

August 27, 2004

MEMORANDUM TO: Luis A. Reyes
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary /RA/

SUBJECT: STAFF REQUIREMENTS - SECY-04-0107 - ST. JOSEPH
MERCY HOSPITAL: RADIATION EXPOSURES OF MEMBERS
OF THE PUBLIC - REVIEW OF DOSE RECONSTRUCTIONS

The Commission has approved the staff's recommendations subject to the comments noted below.

As stated in the paper, the staff should prepare a generic communication to appropriate licensees to address their responsibilities during an unplanned event. Additionally, this communication should take a broader view than what the staff proposed and address the management of an event in progress and collection of potential data necessary for conducting dose reconstruction after the event. For example, as part of managing the dose, licensees will need to consider, when appropriate, the issuance of dosimetry to 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.

(EDO) (SECY Suspense: TBD - staff should provide suggestion)

The staff should focus on the need to quickly adjust radiation exposure limits. As proposed by the staff in SECY-04-0107, development of procedures that could be used to quickly grant approvals of exemption to the dose limit under exceptional circumstances should begin. However, staff should also consider additional methods that address radiation exposure limits for cases such as this (options for staff consideration should include use of enforcement discretion, license conditions, rulemaking, or any other method the staff believes would be an effective and efficient utilization of staff resources). For example, the staff could consider establishing dose-based "trigger values" that would permit medical licensees, as part of managing an event, to allow exposures above the public dose limit to visitors of medical patients, 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 developing these methods, staff should consider the Part 20 occupational dose limit as a starting point and evaluate the risk to public health and safety of moving beyond that dose level. Staff will submit a discussion of the options considered and the staff-recommended course of action for Commission approval.

(EDO) (SECY Suspense: TBD - staff should provide suggestion)

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If a licensee conducts a deep dose equivalent dose reconstruction, it is clear that the staff also should conduct a deep dose equivalent reconstruction for direct comparison to the licensee's analysis. However, under those same circumstances, the staff should also conduct a dose reconstruction using effective dose equivalent. Dose reconstructions performed by the staff should adequately document the dose reconstruction methodology in a publicly available document.

The staff should report back to the Commission through the Commission Technical Assistants on the use of Regulatory Information Summary 03-04 as a guide for an industry-wide medical practice for effective dose equivalent estimations for circumstances generally present with patient/visitor exposures and if there is a need to provide additional guidance to the medical community for estimating effective dose equivalents to visitors. The report should include a discussion of staff efforts taken to date and those recommended for future action to encourage the development of industry-wide practices for calculating effective dose equivalents under the circumstances associated with visitors to medical patients. Staff should also identify potential groups that might lead this effort such as the Health Physics Society or a specific medical society.

(EDO) (SECY Suspense: TBD - staff should provide suggestion)

The Commission has approved the proposed letter to Dr. Henry Royal, as shown in the attachment.

The staff should revise the Review of the Dose Reconstructions in Attachment 1 to SECY-04-0107 as follows:

1. On page A-8, paragraph 1, delete lines 8 through 12 and replace with the following: "Region III's inspection report does not specify the type of dose estimated. Region III did use an approach equivalent to the licensee's approach and calculated a whole body dose, which results in deep dose equivalent. This approach allowed Region III to directly compare its estimate with the licensee's calculations. However, one lesson learned from this event is that our inspector reports should more clearly state the type of dose calculated."
2. On page A-8, paragraph 2, delete the last sentence (NMSS does not ... reasons.).
3. On page A-8, insert a new paragraph after the 2nd paragraph which reads: "We also recognize that there are currently no accepted industry-wide medical practice guidelines for calculating effective dose equivalent doses from point measurements or for situations such as this specific case where the radiation field is neither uniform over the patient's body nor uniformly incident on the patient's body surface. Dr. Marcus and Dr. Siegel have proposed an approach for correcting survey data to obtain an estimate of effective dose equivalent for this specific case. However, NMSS does not agree with the approach proposed by Dr. Marcus and Dr. Siegel for either this specific case or for use generically for two specific reasons."
4. On page A-8, paragraph 3, revise line 1 to read ' ... first reason point to note is that the

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factor'

5. On page A-8, last paragraph, revise line 1 to read 'The second reason is that the survey data'
6. On page A-11, paragraph (4), revise lines 5 through 9 to read ' ... and not on calculations and it is not clear : ~~NMSS notes that Region III's inspection report does not mention deep dose equivalent or total effective dose equivalent, but provides only a dose, without qualification. Although the intended quantity was likely the deep dose equivalent, a question, rather than an assumption, would have been appropriate. It is also unclear how the ACMUI~~

Attachment: Revised letter to Dr. Henry Royal

cc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
CFO
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)

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Revised letter to Dr. Henry Royal

August XX, 2004

Henry D. Royal, M.D.
President
Society of Nuclear Medicine
1850 Samuel Morse Drive
Reston, Virginia 20190-5316

Dear Dr. Royal:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am providing a final response to your letter on the St. Joseph Hospital dose reconstruction. In my previous letter on this same subject dated January 12, 2004, I had indicated that the NRC staff will review the reconstruction prepared by Drs. Carol Marcus and Jeffrey Siegel. I had also indicated that the Advisory Committee on the Medical Use of Isotopes (ACMUI) will also be asked to review that reconstruction, as well as NRC's dose assessments, and to perform its own calculations as necessary. These reviews have been completed, and this letter is to inform you of our conclusions.

This specific dose reconstruction demonstrates the problems encountered when there is very little data directly available from the event to conduct an accurate dose reconstruction. When viewed independently, all three analysis (Drs. Marcus and Siegel, ACMUI, and the staff) make reasonable assumptions and reach different conclusions. The staff's analysis was based on data obtained by interviewing individuals directly involved in the event, however, the data was acquired a considerable time after the event occurred. The other two analyses also have uncertainties, in that there were assumptions about individual behavior and the geometry of the room that did not conform to the reported facts associated with this event. Although the assumptions may or may not be valid, they are opinions and as such are subject to challenge. However, in all three analyses, the calculated exposure received by the individual in this case is well above the regulatory limit.

Based on careful review of the dose reconstruction by Drs. Marcus and Siegel, input from the ACMUI, as well as our staff's extensive calculations, NRC has concluded that the original dose estimate of 15 cSv (15 rem) obtained by NRC's Region III staff is not overly conservative and is within a reasonably plausible scenario. We have come to this conclusion because our reviews showed that Region III staff used an appropriate method to calculate the dose, obtained necessary data by direct and detailed interviews with the exposed member of the public and the hospital staff on duty at the time of the exposures, and confirmed that the information provided separately by the exposed person and by the hospital staff was consistent.

It has not proven possible to resolve the differences between NRC's and the licensee's dose estimates. Both estimates used identical methods of dose assessment, based on the daily dose rate surveys made by the licensee at the patient's bedside. The difference between the two is due to differences in estimated exposure durations for the family member. This difference, in turn, arose from differences in the recollection of the details of the event by the family member during separate interviews with the NRC and the licensee. The details differed in some respects in the different interviews, and were not entirely consistent. This is not

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surprising considering the difficult circumstances for the family member during which the exposures occurred, and also the fact that the interviews took place as much as 3 months after the incident.

The dose reconstructions performed by Drs. Marcus and Siegel and the ACMUI review relied on a calculated dose rate to the family member considering the 285 millicurie source term, instead of using the survey data more directly. NRC has concluded based on its own detailed calculations that this approach carries a larger uncertainty than that based on the radiation surveys. The reason is that there is little numerical data available in this case on which to base an accurate dose rate calculation, and assumptions therefore were necessary to substitute for the missing data. These assumptions were based on what was considered reasonable behavior on the part of the family member, as opposed to information collected from the people involved. Available evidence strongly indicates that the assumptions made do not represent the pattern of exposure that actually occurred. Furthermore, our own calculations show that the radiation fields around the patient were such that relatively small changes in such assumptions could have a large impact on the assessed dose rate. The ACMUI review, in particular, highlighted the variability associated with these dose calculations.

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 that could be used to permit visitors of medical patients to be exposed to doses above the public dose limit under exceptional circumstances if certain conditions are met.

The NRC agrees with you that effective dose equivalent is a more suitable quantity for assessing risk than deep dose equivalent. However, we also recognize that there are currently no acceptable industry-wide medical practice guidelines for calculating effective dose equivalent doses from point measurements or for situations such as this specific case where the radiation field is neither uniform over the patient's body nor uniformly incident on the patient's body surface. We highly encourage the medical industry, perhaps in concert with the Health Physics Society, to develop peer reviewed guidelines for these important dose calculations.

I would like to thank you for pointing out an area of our procedures and documentation that could be improved to better address situations such as this one. Details of the analysis performed by the staff of the various reconstructions may be found in the staff's report to the Commission, available on NRC's Agency-wide Documents Access and Management System (ADAMS), accession number ML041450268 [new number to be assigned to revised document].

Sincerely,

Nils J. Diaz

cc: Simin Dadparvar, M.D.
President, American College of Nuclear Physicians

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