Risk-Informed/Performance-Based Regulation
Within the Materials Programs

The terms *risk-informed* and *performance-based* (RI/PB) are defined in NRC's *Strategic Plan: Fiscal Years 2008-2013* (NUREG-1614). The staff defined *risk-informed* as "… a decision-making approach that uses risk insights, engineering judgment, safety limits, and other factors …." It is used for establishing requirements that focus on issues commensurate with their importance to public health and safety (e.g., the risk to human health associated with exposure to ionizing radiation). Probabilistic risk assessment (PRA) is generally understood to define the systematic method used to address three particular questions[1] as they relate to the performance of a particular system, including the human component. PRA is an important tool used in implementing a risk-informed approach.

As discussed in Enclosure 1, the staff provided the Commission with a number of papers on RI/PB regulation and the PRA *Policy Statement.* A summary of these papers and how they apply to the Commission's waste management programs, including low-level radioactive waste (LLW), can be found in several Commission Papers. See COMSECY-96-061, SECY-98-0138, SECY-98-0144, and SECY-99-0100.

The NRC staff defines the term *performance-based* as "… using performance assessment results as the primary bases for decision-making …." Performance-based regulations are measurable, calculable, or have objectively observable parameters, and provide for flexibility in determining how to meet the established performance criteria. NRC's LLW disposal regulation in Part 61 contains four performance objectives, two of which are evaluated using performance assessments that use models, parameters, and assumptions about future site conditions in determining whether a disposal facility can protect people and the environment.

Upon review of the Commission papers referenced above, as well as consideration of the past Part 61 development process described in NUREG-1853, the staff believes that the current LLW regulation is mostly RI/PB, although further improvements are possible. In fact, Part 61 is likely one of the earliest examples of the application of RI/PB principles within the agency.

When considering those RI/PB principles[2], it should be noted that the current Part 61 regulatory model is based on a tiered waste classification system that emphasizes an integrated systems

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[1] These questions are *"What can go wrong?", "How likely is it?", and, "What are the consequences?"* These questions represent the so-called Kaplan-Garrick (1981) risk triplet.

[2] In these papers, the staff previously noted that nuclear materials regulatory framework for the implementation of RI/PB principles was somewhat different from the regulatory framework used for nuclear power reactors. These differences stem primarily from differences between nuclear power reactors as engineered, man-made dynamic systems as opposed to waste disposal systems, which are essentially passive, natural systems that rely on some limited engineering measures. These differences also stem from differences between the PRAs themselves that have been used to evaluate nuclear power reactor safety and performance assessments that have been widely used to evaluate the waste disposal systems. For these reasons, the staff have concluded that the reactor PRA framework is not directly applicable to nuclear material uses because of differences among the activities regulated by the Office of Nuclear Material Safety and Safeguards (NMSS, which, at the time, included NRC's LLW programs) and those of the nuclear power reactor program, individually, as well as collectively between those NMSS activities and those found in the reactor program.

Nevertheless, the staff did note in SECY-99-0100 that the respective approaches used within the agency to evaluate risk regardless of the program in question are essentially in harmony because they address the fundamental questions raised by the Kaplan-Garrick risk triplet when evaluating any potential hazard. When focusing on risk, the

approach to the disposal of commercial LLW, including site selection, disposal facility design and operation, minimum waste form requirements, and disposal facility closure. This model also relies on limited institutional controls. To reach any licensing determination, applicants must demonstrate that the performance objectives of Subpart C would be met, with reasonable assurance. To meet those performance objectives, Part 61 license applicants need to prepare an assessment of potential future dose impacts to the general population as well as to individuals that might occur as a result of the operation of a commercial LLW disposal facility. Technical analyses (presently termed 'performance assessment,' although not described as such at the time the rule was first promulgated), would be used to estimate these future radiological doses. The requisite technical analyses and associated information needs for both the analyses and any licensing determination based on those analyses are provided in § § 61.13(a)-(d). As early as 1982, the staff began to undertake a variety of performance assessment-related projects intended to aid in the evaluation of various features (both natural and man-made) of a Part 61-type of facility.[3]

Part 61 is thus intended to be performance-oriented rather than prescriptive in the sense that the rule has four performance objectives that must be met, with the result that Part 61's technical criteria are written in relatively general terms, allowing applicants to demonstrate how their proposals meet those criteria for various specific near-surface disposal methods, consistent with the ultimate goal of meeting the performance objectives. The *Statements of Consideration* for both the draft and final rule provided the overall philosophy and concepts supporting Part 61.[4]

The three-tier waste classification system at § 61.55(a) provides some level of assurance that the performance objectives at § 61.42 will be met. The Part 61 classification system described in that section of Part 61 considered human intrusion scenarios, which were believed to constitute the largest potential dose to any receptor. Key decision parameters in the waste classification system are the physical stability of the waste form as well as its isotopic concentration. The concentration limits were based on the staff's understanding at the time

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staff also found that the objectives of the materials regulatory framework were essentially the same as those for the power reactor framework, namely to: (a) enhance safety by focusing NRC and licensee resources in areas commensurate with their importance to health and safety; (b) provide a framework for using risk information in all regulatory matters; and (c) allow use of risk information to provide flexibility in licensing and operational areas.

[3] Many of the products associated with the NRC-sponsored research effort are described in the references cited in NUREG-1573.

[4] In SECY-98-0138, in specific reference to questions concerning Part 61, the staff noted that the Commission's LLW rule fundamentally demonstrated a RI/PB approach to regulation, supplemented by a secondary level of requirements that were both deterministic and prescriptive. It is important to note that prior to issuance of the *1995 PRA Policy Statement*, the staff had already in-place a long-standing strategy to risk-inform the evaluation of LLW disposal facilities through the use of performance assessment methods. See Starmer, Deering, and Weber (1988). In implementing that strategy, the staff developed a LLW performance assessment plan in 1992 outlined in SECY-92-060. Consistent with that plan, the Sandia National Laboratories was retained to provide performance assessment technical assistance to the staff, documented in Kozak et al. 1990, which led to the publication of an early LLW test case calculation in 1992 (DOE et al., 1992). The staff subsequently updated the test case (i.e., Cady and Thaggard, 1994) in connection with the development of guidance on the attributes of an acceptable LLW performance assessment methodology. In connection with the development of those recommendations, the staff was communicating with the Commission on key policy issues associated with any LLW performance assessment in SECY-96-103. In response to Commission direction, following public comment, those key policy issues were later codified in NUREG-1853 (NRC 2000) ─ the Branch Technical Position on LLW performance assessment. This history is outlined in more detail in Eisenberg et al. (2000).

(circa 1978) of the characteristics and volumes of LLW reasonably expected for commercial disposal through the year 2000, as well as potential disposal methods likely to be used. The NRC viewed these parameters as important because they provide the minimum information necessary for basic decisions on the safe handling and disposal of commercial LLW.

Nevertheless, upon independent review by the Commission's former Advisory Committee on Nuclear Waste and Materials, as well as more recent reviews by the Advisory Committee on Reactor Safeguards, recommendations have been advanced on how to improve the RI/PB character of Part 61.

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