# Summary of the Paper
# 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 U.S. 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, 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 which the system is to perform, the objectives to be achieved by the system, and the measures of performance which 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 which make management of these complex systems possible.

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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 which 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 which incorporate many complex technical disciplines and which 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 which serve to identify and integrate problems early.

Application to the NRC 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," has 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 meet.

Second, 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. In order 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, the 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, the 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 what must be done to meet the regulation, called regulatory uncertainties, or what organization is responsible for implementing the various sections, called technical 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 while 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, 7 through major rulemakings, and 3 with minor changes to 10 CFR Part 60. Eighteen need to be further analyzed before a final determination can be made, while 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 if 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 finding 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 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."

Besides evaluating 10 CFR Part 60 for uncertainties with implementation, the staff is also reviewing the regulation to determine if there are uncertainties dealing with how DOE can demonstrate compliance with the regulation. These uncertainties are 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, in the License Application Review Plan, or through a Staff Technical Position that is directed specifically at the issue. To date, the staff work in identifying technical uncertainties has been limited; however, as the staff begins to conduct more work in determining how to implement 10 CFR Part 60, it 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 the staff will need to have to conduct its review of the license application. In the vernacular of the Systematic Regulatory Analysis, these are known as Technical Review Components. They 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, Technical Review Components will be prepared 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 the individual sections of the License Application Review Plan. Compliance Determination Strategies will be used to guide the staff on the level of review that should be conducted for that particular section 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 Strategies identify to the staff the minimum level of review it must do.

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 technical disciplines, and prepare example evaluation findings which will establish the objectives of the staff's review. Their development will be some of the most complex technical work conducted by the NRC staff in its program. Like Technical Review Components and Compliance Determination Strategies, Compliance Determination Methods will be developed through 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 by September 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 design basis events. 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 10 CFR Part 60 to existing design criteria.

This ensured that changes made to the rule were complete and implemented the Commission's policy on defense in depth. In addition, the wording of the rulemaking were reviewed under the Systematic Regulatory Analysis to determine if any regulatory uncertainties existed before they are 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. 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.

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 the 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. Each of these items is being developed through the Systematic Regulatory Analysis. 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 the Compliance Determination Strategies discussed earlier. And, Items 3) through 6) are all part of the Compliance Determination Methods being developed under the Systematic Regulatory Analysis.

Benefits to NRC Program

Use of systems engineering in the NRC high-level waste program has benefitted 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 ensure that the focus of contentions admitted at the hearing are on compliance with the requirements not on what the regulations mean. Second, the staff is able to group the requirements into a common set that allow for the analysis of them with a view for integration and interface considerations. 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. This is 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.