

REGULATORY SYSTEMS-BASED LICENSING GUIDANCE DOCUMENTATION

Mark Stephen Delligatti, U.S. Nuclear Regulatory Commission  
Mail Stop 4H3  
Washington, DC 20555  
(301) 492-0430

ABSTRACT

The U.S. Nuclear Regulatory Commission (NRC) has developed a series of licensing guidance documents based on the regulatory requirements in Part 60 of Title 10 of the Code of Federal Regulations (10 CFR Part 60). This regulatory systems-based approach to licensing guidance documentation relies on the definition of the high-level waste repository in 10 CFR Part 60. A document which is important for the frame-work it gives to other programmatic licensing guidance is the Draft Regulatory Guide "Format and Content for the License Application for the High-Level Waste Repository" (FCRG). The FCRG describes a format and content acceptable to NRC for a high-level waste repository license application pursuant to the requirements of 10 CFR Part 60. Other licensing guidance documents will be compatible with the FCRG.

INTRODUCTION

The Nuclear Waste Policy Act, as amended, authorizes the creation of a program for the development of the nation's first geologic repository for high-level radioactive waste. Under this program the U. S. Department of Energy (DOE) is responsible for siting and building the repository while NRC is responsible for its licensing. Just as the development of the repository is a first-of-a-kind activity, so is the regulator-licensee relationship of NRC and DOE. 10 CFR Part 60 implements NRC's licensing responsibilities. Since 10 CFR Part 60 is a new regulation for a unique program, it has been necessary for the NRC staff to develop a set of licensing guidance documents for the NRC staff and DOE to use in the development and review of the license application.

The NRC staff has determined that there are generally four types of guidance documentation needed for this program: Staff Positions, Staff Technical Positions, Regulatory Guides, and the License Application Review Plan. Each of these documents serves a different function in the high-level waste program. While only Regulatory Guides and Staff Technical Positions are specifically issued as guidance to DOE, the other two types indirectly provide guidance to DOE. Historically, Regulatory Guides have been used by NRC to provide guidance on how compliance with regulations can be demonstrated. They are issued by NRC's Office of Nuclear Regulatory Research. In the high-level waste program, NRC will only be issuing three Regulatory Guides because Staff Technical Positions will be the preferred documents for providing guidance to DOE on demonstrating compliance with specific regulatory requirements in 10 CFR Part 60. Staff Technical Positions are equivalent to Regulatory Guides, but are issued by NRC's Office of Nuclear Material Safety and Safeguards, the program office with lead staff responsibilities for NRC's high-level waste repository activities.

*Delligatti*

While Regulatory Guides and Staff Technical Positions provide guidance to DOE, the License Application Review Plan and Staff Positions provide guidance to the NRC staff in its review of the DOE license application. The License Application Review Plan will contain the review procedures and acceptance criteria that the NRC staff will use to evaluate DOE's License Application. Staff Positions are issued by the NRC staff to offer its interpretation of a specific requirement in 10 CFR Part 60. Because these two guidance documents will be used by the NRC staff in judging the adequacy of the License Application, DOE is advised to use them as well.

It should be noted that compliance with Staff Technical Positions, Regulatory Guides and the License Application Review Plan is not mandatory. None of these documents can be substituted for the NRC's regulations. They simply offer an approach that is acceptable to the NRC staff for meeting the regulations. Alternative solutions may also be acceptable.

#### REGULATORY GUIDES IN THE HIGH-LEVEL WASTE PROGRAM

As stated earlier, the NRC will issue three Regulatory Guides in the high-level waste program. The first of these, Regulatory Guide 4.17, "Standard Format and Content of Site Characterization Plans for High-Level Waste Geologic Repositories" was developed in the early stages of the high-level waste repository program to provide guidance to DOE when its Site Characterization Plan was being prepared.

The other two licensing regulatory guides currently under development are: the FCRG, which provides guidance to DOE in the preparation of its License Application and the Draft Regulatory Guide under preparation "Topical Guidelines for the Licensing Support System." The Draft Regulatory Guide "Topical Guidelines for the Licensing Support System" will provide all of the participants in the licensing proceedings with guidance on the information which the NRC staff believes should be included in the Licensing Support System. The Licensing Support System is the electronic data base and information retrieval system which was developed through a negotiated rulemaking in which all parties in the licensing process participated. The function of the Licensing Support System is to facilitate the legal discovery portion of the licensing proceedings by having all relevant documents available and accessible to all parties in electronic format.

The third regulatory guide, the FCRG, is important to the high-level waste repository program because a license application can only be docketed by NRC if the application is complete. The FCRG provides a framework for developing a complete application. Its utility is enhanced because the License Application Review Plan will have the same structure as the FCRG. Therefore, it is important for the License Application to follow the FCRG. The FCRG provides DOE with the guidance that is necessary to deliver the quality license application which is needed if the NRC staff is to be able to expeditiously review it and conform to the statutory three year licensing schedule. Adhering to the FCRG will also simplify the NRC staff's review of the License Application to determine its completeness prior to docketing, and to conduct

the detailed technical reviews needed to determine if DOE has complied with the NRC's regulations.

In this paper, the structure of the FCRG and the approach used by the NRC staff in its development will be discussed.

## DESCRIPTION

The high-level waste repository program poses unique challenges to NRC. While the agency has a large amount of experience in licensing various nuclear facilities, the high-level waste repository licensing is the first to be carried out under 10 CFR Part 60. No guidance documentation existed for this program because it is unique and involves the licensing of a first-of-a-kind facility. This paper focuses on the FCRG because its design and format serve as the basis for the other general guidance documents.

The basic regulatory requirement outlining the information to be provided in the License Application is 10 CFR 60.21, "Content of the License Application." 10 CFR 60.21 identifies the general information that must be provided in the License Application. Because 10 CFR 60.21 does not explicitly describe how technical requirements should be addressed or discuss the structure of the application, the NRC staff has prepared the FCRG. The FCRG is designed to show that the requirements of 10 CFR Part 60 can be logically addressed in the License Application through a systems based approach that integrates compliance demonstration for related regulatory requirements. This approach recognizes the unique characteristics of 10 CFR Part 60 in which three major repository systems must function as multiple barriers which allow for safe operations and a post-closure waste isolation capability. These requirements are stated in terms of design and siting criteria; specific performance objectives related to waste isolation and retrieval; and total post closure system performance demonstration.

The approach taken in the FCRG is somewhat different from the approach taken in the standard format and content guide for reactors, Regulatory Guide 1.70. The FCRG was constructed using a systems-based approach that is consistent with repository systems described in 10 CFR Part 60. By choosing to follow this approach in the FCRG, the NRC staff wanted a demonstration that all applicable requirements for each subsystem were considered in an integrative systematic manner. An example of how the approaches to the two guides differ can be found below in the discussion of Chapter 4 of the FCRG.

The FCRG was developed by a team representing various technical disciplines in the high-level waste repository program. This ensured that all aspects of the high-level waste repository program were considered in the development of the FCRG. The team members were able to assist each other in ensuring that the sections of the FCRG were consistent both internally and among sections. In a section by section review of the completed guide, the team reviewed the completed guide to ensure that: the contents of the other sections of the FCRG supported the section being reviewed; the information in the section being reviewed was consistent with information provided in the

other sections; and there were no omissions that would affect reviews by technical disciplines other than the lead discipline. The importance of addressing all of the applicable regulatory requirements of 10 CFR Part 60 in the FCRG, and hence in the license application, has been mentioned several times. In the FCRG, this was accomplished by the development of a crosswalk (Appendix A of the FCRG) in which each applicable requirement from 10 CFR Part 60 is referenced to at least one section of the FCRG. This provides the applicant with a method of ensuring that, in each section of the License Application, all necessary information is addressed.

A particular concern in developing this FCRG was to ensure that duplication of information was minimized and that only relevant information was included. This concept is illustrated in the ways that similar information required in two sections of the guide can be presented without repetition. If the same analyses are needed to support more than one section or chapter of the FCRG, it is not necessary to repeat the analyses in two places in the guide. Rather, it is acceptable to present the analyses in one location and reference them in subsequent locations, using the results as needed to demonstrate compliance with specific regulatory requirements.

#### FCRG APPROACH

Each chapter of the FCRG contains a descriptive section that presents information on each system/subsystem/component and a compliance section that describes how each section complies with the applicable 10 CFR Part 60 requirements. Where appropriate, a third part was added to discuss compliance with the relevant subsystem performance objectives from 10 CFR Part 60. Each section of the FCRG comprises a system or specific aspect of the repository.

By adopting an approach based on the integration of the regulatory requirements for the various systems as described in 10 CFR Part 60, the NRC staff was able to ensure that the systematic intrarelations and interrelations were maintained and addressed within the framework conceived by the authors of the regulation. Chapters 3 through 6 of the FCRG represent consideration of the main systems of the repository as defined in 10 CFR Part 60. These include the Natural System; the Geologic Repository Operations Area; the Engineered Barrier System; and Overall System Performance Assessment (Chapters 1 and 2 are concerned with general information). Table 1 depicts the major chapter headings of the Table of Contents of the FCRG.

Chapter 3, "The Natural Systems of the Geologic Setting," considers all aspects of the Natural System which is defined in 10 CFR Part 60 as being comprised of: the Geologic System, the Hydrologic System, the Geochemical System, and the Climatological and Meteorological Systems. For each of these systems, any applicable favorable and potentially adverse conditions must be addressed. In addition, the NRC staff recognized the need to consider integrative aspects of the Natural System performance in order for certain of the regulatory requirements in 10 CFR 60.21 to be fully addressed. This concern led to the development of Section 3.1.5, "Integrated Natural System Response to the Maximum Design Thermal Loading" and Section 3.3.6,

"Effectiveness of Natural Barriers Against the Release of Radioactive Material to the Environment" which speak to regulatory requirements in 10 CFR 60.21(c)(1)(i)(F) and 10 CFR 60.21(c)(1)(ii)(D), respectively. Section 3.3.5 addresses compliance with the pre-waste emplacement ground-water travel time subsystem performance objective.

In Chapter 4, all aspects of the Geologic Repository Operations Area are addressed. This includes the major subsystems defined as: surface facilities, subsurface facilities, and shafts and ramps. Each subsystem is composed of structures, systems, and components. Those structures, systems and components which are important to waste isolation must be identified for each of the major subsystems. All requirements related to a particular subsystem are contained in the section of Chapter 4 where that subsystem is addressed.

For example, within the section of Chapter 4 where the surface facilities subsystem of the Geologic Repository Operations Area is considered, there are separate subsections on the hot cell, fire and explosion protection system, emergency systems, and eight other systems that the NRC staff identified as part of the surface facilities of the Geologic Repository Operations Area. In addition, the NRC staff requires that any other surface based systems be identified in the license application. For each system identified, DOE is required to demonstrate compliance with all applicable requirements. Hence, for the on-site transportation system (for example), DOE is required to demonstrate compliance with all of the design requirements applicable to that system, including radiation protection. This approach is different from the approach in the reactor format and content guide. In the reactor format and content guide all radiation protection information for design and operation are in one chapter. By contrast, the FCRG requires those design considerations for radiation protection to be included in the information for each system to which they apply, while the operational aspects of the radiation protection program which it would not have been appropriate to consider under the Geologic Repository Operations Area discussion are to be included in Chapter 7, "Conduct of Repository Operations." The benefit that the FCRG approach offers to designers and reviewers is that all regulatory requirements applicable to a particular system are addressed in one section of the guide.

Finally, Chapter 4 addresses compliance with the performance objectives for the Geologic Repository Operations Area. These are related to protection against radiation exposures and releases of radioactive material to unrestricted areas and retrievability of waste.

Chapter 5, "Engineered Barrier Systems," addresses all aspects of the waste package and the waste form. In addition, this chapter recognizes the need to ensure integration of information on the underground facility, which was discussed in Chapter 4, and the engineered barrier system/waste package emplacement environment. While it is likely that the majority of information on the design aspects of radiation protection relative to the underground facility would have been provided in Chapter 4, Chapter 5 provides an additional opportunity for the discussion of information on design related information on the radiological safety of workers in the underground facility.

during waste emplacement. As was the case in Chapters 3 and 4, this chapter also addresses the relevant subsystem performance objectives. In the case of the Engineered Barrier System, the subsystem performance objectives are related to containment and release rate requirements.

While Chapters 3 through 5 of the FCRG address the three major repository systems defined in 10 CFR Part 60, Chapter 6 addresses the regulatory requirements for an Overall System Performance Assessment. In keeping with the chapter format described above, this chapter calls for a description of the approach, models, processes and events which comprise the performance assessment. This is followed by sections on compliance with the regulatory requirements related to the cumulative release of radioactive materials; and for compliance with the requirements for the undisturbed performance of the overall repository system. Compliance with the regulatory requirements related to the cumulative release of radioactive materials involves a demonstration of compliance with the performance objective for containment in the Environmental Protection Agency (EPA) standards. This involves development of a single complementary cumulative distribution function displaying the likelihood that cumulative releases of radioactive material to the accessible environment over 10,000 years will not exceed the release limits of the EPA standards. Compliance with the requirements for undisturbed performance speak to the EPA standards for individual dose rates and groundwater protection. In another example of the FCRG approach of ensuring the appropriate integration of information, this chapter also addresses the regulatory requirements relating to the isolation of waste in terms of favorable conditions and potentially adverse conditions.

The FCRG format also allows for the logical inclusion of other information and technical requirements from 10 CFR Part 60. The repository non-system specific information comprises the remaining chapters of the FCRG. These include Chapters 7 through 11 which are: "Conduct of Repository Operations;" "Performance Confirmation Program;" "Land Ownership and Control;" "Quality Assurance;" and "Emergency Planning" respectively.

An example of how the FCRG addresses the repository non-specific information requirements can be seen in Chapter 7. As was the case in the chapters covering system-specific information, all of the requirements specific to repository operations are addressed in this chapter. For example, the information about the radiation protection program for operations is therefore, these requirements can be addressed clearly and logically in the appropriate location. Activities like dosimetry, badging and entry control would be discussed in Chapter 7. Similarly, other specific operational requirements like procedure generation and the maintenance program are discussed in this chapter.

## CONCLUSIONS

Over the next several years the further development and enhancement of the documents discussed in this paper will continue. The NRC staff is currently reviewing the public comments received on the FCRG. The NRC staff has

suggested that, after the public comments have been addressed, DOE should develop an annotated outline of the license application, based on the FCRG to ensure that DOE's understanding is calibrated with the NRC staff's intent.

At the heart of NRC's responsibility in the high-level waste repository program, as in all other NRC licensed activities, is the public's health and safety. In this program, in particular, public health and safety will only be ensured through sound technical achievement and the application of that technical achievement to all aspects of the program. The NRC staff can contribute to this goal by continuing to provide clear usable timely regulatory guidance.

TABLE 1  
MAJOR CHAPTER HEADINGS OF THE FCRG

Introduction

License Application

1. General Information

Safety Analysis Report

2. General Information for the Safety Analysis Report

3. The Natural Systems of the Geologic Setting

4. Geologic Repository Operations Area: Physical Facilities

5. Engineered Barrier Systems

6. Overall Systems Performance Assessment

7. Conduct of Repository Operations

8. Performance Confirmation Program

9. Land Ownership and Control

10. Quality Assurance

11. Emergency Planning

Appendix A. Cross-Index Between 10 CFR Part 60 and the Guide