

June 28, 1999

COMMISSION VOTING RECORD

DECISION      SECY-99-100

ITEM:

TITLE:            FRAMEWORK FOR RISK-INFORMED REGULATION IN THE OFFICE OF NUCLEAR MATERIAL SAFETY  
AND SAFEGUARDS

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of June 28, 1999.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission, and the SRM of June 28, 1999.

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Annette Vietti-Cook  
Secretary of the Commission

Attachments: 1. Voting Summary  
2. Commissioner Vote Sheets  
3. Final SRM

cc: Chairman Jackson  
Commissioner Dicus  
Commissioner Diaz  
Commissioner McGaffigan  
Commissioner Merrifield  
OGC  
EDO  
PDR  
DCS

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VOTING SUMMARY - SECY-99-100

RECORDED VOTES

	<b>APRVD</b>	<b>DISAPRVD</b>	<b>ABSTAIN</b>	<b>NOT PARTICIP</b>	<b>COMMENTS</b>	<b>DATE</b>
CHRM. JACKSON	X				X	4/21/99
COMR. DICUS	X				X	5/17/99
COMR. DIAZ	X				X	5/12/99
COMR. McGAFFIGAN	X				X	5/27/99
COMR. MERRIFIELD	X				X	4/16/99

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and provided some additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on June 28, 1999.

## **Chairman Jackson**

The staff approach and framework for risk-informed regulation in NMSS has been well thought out as an overall structure, although the details of establishing and implementing specific risk-informed approaches are left to future implementation steps. The NMSS framework has been patterned after the reactor framework, while appropriately recognizing the need for different safety goals and risk-management strategies in the two programs. I approve of the staff proposed framework, including the joint ACRS/ACNW subcommittee to provide technical peer review. The staff has indicated that an unbudgeted 6 FTE would be reprogrammed from other, as yet, unidentified NMSS efforts in FY 2000. The Planning, Budgeting and Performance Management (PBPM) Process should be used for any reprogramming actions. However, if high-priority activities will be impacted by the FTE reprogramming, I agree with Commissioner Merrifield's request for staff to inform the Commission.

As staff proceeds with this effort, the staff should develop a material safety goal, analogous to the NRC reactor safety goal, to guide NRC and to define what "safety" means for the materials program. The staff should develop this goal through an enhanced participatory process including broad stakeholder participation. The staff also should consider whether critical groups can be defined for classes of material use, consistent with recent Commission decisions in the License Termination Rule (Part 20) and the proposed rule on high-level waste disposal at Yucca Mountain (Part 63). Defining these critical groups will be essential in estimating total detriment (or collective risk) to the population. I would expect that full development and implementation of a material safety goal will have broad ramifications on the use and regulation of radioactive materials by providing a yardstick for measuring the effectiveness of materials regulation in a consistent and defensible manner.

## **Commissioner Dicus**

I approve the staff's proposals subject to the following.

I join Chairman Jackson and Commissioners Diaz and Merrifield in expressing concern about the need to reprogram FTEs from NMSS to proceed with this effort. I would, however, prefer that staff, as early as possible, identify to the Commission NMSS program areas that may be considered as sources for this purpose. This will enable the Commission, at an early stage, to consider the possibilities and provide preliminary guidance to the staff. Using this preliminary guidance, staff may then proceed with development of final recommendations to the Commission in this regard.

One of the important lessons to be learned from the orphan source issue is that the consequences of inadequate NRC regulatory oversight are not limited to health risks. Property damage, in particular, the costs associated with cleanup of property that has become accidentally radioactively contaminated, can run into the millions of dollars per incident. Protection of property is a responsibility of the NRC and is provided for in the AEA and in NRC regulations. The NMSS framework should, therefore, include as a goal, avoidance of property damage and staff should develop appropriate metrics for it.

Staff is to be commended for for well drafted, well thought out approach for this important subject.

## **Commissioner Diaz**

## **Commissioner McGaffigan**

I approve the staff recommendation to begin implementation of a framework for risk-informed regulation of materials uses and I offer the following comments for the staff's consideration.

### *General Comments:*

I share Commissioner Merrifield's concern regarding the potential resource impact associated with reprogramming within the Office of Nuclear Materials Safety and Safeguards to fully support the proposed framework. I also agree with Commissioner Merrifield that the staff should keep the Commission informed of potential delays in or adverse effects to other products identified as high priority by the Commission.

Moreover, I have more fundamental concerns with applying a risk framework across the materials program and they are as follows.

- First, the paper indicates that the first step in implementing the risk assessment framework will be to identify the specific regulatory applications that are amenable to expanded use of risk assessment information and that, as part of the process, consideration will be given to costs versus benefits. In my opinion, cost versus benefit is a very critical factor in the decision making process. It is conceivable that there are materials uses where the benefit from applying risk assessment information for the purposes of reducing risk or regulatory burden is not obvious or is negligible and the associated cost is unacceptable to NRC or its licensees. I would not expect the staff to blindly apply a new risk management strategy in such cases. Rather, the expected payoff of applying a new strategy must be worth the total investment.
- Secondly, it is conceivable that the existing generation of risk assessment tools, which were designed primarily for application to nuclear power reactors and nuclear waste repositories, are inadequate to address the unique and wide variety of risks and contributing factors present in the materials use arena. For example, some materials use systems rely almost entirely on the human/device interface with a minimal or no independent verification system to prevent an accident, e.g., portable industrial devices.
- Third, as the paper points out, the risk associated with reactors derives primarily from low-probability, high-consequence events whereas the risk associated with materials uses and disposal derives primarily from higher probability, low-consequence events. This difference could necessitate the use of different risk goals depending on cost-benefit considerations or other factors that may vary from one materials use to another. The staff should remain ever mindful of this important difference when determining whether a specific regulatory application is amenable to the use of risk assessment information, particularly in cases where its use has been non-existent or extremely limited in the past.
- Finally, unlike the power reactor program, the national materials program includes an Agreement State component that must be factored into the decision making process to avoid duplication, gaps, or conflicts in the national program.

I do not agree with Chairman Jackson's comment that the staff should proceed at this time to develop a materials safety goal to define what "safety" means for the materials program. I strongly believe that developing a materials safety goal is premature due to the lack of staff, industry and Commission experience in this area. Moreover, the use of an enhanced participatory process to define the safety goal would be extremely resource intensive for a program that must divert significant resources from other materials program areas just to support the framework proposed by the staff. In my opinion, the staff should implement the proposed framework, gain experience with applying available risk assessment tools and analyzing outcomes, and conduct further analyses before making any recommendation to the Commission on whether a single safety goal or range of safety goals is appropriate. Hence, this effort would more appropriately be considered a long-range program goal rather than an intermediate one. I would also note that the staff effort to develop a safety goal for the reactor program was resource intensive and has not proven to be particularly useful for industry or NRC. In fact, the reactor safety goal policy statement is currently being considered for revision, an effort that I suspect will prove difficult and controversial. Even NRC's Advisory Committee on Reactor Safeguards (ACRS), who is the foremost advocate for revising the reactor safety goal, in its April 19, 1999 letter to the Chairman, expresses concerns over the time and effort involved in revising the reactor safety goal and developing an overarching safety goal that would apply to all licensees. I also agree with the observation of some ACRS members who would like to see "progress that provides practical benefits" before the scope of the policy statement is broadened and who believe that efforts to develop an overarching safety goal would "divert resources from other more important activities, without sufficient likelihood of near-term results." Clearly, it is premature to make development of a safety goal for the materials program a high priority for the risk assessment program.

*Specific Comments:*

1. Transportation -- The paper states that the staff intends to encourage more risk-informed decision making with the Department of Transportation (DOT **EXIT**) and the International Atomic Energy Agency (IAEA). As part of this effort, the staff should work with DOT and IAEA to revise the current IAEA removable contamination standard of  $4\text{Bq}/\text{cm}^2$  for transportation packages, since it was originally derived for hand-held small packages and not spent nuclear fuel transportation casks, and since it appears to me to go well beyond any health or safety requirement.
2. Clearance -- It is not clear from reviewing the charts in Attachments 2 and 3 which group of materials uses the current clearance rulemaking effort falls into.
3. Part 20 -- The paper states that more restrictive Part 20 limits are being considered for specific activities or sources. I believe any consideration of Part 20 limits must include a look at implementation of the dose limits and methodologies contained in Report No. 60 of the International Commission on Radiation Protection (ICRP). Also, it is clear from the April 1999 First Review Meeting Summary Report of the Convention on Nuclear Safety that the United States is increasingly isolated in not having adopted ICRP 60's recommendations in our rules and practices.
4. Uranium Recovery -- The paper states that the Center for Nuclear Waste Regulatory Analyses (CNWRA) is starting a project to assess the risks associated with in-situ leach extraction of uranium and that the risk insights gained will be used to support risk-informed rulemaking for such facilities. It is unclear how or when the CNWRA's findings will be considered by the staff when addressing any Commission direction that may result from a decision on [SECY-99-013](#), "Recommendations on Ways to Improve the Efficiency of NRC Regulation at *In Situ* Leach Uranium Recovery Facilities" currently before the Commission.

**Commissioner Merrifield**

I approve the staff's three recommendations as outlined in [SECY-99-100](#) to implement a framework for risk-informed regulation of materials issues. This is a complex issue which will require a disciplined approach to resolve. Although I recognize that this is an important issue, I do have concerns about the impact of the resource requirements of this change on the overall budget process within NMSS. This paper recommends reprogramming six FTE from other, as yet, unidentified NMSS efforts in FY 2000. For now, I am comfortable in letting the normal Program, Budgeting, and Performance Management process address the reprogramming. But I want to caution senior management to be conscientious of informing the Commission if this reprogramming delays or adversely affects other products identified as high priority by the Commission.