



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

August 27, 2004

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-04-0107

TITLE: ST. JOSEPH MERCY HOSPITAL: RADIATION
EXPOSURES OF MEMBERS OF THE PUBLIC -
REVIEW OF DOSE RECONSTRUCTIONS

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of August 27, 2004.

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 Vietti-Cook", written over a horizontal line.

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

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VOTING SUMMARY - SECY-04-0107

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. DIAZ	X				X	7/16/04
COMR. McGAFFIGAN	X				X	8/10/04
COMR. MERRIFIELD	X				X	7/27/04

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 August 27, 2004.

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Commissioner Comments on SECY-04-0107

Chairman Diaz

I approve the staff's recommendations subject to the comments below, and the proposed letter to Dr. Henry Royal as edited.

The staff has presented a well-supported analysis of the dose reconstruction of the Saint Joseph Mercy Hospital exposure event. Radiation exposure in the practice of medicine is a sensitive and complex issue, and the lessons learned from the review of this event, as reflected in the staff's recommendations, underscore the necessity of having policies and the supporting processes that balance the needs of patients and their loved ones with verifiable means to demonstrate adequate protection of public health and safety. Therefore, I approve the staff's recommendations, as amplified below.

In carrying out the proposed course of action, the staff should particularly focus on the need to adjust radiation exposure limits in a timely manner. To this end, the staff could consider alternatives other than exemptions (e.g., license conditions) to allow higher public doses in cases similar to that which is the subject of this SECY paper. For example, the staff could consider establishing dose-based "trigger values" that would permit medical licensees to allow elevated exposures to members of the public, concurrent with enhanced radiation monitoring and data recording. In such a graded approach, the highest exposure level could require advanced NRC approval, whereas the lowest exposure level could require NRC notification at the appropriate time.

In addition, the staff should reevaluate the appropriateness of applying the Part 20 occupational dose limit in such cases where higher public doses may be warranted.

Commissioner McGaffigan

I approve the staff's recommendations in the report on the St. Joseph Mercy Hospital case, as modified by Commissioner Merrifield. I agree completely with Commissioner Merrifield that the report has a very defensive tone and I therefore agree with his edits to the report. It was not my intent to make the staff feel defensive about the work that they had performed in this reconstruction. I had, and still have, confidence in the staff and its ability to perform accurate dose reconstructions. After the SNM letter was issued, I saw it as an opportunity for the staff to analyze and consider other opinions and methodologies to determine if there were ways to improve its calculations. I believe this was accomplished and the staff did find a few ways to improve the process. I believe they should move forward with implementing these improvements.

The one area in which I do not completely agree with the Chairman and Commissioner Merrifield is in developing procedures to quickly grant exemptions for increased doses to visitors. I agree that the staff should consider a rulemaking approach for allowing higher dose limits for visitors. However, I think it is very important that the staff be able to grant exemptions

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until the rulemaking is complete. With the incredible number of rulemakings activities that the staff currently has in the queue, I do not think this rulemaking will be completed for many years. For the years between now and when the rule is finalized, I think that it is important for the staff to have a method for quickly making determinations to allow families and other visitors to receive higher doses when there are exceptional circumstances. I do not want to be responsible for keeping a parent away from a dying child simply because the NRC has not gotten around to rulemaking yet. The St. Joseph case is not unique, and the NRC should be able to react quickly and grant an exemption if one is needed until the rulemaking can be finalized.

I also agree with the comments of the Chairman and Commissioner Merrifield on the proposed letter to Dr. Royal subject to my additional edits below.

The 5th paragraph of the Letter to Dr. Royal should be deleted and replaced with the following paragraph.

“As a result of your letter and our subsequent analysis the NRC is considering some changes in procedures and documentation for future events. For example, the present case suggests that licensees need to be reminded that they have the prime responsibility for promptly recognizing that an event occurred, understanding the types of information that will likely be needed to perform accurate dose reconstructions and promptly gathering this information. NRC is considering developing generic information and communications in this area. The staff is also considering developing internal guidance and training for NRC inspectors to more fully document findings, dose estimates, and discussions of alternate points of view in inspection reports. Finally, the staff is considering developing procedures and rulemaking that could be used to permit family members to receive higher doses under exceptional circumstances if certain conditions are met.”

Commissioner Merrifield

I approve with modifications discussed in the following paragraphs the staff recommendations in SECY-04-0107, St. Joseph Mercy Hospital: Radiation Exposures of Members of the Public - Review of Dose Reconstructions. Before I discuss the specific revisions necessary, I will state that the staff paper and recommended letters are too defensive in nature. It was never my intention for the staff to write a rebuttal to the Society of Nuclear Medicine (SNM) or the Advisory Committee on the Medical Use of Isotopes (ACMUI) to defend the specific staff actions in the St. Joseph's Hospital case. My intentions were to use the St. Joseph's Hospital case to evaluate if we should change the manner and methodology for conducting future dose reconstructions. I also wanted a procedure for a dose reconstruction methodology which is made publically available so that both licensees and the general public could better understand how NRC will conduct dose reconstructions. Through these efforts, I had hoped that there could be some convergence on a shared set of best practices. While this effort did not result in such an outcome, I remain hopeful that this objective can still be accomplished with some modifications to the specific staff recommendations.

My vote will be focused on two specific areas: (1) a discussion on the recommendations and

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(2) a discussion of the staff report itself.

Recommendations:

I agree with the staff proposal in recommendation 1 to prepare a generic communication to appropriate licensees to address their responsibilities during an unplanned event. This communication should go further and address the management of an event in progress and conducting dose reconstruction after the event. As part of managing the dose, licensees will need to consider, when appropriate, the issuance of dosimetry to appropriate visitors to allow a more accurate dose reconstruction to be conducted, when necessary. Also, considerations should be given to issuing alarming dosimetry to provide early warning of a problem.

I agree with the staff proposal in recommendation 2 that when the staff conducts a dose reconstruction the staff should adequately document the dose reconstruction methodology in a publically available document. The lack of such documentation was a key reason I requested the development of this report.

I have problems with the staff proposal to develop a process for quickly granting exemptions if certain exposures to family visitors are approaching some limit based on unique circumstances in a specific case. I agree with the Chairman that a different approach should be considered and would support his suggested rulemaking approach and even applying the higher occupational dose limits under limited circumstances for appropriate visitors, particularly when there is a parent/child or other close family relationship.

There is a fourth issue which was not specifically addressed in the staff recommendations but was raised by SNM and the staff agreed with the SNM position. This issue concerns the use of effective dose equivalent as a more relevant measure of exposure than deep dose equivalent. The staff authorized the use of effective dose equivalent in Regulatory Issue Summary 2003-04, but our licensees are still free to use deep dose equivalent in dose reconstructions because that is what is specifically mentioned in our regulations. If a licensee does a deep dose equivalent dose reconstruction, I recognize the need for the staff to also conduct a deep dose equivalent reconstruction for direct comparison to the licensee's analysis. However, under those same circumstances, staff should also conduct a dose reconstruction using effective dose equivalent so that the Commission is better informed on any subsequent enforcement decisions. In addition, publication of our results may encourage licensees to use similar calculations in the future.

I will note however, that although both the staff and the SNM believe that the use of effective dose equivalent is more relevant, there are currently no accepted industry-wide medical practices for effective dose equivalent estimations for circumstances generally present with patient/visitor exposures. What is the staff doing to encourage the development of industry-wide practices and which group should lead this effort (the Health Physics Society or a specific medical society)? The staff should report back to the Commission through the Commission Technical Assistants the status of this effort.

Staff Report Language:

There are several instances where the staff's report becomes too defensive. The report

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chastises the SNM and ACMUI for making inappropriate assumptions but then admits that the original staff analysis is not clear and that the assumptions are probably correct. This occurs on both pages A-8 and A-11. I have attached some edits for staff report. These edits do not change the staff conclusions.

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