

# POLICY ISSUE NOTATION VOTE

October 7, 2004

SECY-04-0182

FOR: The Commissioners

FROM: Luis A. Reyes  
Executive Director for Operations

SUBJECT: STATUS OF RISK-INFORMED REGULATION IN THE OFFICE OF  
NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

PURPOSE:

To provide a progress report on the systematic process being developed for risk-informing regulation in the Office of Nuclear Material Safety and Safeguards (NMSS), to describe the staff's plan to use the proposed approach on selected NMSS activities, and request approval to discontinue this report.

BACKGROUND:

The staff proposed an approach to risk-inform NMSS regulatory activities in SECY-99-100, "Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards," dated March 31, 1999. This approach was designed to: 1) focus Agency and licensee resources on areas commensurate with their importance to safety; 2) provide a framework for using risk information; and 3) where amenable, use risk information to provide flexibility for making decisions and managing the workload in NMSS more effectively. The framework defined the potential areas where risk-informing can play a role in the regulation of NMSS activities and, as part of its implementation, the staff proposed to develop risk metrics

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and goals to help guide the risk-informed activities. In a Staff Requirements Memorandum (SRM) dated June 28, 1999, the Commission approved the staff's proposal in SECY-99-100 to develop risk metrics and goals and to address risk management practices consistent with other Agency policies.

On June 24, 2003, the staff provided the Commission with a status of risk-informed regulation in NMSS activities in SECY-03-0126, "Risk-Informed Regulation for the Office of Nuclear Material Safety and Safeguards: Status Report and Plan for Future Work." This update described: 1) examples of areas where the staff has successfully used a risk-informed approach to improve effectiveness and efficiency; 2) the development of guidance documents to help the staff consistently and effectively apply a risk-informed approach; and 3) plans for continuing to risk-inform NMSS activities. In an SRM dated October 22, 2003, the Commission approved the staff's plans to continue advancements in risk-informing its regulatory activities and directed the staff to provide the Commission with biannual reports on the progress made in developing risk metrics, tools, data, and guidance for implementing risk-informed approaches for the materials and waste arenas.

The staff partially responded to SRM-SECY-03-0126 by providing a memorandum to the Commission, on July 9, 2004, that described the status of the ongoing risk-informed activities in NMSS. The memorandum informed the Commission that NMSS plans to transition from the development of a systematic risk-informing approach to the implementation of such an approach on a case-by-case basis. Because essentially all resources in NMSS in the upcoming years are obligated for programmatic activities, the Risk Task Group (RTG), which has led this development of a systematic risk-informing framework, was phased out at the end of fiscal year (FY) 2004. The application of the systematic risk-informing approach will be carried out by the NMSS divisions, as appropriate, and within the available resources.

#### DISCUSSION:

Risk-informing is a powerful tool to plan for NMSS programmatic activities and to leverage available resources to complete the planned activities while accommodating emergent work. As directed by the Commission in SRM-SECY-99-100 and SRM-SECY-03-0126, NMSS continues to expand the use of risk information to regulate activities in the material and waste arenas. Additionally, NMSS has developed a systematic risk-informing process and some of the associated preliminary decision considerations that integrates the consideration of different types of health impacts with other factors involved in risk-informed decision-making.

The proposed systematic risk-informed process, which has been developed in cooperation with the Office of Nuclear Regulatory Research (RES), contains the following four major steps:

1. Clearly define the regulatory issue and any preliminary alternative action(s);
2. Decide whether to risk-inform;
3. If a risk-informed approach is to be used, perform a risk assessment as needed; and
4. Apply risk-informed decision method

A summary of this proposed four-step risk-informing decision-making process is provided in Attachment 1.

The proposed approach, including specific decision methods, have been documented in a draft guidance report for use by NMSS staff and not for public release until it is finalized. The purpose of the guidance document is to provide a structured framework that integrates the consideration of risk with other factors to facilitate staff's use of risk insights in making decisions. Because each activity involves a range of potential radiation impacts, including routine doses, chronic exposures, and potential accident risk, risk insights for each of these potential impacts can contribute to decision making. This document provides guidance to staff as to how such risk insights can be considered. The draft approach for risk-informing is neither a regulatory requirement, nor does it replace existing guidance for regulating nuclear material and waste activities. This method is meant to be a supplementary tool to guide staff in risk-informing decisions. In addition, the draft guidance document, while useful in its present form, is continually being improved upon. It may require modification or the addition of new criteria, some of them adapted to particular needs or application areas. It is intended to be a living document incorporating the lessons learned as NMSS continues to risk-inform specific activities.

NMSS and RES staff, the NMSS Risk Steering Group, and the members of the Advisory Committee on Nuclear Waste (ACNW) have reviewed and provided comments on the key features of the proposed risk-informed process. Comments from these groups have been considered and incorporated into the current draft of the guidance report. The next step is to apply the proposed systematic approach documented in the draft guidance report on a case-by-case basis. The application of the proposed process to NMSS-regulated activities will provide an opportunity for the staff to learn, critique, and suggest possible improvement of the systematic process and will facilitate staff's acceptance of the risk-informed approach. In addition, results from a working group and pilot studies that evaluated the proposed process, demonstrated that the use of a systematic risk-informed approach would lead to more transparent decisions and achieve resource savings while maintaining or improving safety (see Attachment 2 on the potential resource savings). It is expected that similar results will be obtained in future applications of the systematic risk-informed approach.

Since separate funding has not been allocated for risk-informing NMSS activities, starting in FY 2005 and beyond, staff will identify those ongoing and emerging activities that are feasible and beneficial by using the screening process in Step 2 of the process. These selected NMSS activities may include licensing casework, inspection, rulemaking, and guidance and developmental work. If public interactions are part of those routine programmatic activities, NMSS will use this opportunity to obtain public feedback on the proposed process.

RES will continue to provide assistance on performing realistic risk calculations, such as data collection and interpretation, modeling approaches, and analysis. RES will also assist in revising and updating the draft risk-informed guidance to reflect lessons learned, as resources permit. Furthermore, RES will assist in addressing recommendations from the June 9, 2004, ACNW letter, such as defining the quality of nuclear material risk assessments, as more knowledge and experience on NMSS risk assessments become available.

In addition, a communication plan has been developed for outreach so that the NMSS management, the staff, and other offices have a clear understanding of NMSS' goals, desired outcomes, and plans for continuing the risk-informed effort.

#### RESOURCES:

As a result of the FY 2006 Planning, Budgeting, and Performance Management process, NMSS concluded that it is necessary to make resources that had been allocated to RTG to other, higher-priority work, including emerging casework. Funding for the RTG in FY 2004 was \$400K and 4 FTE and is discontinued after FY 2004. NMSS will continue its commitment to risk-inform activities through integrating that focus into its day-to-day operations and carrying out these activities in individual programs that are budgeted. RES' budgeted resources to provide assistance for this effort decline from \$100K and 0.8 FTE in FY 2005 to \$0K and 0.8 FTE in FY 2006. Any subsequent program modifications will be implemented through the normal budget process.

#### CONCLUSION:

A systematic risk-informing framework has been developed in NMSS to improve regulatory activities, enhance safety, and perform work in a more effective and efficient way. The staff plans to continue expanding the use of risk-informed methods on materials and waste regulatory activities. The next step is the application of the proposed process, on a case-by-case basis, to resolve key safety and security issues, to inform and involve stakeholders, and to gain insights to ensure that staff's actions are effective, efficient, realistic, and timely. The staff will continue to keep the Commission informed of ongoing activities through the Risk-Informed Regulation Implementation Plan updates.

The Commissioners

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COORDINATION:

The Office of the General Counsel has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objection.

*/RA/*

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Executive Director  
for Operations

Attachments:

1. Overview of a Framework for Risk-Informed Decision-Making in NMSS
2. Potential Resource Savings by Using a Systematic Risk-Informing Process

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\* See Previous Concurrence

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|--------|------------------------|--------------|----------|----------|----------|--|
| OFFICE | NMSS/RTG               | NMSS/RTG     | NMSS/RTG | RES/DRAA | NMSS     |  |
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| DATE   | 09/23/04               | 09/23/04     | 09/23/04 | 09/23/04 | 09/22/04 |  |
| OFFICE | OCFO                   | RES          | OSTP     | NRR      | OGC      |  |
| NAME   | RHesselink*            | CPaperiello* | PLohaus* | SBlack*  | JGray*   |  |
| DATE   | 09/28/04               | 09/28/04     | 09/8/04  | 09/17/04 | 09/27/04 |  |
| OFFICE | D/NMSS                 | DEDMRS       | EDO      |          |          |  |
| NAME   | MVF for<br>JStrosnider | MVirgilio    | LReyes   |          |          |  |
| DATE   | 09/30/04               | 10/06/04     | 10/07/04 |          |          |  |

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