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**Overview of the Nuclear Regulatory Commission  
and Its Regulatory Process for the Nuclear Fuel  
Cycle for Light Water Reactors**

**Prepared by  
Jim Lieberman- Lead  
Joe Gray  
Charley Haughney  
Robert Pierson**

**Talisman International, LLC  
1000 Potomac Street, N.W.  
Suite 300  
Washington, D.C. 20007**

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## **Overview of the Nuclear Regulatory Commission and Its Regulatory Process for the Nuclear Fuel Cycle for Light Water Reactors**

This paper provides a brief description of the United States Nuclear Regulatory Commission (NRC) and its regulatory process for the current nuclear fuel cycle for light water power reactors (LWRs). It focuses on the regulatory framework for the licensing of facilities in the fuel cycle. The first part of the paper provides an overview of the NRC and its regulatory program including a description of its organization, function, authority, and responsibilities. The second part of the paper provides a summary of the key aspects of the NRC regulatory program and the associated regulations in the following areas:

1. Radiation Protection
  - Part 20 Standards for protection against radiation (cross cutting regulation)
2. Mining, Milling, and Conversion
  - Part 40 Domestic licensing of source material
3. Power Reactors
  - Part 50 Domestic licensing of production and utilization facilities
  - Part 52 Licenses, certifications, and approvals for nuclear power plants
4. High-Level Waste Disposal
  - Part 60 Disposal of high-level radioactive wastes in geologic repositories
  - Part 63 Disposal of high-level radioactive wastes in a geologic repository at Yucca Mountain, Nevada
5. Low-Level Waste Disposal
  - Part 61 Licensing requirements for land disposal of radioactive waste
6. Enrichment, Fuel Fabrication, and Mixed Oxide Fuel
  - Part 70 Domestic licensing of special nuclear material
7. Transportation of Fresh and Spent Fuel
  - Part 71 Packaging and transportation of radioactive material
8. Storage of Spent Fuel
  - Part 72 Licensing requirements for the independent storage of spent nuclear fuel and high-level radioactive waste, and reactor-related greater than Class C waste
9. Reprocessing
  - Current regulation in Part 50 and NRC efforts to develop a new framework
10. Security and Safeguards
  - Part 73 Physical protection of plants and materials (Cross cutting Regulation)
  - Part 74 Material control and accounting of special nuclear material (Cross cutting Regulation)
  - Part 75 Safeguards on nuclear-implementation of US/IAEA agreement

## ABBREVIATIONS

ACRS	Advisory Committee on Reactor Safeguards
AEA	Atomic Energy Act of 1954
AEC	Atomic Energy Commission
ALARA	As low as reasonably achievable
COL	Combined construction and operating license
CP	Construction permit
DCR	Design certification by rule
DOE	Department of Energy
DOT	Department of Transportation
EDO	Executive Director for Operations
EIS	Environmental Impact Statement
EPA	Environmental Protection Agency
ERA	Energy Reorganization Act of 1974
ESP	Early site permit
GDC	General design criteria
GTCC	Greater than Class C
HLW	High-level radioactive waste
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IROFS	Items relied on for safety
ISA	Integrated safety analysis
ISFSI	Independent spent fuel storage installation
ITAAC	Inspections, tests, analyses and acceptance criteria
LLW	Low-level radioactive waste
LWR	Light water reactor
MOU	Memorandum of understanding
MOX	Mixed Oxide
NEI	Nuclear Energy Institute
NEPA	National Environmental Policy Act
NRC	Nuclear Regulatory Commission
NWPA	Nuclear Waste Policy Act
OL	Operating license
PRA	Probability risk assessment
PWR	Pressurized water reactor
RM	Radioactive material
SNF	Spent nuclear fuel
SNM	Special nuclear material
TEDE	Total effective dose equivalent
YMP	Yucca Mountain Project

## Glossary<sup>1</sup>

### **Byproduct material**

As defined by NRC regulations includes any radioactive material (except enriched uranium or plutonium) produced by a nuclear reactor. It also includes the tailings or wastes produced by the extraction or concentration of uranium or thorium or the fabrication of fuel for nuclear reactors. Additionally, it is any material that has been made radioactive through the use of a particle accelerator or any discrete source of radium-226 used for a commercial, medical, or research activity. In addition, the NRC, in consultation with the EPA, DOE, DHS and others, can designate as byproduct material any source of naturally-occurring radioactive material, other than source material, that it determines would pose a threat to public health and safety or the common defense and security of the United States.

### **Design-basis threat (DBT)**

The DBT is a description of the type, composition, and capabilities of an adversary. The NRC and its licensees use the DBT as a basis for designing safeguards systems to protect against acts of radiological sabotage and to prevent the theft of special nuclear material. The DBT is described in detail in 10 CFR 73.1.

### **Deterministic (probabilistic)**

Consistent with the principles of "determinism," which hold that specific causes completely and certainly determine effects of all sorts. As applied in nuclear technology, it generally deals with evaluating the safety of a nuclear power plant in terms of the consequences of a predetermined bounding subset of accident sequences. The term "probabilistic" is associated with an evaluation that explicitly accounts for the likelihood and consequences of possible accident sequences in an integrated fashion.

### **General license**

Unlike a specific license, a person does not apply for a general license nor is a document issued granting a license. A general license is issued by operation of the regulation. A person has a general license if the conditions of a regulation authorizing a general license are met. An example of a general license is the license issued by 10 CFR 72.210 that authorizes a person to store SNF at an ISFSI at a power reactor site if the person is allowed to possess a power reactor under 10 CFR Part 50 and if the conditions of 10 CFR 72.212 are met.

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<sup>1</sup> The source for the definitions in this Glossary is the definitions in the NRC Glossary at: <http://www.nrc.gov/reading-rm/basic-ref/glossary.html#A>.

**Low-level radioactive waste (LLW)**

Low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2) [mill tailings], (3) [discrete radium 226 sources], and (4) [material made radioactive by particle accelerators] of the definition of *Byproduct material* set forth in 10 CFR 20.1003.

**Performance-based regulation**

Performance-based regulation is a regulatory approach that focuses on desired, measurable outcomes, rather than prescriptive processes, techniques, or procedures. Performance-based regulation leads to defined results without specific direction regarding how those results are to be obtained. At the NRC, performance-based regulatory actions focus on identifying performance measures that ensure an adequate safety margin and offer incentives for licensees to improve safety without formal regulatory intervention by the agency.

**Probabilistic risk assessment (PRA)**

A systematic method for assessing three questions that the NRC uses to define “risk.” These questions consider (1) what can go wrong, (2) how likely it is, and (3) what its consequences might be. These questions allow the NRC to understand likely outcomes, sensitivities, areas of importance, system interactions, and areas of uncertainty, which the staff can use to identify risk-significant scenarios. The NRC uses PRA to determine a numeric estimate of risk to provide insights into the strengths and weaknesses of the design and operation of a nuclear power plant.

**Risk-informed regulation**

An approach to regulation taken by the NRC, which incorporates an assessment of safety significance or relative risk. This approach ensures that the regulatory burden imposed by an individual regulation or process is appropriate to its importance in protecting the health and safety of the public and the environment.

**Source material**

Uranium or thorium, or any combination thereof, in any physical or chemical form, or ores that contain, by weight, one-twentieth of one percent (0.05 percent) or more of (1) uranium, (2) thorium, or (3) any combination thereof. Source material does not include special nuclear material.

**Special nuclear material (SNM)**

Plutonium, uranium-233, or uranium enriched in the isotopes uranium-233 or uranium-235 and any other material that the Commission determines to be special nuclear material in accordance with the Atomic Energy Act, but does not include source material. Such a determination requires the Commission finding, with the assent of the President and notice to Congress with a waiver provision, that the material is capable of releasing substantial quantities of atomic energy

and that the determination is in the interest of the common defense and security. The NRC has not declared any other material as SNM.

**Specific license**

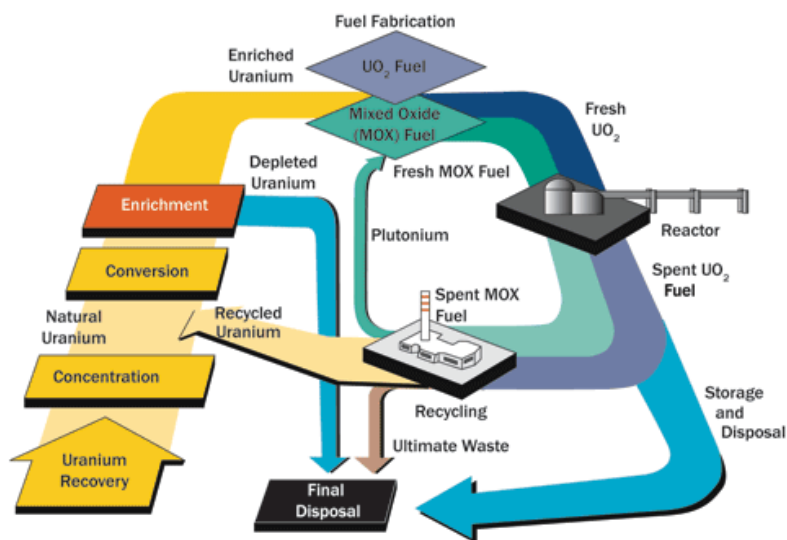
A specific license is a license that has been issued by the NRC to a particular person based on an application that has been submitted by that person.

## Overview of NRC and Its Regulatory Program

The Nuclear Regulatory Commission (NRC) is an independent regulatory agency that was established in January 1975 by the Energy Reorganization Act of 1974 (ERA). The ERA also created the Energy Research and Development Administration (now the Department of Energy (DOE)) and dissolved the Atomic Energy Commission (AEC). The NRC is made up of five Commissioners who serve staggered five year terms. The Commissioners are nominated by the President and confirmed by the Senate. The President also appoints one of the Commissioners to be the Chairman. The Chairman serves at the pleasure of the President, but the Commissioners may only be removed for misfeasance or malfeasance. No more than three of the Commissioners may be from the same political party. Except for the Commissioners, the employees of the NRC are career civil servants. The staff of the NRC is headed by the Executive Director for Operations (EDO).

The NRC is headquartered in Rockville Maryland and has four regional offices in Atlanta, GA, King of Prussia, PA, Lisle, IL, and Arlington, TX. Its budget in FY 2010 was \$1,067 million but only about \$155 million is from appropriated funds. The remainder of the NRC's funding comes from fees paid by licensees. In FY 2010 NRC had staffing level approval up to 3960 FTE's.

The Atomic Energy Act of 1954 (AEA) and the ERA provide the foundation for the NRC's mission to regulate utilization (i.e. reactors) and production (i.e., reprocessing) facilities and the use of nuclear material, i.e., byproduct, source, and special nuclear materials (SNM), to ensure adequate protection of public health and safety, to promote the common defense and security, and to protect the environment. The AEA provides the authority to promulgate licensing and regulatory requirements by rule or order and to oversee, inspect, regulate and take enforcement action. The NRC regulates civilian nuclear power plants and the nuclear fuel cycle see Figure 1, as well as other uses of nuclear materials including nuclear medical diagnostics and therapy, academic activities at educational institutions; research; industrial applications, such as gauges and testing equipment; and the transport, storage, and disposal of nuclear materials and wastes.



Source: U.S. Nuclear Regulatory Commission

Figure 1 - Uranium Fuel Cycle (From NUREG 1350, Volume 11 (2009))



Activities outside of the NRC regulation include conventional mining (where uranium ore is removed from deep underground shafts or shallow open pits) and activities involving materials that are not source, byproduct, or special nuclear materials such as wastes containing relatively dilute amounts of naturally occurring radioactive materials.

The Environmental Protection Agency (EPA) has the responsibility for setting standards for the total amount of radiation released to the general environment from all facilities combined in the uranium fuel cycle. Consequently, EPA sets the off-site release standards that the NRC incorporates into its regulations governing the uranium fuel cycle.

NRC also has the responsibility to regulate certain DOE facilities designated in section 202 of the ERA, including facilities used primarily for the storage of high-level radioactive waste (HLW) resulting from activities licensed under the AEA, facilities “authorized for the express purpose of subsequent long-term storage” of HLW generated by the DOE, and facilities used for the purpose of fabricating mixed oxide (MOX) fuel for use in commercial nuclear reactors.<sup>2</sup> NRC also has the responsibility for licensing any DOE disposal of HLW and spent fuel including disposal at Yucca Mountain under the Nuclear Waste Policy Act (NWPA)

NRC works closely with the various States and pursuant to the AEA has entered into agreements with 37 states to relinquish NRC’s AEA authority for certain non-reactor functions. Subject to the NRC oversight to ensure compatibility with NRC requirements and to ensure the adequacy to protect the public health and safety, these Agreement States have assumed the regulatory responsibility for more than 19,500 licenses including some uranium recovery facilities, LLW disposal sites, and LLW waste processing facilities. The NRC retains jurisdiction for fuel conversion, enrichment, and fabrication facilities. NRC regulates 104 power reactors, 31 test and research reactors and about 3000 other licensees including material and fuel cycle licensees. The NRC also participates in a wide range of other international activities including the development of international standards that not only strengthen the NRC regulatory efforts, but enhance the safety and security of peaceful nuclear activities worldwide.

To fulfill its fundamental purpose to protect public health and safety, the NRC performs the following regulatory functions described in Figure 2: 1) establishes standards and regulations, 2) issues licenses for nuclear facilities and users of nuclear materials under the standards and guidance, 3) provides oversight of licensees, 4) evaluates operational experience at licensee facilities to inform development of standards and regulations, and 5) provides support for Commission decisions concerning the above functions.

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<sup>2</sup> The NRC does not have jurisdiction under section 202 to regulate the current HLW storage tanks at DOE facilities. See, NRC: Office of Nuclear Material Safety and Safeguards; In the Matter of Department of Energy, (Savannah River High-Level Waste Tanks); Response to NRDC Petition, 65 FR 62,377 (October 18, 2000) and *NRDC v. USNRC*, 606 F2d 1261, 1267 (D.C. Cir.1979).



Figure 2 - NRC Regulatory Functions (From NUREG 1350, Volume 11 (2009))

These functions are carried out by a number of program offices reporting to the EDO including the Office of Nuclear Reactor Regulation for existing reactors and the Office of New Reactors for new applications; the Office of Nuclear Materials, Safety, and Safeguards for fuel cycle activities; the Office of Federal and State Materials and Environmental Management Programs for among other things uranium recovery, decommissioning, and Agreement States; the Office of Nuclear Security and Incident Response for security and emergency response activities; the NRC regional offices where most inspectors are located; the Office of Research which conducts confirmatory R&D to inform development of regulations and guidance; and the Offices of Enforcement and Investigations. The NRC regulatory programs are designed to achieve the following strategic outcomes:

- Prevent the occurrence of any nuclear reactor accidents,
- Prevent the occurrence of any inadvertent criticality events,
- Prevent the occurrence of any acute radiation exposures resulting in fatalities,
- Prevent the occurrence of any releases of radioactive materials that result in significant radiation exposures or cause significant adverse environmental impacts, and
- Prevent any instances where licensed radioactive materials are used domestically in a manner hostile to the United States.

It is important to appreciate that while the NRC is responsible for regulating, licensees are responsible for the safe use of nuclear material and the safe design, construction, and operation of nuclear facilities. Applicants are required to submit to the NRC staff, license applications to build and operate nuclear fuel cycle facilities.<sup>3</sup> The NRC reviews the applications and issues safety and security evaluations to ensure that issuance of licenses will be consistent with the public health and safety and not be inimical to the common defense and security. NRC license application reviews are often lengthy and detailed requiring the applicant to provide additional

<sup>3</sup> The NRC also regulates the storage casks for SNF at these facilities and any transportation of the SNF including the shipping containers

information until the NRC is satisfied that the NRC regulations and standards have been met and that a license should be issued.

In addition to the safety and security reviews that the NRC performs for each application, as part of the licensing process the NRC also considers the environmental impacts and benefits of proposed licensing actions (except for activities that fall under the categorical exclusions of 10 CFR Part 51) to meet its obligations under the National Environmental Policy Act (NEPA). Based on the applicant's environmental report and independent reviews, the NRC prepares either an environmental assessment or an environmental impact statement (EIS). The result of that environmental review is factored into the NRC licensing decision process. Prior to the NRC issuing a licensing to construct or operate a reactor or a reprocessing facility (under current regulations), the application is reviewed by the Advisory Committee on Reactor Safeguards (ACRS), an independent body of nuclear, engineering, and safety experts appointed by the Commission. At the request of the NRC, the ACRS may review generic safety issues or may review important technical issues for other types of facilities.

The NRC process is an open process. Subject to limited exceptions, all material submitted to the NRC associated with a license and its application is public as are meetings with an applicant and licensee. An important part of the NRC licensing process is public participation. The NRC regularly conducts public meetings in the vicinity of facility sites to discuss significant applications and scoping efforts for environmental reviews. In addition, each application for a license is subject to an opportunity for a public hearing before the Atomic Safety and Licensing Board. To provide public notice of its meetings NRC provides at least ten days notice on its web site before it can meet with a licensee. Members of the public, who cannot attend meetings in person, can often listen to meetings via phone and in some cases by video.

Public participation at the NRC can be categorized into two levels: informal and formal. Informal participation includes participation of the public at NRC meetings and workshops, commenting on rulemakings, submitting petitions for rulemakings, requesting that the NRC initiate enforcement actions, and submitting written or oral statements to a licensing board to be entered into the hearing record. Formal participation involves becoming a party to a hearing. Members of the public may seek formal participation by submitting a petition to intervene as a full party in an adjudicatory hearing. NRC hearings are somewhat formal following the rules of procedures of 10 CFR Part 2 and the Administrative Procedure Act. Unlike participation at a NRC public meeting, to participate in a NRC hearing as a party, more than a general concern or opposition to a facility is needed. Participating as a party in a NRC hearing is a substantial undertaking. While not required, in view of the nature of the process, the issues involved, and the consequences of the decisions, most participants in NRC hearings are represented by counsel.<sup>4</sup> In most cases whether or not a licensing hearing is held depends on whether there is an interested party demonstrating standing and having at least one contention admitted into such a licensing proceeding. However, the AEA specifies that, in the case of reactors and reprocessing

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<sup>4</sup> The NRC is prohibited from funding public participation in NRC proceedings. Prohibition on Use of Energy and Water Development Appropriations to Pay Intervening Parties in Regulatory or Adjudicatory Proceedings, Pub. L. 102-377, title V, § 502, Oct. 2, 1992, 106 Stat.1342, provided that: "None of the funds in this Act or subsequent Energy and Water Development Appropriations Acts shall be used to pay the expenses of, or otherwise compensate, parties intervening in regulatory or adjudicatory proceedings funded in such Acts."

facilities at the construction permit stage, under 10 CFR Part 50 and prior to the issuance of a combined license under Part 52, a mandatory public hearing be held before a final licensing decision is made. The decisions of the Licensing Boards may be appealed to the NRC Commissioners and, ultimately, to the Federal courts.

The NRC regulatory process continues after a license is issued. The NRC conducts periodic inspections of licensed activities, investigates allegations of willful misconduct, obtains and reviews reports from licensees, and obtains input from workers. If the results of these oversight actions identify violations, enforcement action such as notices of violations, civil penalties, orders suspending, modifying, or revoking licenses, and referrals to the Department of Justice for consideration of criminal prosecution may result. Orders may be issued for substantial safety problems. As part of the NRC's emergency preparedness activities, the NRC operates a 24/7 emergency response center in order to evaluate and respond to abnormal conditions or accidents that occur at licensed nuclear facilities. The NRC also has a process for the public to petition the NRC to take enforcement action.

There is a public process that leads to license termination if the NRC standards for license termination are met. When a license expires or when a licensee ceases its licensed activities, the licensee is responsible to decommission its facilities. Power reactor and major fuel cycle facility licensees are required to have sufficient funds for decommissioning.

The above regulatory and license processes are more fully described in the NRC regulations found at 10 CFR. The remainder of this paper provides a summary of the key aspects of the NRC regulatory program for the uranium fuel cycle and the associated regulations in the following areas:

- Part 20-Radiation protection
- Part 40-Mining, milling, and conversion facilities
- Part 50- Power reactors
- Parts 60&63-High-level waste disposal including disposal of HLW in a geologic repository at Yucca Mountain, Nevada
- Part 61-Low-level waste disposal
- Part 70-Enrichment, Fuel Fabrication, and MOX Fuel facilities
- Part 71-Transportation of fresh and spent fuel
- Part 72-Storage of spent fuel
- Part 7x-Reprocessing (regulation under development)
- Parts 73-75-Security and safeguards

## 1. **Radiation Protection** (10 CFR Part 20, Standards for protection against radiation)

### **Introduction**

Part 20 provides the NRC regulations for the standards for protection against ionizing radiation resulting from all activities conducted by licensees of the NRC. Agreement States are required to adopt these standards. It is the purpose of Part 20 to ensure that the total dose to an individual

(both workers and members of the public), including doses resulting from licensed and unlicensed radioactive material other than background, do not exceed the NRC criteria. The current Part 20 was last revised in 1991 and implements the 1987 Presidential guidance on occupational exposure that generally adopts the philosophy and methodology of the International Commission on Radiological Protection (ICRP) Publication 26 and 30.

### **Regulatory Framework**

Part 20 requires licensees to establish radiation protection programs to ensure that regulatory standards are met and that occupational and public doses are as low as reasonably achievable (ALARA). This includes requirements for surveying, access controls, respirator use, labeling, record keeping, and reports. In general, it sets the occupational dose limit at 5 rems (.05 Sv) total effective dose equivalent (TEDE) and the public dose limit at .1 rem (1mSv) TEDE. It also sets limits on gaseous and liquid releases to the environment for licensed material to ensure that the public dose limit is met. In addition, licensees involved in the uranium fuel cycle are required to meet the EPA's generally applicable environmental radiation standards of 40 CFR Part 190. Except for reprocessing facilities, meeting Part 190 does not appear to be a challenge for NRC licensees. Subpart E of Part 20, the NRC License Termination Rule, sets the radiation standards for decommissioning and license termination. It provides criteria for unrestricted and restricted releases. The dose limits in Part 20 are risk-informed. However, there are also numerous specific prescriptive requirements focused on ensuring that the actual radiation exposures to workers and the public are much lower than the actual dose limits.

### **Potential Changes**

The NRC is considering revision of the NRC's radiation protection regulations to achieve greater alignment with more recent recommendations of ICRP Publication 103. The NRC is engaging stakeholders as part of this effort. Updating radiation standards may result in a substantial cost to the industry. The NRC Commission has expressed the view that the current NRC regulatory framework continues to provide adequate protection of the health and safety of workers, the public, and the environment. The NRC's position is that from a safety regulation perspective, ICRP Publication 103 proposes measures that go beyond what is needed to provide for adequate protection.<sup>5</sup> In some cases, the ICRP 103 values are more limiting and in other cases it provides for some flexibility. For example, while the NRC occupational dose limit of 5 rem (50 mSv) per year continues to align with the maximum value for any year recommended by the ICRP, ICRP provides for a 20 mSv (2 rem) per year average occupational dose limit. Biological and radiation weighting factors have been revised by ICRP 103, and many of the metabolic models have likewise been updated which may be less restrictive for some licenses than current standards. The NRC is also interacting with EPA on 40 CFR Part 190 issues.

## **2. Mining, Milling, and Conversion (10 CFR Part 40, Domestic licensing of source material)**

### **Introduction**

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<sup>5</sup> NRC Staff Requirements Memorandum on SECY-08-0197 (April 2, 2009).

Part 40 contains the NRC regulations for licensing the receipt, possession, use, transfer, and processing of source material. Source material is uranium or thorium, in any physical or chemical form, which contains 0.05% or more of uranium or thorium<sup>6</sup> by weight. Part 40 applies to the initial steps in the nuclear fuel cycle: 1) situ leach mining of natural uranium ore (The NRC does not regulate conventional mining), 2) milling of the ore from the mines into a mixture of uranium oxides ( $U_3O_8$ ) called yellowcake, and 3) conversion of the yellowcake into uranium hexafluoride ( $UF_6$ ). The  $UF_6$  is then enriched in its gaseous phase to increase the amount of the fissile isotope  $U^{235}$  to be used as fuel in the current fleet of nuclear reactors at uranium enrichment plants that are licensed under Part 70, which is discussed later in this report.<sup>7</sup> Part 40 also addresses certain mill tailings and related waste containing thorium or uranium defined in the AEA as section 11e.(2) byproduct material.

### **Regulatory Framework**

Part 40 applicants must demonstrate that their activities are not inimical to the public health and safety or common defense and security. Part 40 includes provisions for an emergency plan that includes planned response to accidental releases of radioactive material and provisions for the control of hazardous chemicals; an environmental report; and a decommissioning funding plan. Part 40 also contains provisions for general licenses and exemptions, but these provisions would not apply to fuel cycle licensees. Uranium milling produces a large volume of 11e.(2) byproduct material that contains radium that poses a long term potential hazard to the public health and safety as a consequence of the radon decay product of radium. Appendix A of Part 40 provides technical, financial, ownership, and long term site surveillance criteria related to the siting, operation, decontamination, decommissioning, and reclamation of sites with mills and tailing piles. Part 40 is a prescriptive regulation.

- 3. Power Reactors** (10 CFR Part 50 – Domestic Licensing of Production and Utilization Facilities and 10 CFR Part 52 – Licenses, Certifications, and Approvals for Nuclear Power Plants)

### **Introduction**

The AEA provides the authority and responsibility for the NRC to license and regulate commercial power reactors in the United States. A license is required to construct and operate a reactor. The AEA provides a number of statutory provisions, processes and restrictions that are applicable to licensing of commercial reactors. These provisions include limiting the initial term of the reactor license to 40 years (§103); restricting foreign ownership (§103); requiring individuals who operate facilities to be licensed (§107); requiring demonstration of technical and financial qualifications (§182); construction permits (CPs), operating licenses (OLs), and authorization for the NRC to issue a “combined construction and operating license” (§185); and hearing requirements (§189). The essential bases and standards for NRC licensing and regulation of commercial reactors, as specified in sections 103 and 182 of the AEA are an NRC

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<sup>6</sup> The U.S. current domestic fuel cycle is uranium-based, so the rest of this paper will only refer to uranium.

<sup>7</sup> The former DOE gaseous diffusion enrichment plants are certified rather than licensed by the NRC under 10 CFR Part 76.

finding of reasonable assurance of adequate protection of the public health and safety and to promote the common defense and security.

Pursuant to this authority, the NRC (and before it the AEC) promulgated a number of major rules to address the licensing, regulation and eventual decommissioning and license termination of power reactors. These rules are based on, and derived from, the standards and requirements of the Atomic Energy Act of 1954 and they give technical and legal substance and detail to the general requirements of the AEA. The primary rules bearing on the licensing and regulation of power reactors are those in 10 CFR Part 50 and Part 52.<sup>8</sup>

### **Regulatory Framework**

10 CFR Part 50 is the basic framework established by the Commission to license and regulate power reactors. Part 50 implements the AEA required two-step licensing process (involving, first, issuance of a construction permit authorizing the siting and construction of the reactor facility, followed by issuance of an operating license authorizing operation under specified operating terms and conditions once construction has been essentially completed.). Part 50 and its subparts specify the requirements for a license; classes and descriptions of licenses; the contents of applications for CPs and OLs; the standards for issuance of licenses and regulatory approvals; limitations and conditions on CPs and OLs; the license change process; codes and standards; inspection, reporting and notification requirements; license transfer processes; backfitting provisions;<sup>9</sup> and the enforcement process. Appendices to Part 50 also establish substantive technical standards and requirements for power reactors, including General Design Criteria (GDC) for nuclear power plants, quality assurance criteria, financial data requirements, effluent release guidelines, radiological emergency planning and preparedness requirements, fire protection requirements, and earthquake engineering criteria.

The original Part 50 framework was basically deterministic in nature and approach. It generally specifies prescriptive requirements and operating limits and directs the use of specific prescriptive analysis methodology. Risk-informed assessments and the development and use of risk insights and performance-based approaches have gradually been introduced and incorporated into certain aspects of the Part 50 framework – in particular, the maintenance rule (§ 50.65), the rule providing for risk-informed treatment of structures, systems and components (§ 50.69), and the fire protection requirements allowing the use of National Fire Protection Association Standard 805 (§ 50.48). The adoption of these provisions has signaled a significant move toward more risk-informed, performance-based licensing and regulation of power reactors. Part 50 licensees have also developed probabilistic risk assessments (PRAs). Consistent with the

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<sup>8</sup> Important regulatory requirements and processes for power reactors are contained in other parts of NRC regulations (most of which are referenced in Parts 50 and 52). These include: Part 20 (radiation protection, license termination); Part 21 (reporting defects and noncompliance); Part 26 (fitness-for-duty programs); Part 51 (environmental protection regulations for domestic licensing and regulation); Part 54 (power reactor license renewal); Part 55 (reactor operators' licenses); 10 CFR Part 73 (physical protection of plants and materials); 10 CFR Part 100 (reactor site criteria); and 10 CFR Part 140 (financial protection requirements). Also, 10 CFR Part 2 deals with notice and hearing requirements related to, among other things, reactors and reactor licensing and enforcement.

<sup>9</sup> Part 50 includes a backfit provision (10 CFR 50.109) which imposes strictures and cost-benefit process considerations on the NRC when the agency seeks to impose post-licensing requirements that are not necessary for safety or to bring a licensee back into compliance.

move to risk-informed performance-based licensing and regulation of power reactors, the NRC developed a reactor oversight process (to replace the former “Systematic Assessment of Licensee Performance” process) that uses risk insights, safety focus, objective performance indicators, graded inspection findings and regulatory action thresholds to assess and continually monitor power reactor licensee performance in a more risk-informed, performance-oriented manner.

Licensing reactors under Part 50 is a complex undertaking. Currently, there are 104 licensed power reactors at 66 sites based on 80 different designs from four different reactor vendors. Part 50 and its appendices and associated regulations contain numerous technical requirements that power reactors must meet. The NRC has issued standard review plans, regulatory guides and various generic communications in the interest of achieving a consistent approach to regulation and predictability and to guide the NRC staff, applicants and licensees. The regulatory process established by Part 50 is designed to provide both defense-in-depth and redundancy in safety measures to ensure adequate protection of the public health and safety.

10 CFR Part 52 is a licensing and approval process intended to make the power reactor licensing process more efficient and effective and intended to encourage more standardization in reactor designs. Part 52 establishes processes and standards for the NRC to (1) approve and certify reactor designs by rule called a design certification by rule (DCR); (2) issue early site permits that authorize siting and, where a limited work authorization is part of the ESP application, authorizes limited construction of a nuclear power plant in advance of the combined construction and operating license (COL), and (3) issue a COL. A COL authorizes construction and resolves most operating license issues in a single proceeding but defers authorization to operate until specified “inspections, tests, analyses and acceptance criteria” (ITAAC) are determined to be satisfied.<sup>10</sup> Once the ITAAC are met following the completion of construction and testing, NRC may authorize operation of the reactor unless a person demonstrates that one or more ITAAC have not or will not be met and the consequences of that nonconformance would be contrary to providing reasonable assurance of adequate protection of the public health and safety. Resident inspectors are a key part of the NRC reactor oversight program, both during construction and during operations.

In the main, Part 52 references specific regulations and requirements in Part 50 (and other parts of 10 CFR) for the technical requirements that must be satisfied to obtain a DCR, ESP or COL under Part 52 processes. Each new nuclear power plant under Part 52 is required to develop and maintain a PRA for the plant.

Part 52 is configured to provide substantial flexibility to COL applicants. An applicant for a COL under Part 52 may reference a previously issued ESP and/or a DCR as part of its COL application. In this way, earlier separate approvals of the site and/or reactor design would not be revisited and the COL application review will focus on ensuring that the site and reactor design interface issues and conditions are resolved. Alternatively, a COL applicant can apply for approval of a new site and a reactor design that does not have a DCR, in which case all siting and reactor design issues would need to be addressed and resolved in the COL proceeding itself.

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<sup>10</sup> Part 52 established these processes by rulemaking in the late 1980s. The COL process was later embodied in an amendment to AEA Sec. 185.



Based on the information from the NRC web site, the NRC has: 1) issued four DCRs and six are being reviewed; 2) issued four ESPs and two are being reviewed; and 3) currently has 18 COLs under review in various stages.

### **Potential Changes**

The NRC is considering a number of changes to Parts 50 and 52. These changes include modifications to the emergency planning and preparedness rules and updating safety requirements involving issues such as debris accumulation in pressurized water reactor sumps and risk-informed changes to loss-of-coolant-accident technical requirements. The NRC also is involved in major work and rulemaking related to ITAAC resolution processes for COLs. This rulemaking effort needs to be settled before new plants with COLs reach final construction stages. The NRC is continuing to work on physical security matters related to power reactor licensing and regulation.

4. **High-Level Radioactive Waste Disposal** (10 CFR Part 60 – Disposal of High-Level Radioactive Wastes in Geologic Repositories and 10 CFR Part 63 – Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada)

### **Introduction**

Disposal of HLW is addressed in 10 CFR Parts 60 and 63 of NRC's regulations. In 1983, NRC promulgated Part 60 using the authority provided by the AEA, the ERA, and the NWPA of 1982. Part 60 sets out the rules governing the licensing of the DOE to construct, and to receive and possess source material, special nuclear material and byproduct material at, a geologic repository sited, constructed or operated in accordance with the NWPA. Part 60 explicitly does not apply to the licensing of a geologic repository at Yucca Mountain, Nevada. The Energy Policy Act of 1992 directed the NRC to modify its repository regulations to be consistent with new standards that the EPA would develop specifically for Yucca Mountain. As a result, the NRC adopted Part 63 that only applies to Yucca Mountain.

Part 60 is intended to deal with HLW – reprocessing wastes and irradiated reactor fuel – and other wastes that DOE may propose (see 10 CFR 60.102(b)(4)) to dispose or store in a geologic repository. It provides a multi-stage approach for licensing and oversight of DOE that involves: pre-application site characterization; construction authorization; issuance of a license to receive and possess HLW at the geologic repository operations area; license amendments to address permanent closure; and, finally, license termination. In general, this approach parallels the traditional reactor licensing process under the AEA. The regulatory concept of Part 60 for disposal of HLW is to focus on two time periods: for several hundred years following permanent closure of the repository, special emphasis is placed on the ability to contain waste by waste packages within engineered barrier systems (the containment period); after the containment period, emphasis is placed on the ability to achieve waste isolation by the characteristics of the geologic repository.

Part 63 prescribes rules governing the licensing of DOE to receive and possess HLW at Yucca Mountain, Nevada. Part 63 is, in many ways, based on concepts, processes and approaches of

Part 60, but modified to incorporate the requirements of the NWPA amendments of 1987, which restricted DOE's repository development to a single site at Yucca Mountain. Among other things, Part 63 reflects the special status of the State, affected Indian tribes, and affected units of local government (Subpart C). Part 63 was subsequently amended and updated to incorporate the EPA standards developed pursuant to directives of the Energy Policy Act of 1992 and later Court of Appeals rulings on the EPA standards.

### **Regulatory Framework**

10 CFR Part 60 is the basic framework established by the Commission to site, license and regulate the disposal of HLW by DOE. Although there are a number of prescriptive provisions in Part 60, the rule and framework have many performance based elements. The key provisions of Part 60 include:

- Subpart A contains the General Provisions for licensing and regulation and includes the stipulation that, except for certain preliminary activities, authorization and a license from the NRC are required for DOE to commence construction and receive waste at a geologic repository operations area.
- Subpart B covers the requirements for Licenses. It begins with pre-application review matters with provisions addressing site characterization and the requirements for a site characterization plan. Next, the requirements for license applications are specified with detailed descriptions of the contents of the Safety Analysis Report and the stipulation that DOE is to prepare an environmental impact statement. Subpart B then sets out the overall findings on safety<sup>11</sup>, common defense and security<sup>12</sup> and the environment that must be made to issue a construction authorization, specifies conditions of the construction authorization, and establishes a process for amending the construction authorization. Next under Subpart B are the specific requirements<sup>13</sup> for a license to receive and possess source, byproduct and special nuclear materials, provisions on conditions of the license and license specifications (like technical specifications in reactor licenses), and provisions on license change and amendment processes. Finally, Subpart B addresses Permanent Closure, specifying requirements for a license amendment and plan for permanent closure followed eventually by an application to terminate the license.

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<sup>11</sup> The Commission must find that there is reasonable assurance that the types and amounts of radioactive materials described in the application can be received, possessed and disposed of in a geologic repository operations area of the design proposed without unreasonable risk to the public health and safety. This finding is to be based on various findings required by the provisions of Part 60. Part 51 sets out the standards for NRC to adopt the DOE's EIS and the environmental/NEPA findings that NRC must make in repository licensing.

<sup>12</sup> The Commission must find that there is reasonable assurance that the activities proposed in the application will not be inimical to the common defense and security.

<sup>13</sup> The general standards/findings for issuance of the license to receive and possess are that: construction has been substantially completed in conformity with the application, the AEA and the Commission's regulations; activities will be conducted in conformity with the application, the Act and the regulations; and issuance of the license will not be inimical to the common defense and security and will not constitute an unreasonable risk to public health and safety (§ 60.41).

- Subpart C of 10 CFR Part 60 addresses participation by State Governments and affected Indian Tribes in review and licensing activities for a geologic repository.
- Subpart D contains the requirements for record-keeping and reporting by DOE and provides for tests and inspections by NRC.
- Subpart E of Part 60 sets out in some detail the Technical Criteria -- performance objectives, and site and design criteria -- that are to be applied to license a geologic repository. While the performance objectives and criteria are stated in unqualified terms, the regulations make clear that “it is not expected that complete assurance that they will be met can be presented. A reasonable assurance, on the basis of the record before the Commission, that the objectives and criteria will be met is the general standard that is required.”<sup>14</sup> Subpart E specifies the performance objectives of the repository operations area: for radiation protection and radioactive material release until permanent closure; and for waste retrievability until the completion of a performance confirmation program. It provides the overall system performance objective for the repository after permanent closure based on standards to be developed by EPA (§60.112), and establishes performance objectives of particular barriers (engineered barriers, geologic setting) after permanent closure (§ 60.113). Sections 60.121 and 60.122 specify requirements for land ownership and control (land must be under DOE control or permanently withdrawn and reserved for DOE use), and establish detailed siting criteria. Subsequent sections (60.130 – 136) specify design criteria for the repository operations area (including surface facilities, the underground facility, design of seals for shafts and boreholes, requirements for a preclosure controlled area) and related matters (criteria for waste packages and components).

10 CFR Part 63 is the basic framework established by the Commission to license (including issuance of a construction authorization) and to regulate the disposal of HLW by DOE at Yucca Mountain, Nevada. Part 63 has many of the usual provisions of a licensing rule like Part 60, but, because of the NWPA amendments of 1987 and 1992 and the Energy Policy Act of 1992, Part 63 and other parts of NRC regulations (e.g., Part 2 on hearings) have special features (in addition to the focus on a specific site), that are different from Part 60 in order to incorporate statutory directives and judicial decisions. Notable differences and special features involve–

- NRC review and comment on site characterization studies and findings of DOE for Yucca Mountain, including opportunity for public comments, as part of pre-licensing activities (§63.13).

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<sup>14</sup> “For § 60.112 and other portions of this subpart that impose objectives and criteria for repository performance over long times into the future, there will inevitably be greater uncertainties. Proof of the future performance of engineered barrier systems and the geologic setting over time periods of many hundreds or many thousands of years is not to be had in the ordinary sense of the word. For such long-term objectives and criteria, what is required is reasonable assurance, making allowance for the time period, hazards and uncertainties involved, that the outcome will be in conformance with those objectives and criteria.” 10 CFR 60.101 (a)(2).

- A formal three-step licensing process with opportunities for administrative hearings on construction authorization, the license to receive and possess spent fuel and HLW and closure; for this licensing process, DOE, NRC staff and potential hearing participants are required to preserve, maintain and update their respective document collections in an electronic discovery and document disclosure system called the Licensing Support Network.
- Performance standards: pre-closure (§63.111) and post-closure (§ 63.113) standards that emphasize risk-based analysis and the use of a Total System Performance Assessment for the post-closure period that covers the period of geologic stability (about 1 million years).
- The concept of the “reasonably maximally exposed individual”, defined for the Yucca Mountain area, for the performance assessments (§63.312).
- Pre-closure public health and environmental standards (Subpart K).
- Based on EPA’s latest (2008) Yucca Mountain standard-setting and independent NRC work, post-closure public health and environmental standards for Yucca Mountain: postclosure individual protection standards for 10,000 years following closure (15 mrem/yr.) and for the period after 10,000 years but within the period of geologic stability (100 mrem/yr.); post-closure individual protection standards for human intrusion; separate groundwater protection standards; and limits on the requirements for the performance assessment (Subpart L).
- Adoption of EPA’s preferred criterion of “reasonable expectation” for purposes of judging compliance with the postclosure performance objectives (§63.311) while retaining “reasonable assurance” elsewhere such as for preclosure performance and construction authorization.
- Reliance on health based standards for postclosure performance rather than relying on meeting cumulative release limits and separate, quantitative, subsystem performance objectives.

### **Potential Changes**

Although the NRC has two proposed rules that would impact Parts 60 and 63 (geologic repository operations area security and material control and accounting requirements that involve post-September 11, 2001 security upgrades and geologic repository fitness-for-duty requirements), the rules are identified as “long-term” rulemaking actions with no schedule for completion. Because the HLW disposal area is currently being reviewed and reassessed and it is possible that new directives or approaches will result, the exact nature and timing of potential changes to Parts 60 and 63 is uncertain.

5. **Low-Level Waste Disposal** (10 CFR Part 61, Licensing requirements for land disposal of radioactive waste)

### **Introduction**

The NRC's regulations for the disposal of low-level radioactive waste (LLW)<sup>15</sup> at near surface land disposal sites are found in Part 61 and are applicable to persons subject to the jurisdiction of the NRC who dispose of LLW received from other persons.<sup>16</sup> Part 61, which was issued in 1982, describes how the NRC will license construction, operation, and closure of LLW disposal facilities. States and their LLW Waste Compacts are responsible under the Low-Level Radioactive Waste Policy Amendments Act of 1985 for providing for the disposal of LLW except for waste that is greater than Class C (GTCC), which is discussed below.<sup>17</sup>

A LLW near surface disposal facility includes the land and buildings necessary to carry out the disposal. The disposal site is that portion of the facility which is used for the actual disposal and includes the disposal units (generally trenches) and a buffer zone. The buffer zone is the area that lies under the site and the surface portion of the site around the disposal units. It provides for a controlled space for monitoring to provide early warning of radionuclide movement and time to take mitigative measures if needed. Near surface disposal is at depths down to approximately 30 meters below the land surface.

LLW disposal sites must be on land owned by either the State or the Federal government with provision for active institutional controls for a period of up to 100 years. No site has actually been licensed under the provisions of Part 61 as all of the current disposal sites in the United States are in, and licensed by, Agreement States. Nevertheless, since Agreement States must maintain requirements that are adequate and compatible with NRC requirements, Part 61 is the LLW disposal standard in the United States.

## **Regulatory Framework**

The framework of Part 61 provides both deterministic and performance-based requirements. From a deterministic perspective, a disposal site must meet specific technical requirements and waste must meet the applicable waste classification criteria. From a performance-based perspective, Part 61 provides that the site must be subject to a technical analysis (commonly called a performance assessment) demonstrating that the site meets the performance objectives of

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<sup>15</sup> LLW addresses waste consisting of byproduct, source, and special nuclear material. Naturally occurring radioactive material is not a subset of LLW under the NRC regulations and the various federal statutes. However, under Section 651(e) of the Energy Policy Act of 2005, discrete radium-226 sources and material made radioactive by use of a particle accelerator must be disposed of at an AEA or an Agreement State licensed facility or at a disposal facility in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, also known as the Resource Conservation and Recovery Act (RCRA). States regulate the disposal of diffuse naturally occurring radioactive waste.

<sup>16</sup> Disposal of waste by an individual licensee of its waste on its property is addressed by 10 CFR Part 20 and is very limited.

<sup>17</sup> Under the Low-Level Radioactive Waste Policy Acts of 1980 and 1985, States have formed 10 regional compacts to establish LLW disposal sites. A compact may exclude waste generated outside the compact and limit waste from being exported outside the compact. The US Ecology site in Hanford, WA, accepts waste only from within the Northwest Compact and Rocky Mountain Compact. The EnergySolutions site in Barnwell, SC, only accepts waste from the Atlantic Compact. The EnergySolutions site in Clive Utah only accepts Class A waste from outside the Northwest Compact. The Waste Control Specialists site in Andrews Texas soon to be under construction may accept waste from within the Texas Compact and recently received authorization from the Texas Compact to dispose of waste from outside the Texas compact. Except for Waste Control Specialists, attempts to develop disposal sites have failed under the compact system.

Part 61, Subpart C that address: (1) protection of the general population from releases of radioactivity; (2) protection of individuals from inadvertent intrusion into the site and occupying it or contacting the waste; (3) protection of individuals during operations; and (4) stability of the disposal site after closure. Thus, notwithstanding meeting the technical requirements, a disposal site must meet the performance objectives. The result is a systems approach that considers the integrated performance of all the disposal system performance, i.e., the site, the waste form, the engineering and facility design, the operation, and the closure, in determining whether the performance objectives have been met.

The technical requirements of Part 61 include provisions addressing 1) the suitability of the site for long term isolation of waste (§61.50); 2) the design of the site including its ability to provide long term isolation without active maintenance following site closure (§61.51); 3) the site's operation and closure plans (§61.52); 4) environmental monitoring (§61.53); 5) characteristics of waste (§61.56); 6) labeling of waste (§61.57); 7) institutional controls after site closure (§61.59); and 8) financial assurance to address construction, disposal operation, closure, and institutional controls (§§61.61-63).

In addition, Part 61 provides for a waste classification system. Section 61.55 provides for four classes of waste: Class A, Class B, Class C, and greater than Class C (GTCC). The classification of a particular waste stream is determined based on the radionuclide concentrations described in Tables 1 and 2 of §61.55. The bases of these tables were described in the Environmental Impact Statement (NUREG-0945, November 1982) that supported the issuance of Part 61. Class A, B, and C waste is suitable for near surface disposal. Generally Class A and Class B waste will present an acceptable hazard to an intruder within about 100 years. Class B waste must meet more stringent stability provisions than Class A waste. Class C waste must be disposed of at greater depths than Class A or B waste or provide for an intruder barrier designed for at least 500 years. GTCC waste generally is not suitable for near surface disposal. Such waste must be disposed in a geologic disposal facility unless the Commission approves of the disposal at a licensed Part 61 site.<sup>18</sup> Disposal sites may be licensed for one or more classes of waste.<sup>19</sup>

Part 61 requires a performance assessment to demonstrate that there is reasonable assurance for protection of the general population from releases of radioactivity that considers pathways from air, soil, groundwater, surface water, plant uptake, and burrowing of animals. The performance assessment must also demonstrate that there is reasonable assurance that an inadvertent intruder will be protected.<sup>20</sup> The assessment must also consider long term site stability and take into consideration natural processes such as erosion, settlement, water infiltration, migration of radionuclides, etc. Part 61 contains a provision in section 61.58 that provides the NRC with discretion to authorize alternative provisions for the classification of waste and waste

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<sup>18</sup> In accordance with the Low-Level Radioactive Waste Policy Amendments Act of 1985 the Federal government is responsible for the disposal of GTCC waste. Currently, there is no disposal option for GTCC waste.

<sup>19</sup> EnergySolutions site in Clive Utah is only licensed for Class A waste. The EnergySolutions site in Barnwell, SC, and the US Ecology site in Hanford, WA, are licensed for Class, A, B, and C waste. The WCS site in Andrews Texas soon to be under construction is also licensed up to Class C waste.

<sup>20</sup> NRC recognizes that there is controversy over whether a performance assessment addressing intruder exposure is necessarily required for Class A waste in light of the other provisions of Part 61. Blending of Low-Level Radioactive Waste, SECY-10-0043, Enclosure at 18 (April 7, 2010).

characteristics based on a site specific performance assessment demonstrating that there is reasonable assurance that the performance objectives of Subpart C are met.<sup>21</sup>

During the NRC licensing process, the NRC consults with States and Tribes whose interests are affected by the proposed disposal facility, and there are procedures for their participation in the NRC review of the application. This consultation is in addition to their participation in the formal hearing process, if one is held on the application.

As part of the NRC licensing process, the NRC considers the applicant's environmental report along with the technical aspects of the application and the NRC prepares its own Environmental Impact Statement. The NRC, as provided in § 61.23, will grant a license if issuance will not be inimical to the common defense and security and will not constitute an unreasonable risk to the health and safety of the public, and, among other things, the NRC finds:

- The applicant's proposed disposal site, disposal design, land disposal facility operations (including equipment, facilities, and procedures), disposal site closure, and post closure institutional controls are adequate to protect the public health and safety in that they provide reasonable assurance that 1) the general population will be protected from releases of radioactivity, 2) individual inadvertent intruders are protected, and 3) long-term stability of the disposed waste and the disposal site will be achieved and will eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following closure.
- The applicant's proposed land disposal facility operations, including equipment, facilities, and procedures, are adequate to protect the public health and safety in that they will provide reasonable assurance that the standards for radiation protection in 10 CFR Part 20 will be met.
- The applicant's demonstration provides reasonable assurance that the applicable technical, financial assurance, physical protection, institutional control, criticality, and environmental requirements have or will be met.

### **Potential Changes**

The NRC is considering changes to Part 61 that will make Part 61 more risk-informed and performance-based. The focus of this change involves depleted uranium and blended waste that is at or near the Class A limits. These waste streams were not fully considered in the development of the waste classification criteria in §61.55. The depleted uranium issue arises from the desire of DOE to dispose of its large amounts of depleted uranium primarily from uranium enrichment activities. The blended waste issue arises in part as a result of the closure of the Barnwell facility to facilities not in the Atlantic Compact that removes access to most generators of Class B and C wastes. The result of the rulemakings on depleted uranium and blended waste are expected to strengthen requirements for performance assessments, set time for compliance periods, update the dose methodology used in Part 61, and clarify dose standards for intruders. In addition, the NRC is considering a risk-informed, performance-based comprehensive revision to Part 61 that may reconsider the current waste classification system.

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<sup>21</sup> Agreement States are not required to adopt his provision to maintain compatibility and adequacy. Utah for example has not adopted it.

Options being considered include revising the concentrations in the current classification system, adopting a system similar to DOE's that is risk-informed and performance-based that does not depend on waste classification, and aligning Part 61 with recommendations of International Atomic Energy Agency's (IAEA). Currently, the NRC staff plans to submit rulemaking recommendations to the Commission in 2012 after engaging stakeholders.<sup>22</sup>

## **6. Enrichment, Fuel fabrication, and MOX Fuel (10 CFR Part 70 – Domestic licensing of special nuclear material)**

### **Introduction**

The NRC regulations for the licensing of facilities for the possession and use of SNM are found in Part 70. This includes the regulation of facilities for the enrichment of SNM to make reactor fuel and the fabrication of uranium based fuel from the enriched material.<sup>23</sup> It also addresses the licensing of a MOX fuel fabrication facility that utilizes plutonium. The performance of work for the Department of Energy at a United States Government owned or controlled site, including the transportation of SNM to and from these sites, is exempt from NRC regulation as are certain activities of the Department of Defense.

### **Regulatory Framework**

Part 70 focuses on the safe possession and use of SNM. Those licenses, which are authorized to possess a critical mass of SNM and enrich and fabricate fuel, must meet Subpart H of Part 70, which was incorporated into the regulation in 2000 and which provides a set of risk-informed performance-based requirements. It provides base line design criteria, sets performance objectives, and requires applicants and existing licensees to conduct an integrated safety analysis (ISA) to 1) identify facility and external hazards and their potential for initiating accident sequences, 2) potential accident sequences, their likelihood and consequences, and 3) identify items relied on for safety (IROFS) which are needed to preclude or mitigate the consequences of these accidents. Part 70, as a performance-based regulation, requires that protection of both the workers at the facility and the public be demonstrated by the IROFS that are identified by the ISA.

The requirements for a license to possess or use a critical mass of SNM includes consideration of: 1) protection of the licensee's workers and the public from radiation and chemical exposures; 2) site selection including the ability to withstand the effects of earthquakes, tornadoes and other severe natural phenomena; 3) protection of the facility and SNM from severe fires; 4) prevention of nuclear criticality accidents; 5) confinement of the SNM under both normal and accident conditions; 6) plans for emergency response; 7) security protection from attempts at SNM divergence or radiological sabotage; 8) development of an Environmental Assessment or an EIS, as required; 10) approved management measures which typically include the required quality, maintenance, and configuration requirements to ensure availability of the identified IROFS; 11)

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<sup>22</sup> SECY-10-0165, Staff's Approach to Comprehensive Revisions to 10 CFR Part 61 (December 27, 2010).

<sup>23</sup> Gaseous diffusion plants are regulated under 10 CFR Part 76, which is a special regulation, developed just for the NRC regulatory oversight of the former DOE facilities.



financial assurance for operation and decommissioning; and 12) a material control and accounting plan and a security plan, as required by the type and quantity of SNM,.

The MOX facility at the Savannah River Site currently undergoing reviews would be the first fuel fabrication facility licensed by the NRC that converts weapons-grade plutonium into fuel for commercial nuclear reactors. The licensing process is being done in two stages to first authorize construction, and then after construction, authorize operation. The review of the MOX facility will include all of the areas identified in the previous paragraph.

### **Potential Changes**

The NRC is considering two changes to Part 70. The first effort, which is yet to be initiated, would amend the regulations to incorporate the provisions of security orders that the NRC issued in response to the terrorist attacks of September 11, 2001. The second effort is to respond to a rulemaking petition to clarify NRC reporting requirements for certain events which occur at fuel facilities.

## **7. Transportation of Fresh and Spent Fuel (10 CFR Part 71 – Packaging and Transport of Radioactive Material)**

### **Introduction**

The Department of Transportation (DOT) under its statutory authority has the responsibility for nearly all aspects of the safe transport of hazardous materials including radioactive materials (RM). However, the NRC also has transportation jurisdiction for RM under the AEA. The DOT and the NRC have entered into a Memorandum of Understanding (MOU)<sup>24</sup> to set out how this concurrent authority will be exercised to minimize the duplication of effort. The NRC has the responsibility under the MOU for the certification and approval of packages used to transport highly RM such as spent nuclear fuel (SNF) and fissile materials such as fresh reactor fuel. DOT regulates the safety of routes such as highways and railways and carriers of RM. DOT often delegates aspects of route safety to the states, as an example, highway and bridge inspections. Under DOT authority, states may inspect the carrier, package and conveyance. The NRC regulates the security of SNF and fresh fuel shipments along these routes. To allow compatible shipments of RM across international borders, both NRC and DOT regulations incorporate nearly all aspects of the IAEA regulations.<sup>25</sup> The NRC's transportation regulations are found at 10 CFR Part 71.

### **Regulatory Framework**

Part 71 is a highly deterministic regulation with specified requirements for package performance in both normal and accident conditions. Starting in the 1980s, the NRC staff began a series of transportation risk assessments, which examined the potential consequences of transportation accidents beyond the already strict requirements in Part 71. The first of these assessments is

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<sup>24</sup> See 44 FR 38690 (July 2, 1979).

<sup>25</sup> IAEA Safety Requirements TS-R-1, Regulations for the Safe Transport of Radioactive Material, 2009

commonly called "The Modal Study,"<sup>26</sup> since the study considers multiple modes of transport, such as highway or rail. The Modal Study and subsequent risk assessments<sup>27</sup> showed that Part 71 packaging requirements provided ample confinement of the RM contents and a very high level of public protection.

Nearly all shipments in the US are shipped under one of the general license provisions of 10 CFR 71, Subpart C. For example, any NRC licensee may ship RM to any authorized recipient, provided the shipper properly loads the contents into a package certified by the NRC. The shipper must also follow all the conditions of use specified in the package certificate. For nearly all of its RM shipments, the DOE can self-certify its packages. However, the NWPA requires that the DOE use NRC-certified packages to ship SNF and HLW to the high-level waste repository.<sup>28</sup>

Prior to certification, the NRC staff reviews an application that is required by Part 71 to describe the package's detailed design features to ensure that the package can maintain adequate containment of the RM contents under specified normal and accident conditions. Considerations include package radiation exposure limits, adequacy of package lifting equipment and attachments to the conveyance, adequacy of the designer's QA program, external atmospheric temperature and pressure extremes, drops and vibration, and compression and penetration loads. For the hypothetical accident, the package must be able to maintain RM containment and subcriticality under a severe accident sequence: a 5 meter drop and tip-over at the most limiting drop angles, severe crush and puncture, total immersion in a severe fire, and immersion in 15 meters of water. An additional immersion standard applies to SNF that requires the package be designed so that its undamaged containment system can withstand an external water pressure of 200 meters of water. Package performance under the hypothetical accident conditions can be demonstrated by test, analyses, or combinations thereof. SNF shipments have been made in the US without any semblance of package failure.

Part 71, Subpart G includes provisions for detailed inspection and leak testing of packages prior to shipment. The shipper must also measure the external temperature and radiation levels of the package and place required placarding on the package and conveyance. A detailed set of records must accompany the shipment. Shippers must provide advanced notification to each state through which the shipment passes (§71.97). The vast majority of shipments of SNF are by rail. DOE's plans for shipment of SNF and HLW to a licensed HLW repository, when one is licensed, include the use of satellite tracking and dedicated trains.

### **Potential Changes**

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<sup>26</sup> These two documents constitute "The Modal Study:" L. E. Fischer, et al., "Shipping Container Response to Severe Highway and Railway Accident Conditions," NUREG/CR-4829, Lawrence Livermore National Laboratory, February 1987 and W. R. Lahs, "Transporting Spent Fuel, Protection Provided Against Severe Highway and Railroad Accidents, NUREG/BR-01 11, US NRC, March 1987.

<sup>27</sup> See for instance, J. D. Sprung, et al., "Spent Nuclear Fuel Transportation Package Performance Study Issues Report," NUREG/CR-6768, US NRC, January 2001.

<sup>28</sup> See NWPA, Sections 137(a) and 180.

Since the NRC and DOT regulations are largely compatible with IAEA regulations, the NRC and DOT normally engage in conforming rule makings consistent with the IAEA 5-year revision cycle. Recently, the NRC has proposed a rule that would require shippers to provide advanced notification of SNF shipments to federally recognized Indian tribal governments. Several times each year the NRC amends Part 72 to add new certificates or amend existing certificates for dual-purpose SNF packages. Dual-purpose casks are designed and certified for both storage and transportation and thus conform to both Part 71 and Part 72 design requirements and are affected by these Part 72 rule makings. The NRC has issued several proposed rule changes that would establish standards and for the protection of SNF shipments from theft, diversion, or radiological sabotage. These rule changes would largely incorporate security orders that the NRC issued in response to the terrorist attacks of September 11, 2001.

8. **Storage of Spent Fuel** (10 CFR Part 72, Licensing requirements for the independent storage of spent nuclear fuel, high-level radioactive waste, and reactor-related greater than Class C (GTCC) waste)

### **Introduction**

Part 72 contains the NRC's regulations for the dry storage of power reactor spent fuel on or off a reactor site and for pool storage away from a reactor site.<sup>29</sup> It also addresses the licensing of the DOE for Monitored Retrievable Storage (MRS) facilities and the issuance of Certificates of Compliance for approving spent fuel storage cask designs. Part 72 provides flexibility for regulating a variety of spent fuel storage options.

Many licensing actions involving dry cask storage systems at reactor sites include the consideration of the transportability of the dry storage casks. This effort results in the NRC approval of a spent fuel storage system that is suitable for both storage and transportation and is normally called a dual-purpose system. The relevant certification of the transportation function of these dual-purpose systems is discussed above in the report section on 10 CFR Part 71, which is the NRC regulation pertaining to the safety of packages that are used to transport of spent fuel.

### **Regulatory Framework**

Part 72 is a largely deterministic regulation. Its requirements provide a framework for ensuring safe storage of the spent fuel. Although a risk analysis of a pool storage system might provide some insight, the passive design of a dry storage system makes it less likely to benefit from a risk-based analysis.<sup>30</sup>

The requirements for licensing spent fuel storage includes consideration of: 1) protection of the licensee's workers and the public from radiation exposures; 2) site selection including the ability to withstand the effects of earthquakes, tornadoes and other severe natural phenomena; 3) protection of the spent fuel storage system from severe fires and cask drop accidents; 4)

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<sup>29</sup> Spent fuel pools at reactors are licensed under 10 CFR PART 50.

<sup>30</sup> Passive, static components like a cask are not subject to a variety of complex, potential failure initiators and interactions from systems with a large number of active components like pumps, circuit breakers, valves, and the like.

prevention of nuclear criticality accidents; 5) containment of the spent fuel under both normal and accident conditions; 6) removal of decay heat from the spent fuel; 7) plans for emergency response; 8) security protection from attempts at radiological sabotage; 9) development of an Environmental Assessment or an EIS, as required; 10) an approved quality assurance program; 11) financial assurance for operation and decommissioning; 12) training and certification of operators; and 13) control and accounting of the SNM contained within the spent fuel.

Power reactor licensees have two options for obtaining a license to store their excess SNF. They can obtain a separate Part 72 site-specific license, or they can make use of a general license providing they use a dry storage system that has a NRC Certificate of Compliance for the storage of spent fuel. The general license is issued by operation of Part 72, Subpart K, and does not require an application or provide for an opportunity for a hearing. The general license provision does not apply to an MRS. The process for a specific license under Part 72 provides an opportunity for an adjudicatory hearing

Part 72 licenses are issued for terms of 20 years; however, a license for an MRS would be issued for a term of 40 years. These licensees may be renewed for additional terms, providing that a renewal application has been filed prior to the expiration of the license. Any renewal application would need to provide a detailed technical basis as to why the spent fuel can continue to be safely and securely stored for an additional term.

From a procedural standpoint, the NRC regulations do not restrict the number of license renewal terms that may be considered. However, the NRC has not developed a technical basis for a large number of consecutive license terms. For instance, most dry cask storage system design and safety bases have been for 20 years. A few of these systems have had their licenses or certificates extended for an additional 20 years. Although analyses and research to develop the needed safety basis for very long-term interim spent fuel storage have begun, the completion of such safety bases is most likely years away. For this reason, one should not assume that the present spent fuel storage facilities, whether at reactor sites or at a centralized interim storage facility would necessarily be shown to be adequate for such long storage terms.<sup>31</sup> However, the NRC has recently updated its waste confidence decision and has made a generic finding, codified at 10 CFR 51.23 (a), that current design spent fuel may be safely stored and without significant environmental impact for at least 60 years past the life of the reactor that is the source of the spent fuel.<sup>32</sup> In this recent rule making, the Commission amended one of its environmental findings in 10 CFR 51.23 (a) to state

The Commission has made a generic determination that, if necessary, spent fuel generated in any reactor can be stored safely and without significant environmental

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<sup>31</sup> For a full appreciation of the effort needed to establish a long-term safety basis for spent fuel storage, see Nuclear Waste Technical Review Board (NWTRB) report, *Evaluation of the Technical Basis for Extended Dry Storage and Transportation of Used Nuclear Fuel*, December 2010.

<sup>32</sup> Consideration of Environmental Impacts of Temporary Storage of Spent Fuel After Cessation of Reactor Operations; Waste Confidence Decision Update; Final Rule 75 FR 81,032 (December 23, 2010). The NRC recognizes that potential new fuels, such as fuels having different cladding, internal materials, different assembly designs, different operating conditions, and fuels with higher burn-up limits than current burn-up limits may need further review to demonstrate that extended storage can be accomplished safely. Waste Confidence Decision Update, 75 FR 81,307, to 81,701 (December 23, 2010).

impacts for at least 60 years beyond the licensed life for operation (which may include the term of a revised or renewed license) of that reactor in a combination of storage in its spent fuel storage basin and at either onsite or offsite independent spent fuel storage installations.

### **Potential Changes**

Aside from periodic rulemakings to add a certified cask design or to amend an existing cask certificate, there is a rulemaking to amend the regulations to incorporate the provisions of security orders that the NRC issued in response to the terrorist attacks of September 11, 2001. In addition, as part of the recent rulemaking on waste confidence and due to the uncertainty regarding the timing of the availability of a geologic repository for SNF and HLW, the NRC has directed its staff to develop a plan for a longer-term rulemaking and EIS to assess the environmental impacts and safety of long-term SNF and HLW storage beyond 120 years.<sup>33</sup>

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## **9. Reprocessing**

### **Introduction**

Reprocessing refers generally to the processes necessary to separate spent nuclear reactor fuel into material that may be recycled for use in new fuel and material that would be discarded as waste. While there are facilities operating in foreign countries, there are no NRC licensed reprocessing facilities currently operating in the United States. It has been more than 40 years since a reprocessing facility has been licensed for operation in the United States.<sup>35</sup>

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<sup>33</sup> Id., at 81,040.

<sup>34</sup> Id., at 81,040.

<sup>35</sup> The Nuclear Fuel Services plant at the Western New York Nuclear Service Center at West Valley, New York (West Valley) was the only commercially operating reprocessing facility in the United States. It was licensed by the then AEC in 1966 and ceased reprocessing operations in 1972. Allied General Nuclear Services (AGNS) at Barnwell, South Carolina received a construction permit in 1970 and submitted an application for an operating license in 1973. The AGNS plant, though built, never received an operating license because of the policy decision by the United States Government to not support spent fuel reprocessing. This policy decision has been reversed but until recently, there has been essentially no interest in building a reprocessing facility. The Midwest Fuel Recovery Plant in Morris, Illinois (GE Morris) received its construction permit from the AEC in 1967. In 1972, GE halted construction because the design did not operate as expected and consequently, it did not pursue an operating license. In 1976, Exxon applied for a construction permit to construct a reprocessing facility, but no action was taken on the application.

Reprocessing facilities are defined by the AEA as production facilities and as such are subject to many of the same requirements to which reactors are subject. See, section 3, above, on reactors. Currently, 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” provides the licensing framework for reprocessing facilities. NRC has recognized that since Part 50 was last used for licensing a reprocessing facility, Part 50 has evolved to focus on LWR's and has many LWR specific GDCs, which need to be addressed and which would have limited or detrimental applicability in commercial reprocessing facility design and technology. Consequently, its use for reprocessing facilities would create a licensing process that would be “inefficient, unstable, and unpredictable.”<sup>36</sup>

If a reprocessing facility is proposed to be licensed in the United States, NRC will need to have a regulatory framework that is suitable for reprocessing facilities and that recognizes the hazards associated with reprocessing. It is important that the regulatory framework for recycling be well defined by the NRC. Knowing the applicable requirements will be indispensable to the designers of advanced fuel cycle work. NRC has initiated action to develop a revised regulatory framework to address reprocessing as described below.

### **Regulatory Framework Development**

Since reprocessing facilities are more like a complex fuel cycle facility that are licensed under Part 70 than a reactor, NRC is evaluating the use of 10 CFR Part 70 with appropriate modifications for licensing a reprocessing facility. Part 70 with its risk-informed, performance-based approach provides a useful model for a new regulatory framework that would be technology neutral to allow alternative methods for separation. However, a number of significant changes would need to be made to Part 70 to address procedural and substantive requirements necessary under the AEA including both the two-step licensing process (construction permit and operating license) and combined license process for production facilities, technical specifications, and licensing of individual reprocessing operators. Additional substantive requirements are also needed because of the nature of a recycling facility with a greater source term than other fuel cycle facilities.<sup>37</sup>

The Nuclear Energy Institute (NEI) provided the NRC a white paper in December 2008 that contained a draft regulatory framework to support licensing of a reprocessing facility.<sup>38</sup> It was intended to be an information source and serve as a foundation for discussions on a new framework. NEI proposed a new set of regulations, called Part 7x, based on the risk-informed and performance-based approach of 10 CFR Part 70. Part 7x incorporated provisions from Parts 50, 52, 70, and 72. The underlying safety standard for the NEI approach was that the facility needed to meet the performance requirements of Part 70 that would ensure that the design and

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<sup>36</sup> NRC Fact Sheet on “Development of Regulations for Spent Nuclear Fuel Reprocessing Facilities,” ADAMS ML102720179 (2010).

<sup>37</sup> A good resource on issues associated with reprocessing is found in NUREG-1909, “Background, Status, and Issues Related to the Regulation of Advanced Spent Nuclear Fuel Recycle Facilities: ACNW&M White Paper,” (2008).

<sup>38</sup> NEI Regulatory Framework for an NRC Licensed Recycling facility, ADAMS ML083590130 (December 19, 2008).

operation of the facility would be protective of the public health and safety. It also reflected a fundamental element of the NRC safety philosophy that designs and operations should provide for defense-in-depth protection against accidents. It expanded the 10 design criteria of Part 70 to 28 criteria that would be applied to the design and integrated safety analysis to demonstrate that there is reasonable assurance that the performance objectives would be met under accident and normal conditions including the consequences of natural phenomena. Unlike Part 70 and as required by the AEA, proposed Part 7x includes provisions for operators to be licensed, technical specifications be established, and quantitative risk assessments be completed. It also provides for adjudicatory hearings similar to Parts 50 and 52 to meet the AEA requirements for a production facility.

As part of its effort to develop a new framework, in May 2009 the NRC staff prepared a Commission paper that described 23 gaps in the current regulatory process that it needed to address.<sup>39</sup> Fourteen of these gaps were considered to be of high priority that must be resolved to establish an effective and efficient regulatory framework. The high priority gaps that the NRC identified are:

- Regulatory Framework Options, Part 50 or Part 70
- Independent storage of high level waste
- Waste incidental to reprocessing
- Exclusion of irradiated fuel reprocessing facilities in 10 CFR 74.51
- Risk considerations for a production facility licensed under 10 CFR Part 70
- Definitions for reprocessing related terms
- Licensed operators and criteria for testing and licensing operators
- Risk-Informing 10 CFR Part 73 and 10 CFR Part 74
- Baseline design criteria
- One-step licensing with inspection, testing and acceptance criteria (ITAAC) requirements
- Technical specifications
- Financial protection requirements and indemnity agreements (10 CFR Part 140)
- Schedule of fees (10 CFR Part 170)
- Annual fees (10 CFR Part 171)

The NRC staff also recognized the need to coordinate its efforts on the regulatory framework with ongoing rulemaking efforts, in physical security and material control and accounting, to amend Parts 73 and 74, as well as, the ongoing efforts to consider revision to the NRC radiation protection standards in Part 20. The NRC is also aware that there are issues with the EPA effluent limits established by the EPA in its regulations at 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations," that establish dose and effluent limits for uranium fuel cycle operations including the reprocessing of spent uranium fuel. The EPA limits are based on 1) a collective population dose that is likely to be overly conservative for small doses in large populations, 2) the assumption of 1,000 GWe of nuclear power that is not currently realistic and 3) the assumption of 25 1,500 MTIHM/yr reprocessing plants, which again is not realistic, and 4) relatively short cooling times before reprocessing of the used fuel

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<sup>39</sup> SECY-09-0082, Update on Reprocessing Regulatory Framework - Summary of Gap Analysis (May 28, 2009).

begins.<sup>40</sup> The limitation in Part 190 on the quantities of Kr-85 and I-129 allowed to be released may pose a challenge for reprocessing facilities because of cost and ALARA concerns. However, as these limits are established by the EPA, they are not considered in the NRC regulatory gap analysis. The NRC is interacting with the EPA on the Part 190 issues.

The NRC has held several public meetings with stakeholders including meetings with NEI to address its whitepaper and the NRC Gap analyses. It also held public workshops in Rockville, MD and Albuquerque, NM to discuss major issues associated with the development of a regulatory framework for a potential rulemaking for spent nuclear fuel reprocessing facilities. It is noted that at these public meetings and workshops, opposition to rulemaking was expressed by some members of the public.

Currently, the NRC is continuing to work on its gap analyses and a technical basis document that is needed to support a rulemaking. It is also initiating environmental activities in preparation for a rulemaking effort. The last announcement of the NRC schedule, provided at the October 2010 Albuquerque workshop, set an NRC goal to produce a draft rule for comment in 2014 and a final rule in 2015. This schedule assumed that the NRC Commission provided the necessary approvals and resources for a rulemaking.

11. **Security and Safeguards** (10 CFR Part 73 – Physical Protection of Plants and Materials; 10 CFR Part 74 – Material Control and Accounting of Special Nuclear Material; and 10 CFR Part 75 – Safeguards on Nuclear Material-Implementation of US/IAEA Agreement)

### **Introduction**

The NRC has established security and safeguards regulations to carry out the agency's responsibility under the AEA to promote the common defense and security and protect public health and safety by guarding against theft or diversion of SNM and radiological sabotage.

### **Regulatory Framework**

Part 73 is a cross-cutting regulation that addresses activities licensed under 10 CFR Parts 50, 52, and 70. It addresses both physical plants and nuclear materials. Part 73 prescribes requirements for the establishment and maintenance of a physical protection system to protect SNM at fixed sites and in transit and to protect plants where SNM is used. This part of the regulations also requires that design systems be in place to protect against acts of radiological sabotage and to prevent the theft of SNM. This regulation also addresses the physical protection of commercial nuclear power plants from radiological sabotage. It would also address reprocessing facilities.

The safeguards requirements in Part 73 together with requirements in Parts 50 and 70 includes physical controls such as fences and locks, access controls such as background checks and fingerprinting of employees, communications, contingency plans, guard force requirements,

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<sup>40</sup> NRC Slides for Albuquerque Workshop, "Reprocessing and Recycling: Environmental Protection," ADAMS ML102980320 (October 20, 2010).



response capabilities and drills. These requirements are graded based on the significance of the materials and facilities to be protected. Facilities subject to Part 73 are required to have a site specific plan which describes implementation of the regulation. The adversary for both radiological sabotage and theft and diversion of SNM are defined in terms of a design basis threat (§73.1).

Part 74 establishes the requirements for the control and accounting of SMM at fixed sites and for documenting the transfer of SMM to prevent or detect the loss of SMM. It requires use of statistical and accounting measures to maintain knowledge of SNM quantities present in each area of a facility. It includes the use of physical inventories and material balances to verify the presence of material or to detect the loss of material through theft or diversion. The regulation is performance oriented and provides for a graded approach to regulation based on the category of SNM.<sup>41</sup> Each facility has a site specific plan which describes implementation of the regulation.

Part 75 establishes the system of nuclear material accounting and nuclear material control to implement the Agreement between United States and the IAEA for the application of safeguards in the United States. Part 75 requires that the licensees subject to Part 75, including reactors, fuel fabrication plants, and independent spent fuel installations, provide access to IAEA representatives.

### **Potential Changes**

An effort to amend the regulations to incorporate the provisions of security orders that the NRC issued in response to the terrorist attacks of September 11, 2001 is anticipated. These regulations would also need to be reviewed as part of the development of the regulatory framework or reprocessing.

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<sup>41</sup> There are three categories of SNM described in §70.4 and 73.3. SNM of low strategic significance (sometimes referred to as Category III quantity of material), SNM of moderate strategic significance (sometimes referred to as Category II quantity of material), and SNM of strategic significance containing a formula quantity (sometimes referred to as Category I quantity of material).