UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

May 7, 1984

MEMORANDUM FOR: Robert E. Browning, Director
Division of Waste Management

FROM: F. Robert Cook, Senior On-Site Licensing Representative, Basalt Waste Isolation Project (BWIP)

SUBJECT: COMMENTS ON NRC REVIEW PLAN: QUALITY ASSURANCE PROGRAMS FOR SITE CHARACTERIZATION OF HIGH LEVEL NUCLEAR WASTE REPOSITORIES, MARCH 1984

1. The "abstract' focuses on the importance of DATA at the expense of other important information, for example, analyses, quality assurance information and other information supporting a license application. The word "information" rather that "data" should be used in the abstract.

2. Revise the 3rd sentence of the 2nd paragraph on page 3 as follows: "This review will be divided into basically four activities which will include: (1) review of the description of the quality assurance program required by 10CFR60 as presented in the Site Characterization Plan or elsewhere, (2) review of other software, including procedures to be developed and utilized for design and site characterization activities, (3) site visits and inspections of specific laboratory and field activities implementing the QA plan with interviews of cognizant personnel and (4) and inspection or overchecking of hardware and natural system characteristics."

3. Revise the BACKGROUND, page 6, as follows: "DOE and its contractors are currently involved in performing laboratory and field investigations (site characterization activities) in various technical areas such as geology, hydrology, seismology, geophysics, geochemistry, rock mechanics, radiation effects, and others--all of which are generally considered part of geotechnical studies explorations and/or investigations. In addition other engineered system design activities are being performed in the areas of metallurgy, manufacturing process development, engineered barrier material characterization, radiation effects and others. Data being gathered and analyzed in these activities and other information will be used by DOE to support a license application required by 10CFR60 and provide the basis for the Commission to issue a construction authorization in the process of considering the license application. It is also expected that DOE will use computer codes in conjunction with site characterization, design and construction activities, and that these codes will be documented

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in the Site Characterization Plan and license application as appropriate for analyses that are to be accomplished after submittal of the plan or application, as the case may be. NRC concerns regarding public health and safety have been established in the regulatory requirements (10CFR60) for nuclear waste repositories. As part of the regulatory requirements, a quality assurance (QA) program shall be implemented by DOE for all systematic actions necessary to provide adequate confidence that the geologic repository and it's subsystems or components will perform satisfactorily in service. Therefore, an NRC review plan is necessary to guide the Staff in its evaluation of the adequacy of any QA program being considered."

The changes in (3) above are intended to clarify the appropriate scope and applicability of a QA program and to eliminate the notion that the review plan establishes additional CRITERIA. The context of a Staff review of a QA program should be that it is a sampling of the overall adequacy of any given plan and not a complete check of the plan relative to minimum requirements. This change stems from lessons learned in the reactor arena, reported in the recent Report to Congress, where it was described how licensees set their goals at the minimum REQUIRED by Staff and, as a result, the respective QA systems lost their effectiveness.

4. As part of the background I consider two terms are of key importance in describing the scope of QA programs required by 10CFR60. They are DESIGN and separately CONSTRUCTION. Both need definition in the subject review plan.

The term DESIGN throughout Part 60 is used as a noun or noun adjective; hence the definition in the Atomic Energy Act, Section 11i, appears appropriate--"The term 'design' means (1) specifications, plans, drawings, blueprints, and other items of like nature; (2) the information contained therein; or (3) the research and development data pertinent to the information contained therein."

The term CONSTRUCTION as used in the context of Subpart G of 10CFR60, Quality Assurance, has a broader connotation than is suggested in its usage in the definition of the term "commencement of construction" in Part 60.2, Definitions. The definition in 10CFR21.3(c) is nearly appropriate for describing the application of a quality assurance program for a repository. This definition follows: " 'CONSTRUCTING' or 'CONSTRUCTION' means the design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and consulting services related to the facility or activity that are important to safety." Note I would make a slight change to make the grammatical use of the term 'design' consistent with the definition above. Specifically, I would add the word 'activities' after the word 'design' in the definition of CONSTRUCTING or CONSTRUCTION quoted above.

5. On page 7, first sentence, delete the words 'including those' since they do not add any meaning to the statement, but could suggest that there are requirements for QA elsewhere. Shorten the second sentence to 'These are included in the following sections.'

6. Concerning paragraph 1.2.1, page 7, reference should be made to 10CFR21.41, 10CFR60.75(b) and 10CFR19.15 for Commission access to records and individuals. Such access is equally necessary during design and site characterization as it is after a license application is made or a license is issued, since decisions, data collection and other activities important to of the potential repository design and siting as they affect health and safety are being accomplished during these early phases of the project's activities. The appropriate sections quoted from the respective regulations should be repeated in the text of the subject review guide.

7. The sections of Part 60 that refer to the "site characterization REPORT" need a footnoot to explain that the terminology will be changed to be consistent with NWPA.

8. Section 1.2.3, page 11, should refer to the "QA plan, procedures and other information pertinent to the development of th plan and procedures" in lieu of "QA methods" contained in the 8th line. Also in the 6th line "data collection" is to restrictive. The word "activities should be used instead of "data collection".

9. Information regarding the qualifications of the personnel preparing the QA plans and its respective procedures should also be identified as an area to be reviewed. Since our review will only be a sampling, knowledge of qualifications is of primary importance. This idea should be incorporated in paragraph 1.2.3.

10. The first paragraph of 2.1, page 12, tends to limit the scope of aspects of QA plans that should be described in the Site Characterization Plan by identifying various specifics. This section should only refer to the format and content guide for the Site Characterization Plan, otherwise conflicting and/or redundant Staff positions will result.

11. Section 2.2, pp. 12-14,indicates that geotechnical work including exploration techniques, test procedures, data acquisition data reduction, and interpretation of results does not lend itself to approaches which are highly prescriptive and goes on to require application of peer reviews of nearly all activities. It is not the function of the subject review plan to require peer reviews, or as far as that goes, anything outside the regulations. This notion of requiring peer reviews should be eliminated from the review plan. The idea of reviewing the adequacy of procedures prescribing peer reviews and the overall application of peer reviews as part of the QA plan is appropriate, however. This section should note that research and

development as applied to engineered systems during design activities make use of peer reviews and contain analogous problems in specifying highly prescriptive approaches. However experience in other licensing arenas provides models which the Staff may use in reviewing the geotechnical areas of the QA plan.

Additional comments will be forwarded separately.

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