of the installation tests shall be identified, documented, and maintained as records according to established procedures.</p>					of Acquired software. Requirements for acquired software, including test case specifications, documentation, etc., are identified in Table 1 Life Cycle Software Requirements and Section 2.2.1.
<p>6.4.2 NQA-2 Part 2.7 Requirements for Software Procurement</p> <p>A. The procurement of software and related services shall be performed in accordance with section 2.3 of this QAPD.</p> <p>B. Once the software has been installed, but before its use, the sponsoring organization shall perform user acceptance to verify the functional capability of the software and the acceptability of the supplier supporting documentation (e.g., the user manual, technical specification, and the results of supplier testing).</p> <p>C. For procured software, the supplier shall report software errors and failures to the sponsoring organization. The sponsoring organization shall also report software errors to the supplier.</p>	√			NP 4-1 NP 19-1, Section 2.2.1 NP 4-1 and NP 19-1	<p>B. All CD software used on WIPP program falls under NP 19-1, Section 2.2 for both procured and s software developed in-house. Requirements in Section 2.2 for CD software include testing to verify functional capability and evaluation of supporting documentation.</p> <p>Contracts for procured software must comply with all QAPD requirements (as defined by their own program) and is required by NP 4-1, section 2.1.3. Software under the SNL QA program is addressed in NP 19-1, section 2.3.7.3.</p>
<p>6.5 SOFTWARE DEVELOPED UNDER OTHER QA PROGRAMS</p> <p>6.5.1 Basic Requirements</p> <p>Software that has not been developed or approved in accordance with this QAPD shall be evaluated to determine its adequacy to perform intended functions. The evaluation shall be documented. The software shall be initially:</p>	√			NP 19-1, Section 2.2.1 Appendix B	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>shall be documented. The software shall be uniquely identified and controlled prior to the evaluation, clearly traceable to the software requirements, accepted by the sponsoring organization, and placed under configuration control prior to use.</p> <p>6.5.2 NQA-2 Part 2.7 Requirements</p> <p>The evaluation of existing software developed in accordance with other QA programs shall serve as the basis to</p> <p>A. Determine the adequacy of existing verification and validation activities and software documentation to support operations and maintenance.</p> <p>B. Identify the activities to be performed and the documentation necessary to accept the software for its intended use and place it under configuration control. The evaluation shall be documented and shall contain, at a minimum:</p> <ol style="list-style-type: none"> 1. User application requirements 2. Test plans and test cases required to validate software acceptability 3. User documentation as described in Section 6.8.2.6 	√			<p>NP 19-1, page 8 Table Notes #4 Section 2.2.1 item A</p> <p>NP 19-1, Section 2.2.1</p>	<p>As software is modified, it is required that all baseline components be evaluated for impact, including the Design Document.</p>
<p>6.6 SOFTWARE DEVELOPMENT AND LIFE CYCLE</p> <p>6.6.1 Basic Requirements</p> <p>The developmental activities of software projects subject to this QAPD shall be identified in documented and approved plans to ensure that the project proceeds in an orderly and traceable manner. Sufficient information shall be provided to clearly indicate the necessary tasks, the deliverables, and baselines for each phase, the required reviews, appropriate milestones, and the responsibilities associated with each task.</p> <p>Software project development plans shall identify the items that need to be baselined and the methods to be used for controlling the configuration of those baselines throughout the development process. Configuration control planning for software are addressed in Section 6.7 of this QAPD.</p>	√			<p>NP 19-1, Section 2.3.1, Appendix B</p>	
<p>6.6.2 NQA-2 Part 2.7 Requirements</p> <p>A. The activities associated with the evolution of the software shall be accomplished using an iterative or sequential approach. The approach shall include the analysis of the problem under study, the transformation of the analysis into the design, the implementation of the design into validated computer software, and the development of sufficient documentation to</p>	√			<p>NP 19-1, Section 2.3 Table 1</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>demonstrate that the specified requirements have been successfully included in the computer software.</p> <p>B. The iterative or sequential approach to software development consists of phases, with each phase leading to the development of a specific work product representing components of the software baseline. The software phases are:</p> <ol style="list-style-type: none"> 1. Definition of requirements 2. Design 3. Implementation 4. Testing 5. Installation and checkout 6. Operations and maintenance 7. Retirement <p>C. Following the development of the software quality plan, no strict sequence of performing activities is required (i.e., activities may be performed serially or recursively) provided that all the specified requirements for each software development phase have been met and the intent of the requirements has not been subverted.</p>	√			<p>NP 19-1, Section 2.3 Table 1</p> <p>NP 19-1, Section 2.3</p>	
<p>6.6.2.1 Requirements Phase</p> <p>Software requirements shall be specified, documented, and reviewed. These requirements shall pertain to functionality, performance, design constraints, data attributes, and external interfaces (e.g., hardware limitations) as outlined in section 6.6.2. Each requirement shall be specified in sufficient detail to permit the accomplishment of design and validation activities. Software requirements shall be traceable throughout the software development cycle, and a verification and validation plan shall be prepared after the software requirements have been documented and approved.</p>	√			<p>NP 19-1, Section 2.3.2 Appendices C and D</p>	
<p>6.6.2.2 Design Phase</p> <p>The software design shall be based on the software requirements and shall be documented and reviewed. The design shall specify the overall structure (control and data flow) and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures). The design may necessitate the modification of the requirements documentation and the verification and validation plans.</p>	√			<p>NP 19-1, Section 2.3.3 Appendix E</p>	
<p>6.6.2.3 Implementation Phase</p> <p>The software design shall be translated into a form (programming language) suitable for processing by a</p>	√			<p>NP 19-1, Section 2.3.4 Appendix F, H, and I</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
computer. The executable software shall be analyzed to identify and correct errors.					
<p>6.6.2.4 Testing Phase</p> <p>Test requirements and acceptance criteria shall be specified, documented, and reviewed and shall be based upon applicable design or other pertinent technical bases. Appropriate tests, such as verification tests, requirements-driven tests, hardware integration tests, and in-use tests, shall be controlled. Software testing, using documented test plans, test cases, and test results are the primary methods of software validation.</p> <p>Testing of software shall be performed to the extent that unintended functions are identified and reviewed and their impact determined and corrected. If appropriate, determine if modifications of the requirements, the design, the implementation, or the test plans and test cases are required.</p> <p>Design-driven tests shall be used to demonstrate the capability of the software to produce valid results for test problems encompassing the range of intended use as defined by the software documentation. Testing of software used for operational control shall demonstrate the required performance over the entire range of the controlled function or process. Acceptable test methods consist of:</p> <p>A. Hand calculations</p> <p>B. Calculations using comparable proven problems</p> <p>C. Empirical data and information from confirmed published data and correlations or technical literature</p> <p>D. Comparison with other validated software of similar purpose</p> <p>E. Manual inspections or qualitative checks not involving numerical manipulation (examples include visual inspection of database reformatting or data plotting).</p> <p>Requirements-driven tests shall be used to validate software by comparing test results of software execution with objective evidence obtained by the above methods. The results of this evaluation shall be of sufficient scope and depth to prove the capabilities and limitations delineated in the software documentation.</p>	<p>√</p> <p>√</p> <p>√</p> <p>√</p> <p>√</p> <p>√</p> <p>√</p>			<p>NP 19-1, Section 2.3.2 and 2.3.5 Appendix D, and H</p> <p>NP 19-1, Appendix D #7</p> <p>NP 19-1, Appendix D, and H</p> <p>NP 19-1, Appendix D, and H</p> <p>NP 19-1, Appendix H</p> <p>NP 19-1, Appendix H</p>	
<p>6.6.2.5 Installation and Checkout Phase</p> <p>A. During installation and checkout, the software becomes part of a system consisting of applicable software components, hardware, and data. The process of integrating the software with other applicable components may consist of installing both the hardware</p>	<p>√</p>			<p>NP 19-1, Section 2.3.6</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>and software, converting or creating databases, and verifying that all components of the system have been included in the installation. Test problems shall be developed and documented to permit confirmation of the acceptable performance of the software in its operating environment. Installation and checkout of software shall consist of the</p> <ol style="list-style-type: none"> 1. Execution of tests for installation and integration 2. Documented acceptance of the software for operational use 3. The placement of the software under configuration control prior to use <p>B. Completion of the installation and checkout activities establishes the software baseline.</p>	√			NP 19-1, Section 2.3.7.4	
<p>6.6.2.6 Operations and Maintenance Phase</p> <p>converting Operation of the software is conducted by the user in accordance with the operation and usage instructions described in the software user documentation. Once the software has been made available for use, the software requirements and the design integrity shall be maintained. Maintenance activities shall be performed and documented in a traceable, planned, and orderly manner.</p> <p>In all cases, verification and validation of software shall be completed and approved and corrective actions performed, as necessary, prior to relying upon the software to perform its intended function.</p> <p>A. Post Installation Maintenance</p> <p>Software shall be maintained to remove latent errors (corrective maintenance), to respond to new or revised requirements (perfective maintenance), or to adapt the software to changes in the operating environment (adaptive maintenance). Software modifications shall be approved by authorized personnel, documented, verified, validated, and controlled.</p> <p>B. In-Use Tests</p> <ol style="list-style-type: none"> 1. Test problems shall be run whenever the software is installed on a different computer or when significant hardware or system software configuration changes are made. These tests shall be documented, performed by an individual technically competent in the subject area(s), and serve as the basis for determining if the software still meets specified requirements. 2. Periodic in-use manual or automatic self-check 	√			NP 19-1, Sections 2.3.4 and 2.3.7 Appendices F, G, and J	
	√			NP 19-1, Section 2.3.7	
	√			NP 19-1 Section 2.3.7.2	
	√			NP 20-1, Appendix A	Self check routines are only identified for DAS

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>6.7.2.2 Requirements</p> <p>Verification review(s) of software requirements shall ensure that the requirements are complete, verifiable through testing, consistent, and technically feasible as described in section 6.6.2.1.</p>	√			NP 19-1, Appendix C	
<p>6.7.2.3 Design</p> <p>Verification review(s) of software design shall evaluate the technical adequacy of the design approach and ensure that all the requirements have been addressed and that the design is complete, verifiable (through testing, using approved test plans and test cases), consistent, technically feasible, and traceable to the software requirements as described in section 6.5.2.2.</p>	√			NP 19-1, Appendix E	
<p>6.7.2.4 Implementation</p> <p>Verification of the implementation of software design shall consist of the examination of software logic and source code to ensure adherence to standards and conventions and to ensure that the design has been implemented as described in section 6.5.2.3.</p>	√			NP 19-1, Appendix F	
<p>6.7.2.5 Testing</p> <p>Verification of software testing shall consist of reviews to ensure that the specified test criteria, the expected results, and the software development documentation have been met as described in section 6.5.2.4.</p>	√			NP 19-1, Appendix D and H	
<p>6.7.2.6 Installation and Checkout</p> <p>Verification of installation and checkout activities consists of reviews to ensure that the software baseline has been established.</p>	√			NP 19-1, Appendix I	
<p>6.7.3 Validation</p> <p>A. Software validation is primarily a formal testing activity that shall be performed prior to installation and checkout. It shall be used to demonstrate that the computational model embodied in the software is an acceptable representation of the process or system for which it is intended and that the software produces correct solutions within defined limits for each parameter employed.</p>	√			NP 19-1, Appendix H	
<p>B. Validation methods, test data, software-generated results, and conclusions shall be documented in a form that can be understood by an independent individual technically competent to use the software for the particular problem under study. The documentation shall be reviewed to assess the adequacy and correctness of the documentation in meeting the</p>	√			NP 19-1, Appendix H	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>requirements of this section of the QAPD and the overall acceptability of the software for the intended use.</p> <p>C. When the adequacy of the conceptual, mathematical, or computational models or the suitability of procedures and methods cannot be established through testing, alternate calculations, or reference to previously established standards and practices, a documented peer review shall be performed to meet the software validation requirements.</p> <p>D. The validation of software modifications shall be subject to selective regression testing to</p> <ol style="list-style-type: none"> 1. Detect errors introduced during the modification of the systems or system components 2. Verify that the modifications have not caused unintended adverse effects 3. Verify that the modified system(s) or system component(s) still meets specified requirements 	<p>√</p> <p>√</p>			<p>NP 19-1, Appendix D</p> <p>NP 19-1, Section 2.3.7.2</p>	
<p>6.8 SOFTWARE CONFIGURATION MANAGEMENT</p> <p>6.8.1 Basic Requirements</p> <p>Implementation of baseline and change control processes are fundamental to configuration management. A baseline is a collection of all approved components of the software development cycle. As each component is approved it is added to the overall software baseline. A software baseline serves as the basis for further development and maintenance that can be changed only through the use of formal change control procedures. Change control is the process by which a change to a baseline is proposed, evaluated, and approved or rejected.</p> <p>Software configuration controls shall be planned, including the identification of organizational positions that are authorized to make changes, and the methods, procedures, and instructions to be used to control the identification of, access to, changes to, and the status of computer software. Configuration control documents shall indicate how changes will be validated, including regression testing, and how the tests will be documented. These control documents shall be formally reviewed, approved, and in place before the release of the software for use.</p>	<p>√</p> <p>√</p> <p>√</p>			<p>NP 19-1, Section 2.3.7.4</p> <p>NP 19-1, Section 2.3.7 Appendix J, D</p> <p>NP 19-1, Section 2.3.7 Appendix J, D</p>	
<p>6.8.2 NQA-2 Part 2.7 Requirements</p> <p>6.8.2.1 Configuration Identification</p> <p>Software shall be placed under configuration control as each configuration item is approved. A software baseline shall define the most recent approved software</p>	<p>√</p>			<p>NP 19-1, Section 2.3</p>	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>configuration. The configuration items and their associated documentation shall be traceable to one another. A labeling system for configuration items shall be implemented that</p> <p>A. Uniquely identifies each configuration item</p> <p>B. Identifies changes to configuration items by revision or version identifier</p> <p>C. Provides the ability to uniquely identify each approved configuration of the revised software that is available for use</p>					
<p>6.8.2.2 Configuration Change Control</p> <p>A. Changes to software shall be systematically proposed, evaluated, documented, and approved to ensure that the impact and rationale for making the change is carefully assessed prior to updating the software baseline. Changes to previously accepted software shall be subject to the same level of control as the original software.</p> <p>B. Information concerning approved changes shall be transmitted to all affected organizations. All changes shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes. Only authorized changes shall be made to software baselines. Software verification activities shall be performed for the change as necessary to ensure that the change is appropriately reflected in the software documentation and to ensure that traceability is maintained. The degree of software validation shall be commensurate with the nature and scope of the change.</p>	√			NP 19-1, Section 2.3.7	
<p>6.8.2.3 Configuration Status Accounting</p> <p>Information shall be maintained that reflects the current status of the software baseline. This includes the identity and version of the approved configuration and the status of any proposed and approved changes to the baseline components. This information shall be available to all designated users of the software upon request.</p>	√			NP 19-1, Section 2.3.7.4	
<p>6.9 DOCUMENTATION</p> <p>6.9.1 Basic Requirements</p> <p>Software shall be described in one or more documents that detail user instructions, technical bases, functional requirements, and maintenance-related information sufficient to allow independent verification and maintenance and to provide traceability of the documentation to the software. The documentation shall be reviewed by an individual competent in the technical subject area for which</p>	√			NP 19-1, Section 2.3	

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>4. Describe the design in a manner that can be translated into executable code</p> <p>6.9.2.4 Verification and Validation Documentation</p> <p>A. Software verification and validation documentation shall consist of associated plans and shall describe the activities (including the results of reviews and tests) and the criteria for accomplishing the verification of the software throughout the software evolution process. The documentation shall also specify the hardware and software configurations pertinent to the software verification and validation.</p> <p>B. Software verification and validation documentation shall be organized in a manner that allows traceability from the software requirements to both the software design and to the validated capabilities of the software.</p>	√			<p>NP 19-1, Sections 2.3.2 and 2.3.5 Appendices D and H</p> <p>NP 19-1 Sections 2.3.2 and 2.3.5, Appendices D and H</p>	
<p>6.9.2.5 Change Documentation</p> <p>Changes to software shall be formally documented. This documentation shall contain a description of the change, the rationale for the change, and the identification of affected configuration items of the software baseline.</p> <p>6.9.2.6 User Documentation</p> <p>User documentation should be sufficient to allow any qualified user (i.e., one having adequate technical background) to install and run the software and properly respond to errors. User documentation, at a minimum, shall include</p> <p>A. The software name and version identifier</p> <p>B. Statement(s) of functional requirements and system limitations, including hardware</p> <p>C. An explanation of the mathematical models and derivation of the numerical methods used in the software design; physical and mathematical assumptions on which the software is based shall be included, along with an explanation of the capabilities and limitations inherent in the software</p> <p>D. Instructions that describe user interaction with the software, user messages initiated as a result of improper input and how the user can respond, the identification and description of input and output specifications and formats, and input parameters</p> <p>E. A description of any required training necessary to use the software</p>	√ √ √			<p>NP 19-1, Appendix J</p> <p>NP 19-1, Appendix J</p> <p>NP 19-1 Section 2.3.4 Appendix G</p>	<p>QAPD Section 6.8.2.6, see NP 19-1 Section 2.3.4 Appendix G</p>

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
F. Information for obtaining operation and maintenance support					
6.9.2.7 Error Documentation Documentation of errors detected during the use of the software following installation and checkout shall be maintained. This documentation can be used for process improvement and to prevent recurrence of errors during the development and maintenance of other software. This documentation shall contain the identity of the software, the classification of the error in terms of its significance to the integrity of the software output, and the corrective action(s).	√			NP 19-1 Section 2.3.7.3, Appendix K	
6.10 PROBLEM REPORTING AND CORRECTIVE ACTION 6.10.1 Basic Requirements Problems (i.e., errors, faults, failures, etc.) detected in released software shall be promptly reported in accordance with documented procedures. When problems are detected in a software item, work previously performed using versions of the software that contain that problem shall be evaluated to determine the impact on the completed work. The evaluations shall be documented and retained in accordance with records requirements.	√			NP 19-1 Section 2.3.7.3	
6.10.2 NQA-2 Part 2.7 Requirements A. A system shall be established and maintained to record, classify, analyze, track, and report software problems (in released versions) and the associated corrective actions. Problems shall be promptly reported to any affected organizations and the resolution shall be formally processed.	√			NP 19-1, Appendix K	
B. When problems are discovered in software or software results, the sponsoring organization shall determine the affect on previous use(s) and the need for corrective action based on sufficient information obtained from the affected users. Corrective action shall ensure that <ol style="list-style-type: none"> 1. Problems are identified, evaluated, documented and, if required, corrected 2. Problems are assessed for their impact on past and present uses of the software 3. Changes to software are in accordance with the software configuration management requirements of this section of the QAPD 4. Results are provided to the affected users along with any revised software documentation 	√			NP 19-1 Section 2.3.7.3, NP 19-1 Section 2.3.7.3, Appendix K	
C. Problems that could significantly affect decisions based					

QAPD (REV 4) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
<p>upon prior use or that require significant modification to the software shall be identifiable to all users. Errors that have been determined to represent a condition adverse to quality shall be controlled in accordance with section 1.3 of this QAPD.</p> <p>ACCESS CONTROL</p> <p>To the extent appropriate, controls shall be established to permit authorized and prevent unauthorized access to software that has been accepted in accordance with this section.</p>	<p>√</p> <p>√</p> <p>√</p>			<p>NP 19-1 Appendix K, NP 16-1</p> <p>NP 19-1 Sections 2.3.6.2 and 2.3.6.3</p>	

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