

SA-17 Safety Strategic Plan Goal

Implementation Activity: Implementation of Part 70 revision

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health, safety, and the environment.

Strategy 1: Develop, maintain, and implement licensing and regulatory programs for reactors, fuel facilities, materials users, spent fuel management, decommissioning sites, and waste-related activities to protect public health, safety, and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Secondary FY 04-09 Strategic Plan Goal: Ensure openness in our regulatory process.

Primary Priority: Medium

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On September 18, 2000 (65 FR 56211), the Commission published a final rule (Part 70) amending its regulations governing the domestic licensing of special nuclear material (SNM) for certain licensees authorized to possess a critical mass of SNM. The Commission's action was in response to a "Petition for Rulemaking," PRM-70-7, submitted by the Nuclear Energy Institute, which was published on November 26, 1996 (61 FR 60057). The majority of the modifications to Part 70 are included in a new Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material." These modifications were made to increase confidence in the margin of safety at the facilities affected by the rule, while reducing unnecessary regulatory burden, where appropriate.

In developing the rule, the Commission sought to achieve its objectives through a risk-informed and performance-based regulatory approach by requiring licensees to; (1) perform an integrated safety analysis (ISA) to identify significant potential accidents at the facility and the items relied on for safety (IROFS); and (2) implement measures to ensure that the IROFS are reliable and available to perform their functions when needed.

In December 2001, NMSS/Fuel Cycle Safety and Safeguards (FCSS) staff, along with the Risk Task Group and Part 70 stakeholders, finalized a standard review plan to implement the requirements of Subpart H. NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," complements 10 CFR Part 70 by identifying the specific information to be submitted by an applicant and evaluated by the staff. This guidance document, which was published in March 2002, will assist the licensees in conducting ISAs and the staff in reviewing ISA documentation. In September 2003, July 2004, and February 2005, FCSS held ISA workshops with industry and the public to discuss implementation of the Part 70 Subpart H requirements, obtain industry comments and feedback, and identify areas that needed additional study and/or guidance. From March to June 2004, FCSS also held six internal staff workshops to discuss ISA requirements, implementation, and issues. As issues have been raised and addressed, the Nuclear Regulatory Commission (NRC) has developed draft ISGs to further guide and document its approach to these issues. Interim staff guidance is

being prepared for nine areas. NRC provided the nine ISGs to industry since the summer of 2004. Seven of these have been issued in final form (ISGs 1, 3, 4, 5, 8, and 9); two (ISGs 6 and 7) – dealing with meeting the October 1, 2004 deadline -- have been cancelled due to a lack of need; and one (ISG 2) is still under internal review and revision. The staff held a workshop an additional workshop in August 2005, to discuss issues related to inspection of the ISA implementation. The staff discussed other implementation issues with stakeholders as part of the Fuel Cycle Information Exchange, held on August 30 and 31, 2006, and June 12 and 13, 2007.

The staff began conducting ISA summary reviews in fiscal year (FY) 2004 for individual amendment requests, for certain existing and new processes, and for a new centrifuge enrichment license application in FY 2004. To date, all licensees required to submit an ISA summary have done so. All ISA Summaries were submitted by the regulatory due date of October 18, 2004 or as part of a new license application. The staff reviews of these ISA summaries have shown that each licensee has used varying approaches to satisfy the requirements of 10 CFR 70.61. The submittals were accepted based on the acceptance criteria identified in NUREG-1520; however, all of the ISA submittals have required formal Requests for Additional Information as well as site visits and verbal communication with the licensees to clarify the ISA methodologies used and means of implementation. These reviews will continue through FY 2008.

The following important issues remain for completing the transition of ISAs to a more risk-informed approach: the treatment of dependent failures, human reliability, the treatment of uncertainty, the aggregation or assembly of the scenarios into overall facility or system measures of risk, and the chemical toxicity of soluble uranium.

The Division of Fuel Cycle Safety and Safeguards is forming an Advisory Committee, the Fuel Cycle Advisory Committee to provide advice to the Director of FCSS on policy and technical issues that arise in regulating the material licensed under 10 CFR Part 70. As more issues come to light, the NRC will use this Advisory Committee and its working groups to continue to revise or augment the ISGs to provide clarification and support consistency in the reviews of the ISA summaries. As experience is gained and consensus developed on the ISGs, consideration will be given to modifying NUREG-1520 to incorporate risk insights and lessons learned through the licensing of facilities such as the Mixed Oxide Facility and the National Enrichment Facility. It is assumed that now that these initial models have been developed and the data requirements are better defined, a greater amount of objective data will become available in the future. For example, operational and maintenance data from these systems can be fed back into the models to replace or validate initial assumptions. Additionally, the availability of this data will allow the uncertainties associated with the systems to be better quantified. In this way, the ISA process will achieve its true objective; to accurately reflect the facility processes and hazards and ensure those hazards are appropriately managed and controlled.

Additionally, efforts have been made to risk-inform the inspection guidance for Part 70 licensees. Inspection procedures for Category I and III facilities are being upgraded to reduce inspection duplication and allocate time spent on each procedure based on risk significance. The procedures focus on risk-significant activities for headquarters and regional inspectors and provide guidance for inspectors on the appropriate risk-significant items to evaluate in a licensee's program. As of July 2006, 16 procedures have been revised and six of these have been approved and issued.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Finalize standard review plan for 10 CFR Part 70, Subpart H			December 2001	NMSS/FCSS/TSG
Publish standard review plan for 10 CFR Part 70, Subpart H			March 2002	NMSS/FCSS/TSG
Initiate technical reviews of fuel cycle licensees' ISA summaries	as received from licensees		September 2005	NMSS/FCSS/TSS