



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

January 18, 2005

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-04-0182

TITLE: STATUS OF 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 January 18, 2005.

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".

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO

VOTING SUMMARY - SECY-04-0182

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. DIAZ	X				X	11/19/04
COMR. McGAFFIGAN	X				X	1/4/05
COMR. MERRIFIELD	X				X	11/16/04

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 January 18, 2005.

**Chairman Diaz's comments on SECY-04-0182 "Status of Risk-Informed Regulations
in the Office of Nuclear Materials Safety and Safeguards"**

I approve the staff's recommendation to discontinue the biannual report on staff's progress for developing risk metrics, tools, data, and guidance for implementing risk-informed approaches for the materials and waste arenas. I agree with the comments of Commissioner Merrifield. In addition, the staff should consider applying the Risk-Informed Decision-Making Guidance to all planned and emergent regulatory activities within a Division. Using the results staff should identify one or more risk-informed regulatory products that would be tracked in the Operating Plans in each year. 

NOTATION VOTE

RESPONSE SHEET

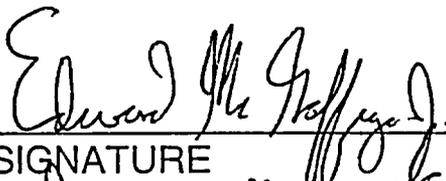
TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MCGAFFIGAN
SUBJECT: **SECY-04-0182 - STATUS OF RISK-INFORMED
REGULATION IN THE OFFICE OF NUCLEAR
MATERIAL SAFETY AND SAFEGUARDS**

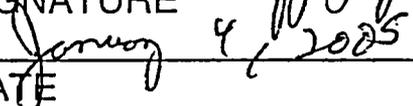
Approved Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached comments.



SIGNATURE


DATE

Entered on "STARS" Yes No _____

Commissioner McGaffigan's Comments on SECY-04-0182

I approve the staff's proposed approach for applying a risk informed approach to selected NMSS activities subject to a significant change in the preliminary draft guidance document the staff plans to use for this process. I also approve the staff's plan to discontinue the biannual progress reports. However, the staff should keep the Commission informed of significant activities and I agree with Commissioner Merrifield that the staff should present an overview of these activities during the annual Commission briefings on the Materials and Waste programs.

I have been dubious about the idea of risk-informing NMSS, especially in the form of safety goals as directed in the June 28, 1999 SRM on SECY-99-100. At that time, I believed, as I do today, that NMSS does not need new safety goals, it has safety goals built into the regulations. I opposed developing or using new safety goals in NMSS which would essentially lower the limits in Part 20 to unreasonable levels. This was the approach taken in the Brookhaven National Laboratory draft report "Draft Safety Goals for the Materials and Waste Arenas," dated November 15, 2002. As I stated in my vote on SECY-03-0126, I believe the safety goal concept outlined in the Brookhaven report is deeply flawed, and the safety goals which they developed are not necessary, realistic or practical.

I am glad to see that staff has diverted from the Brookhaven approach in the new draft guidance document "Risk-Informed Decision-Making for Nuclear Materials and Waste Applications," dated September 24, 2004 and does not use safety goals. I am also glad to see that the Risk Task group is being disbanded. Now, with these two steps I believe NMSS is headed in the direction that I thought risk informing should have taken 6 years ago. However, even with these changes, I still have significant concerns.

The draft decision making document contains extremely low values for risk which are considered by the staff to be "negligible", meaning it would be impossible to justify the cost of developing and implementing a new requirement if it is only protecting against a negligible risk. The risk levels outlined in the report (i.e., 1 mrem/yr) are extremely negligible. Society as a whole considers natural background radiation as negligible and that equates to roughly 300 mrem a year. The definition of what is negligible is situation dependent. So I am concerned that once the NRC defines a specific value for what is considered negligible, like 1 mrem/yr, then any value that is above that number might no longer be considered negligible. I think it would be very difficult for the staff to say that 2 or 5 or 10 mrem/yr is not negligible in most situations and I would not want the staff to be in the position that they would have to make that argument. I believe there are a range of risk values that would be considered negligible depending on the circumstances.

I understand that the staff intends to use these negligible values as a first level screening tool. No matter what the circumstances, 1 mrem/yr would always be considered negligible, and more work would have to be performed to determine if higher values in a particular circumstance were negligible or not. That does not allay my fears that these numbers will be misused. These very low levels could easily be turned into goals that licensees are forced to reach. For example, these values could become default ALARA levels or be used as if they were a regulatory limit. It will take very strong management oversight to ensure that these numbers are used only as a tool to screen decisions or activities in a cost/benefit process.

A perfect example of potential misuse of these values can be found in Appendix F. This appendix attempts to create bins for the risk levels that are considered "Tolerable" or "Marginally Tolerable" risk to be used during inspections. Based on this methodology it appears that a licensee could receive a Yellow finding for "marginally tolerable" risk if a member of the public receives doses far less than 100 mrem/yr. Similar results would apply for occupational doses. Are we saying that Part 20 is wrong? That 40 mrem/yr is so "marginally tolerable" that a licensee should receive a violation? This is unacceptable. This strikes me as NRR-envy at its worst. These risk values should never be used in this type of situation, as a set of values against which violations are written. These values are not regulatory limits and should not in any way be treated as if they were regulatory limits. This is why I will only approve use of this guidance document if Appendix F "Risk-Informing the NMSS Inspection Process" is completely removed. I doubt OGC was consulted much about Appendix F. As I stated previously, I believe it will take strong management oversight of this process to prevent it from being misused. That strong management oversight should have recognized the danger in using these values and should have removed Appendix F before it came to the Commission.

In addition, I have two specific comments concerning the SECY paper itself. The first is in the Conclusion section on page 4. In this section the paper states that the risk-informing framework has been developed to help NMSS resolve key safety and security issues. If I am dubious about risk-informing safety, I am *extremely* dubious about risk-informing security. The security arena is distinctly different than the safety arena and is more consequence-informed than risk-informed. For security, there are no initiating event probabilities, no fault tree probabilities, and in material space, very limited PRA type information. I warn the staff to be very cautious in this area.

The second comment concerns Step 3 in Attachment 1. In this step the paper states that "Proposed new requirements to lower risk, when it is already in the negligible risk region should *normally* not be pursued." Normally? I believe they should never be pursued. If the risk is in the negligible range new requirements to lower that risk should NEVER be pursued. There is no justification for spending valuable resources to make the risk lower than negligible. The purpose of risk-informing our regulations and actions is to help focus resources on the highest risk areas. This in turn means reducing the instances where resources are spent trying to lower already insignificant risk numbers. So, to say that there could be situations where resources would be spent to lower negligible risks, runs counter to the entire initiative.

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NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MERRIFIELD
SUBJECT: **SECY-04-0182 - STATUS OF RISK-INFORMED
REGULATION IN THE OFFICE OF NUCLEAR
MATERIAL SAFETY AND SAFEGUARDS**

Approved Disapproved Abstain

Not Participating

COMMENTS:

See attached comments.



SIGNATURE

12/16/04

DATE

Entered on "STARS" Yes No

Comments from Commissioner Merrifield on SECY-04-0182:

I approve, as modified below, the staff's proposed course of action concerning future efforts to risk inform regulations related to the Office of Nuclear Material safety and Safeguards.

I agree that it is appropriate to phase out the Risk Task Group and implement appropriate risk informed regulatory changes on a case by case basis. Appropriate documentation has been prepared to provide guidance to individual Divisions and Branches on how to proceed in this effort. However, there is still a need for senior management to review the effort as a whole to ensure that the project remains focused on the overall objective. It is not necessary for staff to provide an annual report solely on this subject. However, an overview of this topic should be presented as part of the annual Commission briefings on the Materials and Waste programs.



4/16/04