

NUCLEAR REGULATORY COMMISSION

NRC-2013-0254

**Conceptual Example of a Proposed Risk Management Regulatory Framework Policy
Statement**

AGENCY: Nuclear Regulatory Commission.

ACTION: Conceptual example of a proposed policy statement; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a document entitled: "White Paper on a Conceptual Example of a Proposed Risk Management Regulatory Framework Policy Statement" (ADAMS Accession No. ML13273A517) and requesting public comment. The conceptual statement would set forth a possible Commission policy regarding the use of a structured decision-making model that results in risk-informed and performance-based defense-in-depth protections to: ensure appropriate personnel, barriers, and controls to prevent, contain, and mitigate possible inadvertent exposure to radioactive material according to the hazard present, the relevant scenarios, and the associated uncertainties; and ensure that the risks resulting from the failure of some or all of the established barriers and controls, including human errors, are maintained acceptably low. The white paper is an illustration of the staff's work in progress and is expected to be modified as both internal and external review is solicited and considered.

DATES: Please submit comments by January 10, 2014. Comments received after this date will be considered if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- **Federal Rulemaking Web site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2013-0254. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual(s) listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Mail comments to:** Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: 3WFN-06-44M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on accessing information and submitting comments, see “Accessing Information and Submitting Comments” in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Mary Drouin, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-251-7574; e-mail: Mary.Drouin@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC-2013-0254 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this document by any of the following methods:

- **Federal Rulemaking Web site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2013-0254.

- **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.

B. Submitting Comments

Please include Docket ID NRC-2013-0254 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Discussion

As part of the NRC strategic plan's goal of "openness," a white paper on a Conceptual Example of a Proposed Risk Management Regulatory Framework (RMRF) Policy Statement (ML13273A517) is being issued to both inform public stakeholders of the work and to start soliciting stakeholder feedback with regard to an NRC working group's early draft. An NRC inter-office working group has been chartered to develop a conceptual draft of a RMRF Policy Statement for Commission consideration. The document is a work in progress and has been developed to illustrate a potential organization, structure, and content of a conceptual policy statement. It is expected that as the Conceptual Example of a Proposed RMRF Policy

Statement is modified that additional notices, requesting public comment will be published in the *Federal Register*. In early 2011, at the request of Chairman Gregory B. Jaczko, Commissioner George Apostolakis lead a Risk Management Task Force (RMTF) to evaluate how the agency should be regulating 10 to 15 years in the future. More specifically, the RMTF was chartered “to develop a strategic vision and options for adopting a more comprehensive and holistic risk-informed, performance-based regulatory approach for reactors, materials, waste, fuel cycle, and transportation that would continue to ensure the safe and secure use of nuclear material.” The NUREG-2150, “A Proposed Risk Management Regulatory Framework,” was published in April 2012 (ML12109A277). This report describes the findings and recommendations of this evaluation. The report provides findings and recommendations which are compiled into two groups. The first group addresses agency-wide, more strategic issues, recommending that “The NRC should formally adopt the proposed Risk Management Regulatory Framework through a Commission Policy Statement.” The second group addresses what changes would be needed in specific program areas (e.g., power reactors and materials) in the next several years to ensure that the framework is implemented.

The agency-wide findings of the RMTF are:

- Finding: Whether used explicitly, as for power reactors, or implicitly, as for materials programs, the concept of defense-in-depth has served the NRC and the regulated industries well and continues to be valuable today. However, it is not used consistently, and there is no guidance on how much defense-in-depth is sufficient.

- Finding: Risk assessments provide valuable and realistic insights into potential exposure scenarios. In combination with other technical analyses, risk assessments can inform decisions about appropriate defense-in-depth measures.

Considering these findings, the RMTF proposes that “The NRC should formally adopt the proposed Risk Management Regulatory Framework through a Commission Policy Statement.”

The RMTF notes that the proposed framework includes several important benefits:

- Updated knowledge from contemporary studies, such as risk assessments, would be incorporated into the regulations and guidance, thereby improving their realism and technical basis.
- Implementation of a systematic approach would foster a consistent regulatory decision-making process throughout the agency and improve resource allocation.
- Consistency in language and communication would be improved across the agency and externally.
- Support of issue resolution would be achieved in a systematic, consistent, and efficient manner.

The RMTF also notes that implementation of the proposed framework would also pose challenges:

- A change would be required within the agency and externally to increase understanding of the value and use of risk concepts and risk management language.

- The proposed risk-informed and performance-based concept of defense-in-depth may require the development of additional decision metrics and numerical guidelines.
- The approach would likely require developing new or revised risk-assessment consensus codes and standards.
- A long-term commitment from the Commission and senior agency management would be required for implementation.

To assist in the review and comment process, the NRC is requesting the public address the specific questions listed below.

Overall Questions:

- 1) Is there a need for such a policy statement? If so, why? If not, why not?
- 2) Do you see any benefits in such a policy statement? If so, what are they? If not, why not?
- 3) How could the proposed RMRF policy statement be made more useful to licensees and/or certificate holders, applicants and other stakeholders?
- 4) Is the policy statement sufficiently flexible to address the specific program area activities (e.g., reactor versus transportation) with regard, for example, to the type of risk analyses, to the defense-in-depth principles?
- 5) What implementation challenges do you foresee?
- 6) A policy statement generally states the Commission's expectation regarding a particular subject. How to meet the Commission's expectation is not included in the policy statement. If

approved by the Commission, the staff plans to develop associated implementation guidance.

What should be the scope and extent of this guidance to be helpful? For example,

a. For program area of interest, what would be the appropriate decision criteria for determining adequate defense-in-depth?

b. What specific issues or actions should the guidance address in order to implement the policy statement for a particular program area (of interest)?

7) Does the proposed policy statement appropriately integrate security considerations into the RMRF? If not, why not?"

Sections I and II

8) Are these two sections (Background and Development of Risk Management Regulatory Framework Policy Statement) informative? Do they provide useful information in helping to clarify the need, purpose, goals, etc. of the policy statement in Section III? What information is not necessary and what type of information should be added, if any?

Section III

9) Is the purpose and goal of the proposed conceptual policy statement clear? If not, where is clarification needed?

10) Is the proposed conceptual RMRF policy statement useful in clarifying the Commission's intent to use a risk-informed and performance-based defense-in-depth approach in performing its regulatory function? If not, what needs to be clarified?

Section II

11) Should the current PRA policy statement (60 FR 42622, August 16, 1995) be replaced or subsumed/incorporated into this policy statement?

12) What would be the benefit? What would be the detriment?

Section III.B

13) If subsumed, is the proposed manner of incorporating the PRA statement reasonable? If not, why not?

14) Should the policy statement establish a Commission expectation that for all program areas, licensees and/or certificate holders are expected to have a risk analysis that is commensurate with the activity and technology?

Section III.A:

15) Do the proposed key elements in the RMRF process represent a complete and reasonable set?

a. If not, what modifications should be made?

b. Are other elements needed to cover the full spectrum of regulated activities?

c. Are the elements sufficient to develop a consistent decisionmaking approach across all regulated activities?

Section III.C:

16) Should defense-in-depth be a key aspect of a RMRF? If not, why not?

17) Will such proposed draft policy statement be useful in determining the extent of defense-in-depth needed in each program area?

18) Is the approach proposed for characterizing defense-in-depth clear? If not, where is clarification needed? Is the strategy reasonable? If not, why not?

19) Is the definition provided for defense-in-depth clear? If not, why not?

- 20) Are the key attributes identified reasonable and complete? If not, why not?
- 21) Are the basic levels of prevention and mitigation reasonable? If not, why not?
- 22) Are the definitions of prevention and mitigation clear and reasonable? If not, why not?
- a. Are they sufficiently flexible to support all program areas? If not, where not?
- b. Should and can these levels be further detailed (i.e., more specific) and still be sufficiently flexible to support all program areas?
- 23) Is it reasonable to expect the levels of defense to be independent such that failure of one level does not lead to failure of subsequent levels? If not, why not?
- a. Should the NRC accept different levels of rigor, or different levels of confidence, in demonstrating that there is independence between levels? Could the level of rigor vary depending upon the nature of the activity and the risks associate with loss of independence?
- b. Are there any other considerations that should be taken into account in determining the acceptable level of rigor or confidence in demonstrating independence between layers?
- 24) Is it reasonable to expect the following with regards to defense-in-depth:

- a. Ensure appropriate barriers, controls, and personnel are available to prevent and mitigate exposure to radioactive material according to the hazard present, the credible scenarios, and the associated uncertainties; and
 - b. Ensure that the risks resulting from the failure of some or all of the established barriers and controls, including human errors, are maintained acceptably low consistent with the applicable acceptance guidelines.
 - c. Overall, ensure that each regulated activity has appropriate defense-in-depth measures for prevention and mitigation of adverse events and accidents.
 - d. If the expectations of a, b, or c are not reasonable, why not?
- 25) Are the proposed defense-in-depth principles and decision criteria complete? Are they useful in deciding the extent of defense-in-depth needed in a program area? If not, how should they be improved?

Section III.D:

- 26) Are the proposed program area specific policy considerations clear and complete? If not, what modifications should be made? Are others needed to cover the full spectrum of regulated activities?

Dated at Rockville, Maryland, this 4th day of November, 2013.

For the Nuclear Regulatory Commission.

/RA/

Richard P. Correia, Director,
Division of Risk Analysis,
Office of Nuclear Regulatory Research.