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RJ/WHITE PAPER MEMO

MEMORANDUM TO: HLWM Staff

FROM: B. J. Youngblood
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

SUBJECT: PAPER ON DEVELOPMENT AND IMPLEMENTATION OF THE DIVISION OF HIGH-LEVEL WASTE MANAGEMENT PROACTIVE PROGRAM

I have enclosed for your information a copy of the subject paper, which emphasizes the Systematic Regulatory Analysis and Iterative Performance Assessment and how these activities help identify, prioritize, and integrate work in our proactive program. This paper supported the August 28, 1991, staff briefing on the proactive program to the Advisory Committee on Nuclear Waste.

/s/

B. J. Youngblood, Director
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

cc: R. Bernero, NMSS
G. Arlotto, NMSS
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S. Treby, OGC
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DEVELOPMENT AND IMPLEMENTATION OF

THE DIVISION OF HIGH-LEVEL WASTE MANAGEMENT PROACTIVE PROGRAM

August 1991

Division of High-Level Waste Management
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

DEVELOPMENT AND IMPLEMENTATION OF

THE DIVISION OF HIGH-LEVEL WASTE MANAGEMENT PROACTIVE PROGRAM

1.0 INTRODUCTION

1.1 Purpose

The purpose of this paper is to describe how the U. S. Nuclear Regulatory Commission (NRC) staff of the Division of High-Level Waste Management (HLWM) develops and implements the proactive component of its overall High-Level Waste Repository Program. The paper will specifically focus on how proactive work has been identified, prioritized, and integrated and how this effort is now being enhanced by the Systematic Regulatory Analysis (SRA) of 10 CFR Part 60 and the Iterative Performance Assessment (IPA). In addition, the development and implementation of the Office of Nuclear Regulatory Research (RES) Program in support of the HLWM proactive program will be addressed.

1.2 Overall HLWM Repository Program

The goals, objectives, and activities of the overall HLWM Repository Program are described in NRC's Five-Year Plan and in the HLWM staff's Regulatory Strategy presented in SECY-88-285. The goals of the overall HLWM Repository Program are to conduct effective pre-license application consultation and an effective license application review to facilitate a construction authorization decision for a geologic repository within the 3-year time period mandated by the Nuclear Waste Policy Act (NWPA), as amended.

To achieve this goal, the program's three major objectives during the pre-license application phase are to: (1) refine the regulatory framework so that it is clear and complete; (2) identify and resolve potential licensing issues using guidance to the U.S. Department of Energy (DOE) to help ensure that DOE submits a complete and acceptable license application; and (3) develop the staff's technical capabilities to review DOE's site characterization program and license application.

The activities for achieving the program's objectives have been divided into proactive and reactive components. The proactive activities generally do not depend on an action by DOE, but are timely enough to support DOE's program. Proactive activities are in the following three Five-Year Plan/Budget areas: (1) NWPA regulatory requirements and technical guidance (e.g., rulemakings and staff technical positions (STPs)); (2) technical assessment capability for repository licensing review (e.g., review plans, analysis methods, and IPA); and (3) SRA. In contrast to proactive activities, reactive activities are responsive to DOE actions and are activities in the following two Five-Year

Plan/Budget areas: (1) quality assurance (e.g., reviews and audits) and (2) pre-licensing and site characterization reviews (e.g., study plan reviews).

As mentioned previously, this paper focuses on the proactive program.

2.0 HLWM PROACTIVE PROGRAM

2.1 Program Overview

Two of the most basic products that will be developed by the HLWM proactive program are the Format and Content Regulatory Guide (FCRG) for the license application and the License Application Review Plan (LARP). These are the primary guidance documents addressing the license application. The FCRG gives guidance to DOE on the general information needed in the license application. The LARP, on the other hand, will be issued as guidance to the HLWM staff and will describe how the staff will review DOE's license application to determine if DOE has acceptably demonstrated compliance with 10 CFR Part 60. It also will help guide the staff's review of DOE's program during the pre-license application phase. Therefore, the LARP also will provide indirect guidance to DOE.

Before completion of the FCRG and the LARP, HLWM may need to provide pre-licensing guidance to DOE in areas where there are issues of immediate concern, such as those that could affect site characterization or those that might need a long lead-time to address. Issuance of this pre-licensing guidance is done through a number of methods. The staff may provide feedback to DOE as part of its reactive program by commenting on DOE documents such as the Site Characterization Plan. Alternatively, the staff may issue STPs that are developed through the proactive program for a few of the most important technical areas. STPs provide guidance to DOE on acceptable methods it can use to demonstrate compliance with 10 CFR Part 60. Eventually, the STPs will be incorporated into the LARP by reference or by restating the positions contained in them directly in the LARP, as acceptance criteria.

As another activity of its proactive program, the staff is evaluating 10 CFR Part 60 to identify areas where changes or clarifications are needed. Rulemakings are used to make changes to 10 CFR Part 60, whereas guidance documents such as the FCRG, LARP, and staff positions (SPs) can serve to clarify the meaning of the regulation. This work will help the staff ensure that the regulatory framework for licensing a repository is adequate, and that ambiguities in the regulations will not become a major focus in the licensing hearing.

The program's proactive activities also include analysis method preparation and IPA. Under analysis method preparation, the staff's focus is on developing analytical methods needed to make determinations of compliance with subsystem performance objectives and other requirements of 10 CFR Part 60. Under IPA, the staff's focus is on developing a capability to evaluate the overall system performance objective. However, in actual implementation, both

are closely coordinated to assure development of a comprehensive technical review capability. Because of its importance in developing and implementing the proactive program, IPA is further described in section 2.3.

The final proactive activity is the SRA. Because of its importance to developing and implementing the proactive program, it is described in Section 2.2.

2.2 Systematic Regulatory Analysis (SRA)

In general, the SRA is a disciplined and documented process specifically developed by the HLWM and the Center for Nuclear Waste Regulatory Analyses (CNWRA) staffs to apply the principles of systems engineering to the needs of the NRC's HLWM program. SRA defines a framework in which technical work is conducted and documented. This framework includes a process for systematically and comprehensively analyzing 10 CFR Part 60 to identify and conduct the appropriate staff work needed to support licensing. The framework is a tool that helps focus, in a consistent and documented manner, the staff's technical and programmatic judgments. This approach is particularly well suited for dealing with some of the challenging aspects of the repository licensing program (e.g., it is complex, first-of-a-kind, multi-disciplinary, and of long duration). The SRA process is designed to be a tool for the staff to use throughout the licensing process to effectively and efficiently manage the HLWM program. The staff considers it a key method in helping it identify, prioritize, and integrate work. As a result, the staff will have greater confidence that all the necessary work is done to achieve the program's objectives, that the work is done in a consistent and coordinated manner, that the work has been done as efficiently as possible, and that it is sufficiently documented to preserve a record for future reference.

Specifically, the SRA process defines a number of analyses of 10 CFR Part 60. The first analysis involves placing those parts of the regulation covering common areas into groups called regulatory requirements. In addition, each regulatory requirement is subdivided into regulatory elements of proof, which are direct statements from the regulation as to what must be proven by DOE in order to demonstrate compliance with that portion of the regulation. This analysis is important because it provides a description of the often very complex logical interrelationships between the various portions of 10 CFR Part 60. The regulatory requirements and their associated regulatory elements of proof are the starting point and foundation for all further SRA analyses, which are described below.

Each regulatory requirement is analyzed, and where the existing regulation is unclear or incomplete, regulatory uncertainties are identified. Similarly, where the roles or actions of organizations responsible for implementing a portion of the regulation are unclear, institutional uncertainties are identified. Once these uncertainties are identified, each uncertainty is analyzed using criteria to both prioritize and identify the appropriate method for the staff to use to reduce the uncertainty. The results of these analyses, including the rationales for the decisions, are documented.

Alternative reduction methods include major rule, minor rule, or guidance. Based on the uncertainty reduction methods selected, the staff will prepare the appropriate document to reduce the uncertainty.

Each regulatory requirement is further analyzed to select the type of license application review that is appropriate. Five standard types of reviews have been defined, which involve different levels of detail and different review methods. The type of review is then used to develop the review strategy that will be included in the LARP sections dealing with the regulatory requirement. The review strategy is used to help the staff streamline its work and optimize its resources during the license application review. It does this by focusing the staff work on those areas most important to compliance with 10 CFR Part 60 and identifying those areas where more detailed reviews and rigorous methods of review will be needed. In addition, the review strategy will help identify what research, model development, and pre-license application reviews are needed to prepare for the staff's license application review.

An additional analysis of each regulatory requirement consists of developing, within the bounds of the review strategy already developed, the review methods, procedures, and acceptance criteria that the staff will use to evaluate DOE's license application. The detailed information needs that the staff will use to implement each review method also will be identified. The results of this analysis will be direct input to the LARP.

Each regulatory requirement also is analyzed to identify the general information that DOE should provide in its license application. These general information needs will be used as direct input to the FCRG. Because the staff has already developed a draft FCRG, many of the general information needs for the various regulatory requirements have already been developed in draft form. Therefore, in this case, the SRA process will help the staff identify any additional information needs that should be included in the FCRG and will also serve as a check of the draft FCRG material.

Another analysis is the identification of technical uncertainties. Technical uncertainties can be questions of "how to" or "how well" to do something or questions about the site or repository-induced conditions or processes. Those technical uncertainties that the staff judges to pose a high risk of non-compliance with 10 CFR Part 60, and, in particular, the performance objectives, are identified as key technical uncertainties. These key technical uncertainties are considered by the staff in applying criteria to select the appropriate review strategy and in developing the review methods, procedures, and acceptance criteria. In this way, the staff's review methods for each regulatory requirement are focused on the most important technical uncertainties that must be addressed in evaluating repository performance and determining compliance. This analysis is, therefore, a primary method for prioritizing the work needed to prepare for the license application review, as well as the review itself.

Finally, the staff recognizes the exploratory and evolving nature of the repository program, as well as the need for flexibility under these conditions. Because of this, the staff expects to apply the SRA process iteratively. The staff's initial judgments and products resulting from applying the SRA process may be reevaluated periodically, as needed, based on new information, new insights, or as new analytical methods become available. For example, the staff's initial judgments in identifying key technical uncertainties that pose a high risk of non-compliance will eventually need to be evaluated more quantitatively by using sensitivity analysis methods developed by the IPA activity. Any changes that result may lead to changes in the review strategies or review methods.

2.3 Iterative Performance Assessment (IPA)

A second activity being conducted in parallel with SRA is IPA. IPA is an iterative process of technical analyses primarily using predictive models and computer codes to obtain quantitative estimates of repository performance. More specifically, IPA consists of developing system descriptions and conducting scenario analyses, consequence analyses, performance measure calculations, sensitivity and uncertainty analyses, and comparisons to regulatory standards. These analyses are repeated as new data and increased understanding become available. Through this iterative process, progressively refined assessments of repository performance as it relates to performance objectives in 10 CFR Part 60 may be obtained.

The overall objective of the IPA program is for the NRC staff to develop, maintain, and enhance its capability to perform an effective review of DOE's performance assessment, which will be the principal way that DOE will demonstrate compliance with the performance objectives of 10 CFR Part 60, in its license application. IPA also provides a tool for technical integration because it provides the structure for examining couplings between phenomena that might not be adequately evaluated within the limits of a specific technical discipline. In addition, the multi-disciplinary involvement with data inputs, assumptions, and code development more clearly defines activities and interfaces of the many disciplines involved. In this way, IPA also contributes to programmatic integration.

The other objectives of IPA are:

(1) support the development of regulatory guidance and the LARP, especially in developing and refining the basis for the review strategies and review methods for the performance objectives;

(2) provide practical insights into the feasibility of implementing existing requirements of 10 CFR Part 60 and 40 CFR Part 191, and the alternatives that might be considered; and

(3) support the pre-license application reviews of DOE's site characterization program (including field and laboratory studies, early performance assessments and performance allocations, and design analyses).

IPA will achieve these objectives by illustrating how site characterization data and general information can be used to demonstrate regulatory compliance. In the course of such exercises, the need for additional site characterization data, regulatory guidance, or potential change to regulations might be identified. Sensitivity and uncertainty analyses will be key to identifying those data, assumptions, or regulatory interpretations with the greatest potential for introducing uncertainty into demonstrations of compliance.

IPA complements the SRA process by feeding the results of integrated technical analyses back into the SRA process. As mentioned previously, knowledge gained through IPA will be used to reevaluate the significance of key technical uncertainties initially identified in an SRA analysis, and thereby provide a quantitative basis for determining the need to revise the key technical uncertainties and associated review strategies. As the SRA process is developed, it will help to ensure that IPA activities are appropriately focused to contribute in a logical fashion to regulatory products and, eventually, the review of the license application, by ensuring that the work performed is relevant to the regulatory process.

3.0 HLWM PROACTIVE PROGRAM DEVELOPMENT AND IMPLEMENTATION

The staff's approaches for identifying, prioritizing, and integrating work are principal elements of developing and implementing the HLWM program. In this section, the approaches that have been used for each of these elements are discussed. Furthermore, how the existing approaches are being enhanced by using the SRA and IPA processes will be addressed. It is important to emphasize that the staff is in the process of developing the SRA and IPA. Therefore, these approaches are just beginning to be applied to the program.

3.1 Identifying Work

The approach used to date to identify topics for proactive work consisted of: (1) independent staff judgment regarding needs; (2) results of research; and (3) interactions with DOE and others. Such interactions included staff reviews of DOE documents submitted to NRC, dialogue with DOE and others on technical issues, and requests from DOE, or others, for guidance or regulatory changes (e.g., DOE's petition for a rulemaking regarding Design Basis Accident Dose Limit). Using this approach the staff identified the work which it is now undertaking in the proactive program. However, this approach, while controlled, was not systematic or comprehensive and the rationales for decisions were not always documented.

SRA and IPA are now reaching a state of development where the staff can begin to use these tools as a more comprehensive approach to enhance the identification of work. For rulemaking and STP work, the SRA is being used to identify areas in the existing rule requiring changes or where the rule appears to be incomplete. In addition, it identifies areas where these are questions or concerns regarding how compliance with 10 CFR Part 60 can be determined. This enhanced approach will give the staff greater confidence that the appropriate rulemaking or STP topics have been identified. Once the STPs or rulemakings are identified, the staff has defined the areas where some of its proactive work should be done. Also, the identification of these areas help the staff to identify where research work might be needed to support these efforts.

As key technical uncertainties are identified using SRA and IPA, and as the review strategies are developed, the staff will be able to identify, in a consistent, better justified, and well documented manner, the specific research, model development, or pre-license application reviews that are needed to develop the LARP and prepare to review the license application. Because the development of the LARP is just beginning, the SRA process is being used to identify and conduct the specific work needed for preparing the LARP. The review strategies will also identify what type of modeling capability to develop, to review key technical uncertainties. Specifically, the review strategies will identify where the staff will need to develop its capability to use models already developed by DOE or other parties, or where the staff will need to independently develop its own models and capability to apply them. Such development work might be done by HLWM, RES, or as a joint effort, similar to the way the IPA is currently being developed. Similarly, the review strategies will identify where research work is needed to support the LARP. Complementing the SRA process is the practical experience gained from exercising the models and codes as part of the IPA.

3.2 Prioritizing Work

The staff prioritizes its work annually as part of the development of the Five-Year Plan and Budget and during the year, as the program is implemented. Ongoing work has been prioritized by considering one or more of the following factors: programmatic needs, importance, timing, and resource constraints. Programmatic needs include, for example, the need for a LARP or the FCRG based on past licensing experience. Importance can depend on many factors such as impact on DOE site characterization activities, potential adverse impacts on waste isolation due to DOE's site characterization activities, importance to repository performance, risk of non-compliance with 10 CFR Part 60 requirements, or resolution of regulatory uncertainties with 10 CFR Part 60. Timing considers DOE's program schedules and the lead time needed by the staff for developing guidance or preparing for reviews of DOE's program. Finally, resource constraints involve limitations in HLWM staff, CNWRA funding, and availability of appropriate technical expertise.

As the SRA process is developed and implemented, it will be used to help prioritize work in many ways. The SRA, through the development and application of criteria, will help focus the staff's considerations and decisions in assigning priorities. For example, as described in Section 2.2, prioritization criteria will help the staff determine the appropriate type of license application review, based on the technical uncertainties most important to compliance with 10 CFR Part 60. This prioritization analysis will also prioritize the regulatory requirements, the technical uncertainties most important to compliance, and the pre-license application activities needed to support the type of license application review selected.

In addition, the SRA data base will provide the staff with the information pertinent to prioritizing work. Finally, the SRA process requires that the rationales supporting many prioritization decisions are documented for future staff use and management review.

IPA will also begin to support the staff in prioritizing its work by providing the overall system modeling capability that can be used to conduct sensitivity analyses, to determine, quantitatively, the importance of many factors to repository performance. These quantitative results will greatly enhance the staff technical judgments presently being used and thereby strengthen the justifications or rationales for priorities. In particular, IPA will be able to check the initial judgments the staff will make in applying the prioritization criteria, to determine the appropriate type of license application review. Furthermore, results of sensitivity analyses will contribute to a more complete record documenting the staff's decisions.

3.3 Integrating Work

Ongoing HLWM work is integrated through the HLWM matrix management organizational structure. The staff has relied on, and has had success in, effectively using multi-disciplinary teams for conducting much of its work. Team meetings and informal team member discussions have contributed to exchange of information and views among the various disciplines. Both the Site Characterization Analysis and the draft FCRG are examples of where multidisciplinary teams were used to achieve integration of information in the product.

In addition, the staff uses review plans and procedures to help integrate its work. Within these plans, formal steps or tasks are identified, scheduled, and staff assigned to explicitly focus on technical integration of the work. Such explicit integration steps were identified in the staff's Site Characterization Review Plan.

The SRA process is intended to greatly enhance the integration of work. SRA and the associated relational data base have been designed and are being developed to provide an effective and efficient tool for integration. As the SRA process is conducted, relationships of information on many levels are explicitly identified, documented, and entered into the relational data base.

with HLWM and the CNWRA, currently is developing a draft overall research program plan. Specific research work also is refined and focused through technical discussions, management meetings, and formal reviews of proposed research tasks involving the staff of RES, HLWM, and the CNWRA. Based on these interactions, RES has developed statements-of-work for its contractors that address the user needs. The contractors have developed research work plans that respond to the statements-of-work and guide the actual research work.

In identifying the existing user needs, HLWM used its judgment based on pre-licensing experience to refine and focus the areas where it believes research is needed. This pre-licensing experience includes insights gained from the initial SRA and IPA activities, research conducted to date, reviews of DOE's site characterization work and design activities, and interactions with DOE and others.

Like the prioritization of HLWM work, the identified research needs have also been prioritized according to one or more of the following considerations: (1) programmatic needs; (2) importance; (3) timing; and (4) resource constraints. These factors have already been described in Section 3.2.

As the SRA and IPA processes are further developed, the staff will also use them for identifying and prioritizing needed research. As mentioned previously, the review strategies that will be developed under the SRA and IPA will allow the staff to identify areas that are judged most important to compliance. For some areas, detailed safety reviews of the license application will rely on the use of NRC research results. This identification will help the HLWM staff revise its research user needs in a more systematic and comprehensive way that is more directly linked to its license application review needs and those areas that are most important to repository performance and determining compliance. In this way, the priorities of research can be clearly justified and documented. The research needs identified as a result of the SRA review strategy development will be compared to the ongoing research program and necessary adjustments will be made. As research work progresses, the staff will evaluate the results as part of the SRA process, to determine if additional research is needed to satisfy review needs.

Integration of research activities occurs in many ways. First, there is coordination between HLWM and RES. This includes the process, described above for identifying research needs and developing the research program plan. It also is achieved by HLWM reviews of research program activities and products with resulting comments to RES. The CNWRA also plays an important integrating role because it conducts both the research and HLWM work. Integration will also be enhanced by using the integrating features of the SRA to link the research needs and results to the specific review strategies and methods that HLWM will be developing for the LARP. Through this mechanism, the results of research will become linked to many products of the HLWM program, so that together, they will provide the staff with the capability to review the license application and determine if DOE has adequately demonstrated compliance with 10 CFR Part 60 requirements.

5.0 CONCLUSION

The HLWM staff has developed and is implementing a structured program with formal controls to ensure that there are mechanisms in place to direct and support its ongoing proactive work. In addition, these mechanisms help HLWM to identify, prioritize, and integrate the work of its program. However, the pace of work completed by HLWM is often constrained by the availability of resources including the availability of appropriate technical expertise.

As implementation of the SRA and IPA by HLWM continues, the staff will have available to it a process that will give it a systematic and disciplined approach for performing its work. It provides a framework that helps the HLWM staff identify activities and issues that need to be explored and considered in the program. The final decisions on what work to pursue and in what order are determined by close coordination among HLWM, RES, and the CNWRA. This process is ultimately controlled by staff and dollar resources available to the program.