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PREPARING A SAFETY ANALYSIS REPORT USING THE BUILDING BLOCK APPROACH

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ABSTRACT

The credibility of the applicant in a licensing proceeding is severely impacted by the quality of the license application, particularly the Safety Analysis Report. An incomplete, unintelligible, and inconsistent document creates extra hardship for the reviewers, the review board, and the expert witnesses who will be required to support the contents of the document in the event contentions are raised in the licensing hearing. To ensure the highest possible credibility, the building block approach was devised to support the development of a quality Safety Analysis Report. The approach incorporates a comprehensive planning scheme that logically ties together all levels of the investigation and provides the direction necessary to prepare a superior Safety Analysis Report.

intermediate levels of interpretive analysis, and finally results in the preparation of a superior Safety Analysis Report. The key to the approach is the preparation of a plan, not unlike a construction plan, that contains the logical linkage among the elements of the structure.

Planning for the building block approach is currently being developed by the Yucca Mountain Project Office, Regulatory and Site Evaluation Division, and their Technical and Management Support Services contractor, for use in the eventuality that a license application and Safety Analysis Report are deemed appropriate for the Yucca Mountain Site. Application of the approach utilizes personnel of many disciplines, and for its ultimate success, the approach relies on the experience of the regulatory and licensing staff.

INTRODUCTION

The Yucca Mountain site is being investigated to determine its acceptability as a site for a high-level radioactive waste repository. The investigation consists of field and laboratory testing and analysis to determine the geologic conditions at the site. This activity is called site characterization. If site characterization is completed with a finding that the site is suitable for a repository, and if the assessment of the expected performance of the site, considering both geologic conditions and repository and waste package designs, indicates the site will be acceptable, then the next step taken by the U.S. Department of Energy (Department) will be to apply to the U.S. Nuclear Regulatory Commission (Commission) for a license or authorization to construct the repository. To support the license application, the Department will prepare a Safety Analysis Report.

THE SAFETY ANALYSIS REPORT

The Safety Analysis Report will provide the Commission with information to assist them in making a determination regarding the reasonableness of the risk to the health and safety of the public represented by the construction and operation of the repository. The Commission's rules and regulations in 10 CFR 60.21(c) describe, in general terms, the information they expect to see reported in the Safety Analysis Report. In addition, the Commission plans to issue a regulatory guide in 1990 that will provide the details of the content and format of the Safety Analysis Report (a table of contents for the Format and Content Regulatory Guide for the License Application for the High-Level Waste Repository was issued on August 25, 1989).

THE TYPICAL LICENSE APPLICATION PREPARATION

Most nuclear licensing activities have an advantage that high-level waste repository licensing does not have: the existence of a sizable file of licensing precedence. The preparation of a Safety Analysis Report is simplified considerably by having one or more

The building block approach is the name given to a process that builds from the elementary results of site characterization investigations and design activities, through

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similar documents to refer to. It can become as easy as filling in the blanks related to the current licensing objective. The potential applicant, working with another licensee's approved Safety Analysis Report, has many other items available to provide guidance. There are the supplements and amendments resulting from the licensing review by the Commission and the actions of the review board, there is the license maintenance record developed as a result of regulation or operation amendments, and there is the experience record obtained from periodic licensee reports over the time that the licensed installation has been in operation. With all this help, the newly prepared Safety Analysis Report can be much improved over the pattern and content of the original. The applicant knows in advance exactly what technical support information is required. It is a simple matter to obtain the required information from the appropriate engineer or scientist and to incorporate the license-specific information into the Safety Analysis Report.

THE HIGH-LEVEL WASTE REPOSITORY LICENSE APPLICATION PREPARATION

The advantage of a file of licensing precedence does not exist for preparing a license application for a high-level radioactive waste repository. Not only is there no previous application for the same type of license, there has never been a license application covering a performance period of several thousand years. To compound the difficulties posed by this first-of-a-kind application, the applicant will be continually aware of the unparalleled public interest in this proceeding. The interest will focus on the case presented by the Department in the Safety Analysis Report for this significant activity. All parties to the proceeding will be interested in the defensive strategies used by the intervenors, and the handling of the review by the regulators. Apart from the official interactions resulting from the Commission's review and the hearing process, all parties can be expected to be second-guessed by the many interested observers. The Department will be criticized for not having enough, or proper, information to support their positions. The Commission staff will be criticized for making findings without sufficient supporting evidence and also for requiring excessive evidence for their reviews. The Atomic Safety and Licensing Board will be called pro-applicant, pro-staff, pro-State, pro-intervenor, anti-everything, unduly restrictive, and far too lenient. There will be pro and con arguments identified with all of the other parties to the proceeding.

Consequently, it is in the best interest of all parties involved for the Department to produce the best Safety Analysis Report possible at the time that their license application is made. The building block approach for preparing

the Safety Analysis Report is a concept devised to obtain that high quality product.

THE BUILDUP

To build a structure out of building blocks, a blueprint of the planned target is needed. In the present case, the target is the Safety Analysis Report. A typical outline for a Safety Analysis Report was prepared by the Department, using the content, criteria, and other requirements that appear in the Commission's regulation, 10 CFR Part 60, and knowledge of the general format of Safety Analysis Reports prepared for other licensed activities. After the Department's Safety Analysis Report outline was completed, the Commission prepared a format and content guide that provides the outline for the license application (including the Safety Analysis Report) which is now being followed. The outline is the blueprint. Using the outline, the site and repository information-gathering activities can be matched with the eventual use of the information in the Safety Analysis Report. The remaining task is to place the blocks in the right order.

Foundation

The blocks in the foundation of the structure are the basic information provided by site characterization and design activities. Various plans that will be used by the Yucca Mountain Project to provide direction for their efforts, such as the Site Characterization Plan, and Design Program Plan, will define the basic studies, investigations, activities, and design efforts. The data or information identified in the plans for investigation is linked using the Safety Analysis Report outline to the sections requiring that input. That data or information may be needed in several locations and may be used in several different combinations to satisfy the foundation requirements of the report. The building block approach ensures that the proper distribution of information is made by identifying in advance the links between the providers and users of information. In practice, the establishment and tracking of the multiple links between the determination and destination of information is managed using a computer-based relational data base.

The information becomes available for use in the Safety Analysis Report only after it enters a controlled environment. Uncontrolled data can only produce an uncontrolled report. That does not conform with the goal of providing the best Safety Analysis Report possible at the time of its submission.

Middle Course

The middle course of building blocks consists of interpretive reports built on the information provided in the foundation. It is

higher-level technical data documenting the results of technical activities and the performance assessments developed from those activities. It is derived by combining, processing, and interpreting foundation results to fulfill the secondary needs of the applicable study. This middle course of advanced data and information is linked both from the foundation level and to its eventual use in the Safety Analysis Report.

It quickly becomes obvious that without the blueprint (Safety Analysis Report outline) of the desired product goal, and the construction plans (linking logic) for reaching that goal, all of the building blocks in the world would only be sitting around on pallets, not contributing to any product.

Apex

Because the laborious but essential identification has been made of all of the paths from characterization studies and design products, through the development of basic data, and on to the formation of higher-level technical information and performance assessments, the building block approach ensures that a thorough basis exists for input to the Safety Analysis Report. The apex of the building block structure is the determination of sufficiency of information in each investigative element to support the licensing strategy proposed for that element. A working group of knowledgeable professionals in each scientific and engineering discipline, will assess the available information in the lower building block tiers and determine when it is sufficient to support the proposed position. If not sufficient, one of two steps may be taken: call for additional investigation, or establish an alternative position that is sufficiently supported by the information. When the existing data is sufficient to support the position, the suite of information under consideration will be converted into the appropriate section of the Safety Analysis Report.

REGULATORY INTEGRATION

The development of this collection of engineering and scientific findings into a licensing document is a sensitive task. The process of investigation, interpretation, indication of ancillary impacts, and finally determination of the sufficiency of the information base will have created a sizable quantity of data and information from which to write a section of the Safety Analysis Report supporting a particular position. All of the information obtained must be presented with complete candor. All of the potential interpretations of that data must be applied in a strictly unbiased manner. This is definitely not the place for championing any personal or professional bias. The investigator, because of

his or her qualifying experience with the subject matter, will be required to describe the technical conclusions of the investigation and to develop the interpretive variations in writing. But who will locate and defuse any latent bias? Who will provide the appropriate regulatory emphasis? Who will see that only reasonable interpretations of regulations and regulatory guidance are used?

Enter the regulatory integrator. This function of the license applicant's cadre of specialists is vitally important to the proper completion of the apex blocks that crown the structure and become the Safety Analysis Report. The regulatory integrator or regulatory-oriented technical analyst will work with the investigators who develop and interpret the data and make the conclusions to be represented in the licensing position. The regulatory integrator will see that the investigators are given the correct section of the annotated outline for the Safety Analysis Report, as contained in the Commission's Format and Content Regulatory Guide, and that the investigators are coordinated with regard to who will author each segment of the section. The regulatory integrator will evaluate the draft section thus produced, indicating where ambiguity should be removed, locating and defusing any apparent author bias, and applying appropriate regulatory emphasis. Instances of misapplied interpretation of the regulations will also be noted. The authors will work with the regulatory integrator to resolve any proposed changes. The result of this process is a quality section that, when consolidated with all sections of the Safety Analysis Report, will withstand scrutiny by all interested parties.

With the help of regulatory integration, the document buildup can progress naturally from its foundation in myriad data and information determinations to less numerous, but even more important, higher-level technical assessments of the data and information, and finally, to the few major sections that make up the Safety Analysis Report.

THE CONCLUSION

The building block approach makes the maximum advantage of following the logical progression of information from its inception in site characterization and design, through its augmentation by interfacing with other information, interpreting results, and applying performance assessment, to its ultimate use in the Safety Analysis Report.

Close management and efficient utilization of the enormous amount of information is made possible by completely pre-defining the interrelationships from the studies to the Safety Analysis Report.

A two-way winnowing of proposed information needs is possible using the detailed logic connections. Information needs may be identified that do not clearly feed the Safety Analysis Report and, likewise, Safety Analysis Report topics may be identified for which no apparent information is being collected. In either case, the ability to identify these discrepancies makes their correction possible.

Considering all of the above, the building block approach will provide overall efficiency for the preparation of a superior Safety Analysis Report in the event that the investigation of the Yucca Mountain Site indicates that a license application is required.

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