

U.S. DEPARTMENT OF ENERGY
memorandum

DATE: April 28, 1983

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S-10

'83 MAY -3 P5:24

SUBJECT: Additional Information Related to Meeting with NRC on Quality Assurance

TO: Distribution

Attached for your information is the QA chapter from NRC's draft Site Characterization Analysis of the BWIP Site Characterization Report. NRC staff has indicated that they would like to discuss it in the meeting planned for May 12, 1983, along with their proposed review plan for site investigations.

The meeting is scheduled to start at 9:00 am, in room E-401, here in Germantown, Maryland. I will get an agenda to you as soon as possible.

T. P. Longo
Thomas P. Longo
Nevada Repository Team
Nuclear Waste Policy Act
Project Office

Attachment

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10 QUALITY ASSURANCE PROGRAM

10.1 Introduction

Section 60.11(a) of proposed 10 CFR 60 identifies quality assurance (QA) as a key element of site characterization activities for a nuclear waste repository. An adequate QA program is necessary to ensure confidence in the geotechnical data obtained for site characterization and to support potential licensing of the BWIP site.

10.2 Description and Evaluation of the BWIP QA Program

SCR Chapter 18 addresses 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," as required by proposed 10 CFR 60, Subpart G. The administrative procedures presented in the SCR are based on the 18 criteria of 10 CFR 50, Appendix B and appear to be relatively well developed. However, detailed test plans and technical procedures are not provided or referenced in most of the technical areas described in the SCR. An important element of a QA program is that there be documented procedures guiding the activities related to safety (10 CFR 50 Appendix B, Criterion V). Therefore it is necessary that detailed technical procedures be developed for each technical area following the requirements spelled out in the administrative QA procedures. These technical procedures should contain instructions for actual performance of testing and investigations. In addition to providing a framework for an adequate QA program, DOE should also provide evidence of proper implementation of the program. In the description of site characterization activities in the SCR, a detailed description of the QA procedures (as described in SCR Section 18.5) in each program area is lacking (e.g., detailed QA program for the exploratory shaft is not provided, see page 14.3-73). This concern is discussed in more detail in the following narrative.

An important first question in conducting licensing assessments will relate to quality of data used in support of the license application for the proposed site and repository design. In addition to questioning relevance and completeness of data supplied in the license application, the licensing process must explicitly address the question of whether or not data are of adequate quality so that licensing determinations can be made with reasonable confidence.

The quality of data is virtually determined by the specific data gathering methods and procedures that are used. It is important, therefore, that specific methods to be used in data gathering and in the site characterization program be the subject of the prelicensing consultation between DOE and NRC. The need to deal with the question of data gathering methods was identified in RG 4.17 (Section 1.3).

10.2.1 Level of Detail of Plans and Procedures Needed

The SCR does not present adequate details regarding implementation of site characterization plans. A complex technical program must 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 should go from identification of general performance objectives and criteria to detailing specific technical procedures. Figure 10.1 illustrates this, and it is consistent with what the staff understands the BWIP planning structure to be. Quality assurance must be applied at all levels of the program.

As shown in Figure 10.1, site characterization planning must start by considering EPA and NRC criteria. After a site is selected for further investigation, specific issues are identified, based on regulatory criteria and preliminary evaluation of repository performance.

The program can then be divided into program areas related to technical disciplines. 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.

The development of the test plans and test methods is an important element in providing quality assurance for site characterization data. Figure 10.2 illustrates the development and chronology of events in planning and performing a testing program. This also shows the role of QA throughout the procedure, including how QA procedures incorporate reviews by (1) technical management and (2) peer review groups.

Figure 10.2 also illustrates the point where data should be documented (i.e., document test results) prior to analysis of test results. All data should be recorded under full QA requirements at this point in the test program. This data should be available to all interested parties (e.g., NRC, State programs, etc.) for inspection at an early date after it is documented.

In reviewing the SCR, the staff generally found that test plans and test procedures were not provided or referenced (see Figure 10.1). The SCR stops at the "information needs" level. The information presented is very general and does not give the staff enough detail to provide comments on test plans. Some procedures have been examined in previous workshops with DOE, but the staff expected this information to be at least referenced in the SCR. The staff recognizes that not all test plans and procedures may be needed at this time. However, some test plans (e.g., exploratory shaft and waste package development testing) should be available for QA review. Each chapter of this Draft SCA includes comments on the level of detail of the plans provided and gives examples of deficiencies.

10.3 NRC Conclusions and Comments

SCR Chapter 18, "Quality Assurance," addresses the 18 criteria of 10 CFR 50, Appendix B, and it appears to be relatively well developed. However, details on implementation of the QA program are not presented.

Comments on QA needs in various technical program areas are provided in the relevant chapters and Appendix B of this Draft SCA. The NRC staff's specific comments on QA are as follows:

- (1) Many documents are referred to in the discussion of the QA program. These include: implementing functional procedures manuals, the BWIP procedures manual, the Rockwell data package manual, and the Rockwell functional manual. However, these are not listed as references at the end of the chapter. No BWIP document is referenced at the end of the QA chapter. So that implementation of the QA program described in Chapter 18 can be monitored, all of these documents should be identified and referenced in the QA chapter.
- (2) SCR Section 18.11 states that test plans are prepared for each major test program. However, few detailed test plans are referenced in the SCR for any of the major test programs mentioned. For example, the discussion of the exploratory shaft in Chapter 17 does not reference any detailed test plan. Because this activity was scheduled for January 1983, a detailed QA program and test plan for the exploratory shaft (as mentioned on SCR page 14.3-73) should be available now. This specific item was raised to DOE in January 1983 (Miller, 1983) and is discussed in Section 6.3.3. Further, few of the planned individual tests listed in the SCR provide any reference to test plans. Also, RG 4.17 requested a description of the QA program to be applied to each planned test and a discussion of the limitations and uncertainty in the data. No such details are included in any of the plans listed in SCR Chapters 13 through 16. Plans that contain the technical procedures to be used during site characterization activities should also be made available for review.
- (3) SCR Section 18.3 does not address the methods to be used to define the degree to which analytic methodologies should be validated for application to any particular time in repository history. Methods for reliability analyses, as well as requirements for establishing reliability design requirements for components and systems, should be developed early in the design program. Reference is made to DOE-RL Order 5700.2 (DOE-RL, 1982) and DOE Order 6430 (DOE-HQ, 1981) which identify the process for design and planning. These documents contain the information to be presented in the conceptual design. The SCR does not contain reference to such information. DOE should address this area in the near future.

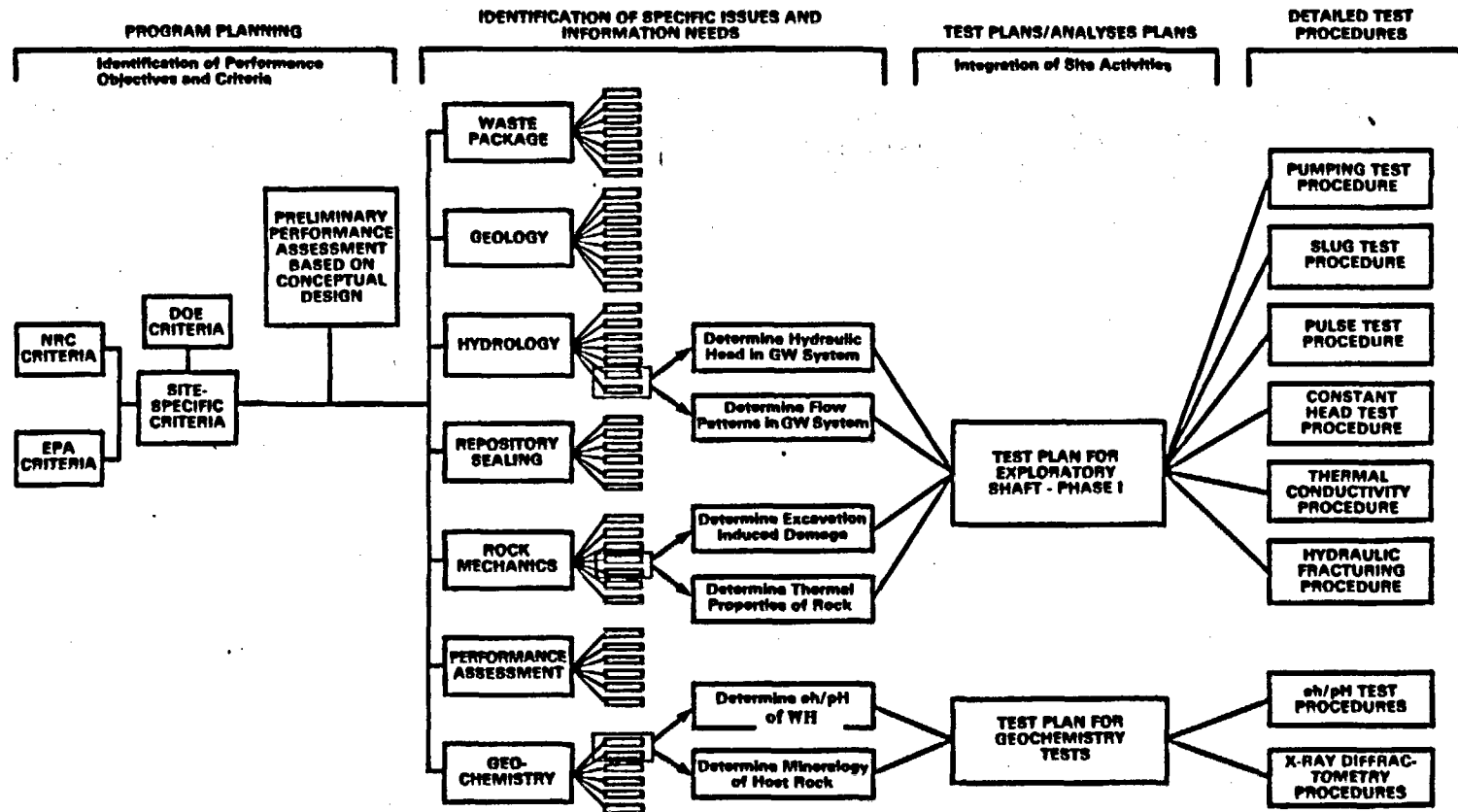
In summary, although the administrative procedures appear to be relatively well developed, the SCR is deficient because it does not provide or reference enough detail on the QA methods to be used in each technical area for the staff to make an independent evaluation of the quality of data being gathered and to be gathered.

REFERENCES

DOE-HQ, 1981, "General Design Criteria for Department of Energy Facilities," DOE Order 6430 (Draft), U.S. Department of Energy, Washington, D.C., June 10, 1981.

DOE-RL, 1982, "Project Management Systems," DOE-RL Order 5700.2, U.S. Department of Energy, Richland Operations Office, Richland, Washington, March 15, 1982.

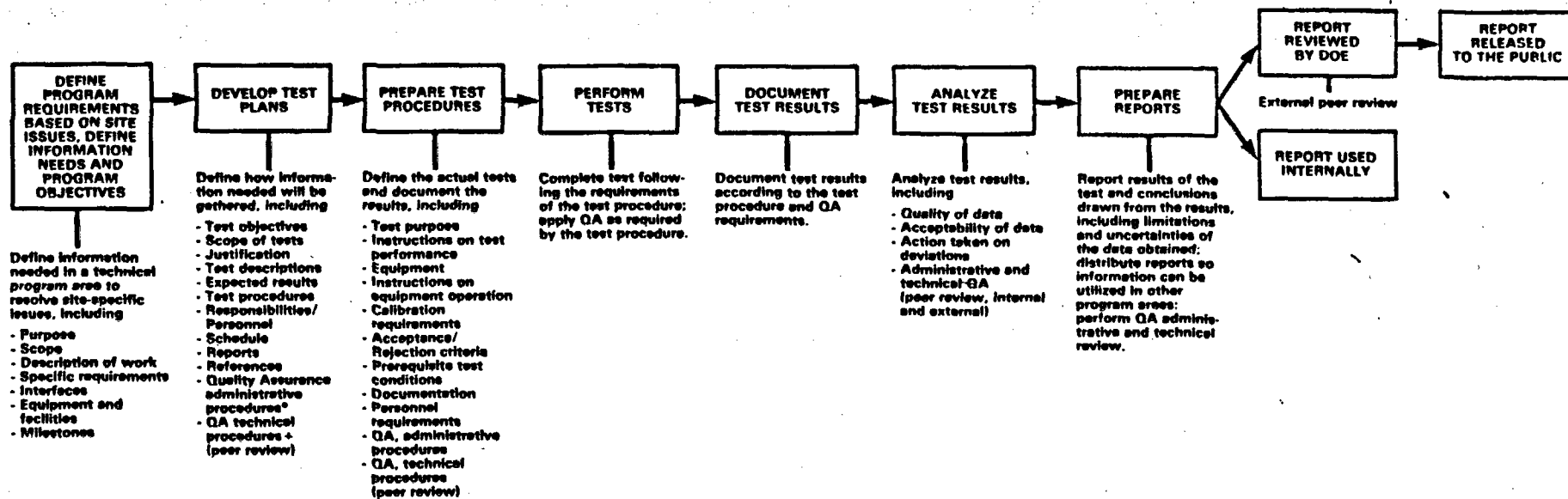
Miller, H. J., NRC, letter to J. H. Anttonen, BWIP, "Additional Information Request on the BWIP Exploratory Shaft Construction and Sealing Program," January 13, 1983.



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.

Figure 10.2 Test method development (illustrative)



*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.

Figure 10.1 Technical program control: test plans and procedures (illustrative)