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CONTRIBUTION TO COMMISSION PAPER ON EPA PROPOSED STANDARD—APPLICATIONS OF LESSONS LEARNED FROM SYSTEMATIC REGULATORY ANALYSIS TO REVISION OF 10 CFR PART 60

Since 1987, the Nuclear Regulatory Commission (NRC) and the Center for Nuclear Waste Regulatory Analyses (CNWRA) staffs have applied the principles of systems engineering to assist in integrating and streamlining the implementation of the high-level waste (HLW) regulatory program. The decision to do this considered (i) the extreme technical and programmatic complexity of the program, (ii) the need for long-term consistency of program implementation through use of standardized criteria and documentation of decisions, and (iii) the legislatively mandated three-year licensing decision timeframe. The resulting unique refinement of systems engineering techniques for the HLW program has been termed Systematic Regulatory Analysis (SRA). As envisioned, SRA and iterative performance assessment combine to provide programmatic and technical integration for the NRC HLW program.

One of the most far reaching and continuing aspects of SRA has been a systematic analysis of 10 CFR Part 60. This analysis was conducted for the following purposes.

- **Verify the adequacy and sufficiency of 10 CFR Part 60:** This process included completing a HLW repository functional analysis (Romine, 1992); development and analysis of repository operations phase and isolation phase regulatory criteria (Hageman and Chowdhury, 1992; DeWispelare and LaPlante, 1993; and Hageman and Chowdhury, 1994); and detailed examination of 10 CFR Part 60 to identify regulatory, institutional, and technical uncertainties (Weiner et al., 1990).

- **Define the regulatory structure:** This effort was conducted to define the way in which the various sections and requirements within 10 CFR Part 60 were interrelated in order that an integrated, multidisciplinary license application review could be executed in an efficient and timely manner.

- **Identify techniques for streamlining the licensing process:** The first part of this effort was to provide a license application format and content guide to the Department of Energy (DOE) based on the regulatory structure discussed above (Nuclear Regulatory Commission, 1990). Then, guidance was developed by the staff for license application review in the form of a license application review plan (LARP) based on the same regulatory structure and consistent with the format and content guide (Nuclear Regulatory Commission, 1995). The various sections of the LARP were developed using a set of analysis techniques and criteria applicable to all staff technical disciplines. The intent of this effort was to ensure that a high quality license application was received which was based on the same regulatory structure and format used by the staff to prepare the review plans. As a result, license application review could be technically adequate, integrated across all applicable technical disciplines, and meet the legislated time mandate.

- **Identify key technical uncertainties and methods for addressing them early in the program:** Key technical uncertainties (KTUs) guided the research and technical assistance programs and focused resources on the most important licensing issues. The codes, methods, and techniques developed to address these uncertainties were incorporated into

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the individual review plans of the LARP to support compliance determinations. The KTUs were subsequently consolidated into ten key technical issues which form the basis for the current NRC HLW regulatory program.

- **Support the HLW regulatory program with an automated database system:** This system has evolved into the Consolidated Document Management System (CDOCS) which contains searchable and retrievable copies of relevant regulatory and technical documents, an open item tracking system, the capability to cut and paste information into WordPerfect documents to support integrated analysis, planning, review activities, and a unique report-generating feature for preparing automatically updated reports such as the status of open items or the LARP.

The application and evolution of SRA has resulted in lessons learned that should be applied as 10 CFR Part 60 is revised to implement the new Environmental Protection Agency (EPA) standard. The remainder of this appendix discusses these lessons and the plans and recommendations for incorporating them into the revised 10 CFR Part 60.

- **Lesson 1:** Functional analysis techniques can be used to evaluate the adequacy and sufficiency of a regulation. However, they are best applied prior to developing the regulation.

  — **Discussion:** CNWRA performed a functional analysis of a geologic repository physical system to determine whether all health and safety related repository functions were adequately addressed in 10 CFR Part 60. While the regulation was found to be adequate in almost all respects, it had not been prepared in a manner that clearly reflected the regulatory functional interrelationships. As a result, the functional analysis and its results were difficult to correlate to the regulation and to convey to the staff. This lack of clarity in the regulatory functional interrelationships has contributed to a lack of consensus as to how 10 CFR Part 60 should be implemented.

  — **Application to revised 10 CFR Part 60:** There will be two top level regulatory functional requirements: (i) 10 CFR Part 20 for preclosure operations, and (ii) the dose or risk criterion promulgated in the revised EPA standard for the postclosure period. The functional analysis already conducted for the repository system will serve as a foundation for revising 10 CFR Part 60 considering these two top level requirements.

- **Lesson 2:** Regulatory requirements relating to performance objectives; features, events, and processes (FEPs); or design requirements must be critically examined to ensure that they are clearly and unambiguously stated, and implementable with respect to compliance demonstration and determination.

  — **Discussion:** Nearly 60 percent of regulatory and institutional uncertainties identified through the SRA process related to the meaning of regulatory requirements in these areas. Examples of language that caused such unintended difficulty include: (i) substantially complete containment, (ii) fastest path of radionuclide travel, (iii) disturbed zone, (iv) extreme erosion, and (v) adequately evaluated and investigated. Attempting resolution of these uncertainties required

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significant resources from DOE and NRC. In all of these examples, identifying a quantitative measure for the requirement presented significant difficulty. Items (i) through (iii) were related to subsystem performance objectives that had no direct functional link to the total system performance objective, complicating evaluations of system performance. Another recurring issue surrounding these uncertainties was the degree of specificity appropriate for the regulation. Providing an extensive and detailed list of requirements has the liability that important items may be overlooked by NRC. However, avoiding specificity in the regulation could result in DOE failing to address important FEPs or design issues.

— **Application to revised 10 CFR Part 60:** In keeping with National Academy of Sciences (NAS) recommendations and Congressional direction, there will be no quantitative subsystem performance objectives. Specification of FEPs and design criteria will be minimized. Generic requirements will be included, NRC staff will examine these requirements for clarity and implementability, and DOE will have the responsibility to properly characterize the site and design the repository in order to demonstrate with reasonable assurance that the performance objectives will be satisfied.

- **Lesson 3:** The interrelationships among regulatory requirements must be clear.

  — **Discussion:** In implementing the existing 10 CFR Part 60, it was not possible to establish a staff consensus on interrelationships of siting and design requirements, anticipated and unanticipated events, performance objectives, and among combinations of potentially adverse and favorable conditions. The lack of consensus complicated the development of an integrated LARP. The lack of clarity also complicated initial DOE efforts in preparing a license application annotated outline.

  — **Application to revised 10 CFR Part 60:** In response to the NAS recommendations and Congressional direction, the staff intends to include a quantitative postclosure performance objective only for the total system. However, qualitative demonstration of performance for each of the subsystem multiple barriers will be required. The revised regulation will contain no separate regulatory requirements for potentially adverse and favorable conditions or anticipated and unanticipated events. Requirements related to FEPs and design criteria will be more generic in nature. Significance of FEPs and design criteria will be evaluated only with respect to their effect on total system performance.

- **Lesson 4:** Regulatory language must be specific concerning the requirements that must be met, yet flexible as to how they must be met to allow the applicant flexibility in demonstrating compliance and for the NRC determining compliance in consideration of changing technology. However, simplicity and clarity are necessary.

  — **Discussion:** Significant resources were expended attempting to clarify appropriate techniques for demonstrating or evaluating compliance. Since overall compliance will be evaluated to the standard of "reasonable assurance," there is, in general, no need to provide modifying language to subordinate requirements. The text of

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the revised regulation should be evaluated specifically for clarity and for implementability.

— **Application to revised 10 CFR Part 60:** Drafters of the revised regulation will be required to demonstrate clarity and simplicity of the text to the extent practical.

- **Lesson 5:** Demonstrating compliance with regulatory requirements should not require the use of technology that is not currently available.

  — **Discussion:** When evaluating acceptable methods for demonstrating compliance with requirements in the existing regulation, it was discovered that current technology was not sufficient in some instances. Examples include: (i) evaluations of four-way coupled processes, (ii) inadequate resolution of geophysical techniques, (iii) inability to validate models, and (iv) predictions of future states. If compliance requires use of such unavailable technology, and alternative methods are not available, the regulation is not implementable, and adequate and sufficient alternative regulatory requirements should be developed.

  — **Application to revised 10 CFR Part 60:** A simplified performance objective for the revised regulation is expected to minimize these problems. Additionally, for the preclosure period, the governing regulation (10 CFR Part 20) has a history of successful application to draw upon for precedent. In general, a consensus has developed concerning the capability of performance assessments to support evaluations of repository compliance for long periods of time, and for concepts of model validation that emphasize developing confidence for model use in specific applications.

- **Lesson 6:** It is necessary to provide guidance for developing review procedures and acceptance criteria that establishes consistent evaluation standards across the full range of disciplines related to HLW disposal.

  — **Discussion:** Experience with developing a format and content guide, a license application review plan, and key technical issues for the existing regulation has led to generic criteria for conducting compliance evaluations. These criteria should be carried forward for use with the revised regulation.

  — **Application to revised 10 CFR Part 60:** Results from development of acceptance criteria and review procedures for the existing regulation will be applied in implementing the revised regulation.

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