

January 30, 2002

MEMORANDUM TO: Ashok C. Thadani, Director  
Office of Nuclear Regulatory Research

FROM: Martin J. Virgilio, Director */RA/*  
Office of Nuclear Materials Safety  
and Safeguards

SUBJECT: USER NEED - REQUEST FOR RESEARCH ASSISTANCE IN  
DEVELOPING MATERIALS AND WASTE SAFETY GOALS, RISK  
METRICS, AND OTHER METHODS, DATA AND GUIDANCE FOR  
IMPLEMENTING RISK-INFORMED APPROACHES

The Office of Nuclear Materials Safety and Safeguards (NMSS) is increasing the use of risk insights and information (i.e., risk-informing) in the nuclear materials and waste safety arenas, where appropriate. A risk-informed approach would improve the NMSS staff's everyday decision-making process and ensure that decisions are focused on meeting the Agency's strategic goals of maintaining safety, improving effectiveness and efficiency, reducing unnecessary regulatory burden, and improving public confidence. However, to better realize the benefits of a risk-informed approach, two key elements would need to be further developed: (1) safety goals and risk metrics for the materials and waste arenas, and (2) methods, data, and guidance for implementing risk-informed approaches. NMSS request assistance from the Office of Nuclear Regulatory Research (RES) in developing these elements.

### **Background**

In Commission paper SECY-99-100 (Reference 1), the NMSS staff proposed a framework for risk-informing the materials and waste arenas. In the Staff Requirements Memorandum (SRM) for SECY-99-100 (Reference 2), the Commission directed the staff to implement this framework and, as it proceeded with this effort, to develop appropriate materials and waste safety goals and risk metrics. The SRM stated that these goals and metrics should: (a) define what safety means for the materials and waste programs, (b) include a goal on the avoidance of property damage, (c) define critical groups for classes of materials use, (d) give due consideration to existing radiation protection standards, (e) allow for equivalent levels of reasonable assurance of adequate protection across the spectrum of regulated activities, and (f) be consistent with risk-informed approaches to nuclear power plant regulation.

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To begin the process of developing safety goals, the NMSS staff conducted case studies; these were retrospective looks at a spectrum of activities in the nuclear materials and waste arenas. The purpose of the case studies was (a) to illustrate what has been done and what could be done in the materials and waste arenas to alter the regulatory approach in a risk-informed manner, and (b) to establish a framework for using a risk-informed approach in the materials and waste arenas.

The case studies established the feasibility of safety goals for the materials and waste arenas. In general, they demonstrated that safety goals and risk metrics can help the NMSS staff make decisions that are consistent and commensurate with the risk that a device, facility or activity presents. From the case studies, as well as from other risk-related studies in NMSS, insights for materials and waste safety goals were drawn. In December 2001, NMSS issued a report that describes the results of the case studies (Reference 3). This report includes preliminary ideas for materials and waste safety goals and describes the philosophy and process under which they were developed.

The case study report also identifies the gaps in the tools, methods, data, and guidance needed to risk inform NMSS activities. To fully realize the benefits of a risk-informed approach, certain tools, methods, data, guidance, and standards may need to be developed. For example, there is a lack of a robust and simple method for incorporating human factors and estimating human reliability in the wide range of situations and activities encountered and performed by NMSS licensees.

### **Potential Uses for Safety Goals**

The case studies, and other risk-related studies in NMSS, demonstrated that safety goals and other measures of what is safe enough would be useful, and perhaps necessary, in risk-informing certain materials and waste regulatory areas. The following are illustrative examples of how risk information and safety goals may be used in the materials and waste arenas.

(a) Identifying Regulated Applications that are Safe Enough (Maintaining Safety and Reducing Unnecessary Regulatory Burden)

Risk assessment performed across a spectrum of regulated applications can identify those which are safe enough a priori, i.e., purely on a risk basis without consideration of costs. To perform such a cross cutting evaluation it is essential that all relevant risk metrics be identified and quantified, and that quantitative safety goals are available for each metric. One cannot say that an area is clearly safe enough unless it is so with respect to workers, public, prompt fatality, stochastic effects, and all other relevant metrics. Application areas that meet all safety goals by a wide margin are then candidates for considering specific regulatory changes that would result in burden reduction while maintaining safety.

(b) Resource Allocation/Activity Prioritization (Improving Effectiveness and Efficiency)

Risk information can be used to prioritize regulatory activities; i.e., to allocate resources to those activities which are estimated to result in the most risk reduction per unit

resource expended. This approach has been used in risk informing inspections in the reactor arena. However, proper resource allocation is difficult for two reasons: (1) one must estimate both the risk of the current situation, and what the risk would be if one changes the allocation of resources; and (2) current risk models and methods do not model the effect of inspection or licensing activities on risk. For example, if one proposes to reduce inspections in a given area, the risk of the current situation may be estimated, but to estimate the risk under reduced inspections may be difficult. The effect of inspections is indirect, in that it influences licensee behavior. In the reactor arena, the risk impact of operational events is evaluated to target inspection activity in areas that appear to be causing increased risk. It is not clear that such an approach is universally feasible across NMSS. There appears to be a need to target risk-informing allocation methods development on specific areas where it would be most productive.

(c) Exemptions from Regulatory Requirements (Reducing Unnecessary Regulatory Burden)

If it is believed that a regulatory requirement could be eliminated, relaxed, or an alternative method used that would still be acceptably safe; a risk assessment could be performed to demonstrate this. Regulatory Guide 1.174 is an example of the use of quantitative safety goals, together with other guidelines, to permit the staff to evaluate whether such an exemption results in a situation that is still acceptably safe, despite being an increase in risk.

(d) Communicating Regulatory Decisions (Enhancing Public Confidence)

The regulatory approaches in certain NMSS areas are subject to intensive critical review by various stakeholders, who may have influence on the public's confidence and on the ultimate decisions. In such situations, it may be a benefit to have a risk analysis that shows that the established safety requirements address all safety concerns, and that the resulting level of risk meets preestablished criteria or approaches safety goals. The scrutability of risk models and data, together with a quantification of uncertainties provides a form of communication that can be effective with the technical community. In addition, complete risk models provide a context or a basis for answering many questions that arise. The ability of NRC staff to provide cogent answers to such questions provides assurance to the attentive public even when they are not capable of independently judging their technical merit themselves.

### Assistance Needed

NMSS requests RES assistance in the following activities:

- (1) Development of safety goals and risk metrics that would support risk-management decision-making and would assist staff in determining whether an acceptable level of safety is being achieved. The safety goal insights drawn from the case studies, and documented in the case study report (Reference 3), should be the starting point for this effort. To the extent possible, this effort should address the Commission guidance provided in the SRM to SECY-99-100.

- (2) Development of other tools, methods, data, guidance, and standards for using risk information in the materials and waste arenas. These would be needed for the various NMSS regulatory areas (e.g., fuel cycle, industrial uses, spent fuel, etc.) and processes (e.g., rulemaking, licensing, inspection, enforcement).

Please contact Lawrence Kokajko in the NMSS Risk Task Group (RTG) after you and your staff have had the opportunity to review this request. The RTG staff will be happy to meet with your staff to discuss details of our user need, their priorities, and coordinate development of the scope of work for each specific activity.

References:

1. US NRC, SECY-99-100, "Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards," March 11, 1999.
2. US NRC, "Staff Requirements Memorandum - SECY-99-100 - Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards," June 28, 1999.
3. NMSS Risk Task Group and Brookhaven National Laboratory, "Risk Informing the Materials and Waste Arenas: Integration of Case Studies and Related Risk Assessments," Volumes 1 and 2, December 2001.

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