APPLICATION OF SYSTEMS ENGINEERING TO THE LICENSING OF A HIGH-LEVEL NUCLEAR WASTE REPOSITORY

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ABSTRACT

This paper provides insight into the work presently being conducted by the Nuclear Regulatory Commission staff in its development of the major documents needed to review the U.S. Department of Energy's (DOE's) License Application. The NRC must make a determination on whether to issue a construction authorization for the repository within three years after submission of the application (unless extended not more than 12 months). Eighteen months of that period have been allocated for staff review. In addition, the repository is a first-of-a-kind facility that has not been previously designed or operated. The NRC staff cannot rely on prototypes, and previous experience in conducting reviews may be limited in use. Therefore, the NRC staff has decided to undertake the development of the necessary licensing documents through the use of systems engineering. In this paper, the basic fundamentals of systems engineering are described, and then their application to the NRC high-level waste program are discussed.

OVERVIEW OF SYSTEMS ENGINEERING

Systems engineering strives to provide methods for integrating the many technical disciplines and socio-econo-political issues associated with complex systems. A wide variety of techniques is available for such integration, and their application to any specific system varies. In all cases, it is necessary, when applying system engineering techniques, to define the task that the system is to perform, the objectives to be achieved by the system, and the measures of performance that are to be evaluated. Systems engineering, in general, provides formalized procedures so that consistency and thoroughness are standardized in an iterative and integrating process. Systems engineering recognizes human limitations in dealing with complex systems and has as a primary goal the development and application of techniques that make management of these complex systems possible.

The techniques of systems engineering grew out of the need to address the development of equipment and the management of projects of increasing complexity. At one time, it was possible for a problem to be structured so that it could be isolated by a few individuals who used one or two disciplines to design, build, and operate a machine or to control a project. However, as societies and technologies became more complex, so did the things that we used and managed. Examples of such things include televisions, computers, military conflict; nation-wide food distribution systems, and so on. We have now come to the point where we are trying to work with systems that incorporate many complex technical disciplines and that involve economic, sociological, political, and environmental issues. In some cases, it has become too expensive or time-consuming to build and test prototypes of these systems. Systems in which significant uncertainty exists in technical, social, or political areas are well-suited to the application of techniques that serve to identify and integrate problems early.

OVERVIEW OF THE NUCLEAR REGULATORY COMMISSION'S HIGH-LEVEL WASTE PROGRAM

There are several reasons why the licensing of a high-level waste repository is an excellent candidate for the application of the principles of systems engineering. First, the NRC requirements for regulating the disposal of high-level nuclear waste, 10 CFR Part 60, "Disposal of High-Level Radioactive Wastes in Geologic Repositories," have never been applied. Because of this, the regulation must be implemented in a structured and logical way that will help ensure that its objectives are being fully met. In addition, much of the ongoing work today deals with the staff's interpretation and implementation of 10 CFR Part 60. It is important that the staff have a mechanism by which it can document the decisions made along with the rationales for such decisions. This is because the repository program is a long-duration activity that will see numerous changes in personnel over its lifetime. Therefore, future staff will need to know and understand decisions made today with respect to 10 CFR Part 60.

Second, the repository itself is a complex system that is comprised of a number of individual systems and subsystems. Integration of the large number of technical disciplines that will eventually be involved in the review of the License Application necessitates a system that will ensure that the necessary interfaces are identified and complete. In addition, the application of the principles of systems engineering will help the staff identify the interactions within the repository system and among the various disciplines performing the License Application review. By using systems engineering, the staff will be implementing an approach that will help it develop the most effective way to successfully perform the assigned job.

A third reason for using systems engineering is that unlike the many reactor and materials licenses issued by the NRC, the high-level waste repository is a unique system for which no prototype or precisely comparable NRC licensing experience exists. Complicating this situation further is the statutory requirement that the NRC complete its licensing action within three years of the date of the license application submittal (unless NRC extends the deadline by not more that 12 months). Eighteen of the 36 months have been allocated for staff review. To develop licensing documents that will allow for the preparation of a high-quality License Application by DOE and a complete review plan for the NRC staff, NRC should ensure that the regulations are complete and clear. In

addition, the staff must ensure that its licensing documents provide sufficient guidance such that when they are applied for the first time they will provide the needed results.

Finally, NRC must also identify those areas for which additional regulatory guidance is needed. Because the applicable regulation has never been implemented before, and because no prototype for a repository exists, the NRC must identify these areas through a more "analytical" approach. Therefore, it is important that the NRC staff conduct an evaluation of the regulation that will allow it to prepare needed guidance on specific regulatory and technical issues, well in advance of the license application.

The overall systems engineering approach being used by the NRC staff in evaluating 10 CFR Part 60 is what is called the Systematic Regulatory Analysis. By using the Systematic Regulatory Analysis, the NRC staff has a number of objectives it is attempting to meet in the preparation of licensing documents. One is ensuring that the existing regulation is clear. This is accomplished by reviewing the requirements presently in 10 CFR Part 60 to determine if there is any uncertainty on: (1) what must be done to meet the regulation (called regulatory uncertainties); or (2) what organization is responsible for implementing the various sections (called institutional uncertainties).

To date, the NRC staff has completed this analysis and has identified 54 uncertainties in the existing regulation. Of these 54, 50 deal with the meaning of the existing requirements, whereas 4 deal with what organization is responsible for implementing portions of 10 CFR Part 60. The staff intends to address 25 of these uncertainties through regulatory guidance, 9 through major rulemakings, and 3 with minor changes to 10 CFR Part 60. Sixteen need to be further analyzed before a final determination can be made, whereas one has already been addressed in a publicly available Commission paper by the staff.

In addition to reviewing the existing regulation for clarity, the staff has also begun work to ensure that 10 CFR Part 60 is complete. At present, the staff has completed its analysis of the operational aspects of 10 CFR Part 60, and recently submitted a rulemaking to the Commission that will address the major findings in this analysis, namely the need for a controlled-use area for pre-closure operation and clarification in the definition of "important to safety" now in 10 CFR Part 60. In Fiscal Year 1993, the staff will conduct the complementary analysis which will cover the post closure aspects of the repository. Not only will this evaluation allow the staff to ensure completeness of 10 CFR Part 60, but it will also help it in reviewing and commenting on the U.S. Environmental Protection Agency (EPA) standard contained in 40 CFR Part 191, "Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes," when it is issued by EPA.

Aside from evaluating 10 CFR Part 60 for uncertainties with implementation, the staff is also reviewing the regulation to determine if there are uncertainties regarding how DOE can demonstrate compliance with the regulation (known as technical uncertainties). As they are identified, the staff will determine if they should be addressed in the format and content regulatory guide for use by DOE in the preparation of the License Application, through a Staff Technical Position that is directed specifically at the issue, or in the License Application Review Plan, . The format and content regulatory guides identifies the information the staff believes DOE needs to present in its License Application, while a Staff Technical Position contains criteria DOE can use to develop methods for demonstrating compliance with 10 CFR Part 60. Both of these are issued as guidance to DOE. On the other hand, the License Application Review Plan is issued to the staff as guidance for it in conducting the review of DOE's License Application.

To date, the staff work in identifying technical uncertainties has been limited. However, as the staff begins to conduct more work in preparing its License Application Review Plan, it will also be determining how to implement 10 CFR Part 60. Through this process, the NRC staff will begin to identify possible technical uncertainties.

Another analysis that the staff will conduct of 10 CFR Part 60, using the Systematic Regulatory Analysis, will be the identification of information that DOE will need to present in the License Application. These information needs will be used by the staff to revise the format and content regulatory guide, which was issued in draft form, for public comment, in November 1990. Like all work conducted within the Systematic Regulatory Analysis, this work will be conducted using procedures.

The staff will also use the Systematic Regulatory Analysis to prepare Compliance Determination Strategies and Compliance Determination Methods, both of which will be major pieces in each of the 101 individual review plans making up the License Application Review Plan. Compliance Determination Strategies will be used to guide the staff on the minimum level of review that should be conducted for that particular individual review plan of the License Application Review Plan. They will be developed within the framework of an overall review strategy that meets existing Commission policy. Although there are four different levels of reviews that the staff can perform, the License Application Review Plan will not limit the staff's review to a particular scope. Rather, if, as the review progresses, the staff finds that it must conduct a more detailed review, it will do so.

Compliance Determination Methods will contain the method and technical criteria the staff will use to conduct its review of DOE's License Application. In addition, they will identify interfaces between individual review plans or technical disciplines, and prepare example evaluation findings that will establish the conclusions expected from the staff's review. Their development will be some of the most complex technical work conducted by the NRC staff in its program. Like the development of the format and content regulatory guide and Compliance Determination Strategies, Compliance Determination Methods will be developed using procedures. They will help ensure that the staff's License Application Review Plan is complete, and that all of the necessary portions of 10 CFR Part 60 have been sufficiently and completely addressed.

APPLICATION TO NRC PROGRAM

To date, the NRC staff has applied systems engineering to the identification of regulatory uncertainties, and has identified several areas where rulemakings are necessary to reduce these uncertainties. A few of these areas, such as the absence of emergency planning criteria and of an overall system performance objective, were obvious. However several others have been identified. For example, the Systematic Regulatory Analysis identified that the requirements of 10 CFR 60.122 could be potentially interpreted in two ways. One

interpretation could be that the requirements of 10 CFR 60.122 were independent requirements and that demonstrating compliance with the performance objectives of 10 CFR 60.112 and 10 CFR 60.113 was not sufficient to meet 10 CFR 60.122. The second was that meeting the requirements of 10 CFR 60.112 and 10 CFR 60.113 was adequate to demonstrate compliance with 10 CFR 60.122. At present, the staff is preparing a rulemaking, that it will present to the Commission late in 1993, to revise the regulations such that only one interpretation is possible. The staff anticipates that the Commission will issue the proposed rulemaking in 1993.

A second example of where the use of the Systematic Regulatory Analysis helped identify rulemaking work that was needed was in the establishment of the controlled-use area for pre-closure operation and clarification in the definition of "important to safety." Although the fact that 10 CFR Part 60 did not contain a controlled-use area like its sister regulation 10 CFR Part 72 was apparent, the Systematic Regulatory Analysis allowed the staff to identify areas where additional work was needed in the design criteria presently in 10 CFR Part 60 such that the NRC's defense-in-depth philosophy would be implemented. This ensured that changes made to the rule were complete and implemented the Commission's policy. In addition, the wording of the rulemaking was reviewed under the Systematic Regulatory Analysis to determine if any regulatory uncertainties existed, before it is provided to the Commission for consideration. This will help eliminate regulatory uncertainties before the final rule is promulgated.

As mentioned earlier, another area where the NRC staff is applying the Systematic Regulatory Analysis is in the development of the format and content regulatory guide. In this guide, the staff identifies to DOE what information must be contained in the License Application such that DOE will be able to prepare a complete and high quality application. A draft version of the guide was issued in November 1990 for public comment, and comments were received. The NRC staff is using these comments along with experience gained in developing the License Application Review Plan and ongoing reviews of DOE submittals to help it update the guide.

The staff expects to issue a final version of the guide in 1994. The staff will begin its work on completing the guide by first taking the information in the draft guide, and determining if it is sufficient and complete. If it is not, the staff will identify what additional information needs should be included, and incorporate them into the final regulatory guide when it is issued. Differences identified to date between the final and draft versions of the guide are minor. They include changes to accommodate the structure the staff found most useful to conduct its review as it prepared the License Application Review Plan. As the staff continues to develop the final guide, it may identify sections of the guide where more information is needed. However, it does not anticipate any major changes to the basic structure of the guide.

During fiscal years 1995 through 1997, the staff will continue to revise the guide as needed to address changes identified through the ongoing development of the License Application Review Plan, and to include appropriate sections or information needs that are new as a result of rulemakings such as emergency planning or design basis events. Information needs for rulemakings identified by the staff are not included until the Commission issues the proposed rulemaking. The staff then plans to issue a revision of the guide in 1998.

The final area where the staff is using the Systematic Regulatory Analysis is in the preparation of the License Application Review Plan. Each section of the review plan will be self standing and contain 1) the applicable regulatory requirements, 2) a review strategy, 3) interfaces for conducting the review, 4) review methods to be used by the staff, 5) acceptance criteria for determining compliance with the regulations, and 6) example evaluation findings that will help establish the objectives of the review. Item 1 is the grouping of applicable 10 CFR Part 60 requirements into a common area. This is one of the first steps in the Systematic Regulatory Analysis, and forms the basis for the rest of the staff's work. Item 2 is part of the Compliance Determination Strategies discussed earlier. Items 3 through 6 are all part of the Compliance Determination Methods being developed under the Systematic Regulatory Analysis.

Work done to date on the License Application Review Plan includes the introduction for the plan itself. This chapter lays out the basic use of the plan, and discusses the overall strategy the NRC staff will use in its review of a License Application for a high-level waste repository. In addition, the staff has completed the grouping of the regulatory requirements in 10 CFR Part 60 into each of the individual review plans to which they belong. This work represents a major accomplishment in establishing a sound structure for the program. It was this work that the staff used to help it identify what changes were necessary to the structure of the format and content regulatory guide described earlier. Finally, the NRC staff has completed the preparation of review strategies for 16 individual review plans, and has also completed in draft the interfaces, review methods, acceptance criteria, and example evaluation finding for the individual review plan for quality assurance. This latter work was based on the review plan presently being used by the staff to evaluate DOE's quality assurance program during site characterization.

At present, the staff is planning to issue Revision 0 of the License Application Review Plan in late 1993. It will include the work completed to date as well as that completed during fiscal year 1993, which will be the review strategies for the remaining 84 individual review plans. As this work is completed, the staff will be identifying any technical uncertainties related to compliance with 10 CFR Part 60. Depending on the severity of the uncertainty, the staff may choose a number of different ways to reduce it. In all cases, it would develop acceptance criteria for the staff to use in reviewing DOE's treatment of the uncertainty. However, in some cases, it could also issue a Staff Technical Position giving guidance to DOE on what DOE can do to demonstrate compliance with the appropriate requirements. The staff could also identify research that it would conduct to support the reduction of the uncertainty, or it could conduct its own technical analysis of the requirement using either computer codes generated by other organizations or codes developed directly by the NRC staff.

In addition to identifying the type of work the staff must do to reduce an identified technical uncertainty, the NRC staff will also use this information to determine the depth of review it will conduct in evaluating that section of DOE's License Application. This is not to say that the staff will be less thorough in its review of the entire application. On the contrary, the NRC staff will be conducting a safety review of all sections of DOE's application where compliance is necessary to make a safety determination for a construction

authorization as defined in 10 CFR 60.31(a). These include those requirements embodied in 10 CFR Part 60, Subparts E, G, H, and I; but for those areas where a technical uncertainty exists, the staff will conduct a more detailed safety review. However, as stated earlier, if the staff finds during its review of the application that it needs to go to a greater depth regardless of whether a technical uncertainty has been identified, it will do so.

Future activities planned for the development of the License Application Review Plan in fiscal years 1994 through 1998 are to conduct an integrating review in fiscal year 1994 of all review strategies completed to date and under preparation in fiscal year 1993. The staff will also begin preparation of the compliance determination methods for some individual review plans in fiscal year 1994 and continue this work through fiscal year 1998 when it plans to issue a final version of the plan. Priority will be given to those individual review plans that will impact ongoing NRC staff work with DOE. These include those that address the potentially adverse conditions contained in 10 CFR 60.122(c), the construction of DOE's exploratory studies facility, and the areas where DOE has begun major design work such as waste package. Over this time, the staff will issue a draft of the License Application Review Plan each fiscal year incorporating new information or modifying existing information based on lessons learned.

OTHER PROGRAM ACTIVITIES

Although the focus of this paper has been the application of systems engineering to the development of the NRC staff's various regulatory documents, it is important to note that there are other parts of the NRC's program that help support preparation. For example, the staff has an extensive effort underway in the development of its capability to conduct iterative performance assessments. It will use the work being completed under this program to not only evaluate how well DOE demonstrates compliance with the EPA standards in 40 CFR Part 191, but will also use it to confirm the presence of technical uncertainties related to compliance with the regulation. Thus, the preparation of the License Application Review Plan is directly supported by the staff's iterative performance assessment capability.

Similarly, the NRC staff has a program where it is developing analysis methods it will use to review DOE's ongoing site characterization and design work. Examples of these are tectonic models, waste package performance, and thermal loading of the repository. When these methods are complete, they, like the iterative performance assessment capability, will become the review methods and acceptance criteria of the License Application Review Plan. In addition, iterative performance assessment and analysis methods along with the License Application Review Plan all help the staff identify interfaces in its technical review areas, plus help ensure that work being conducted by the staff is well integrated.

BENEFITS TO NRC PROGRAM

Use of systems engineering in the NRC high-level waste program has benefited the NRC in a number of ways. First, the staff has been able to evaluate the regulations to help ensure their clarity and completeness. By addressing these now through either rulemakings or regulatory guidance, the NRC is able to work toward focusing the contentions admitted at the hearing on compliance with the requirements not on what the regulations mean. Second, the staff is able to group the requirements into a common structure that allows for the analysis of them with a view toward integration and interface considerations. Third, the identification of interfaces in the development of the License Application Review Plan, iterative performance assessment, and analysis method development helps ensure a technically sound program that is well integrated. And, finally, use of the Systematic Regulatory Analysis will help the staff in preparing complete regulatory guidance documents as well as identifying areas where regulatory guidance is needed. All of these combined will lead to the main benefit of using systems engineering in the NRC's high-level waste program -- being able to conduct the staff's review within the necessary 18 months.

CONCLUSION

This paper has attempted to discuss how the principles of systems engineering are being applied to the NRC's high-level nuclear waste program. By describing and explaining the approach the NRC staff is taking in its Systematic Regulatory Analysis program, it is hoped that insight has been provided to all of the participants involved in the high-level waste program.