

November 7, 2011

Mr. Cass R. Sunstein
Administrator, Office of Information
and Regulatory Affairs
Office of Management and Budget
Washington, D.C. 20503

Dear Mr. Sunstein:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your memorandum dated July 22, 2011, to the Heads of Independent Regulatory Agencies, about Executive Order (EO) 13579, "Regulation and Independent Regulatory Agencies," dated July 11, 2011. Executive Order 13579 encourages independent agencies, such as the NRC, to produce plans for the retrospective analysis of existing rules following the key principles of EO 13563, "Improving Regulation and Regulatory Review," dated January 18, 2011.

In response to EO 13579, the NRC has made available on its Public Web site, <http://www.nrc.gov/about-nrc/plans-performance.html#rules>, an initial Plan (enclosed) addressing retrospective review of existing regulations. The NRC's initial Plan describes the NRC's plans, processes, and activities relating to retrospective review of existing regulations. The NRC's processes include the opportunity for public comment on proposed rules and the NRC's petition for rulemaking process. The initial Plan includes a discussion of NRC's ongoing efforts to (1) incorporate risk assessments into regulatory decisionmaking, and (2) address the cumulative effects of regulation.

On July 12, 2011, the NRC issued the report entitled "Recommendations for Enhancing Reactor Safety in the 21st Century: The Near-Term Task Force Review of Insights from the Fukushima Dai-ichi Accident." The report is available online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>, ML112510271. The Commission has recently directed the NRC staff to engage promptly with stakeholders to review and assess the recommendations of the Fukushima Task Force report for the purpose of providing the Commission with fully informed options and recommendations. The Commission's decision about the options and recommendations contained in the Fukushima Task Force report may substantially affect the NRC's current high-priority rulemaking activities. Thus, it is not an optimal time to solicit public comments on the initial Plan for retrospective analysis of regulations.

Once the Commission reaches a decision, the staff will revise this initial Plan as appropriate. The agency will then update the initial Plan on the NRC's Public Web site and publish it for public comment, with a *Federal Register* notice announcing its availability for comment. The NRC anticipates that this will occur in Calendar Year 2012. The staff will then revise the Plan in response to public input. Once the Plan is finalized, the NRC will post it on its Public Web site and publish another notice in the *Federal Register* announcing its availability.

The Commission is committed to maintaining an effective and efficient regulatory process that is open and transparent.

Sincerely,

/RA/

Gregory B. Jaczko

Enclosure:
[As stated](#)



U.S. NUCLEAR REGULATORY COMMISSION

**INITIAL PLAN FOR A RETROSPECTIVE ANALYSIS OF EXISTING
RULES**

OCTOBER 2011

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I. INTRODUCTION

On January 18, 2011, President Obama issued Executive Order (EO) 13563, “Improving Regulation and Regulatory Review.” Executive Order 13563 directs Federal agencies to develop and submit a plan to the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget. The plan should explain how the agencies 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.

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

The U.S. Nuclear Regulatory Commission (NRC or the Commission) has prepared this Plan as part of its initial response to EO 13579.

II. SCOPE OF THE PLAN

This initial Plan builds on the NRC’s longstanding focus on assuring its regulations are effective, efficient, and up-to-date, recognizing processes that the NRC has long had in place to build a well thought out regulatory framework. Currently, the Commission is undertaking a systematic review of potential actions, including possible updating of regulations, in light of the events at the Fukushima Dai-ichi Nuclear Power Plant in Japan that followed the March 11, 2011, earthquake and tsunami. As outlined below, the NRC has in place a number of programs and activities to assess existing NRC regulations.

III. NRC REGULATORY REVIEW ACTIVITIES

The Commission is committed to maintaining an effective and efficient regulatory process that is open and transparent. Through its existing rulemaking processes, the NRC already identifies, simplifies, and updates outdated regulations to make them more effective and less burdensome.

Key areas of the NRC’s rulemaking processes are discussed below.

A. Incorporation of Risk Assessments into Regulatory Decisionmaking

For the last 20 years, the NRC has incorporated insights from risk assessments into its regulatory decisionmaking. The NRC updates its risk-informed, performance-based plan annually. The plan covers the agency’s three strategic arenas—reactor safety, material safety, and waste management—and focuses attention on risk-significant safety systems, structures, and components, while reducing unnecessary conservatism associated with NRC regulations. In February 2011, Chairman Jaczko established a task force under the direction of Commissioner Apostolakis to enhance the use of risk information in regulatory activities. The task force was directed to develop 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.

B. Annual Update of the NRC's Fees

The NRC reassesses its fees for licensees on an annual basis. The annual rulemaking to revise NRC fees is often the only NRC rulemaking that qualifies as a "significant regulatory action" under EO 12866, "Regulatory Planning Review."

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

C. Addressing the Regulatory Impacts of the NRC's Activities

1. The NRC has a long history of improving processes in order to reduce regulatory burden on external stakeholders. These include (but are not limited to) such initiatives as the NRC Program for the Elimination of Requirements Marginal to Safety (described in SECY-92-263) and the NRC Staff Activities related to the Goal of Reducing Unnecessary Regulatory Burden on Power Reactor Licensees (described in SECY-02-0081).
2. Another key, and continuing, example is the staff's activities to risk-inform its regulations which began with the establishment of the NRC's 1995 Probabilistic Risk Assessment policy statement. 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.
3. Since the late 1990's, the NRC has continued to risk-inform its regulatory activities in an effort to make its regulations both more effective and more efficient, and in so doing reduce unnecessary regulatory burden. Within this same context, the NRC has recently taken additional steps to enhance the openness and transparency of the regulatory process, and to reduce unnecessary regulatory burden, in part by improving the ability of external stakeholders to more fully participate in the rulemaking process. 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) of the new and recently issued regulations already scheduled for implementation. In response to this direction, the staff suggested rulemaking process enhancements which the Commission endorsed in SRM-SECY-11-0032, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process."

D. Periodic Review and Assessment of Significant Regulations

1. The NRC periodically reviews and reassesses its significant regulations. Part of this process is a defined and regularly utilized process, set forth at 10 CFR 2.802, "Petition for rulemaking," allowing the public to submit petitions for rulemaking.
2. The agency recently reviewed its regulations on fitness for duty (10 CFR Part 26, "Fitness for Duty Programs"), emergency preparedness (10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities"), and export and import of nuclear equipment and material (10 CFR Part 110, "Export and Import of Nuclear Equipment and Material").
3. Additionally, the NRC has established a working group and steering committee that is examining recent developments in the international community on standards for radiation protection. Ultimately, these groups will be recommending any appropriate changes to the NRC's regulations in 10 CFR Part 20, "Standards for Protection Against Radiation," a set of regulations that establish generally applicable standards applied by our licensees in protecting the public from the harmful effects of radiation exposure.

E. The NRC Complies with the Regulatory Flexibility Act (5 U.S.C. 610)

The NRC staff has begun developing the regulatory basis for a new revision of the agency's regulations on the medical use of byproduct material. The most recent revision to these regulations in 10 CFR Part 35, "Medical Use of Byproduct Material," significantly reduced the regulatory burden imposed on small entities. The forthcoming rulemaking will comply with the retrospective review requirements under Section 610 of the Regulatory Flexibility Act.

F. Opportunities for Public Participation

1. The NRC already offers opportunities to comment on proposed rules through e-mail and the Federal rulemaking Web site (<http://www.regulations.gov>). The North American Free Trade Agreement requires notification at least 60 days before adoption of a technical regulation, and EO 12889, "Implementation of the North American Free Trade Agreement," dated December 27, 1993, requires a 75-day comment period. The NRC usually provides 75 days to comment on a proposed technical rule. For a complex proposed rule or one with lengthy guidance documents, the NRC may elect to provide a longer comment period.
2. The public may request a revision to existing requirements at any time using the 10 CFR 2.802 petition for rulemaking process.
3. The NRC drafts regulatory analyses to determine the burden associated with each of its rules and issues each regulatory analysis for public comment along with the proposed rule language.
4. The agency uses the Federal rulemaking Web site (<http://www.regulations.gov>) to make it easier for the public to participate in NRC rulemaking activities.

G. Access to Regulatory Compliance and Enforcement Activities

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

H. The NRC Regularly Updates Guidance Documents

In 2006, the NRC started a program to regularly update its regulatory guidance documents in order 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. The NRC anticipates that the Regulatory Guide Update Program will be completed by the end of Calendar Year 2014.

I. The NRC's Regulations Reflect Consensus Standards

The NRC participates in industry consensus standards groups, and incorporates by reference into NRC regulations several voluntary consensus standards (American Society of Mechanical Engineers Boiler and Pressure Vessel Code, Institute of Electrical and Electronics Engineers (IEEE) Std. 603, IEEE Std. 279, National Fire Protection Association 805). The industry consensus standards development process involves regular review and updating of standards, and the NRC revises its regulations as appropriate to reflect updated consensus standards. With respect to certain voluntary consensus standards, the NRC has a routine process in place for review and updating of our regulations to reflect revised standards.

J. Effective Lessons-Learned Program

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

IV. KEY ELEMENTS OF THE PLAN

A. Ensuring Objectivity

1. The Office of Administration (ADM) is responsible for overseeing the activities described in this initial Plan insofar as they involve the following:
 - (a) The retrospective analysis of the NRC's regulations; and

- (b) Consideration of future changes to the NRC's approach to its retrospective analysis. (This will be done in coordination 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 staff 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 Retrospective Review Plan

The Director of the Office of Administration will be responsible for the preparation, update, and implementation of the retrospective review plan.

C. Public Comment

- 1. The NRC is posting this initial Plan on its Public Web site at <http://www.nrc.gov/about-nrc/plans-performance.html#rules> and publishing a notice in the *Federal Register* announcing its availability for public review. The NRC is not requesting public comment on the Plan at this time, because the NRC's near-term retrospective regulatory review activities may be substantially influenced by decisions that have yet to be made related to the NRC's continuing assessment of its existing regulations in light of the Fukushima Dai-ichi events (an effort that, in and of itself, is a retrospective regulatory analysis activity involving substantial public and stakeholder input and involvement).
- 2. After the Commission has provided direction on the rulemaking recommendations in the Fukushima Task Force Report, the NRC expects to develop and issue an updated version of this Plan for public comment, which will also be published on the NRC's Open Government Web site. The NRC will also publish another notice in the *Federal Register* at that time announcing the revised Plan's availability and the opportunity to comment. The NRC anticipates that this will occur in Calendar Year 2012.

D. Publishing the NRC's Plan Online

As part of the NRC's effort to foster a strong, ongoing culture of retrospective analysis, the agency will maintain the Plan on its Public Web site at <http://www.nrc.gov/about-nrc/plans-performance.html#rules>.