U. S. NUCLEAR REGULATORY COMMISSION

DRAFT NRC REVIEW PLAN:

QUALITY ASSURANCE PROGRAMS

FOR SITE CHARACTERIZATION

OF HIGH LEVEL NUCLEAR WASTE REPOSITORIES

Compiled by
High-Level Waste Technical Development Branch
Division of Waste Management

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ABSTRACT

Construction authorization and the licensing of a geologic repository for high-level waste involve assessing whether the geologic setting and the engineered system will perform in concert at a particular site in preventing an accumulation of radionuclides at the accessible environment which would exceed the amounts established by Environmental Protection Agency standards. An important first question in conducting these licensing assessments will relate to the quality of data used in support of the license application for the proposed site. In addition to questioning relevance and completeness of data supplied in the license application, the licensing process must explicitly address the question of whether data are of adequate quality so that licensing determinations can be made with reasonable confidence. Because of this, an adequate quality assurance (QA) program is necessary to ensure confidence in the data obtained during site characterization.

The purpose of this review plan is to provide guidance to DOE on what the NRC staff considers necessary in establishing a quality assurance program for site characterization activities. As part of this guidance, the NRC staff has identified its approach for reviewing the quality assurance programs for site characterization activities. This review will be conducted in three phases which will include: (1) review of the description of the quality assurance program as presented in the Site Characterization Plan, (2) review of technical test plans and procedures to be developed and utilized for site characterization activities, and (3) NRC site visits and inspections of specific laboratory and field activities. This review plan also identifies those items deemed necessary in a QA program for it to be adequate for site characterization activities.

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1.0 INTRODUCTION

1.1 BACKGROUND

DOE and its contractors are currently involved in performing laboratory and field investigations (site characterization activities) involving various technical disciplines such as geology, hydrology, seismology, geophysics, geochemistry, and rock mechanics - all of which are generally considered part of geotechnical studies and/or investigations. In addition, some waste package testing and conceptual design activities will be performed. Data being gathered and analyzed under these activities will be used by DOE to support a license application to NRC for the construction and operation of geological repositories to be used for permanent disposal of high-level nuclear wastes. It is also expected that DOE will use computer codes to support both site characterization activities and license application. NRC concerns regarding public health and safety have been established in the regulatory requirements (10 CFR 60) for nuclear waste repositories. As part of the regulatory requirements, a quality assurance (QA) program must be implemented by DOE for site characterization activities. Therefore, an NRC review plan is necessary to establish the acceptance criteria used in reviewing the DOE QA program.

1.2 REGULATORY FRAMEWORK

The NRC has established regulatory requirements including those related to QA for nuclear waste repositories in 10 CFR Part 60. This includes requirements in both the procedural and technical rules.

1.2.1 PROCEDURAL RULE, 10 CFR 60

The procedural rule identifies when DOE will submit information on quality assurance to the NRC, and what NRC QA activities would be permitted during site characterization. These requirements are as follows:

Site Characterization Report

60.11a 6iii: provisions to control any adverse, safety-related effects from site characterization, including appropriate quality assurance programs.

60.11a 7: a description of the quality assurance program to be applied to data collection.

60.11g: During site characterization...NRC staff shall be permitted to visit and inspect the site and observe excavations, borings, and in-situ tests as they are done.

1.2.2 TECHNICAL RULE, 10 CFR 60

The technical rule identifies the scope, applicability, and implementation of a QA program for nuclear waste repositories in Subpart G of 10 CFR 60. These requirements are as follows:

SUBPART G - QUALITY ASSURANCE

§ 60.150 Scope.

As used in this part, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its subsystems or components will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

§ 60.151 Applicability.

The quality assurance program applies to all systems, structures and components important to safety, to design and characterization of barriers important to waste isolation and to activities related thereto. These activities include: site characterization, facility and equipment construction, facility operation,

performance confirmation, permanent closure, and decontamination and dismantling of surface facilities.

§ 60.152 Implementation.

DOE shall implement a quality assurance program based on the criteria of Appendix B of 10 CFR Part 50, as applicable, and appropriately supplemented by additional criteria as required by § 60.151.

1.2.3 APPLICABLE REGULATORY AND STANDARDS GUIDANCE DOCUMENTS

QA programs for site characterization activities should be based on Appendix B of 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants". A document which provides guidance in meeting the 18 criteria of Appendix B is ANSI/ASME NQA-1-1979, "Quality Assurance Program Requirements for Nuclear Power Plants". The acceptance of NQA-1 by NRC is identified in the March 25, 1983 proposed Revision 3 to Regulatory Guide 1.28. In addition, U. S. NRC Regulatory Guide 4.17, "Standard Format and Content of Site Characterization Reports for High-Level Waste Geologic Repositories," states that DOE should "Describe the quality assurance (QA) programs that have been applied during site exploration activities and that will be applied to data collection during the planned site characterization program. The QA methods should be presented in sufficient detail to allow NRC to make an independent evaluation of the precision, accuracy, reproducibility, analytic sensitivity, and limitation of data

acquisition and analysis methods that were used during site exploration and will be used during site characterization."

All the basic requirements of ANSI/ASME NQA-1-1979, the 18 criteria of 10 CFR 50 Appendix B, and Revision 3 to Regulatory Guide 1.28 may not be applicable to all of the investigations performed during the site characterization. Thus, only the applicable portions of these documents need to be applied to the data gathering.

2.0 DISCUSSION

2.1 QA PROGRAM DESCRIPTION

DOE is required in 10 CFR 60.11 to submit in the Site Characterization Plan (SCP) a description of the quality assurance program to be applied to data collection. An adequate QA program description, properly implemented with the use of documented procedures, is required to provide confidence in the data gathered during site characterization. Each QA program description should identify how the 10 CFR 50 Appendix B criteria will be implemented and how compliance with the criteria will be assured. In addition to the DOE QA program, the QA program of the prime contractor/program manager (for example, Rockwell Hanford Operations for the Basalt Waste Isolation Program) should be described and the interaction of the two programs should be discussed. DOE should also identify the items and activities to be controlled by the QA program. A list of QA procedures and technical procedures should be identified and referenced in the SCP.

2.2 UNIQUENESS OF QA PROBLEMS IN GEOLOGIC INVESTIGATIONS

The 18 criteria of 10 CFR 50 Appendix B were originally written and applied to evaluation and monitoring of power plant hardware that is critical to public health and safety, or the environment. A hardware-oriented QA program seeks to provide, for example, the inspection of key components at prescribed states of production. Many aspects of this hardware-oriented QA program are easily adaptable to geologic investigations. Such items as document control, instrument calibration, quality assurance records, etc. are easily extended to a geotechnical QA program. However, the investigative nature of geologic studies which involve state-of-the-art test procedures, data acquisition, data reduction, and interpretation of results does not lend itself to approaches which are highly prescriptive. Because of this, an essential aspect of the DOE QA program must be an adequate and independent peer review by qualified technical personnel of the procedures/instructions, tests, data acquisition and reductions, analysis, and interpretation of data for each site investigation activity. Further, another essential part of an adequate QA program involves documentation of procedures.

It is important to make a distinction between administrative QA procedures and detailed technical or implementing procedures (Figure 1). Administrative procedures provide instructions for implementation and application of the 18 criteria of 10 CFR 50 Appendix B. (An acceptable method of meeting the 18 criteria is NQA-1 as endorsed by Revision 3 of Regulatory Guide 1.28.) These are generated by the

quality assurance organization (with assistance from the technical organizations) and apply across the board to all technical program areas (e.g., procedures for test plan development). The detailed technical (implementing) procedures are developed by each technical area in response to the requirements spelled out in the administrative quality assurance procedures. These contain instructions for actual performance of testing and investigations (e.g., hydrologic pump tests, setting a packer, etc).

3.0 NRC REVIEW PLAN

The High-Level Waste Technical Development Branch (WMHT) of NRC has the prime responsibility for the review of DOE QA programs for site characterization investigations for nuclear waste repositories. The review of any QA program for site investigations will involve three phases. Phase one will involve the review of the QA program description submitted in the Site Characterization Plan (SCP) for each site as required by 10 CFR 60.11 and the review of the QA Administrative procedures available at each site. These reviews will be conducted by WMHT staff members (with assistance from other groups such as the Quality Assurance Branch, Office of Inspection and Enforcement (I&E)). The SCP will be reviewed in terms of the points outlined in Attachment 1. Attachment 1 is comprised of acceptance criteria for QA for site characterization activities from Section 17.1 of NUREG-0800 and from the March 25, 1983 proposed Revision 3 to Regulatory Guide 1.28. The acceptance criteria are in consonance with the 18 criteria of Appendix B to 10 CFR 50.

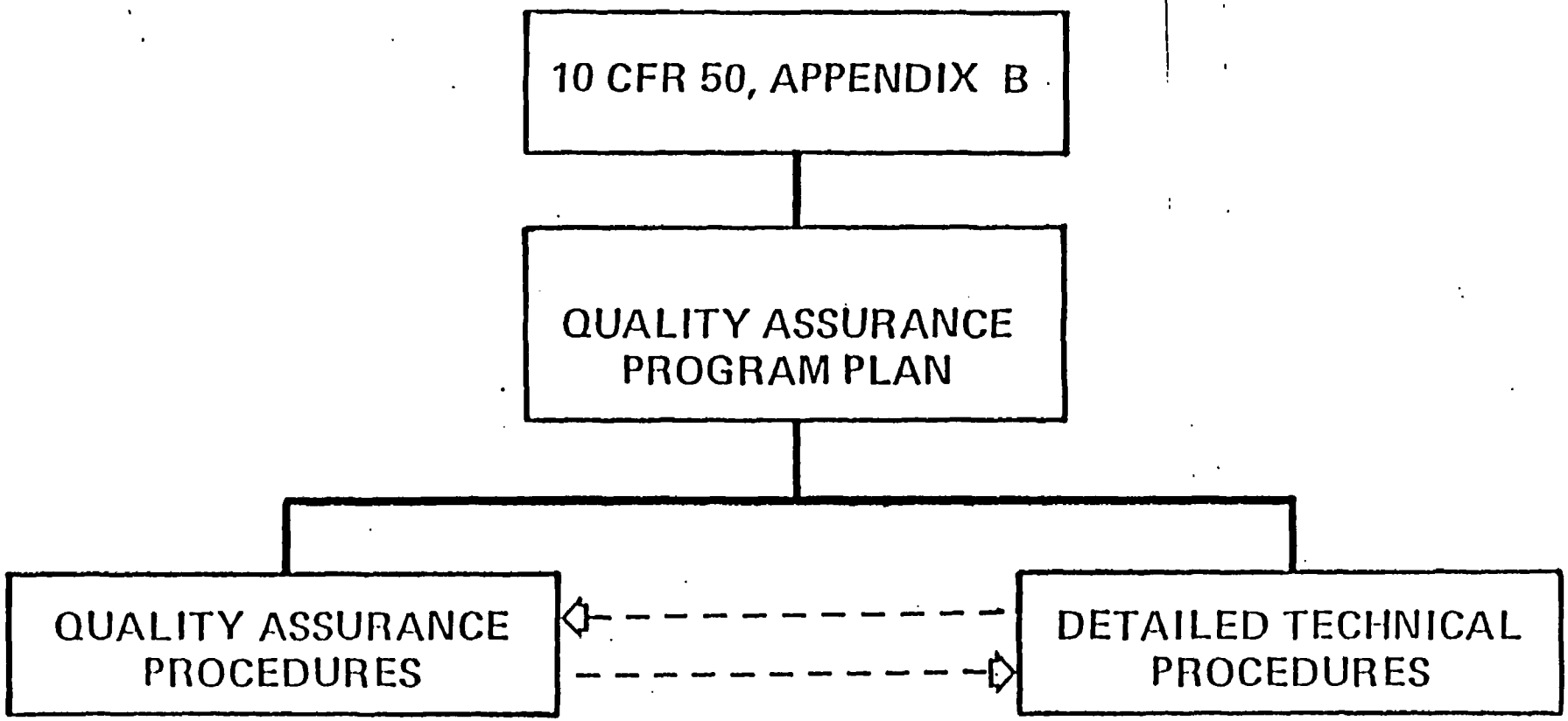
In parallel, phase two will involve NRC technical staff in each technical program area (e.g., geochemistry, hydrology, etc.) evaluating the adequacy of selected technical procedures. Detailed technical procedures should be referenced in the SCP and should be available for staff review at the site. Since the quality of data at any site is virtually determined by the specific data gathering methods and procedures that are used, it is important that specific methods to be used in data gathering and site characterization activities be the subject of the prelicensing consultation between DOE and NRC. The adequacy of technical procedures for the development, documentation, and use of computer codes must also be evaluated by the NRC staff. The specific methods to be used in the control of computer codes should be discussed in prelicensing consultations.

A complex technical program needs to be based on a systematic approach to planning and controlling the program. The plans controlling the conduct of a data gathering program are of varying levels of detail. They go from identification of general performance objectives and criteria to detailing specific technical procedures (Figure 2). Quality assurance needs to be applied at all levels. As shown in Figure 2, site characterization planning must start by considering EPA and NRC criteria. After a specific site is selected, specific issues are identified, based on these criteria and preliminary evaluation of repository performance. The program can then be divided into program areas related to technical disciplines of investigations. These program areas then identify information needed to resolve issues in the site characterization program. From these information needs, "test plans" are developed. These test plans are an integration of activities and identify how the testing will be accomplished. As part of

the test plans, detailed test procedures and instructions are developed which describe in detail what the test involves. The development of these test plans and test procedures is an important element in providing quality assurance for site characterization data. Figure 3 illustrates the development and chronology of events in planning and performing a testing program. This also shows the involvement of QA throughout the entire procedure, including how QA procedures require review by 1) technical management and 2) peer review groups.

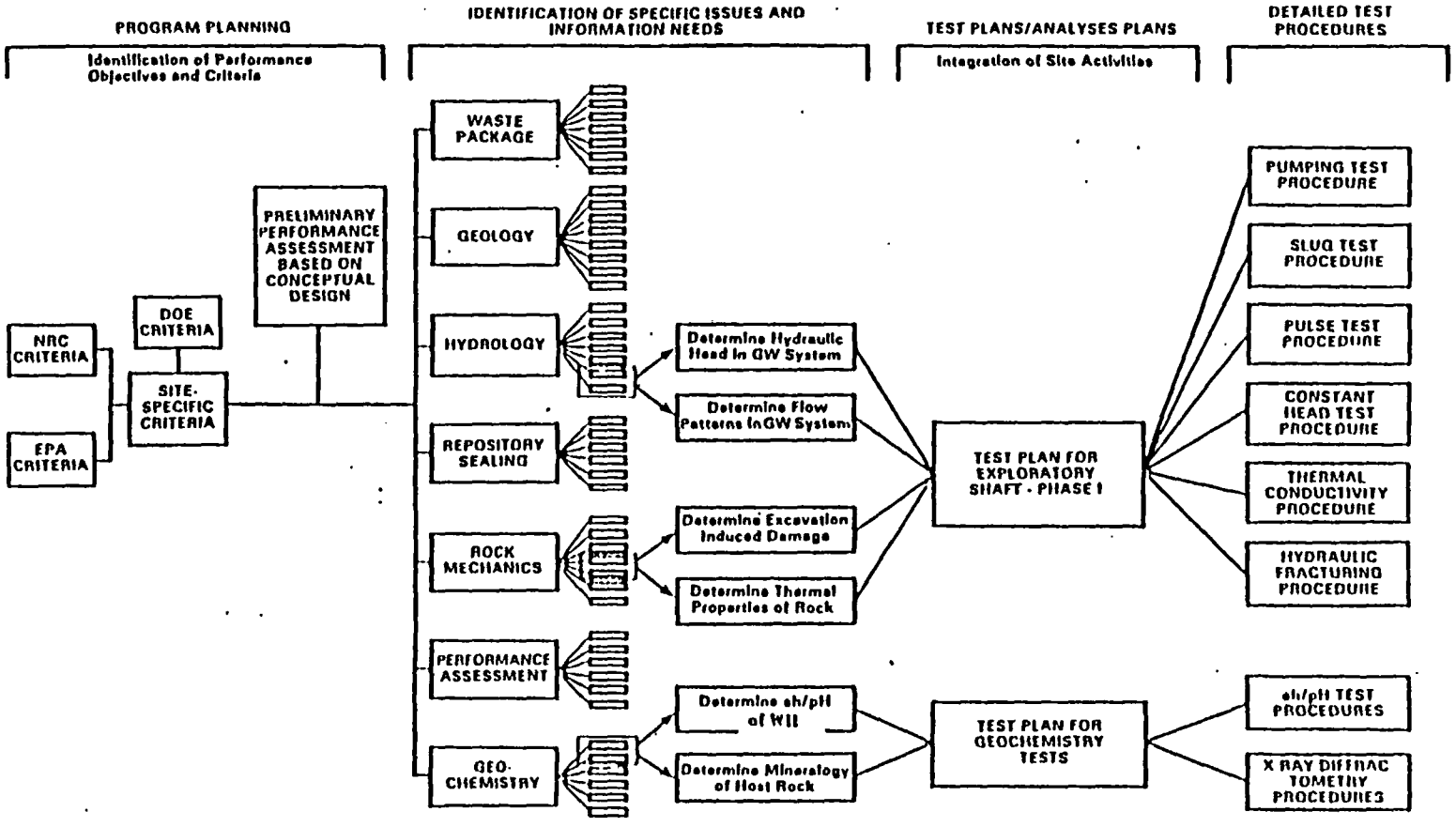
As part of the phase two review, each NRC staff program area (Figure 4) will examine the DOE test plans and procedures in their respective technical area. To the extent practicable, the latest version of DOE test plans and procedures should be either provided in the SCP or referenced and available separately for staff review. This review will also include selective examination of the implementation of the administrative QA controls to each particular technical program area. The results of these reviews (Phases 1 and 2) will be documented in the DSCA for each site.

Phase three will involve NRC site visits and inspections of specific laboratory and field activities (as provided for in 10CFR60 §60.11g) for assurance of implementation of both administrative and technical procedures. This would include reviewing DOE's technical procedures and plans (on a selective basis) to determine whether adequate peer review by qualified technical personnel has been performed in each technical work area. This would also include inspection of data (on a selective basis) after routine QA checks have been performed. Phase three site visits and inspections will be documented in meeting notes.



QUALITY ASSURANCE PROGRAM STRUCTURE

FIGURE 1

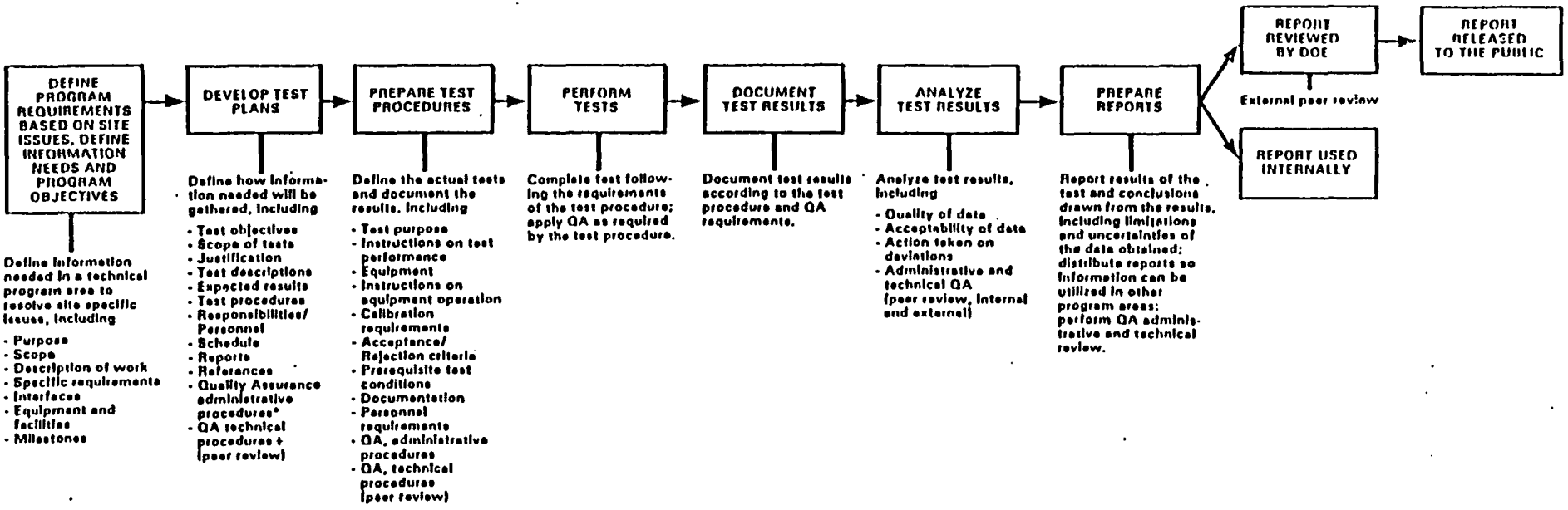


SCOPE OF DIAGRAM:
To show levels of detail involved in developing a technical program.

PURPOSE OF DIAGRAM:
To convey the various levels of detail in planning and controlling a technical program; to define level of detail necessary in executing a technical program properly.

Technical program control: test plans and procedures (illustrative)

FIGURE 2



*QA administrative procedures include procedures for: (1) document control; (2) documented instructions, procedures, and drawings; (3) control of materials, equipment, and services; (4) use of qualified personnel; (5) inspections; (6) documented test plans; (7) control of test equipment; (8) control of samples; (9) nonconformance reports; (10) corrective action; (11) peer review (both management and technical); (12) audits.

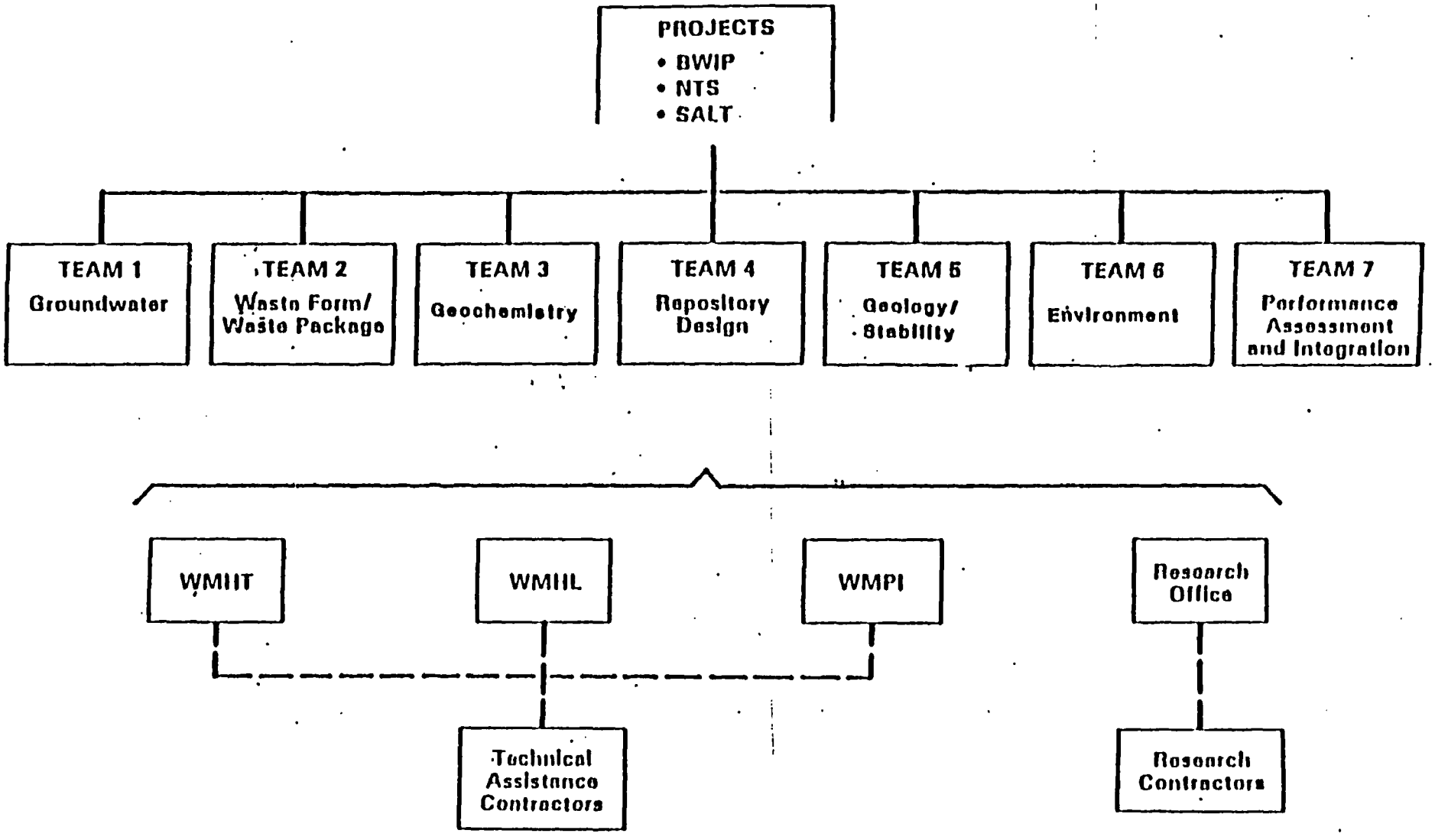
+ QA technical procedures include the actual internal and external peer reviews (both management and technical).

SCOPE OF DIAGRAM:
To show chronology of events in development of a testing program.

PURPOSE OF DIAGRAM:
(1) To show a breakdown sequence of development of plans to resolve problem of timely access to data by NRC. (2) To show the involvement of QA, both administrative and technical, in each step of program.

Test method development (illustrative)

FIGURE 3



SCP REVIEW PROJECTS

FIGURE 4

ATTACHMENT 1

ACCEPTANCE CRITERIA FOR QA PROGRAM*
(HIGH LEVEL WASTE REPOSITORY PROGRAM)

1. The organization elements responsible for the QA program are acceptable if:

   1.1 The responsibility for the overall program is retained and exercised by the DOE through a QA organization at DOE headquarters and at the appropriate field office. While the line organizaton is responsible for performing quality affecting activities properly, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls.

   1.2 DOE describes major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations.

   1.3 DOE describes how responsibility is exercised for the overall QA program. The extent of management oversight from DOE headquarters and from the field office should be addressed.

   1.4 DOE evaluates the performance of work by its prime contractor/program managers at least annually.

   1.5 Qualified individual(s) or organization element(s) are identified within DOE's organization as responsible for the quality of the delegated work prior to initiation of activities.

   1.6 Clear management controls and effective lines of communication exist for QA activities between DOE and its prime contractor/program managers to assure direction of the QA program.

   1.7 Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program and the lines of responsibility.

*Exceptions and alternatives to the acceptance criteria appropriate to a specific activity or item may be adopted provided adequate justification is given.

1.8 The QA organization is involved in the aspects of the high level waste repository program that affect safety. The extent of QA controls is determined by the QA staff in combination with the line staff and is dependent upon the specific activity, its complexity, and its subsequent effect upon public safety.

1.9 DOE and its prime contractors/program managers describe the QA responsibilities of each of the organizational elements noted on the organization charts.

1.10 DOE and its prime contractor/program managers identify a management position within each respective organization that retains overall authority and responsibility for the QA program (normally, this position is the QA Manager) and this position has the following characteristics:

a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.

b. Has effective communication channels with other senior management positions.

c. Has responsibility for approval of QA Manual(s), changes to, and interpretations thereof.

d. Has no other duties or responsibilities unrelated to QA that would prevent his full attention to QA matters.

The individual holding this position is qualified to do so based on his management and QA experience and knowledge.

1.11 Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization (with possible exception for design, item 3.7; certain inspections, item 10.2; and for test data evaluation, item 11.3).

1.12 Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:

a. Identify quality problems.

b. Initiate, recommend, or provide solutions through designated channels.

c. Verify implementation of solutions.

d. Stop unsatisfactory work.

Those persons and organizations with the above authority are identified and a description of how those actions are carried out is provided.

1.13 Provisions are established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel.

1.14 Designated QA individuals are involved in day-to-day site activities important to safety.

1.15 Policies regarding the implementation of the QA program are documented and made mandatory.

1.16 The person at the site responsible for directing and managing the site QA program is identified by position and has appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. This individual is free from non-QA duties and can thus give full attention to assuring that the QA program at the site is being effectively implemented.

2. Activities related to Quality Assurance Program are acceptable if:

2.1 The QA program includes a commitment that items and activities important to safety will be subject to the applicable controls of the QA program. The items and activities covered by the QA program are identified.

2.2 The QA program includes a commitment that any development, control, and/or use of computer programs will be conducted in accordance with the QA program. Guidance for the content of documentation of computer codes is provided by NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management.

2.3 A brief summary of the DOE and prime contractor/program manager QA policies is given.

2.4 a. Provisions are established to assure that quality-affecting procedures required to implement the QA program are consistent with QA program commitments and policies and are properly documented, controlled, and made mandatory through a policy statement or equivalent document signed by an identified, responsible official.

b. The QA organization reviews and documents concurrence with the quality-related procedures relative to QA requirements.

2.5 The QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls are to be applied

to specific items and activities. This effort involves applying a defined graded approach in accordance with importance to safety and affects such disciplines as design, procurement, document control, inspections, tests, special processes, records, audits, and others described in 10 CFR Part 50, Appendix B.

2.6 Existing or proposed QA procedures and detailed technical procedures are identified reflecting that each criterion of 10 CFR Part 50, Appendix B, appropriate to specific items and activities, will be met by documented procedures.

2.7 A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA program to 10 CFR Part 50, Appendix B. These measures should include:

a. Frequent contact with program status through reports, meetings, and/or audits.

b. Performance of an annual assessment preplanned and documented. Corrective action is identified and tracked.

2.8 Indoctrination, training, and qualification programs are established such that:

a. Personnel responsible for performing quality-affected activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.

b. Personnel verifying activities affecting quality are trained and qualified in the principles, techniques, and requirements of the activity being performed.

c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.

d. Appropriate management monitors the performance of individuals involved in activities affecting quality and determines the need for retraining and/or replacement. A system of annual appraisal and evaluation can satisfy this criterion.

e. Qualified personnel are certified in accordance with applicable codes and standards.

2.9 Applicable portions of NQA-1, as endorsed by Regulatory Guide 1.28 Rev. 3, are applied to items and activities important to safety.

3. Activities related to Design Control are acceptable if:

3.1 The design control program includes design activities associated with the preparation and review of design documents (encompasses development and technical type documents pertinent to site investigations) including the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents.

3.2 Organizational responsibilities are described for preparing, reviewing, approving, and verifying design documents.

3.3 Errors and deficiencies in approved design documents are documented, and action is taken to assure that all errors and deficiencies are corrected.

3.4 Design interface controls are described.

3.5 Procedures require a documented check to verify the dimensional accuracy and completeness of design drawings.

3.6 Procedures require that design drawings and specifications be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with procedures and that the documents contain the necessary quality assurance requirements.

3.7 Procedures are established and described for design verification activities which assure that the verifier is qualified and is not directly responsible for the design (i.e., neither the performer nor his immediate supervisor except as noted in 3.8).

3.8 When peer review is used to verify an activity, the use of the performer's immediate supervisor to perform the peer review is limited to those cases where (1) the supervisor is the only technically qualified individual and (2) the need is documented and approved in advance by the supervisor's management. (While review by a performer's immediate supervisor is encouraged, such review does not normally constitute independent peer review nor should the independent peer review be construed to dilute or replace the responsibility of supervisors for the quality of work performed under their supervision.)

3.9 The responsibilities of the verifier(s), the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in procedures.

3.10 Design and specification changes, including field changes, are subject to the same design controls that were applicable to the original design.

4. Activities related to Procurement Document Control are acceptable if:

4.1 Procedures are established for the review of procurement documents by QA personnel to determine that quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and procurement documents have been prepared, reviewed, and approved in accordance with QA program requirements. To the extent necessary, procurement documents should require contractors and subcontractors to provide an acceptable quality assurance program.

4.2 Organizational responsibilities are described for (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluations; and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described.

5. Activities related to Instructions, Procedures, and Drawings are acceptable if:

5.1 Organizational responsibilities are described for assuring that activities affecting quality are (1) prescribed by documented instructions, procedures, and drawings and (2) accomplished through implementation of these documents.

5.2 Procedures are established to assure that instructions, procedures, and drawings include acceptance criteria for determining that important activities have been satisfactorily accomplished.

6. Activities related to Document Control are acceptable if:

6.1 The scope of the document is described, and the types of controlled documents are identified.

6.2 Procedures for the review, approval, issuance, and revision of documents are established. These procedures assure technical adequacy and inclusion of appropriate quality requirements. The QA organization reviews and concurs with these documents with regards to QA-related aspects.

6.3 Procedures are established to assure that correct and applicable documents are available at the location where the activity will be performed prior to commencing the work.

6.4 Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revisions in work areas in a timely manner.

6.5 A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specificiations, drawings, and procurement documents.

6.6 When documents which require verification by peer review are released prior to peer review, they are so identified.

7. Activities related to Control of Purchased Material, Equipment, and Services are acceptable if:

7.1 Organizational responsibilities are described for the control of purchased material, equipment, and services.

7.2 Procedures governing procurement of items or services, including appropriate QA organization participation, provide for:

a) evaluation and selection of suppliers
b) verification of supplier's activities, and
c) receiving inspections

7.3 The service organization furnishes the following records to the purchaser:

a. Documentation that identifies the purchased service and the specific procurement requirements (e.g., codes, standards, and specifications) met.

b. Documentation identifying any procurement requirements that have not been met.

c. A description of those nonconformances from the procurement requirements dispositioned "accept as is" or "repair".

The review and acceptance of these documents should be described in the purchaser's QA program.

7.4 Suppliers' certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented.

7.5 For commercial "off-the-shelf" items where specific QA controls appropriate for nuclear applications cannot be imposed in a practicable manner, special quality verification requirements shall be established and described to provide the necessary assurance of an acceptable item by the purchaser.

8. Activities related to sample and hardware Identification and Control are acceptable if:

8.1 Controls are established and described to identify and control samples and hardware. The description should include organizational responsibilities.

8.2 Procedures are established which assure that identification is maintained either on the samples and hardware or on records traceable thereto and that only correct samples and hardware are used.

8.3 Identification of samples and hardware can be traced to the appropriate documentation such as drawings, specifications, purchase orders, drilling logs, test records, inspection documents, and nonconformance reports.

8.4 Correct identification of samples and hardware is verified and documented prior to release.

9. Activities related to Control of Special Processes are acceptable if:

9.1 The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, is provided.

9.2 Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.

9.3 Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. The QA organization is involved in the qualification activities to assure they are satisfactorily performed.

9.4 Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

9.5 Qualification records of procedures, equipment, and personnel associated with special processes are established and maintained.

10. Activities related to Inspection are acceptable if:

10.1 The scope of the inspection program is described that indicates an effective inspection program has been established. Program procedures provide criteria for determining when inspections are required or define how and when inspections are performed. The QA organization participates in these functions.

10.2 Organizational responsibilities for inspection are described. Individuals performing inspections are part of the QA organization. For inspections requiring special expertise, other individuals may be used provided the independence of the inspection function is maintained.

10.3 A qualification program for inspectors (including NDT personnel) is established and documented, and the qualifications and certifications of inspectors are kept current.

10.4 Inspection procedures, instructions, or checklists provide for the following:

a. Identification of characteristics and activities to be inspected.

b. A description of the method of inspection.

c. Identification of the individuals or groups responsible for performing the inspection operation.

d. Acceptance and rejection criteria.

e. Identification of required procedures, drawings, and specifications and revisions.

f. Recording inspector or data recorder and the results of the inspection operation.

g. Specifying necessary measuring and test equipment including accuracy requirements.

10.5 Procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.

10.6 Inspection results are documented and evaluated, and their acceptability is determined by a responsible individual or group.

11. Activities related to Test Control are acceptable if:

11.1 The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide criteria for determining when a test is required or how and when testing activities are performed. The QA organization participates in these functions.

11.2 Test procedures or instructions provide for the following:

a. The requirements and acceptance limits contained in applicable documents.

b. Instructions for performing the test.

c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled

environmental conditions, and provisions for data collection and storage.

d. Mandatory inspection hold points (as required).

e. Acceptance and rejection criteria.

f. Methods of documenting or recording test data and results.

g. Provisions for assuring test prerequisites have been met.

11.3 Test results are documented, evaluated, and their acceptability determined by a responsible individual or group.

12. Activities related to Control of Measuring and Test Equipment are acceptable if:

12.1 The scope of the program for the control of measuring and test equipment is described and the types of equipment to be controlled are established.

12.2 QA and other organizations' responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program.

12.3 Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) for measurement, inspection, and monitoring. The review and documented concurrence of these functions is identified.

12.4 Measuring and test equipment is identified and traceable to the calibration test data.

12.5 Measuring and test equipment is labeled or tagged or otherwise documented to indicate due date of the next calibration.

12.6 Measuring and test equipment is calibrated at specified intervals based on required accuracy, purpose, degree of usage, stability, characteristics, and other conditions affecting the measurement.

12.7 Calibrating standards have greater accuracy than standards being calibrated to assure that requirements being calibrated will be within the required tolerance. Calibrating standards with the same accuracy may be used if this is shown to be adequate for the requirements.

12.8 Calibration standards are traceable to nationally recognized standards; where national standards do not exist, provisions are established to document acceptability of the standard.

12.9 When measuring and test equipment is found to be out of calibration, evaluations are made and documented to determine the validity and acceptability of measurements performed since the last calibration. Inspections or tests are repeated on items determined to be suspect.

13. Activities related to Sample and Hardware Handling, Storage, and Shipping are acceptable if:

13.1 Sampling and hardware handling, preservation, storage, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.

13.2 Procedures are established and described to control sample and hardware handling, storage, packaging, and shipping in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

14. Activities related to Inspection, Test and Operating Status (17.1.14) are acceptable if:

14.1 Procedures are established to control the application and removal of status indicators such as tags, markings, labels, and stamps, and to record the status of activities as appropriate.

14.2 Procedures are established to control altering the sequence of required inspections and tests.

15. Activities related to Nonconformances are acceptable if:

15.1 Procedures are established for identifying, documenting, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming items and activities. The procedures identify individuals authorized to dispose of and close out nonconformances.

15.2 QA responsibilities related to nonconformance control are described.

15.3 Documentation identifies and describes the nonconformance, dispositions the nonconformance, and includes signature approval of the disposition.

15.4 Nonconformance reports are periodically analyzed by the QA organization to show quality trends, and the significant results are reported to upper management for review and assessment.

16. Activities related to Corrective Action are acceptable if:

16.1 Procedures are established indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures.

16.2 Corrective action is documented and initiated following a nonconformance to preclude recurrence. The QA organization is involved in the documented concurrence of the adequacy of the corrective action to assure that QA requirements are satisfied.

16.3 Followup action is taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner.

16.4 Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition are documented and reported to immediate management and upper levels of management for review and assessment.

17. Activities related to Quality Assurance Records are acceptable if:

17.1 The scope of the records program is described. QA records include geotechnical samples and data, results of reviews, inspections, tests, audits, and material analyses, monitoring of work performance, qualification of personnel, procedures, and equipment, and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports, design review reports, peer review reports, nonconformance reports, and corrective action reports.

17.2 QA and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to QA records.

17.3 Controls ensure that records accurately reflect the as-built (i.e., analyzed, designed, fabricated, installed, and tested) condition of the repository.

17.4 Inspection and test records contain the following where applicable:

a. A description of the type of observation.
b. The date and results of the inspection or test.
c. Information related to conditions adverse to quality.
d. Inspector or data recorder identification.
e. Evidence as to the acceptability of the results.
f. Action taken to resolve any discrepancies noted.

17.5 Suitable facilities for the storage of records are described and utilized.

18. Activities related to Audits are acceptable if:

18.1 Internal and external audits to assure that procedures and activities comply with the overall QA program are performed by DOE and its prime contractors/program managers.

18.2 An audit plan is prepared identifying audits to be performed, their frequencies, and schedules. Audits are regularly scheduled based upon the status and safety importance of the activities being performed and are initiated early enough to assure effective QA.

18.3 Audits include an objective evaluation of the quality-related practices, procedures, instructions, activities, and items and the review of documents and records to ensure that the QA program is effective and properly implemented.

18.4 Audit data are analyzed by the QA organization and the results are reported to management for review and assessment.

18.5 Audits are performed in accordance with pre-established written procedures or checklists and conducted by trained personnel having no direct responsibilities in the areas being audited.