

POLICY ISSUE NOTATION VOTE

June 25, 2004

SECY-04-0107

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

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

PURPOSE:

To report to the Commission the results of staff's reviews of the dose reconstructions for the most exposed member of the public in the St. Joseph Mercy Hospital case, and to obtain Commission approval of the staff's recommendations that stem from insights gained during analysis of this case.

SUMMARY:

Based on its reviews, the staff of the Office of Nuclear Material Safety and Safeguards (NMSS) has concluded that the 15 centisievert (cSv) (15 rem) dose estimated by Region III for the member of the public is the estimate that appears best supported by available data and, based on this data, does not appear to be overly conservative and is probably closest to the true dose.

This conclusion is based on NMSS' determination that Region III used an appropriate method to calculate the dose, obtained the 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 by the exposed member of the public and the hospital staff was consistent. Still, the licensee's data is at variance with parts of Region III's findings,

CONTACT: Sami Sherbini, NMSS/IMNS
(301) 415-7853

leading to a different dose estimate, and it has not proven possible to resolve these differences. The reconstructions proposed by Drs. Marcus and Siegel (supported by SNM) and by the ACMUI were found to be based on reasonable approaches, but the methods used and assumptions made are likely to result in estimates with greater uncertainty than that provided by Region III. The estimates were 1 cSv (1 rem) obtained by Drs. Marcus and Siegel, 3-6 cSv (3-6 rem) obtained by the licensee, 4-9 cSv (4-9 rem) calculated by the ACMUI, and 15 cSv (15 rem) estimated by Region III.

The reconstructions that were reviewed included the alternative dose reconstruction proposed by the Society of Nuclear Medicine (SNM) and prepared by Drs. Carol Marcus and Jeffrey Siegel (Attachment 3); the calculations and report submitted by the Advisory Committee on the Medical Use of Isotopes (ACMUI) (Attachment 5); and the original dose estimates reported by the US Nuclear Regulatory Commission's (NRC's) Region III (Attachment 2).

BACKGROUND:

A hospitalized patient with metastatic thyroid cancer and severely depressed renal function was administered 10.5 gigabecquerel (285 millicurie) ¹³¹I on July 1, 2002, and subsequently died on July 7, 2002. During that period, 20-35 family members were believed to have visited the patient. The licensee estimated that, as a result of their proximity to the patient, about 10-12 of the visitors may have received a dose over the regulatory limit of 0.1 cSv/yr (100 mrem/yr) which was applicable at the time, but less than 0.2 cSv (200 mrem). One close family member who spent a considerable amount of time at bedside was estimated by Region III to have received a dose of 15 cSv (15 rem). The licensee estimated the dose to that person to be 3-6 cSv (3-6 rem). Region III conducted a special inspection of the licensee's facility on October 4-16, 2002. Region III coordinated with NMSS staff during all phases of the inspection, documentation of findings, and assessment of dose, as is normal agency policy for this type of event.

In a December 2, 2003, letter to the NRC Chairman, the SNM President expressed concern that NRC might have been excessively conservative in its assessment of the dose to the family member, and might have overestimated the dose to this family member by at least an order of magnitude. The letter also submitted, for NRC review, an alternative dose reconstruction prepared by Drs. Carol Marcus and Jeffrey Siegel. The reconstruction concluded that Region III may have overestimated the dose to the family member by a factor of up to 17.

The Chairman advised SNM that the NRC staff would review the reconstruction prepared by Drs. Marcus and Siegel; in addition, the ACMUI would be tasked with preparing an independent review of the Region III's dose assessment as well as Drs. Marcus and Siegel's dose reconstruction. ACMUI submitted its report to NMSS on May 14, 2004 (Attachment 4). This paper summarizes the staff's reviews of the reconstruction prepared by the licensee and Drs. Marcus and Siegel, as well as the staff's conclusions based on that evaluation and the independent evaluation performed by the ACMUI.

DISCUSSION:

Based on its own calculations, and after detailed reviews of Drs. Marcus and Siegel's and ACMUI's reconstructions and report, NMSS staff has concluded that Region III's estimate is reliable and as accurate as circumstances permit. The claim that Region III's reconstruction is overly conservative is not supported by the available data. The bases for arriving at this conclusion are presented in detail in Attachment 1 to this paper. NMSS considers Region III's dose estimate of 15 cSv (15 rem), as well as the licensee's estimate of 3-6 cSv (3-6 rem), to be plausible estimates. While both Region III and the licensee used identical methods to estimate the dose, the differences in this case were caused by conflicting reports of what happened. Review of the case led NMSS staff to conclude that Region III's dose estimate is probably closest to the true dose. This conclusion is based on NMSS' determination that Region III used an appropriate method to calculate the dose, obtained the 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 member of the public and by the hospital staff was consistent.

The method used by Region III and by the licensee is based on the assumption that the bedside dose rates measured daily by the hospital staff are representative of the average radiation fields to which the family member was exposed. The justification for this assumption is a statement made by the Radiation Safety Officer (RSO) on duty at the time that each of the bedside measurements was made at the location of the family member's head and torso. The family member would be expected to move from this location during her visit, but observations made by the hospital staff indicated that she sat nearly all the time at the edge of the bed, at the location where the surveys were made, and at times approached the patient much more closely than the survey locations. The dose estimates were obtained by multiplying the dose rate measured on each visiting day by the estimated "stay time" (i.e., the time during which the family member stayed at the patient's bedside) for that day, and adding the daily doses to obtain the total dose.

It is important to stress that the disparity in Region III and the licensee's dose estimates does not represent a range of possible doses, nor does it reflect different levels of conservatism in assessing the doses; rather, these dose estimates were obtained on the basis of two different, and mutually exclusive, exposure scenarios for the period July 2-7, 2002. The family member and members of the staff were interviewed separately by Region III and the licensee. Based on that information, Region III estimated the stay time as 77 hours, starting from July 2 until the patient's death on July 7, while the licensee estimated the stay time as 39 hours, starting from July 5 until the patient's death on July 7. This disparity in stay times accounts for the difference in Region III and the licensee's dose estimate. The accounts provided during the interviews differed in some detail and, in some respects, were inconsistent. However, the stay time estimates in both cases were obtained directly from what the family member and the hospital staff said that the family member did during these visits, and the different estimates reflect different accounts of these activities.

The staff has not been able to reconcile these differences. However, it is not surprising that the different accounts may not have been entirely consistent, since the interviews took place about 3 months after the incident. It is unreasonable to expect that under the circumstances surrounding her visits, the family member would be able to clearly recall what she did during those visits, accounting for each hour of each visit. Region III's estimates of exposure times

were based on detailed accounts provided not only by the family member, but also confirmed by accounts of hospital staff who had observed the family member's activities during her visits, and by the RSO who was on duty between July 2 and July 7, 2002. Thus Region III's dose estimate is supported by the available data. Nevertheless, the licensee maintains that its scenario is more accurate because, it asserts, its interviews were more thorough.

Both Drs. Marcus' and Siegel's and ACMUI's reconstructions viewed the measured dose rates as not being representative of the dose rates to which the family member was exposed. Both approaches used measured dose rates as starting points to normalize calculated radiation fields around the patient. They then postulated a reasonable distance at which the family member would have been expected to sit during her visits, and used that distance to calculate the dose rates to which the family member was exposed.

The methods used by Drs. Marcus and Siegel and by ACMUI to perform their dose rate calculations differed considerably, with the former's tending to be fairly simplified, and the latter's more complex. To calculate dose rates, and in the absence of reliable data on which to base these calculations, both reconstructions assumed, in varying degrees, values for several important parameters that are required to complete the calculations. In addition to these assumptions, both reconstructions also used simplifications in their calculations, to render the calculations manageable. NMSS staff considers that, taken together, these assumptions and simplified methods yielded results that are likely to be much more uncertain than those obtained by Region III and by the licensee. Drs. Marcus' and Siegel's reconstruction led to a dose estimate on the order of 1cSv (1 rem), and ACMUI's calculations yielded an estimate of 4-9 cSv (4-9 rem).

The different dose estimates, although spanning a large range, are not expected to have a significantly different impact on the family member's health. This impact is expected, under any of the dose estimates, to be minimal. In addition, using the lowest estimate of about 1 cSv (1 rem) provided by Drs. Marcus and Siegel still yields a dose that is at least an order of magnitude higher than the regulatory dose limit that was allowed at the time. Enforcement action using Drs. Marcus and Siegel's estimate rather than Region III's estimate, would not be any different. NMSS staff agrees with Drs. Marcus and Siegel, as well as with ACMUI, that attempts should always be made to obtain the most accurate dose estimate possible and justified by the circumstances of the case. In the present case, NMSS staff believes that Region III used an appropriate method to estimate the dose, given the information that was available.

INSIGHTS:

NMSS determined that the results of the inspection by Region III staff, as documented in the associated inspection report, were adequately justified and the report was in accordance with agency policy. However, retrospective consideration of this case suggests that more documentation might have avoided many of the questions and doubts raised by Drs. Marcus and Siegel and by the ACMUI. One of the recommendations proposed in this paper is designed to address this issue.

NMSS believes that timely recognition by the licensee of the potential for exceeding the applicable dose limit in the present case might have prompted appropriate corrective actions and more timely collection of data that might have been needed to estimate doses. A second

recommendation is designed to improve the gathering of data promptly after recognition that an event has taken place.

NMSS staff and ACMUI discussed situations in which it is advantageous for family members to participate in patient care in a manner that will most likely cause the family members to exceed the current 0.5cSv (0.5 rem) limit. A third recommendation is for the staff to develop procedures that would address such situations.

RECOMMENDATIONS:

Based on the insights gained while reviewing this case, as well as on suggestions made by Drs. Marcus and Siegel and by ACMUI, staff proposes the following recommendations for the Commission's consideration. NMSS believes that the methods currently in place to document inspection findings and dose assessments are sound, but may benefit from some minor modifications based on the insights gained from this case. The recommendations are intended to improve performing and reporting dose reconstructions in future cases, and are expected to involve relatively small changes. The staff recommends that the Commission approve the following staff actions:

1. The licensee bears the prime responsibility for recognizing that an unplanned event has occurred, and for accurately assessing doses and other consequences of such an event. Title 10 of the Code of Federal Regulations, Part 20, requires that surveys be made that may be necessary to assess and report doses to workers and members of the public who may be exposed to radiation arising from licensed activities. The licensee is normally the most familiar with the activities that may have led to the event, and also has the most timely access to the data, and should, therefore, be encouraged to develop guidance or other means that (1) will alert them to the fact that an unusual event is occurring or has just occurred, and (2) will ensure that their staff rapidly collect the information that may be needed in a future dose reconstruction. This information would include interviews with the people involved; measurements of distances, source strengths, and radiation fields; bioassay data if the incident involves intakes of radioactive materials; and blood samples for biological dosimetry, if indicated. Supporting documentation, such as calibration certificates for any instruments or sources used; training records; photographs of the equipment and affected areas; and any other information that may help improve the accuracy and reliability of dose assessments, should also be collected.

To assist licensees in understanding this responsibility, the staff intends to issue an appropriate communication alerting licensees to these considerations and suggesting possible approaches for compiling necessary information and data. Achieving this goal should improve the quality of data available in cases requiring dose reconstructions, and should, therefore, result in more accurate and less controversial results.

2. Staff believes that some of the questions by SNM might have been avoided in the present case, if the description of the dose reconstruction had provided more detail. The NMSS staff will review applicable inspection reporting guidance and determine what modifications should be made to better accommodate the special information needs for situations like the St. Joseph Mercy Hospital case. Actions to be considered include presenting all the available data that were used in the reconstruction; describing and

justifying the calculation methods and models used; discussing any assumptions that were found necessary, and the reasons for selecting those assumptions; discussing alternative points of view that are in disagreement with NRC's, e.g., a licensee's assessment; and explaining in the inspection report why, if such is the case, NRC did not accept a licensee's assessment. The staff intends to develop guidance and training on methods to more fully document findings and dose estimates. The staff will also institute procedures for cases involving dose estimates above a trigger level that require higher than normal levels of review or involve significant disagreement between NRC and a licensee. This would be similar to the approach now used in cases of escalated enforcement actions.

3. The staff is considering developing procedures that could be used to quickly grant approval of exemptions to licensees to permit members of the public to be exposed to doses up to the occupational limit, if certain conditions are met. Restricting a member of the public to a limit of 0.5 cSv (500 mrem) in situations where it is important for that person to take part in a patient's care and comfort, may protect against radiation exposure, but the restriction fails to consider the person's overall well-being, and may thus fail to minimize detriment, as defined by the International Commission on Radiological Protection. In that definition, detriment is understood in a wider context than just radiation detriment, and must consider all aspects of the situation, including any non-radiological considerations affecting a person's well-being. The cancer risk to a member of the public at the occupational limit must be viewed in this context as fairly small, in comparison with the emotional hardship, and possibly physical harm, that may result in a situation where meeting the 0.5 cSv (500 mrem) limit, effectively limits the person's ability to provide for a patient's care and comfort. This dose restriction may also place licensees in situations in which they have great difficulty enforcing the limit when a members of the public refuses to observe that limitation.

The staff intends to develop a set of conditions that would be considered sufficient to grant licensees such exemptions, and submit them for Commission approval. Licensees would be required to provide affected members of the public with appropriate dosimetry that would provide a running total dose, thereby permitting close control of exposures and timely adjustments in exposure rates as needed, in order to be granted such exemptions. If approved, the staff would issue a generic communication informing licensees of this policy. No rulemaking would be required because this policy would be instituted as case-by-case exemptions, and the exposures would be required to be carefully controlled and monitored. The exemptions would also be time-limited.

In addition, the staff recommends that:

4. The Commission approve, and the Chairman sign, the proposed letter from the Chairman to Dr. Henry Royal, President of SNM, (Attachment 6) informing him of NRC's conclusions, and of the public availability of NRC's detailed report on this case.

NOTE: The proposed staff actions are expected to be completed within the existing budget, as part of the ongoing efforts to improve program performance, and no additional resources will be required.

COORDINATION:

The Office of the General Counsel has reviewed this Commission Paper and has no legal objections.

/RA Martin J Virgilio Acting for/

Luis A. Reyes
Executive Director
for Operations

Attachments:

1. Staff review of the Marcus\Siegel and ACMUI dose reconstructions
2. NRC Inspection Report
3. Absorbed Dose Reconstruction by Drs. Carol Marcus and Jeffrey Siegel
4. ACMUI Dose Review Subcommittee Charter
5. ACMUI Report
6. Proposed letter from the Chairman to the Society of Nuclear Medicine

In addition, the staff recommends that:

4. The Commission approve, and the Chairman sign, the proposed letter from the Chairman to Dr. Henry Royal, President of SNM, (Attachment 6) informing him of NRC's conclusions, and of the public availability of NRC's detailed report on this case.

NOTE: The proposed staff actions are expected to be completed within the existing budget, as part of the ongoing efforts to improve program performance, and no additional resources will be required.

COORDINATION:

The Office of the General Counsel has reviewed this Commission Paper and has no legal objections.

/RA Martin J. Virgilio Acting for/

Luis A. Reyes
Executive Director
for Operations

Attachments:

1. Staff review of the Marcus\Siegel and ACMUI dose reconstructions
2. NRC Inspection Report
3. Absorbed Dose Reconstruction by Drs. Carol Marcus and Jeffrey Siegel
4. ACMUI Dose Review Subcommittee Charter
5. ACMUI Report
6. Proposed letter from the Chairman to the Society of Nuclear Medicine

ML033520478 *See previous concurrence

OFFICE	MSIB*	NMSS*	MSIB*	IMNS*	OGC*
NAME	S Sherbini	EKraus	TEssig	CMiller	STreby
DATE	05/21/04	05/24/04	05/21/04	5 /27/04	05/27/04
OFFICE	NMSS	DEDMRS	EDO		
NAME	JStrosnider	MVirgilio	MJVirgilio for LAReyes		
DATE	06/04/04	06/25/04	06/25/04		

OFFICIAL RECORD COPY

ATTACHMENT 1

ST. JOSEPH MERCY HOSPITAL
ANN ARBOR - MICHIGAN

RADIATION EXPOSURE OF A MEMBER OF THE PUBLIC
JULY 1-7, 2002

A REVIEW OF THE DOSE RECONSTRUCTIONS PREPARED BY THE
LICENSEE; REGION 111; DRS. CAROL MARCUS AND JEFFERY
SIEGEL; AND THE ADVISORY COMMITTEE ON THE MEDICAL USE OF
RADIOISOTOPES (ACMU)

ATTACHMENT 2

NRC INSPECTION REPORT 030-01997/2002001 (DMNS)
ST. JOSEPH MERCY HOSPITAL

ATTACHMENT 3

ABSORBED DOSE RECONSTRUCTION FOR FAMILY
MEMBER OF 1-131 PATIENT

CAROL S. MARCUS AND JEFFRY A. SIEGEL

ATTACHMENT 4

ADVISORY COMMITTEE ON THE MEDICAL
USE OF ISOTOPES

CHARTER FOR THE SUBCOMMITTEE TO REVIEW
THE DOSE RECONSTRUCTIONS

ATTACHMENT 5

ADVISORY COMMITTEE ON THE MEDICAL
USE OF ISOTOPES

REPORT

ATTACHMENT 6

PROPOSED LETTER FROM THE CHAIRMAN TO THE
SOCIETY OF NUCLEAR MEDICINE