

FEB 01 1991

Mr. Morton E. Wacks
Technical Program Chairman
Waste Management '91'
The University of Arizona
College of Engineering and
Mines, Building 20
Tucson, AZ 85721

Dear Mr. Wacks:

I was pleased to learn that my paper "Conformity of Guidance on Low-Level Waste Disposal Facilities with the Requirement of 10 CFR Part 61" (Log #121) had been accepted for presentation in the Waste Management '91 Symposium.

Per your request, I am enclosing a hardcopy of my paper along with a computer diskette for your use in publishing my paper in the proceedings.

I look forward to attending and participating in the upcoming Symposium.

Sincerely,

(SIGNED) JOHN T. GREEVES

John T. Greeves, Deputy Director
Division of Low-Level Waste Management
and Decommissioning
Office of Nuclear Material Safety
and Safeguards

Enclosures: As stated

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CONFORMITY OF GUIDANCE ON LOW-LEVEL WASTE DISPOSAL FACILITIES WITH THE REQUIREMENTS OF 10 CFR PART 61

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ABSTRACT: The NRC staff has completed an evaluation of whether the Standard Format and Content Guide (NUREG 1199) and the Standard Review Plan (NUREG 1200) comport with the requirements of 10 CFR Part 61. These reviews identified four items [Meteorology, Seismology, Reference to 10 CFR Part 20, and Quality Assurance] that appear not to comport with Part 61. Also, several statements in the SRP are imprecise or incorrectly place emphasis on certain matters as regulatory requirements, rather than regulatory guidance. In addition, the staff evaluated any need for revisions as a result of its review of the Prototype License Application Safety Analysis Reports (PLASAR) submitted by the Department of Energy. Other sections of these documents were identified for updating, based on experience gained during the PLASAR Review and interactions with States responsible for LLW disposal. NRC has taken actions to correct the regulatory requirements items and has provided early notification of the planned corrections to affected States and compacts.

BACKGROUND: The Nuclear Regulatory Commission (NRC) staff issued guidance documents (NUREGs 1199 and 1200) in January 1987, for LLW disposal site license applications. In compliance with the Low Level Radioactive Waste Policy Amendments Act (LLRWPA) of 1985, the staff revised these documents to include engineered alternatives for near-surface disposal. Revision No. 1 was completed in January 1988. Since January of 1988, the NRC staff, States responsible for disposal of LLW, and others have used these guidance documents in preparing for and conducting LLW disposal-site reviews.

Some people have reviewed these documents and have raised questions about whether these guidance documents amount to a

significant expansion of regulatory requirements beyond 10 CFR Part 61. On March 12, 1990, the Commission requested the NRC staff and the Office of the General Counsel (OGC) to: (1) review the Standard Format and Content Guide (SF&C) and the Standard Review Plan (SRP) to ensure that the guidance provided in these documents comports with the specific requirements of the regulations; (2) address any inconsistencies discovered in the staff's review of the PLASARs submitted by DOE; (3) develop a regulatory "road map" that identifies all existing guidance documents that an applicant should consider in its application; and (4) identify concerns that prompt consideration of more restrictive criteria than the regulations themselves. The Commission further requested that these efforts be coordinated with the States, and that conclusions of these reviews, along with recommendations, should be provided to the Commission.

DISCUSSION:

In response to the request by the Commission, the staff and OGC formed a review team to complete the requested actions. Two team members and the OGC representative reviewed each document completely, while the rest of the team reviewed selected sections in their respective technical disciplines. As part of the review process, the team held meetings and conference calls with State representatives (California, Texas, and Pennsylvania) to ensure that any revisions will consider State-identified needs. Meeting minutes were recorded for these meetings, and a complete list of these meetings is provided in Table I.

As a result of this review, the staff and OGC have documented candidate areas for potential rulemaking and revision of the SF&C and SRP as identified in the following discussion. This discussion is separated into three categories: (1) Comport Review; (2) PLASAR Experience; and (3) Interaction with States.

Comport Review

Our review of both the SF&C and SRP was principally based on the standard set forth by the Commission. It is the Commission's view that NRC guidance should accurately reflect what is required in the regulations. Though guidance itself may not be legally binding, it is generally viewed by licensees as mandatory to ensure NRC approval. Guidance should therefore be based on the specific requirements of the regulations and not go beyond what is needed to reasonably demonstrate compliance.

Specifically, for our review, every provision in both the SRP and SF&C characterized as a regulatory requirement should be traceable to some requirement established in Part 61. With but four exceptions in the SRP and one exception in the SF&C, every provision in both documents was traced to a reasonable construction of requirements in Part 61. The four items that were not traceable to a requirement in Part 61 are non-comporting items, and a discussion of each follows. Also, our review acknowledged that some language of the SRP and SF&C is potentially misleading; thus, some sections can be improved through the use of more precise language. The comport review focused on the subsections of the SRP describing what were termed "Regulatory Requirements" under the heading "Acceptance Criteria." Other subsections of the SRP, in particular the subsection entitled "Regulatory Evaluation Criteria" were not part of the focus of the comport review because they are guidance only to NRC staff as to an acceptable method of compliance and do not purport to describe regulatory requirements. However, the SRP will be clarified as to the general intent of the "Regulatory Evaluation Criteria" subsections so as to eliminate possible misinterpretation.

The first non-comporting item is found in SRP 2.2, "Meteorology and Climatology." This section instructs the staff reviewers to use, as a basis for review, criteria contained in 10 CFR Part 50, Appendix A, General Design Criterion 2, "Design Bases for Protection against Natural Phenomena." Since nothing in Part 61 states that applicants or licensees have to apply Part 50 standards, this requirement in SRP 2.2 is not traceable to Part 61 and thus goes beyond what is needed to reasonably demonstrate compliance. However, since there are no current prescriptive regulations that specifically address meteorology and climatology for LLW disposal sites [see 10 CFR 61.12(a), (d)], the reference to Part 50, Appendix A, General Design Criterion 2, "Design Bases for Protection against Natural Phenomena," should be referenced as guidance only under the section "Regulatory Guidance," in SRP 2.2, and the language in the "Evaluation Findings" should be edited for consistency.

The second item is found in SRP 2.3, "Geology and Seismology." As in the first item, this section lists two regulatory requirements that are not traceable to Part 61. It lists as a requirement Part 50, Appendix A, "General Design Criteria for Nuclear Power Plants," as it relates to the design of any safety-related portions of the structures important to safety to withstand the effects of earthquakes. It also lists as a requirement 10 CFR Part 100, Appendix A, "Seismic and Geologic Criteria for Nuclear Power Plants," as it relates to the investigations required to obtain the seismic data necessary to determine site suitability, and as it identifies geologic and seismic factors that have to be taken into account in the siting of the LLW disposal facility. Since Part 61 does not state that applicants or licensees shall comply with either Parts 50 or 100, the SRP, in fact, extends beyond what is needed to reasonably demonstrate compliance in Part 61. However, the staff believes these sections would aid the applicant in meeting the requirements in Part 61 and thus should be clearly referenced as guidance. As a result, the staff will revise the remainder of the text for consistency, in the next amendment to the SRP.

The third item, which refers to 10 CFR Part 20 as an acceptance criterion, is found in SRP 6.1, "Release of Radioactivity." The regulatory requirements identified in 6.1.4, "Release of Radioactivity, Accidents or Unusual Operational Conditions," instruct the staff reviewer to assess the applicant's compliance with the regulations in Part 20. However, although Part 20 applies to all licensees, universally, unless otherwise exempted, it does not establish a licensing design requirement for accidental releases. It covers routine, expected releases of radioactivity. Since SRP 6.1.4 outlines the standard for review for accidents or unusual operational conditions, it is not proper to refer to Part 20 as a regulatory requirement. It can be referenced as guidance. It should be noted that no formal design criteria exist for accidental releases from any NRC-licensed facilities except nuclear power plants.

The fourth item is found in Chapter 9, "Quality Assurance," of both the SF&C and the SRP. These chapters direct the applicant to develop a QA program based on the requirements in 10 CFR 61.12(j). The SRP directs the applicant to NUREG-1293, "Quality Assurance Guidance for a Low-Level Radioactive Waste Proposal Facility," as regulatory guidance.

The term "quality control" (QC) is used in 10 CFR 61.12(j), rather than "quality assurance." Also, 10 CFR 61.12(j) specifically requires that managerial controls and audits be included with the QC requirements, and these are the basic elements of an QA program. The distinction between QA and QC is significant, especially to NRC, which in Part 50, Appendix B, defines both of these terms. QA comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. QA includes a QC program. Typically, QC is considered to be an action within a QA program that is taken by a fabricator, manufacturer, or constructor to control the quality of a material, structure, component, or system to predetermined requirements. Because of the difference in the meaning of QA versus QC, it is important to understand what was intended in the development of Part 61.

Based on a review of Part 61 regulation development, it appears as if the 10 CFR 61.12(j) wording was inadvertently changed by NRC staff from the proposed Part 61 "Quality assurance" terminology to "quality control" in the final Part 61 regulation. Instead of merely changing the terminology in 10 CFR 20.311 (Transfer for disposal and manifests) from "quality assurance" to "quality control," staff also made changes in the wording for 10 CFR 61.12(j). The basis for the 10 CFR 20.311 changes are discussed in the Final Environmental Impact Statement (FEIS), (NUREG-0945, Vol. 2, page B-168/9). There is no discussion in the FEIS for the change from QA in the proposed 10 CFR 61.12(j), to QC.

Since the word changes to the promulgated 10 CFR 61.12(j) were unintentional, the staff proposes a rulemaking action to change the terminology back to QA as contained in the proposed Part 61 regulation. A subsequent action will require staff to make some minor modifications to both SRP 9.1 and NUREG-1293, to conform to the restored QA requirement in Part 61.

OGC and the staff recognized other items in both the SRP and SF&C that could be misinterpreted because of the phraseology of certain sentences. For example, the language in abstracts of both documents needs to be

amended to more strongly indicate that the document is guidance to the requirements in Part 61, and not the requirements in fact, as some have believed. Also, both documents need to be edited to eliminate words that seem obligatory, such as "require/requirement," "comply," "need to," and "must."

Plasar Experience:

After the issuance of the SF&C and SRP, NRC agreed to perform a "mock licensing review" in response to requests by the States for more licensing and technical guidance on engineered alternatives. In November 1988, DOE submitted documents, to NRC to review, that were entitled "Prototype License Application Safety Analysis Report," for design alternatives. The major goal of the PLASAR effort by the NRC staff was to provide assistance to the States and regional compacts, by identifying acceptable and unacceptable alternative design features and concepts in the PLASAR submittals, when evaluated against the acceptance criteria in NUREG-1200. It was also recognized that the mock licensing review would provide the NRC staff with valuable practical experience in using the new SRP, when conducting a licensing review of a LLW facility. The review of the PLASARs allowed weaknesses in the SRPs to be identified by the staff so that future improvements to the guidance documents could be made.

NRC staff concentrated its review efforts on the design and operations-related portions of the PLASAR documents that encompass Sections 3, 4, 5, 6, and 7 of the SRPs. Other SRP sections, for example, Section 2, "Site Characteristics," were either not reviewed by the staff or only minimally assessed, because of the hypothetical nature of the information that would be associated with a fictitious site. The staff did not identify any inconsistencies with its guidance documents as a result of the PLASAR review. However, a number of areas that can be clarified as a result of the review, and staff experience since the last revision of the SRP, have been identified.

Interactions With States

In addition to the Comport and PLASAR reviews, the staff received a number of constructive comments from the States, developers [US Ecology (USE) and Chem Nuclear Systems (CNS)] and consultants (R.F. Weston and Rogers and Associates). There were a number of general and specific comments that are discussed in the following paragraphs.

All participants in the meetings with the staff and OGC agreed that the current SF&C and SRP were good baseline documents for the review of a LLW application. However, some noted that only one document, the SRP, was needed, because it contained the same information covered in the SF&C. The current documents constitute a good road map for identifying reference material needed for LLW site characterization and evaluation. The updated version of these documents should focus on refining the list of reference material, based on the PLASAR review and other experience gained since the last revision. The revised documents and referenced material would then represent an improved regulatory road map for use by applicants and Agreement State regulators. There was some discussion in the meetings about whether the guidance documents asked for too much information. The States and developers commented that generally the requested information was pertinent, and States preferred the applicant to err on the side of submitting more information. Both States and developers noted that providing more information would help reduce the number of questions a regulator would have to ask.

A general comment of some States was that the guidance documents were uneven in level of detail, and redundant. For example, information on monitoring and surface water was requested in numerous sections of the SRP. This caused problems for States and developers who used separate consultants in a compartmentalized manner. In general, it was agreed that revising the documents to limit redundant material would help solve this problem. Technical information should be presented once in the application and referenced in other related sections. A related problem is the need for flexibility in developing the application. For example, CNS commented it makes sense for the unsaturated zone to be characterized in detail for arid sites, but does not for humid sites, where transport time in the unsaturated

zone can be conservatively assumed to be zero. Some State reviewers interpret the guidance documents as requirements and may require detailed information on the unsaturated zone for sites that don't rely on it for meeting performance objectives. Apparently some reviewers and consultants for Agreement States are using the SRP too literally. The NRC review team concluded that the preface to the SRP needs to be strengthened to emphasize that some flexibility needs to be provided for in the review, as long as the applicant explains and justifies the basis for performance of the site and design.

A specific comment made by both USE and the California Department of Health Services was that it was unclear how the guidance documents summarized the findings that are required by 10 CFR 61.23. NRC staff noted that individual sections of the SRP were supporting elements of overall findings. The final Safety Evaluation Report (SER) should be taken as a whole package, where individual sections lead to an overall conclusion that the performance objectives and technical requirements are met. The staff noted that the SRPs were written for use by experienced reviewers. Use of these review procedures by inexperienced reviewers in a compartmentalized approach would be a problem. Such an approach would require close supervision by experienced managers. In response to this concern, the preface and introduction to the SRP should be revised to explain that the reviewers' SER should document all the findings required for the performance objectives and technical requirements in Part 61.

The Texas Low-Level Radioactive Waste Disposal Authority specifically commented that the guidance documents seem to be prepared with a nuclear power plant or high-level waste repository facility perspective. As discussed above in the Comport area, the staff agrees that referring to Part 50, Appendix A, as a requirement, is a mistake and needs to be corrected. However, referencing regulatory guides (RGs) on site characterization (e.g., RG 1.132 and RG 1.138) and American Concrete Institute (ACI) codes such as ACI 349 are quite appropriate. This point was agreed to by most of the States during our discussions. It was suggested that when the SRPs reference other documents, that the staff try to be specific about which sections should apply to a disposal application.

In general, all of the States commented that more guidance was needed for performance assessment and groundwater modeling. They also noted that clarification on floodplain determination and erosion-protection issues needed more attention.

CONCLUSIONS:

As a result of this review and a briefing of the Commission, the NRC staff will complete a number of actions to improve its guidance on disposal of LLW and to assure the guidance comports with 10 CFR 61. The first action is to revise the guidance documents to address the identified comport issues and notify states and compacts of these actions. The SFC and SRP were revised in January to address these issues and copies were mailed to state and compact officials. A proposed rulemaking effort to revise Part 61 to include QA has been initiated within the Commission. An additional revision to the Guidance documents is planned for late 1991 to factor in experience gained during the PLASAR review. The revision planned for in late 1991 will also include a separate section which discusses the requirements within Part 61, specifically identifying the findings to be made on whether the overall performance objectives and other conditions are met, and addressing how individual sections in the SRP contribute to making the findings required by 61.23.

TABLE I

<u>Groups Meeting with NRC</u>	<u>Date</u>
Texas Department of Health (Regulator) and Texas Low-Level Radioactive Waste Disposal Authority (Site Developer)	June 22, 1990
Pennsylvania Bureau of Radiation Protection (Regulator), Weston (consultant), Chem-Nuclear Systems, Inc. (Site Developer) and Judith Johnsrud (Citizen's group)	July 06, 1990
U.S. Ecology, California Operation (Site Developer)	July 11, 1990
Rogers and Associates Engineering Corporation (Developer of PLASAR Application)	July 18, 1990
California Department of Health Services (Regulator) and Weston (Consultant)	July 23, 1990