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SECY-94-106

FOR: The Commissioners

FROM: James M. Taylor
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SUBJECT: USE OF SYSTEMATIC REGULATORY ANALYSIS IN THE HIGH-LEVEL WASTE
REPOSITORY PROGRAM

PURPOSE:

To provide the Commission with a discussion of how the staff is using Systematic Regulatory Analysis (SRA) to undertake its responsibilities in the high-level waste (HLW) repository program.

EXECUTIVE SUMMARY:

SRA is a management process applied to the Nuclear Regulatory Commission's HLW repository program. This paper explains what SRA is, why it is needed, its attributes, activities, accomplishments, and how the staff has implemented the SRA process.

DISCUSSION:

1. What is SRA?

SRA is a management process applied to the regulations and development of guidance and the license review capability for NRC's HLW repository program. It supports the management of both the complex interactions of the components of a deep geological repository and the interdependent requirements of the HLW

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regulation, 10 CFR Part 60. In practice, SRA has defined the approach for planning, organizing, conducting, and documenting the staff's work. SRA was derived from systems engineering for this purpose by the NRC staff and the Center for Nuclear Waste Regulatory Analyses (CNWRA).

2. Why is SRA Needed?

There are two reasons the staff has chosen to use SRA in its HLW repository program. First, unlike the many reactor and material licenses issued by NRC, the HLW geologic repository is a unique system for which no prototype or precisely comparable NRC licensing experience exists. Thus, the Commission's regulation for the disposal of HLW, 10 CFR Part 60, has never been applied. Therefore, the staff requires a technical and programmatic framework for implementing its HLW program that is sufficiently flexible to accommodate the evolutionary nature of the project.

A second reason why SRA is needed is that the geologic repository will have too many complex interactions to be handled by conventional problem simplification methods. Generally, problems can be solved either by reducing them to a manageable number of dominant parameters or by decomposing them into a number of relatively independent units, each of which may be solved separately. Unfortunately, the regulation of geologic disposal of HLW is not amenable to either of these approaches because of the extensive coupling of the component processes and their high degree of non-linearity.

For example, placement of waste packages in the geologic environment will raise temperature profiles near the packages. These increased temperatures may alter the flow of nearby water or water vapor, will probably cause expansion of nearby rock, and could cause nearby minerals to dehydrate. Any of these phenomena could affect the thermal response of the rock, thereby altering temperature profiles. Such coupled thermal-hydrological-mechanical-chemical (TMHC) interactions could affect the degradation of waste packages, groundwater flow, and radionuclide retardation. These interactions are not yet well enough understood to attempt to decouple them, particularly in view of the regulatory need to predict repository performance for 10,000 years.

In addition to the above technical challenges, NRC's regulation itself is internally coupled in ways that encourage a systems approach to its implementation. For example, the natural system performance objective is a 1000-year groundwater travel time; a favorable condition for disposal in the unsaturated zone is a host rock that provides free drainage; and a potentially adverse condition is the potential for changes in hydrologic conditions. Guidance on how to meet these and other hydrologic criteria must be consistent and reflect each criterion's contribution to confidence in meeting with reasonable assurance the overall system performance objective.

SRA provides the structure and the process to address the above technical and regulatory challenges in a prospective manner before licensing.

3. What Are the Attributes of SRA?

A. Defines a Well-Organized, Systematic Set of Specified Activities

SRA defines six activities that the staff should undertake to conduct its technical work (see Section 4(A)). These activities are done in a manner that results in work being completed on higher-order program activities first, to help ensure that work undertaken in the subsequent steps is based on a sound foundation. In its analyses, the staff uniformly applies a set of procedures and criteria across all technical disciplines, which contributes to the completeness, consistency, and integration of the staff's work.

B. Assists the Staff in Identifying and Prioritizing Work and in Allocating Resources

The SRA process helps the staff identify significant regulatory issues related to repository performance and the associated work it should undertake to address these issues. This identification, along with DOE schedules for site characterization work and other NRC program needs, such as the development of necessary licensing documents, is used by the staff to prioritize its work. Prioritizing work in this manner also helps to determine the amount of staff resources that should be allocated to various activities.

C. Facilitates Program Integration

SRA facilitates integration in two different ways. One is the integration of staff technical work, to ensure that all requirements for the site design and for performance are addressed, and that the interrelationships among the different repository systems are evaluated. The second is integration of NRC program activities to ensure that work is coordinated to eliminate duplication of effort and to support overall program objectives.

D. Permits Consideration of Results and Feedback in the Program

SRA's flexibility permits results from ongoing staff work to be considered in all program activities. This helps the staff either confirm that work should continue, or determine when it is appropriate to terminate work in certain areas.

E. Provides Documentation of Results

Finally, SRA is designed to document NRC program decisions and technical results that support the staff's published regulatory documents. Because of the long-term nature of the repository program, many staff members working on the program today may not be conducting the review at the time of a license application submittal. Therefore, documenting the results of program work in a computer database (referred to as the Repository Program Database) will facilitate the staff's licensing review and decision-making process.

4. How has the Staff Used SRA?

A. Description of SRA Activities and Accomplishments

This section describes the six SRA activities and related accomplishments. Specific products are listed in the Enclosure. Because of the evolving nature of the SRA process, the six activities were not conducted in the sequence listed below. Rather, some of the activities have been conducted concurrently.

i. Developed Program Policies

The purpose of this activity was to develop internal staff policy documents that define the program's goals, objectives, and strategies to guide the staff's work in a systematic and consistent way. These policies also established, at a top level, a system for prioritizing and integrating the staff's work.

The staff completed three Commission papers that describe the staff's Regulatory Strategy for the program (see the Enclosure). The Regulatory Strategy primarily establishes the staff's policies for evaluating 10 CFR Part 60 for clarity and sufficiency. For example, policies establish how the staff will identify regulatory and institutional uncertainties as well as how rulemaking and guidance will be used to resolve these uncertainties.

The staff has also completed the Overall Review Strategy (ORS), which complements the Regulatory Strategy. The ORS defines a set of objectives and strategies for pre-licensing reviews, license application reviews, and development of review capability (i.e., License Application Review Plan (LARP), performance assessment, analysis methods, and research). The strategies provide a framework for prioritizing and integrating pre-licensing reviews and development of review capability with the staff's eventual license application review. For example, strategies in ORS are given for the staff to prepare the review strategies for the individual review plans of LARP, which identify five potential levels of review for the license application and the corresponding types of work it needs to complete today to support that review effort. Highest review priority is given to the greatest uncertainty and some research and independent modeling is used to support these reviews. ORS also includes the staff's initial Performance Assessment Strategy.

Finally objectives and strategies from both the Regulatory Strategy and the ORS have been incorporated into the staff's 1994 Management Plan.

ii. Evaluated 10 CFR Part 60 for Sufficiency and Clarity

The purpose of this activity was to evaluate 10 CFR Part 60 for sufficiency and clarity, such that the regulation could either be amended or guidance provided to resolve concerns (i.e., regulatory and institutional uncertainties) identified in the evaluation. Resolution of these concerns will help ensure a clear and complete regulation, thus minimizing the potential for time-consuming disputes about the meaning of the regulation during licensing.

The staff and the CNWRA conducted a functional analysis of a HLW repository independent of 10 CFR Part 60. The resulting functions determined to be related to radiological health and safety were then compared with 10 CFR Part 60, to determine whether they could be adequately regulated by this part. Additional analyses supporting this effort included studies of repository operational and post-closure phase activities, to ensure that they could also be adequately regulated under 10 CFR Part 60.

In addition to analyzing 10 CFR Part 60 for sufficiency, at staff direction, the CNWRA examined 10 CFR Part 60 in detail to identify any potential regulatory or institutional uncertainties. The results included the identification of 43 such uncertainties. Follow-on work by the staff defined an additional 11 uncertainties for a total of 54. These uncertainties were further evaluated by the staff, to examine the best methods for reducing them. This effort determined that 24 can be addressed in regulatory guidance, 10 through major rulemaking, and 3 in minor rulemaking. One institutional uncertainty, related to the implementation of the Resource Conservation and Recovery Act (RCRA), was resolved (as reported in SECY 89-298 and SECY-90-051) by determining that NRC's role does not include independently evaluating DOE's demonstration of compliance with the requirements of RCRA, since this responsibility falls within the jurisdiction of the U.S. Environmental Protection Agency. The remaining 16, such as the definition of "substantially complete containment," were determined to require further analysis, which is a staff activity nearing completion. The conclusions were, in general, that 10 CFR Part 60 is a sound rule. By doing this work early on, the staff was able to ensure that the regulation with which it would be conducting its program could be used with confidence.

The activities discussed above were all performed using procedures and criteria concurred in by the staff, and they yielded a number of regulatory products (see the Enclosure). The functional analyses and comparisons with 10 CFR Part 60 resulted in these CNWRA reports. Uncertainty identification was documented in a CNWRA report and subsequently in a Commission paper that included the recommended resolution methods and their status. This systematic uncertainty identification activity enabled the staff to determine that 10 of the 54 regulatory and institutional uncertainties mentioned above will need major rulemaking. Furthermore, the staff has addressed three of the ten regulatory uncertainties in its July 1993 proposed rulemaking, for clarification of assessment requirements for the siting criteria and performance objectives. This rulemaking would clarify the standard for "adequacy" of investigation and evaluation of potentially adverse conditions. It would also explain that evaluations should consider the interaction of conditions.

iii. Defined Organizational Structure

The purpose of this activity was to define an organizational structure, for the staff's program and regulatory documents, that is based on the requirements in 10 CFR Part 60 that the staff must address.

The staff has defined a two-part organizational structure. First, a general structure has been developed based on the repository system and subsystems

defined in 10 CFR Part 60 and other similar subject areas (see Table 1). Second, the staff has grouped the regulatory requirements of 10 CFR Part 60 into 97 topics, which are organized within the general repository system structure. This organizational structure forms the outline of the LARP and the 97 individual review plans comprising it. It is also similar, at a general level, with the outline for the 1990 draft Format and Content Regulatory Guide (FCRG) for the License Application, the structure of which will be revised to achieve complete consistency with the draft LARP. Since DOE is developing its License Application Annotated Outline following the draft FCRG structure, a common organizational structure is evolving that will significantly contribute to the integration of the primary NRC and DOE licensing documents.

iv. Developing the Staff's LARP

The purpose of this activity is to prepare the LARP, which will ultimately provide the staff with guidance to review DOE's license application. It will also be used by the staff in focusing its pre-licensing reviews of DOE's repository program on licensing needs. As noted above, ORS describes the strategy for developing a draft LARP during the pre-licensing phase as a series of annual revisions, which add the individual review plans completed each year until the LARP is finalized in FY01. The general organizational structure and the 97 topics described in Section 4(A)(iii), above, have been translated into the table of contents including 97 individual review plans. Each individual review plan will consist of a standard set of sections: applicable regulatory requirements; review strategy; review procedures and acceptance criteria; responsibilities and interfaces (information inputs and outputs); and example evaluation findings.

The initial step in preparing individual review strategies is to identify key technical uncertainties, which are technical issues judged by the staff at this time to be most important to the staff's regulatory review and evaluation of repository performance (i.e., they might pose a risk of noncompliance with the performance objectives of 10 CFR Part 60). These key technical uncertainties not only identify the most important technical issues for the NRC staff, but also what review capability (e.g., modeling and research) the staff must develop to be prepared to review how DOE will address them. The staff has used key technical uncertainties as a method of prioritizing its technical work, as well as for integrating all the work needed to review them in DOE's license application.

Once the identification of key technical uncertainties was complete, the staff was able to prepare the review strategies for 93 of 97 review plan sections. By developing the review strategies, the staff was able to identify what type of review was appropriate for each of the 97 individual review plans (see Table 2). With this information, the staff has identified that for those 91 review strategies completed, only 12 review plans will need some amount of independent modeling or research support. This information has helped the staff prioritize its technical work and better integrate it with the review plans in LARP that it supports.

The draft LARP, Revision 0 is currently in press and is planned to be published in May 1994. It consists of the applicable regulatory requirements for all 97 individual review plans, 93 review strategies, and 2 complete review plans ("Potentially Adverse Condition: Evidence of Igneous Activity" and "Quality Assurance"). The review strategy sections define the scope, level, and type of review, including any key technical uncertainties. The two completed review plans provide examples of review procedures and acceptance criteria, interfaces, review responsibilities, and example evaluation findings. Appendix C of LARP, Revision 0 identifies the technical skills needed to implement each review plan, by identifying lead and supporting review responsibilities. Such assignments are used to identify the multidisciplinary teams needed to review DOE's on-going site characterization program. Appendix E of LARP, Revision 0 describes 58 key technical uncertainties identified by the staff in its work to date.

Lastly, the staff has started to use the draft LARP for pre-licensing reviews of DOE's site characterization activities related to erosion and volcanism.

v. Identified Technical Assessment and Staff Research Needs

The purpose of this activity was to identify the specific NRC technical assistance work (such as development of performance assessment models and other analytical methods) and research needed to support the LARP.

The staff's development of review strategies in LARP, Revision 0 has resulted in identifying 12 out of 97 individual review plans that need some research and independent modeling to support the staff's detailed reviews. The staff plans on evaluating the draft LARP review strategies and key technical uncertainties to systematically identify specific needs. This will result in an update to the existing 1992 Research User Needs. The completion of this activity will result in a fully integrated program that links all research and technical assessment work and resulting products to the LARP. Such work should support development of review procedures, methods, and acceptance criteria in the individual review plans.

vi. Revising License Application FCRG

The draft FCRG, issued in 1990, provides guidance to DOE on the format and content of its license application. Although this regulatory guide was prepared before the SRA process was fully developed, it is the staff's intent to prepare its final FCRG in FY95, using the SRA process to achieve consistency with the draft LARP, Revision 0 described below. In addition, the staff will use experience gained from: (1) development of the draft LARP, Revision 0; (2) review of DOE's License Application Annotated Outline; and (3) submission of comments on the draft guide by DOE.

B. How SRA Activities Have Been Conducted

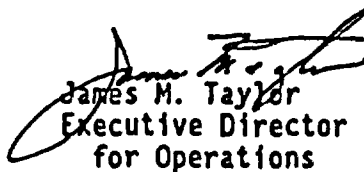
The staff has conducted SRA activities within the requirements of the CNWRA's 10 CFR Part 50, Appendix B, quality assurance program. This program requires that SRA activity use approved procedures. The procedures specify criteria, analysis methods, content and format of products, and requirements for review

and record keeping. The procedures must receive concurrence from NRC and CNWRA management, and staff training in their use must be conducted and documented. These procedures therefore ensure consistency of analysis and product quality across the many staff elements and disciplines. This is an important integrating force. Since the quality assurance program also requires formal reviews, comment resolution, and approval of products, staff management is enabled to maintain appropriate oversight of SRA efforts. The technical staff contribute to procedure development, and the procedures are allowed to evolve in response to regulatory program needs.

The SRA procedural requirements for consistent analysis criteria and product reviews have stimulated an extremely productive working relationship with CNWRA staff. Typically, NRC staff and CNWRA management jointly designate multidisciplinary teams with all appropriate technical disciplines represented to conduct the analyses and document the results. Consequently, staff regulatory and technical expertise is thoroughly integrated with the more focused capabilities of the CNWRA. Both staffs enhance their programmatic and technical knowledge, and the CNWRA has come to better understand the regulatory aspects of its work.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.


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Enclosures: Products Produced
Using the SRA Process

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Table 1
General Organizational Structure

- General Information
- The Natural Systems of the Geologic Repository
- Geologic Repository Operations Area
- Engineered Barrier Systems
- Overall System Performance Assessment
- Conduct of Repository Operations
- Performance Confirmation Program
- Land Ownership and Control
- Quality Assurance
- Emergency Planning

Table 2
Distribution of Review Types in the LARP

<i>Review Type</i>	<i>Number of Review Plans</i>
ACCEPTANCE REVIEWS (Type 1)	97
COMPLIANCE REVIEWS (Types 2 - 5)	(77)
- General Information Review (Type 2)	10
- Safety Review (Type 3)	47
- Detailed Safety Review Supported by Analyses (Type 4)	8
- Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations (Type 5)	12
REVIEW TYPE TO BE DETERMINED	6

Products Produced Using the SRA Process

4Ai. Developed Program Policies

SECY-88-285, "Regulatory Strategy and Schedules for the High-Level Waste Repository Program," October 5, 1988.

SECY-90-207, "First Update of the Regulatory Strategy and Schedules for the High-Level Waste Repository Program," June 7, 1990.

SECY-91-225, "Second Update of the Regulatory Strategy and Schedules for the High-Level Waste Repository," July 29, 1991.

Memorandum from B.J. Youngblood to HLWM Staff, "Subject: Overall review Strategy for the Nuclear Regulatory Commission's High-Level Waste Repository Program," February 19, 1993.

Memorandum from B.J. Youngblood to HLWM Staff, "Division of High-Level Waste Management Repository Program Management Plan (January 1994)," January 31, 1994.

NUREG-1495, "Overall Review Strategy for the Nuclear Regulatory Commission's High-Level Waste," 1994 (in press).

4Aii. Evaluate 10 CFR Part 60 for Clarity and Sufficiency

CNWRA 90-003, "Identification and Evaluation of Regulatory and Institutional Uncertainties in 10 CFR Part 60," February 1990.

CNWRA 91-001, "High-Level Radioactive Waste Repository Functional Analysis," March 1992.

CNWRA 92-007, "Repository Operational Criteria Comparative Analysis," September 1992.

CNWRA 93-001, "Repository Isolation Criteria Study Recommendations Report," January 1993.

SECY-89-339, "Regulatory Strategy for the High-Level Waste Repository Program Description of Uncertainties Being Addressed by the U.S. Nuclear Regulatory Commission Staff," October 31, 1989.

Memorandum from J. Holonich, J. Bunting, and R. Ballard, to B.J. Youngblood, Subject: "Report on Uncertainty Reduction," April 1, 1991.

"Proposed Rulemaking on Clarification of Assessment Requirements for the Siting Criteria and Performance Objectives," July 9, 1992.

4A111. Defined Organizational Structure

Memorandum from M. Delligatti to B.J. Youngblood, Subject: "Report of the Joint U.S. Nuclear Regulatory Commission-Center for Nuclear Waste Regulatory Analyses Structural Task Force on the Compatibility of the Structures of DG-3003, "Format and Content of the License Application for the High-Level Waste Repository" and Regulatory Requirements and Regulatory Elements of Proof of the Systematic Regulatory Analysis," January 13, 1992.

NUREG-1323, "Draft License Application Review Plan for a High-Level Waste Repository," Revision 0, in publication.

Aiv. Developing the LARP

NUREG-1323, "Draft License Application Review Plan for the Review of a License Application for a Geologic Repository for Spent Nuclear Fuel and High-Level Radioactive Waste, Yucca Mountain, Nevada (Revision 0)," 1994 (in press).

Other

CNWRA 92-027, "Review and Analyses of PASS/PADB System for Systematic Regulatory Analysis," December 22, 1992 (letter report).

CNWRA 93-011, "Development Plan for PASS/PADB System Design (version 3.0)," May 11, 1993.

CNWRA 93-009, "Open Item Tracking System (OITS), Version 1.0 User's Guide," November 1993.

CNWRA unnumbered, "User's Guide for Regulatory Program Database (RPD) (version 1.0)," November 1993.