CHAPTER 8

RISK INFORMED, PERFORMANCE BASED LICENSING AND INSPECTION

Section 1. **Purpose.**

(a) This Chapter establishes a risk informed, performance based regulatory framework as it will be applied to licensees regulated by the Program. No undue risk to public health, safety, or the environment shall occur as a result of licensed operations by the licensee under this regulatory framework.

Section 2. **Scope.**

(a) Except as otherwise specifically provided, this Chapter applies to all persons who acquire, own, possess, transfer, offer and receive for transport, use, or dispose of any licensed material pursuant to these rules. Nothing in this Chapter shall apply to any person subject to regulation not relinquished by the NRC.

Section 3. **Regulatory Approach.**

(a) The Department shall determine licensing inspection actions, enforcement, and other decisions by the Program based on the risk informed, performance based regulatory approach which is a combination of the following approaches:

(i) "A risked informed approach" to regulatory decision-making represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues, pertaining to licensed material safety, commensurate with their importance to employee, public health and safety, and environmental protection.

(ii) "A performance based approach" to regulatory decision making represents a philosophy whereby performance standards are established that must be achieved by the licensee, but provides flexibility to the licensee as to the means of meeting those standards. This approach emphasizes results over process and methods and uses those results as the primary basis for regulatory decision-making. This approach incorporates the following attributes:

(A) Measurable (or calculable) parameters (i.e., direct measurements of the physical parameter of interest or of related parameters that can be used to calculate the parameter of interest) that exist to monitor a system, including facility and licensee performance;

(B) Objective criteria to assess performance are established based on risk insights, deterministic analysis, and performance history;

(C) Flexibility for licensees to determine how to meet the established performance criteria in ways that will encourage and reward improved outcomes; and

(D) Failure to meet a performance criteria, while undesirable, will not in and of itself constitute or result in an immediate safety concern.

(b) As part of the risk informed performance based regulatory approach, the Department shall utilize risk insight, engineering analysis and judgment, including the principle of defense-in-depth and incorporation of safety margins, and performance history to:

(i) Focus attention on the areas of greatest potential significance to human ~~H~~ health, safety, and the environment;

(ii) Establish objective criteria for evaluating performance;

(iii) Develop measurable or calculable parameters for monitoring system and license performance;

(iv) Provide flexibility to licensees to determine how to meet the established performance criteria in a way that will encourage and reward outcomes; and

(v) Focus on the results as the primary basis for regulatory decisions.

Section 4. **Changes, Tests, or Experiments.**

(a) Subject to the conditions in Section 4(b) of this Chapter and without obtaining a license amendment pursuant to Chapter 4 of these rules, a licensee may:

(i) Make changes to the components of the licensed facility, which have a nexus to licensed material described in the most updated license application;

(ii) Make changes in the procedures as described in the most updated license application involving licensed material; and

(iii) Conduct tests or experiments not described in the most updated license application involving licensed material.

(b) The licensee shall obtain a license amendment pursuant to Chapter 4 of these rules prior to implementing a proposed change, test, or experiment if the change, test, or experiment would result in or create the following:

(i) More than a minimal increase in the frequency of occurrence of an accident involving licensed materials, previously evaluated in the most updated license application;

(ii) More than a minimal increase in the likelihood of occurrence of a malfunction of facility structure equipment, or monitoring system (SEMS) important to licensed material safety previously evaluated in the most updated license application;

(iii) More than a minimal increase in the consequence of an accident involving licensed material previously evaluated in the most updated license application;

(iv) More than a minimal increase in the consequences of a malfunction of a SEMS important to licensed material safety previously evaluated in the most updated license application;

(v) A possibility for a credible and potentially significant accident scenario of a different type, involving licensed material, than any previously evaluated in the most updated license application;

(vi) A possibility for a malfunction of a SEMS important to licensed material safety with a different result than previously evaluated in the most updated license application; and

(vii) A departure from the method of evaluation of radiological safety described in the most updated license application used by the Department. For NRC licenses transferred and recognized by the Department, a departure from the method of evaluation of radiological safety discussed in the NRC's final safety evaluation report (SER), any federal environmental impact statement (EIS) or environmental assessment (EA), technical evaluation reports (TER), or other analyses and evaluation for license amendments.

(c) For purposes of this Chapter, and as applied to NRC licenses recognized by the Department, SEMS means any SEMS which have been referenced in an NRC SER, TER, EA, or EIS, including supplements and amendments thereof.

(d) Licensees must obtain a license amendment unless the change, test, or experiment is consistent with the Department's and NRC's previous conclusions pertaining to radiological safety, or the basis of, or analysis leading to, the conclusion of actions, designs, or design configuration analyzed and selected in the site or facility's SER, TER, and EIS, or EA performed by the NRC. This would include all supplements and amendments, and TERs, EAs, and EISs issued with amendments to a license. NRC's previous conclusions would include, but would not be limited to Regulatory Issues Summaries (RIS), executive orders, or information notices.

Section 5. **Safety and Environmental Review Panel.**

(a) Each licensee shall develop a Safety and Environmental Review Panel (SERP). The SERP's purpose is to evaluate changes to the license application, procedures, or physical processes to the criteria in Section 4 of this Chapter and determine if the action can be completed without a license amendment.

(b) The SERP shall consist of, at a minimum, the following three members that are employees of the licensee:

(i) One member having expertise in management (e.g., Plant Manager). This member shall be responsible for financial approval for changes;

(ii) One member having expertise in operations or construction. This member shall have responsibility for implementing any operational changes; and

(iii) One member that is the licensee's radiation safety officer (RSO) or equivalent. This member shall maintain the responsibility of assuring changes conform to radiation safety and environmental requirements. The Department may approve a qualified contractor to fulfill this role where circumstances prevent the licensee from utilizing a qualified employee. Department approval must be obtained in writing.

(c) Additional members of the SERP may include, as appropriate, individuals to address and assist with technical aspects such as ground or surface water hydrology, specific earth sciences, or other technical disciplines. Temporary or permanent members, other than the three above-specified individuals, may be consultants or contractors.

(d) The licensee shall maintain records of any changes made pursuant to this Chapter until license termination. These records shall include written safety and environmental evaluations made by the SERP that provide the basis for determining changes are in compliance with Section 4 of this Chapter. The licensee shall furnish, in an annual report to the Department, a description of such changes, tests, or experiments, including a summary of the safety and environmental evaluation of each made pursuant to this Chapter. In addition, the licensee shall annually submit to the Department any changed pages, which shall include both a change indicator for the area changed (i.e., a bold line vertically drawn in the margin adjacent to the portion actually changed), and a page change identification (date of change or change number), to the Operations Plan and Reclamation Plan of the most updated approved license application to reflect changes made under this condition.

(e) All SERP evaluations shall be made available to the Department during site inspections. The Department may review all the SERP evaluations to ensure that it concurs with the conclusions. In events where the Department disagrees with the conclusions of a SERP, an amendment application will be required. The Department may take enforcement action or issue penalties as necessary relative to the SERP evaluations.

Section 6. **Contents of a SERP Evaluation.**

(a) The evaluation through the SERP process must answer the items presented in Sections 4(b) and 4(c) of this Chapter. For each item the evaluation shall present their justification and this document shall be reviewed by the Department at the time of inspection for concurrence. Certain items within Section 4 of this Chapter may require a risk assessment to be performed to determine the significance of an event. Those risk assessments will be reviewed by the Department at the time of the inspection.

Section 7. **Exclusions to the SERP Process.**

(a) The following items shall not be approved through the SERP process and shall be sent to the Department as a license amendment for approval:

(i) Amending license conditions ; and

(ii) Changes to license boundary.

(b) Wellfield data packages must be approved by the Department, but the items having a radiological nexus that do not change from wellfield to wellfield may go through the SERP process.