



Department of Energy
Washington, DC 20585

JUL 20 1992

Mr. Joseph J. Holonich, Director
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Holonich:

As we committed in the February 6, 1992 U.S. Nuclear Regulatory Commission/U.S. Department of Energy management meeting, we are transmitting the enclosed statement "Annotated Outlines for Preparation of License Applications and Their Relationship to the DOE Issues Resolution and the NRC/DOE Licensing Processes" for your information. If you have any questions, please contact Priscilla Bunton of my office at (202) 586-8365.

Sincerely,

John P. Roberts
Acting Associate Director for
Systems and Compliance
Office of Civilian Radioactive
Waste Management

Enclosure:
As stated

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PDR WASTE PDR
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cc:

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**Annotated Outlines for Preparation of License Applications
and Their Relationship to the DOE Issues Resolution
and the NRC/DOE Licensing Processes**

During the U.S. Nuclear Regulatory Commission/U.S. Department of Energy (NRC/DOE) interactions meeting of May 30, 1991, NRC staff suggested that DOE prepare an annotated outline of a license application for the repository based on the NRC Draft Format and Content Regulatory Guide (FCRG) (DG-3003). This suggestion had been discussed briefly with NRC staff by telephone prior to the meeting, and DOE responded that annotated outlines for potential license applications would be prepared for both the mined geologic disposal system (MGDS) and the monitored retrievable storage (MRS) facility. Three other interactions have been held between DOE and NRC staff concerning annotated outlines. These took place on November 20, 1991, February 6, 1992, and June 3, 1992. In December 1991, Commissioner Selin himself suggested that DOE prepare a "bracketed" application. During the June 24, 1992, DOE presentation to the Commission, several Commission members indicated an interest in DOE's continuing annotated outline efforts.

The purpose of this paper is to explain how DOE plans to implement the use of annotated outlines and the associated issue resolution process to interact with NRC to: develop a common understanding of the regulations; respond to and resolve issues; and, further any eventual licensing process under NRC regulations for either the MGDS or MRS, assuming suitable sites are found.

An annotated outline is a draft of a potential license application prepared by DOE following the guidance of NRC. This guidance is provided in the FCRG and, for the MRS, in NRC Regulatory Guide 3.48, (Rev. 1). Among other things, annotated outlines will demonstrate the DOE capability to integrate the NWPAs-required site characterization process, systems engineering and the design process for the MGDS, or the site investigation and evaluation, systems engineering and the design process for the MRS. If suitable sites are identified, annotated outlines will evolve into applications to be used in licensing proceedings under 10 CFR Part 60 or 10 CFR Part 72. An annotated outline is a management tool which facilitates active exchanges, both internal and external, for the identification, clarification, and resolution of issues in a timely manner so as to allow DOE to prepare a license application for an MGDS or MRS, if a suitable site is found. In this way, annotated outlines will close the loop between individual technical or regulatory issues, systems engineering and site characterization or design activities, for an MGDS or MRS, respectively.

The development of annotated outlines is important to the development of documentation which will be acceptable for docketing in an eventual licensing proceeding. Millions of pages of documentation will be docketed and stored in the process of

seeking a license for either the MGDS or MRS. The annotated outlines will provide an organized compilation of data or reference to relevant data and the conclusions drawn from that data. They will document uses of data in performance assessment and design, and document the ongoing resolution of issues in the context of eventual license applications. For the MGDS, it should eliminate some of the anticipated problems of continuity when NRC and DOE personnel leave the program during the long period of prelicensing and licensing interactions.

Unlike the MGDS Semiannual Progress Report, an annotated outline is not simply a compilation of activities, accomplishments, and changes. Such a compilation, by its very nature and the level of project development, i.e., the state which the project has reached, is largely a site characterization document. The scope of the annotated outline initiative is broader. Its organization reflects site characterization as it relates to potential evolution from site suitability to facility licensability. Thus, it is more than a rendition of the history of the development of the project or a snapshot in time of its status. Its focus is the parallel development of site characterization information and the integration of this information into a potential license application based, in part, on NRC staff guidance as to the applicability of regulations in determining how to ensure that public health and safety and the environment are not adversely affected. The annotated outline process will allow DOE to evaluate data collection to satisfy both site characterization and the development of potential license applications. This evaluation of data collection will allow DOE to redirect resources more efficiently to aid site characterization and continue data collection. This is particularly important as the site characterization program is collecting data for a determination of site suitability, and, if the site is found suitable, that data will also be used in materials developed for an environmental impact statement and a licensing proceeding. DOE will endeavor to coordinate the transmittal of the site characterization progress report and the annotated outline for the MGDS to NRC.

Annotated Outline Development Process

Each part of a draft annotated outline will be developed through discussions with DOE project personnel, use of NRC staff published or verbal guidance, and industry experience. DOE personnel will use an annotated outline as a format to develop tables and text for a Safety Analysis Report (SAR) and a license application for each project. This process pinpoints early in license application development process the information that may be needed, assuming suitable sites are found, to complete SARs or license applications under 10 CFR Part 60 or 10 CFR Part 72. Additionally, this process will ensure that this information will be obtained by site specific study programs.

Draft annotated outlines will be revised and refined at appropriate intervals determined by internal DOE Concurrence Review Groups prior to submitting them to NRC staff for their information and to facilitate NRC staff guidance to DOE. As MGDS site characterization and MRS facility designs progress, DOE will update drafts of the annotated outlines based on new information that is developed or obtained. These drafts will also incorporate guidance from the subsequent revisions of the MGDS FCRG or revisions of NRC Regulatory Guide 3.48 (Rev.1) for the MRS, as well as from response to regulatory actions, internal DOE comments and NRC staff comments. The process for development of the annotated outlines will be iterative, with further DOE reviews, revisions, refinements, and transmissions to NRC staff until a site is found to be suitable and a license application can be developed. Each iteration of the MGDS and MRS annotated outlines will be available for public information.

NRC Staff Interaction

The final evolution of an annotated outline into a license application for either the MGDS or MRS cannot take place until a site is found to be suitable. In submitting annotated outlines to NRC staff for their information, DOE does not intend to request they be docketed as part of a license application. However, it must be realized that a license application for a nuclear facility, especially one of the complexity of an MGDS, cannot be completed in the 90 days mandated by Section 114(b) of the Nuclear Waste Policy Act. As a consequence, the preparation of annotated outlines will make it possible for DOE to meet its statutory responsibility and facilitate eventual NRC staff review of the completed MGDS and MRS applications.

DOE will transmit the annotated outlines to NRC to provide information and to facilitate NRC staff guidance to DOE. DOE will not request that NRC staff review the annotated outlines. An annotated outline is a vehicle which allows NRC staff to recognize those areas where DOE requires guidance as a potential applicant under 10 CFR Part 60 or 10 CFR Part 72. Such guidance may identify issues that will have to be addressed. When DOE feels the need for guidance concerning a particular topic, a request for guidance on that topic will be contained in the transmittal letter for that iteration of the annotated outline.

The success of the annotated outline initiative to facilitate issue resolution depends on NRC staff guidance for these first-of-a-kind activities. DOE will be interested in receiving any written or oral feedback that NRC staff wishes to provide for DOE's information and consideration on a subsequent iteration. To provide the benefit of actual experience, DOE will submit formal comments on NRC's FCRG as the need is identified from DOE's internal review and comment on each annotated outline iteration.

Annotated Outlines and Issue Resolution

The annotated outlines will be developed in conjunction with a DOE issue resolution effort. Issue resolution is the process of interaction or negotiation between DOE and NRC regarding technical or programmatic concerns involving the implementation of regulatory requirements. Issues may derive from the annotated outline development process; from comments by NRC staff or other entities at technical exchanges; rulemaking; or, for the MGDS, from the Issues Hierarchy contained in the Site Characterization Plan (SCP) (DOE/RW-0199).

An issue is any regulatory concern with technical and/or programmatic impacts that must be resolved through research, position development, and presentation to the NRC staff, so that the licensing process can move forward. This definition of issue is broader than the definition of issue presented in the Site Characterization Plan for Yucca Mountain site. An issue may be, but is not restricted to (1) an ambiguity in the regulations that needs to be addressed by DOE, (2) new site concerns arising with additional work, (3) residual Site Characterization Analysis open items, or (4) ambiguities arising with respect to review and development of annotated outline iterations.

Issues will be addressed as DOE determines that the data or other information is such that resolution is possible. Resolution of licensing related issues with NRC staff means that DOE and NRC have developed a common understanding of the regulations. Resolution will allow DOE to focus data gathering and resources on those areas where, in DOE's opinion, suitability or licensability remain in question.