



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

August 15, 2012

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-12-0076

TITLE: 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 August 15, 2012.

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-12-0076

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MACFARLANE	X				X	8/3/12
COMR. SVINICKI	X				X	8/3/12
COMR. APOSTOLAKIS	X					6/21/12
COMR. MAGWOOD	X				X	7/27/12
COMR. OSTENDORFF	X				X	7/6/12

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN MACFARLANE

SUBJECT: SECY-12-0076 – PLAN FOR RETROSPECTIVE
ANALYSIS OF EXISTING RULES

Approved X Disapproved Abstain

Not Participating

COMMENTS: Below X Attached None

I approve the draft plan for retrospective review of existing rules and the associated *Federal Register* notice. I concur with several comments from Commissioner Ostendorff including: the proposed edits attached to his vote; that staff should add to the plan a process for retrospectively reviewing existing significant rules; and that the plan should highlight the ways NRC coordinates and communicates with other Federal and state agencies during its rulemaking activities. I also concur with the edits proposed by Commissioner Magwood.



SIGNATURE

8/3/12

DATE

Entered on "STARS" Yes X No

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER SVINICKI
SUBJECT: SECY-12-0076 – PLAN FOR RETROSPECTIVE
ANALYSIS OF EXISTING RULES

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below XX Attached XX None _____

I approve the draft Plan for Retrospective Analysis of Existing Rules and *Federal Register* notice, subject to the attached edits. In developing the final Plan, staff will need to incorporate any activities arising from Commission direction on the cumulative effects of regulation notation vote paper, due to the Commission in the fall of 2012.



SIGNATURE

08/ 3 /12

DATE

Entered on "STARS" Yes ✓ No _____

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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 in order to make them more effective and less burdensome. The NRC's processes also allow for public participation throughout the rulemaking process (see Section III.H), which facilitates the exchange of ideas. The following discussion describes key areas of the NRC's rulemaking process.

A. Incorporation of Risk Insights into Regulatory Decisionmaking

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

B. Performance-Based Regulations

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

1. Because the licensee has greater flexibility in meeting the regulatory requirements, a performance-based approach can result in a more efficient and effective regulatory

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

2. In 2006-2007, the NRC evaluated the overall effectiveness of its recent rulemaking process improvements and identified other options to streamline the rulemaking process. Further improvements continued to enhance the process for developing regulatory basis and emphasized engaging external stakeholders during the development of the regulatory basis. The concurrent development and publication of the guidance and the proposed rule gave members of the public, licensees, and other stakeholders the information necessary to comment intelligently-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 (see Section III.E.3 for details).

D. Significant Regulations

1. The NRC's Annual Fee Rule

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

2. Physical Protection of Byproduct Material

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

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

1. The NRC has a long history of improving processes to reduce 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, and in so doing, reduce 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.¹ 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. In January 2010, the Commission directed NRC staff to consider whether the schedule for implementing the new emergency preparedness rulemaking and future rulemakings should be influenced by the aggregate impact (now referred to as cumulative effects of regulation (CER)) of the new and recently issued regulations already scheduled for implementation. In response to this direction, the staff described several rulemaking process enhancements in SECY-11-0032, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," dated March 2, 2011 (ADAMS Accession No. ML110190027). These enhancements include:
- (a) Interaction with external stakeholders during regulatory basis development;
 - (b) Interaction with external stakeholders during draft guidance development;
 - ~~(c) Guidance published concurrent with rules;~~
 - ~~(d) Request for explicit stakeholder feedback on CER in the proposed rule Register notice; and~~
 - ~~(e) Public meeting on implementation during the final rule stage.~~
- [credit has already been taken for this on p.7, as part of rulemaking process improvements.]*

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

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

1. The NRC's Regulatory Flexibility Procedures (available at: <http://www.nrc.gov/about-nrc/regulatory/rulemaking/flexibility-act.html>) and the NRC's Regulatory Analysis Guidelines require that the factors necessary to evaluate the economic impact of the regulatory action under consideration on small entities be addressed in the Regulatory Analysis.
2. Only a few NRC rulemakings have been found to have a significant impact on a substantial number of small entities and involve byproduct, source, and special

¹ See the NRC's March 29, 2000 press release entitled "NRC to Expand Use of Revised Reactor Oversight Process," (ADAMS Accession No. ML003707640). See also version 4 of NUREG-1649, "Reactor Oversight Process," December 2006, ADAMS Accession No. ML070890365).

- (c) Data needed by the staff in its review of applications for permits or licenses.
- 2. The NRC issues regulatory guides in draft form to solicit public comment and involve the public in developing the agency's regulatory positions. Some draft guides are proposed revisions of existing guides. Draft regulatory guides have not received complete staff review and, therefore, they do not represent official NRC staff positions. In finalizing the guides, the staff considers all comments received during the public comment period, as appropriate.
- 3. In 2006, the NRC started a program to regularly update its regulatory guidance documents to keep these documents current. Under the Regulatory Guide Update Program, the NRC reviews, prioritizes, and, where appropriate, revises all regulatory guides. For any given regulatory guide, this effort may result in a revision to the guide, a finding that the guide does not need revision, or the withdrawal of the guide. When the NRC proposes to revise or withdraw a regulatory guide, the NRC issues an appropriate notice to the public.
- 4. The NRC is in the process of updating the 21 volumes of its "Consolidated Guidance About Materials Licenses" (NUREG-1556).

J. Regulations Reflect Consensus Standards

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

K. Effective Lessons-Learned Program

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

~~IV. REGULATIONS BEING UPDATED IN RESPONSE TO EVENTS AT THE FUKUSHIMA DAI-ICHI PLANT IN JAPAN~~

L. Regulations Being Updated in Response to Events at the Fukushima Dai-ichi Plant in Japan

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Following significant events, ~~such as the event that occurred at the Fukushima Dai-ichi nuclear power plant in March 2011~~, the NRC typically will examine the event for lessons-learned and, depending on the findings, the NRC may decide to revise its regulatory framework. ~~In fact, since March 2011, the NRC has been 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 Fukushima. 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.~~

Currently,

the event that occurred at the Fukushima Dai-ichi nuclear power plant in March 2011.

IV. KEY ELEMENTS OF THE PLAN

A. Ensuring Objectivity

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

- (h) Specify the requirements for a site-specific analysis to demonstrate compliance with low-level waste disposal performance objectives, and the technical requirements needed for this analysis;
 - (i) Selectively align drug testing requirements with Federal drug testing guidelines issued by the U.S. Department of Health and Human Services;
 - (j) Add requirements for licensees that possess significant quantities of uranium hexafluoride;
 - (k) Revise certificate of compliance (CoC) regulations;
 - (l) Update 10 CFR 51.23, "Temporary Storage of Spent Fuel after Cessation of Reactor Operation—Generic Determination of No Significant Environmental Impact," and the Commission's waste confidence decision, if staff determines that spent nuclear fuel and high level waste could be safely stored onsite at nuclear power plants at least 60 years beyond the licensed life of operation; and
 - (m) Modify regulations to enhance the reliability of spent fuel pool systems and equipment during a prolonged station blackout event.
3. In addition to these priorities, the NRC may identify additional regulatory initiatives that may receive priority attention because of the following:
- (a) Commission direction to implement recommendations from a task force established to examine the NRC's regulatory requirements, programs, processes, and implementation in light of information from the accident at the Fukushima Dai-ichi nuclear power plant in Japan following the March 11, 2011, earthquake and tsunami; and
 - (b) Other future and emerging events.
4. Additionally, the NRC's regulations include, for reactors and some of the NRC's larger fuel cycle licensees, a concept called "backfit," which is meant to assure 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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X

c. High-Level NRC Official Responsible for the Final Plan

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

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: Commissioner Apostolakis
SUBJECT: SECY-12-0076 – PLAN FOR RETROSPECTIVE
ANALYSIS OF EXISTING RULES

Approved X Disapproved Abstain

Not Participating

COMMENTS: Below Attached None X



SIGNATURE

6/21/12

DATE

Entered on "STARS" Yes x No

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MAGWOOD
SUBJECT: SECY-12-0076 – PLAN FOR RETROSPECTIVE
ANALYSIS OF EXISTING RULES

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below X Attached X None _____

I approve the draft Plan and *Federal Register* Notice, subject to the attached edits.

Will M. S.
SIGNATURE

27 July 2012
DATE

Entered on "STARS" Yes X No _____

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 in order to make them more effective and less burdensome. The NRC's processes also allow for public participation throughout the rulemaking process (see Section III.H), which facilitates the exchange of ideas. The following discussion describes key areas of the NRC's rulemaking process.

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 - (a) Covers the agency's three strategic arenas (reactor safety, material safety, and waste management); and
 - (b) Describes the NRC's efforts to focus attention on risk-significant safety systems, structures, and components, while reducing unnecessary conservatism associated with the NRC's regulations.
2. In February 2011, the NRC Chairman ~~Jaczo~~ established a task force ~~under the direction of Commissioner Apostolakis~~ to enhance the use of risk information in regulatory activities. The task force developed a strategic vision and options to achieve a more comprehensive and holistic risk-informed and performance-based approach for the regulation of reactors, materials, waste, the nuclear fuel cycle, security, and transportation. As a part of this initiative, the task force sought public comment on a series of questions that provided input for the task force to consider in its work (76 FR 72220; "Incorporation of Risk Management Concepts in Regulatory Programs," November 22, 2011). The task force issued its report "A Proposed Risk Management Regulatory Framework," NUREG—2150, in April 2012 (ADAMS Accession No. ML12109A277).

B. Performance-Based Regulations

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

1. Because the licensee has greater flexibility in meeting the regulatory requirements, a performance-based approach can result in a more efficient and effective regulatory

K. Effective Lessons-Learned Program

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

L. Response to Significant Events

~~IV. REGULATIONS BEING UPDATED IN RESPONSE TO EVENTS AT THE FUKUSHIMA DAI-ICHI PLANT IN JAPAN~~

Following significant events, ~~such as the event that occurred at the Fukushima Dai-ichi nuclear power plant in March 2011,~~ the NRC typically will examine the event for lessons-learned and, depending on the findings, the NRC may decide to revise its regulatory framework. ~~In fact, since March 2011, Currently, -the NRC has been~~ 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 ~~Fukushima 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 could be made. As such, the Fukushima regulatory effort is looking retrospectively at portions of the NRC's regulations.

~~V.~~IV. KEY ELEMENTS OF THE PLAN

A. Ensuring Objectivity

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

- (h) Specify the requirements for a site-specific analysis to demonstrate compliance with low-level waste disposal performance objectives, and the technical requirements needed for this analysis;
 - (i) Selectively align drug testing requirements with Federal drug testing guidelines issued by the U.S. Department of Health and Human Services;
 - (j) Add requirements for licensees that possess significant quantities of uranium hexafluoride;
 - (k) Revise certificate of compliance (CoC) regulations;
 - (l) Update 10 CFR 51.23, "Temporary Storage of Spent Fuel after Cessation of Reactor Operation—Generic Determination of No Significant Environmental Impact," and the Commission's waste confidence decision, if staff determines that spent nuclear fuel and high level waste could be safely stored onsite at nuclear power plants at least ~~60~~-120 years beyond the licensed life of operation; and
 - (m) Modify regulations to enhance the reliability of spent fuel pool systems and equipment during a prolonged station blackout event.
3. In addition to these priorities, the NRC may identify additional regulatory initiatives that may receive priority attention because of the following:
- (a) Commission direction to implement recommendations from a task force established to examine the NRC's regulatory requirements, programs, processes, and implementation in light of information from the accident at the Fukushima Dai-ichi nuclear power plant in Japan following the March 11, 2011, earthquake and tsunami; and
 - (b) Other future and emerging events.
4. Additionally, the NRC's regulations include, for reactors and some of the NRC's larger fuel cycle licensees, a concept called "backfit," which is meant to assure that imposing additional burdens on existing licensees is well justified by the expected benefits in situations in which the new requirement is not necessary to ensure adequate protection of public health and safety.

c. High-Level NRC Official Responsible for the Final Plan

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

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER OSTENDORFF
SUBJECT: SECY-12-0076 – PLAN FOR RETROSPECTIVE
ANALYSIS OF EXISTING RULES

Approved X Disapproved Abstain

Not Participating

COMMENTS: Below X Attached X None

I approve the draft plan for retrospective review of existing rules and associated *Federal Register* notice, subject to the attached edits. The staff's plan documents the extensive existing processes that the agency has in place that address the intent of Executive Order 13563. I commend these efforts. The staff should add to the plan a process for retrospectively reviewing existing significant rules. The staff should also take advantage of ongoing opportunities to evaluate the effectiveness of existing significant regulations and whether the burden imposed is commensurate with our regulatory objectives. The staff's response to Recommendation 1 of the Near Term Task Force review on insights from the Fukushima Dai-ichi accident may provide such an opportunity. Finally, in light of the processes already in place for coordination of the NRC's rulemaking activities with other Federal and state agencies, the staff should also describe these in the plan.



SIGNATURE

7/6/12

DATE

Entered on "STARS" Yes x No

2. Physical Protection of Byproduct Material

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

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

1. The NRC has a long history of improving processes to reduce unnecessary regulatory burden on external stakeholders. These include (but are not limited to) such initiatives as—
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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 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, and in so doing, reduce unnecessary regulatory burden.

K. Effective Lessons-Learned Program

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

IV. REGULATIONS BEING UPDATED IN RESPONSE TO EVENTS AT THE FUKUSHIMA DAI-ICHI PLANT IN JAPAN

Following significant events, such as the event that occurred at the Fukushima Dai-ichi nuclear power plant in March 2011, the NRC typically will examine the event for lessons-learned and, depending on the findings, the NRC may decide to revise its regulatory framework. In fact, since March 2011, the NRC has been 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 Fukushima. 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 ~~could~~ should be made. As such, the Fukushima regulatory effort is looking retrospectively at portions of the NRC's regulations.

V. KEY ELEMENTS OF THE PLAN

A. Ensuring Objectivity

1. The Office of Administration (ADM) is responsible for overseeing the activities described in this Plan insofar as they involve the following:
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- (h) Specify the requirements for a site-specific analysis to demonstrate compliance with low-level waste disposal performance objectives, and the technical requirements needed for this analysis;
 - (i) Selectively align drug testing requirements with Federal drug testing guidelines issued by the U.S. Department of Health and Human Services;
 - (j) Add requirements for licensees that possess significant quantities of uranium hexafluoride;
 - (k) Revise certificate of compliance (CoC) regulations;
 - (l) Update 10 CFR 51.23, "Temporary Storage of Spent Fuel after Cessation of Reactor Operation—Generic Determination of No Significant Environmental Impact," and the Commission's waste confidence decision, if staff determines that spent nuclear fuel and high level waste could be safely stored onsite at nuclear power plants ~~at least 60 years beyond~~ 120 years the licensed life of operation; and
 - (m) Modify regulations to enhance the reliability of spent fuel pool systems and equipment during a prolonged station blackout event.
3. In addition to these priorities, the NRC may identify additional regulatory initiatives that may receive priority attention because of the following:
- (a) Commission direction to implement recommendations from a task force established to examine the NRC's regulatory requirements, programs, processes, and implementation in light of information from the accident at the Fukushima Dai-ichi nuclear power plant in Japan following the March 11, 2011, earthquake and tsunami; and
 - (b) Other future and emerging events.
4. Additionally, the NRC's regulations include, for reactors and some of the NRC's larger fuel cycle licensees, a concept called "backfit," which is meant to assure that imposing additional burdens on existing licensees is well justified by the expected benefits in situations in which the new requirement is not necessary to ensure adequate protection of public health and safety.

c. High-Level NRC Official Responsible for the Final Plan

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