



**U.S. NUCLEAR REGULATORY COMMISSION**  
**DRAFT PLAN FOR RETROSPECTIVE ANALYSIS OF EXISTING RULES**

**DRAFT 11/1/12**

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## I. INTRODUCTION

### A. Executive Order 13563, “Improving Regulation and Regulatory Review”

On January 18, 2011, President Barack Obama issued Executive Order (E.O.) 13563, “Improving Regulation and Regulatory Review.” Executive Order 13563 directs Federal agencies to develop and submit a plan to the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget. The plan should explain how each agency will review existing significant regulations and identify those regulations that can be made more effective or less burdensome while achieving regulatory objectives. Independent regulatory agencies were not covered by this order.

### B. E.O. 13579, “Regulation and Independent Regulatory Agencies”

On July 11, 2011, President Obama issued E.O. 13579, “Regulation and Independent Regulatory Agencies.” Executive Order 13579 recommends that independent regulatory agencies also develop, and issue publicly, plans akin to those required of executive departments and agencies under E.O. 13563.

### C. The NRC’s Initial Plan Published in November 2011

1. In November 2011, as part of its initial voluntary response to E.O. 13579, the U.S. Nuclear Regulatory Commission (NRC or the Commission) published an initial Plan on—
  - (a) The NRC’s Open Government Web page at <http://www.nrc.gov/public-involve/open.html> (under the tabs entitled “Selected NRC Resources” and “Rulemaking”); and
  - (b) The NRC’s plans, budget, and performance Web page (see <http://www.nrc.gov/about-nrc/plans-performance.html>).

The NRC also published a notice of availability in the *Federal Register* (76 FR 70913; November 16, 2011) (see <http://www.gpo.gov/fdsys/pkg/FR-2011-11-16/pdf/2011-29418.pdf>).
2. The initial Plan described the NRC’s long-standing and recent efforts to—
  - (a) Identify, simplify, and update outdated regulations to make them more effective and less burdensome; and
  - (b) Incorporate risk assessments into regulatory decisionmaking.
3. The initial Plan indicated that the NRC’s upcoming regulatory review activities may be influenced by pending decisions related to the Fukushima Dai-ichi events in

Japan. The initial Plan specified that the staff would follow Commission direction regarding the rulemaking recommendations in the Fukushima task force report, "Recommendations for Enhancing Reactor Safety in the 21st Century: The Near-Term Task Force Review of Insights from the Fukushima Dai-ichi Accident" (NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML111861807). The initial Plan also indicated that a revised Plan would be developed and made available for public comment in Calendar Year 2012 (hereinafter referred to as the "draft Plan" or the "draft Plan for public comment").

#### **D. The NRC's Draft Plan for Public Comment**

1. The draft Plan for public comment includes discussion of the following:
  - (a) Efforts to incorporate risk assessments into regulatory decisionmaking;
  - (b) Efforts to address the cumulative effects of regulation;
  - (c) The NRC's methodology for prioritizing its rulemaking activities;
  - (d) Rulemaking initiatives arising out of the NRC's ongoing review of its regulations related to the recent events at the Fukushima Dai-ichi Nuclear Power Plant in Japan; and
  - (e) The NRC's previous and ongoing efforts to update its regulations in a systematic, ongoing basis.
2. Upon receiving comments from stakeholders, the NRC will revise the draft Plan for public comment and ultimately publish a Final Plan during Calendar Year 2013. The NRC expects to voluntarily revise the Final Plan periodically.

## **II. SCOPE OF THE DRAFT PLAN FOR PUBLIC COMMENT**

The safe and secure use of radioactive materials and nuclear fuels for beneficial civilian purposes is made possible by the NRC's adherence to the following principles of good regulation: independence, openness, efficiency, clarity, and reliability. The NRC puts these principles into practice with effective, realistic, and timely regulatory actions that are consistent with its organizational values and its open, collaborative work environment.

The draft Plan for public comment (1) discusses the NRC's longstanding focus on assuring that its regulations are effective, efficient, and up-to-date; and (2) recognizes the processes that have contributed to the NRC's comprehensive regulatory infrastructure. This draft Plan for public comment also refers to actions recommended by the Commission in light of the events at the Fukushima Dai-ichi Nuclear Power Plant in Japan following the March 11, 2011, earthquake and tsunami. As outlined in Section III of this draft Plan for public comment, the NRC has a number of programs and activities in place to assess existing NRC regulations.

### **III. NRC'S PROCESSES, PROGRAMS, AND ACTIVITIES WHICH MEET THE OBJECTIVE OF A RETROSPECTIVE REVIEW OF EXISTING SIGNIFICANT RULES**

The NRC currently has a number of processes, programs and activities in place to assess its existing significant regulations. This section describes the NRC's processes, programs and activities which, when considered in the aggregate, meet the objective of the Executive Order.

Through its existing rulemaking processes, the NRC already identifies, simplifies, and updates outdated regulations in order to make them more effective and less burdensome. Public participation throughout the rulemaking process (see Section III.G) facilitates the exchange of ideas and contributes to the retrospective review of the NRC's regulations.

#### **A. Incorporation of Risk Insights into Regulatory Decisionmaking**

1. For approximately 20 years, the NRC has incorporated insights from risk assessments into its regulatory decisionmaking. The NRC updates its risk-informed, performance-based plan annually (see <http://www.nrc.gov/about-nrc/regulatory/risk-informed/rpp.html>). The risk-informed, performance-based plan—
  - (a) Covers the agency's three strategic arenas (reactor safety, material safety, and waste management); and
  - (b) Describes the NRC's efforts to focus attention on risk-significant safety systems, structures, and components, while reducing unnecessary conservatism associated with the NRC's regulations.
2. In February 2011, the NRC established a task force to enhance the use of risk information in regulatory activities. The task force developed a strategic vision and options to achieve a more comprehensive and holistic risk-informed and performance-based approach for the regulation of reactors, materials, waste, the nuclear fuel cycle, security, and transportation. As a part of this initiative, the task force sought public comment on a series of questions that provided input for the task force to consider in its work (76 FR 72220; "Incorporation of Risk Management Concepts in Regulatory Programs," November 22, 2011). The task force issued its report "A Proposed Risk Management Regulatory Framework," NUREG-2150, in April 2012 (ADAMS Accession No. ML12109A277).

#### **B. Performance-Based Regulations**

The NRC develops performance-based regulations whenever practicable. As described in SECY-98-144, "White Paper on Risk-Informed and Performance-Based Regulation," dated June 22, 1998, performance-based requirements rely upon measurable (or calculable) outcomes to be met, but provide more flexibility to the licensee as to the means of meeting those outcomes.

1. Because the licensee has greater flexibility in meeting the regulatory requirements, a performance-based approach can result in a more efficient and effective regulatory process. This approach differs from the prescriptive regulatory approach that specifies particular features, actions, or programmatic elements to be included in the design or process as the means for achieving a desired objective. Consequently, performance-based regulations can improve the objectivity and transparency of NRC decisionmaking, promote flexibility that can reduce licensee burden, and promote safety by focusing on safety-successful outcomes.
2. The September 1, 2000 document, SECY-00-0191, "High-Level Guidelines for Performance-Based Activities," provides guidelines to identify and assess the viability of making elements of the regulatory framework performance-based. To better inform this effort, the NRC formed the Performance-Based Regulation Working Group, held public workshops, and published draft guidelines for comment. The guidelines to assess if a more performance-based approach is viable for any regulatory initiative include considering whether flexibility for licensees in meeting the established performance criteria exists or can be developed. As the NRC develops performance-based approaches, it will also consider whether the approach will—
  - (a) Increase the effectiveness, efficiency, and realism of the NRC's activities and decisionmaking;
  - (b) Reduce unnecessary regulatory burden;
  - (c) Result in an overall net benefit; and
  - (d) Accommodate new technology.

### **C. Previous Rulemaking Process Improvement Efforts**

The NRC has undertaken multiple reviews of its rulemaking process that have addressed the general principles of regulation described in E.O. 13563.

1. In 1985, the NRC conducted a review effort directed at ensuring that the NRC's rulemakings were necessary, effective, efficient, of high quality, and timely. In 1994, the NRC made changes to its rulemaking process to emphasize pre-planning, which included the consideration of options, regulatory analysis, and evaluation of whether the rule would be cost-effective. From 1997 to 1998, the NRC began to place increased focus on public participation and the increased use of information technology. From 1997 to 1998, there were also efforts to reduce unnecessary regulatory burden.
2. In 2001, the NRC began a broad-scope review of its rulemaking process. As a result of this effort, the NRC made many refinements to that process, which included an increased emphasis on the development of a high-quality regulatory basis, better engagement of external stakeholders in the rulemaking process, improved quality in

the NRC's regulatory analyses, and an increased effort to issue guidance documents concurrent with the proposed rule.

3. In 2006-2007, the NRC evaluated the overall effectiveness of its recent rulemaking process improvements and identified other options to streamline the rulemaking process. Further improvements continued to enhance the process for developing regulatory basis and emphasized engaging external stakeholders during the development of the regulatory basis. The concurrent development and publication of the guidance and the proposed rule gave members of the public, licensees, and other stakeholders the information necessary to comment meaningfully on the proposed rule. The concurrent development and publication of guidance also contributed to increases in the efficiency and effectiveness of the rulemaking effort and to a better final rule. The NRC also recommended other changes to its rulemaking process to—
  - (a) Emphasize the release of draft technical information, draft rule text, statements of consideration, and the regulatory basis for a rule; and
  - (b) Hold public workshops before providing a proposed rule to the Commission.
4. In 2010, the NRC began an effort to evaluate its rulemaking process to consider the cumulative effects of regulation (CER) (see Section III.E.3 for details).

#### **D. Significant Regulations**

1. The NRC's Annual Fee Rule
  - (a) The NRC reassesses its fees for licensees annually. The annual rulemaking to revise the NRC's fees is often the only NRC rulemaking that qualifies as a "significant regulatory action" under E.O. 12866, "Regulatory Planning and Review."
  - (b) The NRC must recover most of its current fiscal year budget through fees for services specified in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended," and annual fees specified in 10 CFR Part 171, "Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC." Fees change each year for a number of reasons, including changes in the agency's total budget, allocation of budgeted resources to fee classes and fee-relief activities, and the number of licensees.

2. Physical Protection of Byproduct Material

Through this rule, the NRC will amend the Commission's regulations to codify security requirements for the use of Category 1 and Category 2 quantities of radioactive material. The objective of this action is to ensure that effective security measures are in place to prevent the use of radioactive materials for malevolent purposes. The rule also addresses background investigations and access controls, enhanced security for use of, and transportation security for, Category 1 and Category 2 quantities of radioactive material.

**E. Addressing the Regulatory Impacts of the NRC's Activities**

1. The NRC has a long history of improving processes to reduce unnecessary regulatory burden on external stakeholders. These include (but are not limited to) such initiatives as—
  - (a) Plans for the elimination of requirements marginal to safety (described in SECY-92-263, "Staff Plans for Elimination of Requirements Marginal to Safety," ADAMS Accession No. ML003766150); and
  - (b) Activities to reduce unnecessary regulatory burden on power reactor licensees (described in SECY-02-0081, "Staff Activities Related to the NRC Goal of Reducing Unnecessary Regulatory Burden on Power Reactor Licensees," ADAMS Accession No. ML020420137).
2. Another notable, and continuing, example of the NRC's efforts to improve processes to reduce regulatory burden on external stakeholders is the staff's activities to risk-inform its regulations, which began in 1994 with the first proposed probabilistic risk assessment (PRA) implementation plan (SECY-94-219, "Proposed Agency-Wide Implementation Plan for Probabilistic Risk Assessment (PRA)" (ADAMS Accession No. ML12116A052). The NRC developed this PRA implementation plan concurrently with its policy statement on PRA ("Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities, Final Policy Statement" (60 FR 42622; August 16, 1995). In that policy statement, the Commission stated its expectation that implementation of risk-informed activities would be expected to reduce unnecessary regulatory burden on licensees.
  - (a) Since the late 1990s, the NRC has continued to risk-inform its regulatory activities in an effort to continue to enhance safety, while reducing unnecessary regulatory burden.
  - (b) On April 2, 2000, the NRC implemented the Reactor Oversight Process (ROP) at all operating commercial nuclear power plants.<sup>1</sup> The ROP was developed to

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<sup>1</sup> See the NRC's March 29, 2000 press release entitled "NRC to Expand Use of Revised Reactor Oversight Process" (ADAMS Accession No. ML003707640). See also version 4 of



provide tools for inspecting and assessing licensee performance in a more risk informed, objective, predictable, and understandable way than the previous oversight process.

3. In January 2010, the Commission directed NRC staff to consider whether the schedule for implementing the new emergency preparedness rulemaking and future rulemakings should be influenced by the aggregate impact (now referred to as cumulative effects of regulation (CER)) of the new and recently issued regulations already scheduled for implementation. In response to this direction, the staff described several rulemaking process enhancements in SECY-11-0032, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," dated March 2, 2011 (ADAMS Accession No. ML110190027). These enhancements include:
  - (a) Interaction with external stakeholders during regulatory basis development;
  - (b) Interaction with external stakeholders during draft guidance development;
  - (c) Request for explicit stakeholder feedback on CER in the proposed rule *Federal Register* notice; and
  - (d) Public meeting on implementation during the final rule stage.

The NRC is updating its rulemaking procedures to incorporate the rulemaking process changes caused by CER.

#### **F. Compliance with the Regulatory Flexibility Act (5 U.S.C. 610)**

1. The NRC's Regulatory Flexibility Procedures (available at: <http://www.nrc.gov/about-nrc/regulatory/rulemaking/flexibility-act.html>) and the NRC's Regulatory Analysis Guidelines require that the factors necessary to evaluate the economic impact of the regulatory action under consideration on small entities be addressed in the Regulatory Analysis.
2. Only a few NRC rulemakings have been found to have a significant impact on a substantial number of small entities and involve byproduct, source, and special nuclear material. Annually, the NRC revises its regulations that assess license, inspection, and annual fees to recover most of its operating budget as required to implement the Omnibus Budget Reconciliation Act of 1990, as amended. As part of each annual revision, the NRC considers the impact of its fees on small entities.
3. An example of the NRC approach for rulemakings that have the potential for a significant economic impact on a substantial number of small entities is the "Medical

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NUREG-1649, "Reactor Oversight Process," December 2006, ADAMS Accession No. ML070890365).

Use of Byproduct Material” rulemaking (67 FR 20250; April 24, 2002) that was determined to have a significant impact on a substantial number of small entities. The development of the final regulations and the associated guidance included numerous interactions and consultations with the potentially affected parties, including representatives of small licensees to an extent that is greater than is provided by the typical notice and comment rulemaking process. In order to assist the small licensees, the NRC sought to eliminate prescriptive requirements wherever possible and to allow greater flexibility in compliance and reduced the training and experience requirements for certain lower-risk activities that are conducted by small licensees. These changes allow small licensees to reduce their compliance costs.

## **G. Opportunities for Public Participation**

1. The NRC offers many opportunities to comment on rulemaking activities, frequently even before the proposed rule stage. The NRC uses the Federal rulemaking Web site (see <http://www.regulations.gov>) to—
  - (a) Post draft rule text and other regulatory basis documents for stakeholder comment in the early stages of the rule development; and
  - (b) Make it easier for the public to participate in all stages of NRC rulemaking activities.
2. The NRC has provided opportunities for public comment on its risk-informed and performance-based activities and its efforts to reduce regulatory burden. For example, the NRC held a public workshop and published its high-level guidelines for performance-based activities for public comment (65 FR 3615; January 24, 2000) and solicited public comments in the development of a strategic vision to better incorporate risk-management concepts into its regulatory programs (76 FR 72220; November 22, 2011).
3. The NRC voluntarily complies with the North American Free Trade Agreement (which recommends notification at least 60 days before adoption of a technical regulation) and E.O. 12889, “Implementation of the North American Free Trade Agreement,” dated December 28, 1993 (which recommends a 75-day comment period). The NRC usually provides 75 days to comment on a proposed technical rule.
4. The public may request, and frequently does, a revision to existing regulatory requirements at any time using the 10 CFR 2.802, “Petition for Rulemaking” process.
5. The NRC generally drafts a regulatory analysis to determine the burden associated with each of its rules, and it issues each regulatory analysis for public comment, along with the proposed rule language. Also, the NRC provided an opportunity for public input on proposed guidance that was to be incorporated into the NRC’s Regulatory Analysis Guidelines (67 FR 6663; February 13, 2002).

6. Each year, the NRC holds the Regulatory Information Conference (RIC). Co-sponsored by the Office of Nuclear Reactor Regulation and the Office of Nuclear Regulatory Research, the RIC annually brings together more than 3,000 participants from more than 30 countries. It provides a unique forum for government, the nuclear industry, international agencies, and other stakeholders to meet and discuss nuclear safety topics and significant regulatory activities.
7. The NRC uses a management directives (MD) system as the official vehicle to communicate internal policy and overall instructions to the NRC staff and other stakeholders. The directives system is identified in the NRC's regulations (10 CFR 1.3, "Sources of Additional Information") as a source of additional information about the agency. The NRC periodically updates Management Directive 6.3, "[The Rulemaking Process](#)," (ADAMS Accession No. ML051680185), to ensure that it accurately reflects the agency's rulemaking process.

#### **H. Access to Regulatory Compliance and Enforcement Activities**

The NRC provides access to its regulatory compliance and enforcement activities on its Web site (see <http://www.nrc.gov>) and through ADAMS. In addition, the NRC Web site provides daily status reports, event notifications, safety performance summaries, inspection reports, enforcement actions taken, press releases, and public meeting information for all nuclear power plants and materials facilities.

#### **I. Regular Updates to Guidance Documents**

The NRC provides guidance in regulatory guides, its NUREG-series publications, and interim staff guidance. In addition to revising guidance in conjunction with rulemakings, the NRC also periodically reviews and revises its guidance.

1. The NRC's Regulatory Guides provide guidance to licensees and applicants on the following:
  - (a) Implementing specific parts of the NRC's regulations,
  - (b) Techniques used by the NRC staff in evaluating specific problems or postulated accidents, and
  - (c) Data needed by the staff in its review of applications for permits or licenses.
2. The NRC issues regulatory guides in draft form to solicit public comment and involve the public in developing the agency's regulatory positions. Some draft guides are proposed revisions of existing guides. Draft regulatory guides have not received complete staff review and, therefore, they do not represent official NRC staff positions. In finalizing the guides, the staff considers all comments received during the public comment period, as appropriate.

3. In 2006, the NRC started a program to regularly update its regulatory guidance documents to keep these documents current. Under the Regulatory Guide Update Program, the NRC reviews, prioritizes, and, where appropriate, revises, all regulatory guides. For any given regulatory guide, this effort may result in a revision to the guide, a finding that the guide does not need revision, or the withdrawal of the guide. When the NRC proposes to revise or withdraw a regulatory guide, the NRC issues an appropriate notice to the public.
4. The NRC is in the process of updating the 21 volumes of its “Consolidated Guidance About Materials Licenses” (NUREG-1556).

#### **J. Regulations Reflect Consensus Standards**

1. The NRC participates in industry consensus standards groups, and incorporates by reference into the NRC’s regulations several voluntary consensus standards—
  - (a) American Society of Mechanical Engineers Boiler and Pressure Vessel Code and Operation and Maintenance Code;
  - (b) Institute of Electrical and Electronics Engineers (IEEE) Standard 603, “IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Systems;”
  - (c) IEEE Standard 279, “Criteria for Protection Systems;” and
  - (d) National Fire Protection Association 805, “Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants.”
2. The industry consensus standards development process involves regular review and updating of standards, and the NRC revises its regulations as appropriate to reflect updated consensus standards.
3. With respect to certain voluntary consensus standards, the NRC has a routine process in place for reviewing and updating its regulations to reflect revised standards.

#### **K. Effective Lessons-Learned Program**

The NRC’s Lessons-Learned Program provides a framework for the orderly identification and correction of significant agency deficiencies, including any deficiencies in the agency’s regulatory scheme. The NRC uses a rigorous process to identify significant lessons learned, develop detailed corrective action plans, subject those plans to formal review and approval, and ensure that the plans have been effective and did not result in any unintended consequences.

## **L. Response to Significant Events**

Following significant events, the NRC typically will examine the event for lessons-learned and, depending on the findings, the NRC may decide to revise its regulatory framework. Currently, the NRC is performing a systematic and methodical review of the NRC's reactor and spent fuel regulations and processes to determine if the agency should make additional improvements to these programs in light of the lessons learned from the event that occurred at the Fukushima Dai-ichi nuclear power plant in March 2011. As a necessary part of this process, the NRC is examining the applicable portions of the regulatory framework in sufficient detail to establish whether deficiencies exist and where amendments or additions should be made. As such, the Fukushima regulatory effort is looking retrospectively at portions of the NRC's regulations.

## **M. Coordination and Communication with Other Federal and State Agencies**

The NRC coordinates with other Federal agencies and with State agencies when developing and conducting regulatory actions. The NRC has Memoranda of Understanding (MOUs) with other Federal agencies that address agency coordination pertaining to rulemaking and processes in place for the coordination with States.

1. The NRC and the U.S. Department of Transportation (DOT) have agreed through a memorandum of understanding (ADAMS Accession No. ML051660625; July 2, 1979) to areas where the two agencies would develop safety standards in consultation with the other agency. The NRC coordinates with the DOT on rulemakings to amend 10 CFR Part 71 that harmonize the U.S. transportation regulations with the International Atomic Energy Agency's (IAEA's) regulations for the safe transport of radioactive material and for rulemakings that would amend the safety standards for the design and performance of packages for fissile material and for quantities of other radioactive materials (other than Low Specific Activity materials) exceeding Type A limits. Examples of this coordination include:
  - (a) NRC participates in meetings where the DOT, as the U.S. competent authority before the IAEA for radioactive material transportation matters, seeks input on proposed changes to the international transportation regulations and public views on the DOT positions on proposed changes to the international transportation regulations.
  - (b) The NRC and the DOT coordinate their rulemakings to maintain consistency in their requirements and to make compliance easier for licensees, certificate holders, and carriers.
  - (c) The NRC and the DOT coordinate the effective dates of their rulemakings to avoid inconsistency in the regulations that apply to domestic transportation of radioactive material.

2. Consistent with a Memorandum of Understanding (Accession No. ML023520399, December 4, 2002), the NRC and the U.S. Food and Drug Administration (FDA) have agreed to share information and to offer each other the opportunity to comment on regulations and regulatory guides or other communications that refer to the activities, policies, or regulations of the other agency. Also, the FDA participates on the Advisory Committee on the Medical Uses of Isotopes (ACMUI), which provides another forum for FDA to provide advice in areas of their jurisdiction and expertise. The ACMUI advises the NRC on policy and technical issues that arise in the regulation of the medical uses of radioactive material.
3. The NRC and State agencies share information on events and the development of regulatory positions and technical bases for rulemakings. The Agreement States (States which, by agreement, have assumed part of the NRC's regulatory authority) are provided an opportunity to participate on teams formed to evaluate petitions for rulemaking and develop proposed and final rules. The Agreement States also have an opportunity to provide comments on the rule and the proposed designations of compatibility categories — compatibility categories establish whether a particular requirement is a matter of compatibility and the flexibility that the States have when developing their requirements — during the development of the proposed rule and the final rule.
4. Part 353 of Title 44 of the *Code of Federal Regulations* provides the memorandum of understanding (MOU) between the NRC and the Federal Emergency Management Agency (FEMA) with regard to radiological emergency preparedness. The MOU establishes a FEMA/NRC Steering Committee that has the responsibility for assuring that the arrangements of the MOU are carried out. Attachment 1 of the MOU states that the purpose of the Steering Committee is to—
  - (a) “Assure coordination of efforts to maintain and improve emergency planning and preparedness for nuclear power reactors as described in the NRC and FEMA rules and the NRC/FEMA MOU on Radiological Emergency Planning and Preparedness;” and
  - (b) “Coordinate consistent criteria for licensee, State and local emergency plans and preparedness.”
5. Additional examples of the NRC's coordination and communication with other Federal and state agencies are described below.
  - (a) During the generation of the emergency preparedness (EP) rule, the Steering Committee formed an EP rulemaking subcommittee consisting of teams from FEMA and the NRC. These teams met monthly to review joint areas of responsibilities and procedures that were impacted by the proposed rulemaking. In addition, the NRC and FEMA held numerous joint workshops around the country to solicit public comments during the rulemaking public comment period

and after the final rule was issued to answer questions about the regulatory changes.

- (b) Rulemakings to amend 10 CFR Part 110, “Export and Import of Nuclear Equipment and Material,” are coordinated with Executive Branch agencies, including the Departments of State, Energy and Commerce.
- (c) NRC participates in the Interagency Steering Committee on Radiation Standards (ISCORS) (<http://iscors.org/>). ISCORS is comprised of eight Federal agencies, three Federal observer agencies, and two state observer agencies.

#### **IV. KEY ELEMENTS OF THE PLAN**

##### **A. Ensuring Objectivity**

1. The Office of Administration (ADM) is responsible for overseeing the activities described in this Plan insofar as they involve the following:
  - (a) Publishing the draft Plan for public comment;
  - (b) Publishing the Final Plan in Calendar Year 2013 after Commission review; and
  - (c) Coordinating future updates to the Final Plan with the NRC’s longstanding Rulemaking Coordinating Committee (RCC).
2. The purpose of the RCC is to ensure consistency in methods used to develop and promulgate rules and to facilitate initiatives for improving all aspects of the NRC’s rulemaking process. In cooperation with the technical offices and the Office of the General Counsel, the RCC provides regular oversight of the rulemaking process, including assuring that there is consistency in the process.

##### **B. Prioritization of Rulemaking Activities**

1. The NRC’s methodology for prioritizing its rulemaking activities is based on the NRC’s Strategic Plan for Fiscal Years (FYs) 2008–2013 (NUREG-1614, Volume 5, dated February 2012 (see <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1614/v5/index.html>), as well as internal and external factors. The NRC’s current Strategic Plan consists of two strategic goals:
  - (a) Safety: Ensure adequate protection of public health and safety and the environment.
  - (b) Security: Ensure adequate protection in the secure use and management of radioactive materials.

These goals reflect the NRC's mission: to license and regulate the Nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety, to promote the common defense and security, and to protect the environment.

2. Based on the NRC's methodology and as reported in the NRC's 2012 Regulatory Plan (ADAMS Accession No. ML121250003), the NRC's highest priority rulemaking activities for FY 2013 and beyond will accomplish the following:
  - (a) Revise the environmental protection requirements for renewing nuclear power plant operating licenses;
  - (b) Solicit stakeholder feedback on rulemaking activities to enhance the capability of maintaining safety through a prolonged station blackout;
  - (c) Develop performance-based acceptance criteria for fuel cladding performance during loss-of-coolant accidents at nuclear power plants;
  - (d) Solicit stakeholder feedback on regulations governing the integration and enhancement of requirements for onsite emergency response capabilities; and develop both new requirements and the supporting regulatory basis;
  - (e) Amend the regulations that govern the medical use of byproduct material related to reporting and notifications of medical events to clarify requirements for permanent implant brachytherapy;
  - (f) Revise the fitness-for-duty requirements specific to drug and alcohol testing of employees working at nuclear power plants and other licensed facilities, and amend the fatigue management requirements pertaining to personnel who perform quality control and quality verification functions;
  - (g) Implement the NRC's authority under section 161A of the Atomic Energy Act of 1954, as amended, and revise existing regulations governing security event notifications;
  - (h) Specify the requirements for a site-specific analysis to demonstrate compliance with low-level waste disposal performance objectives, and the technical requirements needed for this analysis;
  - (i) Selectively align drug testing requirements with Federal drug testing guidelines issued by the U.S. Department of Health and Human Services;
  - (j) Add requirements for licensees that possess significant quantities of uranium hexafluoride;
  - (k) Revise certificate of compliance (CoC) regulations;



- (l) Develop a revised waste confidence decision and rule on the temporary storage of spent nuclear fuel. The revised rule is in response to a June 8, 2012, ruling of the U.S. Court of Appeals for the District of Columbia Circuit that identified deficiencies in the NRC's 2010 waste confidence revision; and
  - (m) Modify regulations to enhance the reliability of spent fuel pool systems and equipment during a prolonged station blackout event.
3. In addition to these priorities, the NRC may identify additional regulatory initiatives that may receive priority attention because of the following:
- (a) Commission direction to implement recommendations from a task force established to examine the NRC's regulatory requirements, programs, processes, and implementation in light of information from the accident at the Fukushima Dai-ichi nuclear power plant in Japan following the March 11, 2011, earthquake and tsunami; and
  - (b) Other future and emerging events.
4. Additionally, the NRC's regulations include, for reactors and some of the NRC's larger fuel cycle licensees, a concept called "backfit," which is meant to ensure that imposing additional burdens on existing licensees is well justified by the expected benefits in situations in which the new requirement is not necessary to ensure adequate protection of public health and safety.

#### **C. High-Level NRC Official Responsible for the Final Plan**

The Director of ADM will be responsible for the preparation, update, and implementation of the NRC's Final Plan.

#### **D. Public Comment**

1. The NRC is posting this draft Plan for public comment on—
- (a) The NRC's Open Government Web site at <http://www.nrc.gov/public-involve/open.html> (under the tabs entitled "Selected NRC Resources" and "Rulemaking"); and
  - (b) The NRC's plans, budget, and performance Web page (see <http://www.nrc.gov/about-nrc/plans-performance.html>).
2. The NRC is also publishing a notice in the *Federal Register* announcing its availability for public review. The public may comment on the draft Plan for 75 days after the Plan is published in the *Federal Register*.

3. This request for public comment is solely for information and program-planning purposes. The NRC will consider the comments submitted and may use them, as appropriate, in the preparation of the final retrospective review plan; however, the NRC does not anticipate responding to each comment submitted.

#### **E. Publishing the NRC's Plan Online**

As a part of the NRC's effort to foster a strong, ongoing culture of retrospective analysis, the agency will maintain the Plan at the following locations:

1. On the NRC's Open Government Web site at <http://www.nrc.gov/public-involve/open.html> (under the tabs entitled "Selected NRC Resources" and "Rulemaking");
2. On the NRC's plans, budget, and performance Web page (see <http://www.nrc.gov/about-nrc/plans-performance.html>); and
3. On the Federal rulemaking Web site (<http://www.regulations.gov>).

#### **F. Final Plan To Be Revised Periodically**

The NRC plans to voluntarily revise its Final Plan periodically. Revisions to the Final Plan will be published in the *Federal Register*, and the public will have an opportunity to comment on the proposed revisions at that time.