



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 6, 2014

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-13-0080

TITLE: FINAL PLAN FOR RETROSPECTIVE ANALYSIS OF
EXISTING RULES

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of January 6, 2014.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

A handwritten signature in black ink, appearing to read "Annette L. Vietti-Cook", written over a horizontal line.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Macfarlane
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
EDO
PDR

VOTING SUMMARY - SECY-13-0080

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MACFARLANE	X				X	12/20/13
COMR. SVINICKI		X			X	12/17/13
COMR. APOSTOLAKIS		X			X	8/30/13
COMR. MAGWOOD		X			X	12/4/13
COMR. OSTENDORFF		X			X	8/29/13

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Allison M. Macfarlane


SUBJECT: SECY-13-0080 – FINAL PLAN FOR RETROSPECTIVE
ANALYSIS OF EXISTING RULES

Approved X Disapproved Abstain

Not Participating

COMMENTS: Below X Attached X None

I approve the final plan and its publication in the *Federal Register*, subject to the attached edits to the plan and the *Federal Register* notice.



SIGNATURE

12/20/13

DATE

Entered on "STARS" Yes X No

AMM Edits



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

DRAFT 7/17/13

ADAMS ACCESSION NO.: ML13137A178

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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."¹ 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. Executive Order 13579, "Regulation and Independent Regulatory Agencies"

On July 11, 2011, President Obama issued E.O. 13579, "Regulation and Independent Regulatory Agencies."² 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) 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 Information Resources" and "Rulemaking"); and
 - (b) The NRC's Plans, Budget, and Performance Web page at <http://www.nrc.gov/about-nrc/plans-performance.html>.

The NRC also published a notice of availability of its initial Plan in the *Federal Register* on November 16, 2011 (76 FR 70913).
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 decision-making.

¹ See <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>.

² See <http://www.gpo.gov/fdsys/pkg/FR-2011-07-14/pdf/2011-17953.pdf>.

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 Published in November 2012

1. On November 23, 2012 (77 FR 70123), the NRC published a draft Plan for public comment, which included discussion of the following:
 - (a) Efforts to incorporate risk assessments into regulatory decision-making;
 - (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 on a systematic, ongoing basis.
2. The NRC received eight comment letters on the draft Plan. The commenters included State organizations, licensees, industry organizations, and individuals. The commenters raised the following six issues:
 - (a) A recommendation that the final Plan include a section requiring review of existing non-power reactors regulations;
 - (b) A suggestion that the intent of the retrospective review could be met through addressing the cumulative effects of NRC regulatory actions, rulemaking, and other NRC regulatory processes;
 - (c) General support for the draft Plan;
 - (d) Claims that the NRC should improve its openness and transparency;
 - (e) Suggestions for technical improvements (e.g., better ways to provide links to documents, etc.); and
 - (f) Claims that thorium is incorrectly classified under the 1954 Atomic Energy Act.

The notice announcing the availability of the final Plan (78 FR XXXX) includes a more detailed summary of the comments received and the NRC's responses to the comments. The final Plan was not revised as a result of the public comments.

II. SCOPE OF THE FINAL PLAN

A. NRC's Adherence to Principles of Good Regulation

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.

B. Focus on Longstanding and Recent Issues

The final Plan 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 final Plan 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 IV of this final Plan, the NRC has a number of programs and activities in place to assess existing NRC regulations.

III. PRIORITIZATION OF RULEMAKING ACTIVITIES

A. The Common Prioritization of Rulemaking (CPR) Process

1. The CPR, the NRC's methodology for prioritizing its rulemaking activities, is based on the NRC's Strategic Plan for Fiscal Years (FY) 2008–2013 (NUREG-1614, Volume 5, dated February 2012),³ 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; and
 - (b) Security: Ensure adequate protection in the secure use and management of radioactive materials.
2. 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. The NRC's highest priority rulemaking activities are reported in the NRC's Regulatory Plan (see Section III.C).

³ See <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1614/v5/index.html>.

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 of that framework 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.

B. Significant Regulatory Actions

The annual rulemaking to revise the NRC's fees qualifies as a "significant regulatory action" under E.O. 12866, "Regulatory Planning and Review."⁴ The NRC must recover most of its current fiscal year budget through fees for services specified in Part 170 of Title 10 of the *Code of Federal Regulations* (10 CFR), "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.

C. Unified Agenda of Regulatory and Deregulatory Actions

The Unified Agenda of Regulatory and Deregulatory Actions,⁵ which the NRC and all Federal agencies publish semiannually, provides an update on all active rulemaking activities. The fall edition of the Unified Agenda contains the NRC's Regulatory Plan,⁶ which contains a statement of the major rules that the Commission expects to publish in the current fiscal year (FY) and a description of the other significant regulatory priorities from the Common Prioritization of Rulemaking (see Section III.A) that the Commission expects to work on during the current FY, the coming FY, and beyond.

⁴ See http://www.regulations.gov/docs/EO_12866.pdf.

⁵ For the most current NRC Unified Agenda see <http://www.reginfo.gov/public/do/eAgendaMain> or <http://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/unified-agenda.html>.

⁶ For the most current NRC Regulatory Plan see http://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_STATEMENT_LIST¤tPub=true&agencyCode=&showStage=active&agencyCd=3150.

IV. 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 E.O. 13579.

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 IV.G) facilitates the exchange of ideas and contributes to the retrospective review of the NRC's regulations.

A. Incorporation of Risk Insights into Regulatory Decision-making

1. For approximately 20 years, the NRC has incorporated insights from risk assessments into its regulatory decision-making. The NRC updates its [risk-informed, performance-based plan](#) annually.⁷ The risk-informed, performance-based plan—
 - (a) Covers the agency's three major 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](#); November 22, 2011). The task force issued its report, NUREG-2150, "A Proposed Risk Management Regulatory Framework," in April 2012 (ADAMS Accession No. ML12109A277). The NRC is currently reviewing its regulatory framework to develop a generic policy statement addressing risk management regulatory framework (RMRF) goals and approaches to implementation of RMRF recommendations.

Comment [SHV1]: Is this accurate? Is there a citation to the Commission's approval of the development of this policy statement?

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](#),"⁸

⁷ See <http://www.nrc.gov/about-nrc/regulatory/risk-informed/rpp.html>).

⁸ See <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/1998/secy1998-144/1998-144scy.pdf>.

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 decision-making, 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](#)"⁹ 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 decision-making;
 - (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.

⁹ See <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2000/secy2000-0191/2000-0191scv.pdf>

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.

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 bases 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.
3. In 2010, the NRC began an effort to evaluate its rulemaking process to consider the cumulative effects of regulation (CER) (see Section IV.D.3 for details).

D. 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.¹⁰ The ROP was developed to provide tools for inspecting and assessing licensee performance in a more risk informed, objective, predictable, and understandable way than the previous oversight process.

3. CER

- (a) 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:
 - (i) Interaction with external stakeholders during regulatory basis development;
 - (ii) Interaction with external stakeholders during draft guidance development;
 - (iii) Request for explicit stakeholder feedback on CER in the proposed rule *Federal Register* notice; and
 - (iv) Public meeting on implementation during the final rule stage.
- (b) The NRC updated its rulemaking procedures to incorporate the rulemaking process changes caused by CER.
- (c) As a follow-up to SECY-11-0032, and in response to Commission direction on that paper, the staff developed SECY-12-0137, "Implementation of the Cumulative Effects of Regulation Process Changes," dated October 5, 2012 (ADAMS Accession No. ML12223A162). The staff requirements memorandum on that paper directed that (among other actions):

¹⁰ 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 Revision 4 of NUREG-1649, "Reactor Oversight Process," dated December 2006 (ADAMS Accession No. ML070890365).

- (i) The staff should continue to develop and implement outreach tools that will allow the NRC to consider more completely the overall impacts of multiple rules, orders, generic communications, advisories, and other regulatory actions on licensees and their ability to focus effectively on items of greatest safety import.
- (ii) Any expansion of the consideration of the CER should be considered in the broader context of actions directed from COMGEA-12-0001/COMWDM-12-0002, "Proposed Initiative to Improve Nuclear Safety and Regulatory Efficiency" (ADAMS Accession No. ML12314A262).
- (iii) The staff should gather input from all interested external parties on the effectiveness of NRC's CER process and provide an implementation status report to the Commission, including any recommendations for improvements derived from lessons learned, within 2 years of the date of this SRM. (Commission Paper anticipated in March 2015.)

E. Compliance with the Regulatory Flexibility Act (5 U.S.C. 610)

1. Section 610 of the Regulatory Flexibility Act (RFA) requires agencies to review those regulations that have or will have a *significant* economic impact on a *substantial* number of small entities every 10 years after publication of such rules as final rules. The purpose of the periodic review is to determine whether the rules should be left unchanged, amended, or rescinded.
2. The NRC's Regulatory Flexibility Act Procedures¹¹ and the NRC's Regulatory Analysis Guidelines¹² 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. The NRC is updating its internal procedures to include a process for submitting Unified Agenda¹³ entries for those rulemakings that require a Section 610 periodic review. Those entries will be added as a periodic review initiation entry in the "Pre-rule" section of the Unified Agenda and will solicit public comment. The NRC will publish the results of the periodic review in the "Completed Actions" section of the Unified Agenda.
3. To further improve transparency, the NRC staff will update its RFA procedures public Web site¹⁴ to include a list of NRC final rules that impact small entities and an indication of whether they must undergo a periodic review required by Section 610 of the RFA. This Web site will also include a link to the periodic review initiation and

¹¹ See <http://www.nrc.gov/about-nrc/regulatory/rulemaking/flexibility-act.html>.

¹² See <http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0058/>.

¹³ For the most current NRC Unified Agenda see <http://www.reginfo.gov/public/do/eAgendaMain> or <http://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/unified-agenda.html>.

¹⁴ See <http://www.nrc.gov/about-nrc/regulatory/rulemaking/flexibility-act.html>.

completion entries in the Unified Agenda for each rulemaking that must undergo a Section 610 periodic review.

4. Only one of the NRC rulemakings (its annual "fee rule") has been found to have a significant impact on a substantial number of small entities. Annually, the NRC revises its regulations that assess license, inspection, and annual fees to recover most of its operating budget as required by 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. The NRC also issues a small entity compliance guide for the annual "fee rule."
5. An example of the NRC's approach toward rulemakings that have the potential for a significant economic impact on a substantial number of small entities is the "Medical 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. The NRC also 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.

F. Small Business Regulatory Enforcement Fairness Act Compliance

1. Section 212 of the Small Business Regulatory Enforcement Fairness Act (SBREFA) requires that for each rulemaking that requires a Regulatory Flexibility Analysis under 5 U.S.C. 605(b), the agency must publish a "small entity compliance guide." The agency is required to publish, distribute, and post on its public Web site compliance guides on the same date of publication of the final rule. In addition, Section 212 of the SBREFA requires that the head of each agency submit an annual report to the appropriate Congressional Committees that describes the status of the agency's compliance with SBREFA.
2. The NRC staff will update its internal procedures to include a listing of the NRC's small entity compliance guides on the previously mentioned Web site that lists all NRC rules that impact small entities and include a link to the NRC's most current status report to Congress.

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 some rulemakings 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](#),"¹⁵ 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. On May 3, 2013 ([78 FR 25886](#)), the NRC published a proposed rule to streamline and clarify its process for addressing petitions for rulemaking. Proposed changes to that process aim to improve transparency and make the process more efficient and effective. The proposed rule would—
- (a) Allow petitioners to consult directly with NRC staff both before and after filing a petition;
 - (b) Incorporate much of the NRC's internal guidance to clarify the information that should be included in a petition;
 - (c) Clarify and expand the criteria for determining whether a petition is complete and sufficient for docketing;
 - (d) Provide explicit criteria that the NRC would use in considering a petition;
 - (e) Clarify the process for resolving a rulemaking petition; and
 - (f) Clarify the process for closing the petition document, which would occur after the NRC denies a petition or initiates a rulemaking to address the petitioner's concerns.

¹⁵ See <http://www.archives.gov/federal-register/executive-orders/pdf/12889.pdf>.

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.
8. On the NRC's public Web site, the NRC's "[Documents for Comment](#)"¹⁶ Web page contains docket information and comment submission deadlines for all documents that the NRC currently has available for public review and comment. The Web page is updated whenever the NRC publishes a *Federal Register* notice announcing the opportunity for public comment. To receive an e-mail whenever the NRC publishes a document for comment, the public can subscribe to the [GovDelivery Subscription Services](#).¹⁷

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 nuclear power plants and materials facilities.

I. Regular Updates to Guidance Documents

The NRC guidance documents include regulatory guides, the NUREG-series publications, interim staff guidance, regulatory issue summaries, topical reports, standard review plans, bulletins, generic letters, and technical specification task force travelers. Section IV.C of this final Plan describes the NRC's effort to concurrently

¹⁶ See <http://www.nrc.gov/public-involve/doc-comment.html>.

¹⁷ See <http://www.nrc.gov/public-involve/listserver.html>.

develop and publish guidance and proposed rules. In addition to revising guidance in conjunction with rulemakings, the NRC also periodically reviews and revises its guidance. For example, the NRC is in the process of updating the 21 volumes of NUREG-1556, "[Consolidated Guidance About Materials Licenses](http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/)" (available at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>). The following is a description of the NRC's process for developing, issuing, and updating Regulatory Guides.

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. Comments on draft regulatory guides can be submitted electronically using the www.regulations.gov Web site and searching under the appropriate docket ID. Suggestions to the NRC for improvement of existing regulatory guides or for the development of new regulatory guides to address new issues can be submitted at any time by completing the online form at <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html>.

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. Examples include the following:
 - (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 or guidance 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. Lessons-Learned and Response Program

1. 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.
2. Following significant events, the NRC typically will examine the event for lessons-learned; 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 further enhancements~~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.

L. Coordination and Communication with Other Federal Agencies, Tribes, and States Agencies

The NRC coordinates with other Federal agencies, Native American Tribal representatives, 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 Native American Tribes and States.

1. The NRC and the U.S. Department of Transportation (DOT) have agreed through an MOU (44 FR 38690; 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) 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 the following:

- (a) The 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 an MOU (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 ~~its~~^{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 rulemaking working groups¹⁸ formed to 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. The appendix to Part 353 of Title 44 of the *Code of Federal Regulations* provides the [MOU](#) (ADAMS Accession No. ML051680117) between the NRC and the Federal Emergency Management Agency (FEMA) with regard to radiological emergency

¹⁸ See MD 5.3, "[Agreement State Participation in Working Groups](#)."

preparedness. The MOU establishes a FEMA/NRC Steering Committee that has the responsibility for assuring that the arrangements of the MOU are carried out.

5. Attachment 1 of the MOU with FEMA 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."

6. The NRC developed a Tribal Protocol Manual to enhance our internal protocols for interactions with Native American tribal governments, that allows for custom-tailored approaches that will address both NRC and Tribal interests on a case-by-case basis. The NRC is preparing a policy statement on consulting with Native American Tribes and a revised Tribal Protocol Manual.

- ~~6.7.~~ 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) rule¹⁹, the EP Rulemaking 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 U.S. Departments of State, Energy, and Commerce.
- (c) The NRC participates in the Interagency Steering Committee on Radiation Standards (ISCORS) (<http://iscors.org/>). The ISCORS is ~~composed~~^{revised} of eight Federal agencies, three Federal observer agencies, and two state observer agencies.
- (d) The NRC chairs the Radiation Source Protection and Security Task force, an interagency task force required by the Energy Policy Act of 2005 that addresses source security. The task force is composed of 14 Federal agencies, and two nonvoting members from the States.

¹⁹ See final rule entitled "Enhancements to Emergency Preparedness Regulations" (NRC-2008-0122; RIN 3150-AI10).

V. KEY ELEMENTS OF THE PLAN

A. Ensuring Objectivity

1. The Office of Administration (ADM) is responsible for 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. 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.

C. Publishing the NRC's Final Plan Online

As a part of the NRC's effort to foster a strong, ongoing culture of retrospective analysis, the agency will maintain the final 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 Information Resources" and "Rulemaking");
2. On the NRC's Plans, Budget, and Performance Web page at <http://www.nrc.gov/about-nrc/plans-performance.html>; and
3. On the Federal rulemaking Web site (<http://www.regulations.gov>), searching on Docket ID 2011-0246.

D. Final Plan To Be Revised Periodically

The NRC plans to voluntarily revise its final Plan periodically. Revisions to the final Plan will be published on the NRC's Open Government Web site; the NRC's Plans, Budget, and Performance Web page; and www.regulations.gov under Docket ID NRC-2011-0246. The Federal rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: 1) Navigate to the docket folder (NRC-2011-0246); 2) click the "Email Alert" link; and 3) enter your e-mail address and select how frequently you would like to receive e-mails (daily, weekly, or monthly).

AMM edits

NUCLEAR REGULATORY COMMISSION

2 CFR Chapter XX

5 CFR Chapter XLVIII

10 CFR Chapter I

[NRC-2011-0246]

Retrospective Analysis under Executive Order 13579

AGENCY: Nuclear Regulatory Commission.

ACTION: Final plan for retrospective analysis of existing rules.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is making available its final Plan for the retrospective analysis of its existing regulations. The final Plan describes the processes and activities that the NRC uses to determine whether any of its regulations should be modified, streamlined, expanded, or repealed. This action is part of the NRC's voluntary implementation of Executive Order (E.O.) 13579, "Regulation and Independent Regulatory Agencies," issued by the President on July 11, 2011.

DATES: The final Plan is effective **[INSERT DATE OF PUBLICATION]**.

ADDRESSES: Please refer to Docket ID NRC-2011-0246 when contacting the NRC about the availability of information for this final Plan. You may access information and comment

submittals related to this final Plan, which the NRC possesses and is publicly available, by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2011-0246. Address questions about NRC dockets to Carol Gallagher; telephone: 301-492-3668; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):**

You may access publicly available documents online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209 or, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

- **NRC's Open Government Web Page:** Go to <http://www.nrc.gov/public-involve/open.html> under the tabs entitled "Selected NRC Information Resources" and "Rulemaking."

- **NRC's Plans, Budget, and Performance Web Page:** Go to <http://www.nrc.gov/about-nrc/plans-performance.html> and select "NRC's Plan for Retrospective Analysis of Existing Rules."

FOR FURTHER INFORMATION CONTACT: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001; telephone: 301-492-3667 or e-mail: Cindy.Bladey@nrc.gov.

SUPPLEMENTARY INFORMATION:

- I. Background
- II. Public Comments on the Draft Plan
- III. Process Improvements
 - A. Regulatory Flexibility Act Compliance
 - B. Small Business Regulatory Enforcement Fairness Act Compliance
- IV. Final Plan for Retrospective Analysis

I. Background

On January 18, 2011, President Obama issued E.O. 13563, "Improving Regulation and Regulatory Review."¹ Executive Order 13563 directs Federal agencies to develop and submit a preliminary plan "under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives." Executive Order 13563 did not, however, apply to independent regulatory agencies. Subsequently, on July 11, 2011, the President issued E.O. 13579,² which recommends that independent regulatory agencies also develop retrospective plans similar to those required of other agencies under E.O. 13563. In the spirit of cooperation, on November 16, 2011 (76 FR 70913), in response to E.O. 13579, the NRC made

¹ See <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>.

² See <http://www.gpo.gov/fdsys/pkg/FR-2011-07-14/pdf/2011-17953.pdf>.

available its initial Plan. A draft Plan was published on November 23, 2012 (77 FR 70123), for a 60-day public comment period that ended on February 6, 2013. After consideration of its processes and the public comments received, the NRC is now publishing its final Plan.

II. Public Comments on the Draft Plan

The NRC received 8 comment letters on the draft Plan. The commenters included State organizations, licensees, industry organizations, and individuals. The NRC staff determined that the comment letters covered six issues. The following paragraphs include a summary of the comments received under each issue and the NRC's responses to the comments.

Issue 1: Final Plan should include a section requiring review of existing non-power reactor (NPR) regulations

Comment: The University of Florida submitted a comment requesting that the NRC include a section in the final Plan that would require the review of existing requirements for NPRs. The University of Florida stated that the NPR community is overburdened by regulations that are marginal to safety and that the NPR community is ruled by NUREGs in a manner that exceeds the statutory constraints of Section 104(c) of the Atomic Energy Act of 1954, as amended (AEA).

Response: The NRC disagrees with the comment. While the NRC understands the NPR community's concern regarding compliance with Section 104(c) of the AEA, the NRC believes that the same principles of good regulation apply to NPR licensees and power reactor licensees alike. The NRC conducts extensive public outreach and a thorough legal review in order to ensure compliance with all sections of the AEA when issuing regulations or other regulatory actions involving NPRs. The NRC's regulations that apply to NPR licensees must

first meet the standard of providing reasonable assurance of protecting the public health and safety. If that standard can be met with regulations that impose a lesser burden on NPR licensees, stakeholders are encouraged to communicate their ideas to the NRC. In addition, the NRC issues guidance materials (Regulatory Guides, NUREGs, etc.) to communicate potential means by which licensees may comply with the regulations. Those guidance materials are not regulations, and licensees are permitted to administer their programs as they see fit, provided licensees can produce a sufficient basis illustrating how their program administration follows the NRC's regulations. The final Plan was not revised as a result of this comment.

Issue 2: Cumulative Effects of Regulation (CER)

Comment: The Nuclear Energy Institute (NEI) submitted a comment on the draft Plan that suggested "the intent of the retrospective analysis could be met through addressing the cumulative effects of NRC regulatory actions, rulemaking and other NRC regulatory processes resulting in greater benefit in safety and resource management." The NEI also asserted that broadening the scope of applicable processes beyond rulemaking to other actions such as orders, generic guidance, and information requests would result in more meaningful improvements.

Response: The NRC agrees that the effort to address CER does contribute, in concert with the other NRC initiatives described in the draft Plan, to the intent of the retrospective analysis. The NRC also notes that SECY-12-0137, "Implementation of the Cumulative Effects of Regulation Process Changes," dated October 5, 2012 (ADAMS Accession No. ML12223A162), provided the Commission with an update on the status of implementing CER and feedback obtained during a May 2012 public meeting. In response, the Commission

issued the staff requirements memorandum (SRM) to SECY-12-0137 (ADAMS Accession No. ML13071A635). Among other items, the SRM directed:

Any expansion of the consideration of the CER should be considered in the broader context of actions directed from COMGEA-12-0001/COMWDM-12-0002, "Proposed Initiative to Improve Nuclear Safety and Regulatory Efficiency."

The staff should continue to develop and implement outreach tools that will allow the NRC to consider more completely the overall impacts of multiple rules, orders, generic communications, advisories, and other regulatory actions on licensees and their ability to focus effectively on items of greatest safety import.

To inform its decision-making in addressing this directive, the NRC staff will obtain public feedback through public meetings. The NRC encourages continued public interaction on the subject of CER. The SRM also directed:

The staff should engage industry to seek volunteer facilities to perform "case studies" to review the accuracy of cost and schedule estimates used in NRC's regulatory analysis (such as the 10 CFR [*Code of Federal Regulations*] Part 73 security upgrades required after the attacks of September 11, 2011 and 10 CFR 50.84c, NFPA 805 program).

The NRC will use the aforementioned public meetings as tools to engage the industry on this initiative and believes that such case studies will result in meaningful insights to inform decisions for improving future regulatory analyses. The final Plan was not revised as a result of this comment.

Issue 3: General Support for the Draft Plan

Three commenters provided general support for the draft Plan. However, some commenters supported the draft Plan and offered comments on areas that could be clarified or improved.

Comment 1: The NEI supported the draft Plan. NEI stated that it understood the NRC's apparent rationale behind committing limited resources to this effort and agreed that there may not be benefit from a wholesale retrospective analysis.

Comment 2: GE Hitachi Nuclear Energy supported "the NRC approach that provides ongoing assessments of regulatory burdens in various NRC actions involving regulations..." However, GE Hitachi Nuclear Energy recommended that the NRC, when periodically revising the final Plan, describe specific review actions and results that have occurred since the last revision of the final Plan.

Response to Comments 1 and 2: The NRC appreciates the support for the draft Plan. When the NRC periodically revises the final Plan, it will consider including review actions and results that have occurred since the last revision of the final Plan. The final Plan was not revised as a result of Comments 1 and 2.

Issue 4: Openness and Transparency

Comment: The Citizens Oversight stated that while the draft Plan included a section called "Opportunities for Public Participation," the draft Plan did not propose any new opportunities for public participation. The commenter complimented the NRC on its January 31, 2013, Commission public meeting on regulatory decision-making. However, the commenter stated that the NRC limits oversight by the public by adopting overly restrictive definitions of standing, providing overly short periods for comments/petitions, making hearings the exception rather than the rule, making the adjudicatory process too formal, and conducting closed Commission meetings. Also, the commenter noted that the NRC had not responded to public comments and questions submitted after a public meeting in Dana Point, California.

Response: The Citizens Oversight comments are beyond the scope of E.O.s 13579 and 13563, and the NRC's draft Plan. Specifically, the Citizens Oversight comments on public

participation relate to such participation in NRC adjudicatory or licensee-specific licensing actions (e.g., standing, petitions for invention, etc.), and not the NRC's regulatory process for regulations. Executive Order 13579 is directed towards the manner in which Independent Regulatory Agencies issue or revise their regulations. To that end, E.O. 13579 recommends that, to the extent permitted by law, Independent Regulatory Agencies abide by a set of general requirements set forth in E.O. 13563, including those associated with public participation. As the Citizens Oversight notes in its comments, the principles of public participation that E.O. 13563 endorses concerns the ability of the public to participate in an agency's adoption of a regulation through the regulatory process. Executive Order 13563 provides that, each agency, to the extent feasible and permitted by law, shall "afford the public a meaningful opportunity to comment through the Internet on any proposed regulation, with a comment period that should generally be at least 60 days." Executive Order 13563 further provides that each agency, to the extent feasible and permitted by law, shall also "provide, for both proposed and final rules, timely online access to the rulemaking docket on regulations.gov..." As stated in Section G of the NRC's final Plan, the NRC already complies with these principles in its regulatory process for the development or modification of regulations.

If the Citizens Oversight seeks to modify the NRC's regulations governing its adjudications, then it should avail itself of the opportunities for public participation that the NRC identifies in its final Plan, such as 1) participation in rulemaking activities related to the NRC's adjudicatory procedures in 10 CFR Part 2; or 2) use of the petition for rulemaking process in 10 CFR 2.802 to request specific revision to those procedures. On May 3, 2013 (78 FR 25886), the NRC published a proposed rule to streamline and clarify its process for addressing petitions for rulemaking. Proposed changes to that process aim to improve transparency and make the process more efficient and effective. The final Plan was not revised as a result of this comment

from the Citizens Oversight; however, the NRC did update Section III of the final Plan to include a description of the aforementioned proposed rule.

Issue 5: Suggestions for Technical Improvements

Comment: The Citizens Oversight suggested several technical improvements, including the following: 1) the NRC should provide direct links to relevant documents, rather than just including an ADAMS accession number; 2) the NRC should include Really Simple Syndication (RSS) feeds on all of its Web pages; and 3) the NRC should remove quotes in URLs. The commenter also noted that links within ADAMS documents do not always work.

Response: The NRC considers this comment out-of-scope with regard to the draft Plan. However, the Office of Information Services is reviewing this comment and may contact the commenter regarding these issues. The NRC would note that the recently developed Documents for Comment page (<http://www.nrc.gov/public-involve/doc-comment.html>) provides links to dockets on www.regulations.gov containing documents with an open comment period. Individuals can subscribe to page updates through GovDelivery³ in order to keep informed of NRC documents that have been published in the *Federal Register* for comment. The final Plan was not revised as a result of this comment.

Issue 6: Thorium is Incorrectly Classified under the 1954 Atomic Energy Act

Two commenters stated that thorium is incorrectly classified under the 1954 AEA and should be placed in a less restrictive category of isotopes of elements.

³ The Federal rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: 1) Navigate to the docket folder (NRC-2011-0246); 2) click the "Email Alert" link; and 3) enter your e-mail address and select how frequently you would like to receive e-mails (daily, weekly, or monthly).

Comment 1: Dr. Alexander Cannara stated that classifications of various radioactive elements that were initiated by the old Atomic Energy Commission are too broad and interfere with various environmental and industrial realities (specifically the rare earth industry).

Comment 2: Stephen Boyd seemed to infer that the NRC should review and presumably revise its regulations to better support the use of thorium reactors. In particular, the commenter suggested allowing public and private efforts to join in the research occurring elsewhere in the world.

Response to Comment 1: Comment 1 from Dr. Cannara is beyond the scope of the NRC's draft Plan. Thorium is already classified differently (as source material) than the other elements that it is compared to (which are categorized as byproduct material). Over the past decade, the staff has acknowledged some concerns about the fact that thorium and uranium are present ubiquitously in nature (unlike byproduct material) and their current classification as source material may result in the regulation of activities not necessarily considered by Congress in enacting the AEA. The final Plan was not revised as a result of Comment 1.

Response to Comment 2: Comment 2 from Stephen Boyd is beyond the scope of the NRC's draft Plan. Thorium is already classified differently (as source material) than the fissile Uranium-235 (which is classified as special nuclear material), with the latter element having much more restrictive limits on possession and use. Although the NRC does periodically review its regulations to identify areas where new technologies may require changes to the regulations, such significant regulatory changes are usually only undertaken when there is reasonable certainty that such technologies will be implemented because the process of significantly revising the regulations may be resource intensive. The NRC will also undertake such revisions at the direction of Congress, usually after appropriate funding is provided. In recent years, some bills have been brought before Congress specifically related to Mr. Boyd's concerns, but

to date, Congress has not passed those bills. The NRC is not aware of any prohibitions against private efforts being involved in foreign research on the subject, although any U.S. Government involvement would likely be through the U.S. Department of Energy. The final Plan was not revised as a result of Comment 2.

III. Process Improvements

While developing this final Plan, the NRC identified changes to improve the clarity and transparency of its processes for compliance with Section 610 of the Regulatory Flexibility Act (RFA) and Section 212 of the Small Business Regulatory Enforcement Fairness Act (SBREFA). The changes are described in the following sections.

A. Regulatory Flexibility Act Compliance

Section 610 of the RFA was enacted in 1980 and requires agencies to review those regulations that have or will have a *significant* economic impact on a *substantial* number of small entities every 10 years after publication of such rules as final rules. The purpose of the periodic review is to determine whether the rules should be left unchanged, amended, or rescinded.

The NRC published its plan for Section 610 reviews in 1981. The NRC provided a status on its compliance with RFA to the Small Business Administration (SBA) in 1992 and 2002. In addition, the NRC provided a status on its compliance to Congress in 2005.

The NRC has one recurring rule that has a significant economic impact on a substantial number of small entities, its annual fee rule. This rule amends the licensing, inspection, and annual fees charged to its applicants and licensees. Given that a final fee rule is published each year, the NRC has determined that it does not require a Section 610 periodic review.

The NRC will update its internal procedures to clarify the NRC staff's responsibilities with regards to the Section 610 periodic reviews and to include a process for submitting Unified Agenda entries for those rulemakings that require a Section 610 periodic review. Entries will be added to the "Pre-rule" section of the Unified Agenda when a periodic review is started and will solicit public comment. The NRC will publish the results of its periodic reviews in the "Completed Actions" section of the Unified Agenda, including whether the rule will be left unchanged, revised, or rescinded.

To further improve transparency, the NRC will update the public Web site⁴ for RFA procedures to include a list of all final NRC rules that impact small entities and whether they must undergo a periodic review required by Section 610 of the RFA. This Web site will also include a link to the periodic review initiation and completion entries in the Unified Agenda for each rulemaking that must undergo a Section 610 periodic review.

Section 610 of the RFA allows agencies to update their plan at any time by giving notice in the *Federal Register*. The information on the public Web site for RFA procedures, which informs the public of which rules must undergo a periodic review and when and provides a link to the results of the periodic review as published in the Unified Agenda, supersedes the NRC's 1981 plan.

B. Small Business Regulatory Enforcement Fairness Act Compliance

Section 212 of the SBREFA was enacted in 1996 and requires that for each rulemaking that requires a Regulatory Flexibility Analysis under 5 U.S.C. 605(b), the agency must publish a "small entity compliance guide." The SBREFA was amended by the Fair Minimum Wage Act of 2007, which requires agencies to: —1) publish, distribute, and post on their public Web sites

⁴ See <http://www.nrc.gov/about-nrc/regulatory/rulemaking/flexibility-act.html>.

compliance guides on the same date of publication of the final rule; and 2) submit an annual report (signed by the head of the agency) to the appropriate Congressional Committees describing the status of the agency's compliance with the Act.

The NRC will update internal procedures to clarify the NRC staff's responsibilities with regards to Section 212 of the SBREFA.

The NRC has issued small entity compliance guides and published them either in the *Federal Register* or in the appropriate document collection on the NRC's public Web site; however, the NRC has not published all of its compliance guides in one location. The public Web site for RFA procedures that lists all NRC rules that impact small entities will also include a listing of the NRC's small entity compliance guides and how they may be accessed.

The NRC has not submitted a status report to Congress regarding its compliance with SBREFA. However, the NRC staff is currently drafting the 2013 status report. A link to the status report will be included on the Web site for RFA procedures.

IV. Final Plan for Retrospective Analysis

The NRC's final Plan describes the NRC's processes and activities relating to retrospective analysis of existing regulations, including discussions of the: 1) efforts to incorporate risk assessments into regulatory decision-making; 2) efforts to address the

cumulative effects of regulation; 3) the NRC's methodology for prioritizing its rulemaking activities; 4) 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 5) the NRC's previous and ongoing efforts to update its regulations on a systematic, ongoing basis.

Dated at Rockville, Maryland, this _____ day of _____, 2013.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-13-0080 – FINAL PLAN FOR RETROSPECTIVE
ANALYSIS OF EXISTING RULES

Approved XX Disapproved Abstain

Not Participating

COMMENTS: Below XX Attached XX None

I approve the final plan for retrospective analysis of existing rules and the *Federal Register* notice announcing its availability, subject to the attached edits. Central to the agency's approach to retrospective review of rules is disciplined cost-benefit analysis. The staff is reminded of the guidance of Office of Management and Budget (OMB) Circular A-4, "Regulatory Analysis," which states: "Sound quantitative estimates of benefits and costs, where feasible, are preferable to qualitative descriptions of benefits and costs because they help decision makers understand the magnitudes of the effects of alternate actions." (OMB Circular A-4 at 26)


SIGNATURE

12/17/13
DATE

Entered on "STARS" Yes ☒ No

KLS Edits



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

DRAFT 7/17/13

ADAMS ACCESSION NO.: ML13137A178

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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."¹ 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. Executive Order 13579, "Regulation and Independent Regulatory Agencies"

On July 11, 2011, President Obama issued E.O. 13579, "Regulation and Independent Regulatory Agencies."² 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) 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 Information Resources" and "Rulemaking"); and
 - (b) The NRC's Plans, Budget, and Performance Web page at <http://www.nrc.gov/about-nrc/plans-performance.html>.

The NRC also published a notice of availability of its initial Plan in the *Federal Register* on November 16, 2011 ([76 FR 70913](#)).
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 decision-making.

¹ See <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>.

² See <http://www.gpo.gov/fdsys/pkg/FR-2011-07-14/pdf/2011-17953.pdf>.

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 Published in November 2012

1. On November 23, 2012 (77 FR 70123), the NRC published a draft Plan for public comment, which included discussion of the following:
 - (a) Efforts to incorporate risk assessments into regulatory decision-making;
 - (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 on a systematic, ongoing basis.
2. The NRC received eight comment letters on the draft Plan. The commenters included State organizations, licensees, industry organizations, and individuals. The commenters raised the following six issues:
 - (a) A recommendation that the final Plan include a section requiring review of existing non-power reactors regulations;
 - (b) A suggestion that the intent of the retrospective review could be met through addressing the cumulative effects of NRC regulatory actions, rulemaking, and other NRC regulatory processes;
 - (c) General support for the draft Plan;
 - (d) Claims that the NRC should improve its openness and transparency;
 - (e) Suggestions for technical improvements (e.g., better ways to provide links to documents, etc.); and
 - (f) Claims that thorium is incorrectly classified under the 1954 Atomic Energy Act.

The notice announcing the availability of the final Plan (78 FR XXXX) includes a more detailed summary of the comments received and the NRC's responses to the comments. The final Plan was not revised as a result of the public comments.

II. SCOPE OF THE FINAL PLAN

A. NRC's Adherence to Principles of Good Regulation

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.

B. Focus on Longstanding and Recent Issues

The final Plan 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 final Plan 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 IV of this final Plan, the NRC has a number of programs and activities in place to assess existing NRC regulations.

III. PRIORITIZATION OF RULEMAKING ACTIVITIES

III. As described below, the NRC prioritizes its ongoing rulemaking activities based on regulatory importance and resources. These rulemaking activities provide a backdrop for the agency's ongoing evaluation of its existing regulations (see Section IV).

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A. The Common Prioritization of Rulemaking (CPR) Process

1. The CPR, the NRC's methodology for prioritizing its rulemaking activities, is based on the NRC's Strategic Plan for Fiscal Years (FY) 2008–2013 (NUREG-1614, Volume 5, dated February 2012)³, 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; and
 - (b) Security: Ensure adequate protection in the secure use and management of radioactive materials.
2. 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,

³ See <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1614/v5/index.html>.

and to protect the environment. The NRC's highest priority rulemaking activities are reported in the NRC's Regulatory Plan (see Section III.C).

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 of that framework 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.

B. Significant Regulatory Actions

The annual rulemaking to revise the NRC's fees qualifies as a "significant regulatory action" under E.O. 12866, "[Regulatory Planning and Review](#)."⁴ The NRC must recover most of its current fiscal year budget through fees for services specified in Part 170 of Title 10 of the *Code of Federal Regulations* (10 CFR), "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.

C. Unified Agenda of Regulatory and Deregulatory Actions

The [Unified Agenda of Regulatory and Deregulatory Actions](#),⁵ which the NRC and all Federal agencies publish semiannually, provides an update on all active rulemaking activities. The fall edition of the Unified Agenda contains the [NRC's Regulatory Plan](#),⁶ which contains a statement of the major rules that the Commission expects to publish in the current fiscal year (FY) and a description of the other significant regulatory priorities

⁴ See http://www.regulations.gov/docs/EO_12866.pdf.

⁵ For the most current NRC Unified Agenda see <http://www.reginfo.gov/public/do/eAgendaMain> or <http://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/unified-agenda.html>.

⁶ For the most current NRC Regulatory Plan see http://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_STATEMENT_LIST¤tPub=true&agencyCode=&showStage=active&agencyCd=3150.

from the Common Prioritization of Rulemaking (see Section III.A) that the Commission expects to work on during the current FY, the coming FY, and beyond.

IV. 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 E.O. 13579.

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 IV.G) facilitates the exchange of ideas and contributes to the retrospective review of the NRC's regulations.

A. Incorporation of Risk Insights into Regulatory Decision-making

1. For approximately 20 years, the NRC has incorporated insights from risk assessments into its regulatory decision-making. The NRC updates its [risk-informed, performance-based plan](#) annually.⁷ The risk-informed, performance-based plan—
 - (a) Covers the agency's three major 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](#); November 22, 2011). The task force issued its report, NUREG-2150, "A Proposed Risk Management Regulatory Framework," in April 2012 (ADAMS Accession No. ML12109A277). ~~The NRC is currently reviewing its regulatory framework to develop a generic policy statement addressing risk management regulatory framework (RMRF) goals and approaches to implementation of RMRF recommendations.~~

Comment [J1]: The Commission has not approved development of a policy statement or implementation of task force recommendations. This matter will be addressed after Commission action on the staff's Recommendation 1 analysis.

⁷ See <http://www.nrc.gov/about-nrc/regulatory/risk-informed/rpp.html>).

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](#),"⁸ 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 decision-making, 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](#)"⁹ 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 decision-making;
 - (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

⁸ See <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/1998/secy1998-144/1998-144scy.pdf>.

⁹ See <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2000/secy2000-0191/2000-0191scy.pdf>.

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.

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 bases 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.
3. In 2010, the NRC began an effort to evaluate its rulemaking process to consider the cumulative effects of regulation (CER) (see Section IV.D.3 for details).

D. 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.¹⁰ The ROP was developed to provide tools for inspecting and assessing licensee performance in a more risk informed, objective, predictable, and understandable way than the previous oversight process.
3. CER
 - (a) 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:
 - (i) Interaction with external stakeholders during regulatory basis development;
 - (ii) Interaction with external stakeholders during draft guidance development;
 - (iii) Request for explicit stakeholder feedback on CER in the proposed rule *Federal Register* notice; and
 - (iv) Public meeting on implementation during the final rule stage.
 - (b) The NRC updated its rulemaking procedures to incorporate the rulemaking process changes caused by CER.

¹⁰ 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 Revision 4 of NUREG-1649, "Reactor Oversight Process," dated December 2006 (ADAMS Accession No. ML070890365).

(c) As a follow-up to SECY-11-0032, and in response to Commission direction on that paper, the staff developed SECY-12-0137, "Implementation of the Cumulative Effects of Regulation Process Changes," dated October 5, 2012 (ADAMS Accession No. ML12223A162). The staff requirements memorandum on that paper directed that (among other actions):

- (i) The staff should continue to develop and implement outreach tools that will allow the NRC to consider more completely the overall impacts of multiple rules, orders, generic communications, advisories, and other regulatory actions on licensees and their ability to focus effectively on items of greatest safety import.
- (ii) Any expansion of the consideration of the CER should be considered in the broader context of actions directed from COMGEA-12-0001/COMWDM-12-0002, "Proposed Initiative to Improve Nuclear Safety and Regulatory Efficiency" (ADAMS Accession No. ML12314A262).
- (iii) The staff should gather input from all interested external parties on the effectiveness of NRC's CER process and provide an implementation status report to the Commission, including any recommendations for improvements derived from lessons learned, within 2 years of the date of this SRM. (Commission Paper anticipated in March 2015.)

E. Compliance with the Regulatory Flexibility Act (5 U.S.C. 610)

1. Section 610 of the Regulatory Flexibility Act (RFA) requires agencies to review those regulations that have or will have a *significant* economic impact on a *substantial* number of small entities every 10 years after publication of such rules as final rules. The purpose of the periodic review is to determine whether the rules should be left unchanged, amended, or rescinded.
2. The NRC's Regulatory Flexibility Act Procedures¹¹ and the NRC's Regulatory Analysis Guidelines¹² 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. The NRC is updating its internal procedures to include a process for submitting Unified Agenda¹³ entries for those rulemakings that require a Section 610 periodic review. Those entries will be added as a periodic review initiation entry in the "Pre-rule" section of the Unified Agenda and will solicit public comment. The NRC will publish the results of the periodic review in the "Completed Actions" section of the Unified Agenda.

¹¹ See <http://www.nrc.gov/about-nrc/regulatory/rulemaking/flexibility-act.html>.

¹² See <http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0058/>.

¹³ For the most current NRC Unified Agenda see <http://www.reginfo.gov/public/do/eAgendaMain> or <http://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/unified-agenda.html>.

3. To further improve transparency, the NRC staff will update its RFA procedures public Web site¹⁴ to include a list of NRC final rules that impact small entities and an indication of whether they must undergo a periodic review required by Section 610 of the RFA. This Web site will also include a link to the periodic review initiation and completion entries in the Unified Agenda for each rulemaking that must undergo a Section 610 periodic review.
4. Only one of the NRC recurring rulemakings (its annual "fee rule") has been found to have a significant impact on a substantial number of small entities (See Section III.B). Annually, the NRC revises its regulations that assess license, inspection, and annual fees to recover most of its operating budget as required by 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. The NRC also issues a small entity compliance guide for the annual "fee rule."
5. An example of the NRC's approach toward rulemakings that have the potential for a significant economic impact on a substantial number of small entities is the "Medical Use of Byproduct Material" rulemaking process (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. The NRC also 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.

F. Small Business Regulatory Enforcement Fairness Act Compliance

1. Section 212 of the Small Business Regulatory Enforcement Fairness Act (SBREFA) requires that for each rulemaking that requires a Regulatory Flexibility Analysis under 5 U.S.C. 605(b), the agency must publish a "small entity compliance guide." The agency is required to publish, distribute, and post on its public Web site compliance guides on the same date of publication of the final rule. In addition, Section 212 of the SBREFA requires that the head of each agency submit an annual report to the appropriate Congressional Committees that describes the status of the agency's compliance with SBREFA.
2. The NRC staff will update its internal procedures to include a listing of the NRC's small entity compliance guides on the previously mentioned Web site that lists all NRC rules that impact small entities and include a link to the NRC's most current status report to Congress.

¹⁴ See <http://www.nrc.gov/about-nrc/regulatory/rulemaking/flexibility-act.html>.

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 some rulemakings 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](#),"¹⁵ 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. On May 3, 2013 ([78 FR 25886](#)), the NRC published a proposed rule to streamline and clarify its process for addressing petitions for rulemaking. Proposed changes to that process aim to improve transparency and make the process more efficient and effective. The proposed rule would—
 - (a) Allow petitioners to consult directly with NRC staff both before and after filing a petition;
 - (b) Incorporate much of the NRC's internal guidance to clarify the information that should be included in a petition;
 - (c) Clarify and expand the criteria for determining whether a petition is complete and sufficient for docketing;
 - (d) Provide explicit criteria that the NRC would use in considering a petition;
 - (e) Clarify the process for resolving a rulemaking petition; and

¹⁵ See <http://www.archives.gov/federal-register/executive-orders/pdf/12889.pdf>.

- (f) Clarify the process for closing the petition document, which would occur after the NRC denies a petition or initiates a rulemaking to address the petitioner's concerns.
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.
8. On the NRC's public Web site, the NRC's "[Documents for Comment](#)"¹⁶ Web page contains docket information and comment submission deadlines for all documents that the NRC currently has available for public review and comment. The Web page is updated whenever the NRC publishes a *Federal Register* notice announcing the opportunity for public comment. To receive an e-mail whenever the NRC publishes a document for comment, the public can subscribe to the [GovDelivery Subscription Services](#).¹⁷

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 nuclear power plants and materials facilities.

¹⁶ See <http://www.nrc.gov/public-involve/doc-comment.html>.

¹⁷ See <http://www.nrc.gov/public-involve/listserver.html>.

I. Regular Updates to Guidance Documents

The NRC guidance documents include regulatory guides, the NUREG-series publications, interim staff guidance, regulatory issue summaries, topical reports, standard review plans, bulletins, generic letters, and technical specification task force travelers. Section IV.C of this final Plan describes the NRC's effort to concurrently develop and publish guidance and proposed rules. In addition to revising guidance in conjunction with rulemakings, the NRC also periodically reviews and revises its guidance. For example, the NRC is in the process of updating the 21 volumes of NUREG-1556, "[Consolidated Guidance About Materials Licenses](http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/)" (available at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>). The following is a description of the NRC's process for developing, issuing, and updating Regulatory Guides.

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. Comments on draft regulatory guides can be submitted electronically using the www.regulations.gov Web site and searching under the appropriate docket ID. Suggestions to the NRC for improvement of existing regulatory guides or for the development of new regulatory guides to address new issues can be submitted at any time by completing the online form at <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html>.

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. Examples include the following:
 - (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;"₁
 - (c) IEEE Standard 279, "Criteria for Protection Systems;"₁ 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 or guidance 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. Lessons-Learned and Response Program

1. 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.
2. Following significant events, the NRC typically will examine the event for lessons-learned; 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~~ further enhancements 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.

**L. Coordination and Communication with Other Federal Agencies, Tribes, and States
Agencies**

The NRC coordinates with other Federal agencies, Native American Tribal representatives, 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 Native American Tribes and States.

1. The NRC and the U.S. Department of Transportation (DOT) have agreed through an MOU (44 FR 38690; 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) 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 the following:
 - (a) The 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 an MOU (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 rulemaking working groups¹⁸ formed to 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. The appendix to Part 353 of Title 44 of the *Code of Federal Regulations* provides the [MOU](#) (ADAMS Accession No. ML051680117) 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.
5. Attachment 1 of the MOU with FEMA 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.”

6. NRC developed a Tribal Protocol Manual to enhance our internal protocols for interactions with Native American tribal governments that allows for tailored approaches that will address both NRC and Tribal interest on a case-by-case basis. The NRC is preparing a policy statement on consulting with Native American Tribes and a revised Tribal Protocol Manual.

6-7. 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) rule¹⁹, the EP Rulemaking 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 U.S. Departments of State, Energy, and Commerce.

¹⁸ See MD 5.3, “[Agreement State Participation in Working Groups](#).”

¹⁹ See final rule entitled “[Enhancements to Emergency Preparedness Regulations](#)” (NRC-2008-0122; RIN 3150-AI10).

- (c) The NRC participates in the Interagency Steering Committee on Radiation Standards (ISCORS) (<http://iscors.org/>). The ISCORS is comprised of eight Federal agencies, three Federal observer agencies, and two state observer agencies.
- (d) The NRC chairs the Radiation Source Protection and Security Task force, an interagency task force required by the Energy Policy Act of 2005 that addresses source security. The task force is composed of 14 Federal agencies and two nonvoting members from the States.

V. KEY ELEMENTS OF THE PLAN

A. Ensuring Objectivity

1. The Office of Administration (ADM) is responsible for 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. 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.

C. Publishing the NRC's Final Plan Online

As a part of the NRC's effort to foster a strong, ongoing culture of retrospective analysis, the agency will maintain the final 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 Information Resources" and "Rulemaking");
2. On the NRC's Plans, Budget, and Performance Web page at <http://www.nrc.gov/about-nrc/plans-performance.html>; and
3. On the Federal rulemaking Web site (<http://www.regulations.gov>), searching on Docket ID 2011-0246.

D. Final Plan ~~To~~ Be Revised Periodically

The NRC plans to voluntarily revise its final Plan periodically. Revisions to the final Plan will be published on the NRC's Open Government Web site; the NRC's Plans, Budget, and Performance Web page; and www.regulations.gov under Docket ID

NRC-2011-0246. The Federal rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: 1) Navigate to the docket folder (NRC-2011-0246); 2) click the "Email Alert" link; and 3) enter your e-mail address and select how frequently you would like to receive e-mails (daily, weekly, or monthly).

NUCLEAR REGULATORY COMMISSION

2 CFR Chapter XX

5 CFR Chapter XLVIII

10 CFR Chapter I

[NRC-2011-0246]

Retrospective Analysis under Executive Order 13579

AGENCY: Nuclear Regulatory Commission.

ACTION: Final plan for retrospective analysis of existing rules.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is making available its final Plan for the retrospective analysis of its existing regulations. The final Plan describes the processes and activities that the NRC uses to determine whether any of its regulations should be modified, streamlined, expanded, or repealed. This action is part of the NRC's voluntary implementation of Executive Order (E.O.) 13579, "Regulation and Independent Regulatory Agencies," issued by the President on July 11, 2011.

DATES: The final Plan is effective **[INSERT DATE OF PUBLICATION]**.

ADDRESSES: Please refer to Docket ID NRC-2011-0246 when contacting the NRC about the availability of information for this final Plan. You may access information and comment

submittals related to this final Plan, which the NRC possesses and is publicly available, by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2011-0246. Address questions about NRC dockets to Carol Gallagher; telephone: 301-492-3668; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):**
You may access publicly available documents online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, [at](#) 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

- **NRC's Open Government Web Page:** Go to <http://www.nrc.gov/public-involve/open.html> under the tabs entitled "Selected NRC Information Resources" and "Rulemaking."

- **NRC's Plans, Budget, and Performance Web Page:** Go to <http://www.nrc.gov/about-nrc/plans-performance.html> and select "NRC's Plan for Retrospective Analysis of Existing Rules."

FOR FURTHER INFORMATION CONTACT: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001; telephone: 301-492-3667 or e-mail: Cindy.Bladey@nrc.gov.

SUPPLEMENTARY INFORMATION:

- I. Background
- II. Public Comments on the Draft Plan
- III. Process Improvements
 - A. Regulatory Flexibility Act Compliance
 - B. Small Business Regulatory Enforcement Fairness Act Compliance
- IV. Final Plan for Retrospective Analysis

I. Background

On January 18, 2011, President Obama issued E.O. 13563, "Improving Regulation and Regulatory Review."¹ Executive Order 13563 directs Federal agencies to develop and submit a preliminary plan "under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives." Executive Order 13563 did not, however, apply to independent regulatory agencies. Subsequently, on July 11, 2011, the President issued E.O. 13579,² which recommends that independent regulatory agencies also develop retrospective plans similar to those required of other agencies under E.O. 13563. In the spirit of cooperation, on November 16, 2011 (76 FR 70913), in response to E.O. 13579, the NRC made

¹ See <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>.

² See <http://www.gpo.gov/fdsys/pkg/FR-2011-07-14/pdf/2011-17953.pdf>.

available its initial Plan. A draft Plan was published on November 23, 2012 (77 FR 70123), for a 60-day public comment period that ended on February 6, 2013. After consideration of its processes and the public comments received, the NRC is now publishing its final Plan.

II. Public Comments on the Draft Plan

The NRC received 8 comment letters on the draft Plan. The commenters included State organizations, licensees, industry organizations, and individuals. The NRC staff determined that the comment letters covered six issues. The following paragraphs include a summary of the comments received under each issue and the NRC's responses to the comments.

Issue 1: Final Plan should include a section requiring review of existing non-power reactor (NPR) regulations

Comment: The University of Florida submitted a comment requesting that the NRC include a section in the final Plan that would require the review of existing requirements for NPRs. The University of Florida stated that the NPR community is overburdened by regulations that are marginal to safety and that the NPR community is ruled by NUREGs in a manner that exceeds the statutory constraints of Section 104(c) of the Atomic Energy Act of 1954, as amended (AEA).

Response: The NRC disagrees with the comment. While the NRC understands the NPR community's concern regarding compliance with Section 104(c) of the AEA, the NRC believes that the same principles of good regulation apply to NPR licensees and power reactor licensees alike. The NRC conducts extensive public outreach and a thorough legal review in order to ensure compliance with all sections of the AEA when issuing regulations or other regulatory actions involving NPRs. The NRC's regulations that apply to NPR licensees must

first meet the standard of providing reasonable assurance of protecting the public health and safety. If that standard can be met with regulations that impose a lesser burden on NPR licensees, stakeholders are encouraged to communicate their ideas to the NRC. In addition, the NRC issues guidance materials (Regulatory Guides, NUREGs, etc.) to communicate potential means by which licensees may comply with the regulations. Those guidance materials are not regulations, and licensees are permitted to administer their programs as they see fit, provided licensees can produce a sufficient basis illustrating how their program administration follows the NRC's regulations. The final Plan was not revised as a result of this comment.

Issue 2: Cumulative Effects of Regulation (CER)

Comment: The Nuclear Energy Institute (NEI) submitted a comment on the draft Plan that suggested "the intent of the retrospective analysis could be met through addressing the cumulative effects of NRC regulatory actions, rulemaking and other NRC regulatory processes resulting in greater benefit in safety and resource management." The NEI also asserted that broadening the scope of applicable processes beyond rulemaking to other actions such as orders, generic guidance, and information requests would result in more meaningful improvements.

Response: The NRC agrees that the effort to address CER does contribute, in concert with the other NRC initiatives described in the draft Plan, to the intent of the retrospective analysis. The NRC also notes that SECY-12-0137, "Implementation of the Cumulative Effects of Regulation Process Changes," dated October 5, 2012 (ADAMS Accession No. ML12223A162), provided the Commission with an update on the status of implementing CER and feedback obtained during a May 2012 public meeting. In response, the Commission

issued the staff requirements memorandum (SRM) to SECY-12-0137 (ADAMS Accession No. ML13071A635). Among other items, the SRM directed:

Any expansion of the consideration of the CER should be considered in the broader context of actions directed from COMGEA-12-0001/COMWDM-12-0002, "Proposed Initiative to Improve Nuclear Safety and Regulatory Efficiency."

The staff should continue to develop and implement outreach tools that will allow the NRC to consider more completely the overall impacts of multiple rules, orders, generic communications, advisories, and other regulatory actions on licensees and their ability to focus effectively on items of greatest safety import.

To inform its decision-making in addressing this directive, the NRC staff will obtain public feedback through public meetings. The NRC encourages continued public interaction on the subject of CER. The SRM also directed:

The staff should engage industry to seek volunteer facilities to perform "case studies" to review the accuracy of cost and schedule estimates used in NRC's regulatory analysis (such as the 10 CFR [*Code of Federal Regulations*] Part 73 security upgrades required after the attacks of September 11, 2011 and 10 CFR 50.84c, NFPA 805 program).

The NRC will use the aforementioned public meetings as tools to engage the industry on this initiative and believes that such case studies will result in meaningful insights to inform decisions for improving future regulatory analyses. The final Plan was not revised as a result of this comment.

Issue 3: General Support for the Draft Plan

Three commenters provided general support for the draft Plan. However, some commenters supported the draft Plan and offered comments on areas that could be clarified or improved.

Comment 1: The NEI supported the draft Plan. NEI stated that it understood the NRC's apparent rationale behind committing limited resources to this effort and agreed that there may not be benefit from a wholesale retrospective analysis.

Comment 2: GE Hitachi Nuclear Energy supported "the NRC approach that provides ongoing assessments of regulatory burdens in various NRC actions involving regulations..." However, GE Hitachi Nuclear Energy recommended that the NRC, when periodically revising the final Plan, describe specific review actions and results that have occurred since the last revision of the final Plan.

Response to Comments 1 and 2: The NRC appreciates the support for the draft Plan. When the NRC periodically revises the final Plan, it will consider including review actions and results that have occurred since the last revision of the final Plan. The final Plan was not revised as a result of Comments 1 and 2.

Issue 4: Openness and Transparency

Comment: The Citizens Oversight stated that while the draft Plan included a section called "Opportunities for Public Participation," the draft Plan did not propose any new opportunities for public participation. The commenter complimented the NRC on its January 31, 2013, Commission public meeting on regulatory decision-making. However, the commenter stated that the NRC limits oversight by the public by adopting overly restrictive definitions of standing, providing overly short periods for comments/petitions, making hearings the exception rather than the rule, making the adjudicatory process too formal, and conducting closed Commission meetings. Also, the commenter noted that the NRC had not responded to public comments and questions submitted after a public meeting in Dana Point, California.

Response: The Citizens Oversight comments are beyond the scope of E.O.s 13579 and 13563, and the NRC's draft Plan. Specifically, the Citizens Oversight comments on public

participation relate to such participation in NRC adjudicatory or licensee-specific licensing actions (e.g., standing, petitions for invention, etc.); and not the NRC's regulatory process for regulations. Executive Order 13579 is directed towards the manner in which Independent Regulatory Agencies issue or revise its regulations. To that end, E.O. 13579, recommends that, to the extent permitted by law, Independent Regulatory Agencies abide by a set of general requirements set forth in E.O. 13563, including those associated with public participation. As the Citizens Oversight notes in its comments, the principles of public participation that E.O. 13563 endorses concerns the ability of the public to participate in an agency's adoption of a regulation through the regulatory process. Executive Order 13563 provides that, each agency, to the extent feasible and permitted by law, shall "afford the public a meaningful opportunity to comment through the Internet on any proposed regulation, with a comment period that should generally be at least 60 days." Executive Order 13563 further provides that each agency, to the extent feasible and permitted by law, shall also "provide, for both proposed and final rules, timely online access to the rulemaking docket on regulations.gov..." As stated in Section G of the NRC's final Plan, the NRC already complies with these principles in its regulatory process for the development or modification of regulations.

If the Citizens Oversight seeks to modify the NRC's regulations governing its adjudications, then it should avail itself of the opportunities for public participation that the NRC identifies in its final Plan, such as 1) participation in rulemaking activities related to the NRC's adjudicatory procedures in 10 CFR Part 2; or 2) use of the petition for rulemaking process in 10 CFR 2.802 to request specific revision to those procedures. On May 3, 2013 (78 FR 25886), the NRC published a proposed rule to streamline and clarify its process for addressing petitions for rulemaking. Proposed changes to that process aim to improve transparency and make the process more efficient and effective. The final Plan was not revised as a result of this comment

from the Citizens Oversight; however, the NRC did update Section III of the final Plan to include a description of the aforementioned proposed rule.

Issue 5: Suggestions for Technical Improvements

Comment: The Citizens Oversight suggested several technical improvements, including the following: 1) the NRC should provide direct links to relevant documents, rather than just including an ADAMS accession number; 2) the NRC should include Really Simple Syndication (RSS) feeds on all of its Web pages; and 3) the NRC should remove quotes in URLs. The commenter also noted that links within ADAMS documents do not always work.

Response: The NRC considers this comment out-of-scope with regard to the draft Plan. However, the Office of Information Services is reviewing this comment and may contact the commenter regarding these issues. The NRC would note that the recently developed Documents for Comment page (<http://www.nrc.gov/public-involve/doc-comment.html>) provides links to dockets on www.regulations.gov containing documents with an open comment period. Individuals can subscribe to page updates through GovDelivery³ in order to keep informed of NRC documents that have been published in the *Federal Register* for comment. The final Plan was not revised as a result of this comment.

Issue 6: Thorium is Incorrectly Classified under the 1954 Atomic Energy Act

Two commenters stated that thorium is incorrectly classified under the 1954 AEA and should be placed in a less restrictive category of isotopes of elements.

³ The Federal rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: 1) Navigate to the docket folder (NRC-2011-0246); 2) click the "Email Alert" link; and 3) enter your e-mail address and select how frequently you would like to receive e-mails (daily, weekly, or monthly).

Comment 1: Dr. Alexander Cannara stated that classifications of various radioactive elements that were initiated by the old Atomic Energy Commission are too broad and interfere with various environmental and industrial realities (specifically the rare earth industry).

Comment 2: Stephen Boyd seemed to infer that the NRC should review and presumably revise its regulations to better support the use of thorium reactors. In particular, the commenter suggested allowing public and private efforts to join in the research occurring elsewhere in the world.

Response to Comment 1: Comment 1 from Dr. Cannara is beyond the scope of the NRC's draft Plan. Thorium is already classified differently (as source material) than the other elements that it is compared to (which are categorized as byproduct material). Over the past decade, the staff has acknowledged some concerns about the fact that thorium and uranium are present ubiquitously in nature (unlike byproduct material) and their current classification as source material may result in the regulation of activities not necessarily considered by Congress in enacting the AEA. The final Plan was not revised as a result of Comment 1.

Response to Comment 2: Comment 2 from Stephen Boyd is beyond the scope of the NRC's draft Plan. Thorium is already classified differently (as source material) than the fissile Uranium-235 (which is classified as special nuclear material), with the latter element having much more restrictive limits on possession and use. Although the NRC does periodically review its regulations to identify areas where new technologies may require changes to the regulations, such significant regulatory changes are usually only undertaken when there is reasonable certainty that such technologies will be implemented because the process of significantly revising the regulations may be resource intensive. The NRC will also undertake such revisions at the direction of Congress, usually after appropriate funding is provided. In recent years, some bills have been brought before Congress specifically related to Mr. Boyd's concerns, but

to date, Congress has not passed those bills. The NRC is not aware of any prohibitions against private efforts being involved in foreign research on the subject, although any U.S. Government involvement would likely be through the U.S. Department of Energy. The final Plan was not revised as a result of Comment 2.

III. Process Improvements

While developing this final Plan, the NRC identified changes to improve the clarity and transparency of its processes for compliance with Section 610 of the Regulatory Flexibility Act (RFA) and Section 212 of the Small Business Regulatory Enforcement Fairness Act (SBREFA). The changes are described in the following sections.

A. Regulatory Flexibility Act Compliance

Section 610 of the RFA was enacted in 1980 and requires agencies to review those regulations that have or will have a *significant* economic impact on a *substantial* number of small entities every 10 years after publication of such rules as final rules. The purpose of the periodic review is to determine whether the rules should be left unchanged, amended, or rescinded.

The NRC published its plan for Section 610 reviews in 1981. The NRC provided a status on its compliance with RFA to the Small Business Administration (SBA) in 1992 and 2002. In addition, the NRC provided a status on its compliance to Congress in 2005.

The NRC has one recurring rule that has a significant economic impact on a substantial number of small entities, its annual fee rule. This rule amends the licensing, inspection, and annual fees charged to its applicants and licensees. Given that a final fee rule is published each year, the NRC has determined that it does not require a Section 610 periodic review.

The NRC will update its internal procedures to clarify the NRC staff's responsibilities with regards to the Section 610 periodic reviews and to include a process for submitting Unified Agenda entries for those rulemakings that require a Section 610 periodic review. Entries will be added to the "Pre-rule" section of the Unified Agenda when a periodic review is started and will solicit public comment. The NRC will publish the results of its periodic reviews in the "Completed Actions" section of the Unified Agenda, including whether the rule will be left unchanged, revised, or rescinded.

To further improve transparency, the NRC will update the public Web site⁴ for RFA procedures to include a list of all final NRC rules that impact small entities and whether they must undergo a periodic review required by Section 610 of the RFA. This Web site will also include a link to the periodic review initiation and completion entries in the Unified Agenda for each rulemaking that must undergo a Section 610 periodic review.

Section 610 of the RFA allows agencies to update their plan at any time by giving notice in the *Federal Register*. The information on the public Web site for RFA procedures, which informs the public of which rules must undergo a periodic review and when and provides a link to the results of the periodic review as published in the Unified Agenda, supersedes the NRC's 1981 plan.

B. Small Business Regulatory Enforcement Fairness Act Compliance

Section 212 of the SBREFA was enacted in 1996 and requires that for each rulemaking that requires a Regulatory Flexibility Analysis under 5 U.S.C. 605(b), the agency must publish a "small entity compliance guide." The SBREFA was amended by the Fair Minimum Wage Act of 2007, which requires agencies to—1) publish, distribute, and post on their public Web sites

⁴ See <http://www.nrc.gov/about-nrc/regulatory/rulemaking/flexibility-act.html>.

compliance guides on the same date of publication of the final rule; and 2) submit an annual report (signed by the head of the agency) to the appropriate Congressional Committees describing the status of the agency's compliance with the Act.

The NRC will update internal procedures to clarify the NRC staff's responsibilities with regards to Section 212 of the SBREFA.

The NRC has issued small entity compliance guides and published them either in the *Federal Register* or in the appropriate document collection on the NRC's public Web site; however, the NRC has not published all of its compliance guides in one location. The public Web site for RFA procedures that lists all NRC rules that impact small entities will also include a listing of the NRC's small entity compliance guides and how they may be accessed.

The NRC has not submitted a status report to Congress regarding its compliance with SBREFA. However, the NRC staff is currently drafting the 2013 status report. A link to the status report will be included on the Web site for RFA procedures.

IV. Final Plan for Retrospective Analysis

The NRC's final Plan describes the NRC's processes and activities relating to retrospective analysis of existing regulations, including discussions of the: 1) efforts to incorporate risk assessments into regulatory decision-making; 2) efforts to address the

cumulative effects of regulation; 3) the NRC's methodology for prioritizing its rulemaking activities; 4) 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 5) the NRC's previous and ongoing efforts to update its regulations on a systematic, ongoing basis.

Dated at Rockville, Maryland, this _____ day of _____, 2013.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.

NOTATION VOTE

RESPONSE SHEET


TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER APOSTOLAKIS
SUBJECT: SECY-13-0080 – FINAL PLAN FOR RETROSPECTIVE
ANALYSIS OF EXISTING RULES

Approved X Disapproved Abstain

Not Participating

COMMENTS: Below Attached X None

I approve the final plan for publishing and the *Federal Register Notice* subject to the attached edits.



SIGNATURE

 8/30/13

DATE

Entered on "STARS" Yes ✓ No

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.

B. Significant Regulatory Actions

The annual rulemaking to revise the NRC's fees qualifies as a "significant regulatory action" under E.O. 12866, "[Regulatory Planning and Review](#)."⁴ The NRC must recover most of its current fiscal year budget through fees for services specified in Part 170 of Title 10 of the *Code of Federal Regulations* (10 CFR), "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.

C. Unified Agenda of Regulatory and Deregulatory Actions

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⁴ See http://www.regulations.gov/docs/EO_12866.pdf.

⁵ For the most current NRC Unified Agenda see <http://www.reginfo.gov/public/do/eAgendaMain> or <http://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/unified-agenda.html>.

⁶ For the most current NRC Regulatory Plan see http://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_STATEMENT_LIST¤tPub=true&agencyCode=&showStage=active&agencyCd=3150.

IV. 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 E.O. 13579.

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 IV.G) facilitates the exchange of ideas and contributes to the retrospective review of the NRC's regulations.

A. Incorporation of Risk Insights into Regulatory Decision-making

1. For approximately 20 years, the NRC has incorporated insights from risk assessments into its regulatory decision-making. The NRC updates its [risk-informed, performance-based plan](#) annually.⁷ The risk-informed, performance-based plan—
 - (a) Covers the agency's three major 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](#); November 22, 2011). The task force issued its report, NUREG-2150, "A Proposed Risk Management Regulatory Framework," in April 2012 (ADAMS Accession No. ML12109A277). The NRC is currently reviewing its regulatory framework to develop a generic policy statement addressing risk management regulatory framework (RMRF) goals and approaches to implementation of RMRF recommendations.

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](#),"⁸

⁷ See <http://www.nrc.gov/about-nrc/regulatory/risk-informed/rpp.html>.

⁸ See <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/1998/secy1998-144/1998-144scy.pdf>.

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.
8. On the NRC's public Web site, the NRC's "[Documents for Comment](#)"¹⁶ Web page contains docket information and comment submission deadlines for all documents that the NRC currently has available for public review and comment. The Web page is updated whenever the NRC publishes a *Federal Register* notice announcing the opportunity for public comment. To receive an e-mail whenever the NRC publishes a document for comment, the public can subscribe to the [GovDelivery Subscription Services](#).¹⁷

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 nuclear power plants and materials facilities.

I. Regular Updates to Guidance Documents

The NRC guidance documents include regulatory guides, the NUREG-series publications, interim staff guidance, regulatory issue summaries, topical reports, standard review plans, bulletins, generic letters, and technical specification task force travelers. Section IV.C of this final Plan describes the NRC's effort to concurrently

¹⁶ See <http://www.nrc.gov/public-involve/doc-comment.html>.

¹⁷ See <http://www.nrc.gov/public-involve/listserver.html>.

- (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 or guidance 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. Lessons-Learned and Response Program

1. 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.
2. Following significant events, the NRC typically will examine the event for lessons-learned; 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.

L. Coordination and Communication with Other Federal, Tribes, and State Agencies

The NRC coordinates with other Federal agencies, Native American Tribal representatives, 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 Native American Tribes and States.

1. The NRC and the U.S. Department of Transportation (DOT) have agreed through an MOU (44 FR 38690; July 2, 1979) to areas where the two agencies would develop safety standards in consultation with the other agency. The NRC coordinates with

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preparedness. The MOU establishes a FEMA/NRC Steering Committee that has the responsibility for assuring that the arrangements of the MOU are carried out.

5. Attachment 1 of the MOU with FEMA 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.”
6. NRC developed a Tribal Protocol Manual to enhance our internal protocols for interactions with Native American tribal governments that allows for custom tailored approaches that will address both NRC and Tribal interest on a case-by-case basis. The NRC is preparing a policy statement on consulting with Native American Tribes and a revised Tribal Protocol Manual.
- 6.7 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) rule¹⁹, the EP Rulemaking 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 U.S. Departments of State, Energy, and Commerce.
 - (c) The NRC participates in the Interagency Steering Committee on Radiation Standards (ISCORS) (<http://iscors.org/>). The ISCORS is comprised of eight Federal agencies, three Federal observer agencies, and two state observer agencies.
 - (d) The NRC chairs the Radiation Source Protection and Security Task force, an interagency task force required by the Energy Policy Act of 2005 that addresses source security. The task force is comprised of 14 Federal agencies, and two nonvoting members from the States

¹⁹ See final rule entitled “[Enhancements to Emergency Preparedness Regulations](#)” (NRC-2008-0122; RIN 3150-A110).

V. KEY ELEMENTS OF THE PLAN

A. Ensuring Objectivity

1. The Office of Administration (ADM) is responsible for 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. High-Level NRC Official Responsible for the Final Plan

The Director of ~~ADM~~ ~~the Office of Administration~~ will be responsible for ~~the preparation, update, and~~ implementation of the NRC's final Plan.

C. Publishing the NRC's Final Plan Online

As a part of the NRC's effort to foster a strong, ongoing culture of retrospective analysis, the agency will maintain the final 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 Information Resources" and "Rulemaking");
2. On the NRC's Plans, Budget, and Performance Web page at <http://www.nrc.gov/about-nrc/plans-performance.html>; and
3. On the Federal rulemaking Web site (<http://www.regulations.gov>), searching on Docket ID 2011-0246.

D. Final Plan To Be Revised Periodically

The NRC plans to voluntarily revise its final Plan periodically. Revisions to the final Plan will be published on the NRC's Open Government Web site; the NRC's Plans, Budget, and Performance Web page; and www.regulations.gov under Docket ID NRC-2011-0246. The Federal rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: 1) Navigate to the docket folder (NRC-2011-0246); 2) click the "Email Alert" link; and 3) enter your e-mail address and select how frequently you would like to receive e-mails (daily, weekly, or monthly).

NOTATION VOTE

RESPONSE SHEET


TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MAGWOOD
SUBJECT: SECY-13-0080—FINAL PLAN FOR RETROSPECTIVE
ANALYSIS OF EXISTING RULES

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below X Attached X None _____

I approve the final plan and its publication in the *Federal Register*, subject to the attached edits.



SIGNATURE

4 December 2013

DATE

Entered on "STARS" Yes X No _____



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

DRAFT 7/17/13

ADAMS ACCESSION NO.: ML13137A178

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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."¹ 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. Executive Order 13579, "Regulation and Independent Regulatory Agencies"

On July 11, 2011, President Obama issued E.O. 13579, "Regulation and Independent Regulatory Agencies."² 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) 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 Information Resources" and "Rulemaking"); and
 - (b) The NRC's Plans, Budget, and Performance Web page at <http://www.nrc.gov/about-nrc/plans-performance.html>.

The NRC also published a notice of availability of its initial Plan in the *Federal Register* on November 16, 2011 ([76 FR 70913](#)).
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 decision-making.

¹ See <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>.

² See <http://www.gpo.gov/fdsys/pkg/FR-2011-07-14/pdf/2011-17953.pdf>.

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 Published in November 2012

1. On November 23, 2012 (77 FR 70123), the NRC published a draft Plan for public comment, which included discussion of the following:
 - (a) Efforts to incorporate risk assessments into regulatory decision-making;
 - (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 on a systematic, ongoing basis.
2. The NRC received eight comment letters on the draft Plan. The commenters included State organizations, licensees, industry organizations, and individuals. The commenters raised the following six issues:
 - (a) A recommendation that the final Plan include a section requiring review of existing non-power reactors regulations;
 - (b) A suggestion that the intent of the retrospective review could be met through addressing the cumulative effects of NRC regulatory actions, rulemaking and other NRC regulatory processes;
 - (c) General support for the draft Plan;
 - (d) Claims that the NRC should improve its openness and transparency;
 - (e) Suggestions for technical improvements (e.g., better ways to provide links to documents, etc.); and
 - (f) Claims that thorium is incorrectly classified under the 1954 Atomic Energy Act.

The notice announcing the availability of the final Plan (78 FR XXXX) includes a more detailed summary of the comments received and the NRC's responses to the comments. The final Plan was not revised as a result of the public comments.

II. SCOPE OF THE FINAL PLAN

A. NRC's Adherence to Principles of Good Regulation

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.

B. Focus on Longstanding and Recent Issues

The final Plan 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 final Plan 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 IV of this final Plan, the NRC has a number of programs and activities in place to assess existing NRC regulations.

III. PRIORITIZATION OF RULEMAKING ACTIVITIES

A. The Common Prioritization of Rulemaking (CPR) Process

1. The CPR, the NRC's methodology for prioritizing its rulemaking activities, is based on the NRC's Strategic Plan for Fiscal Years (FY) 2008–2013 (NUREG-1614, Volume 5, dated February 2012)³, 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; and
 - (b) Security: Ensure adequate protection in the secure use and management of radioactive materials.
2. 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. The NRC's highest priority rulemaking activities are reported in the NRC's Regulatory Plan (see Section III.C).

³ See <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1614/v5/index.html>.

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.

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 - (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](#); November 22, 2011). The task force issued its report, NUREG-2150, "A Proposed Risk Management Regulatory Framework," in April 2012 (ADAMS Accession No. ML12109A277). The NRC is currently reviewing its regulatory framework to develop a generic policy statement addressing risk management regulatory framework (RMRF) goals and approaches to implementation of RMRF recommendations.

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](#),"⁸

⁷ See <http://www.nrc.gov/about-nrc/regulatory/risk-informed/rpp.html>).

⁸ See <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/1998/secy1998-144/1998-144scy.pdf>.

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 decision-making, 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](http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2000/secy2000-0191/2000-0191scy.pdf)"⁹ 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 decision-making;
 - (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.

⁹ See <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2000/secy2000-0191/2000-0191scy.pdf>

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.

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 bases 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.
3. In 2010, the NRC began an effort to evaluate its rulemaking process to consider the cumulative effects of regulation (CER) (see Section IV.D.3 for details).

D. 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.¹⁰ The ROP was developed to provide tools for inspecting and assessing licensee performance in a more risk informed, objective, predictable, and understandable way than the previous oversight process.

3. CER

- (a) 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:
 - (i) Interaction with external stakeholders during regulatory basis development;
 - (ii) Interaction with external stakeholders during draft guidance development;
 - (iii) Request for explicit stakeholder feedback on CER in the proposed rule *Federal Register* notice; and
 - (iv) Public meeting on implementation during the final rule stage.
- (b) The NRC updated its rulemaking procedures to incorporate the rulemaking process changes caused by CER.
- (c) As a follow-up to SECY-11-0032, and in response to Commission direction on that paper, the staff developed SECY-12-0137, “Implementation of the Cumulative Effects of Regulation Process Changes,” dated October 5, 2012 (ADAMS Accession No. ML12223A162). The staff requirements memorandum on that paper directed that (among other actions):

¹⁰ 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 Revision 4 of NUREG-1649, “Reactor Oversight Process,” dated December 2006 (ADAMS Accession No. ML070890365).

- (i) The staff should continue to develop and implement outreach tools that will allow the NRC to consider more completely the overall impacts of multiple rules, orders, generic communications, advisories, and other regulatory actions on licensees and their ability to focus effectively on items of greatest safety import.
- (ii) Any expansion of the consideration of the CER should be considered in the broader context of actions directed from COMGEA-12-0001/COMWDM-12-0002, "Proposed Initiative to Improve Nuclear Safety and Regulatory Efficiency" (ADAMS Accession No. ML12314A262).
- (iii) The staff should gather input from all interested external parties on the effectiveness of NRC's CER process and provide an implementation status report to the Commission, including any recommendations for improvements derived from lessons learned, within 2 years of the date of this SRM. (Commission Paper anticipated in March 2015.)

E. Compliance with the Regulatory Flexibility Act (5 U.S.C. 610)

1. Section 610 of the Regulatory Flexibility Act (RFA) requires agencies to review those regulations that have or will have a *significant* economic impact on a *substantial* number of small entities every 10 years after publication of such rules as final rules. The purpose of the periodic review is to determine whether the rules should be unchanged, amended, or rescinded.
2. The NRC's [Regulatory Flexibility Act Procedures](#)¹¹ and the NRC's [Regulatory Analysis Guidelines](#)¹² 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. The NRC is updating its internal procedures to include a process for submitting Unified Agenda¹³ entries for those rulemakings that require a Section 610 periodic review. Those entries will be added as a periodic review initiation entry in the "Pre-rule" section of the Unified Agenda and will solicit public comment. The NRC will publish the results of the periodic review in the "Completed Actions" section of the Unified Agenda.
3. To further improve transparency, the NRC staff will update its RFA procedures public Web site¹⁴ to include a list of NRC final rules that impact small entities and an indication of whether they must undergo a periodic review required by Section 610 of the RFA. This Web site will also include a link to the periodic review initiation and

¹¹ See <http://www.nrc.gov/about-nrc/regulatory/rulemaking/flexibility-act.html>.

¹² See <http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0058/>.

¹³ For the most current NRC Unified Agenda see <http://www.reginfo.gov/public/do/eAgendaMain> or <http://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/unified-agenda.html>.

¹⁴ See <http://www.nrc.gov/about-nrc/regulatory/rulemaking/flexibility-act.html>.

completion entries in the Unified Agenda for each rulemaking that must undergo a Section 610 periodic review.

4. Only one of the NRC rulemakings (its annual “fee rule”) has been found to have a significant impact on a substantial number of small entities. Annually, the NRC revises its regulations that assess license, inspection, and annual fees to recover most of its operating budget as required by 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. The NRC also issues a small entity compliance guide for the annual “fee rule.”
5. An example of the NRC’s approach toward rulemakings that have the potential for a significant economic impact on a substantial number of small entities is the “Medical 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. The NRC also 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.

F. Small Business Regulatory Enforcement Fairness Act Compliance

1. Section 212 of the Small Business Regulatory Enforcement Fairness Act (SBREFA) requires that for each rulemaking that requires a Regulatory Flexibility Analysis under 5 U.S.C. 605(b), the agency must publish a “small entity compliance guide.” The agency is required to publish, distribute, and post on its public Web site compliance guides on the same date of publication of the final rule. In addition, Section 212 of the SBREFA requires that the head of each agency submit an annual report to the appropriate Congressional Committees describing the status of the agency’s compliance with SBREFA.
2. The NRC staff will update its internal procedures to include a listing of the NRC’s small entity compliance guides on the previously mentioned Web site that lists all NRC rules that impact small entities and include a link to the NRC’s most current status report to Congress.

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 some rulemakings 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](#),"¹⁵ 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. On May 3, 2013 ([78 FR 25886](#)), the NRC published a proposed rule to streamline and clarify its process for addressing petitions for rulemaking. Proposed changes to that process aim to improve transparency and make the process more efficient and effective. The proposed rule would—
- (a) Allow petitioners to consult directly with NRC staff both before and after filing a petition;
 - (b) Incorporate much of the NRC's internal guidance to clarify the information that should be included in a petition;
 - (c) Clarify and expand the criteria for determining whether a petition is complete and sufficient for docketing;
 - (d) Provide explicit criteria that the NRC would use in considering a petition;
 - (e) Clarify the process for resolving a rulemaking petition; and
 - (f) Clarify the process for closing the petition document, which would occur after the NRC denies a petition or initiates a rulemaking to address the petitioner's concerns.

¹⁵ See <http://www.archives.gov/federal-register/executive-orders/pdf/12889.pdf>.

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.
8. On the NRC's public Web site, the NRC's "[Documents for Comment](#)"¹⁶ Web page contains docket information and comment submission deadlines for all documents that the NRC currently has available for public review and comment. The Web page is updated whenever the NRC publishes a *Federal Register* notice announcing the opportunity for public comment. To receive an e-mail whenever the NRC publishes a document for comment, the public can subscribe to the [GovDelivery Subscription Services](#).¹⁷

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 nuclear power plants and materials facilities.

I. Regular Updates to Guidance Documents

The NRC guidance documents include regulatory guides, the NUREG-series publications, interim staff guidance, regulatory issue summaries, topical reports, standard review plans, bulletins, generic letters, and technical specification task force travelers. Section IV.C of this final Plan describes the NRC's effort to concurrently

¹⁶ See <http://www.nrc.gov/public-involve/doc-comment.html>.

¹⁷ See <http://www.nrc.gov/public-involve/listserver.html>.

develop and publish guidance and proposed rules. In addition to revising guidance in conjunction with rulemakings, the NRC also periodically reviews and revises its guidance. For example, the NRC is in the process of updating the 21 volumes of NUREG-1556, "[Consolidated Guidance About Materials Licenses](http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/)" (available at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>). The following is a description of the NRC's process for developing, issuing, and updating Regulatory Guides.

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. Comments on draft regulatory guides can be submitted electronically using the www.regulations.gov Web site and searching under the appropriate docket ID. Suggestions to the NRC for improvement of existing regulatory guides or for the development of new regulatory guides to address new issues can be submitted at any time by completing the online form at <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html>.

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. Examples include the following:
 - (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 or guidance 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. Lessons-Learned and Response Program

1. 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.
2. Following significant events, the NRC typically will examine the event for lessons-learned; 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.

L. Coordination and Communication with Other Federal Agencies, Tribes, and States Agencies

The NRC coordinates with other Federal agencies, Native American Tribal representatives, 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 Native American Tribes and States.

1. The NRC and the U.S. Department of Transportation (DOT) have agreed through an MOU (44 FR 38690; 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) 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 the following:

- (a) The 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 an MOU (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 rulemaking working groups¹⁸ formed to 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. The appendix to Part 353 of Title 44 of the *Code of Federal Regulations* provides the [MOU](#) (ADAMS Accession No. ML051680117) between the NRC and the Federal Emergency Management Agency (FEMA) with regard to radiological emergency

¹⁸ See MD 5.3, "[Agreement State Participation in Working Groups](#)."

preparedness. The MOU establishes a FEMA/NRC Steering Committee that has the responsibility for assuring that the arrangements of the MOU are carried out.

5. Attachment 1 of the MOU with FEMA 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.”
6. NRC developed a Tribal Protocol Manual to enhance our internal protocols for interactions with Native American tribal governments that allows for custom-tailored approaches that will address both NRC and Tribal interest on a case-by-case basis. The NRC is preparing a policy statement on consulting with Native American Tribes and a revised Tribal Protocol Manual.

Additional examples of the NRC’s coordination and communication with other Federal and state agencies are described below.

(e)(a) During the generation of the emergency preparedness (EP) rule¹⁹, the EP Rulemaking 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.

(e)(b) Rulemakings to amend 10 CFR Part 110, “Export and Import of Nuclear Equipment and Material,” are coordinated with Executive Branch agencies, including the U.S. Departments of State, Energy, and Commerce.

(e)(c) The NRC participates in the Interagency Steering Committee on Radiation Standards (ISCORS) (<http://iscors.org/>). The ISCORS is comprised of eight Federal agencies, three Federal observer agencies, and two state observer agencies.

(f)(d) The NRC chairs the Radiation Source Protection and Security Task force, an interagency task force required by the Energy Policy Act of 2005 that addresses source security. The task force is comprised of 14 Federal agencies, and two nonvoting members from the States.

¹⁹ See final rule entitled “Enhancements to Emergency Preparedness Regulations” (NRC-2008-0122; RIN 3150-AI10).

V. KEY ELEMENTS OF THE PLAN

A. Ensuring Objectivity

1. The Office of Administration (ADM) is responsible for 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. High-Level NRC Official Responsible for the Final Plan

The Director of ~~ADM~~ the Office of Administration will be responsible for the ~~preparation, update, and~~ implementation of the NRC's final Plan.

C. Publishing the NRC's Final Plan Online

As a part of the NRC's effort to foster a strong, ongoing culture of retrospective analysis, the agency will maintain the final 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 Information Resources" and "Rulemaking");
2. On the NRC's Plans, Budget, and Performance Web page at <http://www.nrc.gov/about-nrc/plans-performance.html>; and
3. On the Federal rulemaking Web site (<http://www.regulations.gov>), searching on Docket ID 2011-0246.

D. Final Plan To Be Revised Periodically

The NRC plans to voluntarily revise its final Plan periodically. Revisions to the final Plan will be published on the NRC's Open Government Web site; the NRC's Plans, Budget, and Performance Web page; and www.regulations.gov under Docket ID NRC-2011-0246. The Federal rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: 1) Navigate to the docket folder (NRC-2011-0246); 2) click the "Email Alert" link; and 3) enter your e-mail address and select how frequently you would like to receive e-mails (daily, weekly, or monthly).

NUCLEAR REGULATORY COMMISSION

2 CFR Chapter XX

5 CFR Chapter XLVIII

10 CFR Chapter I

[NRC-2011-0246]

Retrospective Analysis under Executive Order 13579

AGENCY: Nuclear Regulatory Commission.

ACTION: Final plan for retrospective analysis of existing rules.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is making available its final Plan for the retrospective analysis of its existing regulations. The final Plan describes the processes and activities that the NRC uses to determine whether any of its regulations should be modified, streamlined, expanded, or repealed. This action is part of the NRC's voluntary implementation of Executive Order (E.O.) 13579, "Regulation and Independent Regulatory Agencies," issued by the President on July 11, 2011.

DATES: The final Plan is effective [INSERT DATE OF PUBLICATION].

ADDRESSES: Please refer to Docket ID NRC-2011-0246 when contacting the NRC about the availability of information for this final Plan. You may access information and comment

submittals related to this final Plan, which the NRC possesses and is publicly available, by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2011-0246. Address questions about NRC dockets to Carol Gallagher; telephone: 301-492-3668; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may access publicly available documents online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

- **NRC's Open Government Web Page:** Go to <http://www.nrc.gov/public-involve/open.html> under the tabs entitled "Selected NRC Information Resources" and "Rulemaking."

- **NRC's Plans, Budget, and Performance Web Page:** Go to <http://www.nrc.gov/about-nrc/plans-performance.html> and select "NRC's Plan for Retrospective Analysis of Existing Rules."

FOR FURTHER INFORMATION CONTACT: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001; telephone: 301-492-3667 or e-mail: Cindy.Bladey@nrc.gov.

SUPPLEMENTARY INFORMATION:

- I. Background
- II. Public Comments on the Draft Plan
- III. Process Improvements
 - A. Regulatory Flexibility Act Compliance
 - B. Small Business Regulatory Enforcement Fairness Act Compliance
- IV. Final Plan for Retrospective Analysis

I. Background

On January 18, 2011, President Obama issued E.O. 13563, "Improving Regulation and Regulatory Review."¹ Executive Order 13563 directs Federal agencies to develop and submit a preliminary plan "under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives." Executive Order 13563 did not, however, apply to independent regulatory agencies. Subsequently, on July 11, 2011, the President issued E.O. 13579,² which recommends that independent regulatory agencies also develop retrospective plans similar to those required of other agencies under E.O. 13563. In the spirit of cooperation, on November 16, 2011 (76 FR 70913), in response to E.O. 13579, the NRC made

¹ See <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>.

² See <http://www.gpo.gov/fdsys/pkg/FR-2011-07-14/pdf/2011-17953.pdf>.

available its initial Plan. A draft Plan was published on November 23, 2012 (77 FR 70123), for a 60-day public comment period that ended on February 6, 2013. After consideration of its processes and the public comments received, the NRC is now publishing its final Plan.

II. Public Comments on the Draft Plan

The NRC received 8 comment letters on the draft Plan. The commenters included State organizations, licensees, industry organizations, and individuals. The NRC staff determined that the comment letters covered six issues. The following paragraphs include a summary of the comments received under each issue and the NRC's responses to the comments.

Issue 1: Final Plan should include a section requiring review of existing non-power reactor (NPR) regulations

Comment: The University of Florida submitted a comment requesting that the NRC include a section in the final Plan that would require the review of existing requirements for NPRs. The University of Florida stated that the NPR community is overburdened by regulations that are marginal to safety and that the NPR community is ruled by NUREGs in a manner that exceeds the statutory constraints of Section 104(c) of the Atomic Energy Act of 1954, as amended (AEA).

Response: The NRC disagrees with the comment. While the NRC understands the NPR community's concern regarding compliance with Section 104(c) of the AEA, the NRC believes that the same principles of good regulation apply to NPR licensees and power reactor licensees alike. The NRC conducts extensive public outreach and a thorough legal review in order to ensure compliance with all sections of the AEA when issuing regulations or other regulatory actions involving NPRs. The NRC's regulations that apply to NPR licensees must

first meet the standard of providing reasonable assurance of protecting the public health and safety. If that standard can be met with regulations that impose a lesser burden on NPR licensees, stakeholders are encouraged to communicate their ideas to the NRC. In addition, the NRC issues guidance materials (Regulatory Guides, NUREGs, etc.) to communicate potential means by which licensees may comply with the regulations. Those guidance materials are not regulations, and licensees are permitted to administer their programs as they see fit, provided licensees can produce a sufficient basis illustrating how their program administration follows the NRC's regulations. The final Plan was not revised as a result of this comment.

Issue 2: Cumulative Effects of Regulation (CER)

Comment: The Nuclear Energy Institute (NEI) submitted a comment on the draft Plan that suggested "the intent of the retrospective analysis could be met through addressing the cumulative effects of NRC regulatory actions, rulemaking and other NRC regulatory processes resulting in greater benefit in safety and resource management." The NEI also asserted that broadening the scope of applicable processes beyond rulemaking to other actions such as orders, generic guidance, and information requests would result in more meaningful improvements.

Response: The NRC agrees that the effort to address CER does contribute, in concert with the other NRC initiatives described in the draft Plan, to the intent of the retrospective analysis. The NRC also notes that SECY-12-0137, "Implementation of the Cumulative Effects of Regulation Process Changes," dated October 5, 2012 (ADAMS Accession No. ML12223A162), provided the Commission with an update on the status of implementing CER and feedback obtained during a May 2012 public meeting. In response, the Commission

issued the staff requirements memorandum (SRM) to SECY-12-0137 (ADAMS Accession No. ML13071A635). Among other items, the SRM directed:

Any expansion of the consideration of the CER should be considered in the broader context of actions directed from COMGEA-12-0001/COMWDM-12-0002, "Proposed Initiative to Improve Nuclear Safety and Regulatory Efficiency."

The staff should continue to develop and implement outreach tools that will allow the NRC to consider more completely the overall impacts of multiple rules, orders, generic communications, advisories, and other regulatory actions on licensees and their ability to focus effectively on items of greatest safety import.

To inform its decision-making in addressing this directive, the NRC staff will obtain public feedback through public meetings. The NRC encourages continued public interaction on the subject of CER. The SRM also directed:

The staff should engage industry to seek volunteer facilities to perform "case studies" to review the accuracy of cost and schedule estimates used in NRC's regulatory analysis (such as the 10 CFR [*Code of Federal Regulations*] Part 73 security upgrades required after the attacks of September 11, 2011 and 10 CFR 50.84c, NFPA 805 program).

The NRC will use the aforementioned public meetings as tools to engage the industry on this initiative and believes that such case studies will result in meaningful insights to inform decisions for improving future regulatory analyses. The final Plan was not revised as a result of this comment.

Issue 3: General Support for the Draft Plan

Three commenters provided general support for the draft Plan. However, some commenters supported the draft Plan and offered comments on areas that could be clarified or improved.

Comment 1: The NEI supported the draft Plan. NEI stated that it understood the NRC's apparent rationale behind committing limited resources to this effort and agreed that there may not be benefit from a wholesale retrospective analysis.

Comment 2: GE Hitachi Nuclear Energy supported "the NRC approach that provides ongoing assessments of regulatory burdens in various NRC actions involving regulations..." However, GE Hitachi Nuclear Energy recommended that the NRC, when periodically revising the final Plan, describe specific review actions and results that have occurred since the last revision of the final Plan.

Response to Comments 1 and 2: The NRC appreciates the support for the draft Plan. When the NRC periodically revises the final Plan, it will consider including review actions and results that have occurred since the last revision of the final Plan. The final Plan was not revised as a result of Comments 1 and 2.

Issue 4: Openness and Transparency

Comment: The Citizens Oversight stated that while the draft Plan included a section called "Opportunities for Public Participation," the draft Plan did not propose any new opportunities for public participation. The commenter complimented the NRC on its January 31, 2013, Commission public meeting on regulatory decision-making. However, the commenter stated that the NRC limits oversight by the public by adopting overly restrictive definitions of standing, providing overly short periods for comments/petitions, making hearings the exception rather than the rule, making the adjudicatory process too formal, and conducting closed Commission meetings. Also, the commenter noted that the NRC had not responded to public comments and questions submitted after a public meeting in Dana Point, California.

Response: The Citizens Oversight comments are beyond the scope of E.O.s 13579 and 13563, and the NRC's draft Plan. Specifically, the Citizens Oversight comments on public

participation relate to such participation in NRC adjudicatory or licensee-specific licensing actions (e.g., standing, petitions for invention, etc.), and not the NRC's regulatory process for regulations. Executive Order 13579 is directed towards the manner in which Independent Regulatory Agencies issue or revise its regulations. To that end, E.O. 13579, recommends that, to the extent permitted by law, Independent Regulatory Agencies abide by a set of general requirements set forth in E.O. 13563, including those associated with public participation. As the Citizens Oversight notes in its comments, the principles of public participation that E.O. 13563 endorses concerns the ability of the public to participate in an agency's adoption of a regulation through the regulatory process. Executive Order 13563 provides that, each agency, to the extent feasible and permitted by law, shall "afford the public a meaningful opportunity to comment through the Internet on any proposed regulation, with a comment period that should generally be at least 60 days." Executive Order 13563 further provides that each agency, to the extent feasible and permitted by law, shall also "provide, for both proposed and final rules, timely online access to the rulemaking docket on regulations.gov..." As stated in Section G of the NRC's final Plan, the NRC already complies with these principles in its regulatory process for the development or modification of regulations.

If the Citizens Oversight seeks to modify the NRC's regulations governing its adjudications, then it should avail itself of the opportunities for public participation that the NRC identifies in its final Plan, such as 1) participation in rulemaking activities related to the NRC's adjudicatory procedures in 10 CFR Part 2; or 2) use of the petition for rulemaking process in 10 CFR 2.802 to request specific revision to those procedures. On May 3, 2013 ([78 FR 25886](#)), the NRC published a proposed rule to streamline and clarify its process for addressing petitions for rulemaking. Proposed changes to that process aim to improve transparency and make the process more efficient and effective. The final Plan was not revised as a result of this comment

from the Citizens Oversight; however, the NRC did update Section III of the final Plan to include a description of the aforementioned proposed rule.

Issue 5: Suggestions for Technical Improvements

Comment: The Citizens Oversight suggested several technical improvements, including the following: 1) the NRC should provide direct links to relevant documents, rather than just including an ADAMS accession number; 2) the NRC should include Really Simple Syndication (RSS) feeds on all of its Web pages; and 3) the NRC should remove quotes in URLs. The commenter also noted that links within ADAMS documents do not always work.

Response: The NRC considers this comment out-of-scope with regard to the draft Plan. However, the Office of Information Services is reviewing this comment and may contact the commenter regarding these issues. The NRC would note that the recently developed Documents for Comment page (<http://www.nrc.gov/public-involve/doc-comment.html>) provides links to dockets on www.regulations.gov containing documents with an open comment period. Individuals can subscribe to page updates through GovDelivery³ in order to keep informed of NRC documents that have been published in the *Federal Register* for comment. The final Plan was not revised as a result of this comment.

Issue 6: Thorium is Incorrectly Classified under the 1954 Atomic Energy Act

Two commenters stated that thorium is incorrectly classified under the 1954 AEA and should be placed in a less restrictive category of isotopes of elements.

³ The Federal rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: 1) Navigate to the docket folder (NRC-2011-0246); 2) click the "Email Alert" link; and 3) enter your e-mail address and select how frequently you would like to receive e-mails (daily, weekly, or monthly).

Comment 1: Dr. Alexander Cannara stated that classifications of various radioactive elements that were initiated by the old Atomic Energy Commission are too broad and interfere with various environmental and industrial realities (specifically the rare earth industry).

Comment 2: Stephen Boyd seemed to infer that the NRC should review and presumably revise its regulations to better support the use of thorium reactors. In particular, the commenter suggested allowing public and private efforts to join in the research occurring elsewhere in the world.

Response to Comment 1: Comment 1 from Dr. Cannara is beyond the scope of the NRC's draft Plan. Thorium is already classified differently (as source material) than the other elements that it is compared to (which are categorized as byproduct material). Over the past decade, the staff has acknowledged some concerns about the fact that thorium and uranium are present ubiquitously in nature (unlike byproduct material) and their current classification as source material may result in the regulation of activities not necessarily considered by Congress in enacting the AEA. The final Plan was not revised as a result of Comment 1.

Response to Comment 2: Comment 2 from Stephen Boyd is beyond the scope of the NRC's draft Plan. Thorium is already classified differently (as source material) than the fissile Uranium-235 (which is classified as special nuclear material), with the latter element having much more restrictive limits on possession and use. Although the NRC does periodically review its regulations to identify areas where new technologies may require changes to the regulations, such significant regulatory changes are usually only undertaken when there is reasonable certainty that such technologies will be implemented because the process of significantly revising the regulations may be resource intensive. The NRC will also undertake such revisions at the direction of Congress, usually after appropriate funding is provided. In recent years, some bills have been brought before Congress specifically related to Mr. Boyd's concerns, but

to date, Congress has not passed those bills. The NRC is not aware of any prohibitions against private efforts being involved in foreign research on the subject, although any U.S. Government involvement would likely be through the U.S. Department of Energy. The final Plan was not revised as a result of Comment 2.

III. Process Improvements

While developing this final Plan, the NRC identified changes to improve the clarity and transparency of its processes for compliance with Section 610 of the Regulatory Flexibility Act (RFA) and Section 212 of the Small Business Regulatory Enforcement Fairness Act (SBREFA). The changes are described in the following sections.

A. Regulatory Flexibility Act Compliance

Section 610 of the RFA was enacted in 1980 and requires agencies to review those regulations that have or will have a *significant* economic impact on a *substantial* number of small entities every 10 years after publication of such rules as final rules. The purpose of the periodic review is to determine whether the rules should be unchanged, amended, or rescinded.

The NRC published its plan for Section 610 reviews in 1981. The NRC provided a status on its compliance with RFA to the Small Business Administration (SBA) in 1992 and 2002. In addition, the NRC provided a status on its compliance to Congress in 2005.

The NRC has one recurring rule that has a significant economic impact on a substantial number of small entities, its annual fee rule. This rule amends the licensing, inspection, and annual fees charged to its applicants and licensees. Given that a final fee rule is published each year, the NRC has determined that it does not require a Section 610 periodic review.

The NRC will update its internal procedures to clarify the NRC staff's responsibilities with regards to the Section 610 periodic reviews and to include a process for submitting Unified Agenda entries for those rulemakings that require a Section 610 periodic review. Entries will be added to the "Pre-rule" section of the Unified Agenda when a periodic review is started and will solicit public comment. The NRC will publish the results of its periodic reviews in the "Completed Actions" section of the Unified Agenda, including whether the rule will be unchanged, revised, or rescinded.

To further improve transparency, the NRC will update the public Web site⁴ for RFA procedures to include a list of all final NRC rules that impact small entities and whether they must undergo a periodic review required by Section 610 of the RFA. This Web site will also include a link to the periodic review initiation and completion entries in the Unified Agenda for each rulemaking that must undergo a Section 610 periodic review.

Section 610 of the RFA allows agencies to update their plan at any time by giving notice in the *Federal Register*. The information on the public Web site for RFA procedures informs the public of which rules must undergo a periodic review and when and provides a link to the results of the periodic review as published in the Unified Agenda; supersedes the NRC's 1981 plan.

B. Small Business Regulatory Enforcement Fairness Act Compliance

Section 212 of the SBREFA was enacted in 1996 and requires that for each rulemaking that requires a Regulatory Flexibility Analysis under 5 U.S.C. 605(b), the agency must publish a "small entity compliance guide." The SBREFA was amended by the Fair Minimum Wage Act of 2007, which requires agencies to—1) publish, distribute, and post on their public Web sites compliance guides on the same date of publication of the final rule; and 2) submit an annual

⁴ See <http://www.nrc.gov/about-nrc/regulatory/rulemaking/flexibility-act.html>.

report (signed by the head of the agency) to the appropriate Congressional Committees describing the status of the agency's compliance with the Act.

The NRC will update internal procedures to clarify the NRC staff's responsibilities with regards to Section 212 of the SBREFA.

The NRC has issued small entity compliance guides and published them either in the *Federal Register* or in the appropriate document collection on the NRC's public Web site; however, the NRC has not published all of its compliance guides in one location. The public Web site for RFA procedures that lists all NRC rules that impact small entities will also include a listing of the NRC's small entity compliance guides and how they may be accessed.

The NRC has not submitted a status report to Congress regarding its compliance with SBREFA. However, the NRC staff is currently drafting the 2013 status report. A link to the status report will be included on the Web site for RFA procedures.

IV. Final Plan for Retrospective Analysis

The NRC's final Plan describes the NRC's processes and activities relating to retrospective analysis of existing regulations, including discussions of the: 1) efforts to incorporate risk assessments into regulatory decision-making; 2) efforts to address the

cumulative effects of regulation; 3) the NRC's methodology for prioritizing its rulemaking activities; 4) 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 5) the NRC's previous and ongoing efforts to update its regulations on a systematic, ongoing basis.

Dated at Rockville, Maryland, this _____ day of _____, 2013.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER OSTENDORFF

SUBJECT: SECY-13-0080 – FINAL PLAN FOR RETROSPECTIVE ANALYSIS OF EXISTING RULES

Approved X Disapproved Abstain

Not Participating

COMMENTS: Below X Attached X None

I approve the final plan for retrospective review of existing rules and companion *Federal Register* notice, subject to the attached edits. I commend the staff for proactively identifying improvements to the agency's process for compliance with the Regulatory Flexibility Act and the Small Business Regulatory Enforcement Act.

W. Ostendorff
SIGNATURE

8/29/13
DATE

Entered on "STARS" Yes X No

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.

B. Significant Regulatory Actions

The annual rulemaking to revise the NRC's fees qualifies as a "significant regulatory action" under E.O. 12866, "[Regulatory Planning and Review](#)."⁴ The NRC must recover most of its current fiscal year budget through fees for services specified in Part 170 of Title 10 of the *Code of Federal Regulations* (10 CFR), "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.

C. Unified Agenda of Regulatory and Deregulatory Actions

The [Unified Agenda of Regulatory and Deregulatory Actions](#),⁵ which the NRC and all Federal agencies publish semiannually, provides an update on all active rulemaking activities. The fall edition of the Unified Agenda contains the [NRC's Regulatory Plan](#),⁶ which contains a statement of the major rules that the Commission expects to publish in the current ~~fiscal year (FY)~~ and a description of the other significant regulatory priorities from the Common Prioritization of Rulemaking (see Section III.A) that the Commission expects to work on during the current FY, the coming FY, and beyond.

⁴ See http://www.regulations.gov/docs/EO_12866.pdf.

⁵ For the most current NRC Unified Agenda see <http://www.reginfo.gov/public/do/eAgendaMain> or <http://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/unified-agenda.html>.

⁶ For the most current NRC Regulatory Plan see http://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_STATEMENT_LIST¤tPub=true&agencyCode=&showStage=active&agencyCd=3150.

IV. 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 E.O. 13579.

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 IV.G) facilitates the exchange of ideas and contributes to the retrospective review of the NRC's regulations.

A. Incorporation of Risk Insights into Regulatory Decision-making

1. For approximately 20 years, the NRC has incorporated insights from risk assessments into its regulatory decision-making. The NRC updates its [risk-informed, performance-based plan](#) annually.⁷ The risk-informed, performance-based plan—
 - (a) Covers the agency's three major 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](#); November 22, 2011). The task force issued its report, NUREG-2150, "A Proposed Risk Management Regulatory Framework," in April 2012 (ADAMS Accession No. ML12109A277). The NRC is currently reviewing its regulatory framework to develop a generic policy statement addressing risk management regulatory framework (RMRF) goals and approaches to implementation of RMRF recommendations.

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](#),"⁸

⁷ See <http://www.nrc.gov/about-nrc/regulatory/risk-informed/rpp.html>.

⁸ See <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/1998/secy1998-144/1998-144scy.pdf>.

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.
8. On the NRC's public Web site, the NRC's "[Documents for Comment](#)"¹⁶ Web page contains docket information and comment submission deadlines for all documents that the NRC currently has available for public review and comment. The Web page is updated whenever the NRC publishes a *Federal Register* notice announcing the opportunity for public comment. To receive an e-mail whenever the NRC publishes a document for comment, the public can subscribe to the [GovDelivery Subscription Services](#).¹⁷

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 nuclear power plants and materials facilities.

I. Regular Updates to Guidance Documents

The NRC guidance documents include regulatory guides, the NUREG-series publications, interim staff guidance, regulatory issue summaries, topical reports, standard review plans, bulletins, generic letters, and technical specification task force travelers. Section IV.C of this final Plan describes the NRC's effort to concurrently

¹⁶ See <http://www.nrc.gov/public-involve/doc-comment.html>.

¹⁷ See <http://www.nrc.gov/public-involve/listserver.html>.

- (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 or guidance 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. Lessons-Learned and Response Program

1. 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.
2. Following significant events, the NRC typically will examine the event for lessons-learned; 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.

L. 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 an MOU (44 FR 38690; 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)

Comment [kas1]: Include information related to the agency's tribal outreach efforts.

5. Attachment 1 of the MOU with FEMA 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."
6. 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) rule¹⁹, the EP Rulemaking 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 U.S. Departments of State, Energy, and Commerce.
 - (c) The NRC participates in the Interagency Steering Committee on Radiation Standards (ISCORS) (<http://iscors.org/>). The ISCORS is comprised of eight Federal agencies, three Federal observer agencies, and two state observer agencies.
 - (d) The NRC chairs the Radiation Source Protection and Security Task force, an interagency task force required by the Energy Policy Act of 2005 that addresses source security.

Comment [kas2]: Include either the number or names of the federal agencies involved.

V. KEY ELEMENTS OF THE PLAN

A. Ensuring Objectivity

1. The Office of Administration (ADM) is responsible for 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

¹⁹ See final rule entitled "[Enhancements to Emergency Preparedness Regulations](#)" (NRC-2008-0122; RIN 3150-AI10).

The NRC will update its internal procedures to clarify the NRC staff's responsibilities with regards to the Section 610 periodic reviews and to include a process for submitting Unified Agenda entries for those rulemakings that require a Section 610 periodic review. Entries will be added to the "Pre-rule" section of the Unified Agenda when a periodic review is started and will solicit public comment. The NRC will publish the results of its periodic reviews in the "Completed Actions" section of the Unified Agenda, including whether the rule will be unchanged, revised, or rescinded.

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⁴ See <http://www.nrc.gov/about-nrc/regulatory/rulemaking/flexibility-act.html>.