TITLE OF PAPER: SYSTEMS ENGINEERING APPLIED TO A REGULATORY PROGRAM

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# SYSTEMS ENGINEERING APPLIED TO A REGULATORY PROGRAM

## BACKGROUND

The United States is in the process of developing a High-Level Radioactive Waste (HLW) Repository. As a first of-a-kind facility, this is a formidable undertaking in itself but will also require the development of government regulations to ensure health and safety of the general public over time periods never before considered. Further, as directed by the U. S. Congress, the U. S. Nuclear Regulatory Commission (NRC) is to complete its licensing hearing process within a three year period, with one additional year possible if justified to Congress.

In order to meet the directives of Congress and to ensure the safe construction, operation, and eventual closure of a HLW Repository the NRC has undertaken an aggressive program to develop regulatory guidance and oversight that will, to the best of our abilities, result in the submittal of a complete and adequate License Application by the U. S. Department of Energy (DOE). The DOE is the government agency chartered by Congress to design, develop and operate the HLW Repository. The NRC program has established basic regulations for the licensing of a HLW repository, Code of Federal Regulations 10 Part 60, but maintains a pro-active program of review and interaction with potential parties to the licensing, primarily the DOE, to identify potential areas of regulatory, institutional or technical uncertainty that could affect the licensing process. NRC clarifying regulatory guidance continues to be

published to assist DOE in interpretation of this Rule and, where necessary, new rulemaking is undertaken to ensure completeness, consistency or clear legal and technical interpretation.

The diversity of technical considerations, the limited regulatory experience for a first-of-a-kind deep geologic repository, coupled with the long time period involved, dictate that a fairly structured program be put in place. Accordingly, the NRC decided to apply systems engineering practices to assist in the internal management of its program. The development of formal system engineering approaches was initiated with the recent start-up of the NRC Federally Funded Research and Development Center, the Center for Nuclear Waste Regulatory Analysis (CNWRA or Center) located in San Antonio, Texas. The Center has been chartered to provide dedicated assistance to NRC.

## SYSTEMS APPROACH

Systems engineering is typically be applied to a physically engineered entity such as an aircraft, machine or manufacturing facility where the interface requirements of separately designed and constructed functional parts is a major concern. However, it is equally applicable to the "soft" products, as for example a regulatory program, where there are many interrelated requirements,. The total regulatory program, as a system, must be complete and sufficient and its performance function is to ensure protection of public health and safety. The regulatory program also has output products, namely regulatory requirements and guidance, which must be both effective and efficient to achieve our

national goals. Therefore application of a systems approach for a regulatory program is equally as important as in manufacturing.

Although complex in the detail of application, the approach employed by NRC in initiating the application of systems engineering to the HLW Repository regulatory program adhered to rather basic steps as follows:

- o Concept Development
- o Requirements Definition
- o Functional requirements
- o System Design
- o Test and Operation

Integral to these process steps is the identification of performance, cost and schedule requirements where particular attention is directed toward evaluation of operability and maintainability of the system.

CONCEPT DEVELOPMENT

The end product associated with the systems engineering approach for the NRC regulatory program is a structured program where requirements, analytical methods, information needs, and status would be recorded in a computerized data base. The basic concept employed derived from

experience in nuclear reactor licensing. Essentially the HLW Repository licensing program progresses from the regulation, to elements of proof (what the licensee must demonstrate) to NRC compliance determination methods, to information needs to NRC assessment of compliance with our regulations and public health and safety. Lacking experience for repository licensing, an addition to this process is the identification of regulatory, institutional and technical uncertainty. Regulatory uncertainties derive from percieved differences in the regulation (omissions, extraneous requirements, or lack of specificity). Institutional uncertainties may derive from a lack of clarity over regulatory authority between agencies. Technical uncertainty may result from lack of a qualified compliance determination method or unfulfilled information needs. As a first of a kind facility, but one where the hearing process is to be completed in three years, the NRC is attempting to identify and resolve, where possible, these uncertainties prior to entering the formal licensing hearing. Our goal is to allocate the three years to an examination of the merits of the application, not litigation to resolve interpretations of NRC's regulatory requirements.

The concept of the end product as a computer accessible, relational information database derives from the need to deal with a highly complex system where there numerous interdependences between engineering design, performance, and the natural conditions of the site. Also, the quantity of information and the long time period involved, where a high turnover in technical staff is to be expected, dictate that a progressive technical record is needed to form an institutional memory. A properly

designed computer accessible database is also a significant management tool in tracking and evaluating a large complex program.

## REQUIREMENTS DEFINITION

The NRC project objective is to develop a requirements based regulatory program through which the systematic performance would result in an efficient and adequate repository licensing process. The program itself is intended to have a relatively well defined structure, or framework, it has, therefore, been referred to as the "Program Architecture". The licensing requirements are established through the HLW Repository Licensing Regulation, 10CFR60, and play a key role in the systems approach but are different from the operational regulatory program performance requirements. The regulatory program requirements are briefly summarized:

- To develop regulatory guidance sufficient for the applicant to prepare a high-quality license application; includes rules, ammendments, and interpretive guidance.

- To develop internal NRC staff and Center staff capability to conduct a comprehensive and timely review of a license application to ensure compliance with the regulations and protection of public health and safety.

- To establish a record which will support the licensing decision process

Appropriately, the requirements should also include a system effectiveness criteria. The system effectiveness criteria that should be applied is a measure of how well a three year licensing was achieved. Since this would occur to late in the program to be useful, intermediate, qualitative criteria, will be invoked. Though not firmly fixed, these criteria are intended to assess: how well the licensing requirements ultimately are complete, sufficient and clearly understood by the potential parties to the hearing; the extent to which the NRC's standard review plan for repository licensing is produced in a timely and efficient manner; and the extent to which the basis for the NRC program and licensing related decisions are adequately documented.

FUNCTIONAL REQUIREMENTS

the functional components of the program structure follow the original concept with modification and addition. The primary functional units are basic to the regulatory process and are:

- Regulatory Requirements (rules and regulations affecting the HLW Repository)

- Regulatory Elements of Proof (what must be demonstrated by Doe in the license application)

- Technical Review Components (the type of information NRC would review in a license application - identified in regulatory guidance documents)

- Regulatory, Institutional and Technical Uncertainties (areas where there may exist questions of interpretation, need, responsibility or method)

- Uncertainty Reduction Methods (the approach that will be followed to resolve or mitigate the uncertainty, such as rulemaking, regulatory guidance, etc.)

- Compliance Determination Method (how NRC will review the license application for compliance with each regulatory requirement)

- Information Needs (information required to execute an Uncertainty Reduction Method or Compliance Determination Method)

- Alternatives Analysis (evaluation and selection between alternatives for Uncertainty Reduction Method and Compliance determination Method - includes performance allocation or priority and resource level commitment)

SYSTEM DESIGN

The process flow diagram developed by the CNWRA to incorporate the above functional elements, other elements and integration steps is included as Figure 1. At each of these process steps provision has been made to record the current information and rationale for a decision that may be made in a computer accessible database. The regulatory analysis is conducted for each regulatory requirement of 10CFR60. For example regulatory requirements for "Substantially Complete Containment", 10CFR60.113(a)(1)(i)(A)., is a specific task and follows the process steps of Figure 1. There are approximately 108 specific regulatory requirements now identified and, in practice, a regulatory requirement may have several parts which may follow different process steps. on the other hand several regulatory requirements may be included in one task effort. The detailed description of the system design is included in the noted references.

The program information is maintained in a relational database which NRC technical staff and management can access through telecommunication lines. The relational aspects of this computer program are intended to provide capability to identify and review the interrelational aspects of the regulatory requirements, technical effort to minimize uncertainty, and to manage the interfaces. the noted references and are not repeated here.

TEST AND OPERATION

The system has had several demonstration test at various stages of development and modifications have been made to improve its usefulness

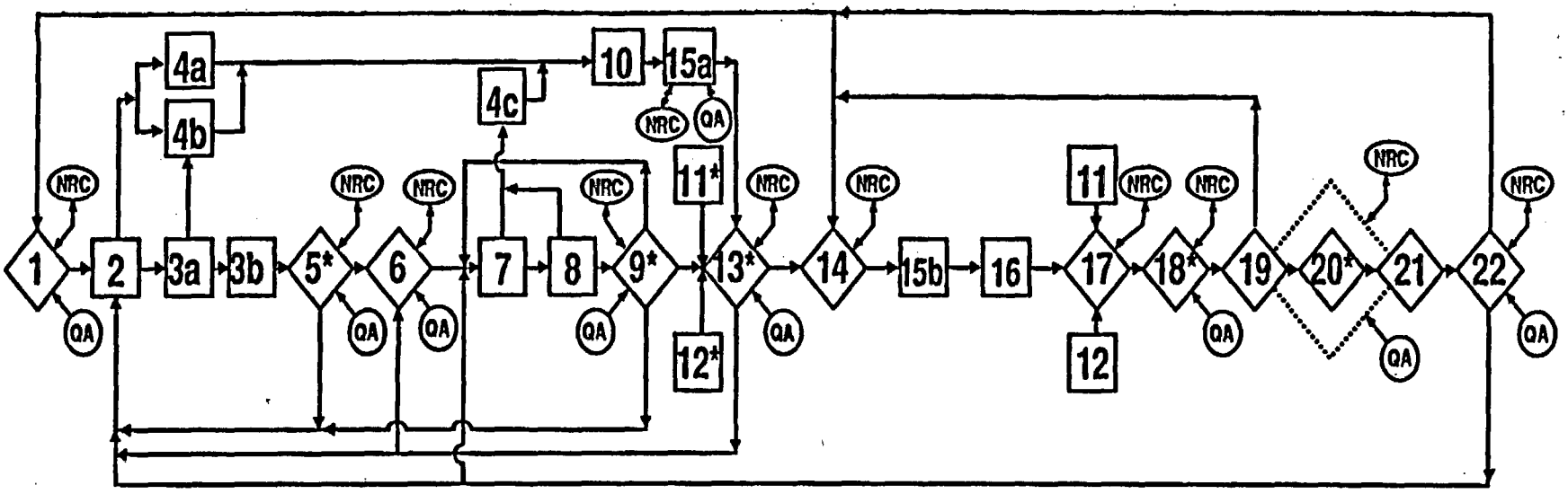
and the "user friendly" aspects of the computer database. To date the system has progressed to the point where regulatory analysis has been conducted to identify regulatory and institutional uncertainties. These were ranked using attribute analysis as a first step in evaluating alternative approaches. Testing is continuing by carrying through two Regulatory Requirement Topics, "Substantially Complete Containment" (10CFR60.113) and Erosion, 10CFR60.122(c)(16). Particular emphasis is directed at the approach for identification of technical uncertainties, the level of detail to be incorporated in the data base and, of special concern, the operability and maintainability of the system with reasonable resource expenditures.

The oral presentation will discuss the development and operational experience.

REFERENCES

1. Center for Nuclear Waste Regulatory Analyses, "Proof of System Demonstration for Program Architecture and Pass," (1988).

2. Center for Nuclear Waste Regulatory Analyses, "Analysis and Evaluation of Regulatory Uncertainties in 10CFR60 Subparts B and E," 88 pp. (1989).




1. Identify Potentially Applicable Statutes and Regulations
2. Analyze and Identify Regulatory Requirements
3a. Identify and List Regulatory Elements of Proof
3b. Identify and List Technical Review Components
4a. Identify and Describe Institutional Uncertainties
4b. Identify and Describe Regulatory Uncertainties
4c. Identify and Describe Technical Uncertainties
5. Review, Revise, and Integrate Regulatory Requirements, Regulatory Elements of Proof, and Technical Review Components
6. Select Subset(s) of Regulatory Requirements for Further Analysis Based on Time-Critical Nature
7. Identify Basic Approach for Compliance Determination Methods
8. Identify Information Requirements for Compliance Determination
9. Review, Revise, and Integrate Compliance Determination Methods and Associated Information Requirements
10. Identify Uncertainty Questions
11. Obtain DOE "Issues", Compliance Demonstration Methods, Information Needs, Uncertainties, and Uncertainty Reduction Methods
12. Obtain State, Tribe, and Other Affected Parties "Issues", Compliance Evaluation Methods†, Information Needs, and Uncertainties
13. Correlate and ConsolidateUncertainties, (Including DOE and State Items), Rank NRC Consolidated Uncertainties; Identify and Review Information Requirements for Uncertainty Reduction
14. Correlate and Consolidate Information Requirements; Select Consolidated Information Requirements for NRC Action; Identify Other Action Agencies
15a. Analyze Alternative Uncertainty Reduction Methods, Draft the Postulated Uncertainty Reduction Language (PURL) for Recommended Rulemakings, and Submit to the NRC for Review
15b. Specify Alternate NRC Programs for Satisfaction of Each Information Requirement and for Uncertainty Reduction
16. Develop Costs, Schedules, and Lead Times for Alternative NRC Programs for Satisfaction of Each Information Requirement and for Reduction of Each Uncertainty
17. Analyze and Perform Tradeoffs of Alternative NRC Programs for Satisfaction of Each Information Requirement and for Reduction of Each Uncertainty
18. Recommend Overall NRC Program Including Overall Research Program Plan
19. Develop and Display the Network and Critical Path for Each Regulatory Requirement
20. Develop and Display Network for Total Program
21. Control and Document Program Structure and Changes
22. Conduct the NRC Program

† Assuming at least one party will perform independent "compliance evaluation".

5/19/89

FIGURE 1. PROCESS DIAGRAM FOR DEVELOPING AND MAINTAINING THE PROGRAM ARCHITECTURE