



# WIPP Library

SANDIA NATIONAL LABORATORIES  
WASTE ISOLATION PILOT PLANT  
QUALITY ASSURANCE PROGRAM DESCRIPTION

Effective Date: 10/01/92

Revision P

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## QUALITY POLICY

The Sandia National Laboratories WIPP Program has the primary objective of supporting the Research and Development Program for the Waste Isolation Pilot Plant. To assure quality in obtaining this objective, Sandia has given priority to assuring the necessary qualified personnel and resources are available to develop and implement an effective quality assurance program. The results of our work must meet the requirements and expectations of the Department of Energy. In the regulatory environment of the project, the importance of an effective QA program must be emphasized.

The concept of quality assurance is not new. The QA Program is an organized and structured management control system developed to achieve success. Management attention and support are integral parts of the QA Program.

The QA Program covers the methods and procedures to be followed, as well as the roles and responsibilities of those involved. The application of the program is graded, so that appropriate levels of attention are provided based on the task's significance and importance to health, safety and programmatic risk. Sandians and Sandia subcontractors must be accountable for the quality of their work. Program quality is a line responsibility. All personnel are expected and encouraged to suggest improvements. Adherence to the SNL WIPP QA Program is mandatory for all Sandia personnel and Sandia subcontractors, contributing to the WIPP project. Quality assurance is an important aspect in assuring the success of the WIPP Program.

  
Wendell D. Weart  
SNL WIPP Project Manager

  
Date

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**A**    SCOPE

This Waste Isolation Pilot Plant (WIPP) Quality Assurance Program Description (QAPD) describes the Quality Assurance requirements applied to Sandia and Sandia sponsored work as the major project participant responsible for the scientific programs and Performance Assessment activities for WIPP. This Quality Assurance program meets the requirements of ASME/ANSI NQA-1 (latest revision and applicable supplements and addenda), DOE 5700.6C, WPIO Plan for the WIPP Quality Assurance Program, Chapter 11 of the Final Safety Analysis Report, DOE/WIPP 105 - Project Office Quality Assurance Plan, DOE/WIPP 103 - Management Directives and EPA QAMS-005/80, Interim Guidelines and Specifications for Preparing QA Project Plans, as applicable. See Figure 1.

**B**    APPLICABILITY

This QAPD is specific to the WIPP Project and takes precedence over any other Sandia organizational Quality Assurance plans, procedures, or instructions. Personnel working on this project are subject to the WIPP QAPD or they may use their own quality assurance plans if the plans have been approved by the SNL QA Chief.

The QA program has adopted a graded approach. As a result, the application of quality requirements is based on the safety hazards and programmatic risks associated with the task. The intent of the graded quality program is to apply controls in varying degrees of formality and detail. This applies the most stringent controls where the hazards and risks are high and reduces the controls where the hazards and risks are low. Because of the unique nature of some R & D work, not all quality assurance criteria will apply to all activities.

**C**    INTRODUCTION

WIPP has been authorized (Public Law 96-164) "as a defense activity of the DOE for the express purpose of providing a research and development facility to demonstrate the safe disposal of radioactive wastes resulting from the defense activities and programs of the United States." Sandia supports the WIPP project by detailing and refining geotechnical understanding of the site, by conducting scientific research to address issues related to disposal of defense waste in salt, by modeling various possible breach scenarios to evaluate compliance with the EPA Standard 40 CFR 191, and by conducting tests and experiments necessary to provide confidence in the performance of the site.

The WIPP Project will be operated as an R & D facility during the Test Phase, but the information collected has a specific application to performance assessment and regulatory compliance. As a result, R & D activities at WIPP must operate under a more restrictive umbrella than found in other R & D operations.

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This plan is based on a principle that comes directly from DOE Order 5700.6C, Quality Assurance. In this order the concept that all work is a process that can be planned, performed, assessed and improved is discussed. The application of this concept is specifically extended, in the DOE Order, to basic research and development, scientific investigation and engineering design.

D PURPOSE

This document ties together many quality concepts and requirements that are applicable to Sandia's work on the WIPP project. The SNL Quality Improvement Plan defines quality as conformance to customer requirements of performance, cost and schedule. In DOE Order 5700.6C, "quality is the degree to which an item or process meets or exceeds the user's requirements and expectations." Quality Assurance is defined in ASME/ANSI NQA-1, an industry standard for nuclear facilities, as "All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service." The QAPD is a management tool that strives to provide a structure, or process, to demonstrate that the project is well planned, reviewed, controlled, documented and provides for continual improvement.

### SNL QUALITY ASSURANCE DOCUMENT HIERARCHY

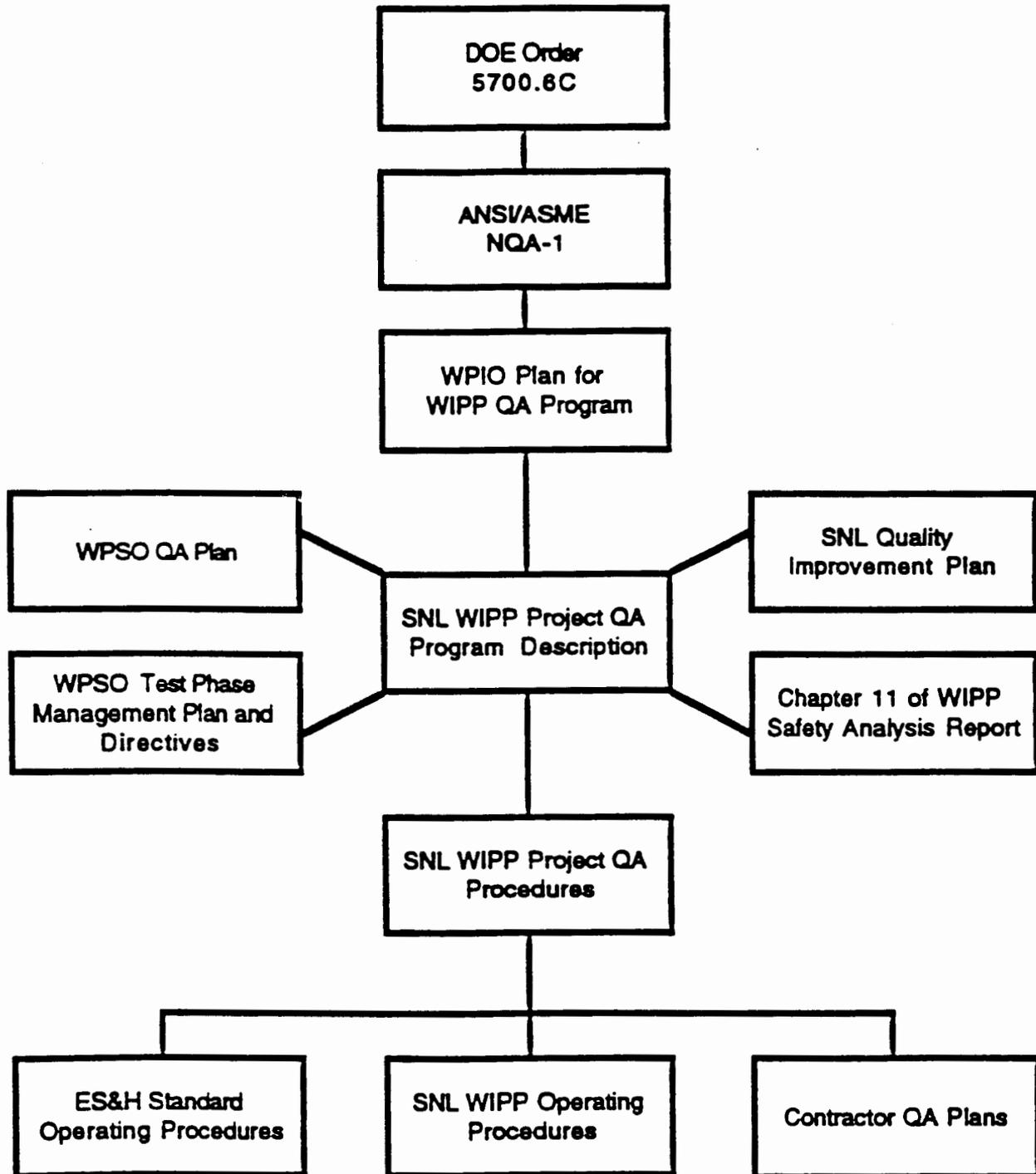


Figure 1.

## 1. ORGANIZATION

1.1 Introduction. This section describes the general organization and responsibilities within the WIPP Project at Sandia National Laboratories. The organizational structure is illustrated in Figure 2.

1.2 Project Personnel. All Sandia and contract personnel must comply with the requirements of this program description or contractors may follow their own plan if approved by SNL QA Chief. Because quality is a function of the individual, all personnel must be responsible for the quality of their work. The individual's role is to meet the quality requirements, while recommending improvements to the quality process. Continuous improvement is the responsibility of all project personnel. All personnel have the authority and responsibility to stop work, if safety or performance assessment considerations are in jeopardy.

1.3 Sandia Management. All management have the responsibility to establish and cultivate principles that integrate quality requirements into daily work. This includes providing staff with the proper information, tools, support and encouragement necessary to reach quality objectives. The Project Manager and Line Managers are expected to demonstrate commitment and leadership to achieve quality through active involvement in the implementation of an effective quality assurance program.

1.4 SNL WIPP Project Manager. The SNL WIPP Project Manager has the overall responsibility and authority for all technical and administrative activities performed by Sandia for the WIPP. These responsibilities include the establishment and effective implementation of a QA program that meets DOE and WIPP requirements. The Project Manager resolves any conflicts or disagreements concerning interpretation or implementation of the QAPD. He is responsible for resolving professional differences of views and opinions. Although the Project Manager may delegate work to others, he retains the responsibility for the work.

1.5 Department Managers. Department Managers are delegated responsibility and authority by the Project Manager for specific technical and administrative tasks and for the application of the requirements of this QAPD to those tasks. One group, Project Management and Systems Integration coordinates planning, scheduling and cost control for the project, but the responsibility for these lies with each line manager.

1.6 Principal Investigators. A principal investigator (PI) is appointed by the responsible Department Manager for each subtask as defined in the WIPP Program Plan for the current year or an equivalent document. The PI's are delegated the responsibility and authority for the overall management, planning, and conduct of their technical area and the application and implementation of the

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**QAPD.** The PI is the primary interface between the Project and Sandia contractors supporting the WIPP. Principal Investigators may delegate their responsibility, in writing, to other project personnel. These delegates then have the same authority as the PI's. They may review and approve documents and make decisions on the PI's behalf.

**1.7 WIPP QA Chief.** The WIPP QA Chief is appointed by and reports to the Project Manager and is delegated the responsibility, authority, access to work areas, and organizational freedom to assure that an appropriate QA program is established, executed, and maintained. The WIPP QA Chief interprets QA requirements; identifies quality problems; initiates, recommends, or provides solutions to quality problems; verifies implementation of solutions, and assures that any unsatisfactory conditions are properly resolved. This authority and responsibility extends to stopping work because of quality concerns, subject to review only by the Project Manager. The WIPP QA Chief shall have sufficient independence from cost, schedule and other responsibilities or duties to implement these QA responsibilities.

**1.8 Field Instrumentation and Testing.** The Project is supported by The Sandia Field Test Organization in the following areas:

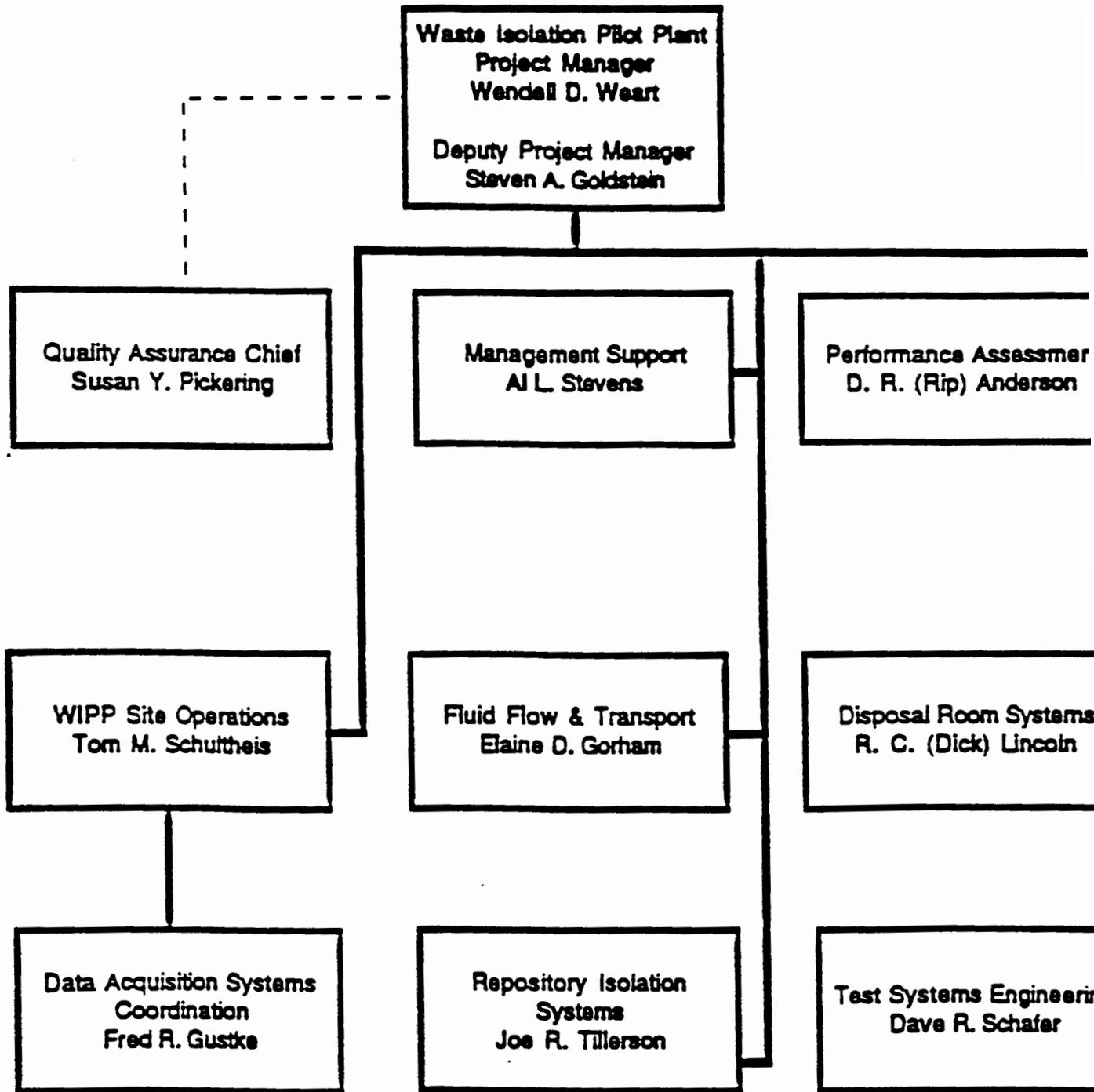
- designs and maintains the data acquisition system (DAS);
- maintains and calibrates instruments;
- records data;
- transports data.

**1.9 Sandians Under the Matrix System.** Expertise from other areas of the Laboratory may be used to support the Project. In these cases, the support staff will report administratively to their own management, but will receive technical direction from the department manager they are supporting. Other agreements may be developed by management, as appropriate.

**1.10 Sandia Contractors.** The quality of any SNL tasks delegated to contractors, remain the responsibility of the Principle Investigator overseeing the contract.

See Figures 2 and 3, for organization charts of the SNL Experimental Program and WIPP Project participants.

# SNL WIPP ORGANIZATION

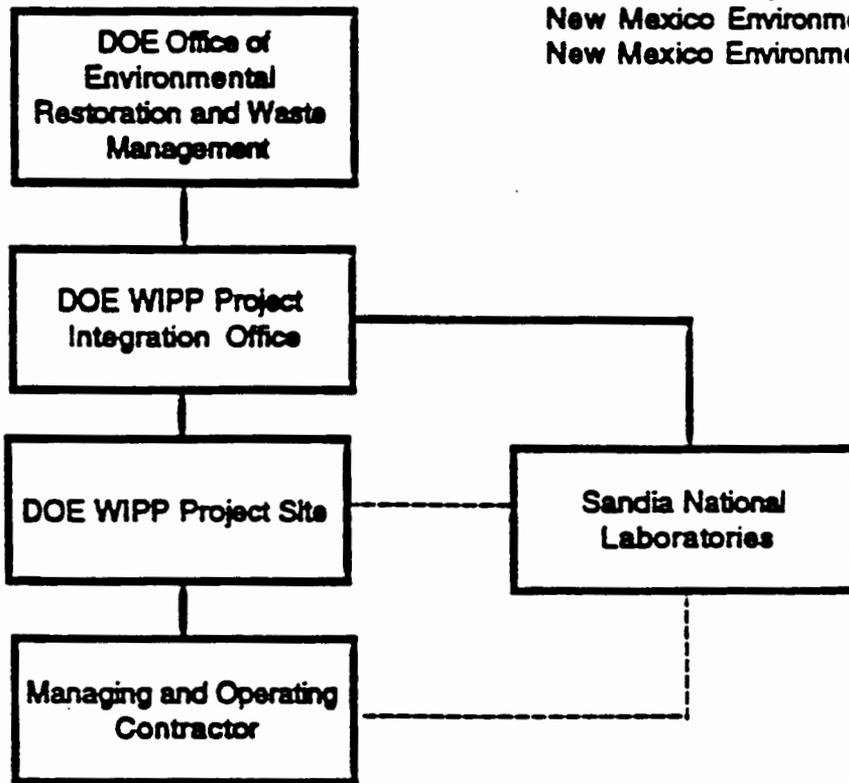


— Technical & Programmatic Direction  
- - - Direct Reporting

Figure 2.

### Organization of WIPP Project Major Participants

Also supplying input to the project:  
Environmental Protection Agency  
National Academy of Sciences  
New Mexico Environmental Department  
New Mexico Environmental Evaluation Group



— Programmatic Direction  
- - - Communication

Figure 3.

## 2. QUALITY ASSURANCE PROGRAM

2.1 Introduction. The successful implementation of the Sandia WIPP QAPD is essential to the achievement of Sandia's objectives and responsibilities within the WIPP Project. Adherence to this QAPD and the implementing procedures is the responsibility of each individual participating in the WIPP Project. Quality is the responsibility of all personnel.

The Sandia WIPP QAPD is formatted to the 18 element structure of ASME NQA-1, although an additional element 19 has been added. Appendix A is a summary matrix of the various implementing documents.

Sandia has the responsibility for all aspects of the Experimental Program from design, implementation, data collection, reduction, analysis and reporting.

2.2 Application. All activities conducted by Sandia at WIPP and associated with experimental design and implementation, data collection, reduction and analysis shall be conducted in accordance with the requirements of this QAPD. Since data are the products or outputs of much of the SNL efforts, the QA program focuses on all activities that influence the quality of data. A quality affecting activity is any activity which will influence the quality of performance assessment utilized data and conclusions generated by that activity. That includes experiment concept and requirements development, experiment design and fielding, data collection, reduction, analysis and reporting. The graded application of quality requirements shall be applied to quality affecting activities.

2.3 Controlled Conditions. All work will be conducted under controlled conditions in accordance with adequately approved documents (Sections 5 and 11). Controlled conditions include the use of appropriate equipment, suitable environmental conditions, and assurance that prerequisites for the given activity have been satisfied. The prerequisites for any activity will be described in the associated documentation, for example, test plans, procedures or work instructions.

2.4 Management Assessment. On an annual basis, SNL management shall assess the overall effectiveness of the entire Quality Assurance Program. The Project Manager shall conduct the assessment with input from the Department Managers. The review will include as appropriate:

- assessment of how well the integrated QA program is working;
- QA Program status, adequacy, compliance and effectiveness;
- action to be taken, if applicable, to improve program, including the identification of any management problems that hinder quality objectives;
- status of incorporation of changes to program requirements;

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- adequacy of resources/personnel to achieve and assure quality; and
- any quantitative criteria that was used to evaluate the program.

2.5 Training. Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained. Department Managers identify job areas and titles, which carry specific training requirements. The training requirements are continuously reviewed as procedures, etc. are revised. Completion of training requirements is evaluated monthly, as well as through audits and overviews. Personnel qualifications are reviewed annually during performance ratings, and needs for retraining, etc, may be identified at that time. Personnel performing or managing activities affecting quality will be trained commensurate with the scope, complexity, and nature of the activity and the education, experience, and proficiency of the person. Training by qualified instructors will be provided, if needed, to:

- achieve initial proficiency;
- maintain proficiency; and
- adapt to changes in technology, methods, or job responsibilities.

2.6 Orientation. It is the line manager's responsibility to ensure that personnel receive orientation, when necessary, in the following subjects, as they relate to a particular function:

- job responsibilities and authority;
- general criteria, including company procedures and standards;
- applicable QA program elements and why they exist;
- potential consequences of improper work.

2.7 Training and Orientation Records. Training and orientation records may take the form of:

- attendance sheets;
- training logs; or
- personnel training records.

These records may include: the objective, content of the program, attendees and date of attendance.

2.8 Continuous Improvement. The entire focus of this program is to promote continuous improvement. Some specific processes used by SNL are: audits and independent assessments, management assessments, peer review and trend analysis.

The SNL-wide self assessment program includes WIPP which is evaluated annually by the Albuquerque DOE office. It allows for the identification of areas needing improvement.

### 3. DESIGN CONTROL

3.1 Application. Design control based on grading for Sandia WIPP activities includes the planning of experiments and the design of equipment and facilities to carry out those experiments. Test Plans or a similar document are used by the responsible PI or contractor to document the experiment design and any design interfaces.

3.2 Design Input and Process. The general concept and justification for the overall SNL Experimental Program was documented in a generic in situ experimental plan (SAND 81-2628). Subsequently, yearly program plans and memos document changes and modification to this generic plan. Presently, a five year program plan is required and will be periodically updated. The Principal Investigator then refines and expands the idea to form a detailed concept. Next, an Experimental Test Plan is written, outlining the steps needed to implement the experiment.

3.3 Design Analysis. If an experiment entails the design of special equipment, a formal design analysis shall be required in accordance with the grading of the activity. The concept of the experimental design is evaluated during the peer review process.

If a formal design analysis is required, the documents shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analysis and verify that the design meets requirements and the results are adequate. These requirements are dependent on the grading of the activity.

Documentation of formal design analyses shall include:

- definition of the objective, purpose and method of the analyses;
- definition of design inputs (criteria, parameters, requirements, etc.) and their sources;
- results of literature searches, other applicable background data and references;
- identification of assumptions and indication of those that must be verified as the design proceeds;
- identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the basis (or reference thereto) supporting application of the computer program to the specific physical problem;
- appropriate units;
- review and approval by the PI, QA, safety and at least one peer.

3.4 Change Control. Design changes shall be governed by control measures commensurate with those applied to the original design.

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**3.5 Equipment Design.** When noncommercial grade items are needed for a test or experiment, the equipment design will be performed by the PI or a designee. The design is documented using either a drawing or sketch. Drawings and engineering sketches are subject to the same design verification requirements (Section 3.6).

When experimental hardware must be designed, the applicable inputs, such as performance requirements, regulatory requirements, codes and standards must be documented. Design methods, materials and processes that are essential to the function of the structure must be selected and reviewed. They may be on the actual engineering sketch or in a stand alone document. Changes from the approved design inputs, including the rationale, shall be approved and documented.

The final design shall be traceable to the design input by documentation to permit design verification and demonstrate the logic used in developing the design.

**3.6 Design Adequacy.** Much of Sandia's work at WIPP involves state of the art testing where detailed technical criteria do not exist or are being developed. Therefore, peer review is relied on to verify design activities based on the grading of the activity. The adequacy of an experimental design is verified by peer reviewer(s) who are not responsible for the experiment design. The adequacy of equipment design drawings and engineering sketches is verified by a qualified individual other than the designer. In both cases, by signing, the reviewer accepts the design as adequate and complete.

**3.7 Drawing Control.** Sketches and drawings will be initialed, to indicate approval, by the responsible scientist or engineer before use on the WIPP project. (See Section 6.0)

**3.8 Modifications to Underground Facilities.** When modifications to underground (UG) facilities are required, Sandia will provide Managing and Operating Contractor (MOC) the necessary drawings, test plans, etc. for MOC to develop the appropriate work document. The responsible PI or engineer will review the package before work is initiated.

**3.9 Computer Programs.** Computer programs are developed, controlled, verified, validated, and changes are documented in accordance with Section 19.

#### 4. PROCUREMENT DOCUMENT CONTROL

4.1 Introduction. Procurement documentation shall be initiated by project staff by means of a PR (purchase requisition). Both technical and quality requirements will be included in the PR as appropriate. PR specifications are incorporated into a Purchase Order (PO) by the Sandia Purchasing Organization.

4.2 Content of PRs. Procurement documents will include provisions for the following, as deemed necessary by the originator (requester):

- scope of Work to be performed by the Supplier and associated deliverables;
- technical Requirements, where necessary, reference to specific drawings, specifications, codes, standards, inspection, test, and acceptance requirements, etc.;
- Quality Assurance Program Descriptions;
- right of access to the supplier's facilities and records for inspection or audit by Sandia and/or DOE;
- documentation and deliverables, including, as applicable, original raw data, data reports, technical reports, etc., to be submitted for information, review, or approval by the Sandia requester;
- submittal times and retention times for contractor maintained records;
- provisions for reporting and approving disposition of all nonconformances;
- identification requirements for spare and replacement parts or assemblies as well as the technical and QA related data for ordering these parts or assemblies.
- hazard assessment information.

4.3 QA Review of PRs. The originator of a WIPP PR designates each PR for review and approval by the Sandia WIPP QA Chief or designee, who ensures that appropriate QA requirements are specified.

4.4 Commercial Grade Items. The requirement for QA review and the subsequent passdown of QA requirements is waived for commercial grade items that satisfy the following criteria:

- Items not subject to design or specification requirements that are unique to nuclear facilities (e.g., calibration requirements, QA program requirements, etc.);
- Items ordered on the basis of specifications set forth in the manufacturer's published product description (e.g., catalog).

4.5 Contractor QA Requirements. Appropriate QA requirements will be selected by the requester in consultation with a QA representative and included in the PR. QA requirements may

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include, but are not limited to:

- submittal for approval by the WIPP QA Chief and the subsequent implementation of a documented QA Program Plan/Manual that meets selected Basic and/or Supplemental Requirements of NQA-1;
- contract specific QA requirements;
- request for a certificate of conformance;
- calibration requirements;
- inspection and test requirements;
- acceptance requirements;
- require contractors to pass down appropriate QA requirements to suppliers;
- right of access;
- nonconformances.

4.6 Change Control. Procurement document changes are subject to the same review and approval requirements as the original. Changes made as a result of bid evaluations or precontract negotiations are reviewed prior to contract award. Release of limited funds, and funding increases or decreases not affecting the original statement of work are not subject to QA review and approval.

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**5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS**

**5.1 Introduction.** Experiments shall not begin until the appropriate document is issued, unless at the written request of DOE. Requirements for preparation, content, review, approval, issue, distribution, and change of these documents are determined by the graded approach. All documents prescribing quality related activities shall include or reference, when applicable, acceptance criteria to be used in determining if the activities have been satisfactorily accomplished and identify QA records generated.

**5.2 Sandia Contractors.** Sandia contractors conducting tests or experiments for the WIPP may either work under the Sandia QAPD or the contractor's Sandia approved Quality Assurance Program Plan (QAPP) as defined by contractual statements. When a contractor's QAPP is used, test plans and procedures are not subject to Sandia review and approval before issuance unless requested by Sandia or required by the contractor's QAPP.

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**6. DOCUMENT CONTROL**

**6.1 Introduction.** The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting the quality of experimental data will be controlled to assure that correct documents are used.

**6.2 Controlled Documents.** Controlled documents for the WIPP Project include the WIPP QAPD, QA Procedures, Requirements Documents, Test Plans, Operations Plans, WIPP Procedures, Drawings and Engineering Sketches.

**6.3 Distribution.** Controlled documents are distributed in accordance with a distribution list.

**6.4 Peer Reviews.** Independent peer reviews are performed to provide a critical evaluation of documents. Peer reviewers may be Sandia staff with expertise equivalent to that of the author (internal peer reviews) or may be a peer review panel or other non-Sandia individual(s) (external peer reviews).

**6.5 Document Availability.** Activities will not start until all documents necessary to perform that activity are at or within useable proximity to the work locations.

**6.6 Change Control.** Major changes to controlled documents shall be subjected to the same review and approval as the original documents. Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.

## 7. CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 Introduction. Procurement controls provide for the following, as appropriate:

- source evaluation and selection;
- evaluation of objective evidence of quality furnished by the Supplier;
- source inspection;
- audit;
- examination of items or services upon delivery or completion.

7.2 Planning. Procurement activities are planned and documented to assure a systematic approach to the procurement process and to assure the integration of the following:

- procurement document preparation, review, and change control;
- selection of procurement sources;
- bid evaluation and award;
- Sandia control of Supplier performance;
- verification (surveillance, inspection, or audit) activities by Sandia, including notification for hold and witness points;
- control of nonconformances;
- corrective action;
- acceptance of item or service;
- QA records.

7.3 Supplier Selection. The selection of Suppliers will be based on an evaluation by the requestor of their capability to provide items or services in accordance with the requirements and the procurement documents before award of contract. It is up to the requestor to ensure that acceptable items and services continue to be supplied.

7.4 Bid Evaluation. Bid evaluations shall determine the extent of conformance to the procurement documents. This evaluation shall be performed by Sandia to evaluate the following subjects, as applicable to the type of procurement:

- technical considerations
- QA requirements
- Supplier's personnel
- Supplier's capability
- Supplier's past performance
- alternates
- exceptions

7.5 Supplier Performance Evaluation. Sandia has established measures to interface with suppliers and to verify Supplier's performance as deemed necessary by Sandia. These measures include:

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- establishing an understanding between Sandia and the Supplier of the provisions and specifications of the procurement documents;
- reviewing Supplier documents that are generated or processed during activities fulfilling procurement requirements;
- identifying and processing necessary change information;
- establishing a method of document information exchange between Sandia and Supplier;
- establishing the extent of source surveillance and inspection activities.

7.6 Control of Supplier Generated Documents. Supplier Generated documents will be submitted to Sandia in accordance with the provisions of the contract. Data (including original raw data), reports, test and/or calibration documentation, etc. will be submitted to Sandia at the contractually specified date. The requester is responsible for review and acceptance of these documents.

7.7 Inspection Codes. The requester or a qualified designee will inspect the procured items to ensure conformance to contract specifications. This inspection includes verification that:

- no damage was sustained during shipment;
- the item received was the item ordered;
- any required testing and/or inspection has been done;
- documentation, as applicable to the item or service, was received and is acceptable;
- the item is adequate for its intended use.

7.8 Acceptance of Items or Services. Before offering the item or service for acceptance by Sandia, the Supplier will verify that the item or service being furnished complies with the procurement requirements. Methods used by Sandia to accept a QA designated item or service from a supplier are as follows:

- Receiving Inspection. Purchased items will be inspected as necessary to verify conformance to specified requirements. Receiving inspection will be performed to verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage and cleanness. Receiving inspection will include a review of Supplier documentation when procurement documents require furnishing such documentation.
- Source Verification. When source verification is used, it will be performed at intervals consistent with the importance and complexity of the item or service, and it shall be implemented to monitor, witness, or observe activities. The results will be documented and furnished to the requester and to the Supplier;
- Certificate of Conformance. A Certificate of Conformance may be used to accept items if it meets the following criteria:

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- The certificate identifies the purchased material or equipment, such as by the PO number or serial number;
  - The certificate identifies the specific procurement requirements met or not met by the purchased item;
  - The certificate is signed or authenticated by a person who is responsible for the QA/QC function;
  - The certification system, including the procedures to be followed in filling out a certificate, and review and approval requirements are described in the Supplier's or Sandia's QA program;
  - Means shall be provided to periodically verify the validity of Supplier certificates and the effectiveness of the certification program when multiple purchases are made from a Supplier.
- post installation testing. When testing is used, test requirements and acceptance documentation will be mutually established by Sandia and the Supplier.
  - service or consultant type contracts. For service or consultant type contracts Sandia will accept the service by any or all of the following methods:
    - technical verification of data produced;
    - surveillance and/or audit of the activity;
    - review of objective evidence for conformance to procurement document requirements such as certifications, reports, etc.

It is the requestor's responsibility to verify that inspection and test requirements have been met before using the procured item.

7.9 Control of Supplier Nonconformances. Services that do not meet procurement documentation requirements will be documented. In cases where supplier's knowingly supplied items or services of substandard quality, this information will be forwarded to the DOE Office of Inspector General.

7.10 Commercial Grade Items. When procuring commercial grade items the items will be inspected.

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**8. IDENTIFICATION AND CONTROL OF ITEMS**

**8.1 Requirements for Identification and Control of Items.** The Test Plan or other guiding documentation for each activity will include a system to provide for identification and control of data, materials, parts, samples, specimens, and components as appropriate. The Principal Investigator has the responsibility to see that such a system is in place and followed. The Principal Investigator will include measures providing for the following:

- physical identification to the maximum extent possible consistent with the planned duration and conditions of storage;
- physical separation, procedural control, or some other appropriate means to provide control where physical identification is impractical or inadequate;
- items having limited calendar or operating life or cycles are identified and controlled;
- items shall be protected from physical damage or loss;
- controlled environment will be provided for those items requiring such controls;
- identification on the item or on records traceable to the item;
- markings, when used, that are clear, unambiguous and indelible, and applied so as not to affect the function of the item;
- transfer of markings to each part when items are subdivided;
- markings which become obliterated shall be restored immediately after discovery.

**8.2 Rationale for Non-inclusion of NQA-1 Supplement, 8S-1.** This QAPD complies with the NQA-1 Basic Requirement for Identification and Control of Items, 8, so that identification and control of items takes place in an orderly, controlled and documented manner. The PI indicates in the Test Plan or guiding documents which aspects are important to the experiment and need to be controlled. This QAPD does not go into the detail required by the supplement which is directed towards manufacturing processes. This flexibility is needed due to the varied and unique array of experiments. This QAPD outlines the general requirements and the PI adds to them as needed. Note: QA approves all Test Plans and WIPP Procedures.

## 9. CONTROL OF PROCESSES

9.1 Processes. Processes affecting the quality of items or activities will be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. These means shall assure that process parameters are controlled and that specified environmental conditions are maintained.

9.2 Special Processes. Special Processes are defined in NQA-1 as "A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product." Examples of special processes include welding, nondestructive examination, and heat treating.

9.2.1 Data Collection. The data collection processes used in the experimental and test program are standard techniques and have been developed within the scientific community. Their reliability has been demonstrated so they are not considered special processes and do not require qualification.

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**10. INSPECTION**

10.1 Inspection. Measures shall be established to provide inspections required to verify conformance of an item or activity to specified requirements if necessary. These measures shall provide for: (1) Inspections to be performed in accordance with written procedures by qualified personnel, who did not perform the work being evaluated; (2) criteria for determining when inspections are required, or how and when inspections are to be performed; (3) sampling methodology, if used; (4) identification of mandatory hold points, and (5) identification of inspections requiring special expertise. Results of all inspection activities shall be documented by the inspecting organization.

10.2 Inspection Records for QA Designated Items. Inspection records for QA designated items will, as a minimum, identify the following:

- item inspected
- date of inspection
- inspector
- method of Inspection, including: acceptance criteria and accuracy and precision of test equipment
- results or acceptability
- reference to information on action taken in connection with nonconformances.

## 11. TEST CONTROL

11.1 Experiment Documentation. Experiment activities will be controlled and conducted in accordance with documented and approved test plans or other appropriately reviewed and approved documentation. A copy of the applicable plan or procedure will be maintained in proximity to the activity. Test and experiment results are documented using automated Data Acquisition Systems (DAS) and/or manual readings recorded on forms or in logbooks. Results are reviewed by personnel during the acquisition and the data reduction phases.

11.2 Logbook Control. Logbooks may be used during experiments to record activities and data. Controlled logbooks are available from site QA, or the experimenter may use a bound logbook more suited to that test/experiment. These logbooks for quality related activities should not be confused with the personal logbooks many engineers and technicians keep. At completion of an activity, or quarterly, whichever ever comes first, the quality related logbooks will be returned to QA.

11.3 QA Overviews. QA representatives will directly observe experiment activities to ensure adherence to plans, procedures, and this QAPD.

- Scheduling. An overview should be conducted at the beginning of each significant activity and periodically during the activity. Weekly Activity Reports and other planning documents will be used as the basis for scheduling overviews.
- Documentation. Sandia overviews will be documented by QA staff. The criteria used in the overviews will be listed on the Plan/Procedure line.
- Content. A brief description of the activity overviewed will be included in the overview. The overview forms may note the conduct of operations, housekeeping, equipment status, procedures maintenance and training.
- Nonadherences/Nonconformances. Any nonadherence to procedures will be noted. If the nonadherence is minor, a Nonconformance Report is not necessary but is tracked and followed-up by QA. However, any nonadherence that renders the quality of the activity unacceptable or indeterminate requires an NCR (Section 15.).
- If there is a nonadherence that is so significant that it may cause damage to equipment, compromise an experiment or endanger personnel, the overviewer may stop work. The stop work order will remain in effect until the unacceptable condition is corrected. This is documented on the overview form.

11.4 Readiness Review. A review of QA and technical procedures, personnel training and experimental prerequisites is required as appropriate per the grading of the activity. This is to verify conformance of the activity to requirements specified in the test

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plan, procedure, etc. The PI coordinates and oversees this review. The PI shall verify, as applicable, the status of:

- Acceptance limits, such as precision and accuracy of instrumentation;
- Mandatory inspections or hold points;
- Test prerequisites and actions taken because of deviations;
- Personnel qualifications;
- Related documentation, such as procedures and forms.

A memorandum of record along with supporting documentation (e.g. checklist) will be submitted to Sandia QA, for records retention, at the completion of the readiness review.

## 12. CONTROL OF MEASURING AND TESTING EQUIPMENT

12.1 Introduction. Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality will be controlled and, at specified periods or before use, will be calibrated and adjusted against equipment having known valid relationships to nationally recognized standards. Gages used for indication only, which do not influence the quality of data collected, do not need to be calibrated. When no nationally recognized standard exists, the basis for calibration will be documented. All measuring and test equipment will be properly handled and stored to maintain accuracy. Records of calibration, including as-found data, when appropriate, will be maintained.

12.2 Traceability. Measuring and test equipment used to obtain data or to calibrate another instrument or system will be calibrated using standards traceable to NIST. All measuring and test equipment will have a unique identifier. This number will be cross referenced to all calibration data and records for that piece of equipment.

12.3 Recall for Calibration. As part of its calibration services to Sandia, the Measurement Standards Laboratory maintains a recall system and a listing of each calibrated item, the calibration interval, i.d. number, and other pertinent information. A list of instruments calibrated at the site and their calibration due date will be maintained.

12.4 Calibration by WIPP Project Personnel. Instruments may be calibrated or calibration may be verified by WIPP project personnel at time of use if:

- written procedures are followed;
- National Institute of Standards and Technology (NIST) traceable standards or other nationally or recognized standards are used;
- the results of the calibration or calibration verification are documented.

12.5 Calibration by Non-Sandia or Non-WIPP Sources. Certificates of Calibration may be accepted from non-Sandia or non-WIPP sources if one of the following criteria are met:

- the supplier has a documented QA Program and uses NIST or equivalent traceable standards that have been audited and approved by the DOE or a DOE Contractor (e.g. Sandia, MOC, etc.);
- the supplier submits adequate documentation of the calibration procedures used, personnel qualifications, and traceability of standards with the calibration results.

12.6 Out of Calibration Instruments. As-found data for instruments determined to be out of calibration will be reported to

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the previous user. An evaluation of the as-found calibration data will be made and documented to determine the validity of the previous inspection or test results caused by the out of calibration instrument. A nonconformance report (Section 15) will be written to document the as-found out of calibration condition.

**12.7 Calibration Status.** The calibration status and date of next calibration of all instruments used to obtain data will be clearly shown on that instrument by means of calibration tags or other appropriate methods, including documentation traceable to the instrument. Uncalibrated instruments, used for indication only, will be tagged as such.

**12.8 Out of Service Instruments.** Any instruments beyond the calibration due date or whose data is questionable will not be used and will be clearly marked or will be segregated into a designated area until the instrument is calibrated.

**12.9 Extension of Calibration Period.** If an instrument currently installed in an experiment passes the calibration due date and must be used to avoid disruption of an experiment, the calibration of that instrument must be checked as soon as possible and a nonconformance report (Section 15) written, assessing the impact to quality. However, due care will be taken before initiation of an experiment to avoid this situation.

**12.10 Calibration Exempt Items.** Calibration and control measures are not required for rulers, tape measures, levels, shop micrometers, and other devices for which the uncalibrated device provides adequate accuracy for its application.

**12.11 Defective Measuring and Test Equipment.** If any measuring or testing equipment is consistently found to be out of calibration or is damaged, it will be repaired or replaced.

### 13. HANDLING, STORAGE, AND SHIPPING

13.1 Requirements. Items will be cleaned, preserved, packaged, shipped, or stored as necessary to protect against corrosion, contamination, physical damage, or any effect that could lower the quality or cause an item to deteriorate. Items will be labeled to maintain the identity of the package and to indicate the need for any special controls or environments.

13.2 Special Treatment Items. When special treatment is required for safety related equipment, critical, sensitive, perishable, or exceptionally expensive articles, the PI is responsible for preparing specific procedures or instructions that preclude damage, loss or deterioration of these items. These instructions can be documented in technical procedures, procurement instructions, Site work instructions, drill requests, sample tracking sheets or other appropriate documents.

13.3 Special Tools and Equipment. When deemed necessary by the PI to ensure safe and adequate handling, special tools and equipment shall be used by operators qualified in their use. If such special handling tools and equipment are used, they will be inspected and tested in accordance with procedures and at specified times (e.g., before use).

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**14. INSPECTION, TEST, AND OPERATING STATUS**

14.1 Introduction. This element applies to items whose status with regard to specific inspections or tests must be evident during the conduct of an activity. The procedures for the activity will specify the method of control.

14.2 Status of Experiments. The on going status of SNL Experimental activities is documented by the following:

- Experimental Weekly Activity Report which may cover such topics as, status, accomplishments, problem areas and upcoming events for the experimental tasks.
- Technical Progress Report which may cover QA, Project Management, Performance Assessment, Site Operations, Fluid Flow and Transport, Disposal Room Systems and Repository Isolation Systems.

14.3 Use of Status Indicators. The inspection, test, and operating status of items will be controlled by calibration stickers, tags, markings and notations in notebooks as necessary to ensure that:

- required inspections and tests are performed; and
- items that have not passed the required inspections and tests are not inadvertently used or operated.

14.4 Application and Removal of Status Indicators. Status indicators may be removed after the original circumstances have been mitigated by the person who applied the tag. The removal of the tag and justification is documented on the appropriate forms by the person who applied the tag or the Cognizant Engineer (CE) overseeing that area.

## 15. CONTROL OF NONCONFORMANCES

15.1 Definition. For the Experimental Program, a nonconformance is a deficiency in characteristic, documentation, or procedure that makes the quality of a data affecting service or activity, or the data itself unacceptable or indeterminate. Such NCR's must be documented. Examples: Unplanned power outage to an experiment, data loss determined to be unacceptable by the PI, multiple gage loss, broken data cable, equipment failure, underground experimental room heater failure, DAS Computer failure, reporting of incorrect results or conclusions, and unplanned or undocumented deviation from plans or procedures.

15.2 Single Item Failures. Single item failures of individual gages, a broken gage, erratic readings resulting in the replacement of a gage, etc. unless the technical personnel overseeing the gages make the determination that they are nonconformances. Any time a gage or instrument in a WIPP underground test/experiment is bumped or otherwise disturbed, the individual will report the incident.

15.3 Responsibility. The person discovering a nonconformance (the originator), after consulting the PI, CE, QA or other appropriate personnel, will take any immediate action necessary to mitigate the consequences. The originator will document the event on a Nonconformance Report (NCR).

15.4 Disposition. The action taken to correct the deficiency, such as use as is, repair, or rework, of nonconforming items will be identified and documented. Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use as is shall be documented. As-built records, if any are required, will reflect the accepted deviation. Personnel performing evaluations to determine the disposition of a nonconformance will have demonstrated competence in the specific area they are evaluating, will have an adequate understanding of the requirements, and will have access to pertinent background information. If the disposition involves repairing or rework the item(s) shall be reexamined prior to use in accordance with approved documents.

15.5 Corrective Action. Corrective action taken to prevent recurrence of the nonconformance, any lessons learned and action taken for improvement will be described in the NCR. Corrective action will not be taken until approvals of the proposed corrective action are obtained (Section 15.6).

15.6 Approval Requirements. In consultation with QA, the originator determines the approval requirements applying the graded approach. Minimum approvals are the CE and QA. All Nonconformances affecting DAS functions require the approval of the DAS Coordinator. Depending on the significance of the NCR, additional approvals may be required. Approvals will be obtained before

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beginning corrective action.

15.7 Significant Nonconformances. Nonconformances with consequences of such significance that could seriously endanger the safety of the work force, the public or the environment or hamper the WIPP project or prevent or seriously delay the achievement of a WIPP milestone, or are symptoms of major programmatic shortcomings, are designated Significant NCRs. Significant NCRs must be submitted to DOE for review and approval of the disposition, and before beginning corrective action. Minimum internal approvals are by the Project Manager, the PI, and the WIPP QA Chief.

15.8 Distribution Requirements. A copy of the NCR will be distributed to the PI, Site QA, and any technical and management personnel affected by the NCR.

15.9 Identification/Segregation. Identification of nonconforming items shall be by marking, tagging, or other methods which shall not adversely affect the end use of the item. The identification shall be legible and easily recognizable. If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified. When segregation and tagging are not possible because of physical conditions such as size, weight, or access limitations, other provisions and/or precautions will be employed to preclude inadvertent use of a nonconforming item. Removal of such tags shall be in accordance with Section 14.4.

15.10 Changes to NCRs. Revisions to NCRs require the same review and approval as the original. The appropriate revision number is noted on the NCR.

15.11 Cancellation of NCRs. If a nonconformance report is cancelled, the person responsible will document the justification.

15.12 Status of NCRs. A nonconformance log will be maintained by QA to track the status of NCRs and corrective action. They are also included in the monthly tracking of open QA items. QA staff will verify that corrective action has been completed and will close out all NCRs. NCRs are included in the project's trend analysis, performed annually.

## 16. CORRECTIVE ACTION

16.1 Introduction. Conditions adverse to quality such as failures, malfunctions, deficiencies, defective items, and nonconformances will be identified promptly, including the root cause, documented on a nonconformance report form (section 15.0), and corrected as soon as possible. (Corrective action reports, CARs, are not part of the SNL program. The function of a CAR is met by the NCR.)

16.2 Evaluation of Corrective Action. The originator of an NCR, in consultation with QA and cognizant personnel, shall evaluate the nonconformance and determine the need for corrective action. An individual will be assigned to complete the stated corrective action, and a target date for that corrective action will be set.

16.3 Verification of Corrective Action. QA is responsible for verifying completion of corrective action. QA signs the NCR attesting to the satisfactory completion of all corrective actions.

16.4 Trend Analysis. Audit reports, nonconformance reports and overviews shall be analyzed on a yearly basis to identify significant quality trends. The SNL QA Chief shall perform the analysis, including root cause. The outcome will be documented and reported to the Project Manager and DOE.

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**17. QUALITY ASSURANCE RECORDS**

**17.1 Introduction.** A process shall be established and implemented to ensure that sufficient records are specified, prepared, reviewed, approved, and maintained to accurately reflect completed work. Upon receipt from the originator, records personnel have the responsibility to meet all requirements for records transmittal, distribution, retention, retrievability, maintenance and disposition. Individual procedures will specify the QA records generated by the activity and the method of authentication.

**17.2 Storage Facilities.** The QA records program shall provide the following requirements:

- documented procedures for collecting, filing, and maintaining the records;
- maintenance of records in dual locations remote enough from each other to eliminate exposure to a simultaneous hazard;
- established rules governing access to and control of the files;
- provisions for storage to prevent damage from moisture, temperature, pressure and biological hazards;
- maintenance of records so they are firmly attached in binders or are placed in folders or envelopes for storage in steel file cabinets or on shelving in containers and
- provisions for special processed records (i.e., photographs, negatives, magnetic media) to prevent damage from excessive light, stacking, electromagnetic fields, humidity and temperature.

**17.3 Safe Keeping.** Measures shall be established to preclude entry of unauthorized personnel into all record storage areas. These measures shall guard against larceny and vandalism.

**17.4 Final Disposition.** Eventually, all SNL records will be turned over to the DOE for final disposition in the National Archives.

## 18. AUDITS

18.1 Summary. Scheduled and unscheduled audits and surveillances will be planned using the graded approach. They are performed to verify compliance with the QA Program and to determine its effectiveness. These assessments are conducted in accordance with written procedures by QA Staff. Audit and surveillance results are documented and reported to responsible management.

18.2 Scheduling. The audits may be scheduled in advance. The frequency of audits is based on an evaluation of applicable and active elements of the QA program and a consideration of previous audit results. The schedule will be published in the annual Program Plan, or in a separate memo and submitted to DOE. In either case, the schedule may be revised to reflect current priorities.

18.3 Audit Response. Follow-up actions are taken where indicated. Responses shall include, as appropriate, action to correct any deficiencies, root cause, action taken to prevent recurrence, lessons learned and action taken for improvement.

18.4 Independent Assessment. The requirement for independent assessment is fulfilled by various independent auditing agencies performing audits of the SNL WIPP QA Program. Outside review agencies, such as DOE and the EM Operational Readiness Review, have and will continue to review the SNL program at WIPP. If the annual assessment is not performed by outside agencies, the assessment will be performed by SNL personnel who are independent of SNL WIPP. This QA Program is subject to audits and reviews by DOE personnel at all reasonable times during Sandia's participation in the WIPP Project. This includes scheduled and unscheduled DOE overviews that supplement the formal audit program.

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**19. COMPUTER SOFTWARE**

19.1 Summary. Following the graded approach, the computer software QA documentation requirements are dependent on the specific program's application. A computer program abstract will be completed and submitted to the SWCF for the computer software program. Validation, verification, and changes to computer software programs shall be documented, as applicable.

**COMPARISON OF DOE 5700.6C, NQA-1 AND SNL WIPP PROGRAM ELEMENTS**

5700.6C	NQA-1	SNL WIPP
1. Program	BR-1, 18-1 & BR-2	Policy Letter QAPP B Applicability QAPP 1.0 Organization QAPP 2.0 Quality Assurance Program QAPP 11.6 Readiness Reviews Procedure 125 Experimental Program Work Requests
2. Personnel Training and Qualification	BR-2, 28-3 & 28-4	QAPP 2.0 Quality Assurance Program QAP 2-2 Qualification and Training Program QAP 18-1 QA Audit Requirements for the WIPP Procedure 61 Experimental Operations Personnel Task Qualification Assurance
3. Quality Improvement	BR-16	QAPP 2.13 Continuous Improvement QAPP 11.5 QA Overviews QAPP 15 Control of Nonconforming Items QAPP 16 Corrective Action QAPP 18 Audits QAP 16-1 Trend Analysis QAP 18-1 QA Audit Requirements Procedure 388 Design Reviews
4. Documents and Records	BR-6, 68-1, BR-17 & 17B-1	QAPP 6.0 Document Control QAPP 17 QA Records QAP 6-1 Document Control QAP 17-1 QA Records Requirements QAP 17-2 Central File Operations QAP 17-3 Records Inventory & Disposition Schedule Procedure 125 Experimental Program Work Requests Procedure 149 Quality Assurance Records/Notebook System at the WIPP Site Procedure 270 Form Management Procedure 277 Engineering Sketch Control Procedure 330 SNL WIPP CAD Drawing Release Procedure Procedure 364 Procedure Review Process Procedure 406 Work Instructions for SNL WIPP Site Personnel
BR - NQA-1 Basic Requirements S - NQA-1 Supplement		

**COMPARISON OF DOE 5700.6C, NQA-1 AND SNL WIPP PROGRAM ELEMENTS**

5700.6C	NQA-1	SNL WIPP
5. Work Processes	BR-6, BR-8, BR-9, BR-12, 12S-1, BR-13, 13S-1 & BR-14.	QAPP 1.2 Project Personnel QAPP 5 Instructions, Procedures, and Drawings QAPP 8 Identification and Control of Items QAPP 9 Control of Processes QAPP 12 Control of Measuring and Testing Equipment QAPP 13 Handling, Storage and Shipping QAPP 14 Inspection, Test and Operating Status QAP 2-3 Graded Approach Procedure 125 Experimental Program Work Requests Procedure 140 Underground Drilling and Core Request and Hole Identification System Procedure 263 Sample Tracking System Procedure 270 Form Management Procedure 276 Recommended Guidance for Writing Procedures Procedure 277 Engineering Sketch Control Procedure 281 Site Procurement-Receiving-Shipping Procedure Procedure 330 SNL WIPP CAD Drawing Release Procedure
6. Design	BR-3 & 3S-1	QAPP 3 Design Control QAP 3-1 Design/Analysis QAP 6-1 Document Control QAP 19-1 Computer Software Requirements Procedure 242 Transfer of As-Built Information Between Sandia and Westinghouse Procedure 277 Engineering Sketch Control Procedure 330 SNL WIPP CAD Drawing Release Procedure Procedure 388 Design Review Procedure
7. Procurement	BR-4, 4S-1, BR-7 & 7S-1	QAPP 4 Procurement Document Control QAPP 7 Control of Purchased Items and Services Procedure 281 Site Procurement-Receiving-Shipping Procedure
8. Inspection & Acceptance Testing	BR-10, BR-11, BR-12, 12S-1 & BR-14	QAPP 10 Inspection QAPP 11 Test Control QAPP 12 Control of Measuring and Testing Equipment QAPP 14 Inspection, Test and Operating Status

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**COMPARISON OF DOE 5700.6C, NQA-1 AND SNL WIPP PROGRAM ELEMENTS**

<b>5700.6C</b>	<b>NQA-1</b>	<b>SNL WIPP</b>
<p><b>9. Management Assessment</b></p> <p><b>10. Independent Assessment</b></p>	<p><b>BR-2</b></p> <p><b>BR-18 &amp; 18S-1</b></p>	<p><b>QAPP 2.5 Management Assessment</b>  <b>QAP 18-1 WIPP Trend Analysis Program</b></p> <p><b>QAPP 2.4 Independent Assessment</b>  <b>QAPP 11.5 QA Overviews</b>  <b>QAPP 18 Audits</b>  <b>QAP 18-1 QA Audit Requirements</b></p>