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 gigabequerel (285 millicurie) ^{131}I 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

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)

1.0 INTRODUCTION

A report dated August 15, 2002, was submitted to the NRC by St Joseph Mercy Hospital, Ann Arbor, Michigan, notifying the agency of exposures of members of the public to radiation that likely resulted in doses in excess of the applicable regulatory dose limit of 0.1cSv/yr (100 mrem/yr). This report was followed by reports dated September 11, 2002 and October 1, 2002, containing additional details of the case and providing dose estimates for the exposed members of the public. These reports prompted a special NRC inspection of the facility, which was conducted from October 4 through 16, 2002. The report for this inspection is available to the public on NRC's Agency-wide Documents Access and Management System (ADAMS), accession number ML023440102. In that report, the NRC detailed its findings and its assessment of the dose to the highest exposed member of the public, which was estimated by the NRC to be 15 cSv (15 rem).

In a letter dated December 2, 2003, and addressed to the Chairman of the NRC, the President of the Society of Nuclear Medicine (SNM) expressed concern that the NRC may have overestimated the dose to the highest exposed member of the public in this case by at least an order of magnitude. The letter also provided a dose reconstruction in support of this claim, which had been commissioned by the SNM and prepared by Drs. Carol Marcus and Jeffrey Siegel. In response, the Chairman, in a letter dated January 12, 2004, advised SNM that the staff would review the reconstruction proposed by Drs. Marcus and Siegel, and that the Advisory Committee on the Medical Use of Isotopes (ACMUI) would also be tasked with preparing an independent review of NRC's dose assessment as well as Drs. Marcus' and Siegel's dose reconstruction.

The reviews by the NRC staff and by the ACMUI have been completed, and this report provides NRC's comments and conclusions.

2.0 SUMMARY OF THE CASE

This section provides a brief summary of the case; additional details may be found in the NRC inspection report, which is accessible to the public as indicated in Section (1.0) above.

A patient with metastatic thyroid cancer was admitted to the St Joseph Mercy Hospital in Ann Arbor, Michigan, and was orally administered 10.5 GBq (285 mCi) of sodium iodide-131 (^{131}I) on July 1, 2002. The patient at that time was suffering from significantly depressed renal function. Soon after administration of the dose, the patient's condition deteriorated, and she died on July 7, 2002. On each day during that period, the hospital's radiation safety staff measured the radiation levels at the patient's bedside and at 1 meter from the patient.

The hospital's radiation safety staff took precautions to minimize radiation exposure to the public by not allowing visitors into the patient's room for the first 24 hours after administration of the ^{131}I, after which visitors were allowed into the room. No restrictions were imposed on the duration of the visits, but visitors were instructed to remain behind shields provided by the hospital. A total of about 20-35 family members were estimated to have visited the patient during her hospital stay. On July 5, 2002, after the patient's condition worsened and it became evident that she would not survive, family members were permitted to go to the patient's bedside, bypassing the shields, to visit for the last time.

An estimated 10-12 persons stood or sat close to the bed on occasion during that period, and are thought to have received doses up to approximately 0.2 cSv (200 mrem). The other family members were estimated to have received doses below the dose limit for members of the public of 0.1 cSv/yr (100 mrem/yr). An exception was a close family member who had apparently on many occasions ignored instructions to stand behind the shields provided. That person was observed to be at bedside essentially continuously during the period between July 5 and 7, 2002, when the patient died. Her actions during the period July 2 to July 5 are controversial, and it is uncertain whether she did or did not stay behind the shields. The NRC inspectors' interviews led them to believe that she did not avail herself of the protection provided by the shields, and that her unshielded exposure to the patient started on July 2. On that basis, Region III estimated her stay time at bedside to be about 77 hours, and the resulting dose, based on the bedside radiation survey results, was estimated to be 15 cSv (15 rem). The licensee, on the other hand, concluded based on their independent interviews that the family member did observe shielding precautions during the period July 2 to July 5, and that her unshielded exposure to the patient started on July 5. As a result, they estimated the bedside stay time to be about 39 hours, and the dose, again based on the bedside radiation survey data, was estimated to be 3-6 cSv (3-6 rem). The dose estimates are not linearly proportional to the exposure durations because the radiation fields varied during this time period.

It is difficult now to resolve the difference in the NRC and licensee exposure scenarios, because the interviews took place about 3 months after the incident, and accounts provided by the family member would not be expected to be very accurate; they are known to be inconsistent in some parts. The Region III inspectors are confident that their reconstruction of what actually happened is reliable and as accurate as circumstances permit. A review by NMSS of available data did not suggest any reason to doubt the validity of this position, which is also supported by statements made by the hospital staff, including the radiation safety officer (RSO), who had observed this family member's behavior during the period in question. However, the data also does not provide compelling reasons to reject the licensee's position. It should be noted that the two dose estimates represent estimates based on two different, mutually exclusive, exposure scenarios, and not a range of estimated doses. The principal differences in this case lie with conflicting reports of what happened, and not with the dose reconstructions themselves.

Both NRC's as well as the licensee's dose estimates are based on two premises: that the accounts provided to them by the family member and by the hospital staff are true and accurate to the extent that details can be remembered, and that the bedside surveys represent the average radiation fields in which the family member was exposed during her bedside visits. The survey data, which was obtained by the RSO on duty during this period, was stated by the RSO to have been made at the location where the daughter was observed to sit during her visits, and in the vicinity of her head and torso. One may question the validity of the accounts on which the dose estimates are based, but NRC is unaware of any reliable information that would prompt reassessment of its position. In addition, the lack of data on which to base any reliable, detailed, theoretical modeling of the radiation fields around the patient support the approach to dose assessment use by both Region III and by the licensee.

NRC recognizes that its dose estimate may be high. On the other hand, this estimate does not take into account activities engaged in by the visitor that likely contributed a significant dose. It

was established during interviews with hospital staff that the family member actively participated in patient care, such as by provided her with food and drink, taking part in bathing and dressing her, and providing hygiene and comfort services. The participation was apparently triggered by the family member's dissatisfaction with the care being provided by the hospital. All of these activities would have brought the family member into much closer contact with the patient than "bedside", and would have placed her in radiation fields that may have exceeded 1 cSv/hr (1 rem/hr). The contribution from these activities were not included in the 15 cSv (15 rem) estimate because there is no data available that would have permitted reliable estimation of its magnitude. If such a contribution was significant, then the 15 cSv (15 rem) estimate may be on the low side of the true dose. In addition, it was discovered that the family member had been sitting during some of her visits close to an unshielded urine bag containing ^{131}I-contaminated urine, and that the radiation fields from that bag were significant. There is no data available to quantify this contribution to the family member's dose, however, and it was therefore not included in the 15 cSv (15 rem) estimate.

3.0 COMMENTS ON DRS. MARCUS' and SIEGEL'S DOSE RECONSTRUCTION

In the following discussion, the close family member who received the highest dose will be referred to as the "visitor" for brevity. Drs. Marcus's and Siegel's dose reconstruction starts with the premise that the survey data described by the hospital staff as having been made at "bedside" should not be used directly in dose assessment because bedside is not a well-defined location. Instead, the authors believed that the dose estimate should be based on calculation of the dose rate to which the visitor was exposed. The reconstruction, however, does not discuss why it is important to know the exact position of the survey relative to bedside if the surveys were made at the visitor's exposure location, as stated by the RSO on duty at the time.

To calculate the dose rate to which the visitor was exposed, the reconstruction used the dose rate measurement at 1 meter made soon after administration of the ^{131}I, which was 0.04 cSv/hr (40 mrem/hr), as the starting point for the assessment. Using this 1 meter reading, together with the inverse square law[1], the distance at which a dose rate of 0.4 cSv/hr (400 mrem/hr) would be measured was calculated to be 31.6 cm. The 0.4 cSv/hr is the "bedside" dose rate measured at that time. The authors then make the assumption that the visitor's distance of closest approach, or bedside, was realistically somewhere between 31.6-100 cm, with an average distance of 65.8 cm. Again using the inverse square law, the authors estimated that the dose rate at 65.8 cm is a factor of 4.3 lower than that at 31.6 cm, and therefore that NRC's dose estimate, which was based on the bedside measurements, must be high by that factor.

The authors then went on to note that they had re-enacted the bedside situation and concluded that the centerline-to-centerline distance between the patient and the visitor must have been in the range of 65-70 cm. They then concluded that the visitor must have sat at a distance in the range of 65-100 cm, with an average of 82.5 cm. Again using the inverse square law, the dose rate at 82.5 cm was estimated to be a factor of 6.8 lower than that at 31.6 cm, and hence NRC's dose estimate was high by that factor.

[1] The inverse square law states that the intensity of the radiation field from a point source in a vacuum decreases as the square of the distance from the source.

The reconstruction also identifies what it believed to be errors that the NRC committed and factors that NRC neglected to take into account. Together with the factor of 6.8 noted above, these additional items led the authors to conclude that NRC had overestimated the dose to the visitor by a factor of 17. The following comments consider each of the items raised in the reconstruction as weaknesses or errors in NRC's approach, and point out the reasons NMSS does not entirely agree with them and therefore with the conclusions based on them.

3.1 USE OF THE BEDSIDE SURVEY DATA

One point that should be noted is that the reconstruction used the radiation field at the mathematical average of the assumed range of distances as representative of the mean radiation field to which the visitor was exposed. However, the radiation field changes non-linearly with distance, and for such a function, the field at the arithmetic mean distance is not representative. A more appropriate mean value to use in this case might be the geometric mean. The geometric mean is closer to the patient than the arithmetic mean, and the dose rate at that distance would therefore be higher than that calculated at the arithmetic mean distance. It should also be noted that use of the mean distance in this manner to estimate dose implies that the visitor spent equal amounts of time at various distances within the specified range, since the average dose rate was not time-weighted. Data obtained from interviews with the visitor and the hospital staff indicate that this is not a valid representation of the actual situation.

Another point to note is that distances in the reconstruction, such as 31.6 cm, 65.8 cm, and 82.5 cm, are given to the nearest millimeter. Although valid mathematically, NMSS staff believes that this practice may lead readers to conclude, erroneously, that the analysis was done to a much higher level of accuracy than was in fact the case. These numbers are rough estimates at best, and one significant figure is all that can justifiably be used in this type of analysis.

A third point that should be noted is that the factors of 4.3 and 6.8 derived by this method are based on data measured soon after administration of the ^{131}I, at which time the activity was in the patient's stomach. However, the activity would soon be taken up into the blood and distributed in the body's organs and tissues. This would change the radiation fields around the patient, and the factor derived for the first day may no longer be valid, and should therefore not be applied to the dose estimate for the entire exposure period without demonstrating the validity of such an approach. The reconstruction did not show how that factor would be expected to change with time, nor did it demonstrate that the factor can be considered approximately constant. It is noted here that the visitor did not receive any exposure during the first 24 hours after administration of the ^{131}I, which is the period for which these factors were calculated.

The use of the inverse square law in a field as complex, and close to a source of radiation as large, as that in the present case is also very questionable, and will provide invalid dose estimates. The inverse square law is strictly applicable only to point sources in a vacuum. It may serve as a rough approximation in air when volume sources are involved, as in this case, but only at distances large enough that the volume source appears as essentially a point. Conventionally, the inverse square law is considered not to be applicable at distances less than about 10 times the largest linear dimension of the source. For a source distributed in the stomach, this would mean a distance of not less than about 2 meters. This distance becomes

larger when the activity is distributed in the body. It should not be used at bedside, as was done in this reconstruction, because it will produce incorrect estimates.

NMSS staff conducted a series of Monte Carlo calculations to determine the shape of the radiation fields around the patient. The Monte Carlo transport code MCNP, Version 5, was used (1). This code was developed and is maintained by the Los Alamos National Laboratory (LANL). The patient was modeled by the Medical Internal Radiation Dose (MIRD) anthropomorphic phantom (2), which was developed at Oak Ridge National Laboratory (ORNL). The phantom contains all the important tissues, organs, and bones in the human body, and has been updated by NRC based on recent data published by ORNL.

Drs. Marcus' and Siegel's reconstruction applied its analysis to the survey data taken soon after administration of the ^{131}I, at which time the activity would be located in the stomach. The Monte Carlo calculations carried out by NMSS therefore uniformly distributed the ^{131}I activity in the stomach contents. Dose rates were calculated at various distances from the patient along a transverse plane passing through the center of the stomach. The results are shown in Figure (1), together with the dose rates calculated using the inverse square law. The inverse square curves were generated using distances of 1.0 and 1.2 meters from the source, which was taken to be at bedside. The MCNP calculations were made for the left side of the patient, which was necessary because there is a considerable difference between the radiation fields on the left and right sides of the patient when the activity is in the stomach. The visitor sat on the left side of the patient.

The two inverse square curves highlight the fact that the particular inverse square curve obtained is sensitive to the assumed position of the source with respect to the survey location. The point at which a dose rate of 0.4 cSv/hr (400 mrem/hr) would be expected, according to these curves, is at about 30 cm from the edge of the bed for the lower inverse square curve, and at about 40 cm from the edge of the bed for the upper inverse square curve, assuming the source is at the edge of the bed. The curves show dose rates close to the edge of the bed that are well into the cSv/hr (rem/hr) range. Other curves could be obtained by changing the position of the source or of the "1-meter" reading location, neither of which are known exactly in this case.

In addition to its sensitivity to the exact location of the "1-meter" survey with respect to the source, the inverse square law is not valid close to a volume source, in this case the patient, and the two curves give incorrect results at all distances within a few meters of the patient, with the error becoming larger at closer distances, such as bedside. The MCNP dose rate curve shows a very different distribution from that predicted on the basis of the inverse square law, and illustrates the inapplicability of that law in this case. The dose rate at the edge of the bed predicted by the MCNP curve shown in Figure (1) is about 0.45 cSv/hr (450 mrem/hr), which is consistent with the reported "bedside" dose rate at that time of 0.4 cSv/hr (400 mrem/hr). Other MCNP curves could have been obtained by making small changes in the assumptions that went into the calculations.

The above considerations show that attempts to calculate the dose rate to the visitor, even using sophisticated Monte Carlo techniques, involve large uncertainties because of the absence of sufficient data to accurately model the radiation fields around the patient and at the location of the visitor. Use of the inverse square law compounds these uncertainties to the

point where the results must be viewed as only qualitative, order of magnitude estimates.

NMSS does not disagree with the statements in Drs. Marcus' and Siegel's report regarding what might be considered reasonable patterns of behavior and reasonable distances at which a visitor may have sat when visiting the patient. Region III determined during its inspection that the visitor's behavior was significantly different from the scenario postulated in Drs. Marcus' and Siegel's report as reasonable. Region III has also determined that, although the distance at which the "bedside" measurements were made was not measured, the hospital staff who made the measurements stated that the locations of these measurements were selected partly because they were the locations at which the visitor was observed to sit at bedside during her visits. The staff, including the RSO on duty at the time, stated that the surveys were made at the location of the visitor's torso and head. It is NRC's judgement that this type of information is more reliable as a basis for dose assessment than the use of the dose rate at 1 meter on the day of administration, the inverse square law, and assumed ranges of distances at which the visitor would reasonably have been expected to sit. Because of these considerations, NMSS views the factors of 4.3 and 6.8 calculated in Drs. Marcus' and Siegel's report to be subject to large uncertainties, and should not be used as reliable indicators of dose.

It should be noted that the bedside dose rate measurements were also used by the hospital radiation protection staff in making their own assessments of the dose to the visitor, in a manner identical to that used by Region III. Although the hospital's dose estimate of 3-6 cSv (3-6 rem) is much lower than the 15 cSv (15 rem) calculated by the Region III, the disagreement is caused by differences in stay time estimates; the dose rates used in both calculations were the same.

3.2 FAILURE TO CORRECT THE SURVEY RESULTS FOR DECAY AND AN ERROR IN THE SURVEY DATA

Drs. Marcus' and Siegel's report states that the survey data should have been decayed to account for exponential decay with an apparent 3.1-day half-life before being used in the dose assessments. The report also stated that "there is an obvious mistake in the dose rate on Day 4, which cannot be the same as it was on Day 3." The results of the daily bedside and 1 meter surveys made by the hospital staff during the patient's stay are shown in Figure(2). The figure shows that, although there is a general trend of decreasing dose rates, the trend is neither constant nor exponential, and is not the same for the bedside and the 1-meter readings. The decrease is uneven, and the bedside readings stabilize on days 4 and 5. An exponential decay would be represented by a straight line with negative slope in Figure (2). A half-life assignment is appropriate for an exponential function, but should clearly not be assigned to the pattern shown in Figure (2).

Regarding the corrections for decay, assuming that the 3.1 day half-life does in fact reflect exponential decay, it can be shown that the difference in dose assessed over a 12-20 hour period with and without decay correction is less than 10 percent. This is probably the worst case situation, because the surveys were not all made at the beginning of each exposure period, and some were made late in the day. The actual decay correction will therefore be less than 10 percent.

NMSS, however, does not believe that the observed pattern of dose rate variation with time is due mainly to decay or excretion. This is partly because the radiological half-life of ^{131}I is about 8 days, and therefore cannot account for the observed changes. In addition, the patient's renal function was severely depressed, and she was therefore not excreting the activity at a rate that would account for the observed changes, nor for the pattern of change. NMSS suspected that the observed changes in dose rate were due mainly to a re-distribution of activity in the body, which started in the stomach following ingestion, was absorbed into the blood, and was then distributed amongst the organs and tissues in the body. This distribution would be affected at least in part by the distribution of the metastatic cancer cells. The differences in the two observed patterns of change in measured dose rates shown in Figure(2) are due partly to the fact that the exact survey locations with respect to the patient probably varied somewhat from day to day, but also because the readings at bedside are much more sensitive to the details of the distribution of activity in the body than they are at 1 meter. The bedside readings would be expected to respond to changes in this distribution in a manner that is different from the readings at 1 meter.

To verify this hypothesis, NMSS performed a series of Monte Carlo calculations, with each set of calculations being performed with the radioactive material located in a different organ or tissue. All calculations were performed using the same total ^{131}I activity. The results are shown in Figure (3). The calculations show the radial distribution of dose rate in a transverse plane through the center of the stomach and at a radial distance of 35 cm from the long axis of the patient. A different set of curves would have been obtained if different transverse planes were used, but the trends would be similar.

The curves clearly show that changes in the distribution of activity in the body have a very large impact on the radiation field outside the body. For example, at an angle of -90 degrees, which corresponds to the left side of the patient, the dose rate falls from about 0.5 cSv/hr (500 mrem/hr) when the activity is in the stomach, to 0.25 cSv/hr (250 mrem/hr) when it is uniformly distributed in the torso, such as in the blood pool, to about 0.05 cSv/hr (50 mrem/hr) if the activity is located in the liver. In other words, moving the activity from the stomach to the liver changes the dose rate at this location by an order of magnitude. The dose rate may also rise after it had fallen if the activity moves from the torso to the ribs and arm bones. The distributions shown in Figure (3) are idealized in that it is unlikely for all of the radioactive material to concentrate in one tissue or organ. The actual distribution would most likely be a distribution amongst a number of tissues and organs. However, the figure clearly shows that the observed changes in bedside dose rates with time were not due mainly to decay but to re-distribution. Decay would have an impact, but it would be secondary in comparison. It is therefore unwarranted to assert that the survey data contain an error, nor is it warranted to make the suggested decay corrections, which are in any case very small. The change in dose rate with time was taken into account in Region III's calculations by using the daily survey data on each day to assess the dose received on that day. The decay effects were stated in the Marcus/Siegel reconstruction to account for an NRC dose overestimation by a factor of 1.5, but based on the above considerations, NMSS believes that this factor is much smaller, and is probably very nearly one.

3.3 FAILURE TO ASSESS THE TOTAL EFFECTIVE DOSE EQUIVALENT INSTEAD OF THE DEEP DOSE EQUIVALENT

Drs. Marcus' and Siegel's dose reconstruction states that the effective dose equivalent is a more relevant quantity in assessing risk to a person than is the deep dose equivalent. To obtain the effective dose equivalent, the reconstruction applied a correction factor of 0.6 to NRC's dose estimate, and concluded that NRC's dose estimate is therefore high by a factor of 1.7 (1/0.6). The factor of 0.6 was obtained from work published by Dr Siegel on patient release after administration of ^{131}I (4). It is based on the observed ratio of the dose rate measured at 1 meter from patients after administration of ^{131}I to the calculated dose rate expected from such patients. It is interesting to note that the authors of the reconstruction assumed that the dose estimate shown in Region III's inspection report was a deep dose equivalent, even though the report does not state that, nor does it specify the type of dose it estimated. Although it is likely that the deep dose equivalent was the intended quantity, it would have been appropriate to raise the issue as a question rather than a statement of fact.

NMSS agrees that the effective dose is a more suitable quantity for assessing risk than the deep dose equivalent, and has in fact provided guidance to its licensees to encourage the use of effective dose rather than deep dose equivalent whenever doses are calculated, such as in this case. Such guidance was provided in NRC's Regulatory Issues Summary (RIS) 2003-04, which is accessible using NRC's ADAMS system (ML030370122). In that RIS, NRC advised its licensees that when dose is calculated, rather than measured using personnel dosimetry, the effective dose equivalent rather than the deep dose equivalent should be used in calculation of the total effective dose equivalent (TEDE). NMSS does not, however, agree with the approach used in Drs. Marcus' and Siegel's report for correcting the survey data to obtain an estimate of the effective dose equivalent for the following reasons.

The first point to note is that the factor of 0.6 is a mean value that has a large uncertainty associated with it. Dr Siegel's published report lists the factor of 0.6 as having a range of 0.37 - 0.9. In addition, the data in this published work was based on patients administered ^{131}I for non-Hodgkin's lymphoma in the form of ^{131}I-tositumomab. There is no reason to suppose, however, that the distribution of activity in such patients, and therefore the radiation fields outside of these patients, would be the same as that for patients with metastatic thyroid cancer and depressed renal function administered sodium-^{131}I, or that the factor is applicable to this particular patient. In addition, the location of the dose rate measurements with respect to the patient may not be the same in the two situations; in one case the survey was from the front of the patient, in the other from the side. Finally, the factor of 0.6 was determined using the theoretical dose rates calculated at 1 meter assuming the patient to be adequately represented by a point source. This may be acceptable for patient release, but it is not for this situation, where the visitor sat much closer to the source than 1 meter. It therefore appears that the factor of 0.6 assumed to apply in this case may not be appropriate, and should not be used to estimate the effective dose rate from the survey data.

The survey data are reported in units of millirem per hour, but NRC does not have the information necessary to determine with confidence the quantity for which the survey instrument was calibrated. Most survey instruments are still calibrated to indicate the exposure rate in roentgens per hour (R/hr), and for purposes of this analysis, it will be assumed that this was the case for the survey instrument used to make the surveys. The conversion from R to effective dose is easily made using published dose coefficients. Using these coefficients and assuming the survey data was in units of R/hr, the effective dose per R, at the photon energies emitted by ^{131}I, is found to be about 0.93. Therefore, using the exposure rate meter readings as an

indicator of effective dose rate will overestimate that dose by a factor of about 1.07 (1/0.93), or essentially 1, rather than the factor of 1.7 indicated in the Marcus\Siegel report. If the meter was in fact calibrated to read millirem per hour directly, then the factor of 1.07 would be much smaller, and probably equal to one. It should be pointed out that this analysis is based on two assumptions: that the visitor was exposed in a more or less uniform radiation field over her body, incident on the front of the body, and that the survey data was taken at a location that was representative of the average radiation field to which the visitor was exposed. Interviews with licensee personnel, including the RSO, indicated that the survey data is representative of the dose rates to which the visitor was exposed. The radiation field, however, was probably not uniform over the visitor's body because of her proximity to the source of radiation. The effect of this non-uniformity cannot be determined because it depends on the degree of non-uniformity, the shape of the radiation field, as well as the exact relationship between the survey location and the visitor's body. The effective dose may therefore be higher or lower than the survey results suggest, but the difference in this case is probably not large.

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3.4 CONCLUSIONS

The scenario and arguments presented in Drs. Marcus' and Siegel's reconstruction are quite reasonable, and may be viewed as representing a realistic description of the behavior of a typical visiting family member. However, the information available to NRC indicates that the actual behavior was quite different from that described in the reconstruction, and was, in some respects, atypical. The approach used in the reconstruction is dependent on the ability to calculate dose rates very close to the patient, to compare these with the measured values. NMSS staff believes that the calculational methods used in the reconstruction were not adequate to permit reasonably accurate calculations of these dose rates, and the results of such calculations therefore probably contain large uncertainties.

4.0 ACMUI CALCULATIONS AND RECOMMENDATIONS

4.1 DOSE RECONSTRUCTION

The ACMUI took a position similar to that in the Marcus/Siegel reconstruction, namely that the survey data should not be used directly, and that a dose rate should be calculated. As in the Marcus/Siegel case, the ACMUI did not indicate why the bedside survey data should not be used directly in estimating dose. The calculational methods used were different from those in the Marcus/Siegel reconstruction, and were, in many respects, much more sophisticated and appropriate for this case. However, simplifications were made that likely introduced large uncertainties in the dose estimates.

In estimating the dose rate, the ACMUI plotted the bedside survey data as a function of time. Monte Carlo calculations of dose rates were made at different distances from the patient, raging from 15 cm to 31.6 cm. The distance that best fit the survey data, using a decay half-time of 3.26 days, was found to be 20 cm, and on that basis it was concluded that the bedside surveys must have been made at that distance from the patient. It was next reasoned that the visitor sitting at bedside probably had her forearms about 37 cm from the patient, based on the width of a typical hospital bed, and the dose rate at that distance was calculated to be 0.65 of the dose rate at 20 cm. This led to the conclusion that NRC's dose estimate, which was based on the survey data, is high by a factor of 1/0.65, or about 1.5. Multiplying NRC's dose estimate of

15 cSv (15 rem) by 0.65 gives a dose estimate of about 10 cSv (10 rem). In these calculations, the patient was modeled as a water-filled cylinder with activity uniformly dispersed in it.

In addition to the factor of 1.5, ACMUI also stated that the survey data should have been decay corrected, and the absence of this correction led to overestimation of the dose by NRC by an additional factor of 1.1. ACMUI concluded that NRC's dose estimate is therefore 1.7 times too high, and the dose estimate should therefore be about 9 cSv (9 rem) rem rather than 15 rem. This is ACMUI's upper limit of their estimated dose range.

ACMUI also assumed that the visitor stood behind shields during her visit between July 2 and July 4. The shields were 1" of lead and, taking this shielding into account, further reduced the dose estimate from 8.8 cSv (rem) to 4.3 cSv (5.6 rem), rounded to 4 cSv (4 rem). ACMUI's final estimated range is 4-9 cSv (4-9 rem).

ACMUI's methods and approach were found by NMSS staff to be sophisticated and appropriate, but several areas of concern were noted, and these are discussed below.

(1) The modeling assumed that the ^{131}I activity was uniformly distributed in the patient's body throughout the period in question. This may not be a valid assumption, and the results of the calculations based on it may therefore contain excessive uncertainties. This is particularly important because the calculations were performed for locations that are very close to the patient. These are the locations that would be expected to be very sensitive to the details of this distribution. NMSS's more detailed Monte Carlo calculations, which permitted placement of the activity in any organ or combination of organs, showed that the assumed distribution of the ^{131}I in the organs has a very significant effect on the radiation fields around the patient. This is clearly shown in Figure(3).

(2) The assumption of a 3.2 day half-life in the calculations may overestimate this effect on the calculated dose rates. As discussed in Section 3.2 above and illustrated in Figures(2) and (3), the apparent changes in survey results may not have been due mainly to decay but most likely resulted from a re-distribution of activity in the patient's body. Since the details of this distribution are not known, it is difficult to reconstruct an accurate profile of the dose rate as a function of time. Taking these changes into account is also not possible if the patient is modeled as a water-filled cylinder with uniformly distributed activity. The changes in dose rate from day to day were taken into account in Region III's assessment by using each day's survey results with that day's occupancy time to estimate the dose for that day. Any deviations due to changes in between surveys were quite small, as was shown in Section 3.2, and corrections for this effect are negligible. Assuming a constant decay half-life of 3.2 days over the exposure period may lead to errors in the result, because the dose rate did not decrease uniformly in this manner, as shown in Figure (2) above.

(3) The ACMUI's assumption that the visitor remained behind the shields during the period of July 2 to July 4 is reasonable but conflicts with information available to the Region III inspectors. The inspectors' reconstruction of events is supported by statements made by several hospital staff, including the RSO and patient care staff on duty during the

period in question. ACMUI does not acknowledge that there is an equally strong alternative scenario, and that there is little basis to make a choice between the two.

(4) The ACMUI reconstruction assumed that Region III estimated the deep dose equivalent in assessing the dose to the visitor, stated that the Region and the licensee should have reported effective dose equivalent instead of deep dose equivalent, and concluded that had this been done, the dose estimate would have been reduced by as much as a factor of 4. The factor of 4 was based on surmise and not on calculations. 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 arrived at the factor of 4 reduction in using effective dose in place of deep dose equivalent.

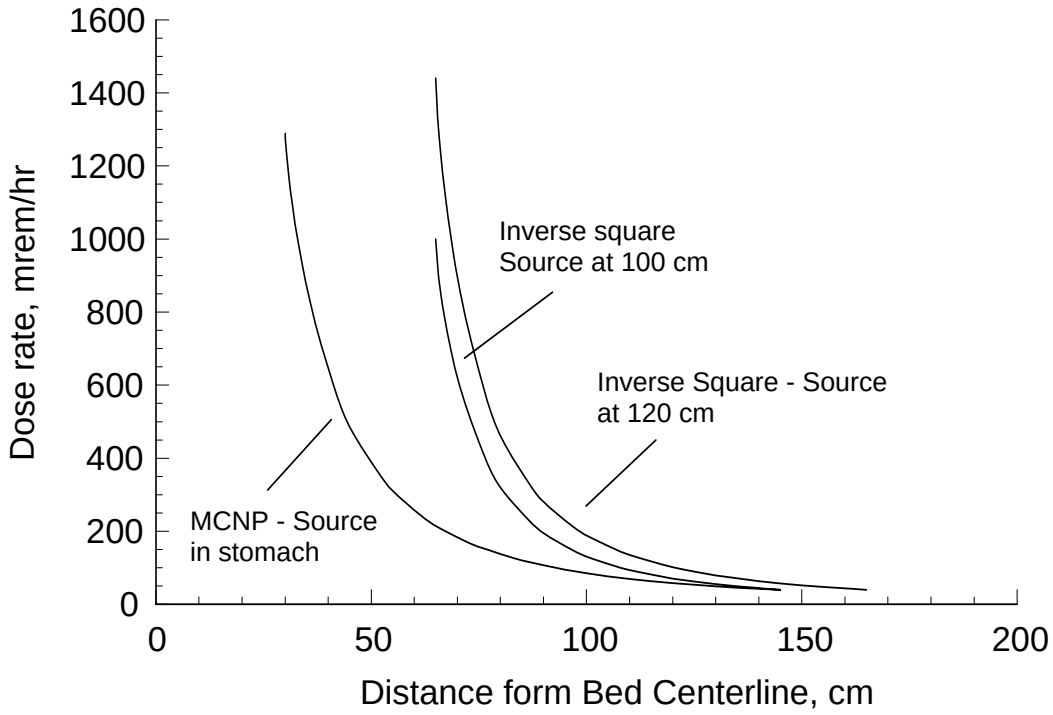
Based on published data (3), the deep dose equivalent at the ^{131}I photon energies is about a factor of 1.3 higher than the effective dose for anterior-posterior exposure in a uniform field. The field in this case was probably not uniform, and therefore the deep dose equivalent would probably be more than a factor of 1.3 higher than the effective dose. However, because the exact relationship of the survey location with respect to the visitor's body is not known, it is not possible to determine if using the survey data as a surrogate for the deep dose equivalent or for the effective dose will lead to over- or under-estimation of the effective dose. If the body was closer to the source than the survey location, then the effective dose will be underestimated. In this case, neither the survey location, nor the position of the visitor with respect to the source are known. What is known is that the surveys were made at the location where the visitor sat, and at a position that corresponded to that of the visitor's torso and head. It is therefore a good approximation to use the survey results as providing reasonable estimates of the visitor's effective dose. The uncertainty in this approach is likely to be much smaller than attempting to determine the relationship between the survey data, the deep dose equivalent, and the effective dose without knowing the location of the surveys or of the visitor, nor the shape of the radiation field at these locations.

The ACMUI method and assumptions were found by NMSS staff to be quite reasonable. However, as in the Marcus/Siegel reconstruction, the method depends on the ability to accurately calculate dose rates very close the patient. The ACMUI Monte Carlo calculations, although much more appropriate in this case than use of the inverse square law, involved simplifications that, in the view of NMSS staff, introduce significant uncertainties in the results. The assumed location of the visitor with respect to the patient is also likely to involve large uncertainties.

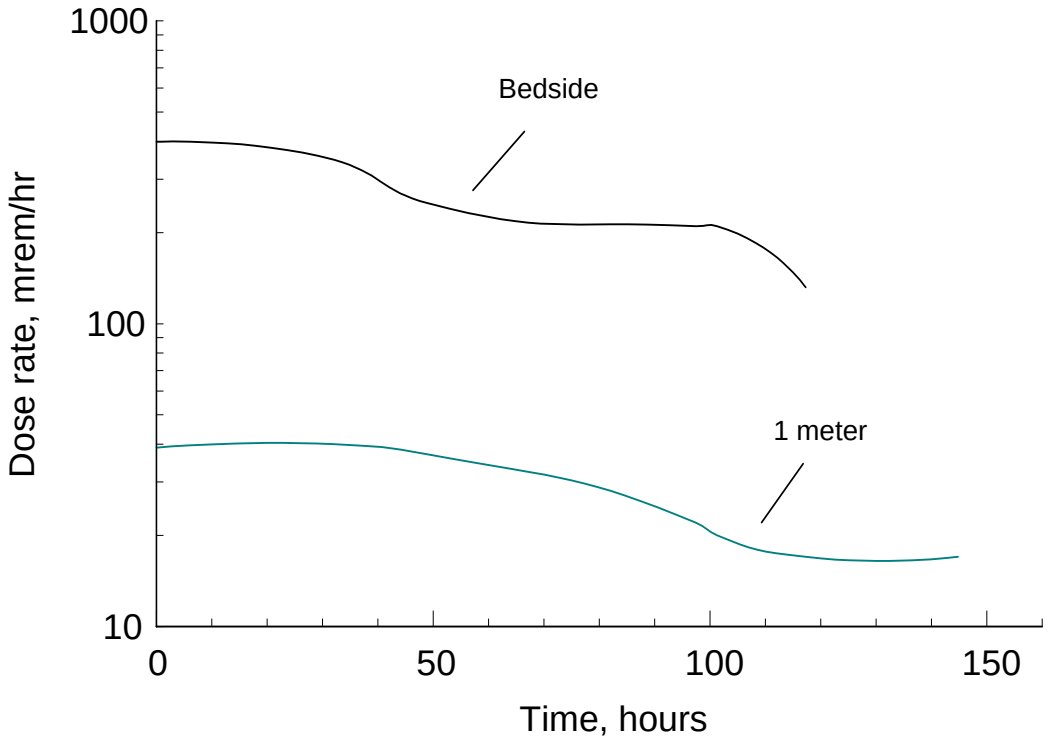
4.2 CONCLUSIONS

The approach taken by the ACMUI to estimate the dose to the visitor were found by NMSS staff to be reasonable and valid. However, the approach depended on the ability to calculate dose rates very close to the patient. It also depended on an assumed location for the visitor with

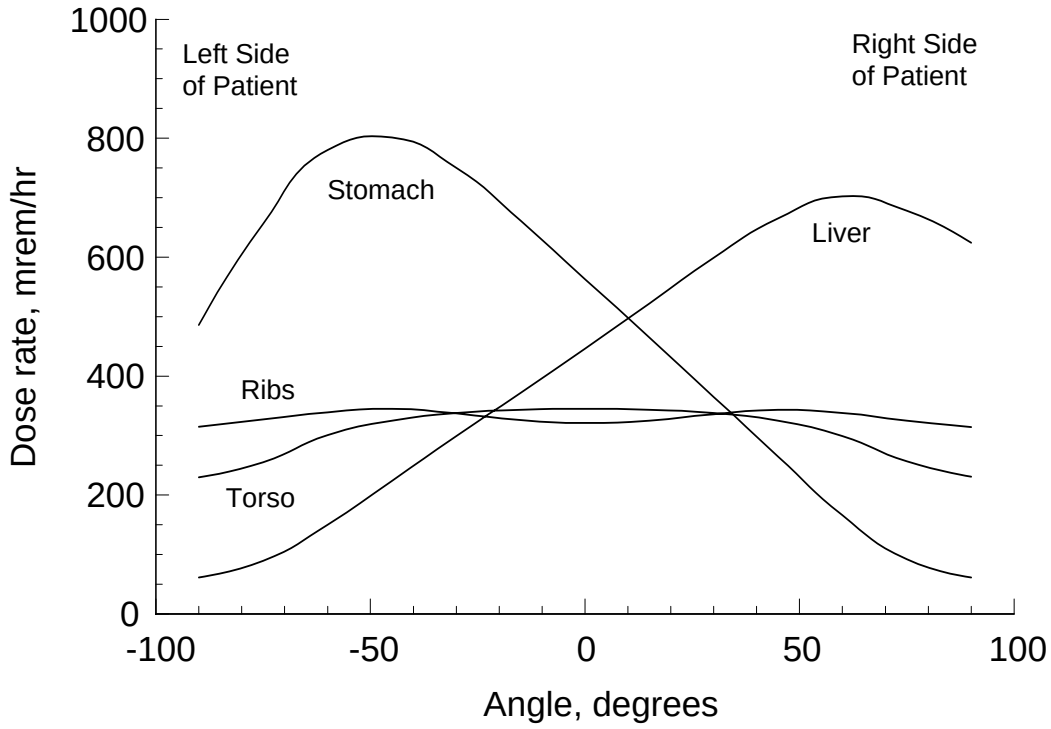
respect to the patient. NMSS staff believes that the methods used in calculating the dose rates close to the patient were not sufficiently detailed for the intended purpose, and were therefore not capable of estimating dose rates close to the patient with adequate accuracy. In addition, the assumptions made in the calculations, particularly regarding the visitor's location, were reasonable but to some degree arbitrary, and may not reflect the actual situation. In the opinion of NMSS staff, these factors, taken together, probably result in uncertainties in the dose estimates that exceed those inherent in the approach taken by Region III and the licensee.



Figure(1) - Variation of dose rate with transverse distance from patient centerline. The activity is uniformly distributed in the stomach.



Figure(2) - variation of measured dose rates at bedside and at 1 meter following administration of the I-131



Figure(3) - Radial dose distribution around the patient in a transverse plane through stomach. All curves were calculated using the same total actvity.

REFERENCES

1. MCNP - A General Purpose Monte Carlo N-Particle Transport Code, Version 5, LA-CP-03-0245, Los Alamos National Laboratory, Los Alamos, New Mexico.

2. Snyder, W.S., Form, M.R., and Warner, G.G., Estimates of Specific Absorbed Fractions for Photon Sources Uniformly Distributed in Various Organs of a Heterogeneous Phantom, Society of Nuclear Medicine: Medical Internal Radiation Dose (MIRD) Pamphlet No. 5 Revised; New York, 1978.

3. Conversion Coefficients for Use in Radiological Protection against External Radiation, ICRP Publication 74, Pergamon Press, New York, 1995.

4. Siegel, JA; Kroll, S; Regan, D; Kaminski, MS; and Wahl, RL; A Practical Methodology for Patient Release After Tositumomab and ^{131}I-Tositumomab Therapy; J. Nucl. Med., Vol. 43, No. 3, 2002.

ATTACHMENT 2

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

December 10, 2002

EA-02-248

Julie MacDonald
Senior Vice President & Chief Operating Officer
St. Joseph Mercy Health System
St. Joseph Mercy Hospital
5301 East Huron River Drive
Ann Arbor, MI 48106-0995

SUBJECT: NRC INSPECTION REPORT 030-01997/2002001(DNMS)
ST. JOSEPH MERCY HOSPITAL

Dear Ms. MacDonald:

This refers to the special inspection conducted from October 4 through 16, 2002, at St. Joseph Mercy Hospital, Ann Arbor, Michigan, with continued in-office review through November 15, 2002. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions regarding your radiation safety officer's October 1, 2002, written report of exposures to several members of the public in excess of the NRC's annual limit of 100 millirem, and to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. The members of the public were family members of a radiopharmaceutical therapy patient who had been hospitalized for compliance with 10 CFR Part 35.75. Our inspectors determined from calculations that the patient's daughter, who was the maximally exposed member of the public, received an exposure of 15 rem total effective dose equivalent. The in-office review included a review of the results of the NRC medical consultant's evaluation of the exposure to the patient's daughter.

The enclosed copy of our inspection report identifies areas examined during the inspection. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel and members of the public. On October 16, 2002, the preliminary inspection findings were discussed with you and members of your staff. The inspection findings and conclusions were discussed with you during a telephone conference call with Gary Shear and Darrel Wiedeman of my staff on November 21, 2002.

Based on the results of our inspection, we identified three apparent violations, which are being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 (enclosed). These apparent violations include the failure to: (1) limit the dose to individual members of the public to 0.1 rem in a year; (2) use procedures and engineering controls, to the extent practical, based upon sound radiation protection principles, to achieve doses to members of the public that are as low as is reasonably achievable; and (3) investigate an overexposure to a member of the public and implement corrective actions. In addition, we identified three potential violations which are not being considered for escalated enforcement

action. These violations include the failure to: (1) include estimates of each individual's dose in your initial August 15, 2002, written report; (2) measure the dose rates in the contiguous unrestricted areas following the administration of a radiopharmaceutical therapy dosage requiring hospitalization; and (3) limit the dose in unrestricted areas to 2 millirem in any one hour.

The NRC contracted with a medical consultant to review the circumstances of this event, specifically with regard to the exposure to the daughter of the therapy patient. Our consultant determined that the exposure to the daughter may result in less than a one percent increase in the lifetime risk of cancer. Enclosed with this letter is a copy of the consultant's report for your review.

Since the NRC has not made a final determination in this matter, no Notice of Violation is being issued for these inspection findings at this time. In addition, please be advised that the number and characterization of apparent violations may change as a result of further NRC review.

A predecisional enforcement conference, open for public observation, to discuss these apparent violations has been scheduled for January 16, 2003, at 1:00 p.m. (CDT) in the Region III office in Lisle, Illinois. The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred; information to determine the significance of a violation; information related to the identification of a violation; and information related to any corrective actions taken or planned. The conference will afford you an opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful.

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

In accordance with 10 CFR Part 2.790 of the NRC's "Rules of Practice," a copy of this letter and Enclosure 1 will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Marc Dapas, Acting Director
Division of Nuclear Materials Safety

Docket No. 030-01997
License No. 21-00943-03

Enclosure 1: Inspection Report 030-01997/2002001(DNMS)
Enclosure 2: NUREG 1600
Enclosure 3: Excerpt from Information Notice 96-28
Enclosure 4: Medical Consultant's Report

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REGION III

Docket No.:	03001997
License No.:	21-00943-03
Report No.:	03001997/2002001(DNMS)
Licensee:	St. Joseph Mercy Health System Ann Arbor, MI 48106-0995
Locations:	St. Joseph Mercy Hospital 5301 East Huron River Drive Ann Arbor, MI
Dates:	October 4 - 16, 2002 w/continued in-office review through November 15, 2002
Exit Meeting:	October 16, 2002 (Preliminary) November 21, 2002 (Final Exit)
Inspector:	Jamnes L. Cameron, Team Leader Darrel Wiedeman, Senior Health Physicist
Approved By:	Gary L. Shear, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

St. Joseph Mercy Health System
Ann Arbor, Michigan
Inspection Report 03001997/2002001(DNMS)

This was a special inspection to review the circumstances, root and contributing causes, and proposed corrective actions associated with an event involving exposures to individual members of the public in excess of 0.1 rem (100 millirem) total effective dose equivalent. The overexposures resulted from close contact, over several days, with a hospitalized patient who had been administered 285 millicuries of sodium iodide iodine-131. The licensee's report indicated that the event may have involved as many as 20 individuals. The licensee's radiation safety officer estimated the highest exposure to be between 3000 and 5600 millirem. The remaining overexposures, involving approximately ten other individuals, were estimated to be between 100 and 500 millirem total effective dose equivalent. The doses to the remaining members of the public were not expected to exceed 100 millirem total effective dose equivalent.

A patient who was administered a therapeutic quantity of sodium iodide iodine-131 on July 1, 2002, and hospitalized in accordance with 10 CFR Part 35.75, retained a significant portion of the administered dosage due to poor renal function, during her hospital stay. As such, radiation levels near the patient remained relatively high during this period. During the treatment period, hospital staff, including the former radiation safety officer (RSO), observed the patient's adult daughter frequently at the patient's bedside. Licensee staff, including the former RSO, did not take prudent precautions to maintain the daughter's dose as low as is reasonably achievable. The inspectors calculated the dose to the patient's daughter to be 15 rem total effective dose equivalent due to her proximity to the patient during her treatment, and the amount of time that she spent in areas of elevated radiation levels. The NRC's medical consultant, Dr. Edward Silberstein, determined that the exposure may result in less than a one percent increase in her lifetime risk of cancer.

After initially determining that public exposures likely exceeded regulatory limits, licensee staff, particularly the former RSO, were slow to investigate the circumstances associated with the overexposure. Licensee management did not initiate their investigation of the overexposures until July 26, 2002, 19 days after the event. The initial investigation was limited to interviews of hospital staff and a review of records of daily patient room surveys, and did not include interviews of the former RSO. The investigation was not conducted in a probing manner commensurate with the potential significance of the exposures.

The licensee's initial written report regarding exposures to members of the public in excess of the regulatory limit was limited to generalities regarding the radiological conditions pertinent to the exposures and the resultant doses to individuals. The report did not include the required information regarding doses to individuals, and included only a reference to exposure from a diagnostic radiology procedure, which was not in any units of dose (e.g., rem, rad, Gray, or Sievert). The licensee's October 1, 2002, follow-up report, provided nearly seven weeks after the initial report, required significant NRC staff involvement in order to obtain a specific dose estimate for any of the members of the public involved, and the technical bases for the estimate.

The inspectors identified three apparent violations of NRC regulatory requirements. The apparent violations included the failure to: (1) limit the dose to individual members of the public to 0.1 rem in a year; (2) use procedures and engineering controls, to the extent practical, based

upon sound radiation protection principles, to achieve doses to members of the public that are as low as is reasonably achievable; and (3) investigate an overexposure to a member of the public and implement corrective actions. In addition, the inspectors identified three potential violations of NRC regulatory requirements. The potential violations included the failure to: (1) include estimates of each individual's dose in the licensee's August 15, 2002, written report; (2) measure the dose rates in the contiguous unrestricted areas following the administration of a radiopharmaceutical therapy dosage requiring hospitalization; and (3) limit the dose in unrestricted areas to 2 millirem in any one hour.

The root cause of the apparent and potential violations was inattention to licensed responsibilities on the part of the former RSO. The former RSO stated that she had become distracted by other duties and responsibilities that affected her ability to focus on the regulatory and safety issues associated with the sodium iodide iodine-131 therapy procedure and the resultant public doses. Furthermore, the former RSO did not communicate her belief that public dose limits had been exceeded until the radiation safety committee meeting on July 17, 2002. After that meeting, licensee management did not investigate the exposures until after the former RSO's termination on July 26, 2002. This was not considered to be timely. The root cause of the potential violation associated with the August 15, 2002, report contents was unfamiliarity with NRC reporting requirements. The licensee's proposed corrective actions were adequate to address the potential violations. The adequacy of the licensee's corrective actions to address the apparent violations will be determined following the predecisional enforcement conference.

Report Details

1. Program Scope and Inspection History

License No. 21-00943-03 authorized St. Joseph Mercy Health System (licensee) to possess and use licensed materials for human medical purposes at the licensee's facilities located at St. Joseph Mercy Hospital, Ann Arbor, Michigan (hospital). The authorization included radiopharmaceuticals for diagnosis and therapy, and sealed sources for therapy.

The NRC last inspected the licensee on January 12, 2000, and identified one violation for failure to include all required information on written directives for radiopharmaceutical therapy. The NRC inspectors confirmed that the licensee's corrective actions for the violation have been adequate to prevent recurrence. This violation is closed. The licensee's failure to include all required information on the written directive did not result in any misadministrations or recordable events. During the previous inspection on February 11, 1997, the NRC identified one violation, involving the licensee's failure to secure from unauthorized access or removal, waste containing technetium-99m. This violation was closed during the January 12, 2000, inspection.

2. Sequence of Events

a. Inspection Scope

The inspection included a review of the sequence of events that resulted in exposures in excess of 100 millirem to several members of the public. The inspection also included tours of licensee facilities; interviews of selected licensee personnel; and reviews of the licensee's August 15, 2002, September 11, 2002, and October 1, 2002, written reports and other associated records.

b. Observations and Findings

On June 12, 2002, the licensee admitted a patient for treatment of metastatic thyroid carcinoma. During the treatment, a licensee authorized user physician prepared a written directive for the administration of 300 millicuries of sodium iodide iodine-131. The authorized user physician initially considered a dosage of 600 millicuries; however, due to the patient's poor renal function, he decreased the dosage to 300 millicuries.

On July 1, 2002, the licensee's former radiation safety officer (RSO) administered the radiopharmaceutical therapy dosage in accordance with the provisions of the written directive. The actual administered dosage was 285 millicuries. The patient remained hospitalized due to her other health problems and the patient control requirements in 10 CFR Part 35.75. The licensee provided the patient a private room with private sanitary facilities, posted the patient room door with the appropriate radiation warning signs, positioned shields at the foot of the bed and between the bed and door to the room, and provided radiation safety instructions to patient care staff, including instructions for the control of visitors. In addition, following administration of the therapy dosage, the RSO measured the radiation levels in the patient's room, the adjoining room, and the hallway outside the patient's room.

Typically, for patients with normal renal function, 90 to 95 percent of the administered dosage of sodium iodide iodine-131, which has not been taken up by the residual and metastatic thyroid tissues, is rapidly filtered from the blood stream (i.e., within 24 to 48 hours post-administration) via the kidneys and excreted in the urine. For such patients, there is a rapid reduction in the external radiation profile commensurate with the biological elimination of the unbound iodine-131. Following this initial rapid decline in external radiation levels, the levels would normally further diminish according to an effective half-life (due to a combination of physical radiological decay and biological elimination) of seven days.

During each day that the patient was hospitalized, the RSO measured radiation levels at the patient's bedside and at one meter from the patient. Due to the patient's poor renal function, typical biological elimination of the iodine-131 did not occur, and there was no initial rapid reduction in radiation levels. Radiation levels measured on July 1, 2002, post-administration of the therapy dosage, were 400 millirem per hour at the bedside and 40 millirem per hour at one meter. Radiation levels measured on subsequent days diminished according to an effective half-life of three to four days.

On July 1, 2002, all of the patient's visitors adhered to the radiation safety precautions instituted by the licensee. The primary precaution taken by the licensee was to not allow any visitors inside the patient's room during the first day after administration of the therapy dosage. This was confirmed through interviews of patient care staff and the patient's daughter. In keeping with its usual practice, the licensee relaxed visitor restrictions 24 hours after the administration of the dosage, and allowed visitors in the room. Hospital staff instructed the visitors to remain behind the shields during visitation; however, the licensee did not impose any stay time restrictions on the visitors.

Between July 2 and 7, 2002, several patient care staff and the RSO observed the patient's adult daughter frequently at the patient's bedside, near the window, where a shield was not located. When they observed this, they reminded the daughter to position herself on the other side of the bed so that she was protected from unnecessary radiation exposure. On July 5, 2002, the patient's physical condition worsened. The RSO and the authorized user physician approved the temporary removal of the bedside shields so that the patient's family members (estimates provided by hospital staff and the daughter vary between 20 and 35 individuals) could visit with the patient for the last time. Based on observations of the patient's room, the inspectors estimated that 10 - 12 individuals could have stood in close proximity to the bed, and received a dose of approximately 200 millirem total effective dose equivalent. Doses to all other family members in the patient's room would not likely have exceeded 100 millirem total effective dose equivalent.

The patient's condition declined until she died on July 7, 2002. Licensee patient care staff and the RSO observed the daughter at the bedside essentially continuously between July 5 and 7, 2002. The former RSO did not recommend further precautions to the daughter to maintain her radiation exposure as low as is reasonably achievable. Suggested precautions could have included maintaining an arm's length from the side of the patient's bed (since radiation levels at one meter were approximately one-tenth of those at the bedside), the use of additional shielding, minimizing the daughter's time at the bedside, or the use of a digital dosimeter to self-monitor the daughter's exposure, which the licensee had available. Part 20.1101(b) to Title 10 of the Code of Federal Regulations (10 CFR) requires that the licensee use, to the extent practical, procedures

and engineering controls, based upon sound radiation protection principles, to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable. The licensee's failure to use procedures and engineering controls, to the extent practical, based upon sound radiation protection principles, to achieve doses to members of the public that are as low as is reasonably achievable, is considered an apparent violation of 10 CFR Part 20.1101(b).

The former RSO stated that during the weekend of July 6 -7, 2002, she repeatedly attempted to contact her supervisor to relay her concern regarding potential exposures to members of the public. Interviews of the supervisor indicated that he had not received any pages or telephone calls to his residence. The supervisor stated that upon his return to work on July 8, 2002, he did not have any messages on his office telephone from the former RSO. Furthermore, he stated that the former RSO did not mention her concerns regarding public doses when she interacted with her supervisor following the patient's death.

Following the patient's death, the former RSO assisted a mortician during the embalming process. The embalming was performed in the hospital morgue. The former RSO provided the mortician with a digital dosimeter to monitor his exposure during the process. The dosimeter recorded an exposure of 35 millirem for the nine-hour procedure. Contaminated body fluids from the decedent were disposed to the sanitary sewer. Based on surveys conducted by the former RSO in the morgue and the patient's room, the licensee did not identify any significant residual contamination.

On July 17, 2002, the licensee's radiation safety committee convened for a regularly scheduled meeting. During the meeting, the committee members discussed the radiopharmaceutical therapy procedure that occurred on July 1 through 7, 2002, and the unique issues associated with it, including visitor control and the death of a patient during therapy. During those discussions, the former RSO indicated for the first time her belief that a member of the public received a dose in excess of 500 millirem, but she had not yet evaluated the extent of the exposure.

Parts 35.21(a) and (b) to 10 CFR require, in part, that the licensee appoint an RSO responsible for implementing the radiation safety program. The licensee, through the RSO, is required to ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. The RSO is required to, among other things, investigate overexposures and deviations from approved radiation safety practices, and implement corrective actions as necessary.

The licensee's former RSO became aware that the daughter of a patient being treated with a radiopharmaceutical was not following the licensee's approved safety practices. In addition, the former RSO suspected that the patient's daughter had received an exposure to radiation in excess of the NRC's regulatory limits and failed to investigate the potential exposure and implement corrective actions. The former RSO's failure to investigate the potential overexposure and implement corrective actions is considered an apparent violation of 10 CFR Parts 35.21(a) and (b).

On July 26, 2002, the licensee terminated the former RSO's employment. Licensee management representatives stated that the termination was not related to the July 1 through 7, 2002, therapy treatment. At the time of her termination, the former RSO had

not yet evaluated the potential exposure to the patient's family members, including the patient's daughter.

c. Conclusions

A patient, who was administered a therapeutic quantity of sodium iodide iodine-131 on July 1, 2002, and hospitalized for compliance with 10 CFR Part 35.75, retained a significant portion of the administered dosage during her hospital stay. As such, radiation levels around the patient remained relatively high during this period. During the treatment period, hospital staff, including the licensee's former RSO, observed the patient's daughter frequently at the patient's bedside. Licensee staff, including the former RSO, did not take prudent precautions to maintain the daughter's dose as low as is reasonably achievable. Two apparent violations of regulatory requirements were identified, including the failure to: (1) use procedures and engineering controls, to the extent practical, based upon sound radiation protection principles, to achieve doses to members of the public that are as low as is reasonably achievable; and (2) investigate an overexposure to a member of the public and implement corrective actions as necessary.

3. Licensee Investigation

a. Inspection Scope

The inspection included a review of the results of the licensee's investigation of an event involving exposures in excess of 100 millirem to several members of the public. The inspection also included tours of facilities; interviews of selected licensee personnel; and a review of applicable procedures, associated records, and written reports.

b. Observations and Findings

Prior to the July 17, 2002, radiation safety committee meeting, the former RSO did not share with others her belief that a member of the public had received a radiation dose in excess of 500 millirem total effective dose equivalent. Before her termination on July 26, 2002, the former RSO had not evaluated the extent of the radiation exposure to the patient's daughter. The former RSO stated that she was focused on other activities, including shielding calculations for diagnostic radiology rooms and State registration of radiation producing devices (i.e., x-ray tubes).

Following termination of the former RSO, licensee management and the newly appointed RSO initiated an investigation into the exposures to members of the public associated with the July 1, 2002, administration of a radiopharmaceutical therapy dosage to a hospitalized patient. The investigation included a review of the records of the results of daily surveys conducted in the patient's room by the former RSO, and interviews of licensee staff who provided care to the patient. Based on anecdotal information obtained from patient care staff, licensee management bounded the maximum exposure received by a member of the public to approximately 3 rem total effective dose equivalent, and equated this to the dose received during a computed tomography (CT) scan.

c. Conclusions

Licensee staff, particularly the former RSO, were slow to investigate the circumstances associated with overexposures to members of the public resulting from the radiopharmaceutical therapy procedure performed on July 1 through 7, 2002. Licensee management did not initiate the investigation until July 26, 2002, nineteen days after the event. The initial investigation was limited to interviews of hospital staff and a review of records of daily patient room surveys, and did not include interviews of the former RSO or members of the patient's family. The investigation was not conducted in a probing manner commensurate with the potential significance of the exposures.

4. Notifications and Reporting

a. Inspection Scope

The inspection included a review of the notifications and reporting to the NRC of an event involving exposures to members of the public which resulted in doses in excess of 100 millirem in a year. The inspection also included interviews of selected licensee employees and a review of associated records and reports.

b. Observations and Findings

Title 10 CFR Part 20.2203(a) requires that each licensee submit a written report within 30 days of becoming aware that an individual member of the public received a dose in excess of the limits in 10 CFR Part 20.1301. Licensee staff initially determined that a member of the public likely received a dose in excess of 100 millirem total effective dose equivalent during the July 17, 2002, radiation safety committee meeting. Licensee staff provided a written notification to the NRC of this event in a letter dated August 15, 2002.

Title 10 CFR Part 20.2203(b) requires that each report required by 10 CFR Part 20.2203(a) describe the extent of exposure of individuals to radiation, including estimates of each individual's dose. The licensee's August 15, 2002, written report described the general radiological conditions in the patient's room, but did not provide specific dose estimates for any of the visitors. Licensee staff stated that the maximum likely dose to the visitors was the same as the dose expected from a CT scan, namely, 3 rem total effective dose equivalent. The licensee's failure to include estimates of each individual's dose in its August 15, 2002, written report is considered a potential violation of 10 CFR Part 20.2203(b).

On August 27, 2002, an NRC inspector contacted the licensee's current RSO to discuss the August 15, 2002, written report and obtain additional information. Since this individual had not been in the RSO position during the time that the event occurred, he was not familiar with any of the event details. The RSO indicated that he would need additional time to obtain the requested information.

On September 11, 2002, the RSO provided a follow-up written report regarding the public exposure event. The report included additional event details; however, the estimate for the maximally exposed individual was "... less than or equal to 3000 (millirem)." In addition, the RSO continued to rely on anecdotal information from patient care staff in developing the dose estimate. The inspector again requested that the RSO re-evaluate the dose estimate, and suggested that he use more definitive information regarding the duration of exposure and proximity of the daughter to the patient.

On October 1, 2002, the RSO submitted a third written report containing the detailed information requested by the inspector. In the subject report, the RSO revised his dose estimate for the patient's daughter to between 3000 and 5600 millirem total effective dose equivalent. The report provided the technical basis for the exposure estimate, including the results of interviews with the daughter.

c. Conclusions

The licensee's initial written report regarding exposures to members of the public in excess of the regulatory limit was limited to generalities regarding the radiological conditions pertinent to the exposures and the resultant doses to individuals. The report did not include the required information regarding doses to individuals, and included only a reference to exposure from a diagnostic radiology procedure, which was not in any units of dose (e.g., rem, rad, Gray, or Sievert). The licensee's October 1, 2002, follow-up report, provided nearly seven weeks after the initial report, required significant NRC staff involvement in order to obtain a specific dose estimate for any of the members of the public involved, and the technical bases for the estimate. One potential violation of regulatory requirements was identified involving the failure to include estimates of each individual's dose in the licensee's August 15, 2002, written report.

5. Public Dose Assessments

a. Inspection Scope

The inspection included a review of the licensee's assessments of doses to members of the public resulting from the July 1, 2002, radiopharmaceutical therapy dosage administration. The inspection also included interviews of selected licensee employees and the therapy patient's daughter, observations of facilities, and a review of associated records and reports.

b. Observations and Findings

Title 10 CFR Part 20.1301(a)(1) requires that the licensee conduct operations so that the total effective dose equivalent to individual members of the public from the licensed operations does not exceed 0.1 rem (100 millirem) in a year. The licensee estimated the daughter's dose to be 3 to 5.6 rem (3000 to 5600 millirem) total effective dose equivalent. The estimate was based on information provided by the daughter regarding her activities between July 5 and 7, 2002. The RSO, who performed the dose estimate, was not aware that the daughter had been near the patient's bedside periodically between July 2 through 5, 2002.

During the inspectors' interviews of the patient's daughter, she provided the following information regarding her proximity to the patient and duration of exposure:

- On July 1, 2002, following administration of the therapy dosage, all family members remained at the doorway to the patient's room during visitation, as instructed by hospital staff.

- Beginning approximately mid-day on July 2, 2002, through the late afternoon of July 5, 2002, the daughter remained at the patient's bedside approximately half of each day.

- Beginning at approximately 5 p.m. on July 5, 2002, after the patient's condition worsened, the daughter remained at the bedside continuously, except for approximately 3.5 hours, until the patient's death on July 7, 2002.

- When at the patient's bedside, the daughter sat against the bed, with her elbows or forearms on the bed.

- No other family members remained in the patient's room for as long, or positioned themselves as close, as the daughter did.

Based on bedside radiation level surveys performed by the former RSO, and the information provided by the patient's daughter, the inspectors calculated the daughter's dose at 15 rem total effective dose equivalent, as follows:

July 2, 2002: 6 hours @ 348 millirem per hour

July 3, 2002: 12 hours @ 250 millirem per hour

July 4, 2002: 12 hours @ 210 millirem per hour

July 5, 2002 (through 5 p.m.): 8.5 hours @ 210 millirem per hour

July 5, 2002 (after 5 p.m.): 7 hours @ 210 millirem per hour

July 6, 2002: 20.5 hours @ 132 millirem per hour

July 7, 2002: 11.5 hours @ 107 millirem per hour

The main difference between the licensee's estimate of the daughter's dose as provided in the October 1, 2002, written report, and the inspectors' estimate was additional detail provided by the daughter during the inspectors' interview on October 4, 2002. The additional detail concerned the daughter's bedside proximity during July 2, 2002 through July 5, 2002, which she had not recalled during earlier conversations with licensee staff. The licensee's failure to limit the dose to individual members of the public from licensed operations to 0.1 rem in a year is considered an apparent violation of 10 CFR Part 20.1301(a)(1). At the time of the inspection, the licensee did not dispute the inspectors' estimate of the daughter's exposure, but the RSO stated that he would need additional time to review the inspectors' assumptions and the outcomes of their calculations.

The former RSO did not measure the radiation levels in an emergency exit stairwell next to the patient's room and along the wall where the head of the patient's bed was located; however, all entry points to the stairwell were via alarmed fire/emergency exit doors. In addition, the former RSO did not survey the area outside the window of the patient's room, which was on the ground floor. The former RSO did not place any shields between the patient's bed and the window. The stairwell and the area outside the patient's window were not restricted for purposes of radiation protection. Title 10 CFR Part 35.315(a)(4) requires that the licensee promptly measure the dose rate in contiguous restricted and unrestricted areas, with a radiation measurement survey instrument, to demonstrate compliance with the requirements of 10 CFR Part 20, after administration of a radiopharmaceutical therapy dosage requiring hospitalization in

order to comply with 10 CFR Part 35.75. The licensee's failure to measure the dose rates in the contiguous unrestricted areas, located in the stairwell and outside the window, following the administration of a radiopharmaceutical therapy dosage requiring hospitalization to comply with 10 CFR Part 35.75 is considered a potential violation of 10 CFR Part 35.315(a)(4).

Title 10 CFR Part 20.1301(a)(2) requires that the licensee conduct operations so that the dose in any unrestricted area from external sources does not exceed 2 millirem in any one hour. The inspectors requested that the licensee evaluate the likely radiation levels in the unrestricted areas that were not surveyed following the administration of the radiopharmaceutical therapy dosage on July 1, 2002. The current RSO determined, based on surveys performed in the patient's room, that the radiation levels in the stairwell adjacent to the room ranged from 10 millirem in an hour on July 1, 2002, to 4 millirem in an hour on July 7, 2002. The current RSO also determined that outside the patient's window, the radiation levels ranged from 17 millirem in an hour on July 1, 2002, to 8 millirem in an hour on July 7, 2002. The licensee's failure to limit the dose in unrestricted areas from licensed operations to 2 millirem in any one hour during the period from July 1 through 7, 2002, is considered a potential violation of 10 CFR Part 20.1301(a)(2).

c. Conclusions

Based on additional information obtained during the inspection, the inspectors calculated the dose to the patient's daughter to be 15 rem total effective dose equivalent, due to her proximity to the patient during the patient's treatment, and due to the amount of time that she spent in areas of elevated radiation levels. At the time of the inspection, licensee staff were not able to re-evaluate their earlier dose estimates based on the recency of the additional information. In addition, the inspectors identified that elevated radiation levels existed in two unrestricted areas during the patient's radiopharmaceutical therapy treatment. However, due to the nature of the areas, exposure to members of the public was not likely. One apparent violation of regulatory requirements was identified for failing to limit the dose to individual members of the public to 0.1 rem in a year. In addition, two potential violations of regulatory requirements were identified, including the failures to: (1) limit the dose in unrestricted areas to 2 millirem in any one hour, and (2) measure the dose rates in the contiguous unrestricted areas following the administration of a radiopharmaceutical therapy dosage requiring hospitalization.

6. Quality Management Program Implementation

a. Inspection Scope

The inspection included a review of the licensee's implementation of its written quality management program procedures which consisted of interviews of selected licensee personnel and reviews of applicable procedures and associated records.

b. Observations and Findings

The written directive for the July 1, 2002, administration of a therapeutic quantity of sodium iodide iodine-131 included a prescribed dosage of 300 millicuries. The administered dosage was 285 millicuries. The written directive was signed and dated by an authorized user physician and included all of the information specified in 10 CFR Part 35.2. Licensee staff verified the dosage in a dose calibrator prior to administration, and confirmed that the dosage was within ten percent of the prescribed dosage.

The inspectors reviewed selected administrations of therapeutic radiopharmaceuticals. The administrations reviewed included nine signed and dated written directives completed prior to July 1, 2002. In each case, licensee staff verified the dosage in a dose calibrator and the identity of the patient prior to administering the dosage. The former RSO audited all administrations of therapeutic quantities of radiopharmaceuticals at least once each year to ensure that the administrations were in accordance with the associated written directive. The former RSO had not identified any recordable events or misadministrations as a result of previous audits.

c. Conclusions

The licensee adequately implemented the written procedures of its quality management program for therapeutic radiopharmaceutical administrations. The inspectors did not identify any problems with regard to those administrations in general, or specifically with regard to the July 1, 2002 administration, which was the subject of this inspection.

7. Licensee Corrective Actions

a. Inspection Scope

The inspection included a review of the licensee's proposed corrective actions for the event involving exposures in excess of 100 millirem to several members of the public. The review included interviews of selected licensee personnel.

b. Observations and Findings

The licensee provided its initial corrective actions in its August 15, 2002, written report of the event involving several public exposures in excess of the regulatory limit. The actions were limited to documenting agreement between the authorized user and anyone visiting patients that have been hospitalized for compliance with 10 CFR Part 35.75, that the visitors will comply with the controls established by the licensee. The licensee also committed to enhancing documentation of visitor stay times within the rooms of patients hospitalized for compliance with 10 CFR Part 35.75, providing larger radiation warning signs for the patient's room door, and making individual education sheets available to visitors.

During the inspection, the licensee provided additional corrective actions in an October 8, 2002 letter. The additional actions included establishing a policy of not allowing visitors into hospitalized therapy (radiopharmaceutical and sealed source) patient rooms. In those instances when an authorized user deems it appropriate for visitors to enter such patient rooms, the licensee will provide more formalized instruction to the visitors regarding visitation restrictions; use available resources to develop a

balanced solution that meets the needs of patients and their families, while fulfilling regulatory responsibilities; and ensure that management is promptly notified of any concerns regarding patient or visitor compliance with radiation safety restrictions or precautions.

c. Conclusions

The licensee's proposed corrective actions were adequate to address the problems associated with the exposures to members of the public arising from the July 1 through 7, 2002 radiopharmaceutical therapy procedure.

8. NRC Medical Consultant's Review

The NRC staff contracted with a medical consultant, Edward Silberstein, M.D., to review the possible health effects associated with the dose to the patient's daughter as a result of this event. Dr. Silberstein opined that the exposure to the patient's daughter may result in less than a one percent increase in her lifetime risk of cancer.

9. Exit Meeting

On October 5, 2002, the inspectors summarized the initial findings at a preliminary exit meeting with licensee representatives. The summary included the inspectors' understanding of the sequence of events, the preliminary dose assessment for the patient's daughter, and the licensee's proposed corrective actions. On October 16, 2002, the Chief, Materials Inspection Branch, and the inspectors summarized the inspection findings at a second preliminary exit meeting with licensee representatives. The summary reiterated the findings from the first preliminary exit meeting, included the identified apparent violations, and described the NRC's process for use of a medical consultant. The final exit meeting was conducted by telephone on November 21, 2002, to discuss the apparent violations. The licensee did not identify any material reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

PARTIAL LIST OF PERSONS CONTACTED

Elizabeth Beger, R.N., Service Delivery Leader, 1000 Oncology Unit
Rayma Bilicki, M.S., Radiation Safety Officer (through July 26, 2002)
Sharlene Campbell, Director, Radiology
John E. Freitas, M.D., Authorized User Physician
Amy S. Harrison, M.S., Medical Physicist
Michelle Hazard, Manager, Radiation Oncology and Radiation Safety
Timothy G. Kensora, M.S., Radiation Oncology Physicist, and
Radiation Safety Officer (after July 26, 2002)
Julie MacDonald, M.S., RN, Senior Vice President, Patient Care Services and
Chief Operating Officer
Mandi A. Murray, Assistant General Counsel
Leonard A. Sullivan, Service Delivery Leader, Environmental Health
patient's daughter* - name withheld to protect personal privacy

ATTACHMENT 3

ABSORBED DOSE RECONSTRUCTION FOR FAMILY MEMBER OF 1-131 PATIENT

CAROL S. MARCUS AND JEFFRY A. SIEGEL

NUCLEAR REGULATORY COMMISSION RADIATION ABSORBED DOSE RECONSTRUCTION FOR FAMILY MEMBER OF I-131 PATIENT

Carol S. Marcus, Ph.D., M.D.[1] and Jeffry A. Siegel, Ph.D.[2]

[1]Division of Nuclear Medicine, Department of Radiology, Research and Education Institute of Harbor-UCLA Medical Center, Torrance, CA 90502

[2]President and CEO, Nuclear Physics Enterprises, 2202 Balsan Way, Wellington, FL 33414

This work was supported in part by the Research and Education Institute of Harbor-UCLA Medical Center.

Please address all correspondence to the following author. Reprints will not be available. Carol S. Marcus, Ph.D., M.D., 1877 Comstock Avenue, Los Angeles, CA 90025-5014. Phone: (310)277-4541, FAX: (310)552-0028, E-mail: csmarcus@ucla.edu. The first author, to whom all correspondence should be directed, is not in training.

Running Title: NRC dose calculation from I-131 patient

NUCLEAR REGULATORY COMMISSION RADIATION ABSORBED DOSE RECONSTRUCTION FOR FAMILY MEMBER OF I-131 PATIENT

Abstract: A terminally ill patient with metastatic thyroid cancer and severe renal insufficiency was treated as an inpatient with 10,545 MBq (285 mCi) $Na^{131}I$. The patient died six days after radiopharmaceutical administration while still in the hospital. A close relative of the patient disregarded the instructions of the Radiation Safety Officer (RSO) and insisted upon staying close to the patient for long periods of time until the patient's death. The licensee later reported to the Nuclear Regulatory Commission (NRC) that this member of the public had likely received a dose in excess of the 1 mSv (100 mrem) regulatory limit. The NRC subsequently performed a dose reconstruction and determined that the family member received an exposure of 15 cSv (rem) total effective dose equivalent (TEDE). An analysis of the NRC's approach and an alternative dose reconstruction, in which the TEDE was determined to be approximately a factor of as much as 17 lower, is presented.

Key Words: Nuclear Regulatory Commission; radiation dose calculation

Case Presentation: A patient with terminal metastatic thyroid cancer and severe renal insufficiency was treated with 10,545 MBq (285 mCi) $Na^{131}I$ and hospitalized in accordance with NRC requirements pursuant to 10 CFR

Part 35.75. The patient died six days after radiopharmaceutical administration while still in the hospital. The RSO measured radiation levels in the patient's room each day, both at 1 meter from the patient and at the patient's bedside. The initial dose rate measurements following radiopharmaceutical administration were 0.040 cSv/h (rem/h) and 0.400 cSv/h (rem/h) at 1 meter and at the bedside, respectively. According to the NRC, these radiation levels diminished with an effective half-time of 3 to 4 days.

A close adult relative of the patient disregarded the instructions of the RSO and insisted upon staying close to the patient for long periods of time until the patient's death. The relative was reminded by licensee staff, including the RSO, to take a position behind a bedside shield. As a result of the relative's proximity to the patient and the amount of time spent in areas of elevated radiation levels, the licensee later reported to the NRC that the relative likely received a dose in excess of the 1 mSv (100 mrem) regulatory limit.

The NRC subsequently performed a dose reconstruction using the RSO's measured dose rate values at the bedside and the daily stay times for the

relative that were determined from interviews with the relative and licensee staff. Details of this analysis are publicly available in NRC's AgencyWide Documents Access and Management System (ADAMS), accession number ML023440102. The NRC assumed that the relative was at the bedside position for the total amount of stay time each day. NRC determined TEDE by multiplying the measured dose rates by the estimated stay times. The dose rates, stay times, estimated TEDE during each day, and the total TEDE are presented in Table 1. As shown in the Table, the TEDE was estimated to be 15 cSv (rem) for the relative. Only the external dose component was considered; no mention is made concerning the possibility or likelihood of internal intake. Therefore the TEDE is equal to the deep dose equivalent (DDE).

SNM/ACNP Concern Over NRC Dose Reconstruction: The Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) were concerned that NRC's dose reconstruction in this case might be overly conservative. Meetings with NRC Commissioners McGaffigan and Merrifield were held to discuss NRC dose reconstructions as well as to suggest the formation of an independent committee composed of experts from the SNM/ACNP and other dosimetry experts to conduct peer reviews

of NRC's dose calculations. On September 9, 2003, NRC Chairman Diaz sent a letter to Henry Royal, M.D., President of the SNM, making the following statements of interest:

(1). "In this particular case, the hospital had performed daily dose rate measurements at the bedside. The NRC estimated the stay times next to the bed based on interviews with the [relative] and the hospital staff. The dose to the [relative] was then calculated using these stay times and the measured exposure rate for each day. Since the NRC staff was able to use measured dose rates and did not have to perform a complex dose reconstruction analysis, the Commission does not feel that the staff's results were overly conservative."

(2). "While we appreciate your offer to have an independent SNM/ACNP Committee review our calculations, we believe the staff gets sufficient support from its existing medical and scientific consultants, contractors, and the ACMUI [Advisory Committee on Medical Uses of Isotopes] in performing and reviewing its dose reconstructions."

(3). "The staff will also continue to evaluate the state-of-the-art in dose reconstruction in order to keep its determinations as realistic as possible."

The NRC thus maintains that its dose reconstruction in this case is accurate, and states that its methods are not overly conservative and are essentially "state-of-the-art". However, the authors present below an alternative dose reconstruction based on the same dose rate and stay time data.

Alternative Dose Reconstruction: The initial dose rate measurement at 1 meter from the patient was 0.040 cSv/h (rem/h). The reasonableness of this measurement can be ascertained by theoretical calculation, according to:

Dose rate at 1 meter (cSv/h) = Γ x A_0 x SF

where Γ = specific gamma ray constant for ^{131}I at 1 m (= 5.95E-6 cSv-m^2/MBq-h); A_0 =10,545 MBq; and SF = shielding factor due to patient attenuation. For ^{131}I this has been reported to be 0.6 (*1*).

Thus, dose rate at 1 meter = (5.95E-6)(10,545)(0.6) = 0.038 cSv/h.

According to this theoretical calculation, the 0.040 cSv/h measurement at 1 meter is therefore realistic and reasonable. (Note: This simple calculation illustrates that even if no dose rate measurements had been obtained, no "complex dose reconstruction analysis" would have been needed.)

No such theoretical calculation can be used to directly verify the initial 0.400 cSv/h dose rate measurement at the patient's bedside since no distance was given. The NRC did not attempt to estimate this distance and apparently assumed that the relative's location corresponded to dose rate levels measured at the patient's bedside. "Bedside" is imprecise and not a standard unit of length. We believe that it is imperative to **reconstruct the distance before you reconstruct the dose.** The initial measured dose rate at 1 m can be used to estimate the distance at which the bedside dose rate measurements were taken. Using the inverse square law, $(40/400)^{1/2}$, the bedside dose rate is estimated to be at a distance of 31.6 cm from the patient. Since this initial dose rate measurement was performed at a time when the activity was mainly confined to the stomach, a point source assumption and use of inverse square is an adequate approximation. Does 31.6 cm realistically represent the distance between the relative and the

patient? If not, the bedside dose rate measurements can not be used to estimate the relative's exposure.

From the NRC's dose reconstruction in the ADAMS document, it is reported that the relative's closest position to the patient was sitting against the bed, with elbows or forearms on the bed. The NRC approach to dose calculation is precisely defined in 10 CFR Part 20. Pursuant to 10 CFR 20.1003, arms distal to the elbow and legs distal to the knee, as well as hands, elbows, feet, and knees, are extremities; doses to extremities are reported as shallow-dose equivalents. For purposes of external exposure, head, trunk, and arms and legs proximal to elbow and knee, respectively, are considered "whole body parts" for which DDEs are calculated. Since TEDE in this case is equivalent to DDE, and pursuant to 10 CFR 20.1201(c) the assigned DDE must be for the part of the body receiving the highest exposure, we first assumed that the patient's proximal arms were at the closest distance to the patient and therefore received the highest exposure. It is reasonable to assume that this patient-to-relative's proximal arm distance could be on the order of 31.6 cm. If the patient's proximal arms remained in this position for the entire stay times, then the bedside dose rates used by NRC to estimate TEDE is a reasonable approach.

It is, however, likely that the relative's body, including proximal arms, was at a further distance for some of the time, due to comfort considerations from prolonged stay times. For example, it is likely that the relative sat back in the chair at least part of the time, instead of being continually hunched forward over the bed. It is not unlikely that this comfort distance could be comparable to 1 meter, while still being "at bedside". It is therefore realistic to assume that the relative's closest distance was at an average "bedside" distance between 31.6 cm and 100 cm, i.e., an average distance of 65.8 cm. That is, the proximal forearm averaged a distance of 65.8 cm from the patient. **In this case, the NRC dose estimate is overly conservative by a factor of $(65.8/31.6)^2 = 4.3$.**

Up to now, we have used NRC regulatory definitions and criteria for the TEDE calculation. TEDE can also be determined in this case for the relative's trunk as the surrogate for "whole body" TEDE. While this approach is not specifically addressed in NRC regulations, we believe it would be prudent to determine this additional dose estimate, especially in this case since the proximal arms and trunk of the body were at significantly different distances from the patient. Thus, if TEDE values are to be used in

a risk assessment, it may be important to differentiate the estimated dose values for the individual's arms from that of the trunk.

Simulated measurements of the patient-relative geometry performed independently by the authors yielded a center-of-gravity to center-of-gravity (umbilicus-to-umbilicus) distance of 65-70 cm. On average, the umbilicus-to-umbilicus distance was therefore between 65 cm and 100 cm, for an average distance of 82.5 cm. **Using this scenario, the NRC dose estimate is overly conservative by a factor of $(82.5/31.6)^2 = 6.8$ using the relative's trunk as the "whole body" part of interest.**

Another important factor to consider is attenuation by the exposed individual's body. The NRC has taken into account the shielding by the patient's body by using a measurement instead of using the specific gamma ray constant for an unshielded point source. However, NRC did not take into account the shielding (i.e., attenuation) by the body of the family member, which requires essentially the same shielding factor as that which applies to the patient. TEDE is not equivalent to dose rate multiplied by time; attenuation by the exposed individual must be taken into account. For ^{131}I, the shielding factor is 0.6 for the patient, as previously discussed (*1*),

and also 0.6 for the family member's body (*2*). The attenuation factor for the DDE according to NRC regulation, however, is different. According to 10 CFR 20.1003, the DDE, "...which applies to whole body exposure, is the dose equivalent at a tissue depth of 1 cm...". Using the linear attenuation coefficient for ^{131}I in tissue-equivalent material (*4*), and a depth of 1 cm, the corresponding attenuation factor for the DDE is $e^{-(0.11)(1)} = 0.9$. **Thus, the NRC overestimated the relative's TEDE, based on its own regulatory criteria, by an additional factor of 1/0.9 = 1.1 based on use of the proximal arm. The TEDE overestimate is 1/0.6 = 1.7 based on the use of the trunk of the body.**

The NRC's dose reconstruction also did not take several other important factors into account. The NRC assumed that the exposure rate at one point in time measured by the RSO was constant for 24 hours, instead of exponentially decreasing. While it is reasonable to ignore decay if the effective half-time is long, in this case it was only 3.1 days based on the time-bedside dose rate data. In addition, there is an obvious mistake in the dose rate on Day 4, which cannot be the same as it was on Day 3 (see Table 1). Finally, at times shortly after dose administration, this patient is not really a point source, but more closely resembles a line source (*3*). This is

especially important at short distances from the patient, since it decreases the exposure relative to that which is calculated using the inverse square law. These three considerations taken together potentially represent an additional NRC dose overestimate by a factor of 1.5.

Thus, the NRC's dose calculation is conservative by a factor of only (1)(1.1)(1.5) = 1.6 using the proximal arms as the body part receiving the highest exposure under the assumption that the proximal arms are always at a distance of 31.6 cm from the patient. If the proximal arms are at an average distance of 65.8 cm, the NRC calculation is conservative by a factor of (4.3)(1.1)(1.5) = 7.1. If umbilicus-to-umbilicus calculations are used, the NRC dose calculation is potentially overly conservative by a factor on the order of (6.8)(1.7)(1.5) =17. The relative's TEDE may well be a maximum of only 0.9 cSv if umbilicus-to-umbilicus calculations are used.

Discussion/Conclusion: A specific dose reconstruction performed by The NRC has been reported. An analysis of the NRC's dose reconstruction methods indicates a potential dose estimate that is overly conservative by a factor of approximately 1.6, 7.1, or 17, depending upon calculation methods

and assumptions. NRC regulations require that the TEDE calculated be for the body part receiving the highest exposure. Nothing in the regulations, however, precludes use of other body parts for the TEDE calculation. We believe that the factor of 17 realistically applies to the true whole body dose in this case, while the factors of 1.6 and 7.1 more accurately reflect the proximal arm dose. If a dose estimate is to be used to determine risk, as was done by the NRC in this case, then we recommend use of not only the regulatory-mandated TEDE value but also the most appropriate TEDE value based on the specific circumstances.

We recognize that "state-of-the-art" dose reconstruction should result in a probability distribution rather than a single dose estimate. The uncertainty for each parameter in the calculation should be modeled and Monte Carlo simulation could then be used to get a frequency distribution of the likely dose. This, however, is beyond the scope of this case report.

All licensees should expect that the NRC performs dose calculations using state-of-the-art dosimetry methods that result in realistic and not overly conservative dose estimates. This is especially important since these dose estimates are used for risk assessment. The large discrepancy in

methodology, criteria used, and estimated dose demonstrated in this case raises important issues. We therefore recommend that the Commissioners consider a case-by-case review of staff dose calculations by an outside expert panel to gain valuable perspectives and alternative calculation strategies.

References

1. Siegel JA, Kroll S, Regan D, Kaminski MS, Wahl RL: A practical methodology for patient release after tositumomab and I-13-tositumomab therapy. *J Nucl Med 2002; 43:354-363.*

2. Sparks RB, Siegel JA, Wahl RL: The need for better methods to determine release criteria for patients administered radioactive material. *Health Phys. 1998; 75:385-388.*

3. Siegel JA, Marcus CS, Sparks RB: Calculating the absorbed dose from radioactive patients: the line-source versus point-source model. *J Nucl Med 2002; 43:1241-1244.*

4. Schleien B, Slaback LA, Jr., Birky, BK: Handbook of Health Physics and Radiological Health, 3rd edition, 1998, Table 5.1, Williams and Wilkins, Baltimore, MD.

Acknowledgements

This work was supported in part by Harbor-UCLA Medical Center, Torrance, CA 90502.

TABLE 1. Bedside dose rates, stay times, and NRC TEDE calculations.

Day	Dose rate at bedside (cSv/h or rem/h)	Stay time (h)	TEDE (cSv or rem)
0	0.400	0	0
1	0.348	6	2.088
2	0.250	12	3.000
3	0.210	12	2.520
4 (through 5 PM)	0.210	8.5	1.785
4 (5 PM - midnight)	0.210	7	1.470
5	0.132	20.5	2.706
6	0.107	11.5	1.231
		Total	14.800

ATTACHMENT 4

ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES

CHARTER FOR THE SUBCOMMITTEE TO REVIEW THE DOSE RECONSTRUCTIONS

ATTACHMENT D

ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES

CHARTER FOR THE SUBCOMMITTEE TO REVIEW THE DOSE RECONSTRUCTIONS

Formation of ACMUI Dose Evaluation Subcommittee

On January 29, 2004, Thomas Essig, ACMUI Designated Federal Official, sent an e-mail message to the ACMUI caused the formation of a Dose Evaluation Subcommittee. Details of the Subcommittee's function is as follows.

Purpose: A Dose Evaluation Subcommittee has been formed to enable the full Committee to provide its advice to the NRC staff regarding a dose reconstruction for the daughter of a patient who had received a radiation exposure in excess of the public dose limit while comforting her dying mother who was undergoing radioiodine therapy at the St. Joseph Mercy Hospital in Ann Arbor, Michigan.

Subcommittee membership:

Dr. Leon Malmud, Chair. Will oversee the Subcommittee and ensure that product delivery schedule is met, including vetting of the Subcommittee's product with the full ACMUI.

Dr. Jeffrey Williamson, Member. Will evaluate the technical details of the dose evaluation, with an eye toward assessing the reasonableness of the 15 rem dose estimate.

Dr. Douglas Eggli, Member. Will provide insights from his perspective as a nuclear medicine physician.

Ms. Sally Schwarz, Member. Will provide radiopharmeceutical insights, as appropriate.

Ms. Nicki Hobson, Member. Will provide patient advocate insights, as appropriate.

Approach: The attached inspection report prepared by NRC Region III contains an assessment of the dose received by the daughter while comforting her mother during her final days. The Dose Evaluation Subcommittee is requested to prepare independent views of the evaluation of radiation exposure received by the daughter. Input data are contained in the attached file. The Subcommittee is specifically requested to evaluate the approach to the dose reconstruction taken by the NRC Region, as well as the critique of the inspection report prepared by Drs. Carol Marcus and Jeffry Siegel (this critique is not available electronically and will be faxed to you). In preparing its report, the Subcommittee should indicate, for each aspect of the dose reconstruction and the Marcus/Siegel critique, whether it agrees or not with the evaluations and representations presented and why.

ATTACHMENT 5

ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES

REPORT

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

ADVISORY COMMITTEE
ON THE MEDICAL
USES OF ISOTOPES

MEMORANDUM TO: Charles L. Miller, PhD, Director
Industrial and Medical Nuclear Safety
Nuclear Materials Safety and Safeguards

FROM: Leon S. Malmud, MD, Chairman
Dose Reconstruction Subcommittee
Advisory Committee on the Medical Uses of Isotopes

DATE: May 14, 2004

SUBJECT: TRANSMITTAL OF THE ACMUI DOSE RECONSTRUCTION SUBCOMMITTEE REPORT TO NRC STAFF

On January 29, 2004, Nuclear Regulatory Commission (NRC) staff requested, under the direction of the Commission, that the Advisory Committee on the Medical Uses of Isotopes (ACMUI) perform an independent evaluation of the NRC staff's method to reconstruct an overdose of radiation to a member of the public, who received the overdose at St. Joseph Mercy Hospital in Ann Arbor, Michigan. The Commission instructed this action because of assertions by Carol Marcus, MD, and Jeffry Siegel, PhD, who claimed that the NRC's dose reconstruction method was overly conservative in this case.

In its charter, the ACMUI's Dose Reconstruction Subcommittee (DRS) was asked to prepare independent views of the evaluation of radiation exposure the daughter received. The DRS was specifically requested to evaluate the approach to the dose reconstruction taken by the NRC, as well as the critique of the inspection report prepared by Drs. Carol Marcus and Jeffry Siegel. In preparing its report, the DRS was requested to indicate, for each aspect of the dose reconstruction and the Marcus/Siegel critique, whether it agrees or not with the evaluations and representations presented, and why.

The ACMUI's DRS has performed its independent review and is now submitting to the NRC staff a report of its findings. See attached.

Attachment: ACMUI DRS Report

Memorandum

TO: Members of the ACMUI

FROM: Jeffrey F. Williamson, Ph.D., acting Chair
ACMUI Dose Reconstruction Subcommittee

DATE: April 29, 2004

SUBJECT: Report to ACMUI

This memo summarizes the Dose Reconstruction Subcommittee's (DRS) recommendations to the ACMUI regarding the St. Joseph Hospital incident. The chronology of this event is fully described in the attached Region III inspection report (Appendix A) and is not repeated here. The charges of DRS, as specified by the Commission and NRC staff were to:

- Independently review Region III's evaluation of dose to the member of the public in question (the patient's daughter) and assess its reasonableness.
- "Review the alternate dose reconstruction methodology submitted by the Society of Nuclear Medicine and provide the results of its assessment." The specific document reviewed by DRS was entitled "Nuclear Regulatory Commission Radiation Absorbed Dose Reconstruction For Family Member Of I-131 Patient" and authored by Drs. Carol S. Marcus and Jeffrey A. Siegel.
- Provide analysis and recommendations, as appropriate, regarding dose-reconstruction methodology.

Review of Region III's dose-calculation methodology.
During the patient's hospitalization, the licensee performed "bedside" measurements and 1 m measurements at approximately daily intervals. Based on documents submitted to Region III by the Licensee and on their own interviews with the individuals involved, Region III concluded that the patient's daughter remained at the patient's bedside for intervals ranging from 6-21 hours per day essentially positioned at the point of licensee bedside measurement. Thus a completely empirical methodology was used.

DRS findings and Recommendations

1. DRS performed independent calculations as described in the attached technical report (Appendix B) and Dr. Williamson's slides presented at the ACMUI meeting of 2 March 2004. The DRS analysis is based upon a computational rather than empirical methodology.

DRS estimates the range of radiation deep dose equivalent (DDE) to the patient's daughter, a "member of the public", to be 4-9 rem in a "best case-worst case" scenario. . Even at the lowest estimate ("best case") of 4 rem, the radiation burden exceeded the 100 mrem allowed.

2. The difference between the DRS upper limit of 9 rem and NRC's 15 rem dose arose from use of a computational methodology, which allowed a more realistic distance to be inferred from the measurements. The discrepancy between the 4 and 9 Rem estimates had to do with the assumptions of the time spent by the daughter near the patient and use of shielding.

3. There was agreement among members of the DRS that the calculations performed by the regional office of the NRC, which produced a radiation burden of 15 rem represented the most conservative scenario that could be plausibly assumed. They were overly conservative, in the sense that they assumed extended, close contact between the patient and the daughter at an unrealistically close distance for extended times, and ignored use of local shielding. More specifically,

   - Use of Monte Carlo simulation to reconstruct the bedside measurement distance, suggested that the bedside measurement distance was an unrealistically short distance for mean patient center-to-daughter surface distance. This methodology was necessary because the Licensee failed to adequately document the daughter's location relative to the point of measurement. Use of this methodology lowered the estimated dose by about 35% for the same exposure times and positions assumed by region III.
   - Use of continuous decay would lower the dose estimate by about 10%.
   - Most importantly, the Licensee post-incident interviews and dose reconstruction led to a different scenario regarding use of body shields and daughter dwell- time distribution than that derived from the Region III interviews. Assuming conservative scenarios consistent with the Licensee's claims that local shielding was used by the daughter during the period 7/2/02 until 7/4/02, DRS estimates an additional reduction of TEDE between 36% and 51%. DRS strongly feels that these differences should have been outlined in the Inspection Report and used to define lower and upper exposure bounds.
   - When the NRC requests that a consultant assess medical risk, the NRC should provide to the consultant an estimate of effective dose equivalent (EDE) as well as TEDE, since EDE is better correlated with any adverse medical effects associated with the exposure.
   - We suggest that a discrepancy, if any, between the licensee and the NRC inspectors, should be described in the final inspection report with data and "high dose-low dose" estimates.

4. The Region III methodology involved multiplying Licensee exposure-rate measurements, presumed to be made at the average position occupied by the exposed subject, and the duration of exposure. This is an appropriate method of dose estimation for many cases. In particular, given the time-distance-shielding scenario assumed by the Region III inspectors, it was an appropriate methodology. However, it relies on the premise that the Licensee has taken adequate steps to measure exposure at the average location occupied by the daughter and to closely monitor the daughter's duration of exposure and utilization of shielding. In

this situation, the Licensee failed to prospectively document the exposure scenario, despite a clear indication that the daughter's 100 mrem limit was clearly exceeded well before the patient's death.

5. Perhaps, prompt contemporaneous notification to the NRC regional office of the unwillingness of the member of the public to comply with the directions of the RSO would have had the desirable effect of assisting in the better documentation of the event.

6. The DRS dose reconstruction effort utilized Monte Carlo simulation, a tool not normally available in the field. Use of such simulations provided a basis for reducing Region III's estimate by 35%. DRS does not recommend that NRC and Licensees use such computing tools for all cases of dose reconstruction. Cases where more sophisticated approaches, including many of the suggestions made by the Marcus-Siegel report, are warranted include the following:
   - o Situations in which adverse medical effects in the exposed individual are possible
   - o The reconstructed dose is near the regulatory limit and a regulatory decision depends upon the reconstructed dose.
   - o The Licensee contests NRC's reconstructed dose.
   - o Inadequate documentation of the location of the irradiated subject relative to the radiation source and/or points of dose measurement
   - o Situations where inverse square law and other widely used approximations are likely to be inaccurate

   Thus, in the SJH case, DRS believes NRC should have supported their empirical dose estimates by an independent computational dose assessment because (a) the licensee disputed NRC's dose estimates and (b) documentation of the daughter position relative to the measurement point was lacking. Because of the short distances involved relative to the size of the source (patient), relatively sophisticated computational tools, capable of modeling patient attenuation and large distributed sources, are indicated. While DRS believes that Monte Carlo tools are certainly useful in this case, DRS believes that uncertainties in (a) duration of the daughter's exposure, (b) use of shielding, and (c) average location of daughter exposure relative to the patient are more significant than uncertainties associated with the dose computation methodology itself.

7. A review of the alternative dose reconstruction by Drs. Marcus and Siegel (M&S) is attached (Appendix C). In summary,
   - o DRS agrees with M&S that Region III should have supported their measurement-based dose estimation with an independent computational estimate.
   - o DRS does not agree with the large errors (factors of 1.6 and 6.8 for integrated DDE at the measurement point and reconstruction distance proposed by M&S, respectively). By comparison, the corresponding overestimates identified by DRS are factors of 1.1 and 1.7 respectively. The main reason for the discrepancies is use of insufficiently accurate approximations by M&S to model the effects of distance and patient attenuation in the presence of an extended volume source.
   - o M&S state "All licensees should expect that the NRC performs dose calculations using state-of-the-art dosimetry methods that result in realistic and not overly conservative dose estimates." However, their paper does not define "state-of-the-art." In the

opinion of DRS, the specific computational methods used by M&S fall short of any reasonable interpretation of this standard. In section 6 above, DRS describes a range of circumstances in which more sophisticated dose calculation tools are indicated.

- M&S by implication associate inaccurate or non-"state-of-the-art" dose calculation methodologies with "overly conservative" dose estimates. DRS agrees that modeling inaccuracies can contribute to dose overestimates as well as underestimates. However, by far the most significant contribution to conservatism are assumptions regarding duration of exposure, distance of exposure and use of local shielding.

8. A concern of the committee is how such a similar situation in the future might be handled in a more optimal manner for both the public and licensee. Therefore, the subcommittee recommends that the ACMUI recommend that the NRC develop guidance or rule changes in collaboration with the ACMUI regarding (1) prompt notification of the regional NRC office of non-compliance by a member of the public and (2) maximum permissible dose levels for caregivers, family members, and friends of radioactive patients who choose to ignore dose limits for members of the public.

9. Region III, the Licensee, and the published M&S commentary all appear to accept DDE is the appropriate dose-reconstruction endpoint for assessing regulatory compliance. Recently Dr. Marcus has brought to DRS' attention Regulatory Issues Summary 2003-04 (RIS03-04) and its relevance to the SJH case. RIS03-4 clearly allows, if not encourages, Licensees and NRC inspectors to use EDE Licensees are encouraged to use the effective dose equivalent in place of the DDE in all situations that do not involve direct monitoring of external exposures using personnel dosimetry. DRS believes that the Licensee could have evaluated the daughter's radiation exposure in terms of EDE and that its use should have been considered by Region III. Because of the radiation field nonuniformity and the unidirectional exposure of the daughter, reporting EDE rather than DDE would have reduced the daughter's calculated exposure significantly (possibly by as much as a factor of 4).

   In general, DRS believes that EDE is a better surrogate for medical risk and therefore a more rationale choice as a regulatory compliance endpoint. While its implementation for uniform isotropically distributed sources is straightforward, there are no accepted industry-wide medical practice guidelines for EDE estimation from point measurements or from first principles for situations such as the SJH case, wherein the radiation field is neither uniform over the subject's body nor uniformly incident on the subject's body surface. DRS recommends that at ACMUI's next face-to-face meeting, it consider the problems of practical estimation of EDE and how to encourage adoption of EDE in dose reconstructions and other radiation safety scenarios involving members of the general public as specified by Regulatory Issues Summary 2003-04.

ACMUI Dose Reconstruction Subcommittee (DRS)
Appendix B: Technical Report
15 April 2004

Interview of Region III Inspectors by DRS members

- DRS interviewed Mr. Cameron and Mr. Wiederman (C&W) from Region III, who performed St. Joseph's Hospital inspection
- Additional information gleaned
  - Licensee found minimal or no contamination in patient room
  - C&W provided times/dates of bedside and "1 m from bedside" measurements performed by licensee. However, exit and entry times of the daughter are not available.
  - C&W reported that a urine collection bag, placed near the patient bed, contained a significant radiation burden. During part of the daughter's exposure, this bag may have been separately shielded. DRS did not include the urine bag as an additional radiation burden, but assumed that it was included in the Licensee's bedside and 1 m dose measurements.
  - C&W stated they interviewed daughter for about 90 minutes: pertinent findings
    - Daughter did indeed "move around": bathed, fed and provided other basic care to patient. However, daughter insists she sat in the position assumed by the Region III calculations.
    - Daughter sat in chair facing the bed and patient's left side. Daughter's knees were placed against lowered bed rail and sat leaning forward with her elbows on edge of mattress.
    - C&W stated that licensee personnel performed bedside measurements at the point where they believed daughter's forearms were positioned
    - C&W had the impression that daughter was so attached to her mother (the patient), that using the "general rationale person model," a person who seeks to minimize discomfort, would not yield a good approximation to the daughter's time-space distribution around the patient.
    - Nursing notes are insufficient to provide definitive factual confirmation of the daughter's dwell times or distance assumptions
    - C&W believed that sometimes the daughter was closer than the stated distance and sometimes further. Also, the daughter was exposed by a urine reservoir, which was not otherwise included in the calculations. Hence they still believe that their assumption is a reasonable average.

- The DRS achieved consensus on the following issues:
  - C&W beliefs notwithstanding, that the daughter could have sat rigidly in a single position for so long still seems implausible.
  - C&W were unable to provide any factual basis for assuming other average distances or non-unity occupancy factor.
  - DRS is not aware of any industry guidance or scientific studies (e.g., time motion studies) which are applicable to this case and could provide the basis for an alternative set of time-distance assumptions.

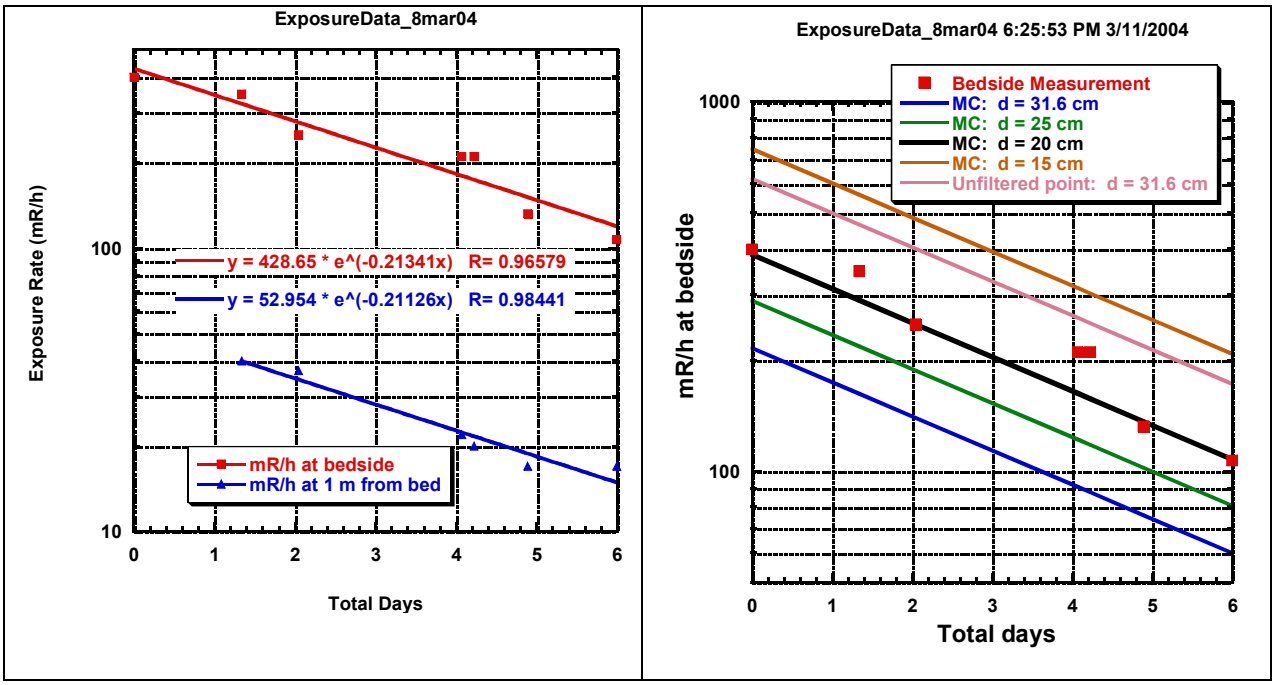
- Data available from this interview do not permit quantitative assessment of dose estimation uncertainty due to dwell time and distance uncertainties.
- Given the data available to inspectors and lacking an objective basis for constructing plausible alternative scenarios factual basis, their assumptions seemed reasonable.

Interview of Ralph Lieto on 3/12/04 and review of SJH written materials

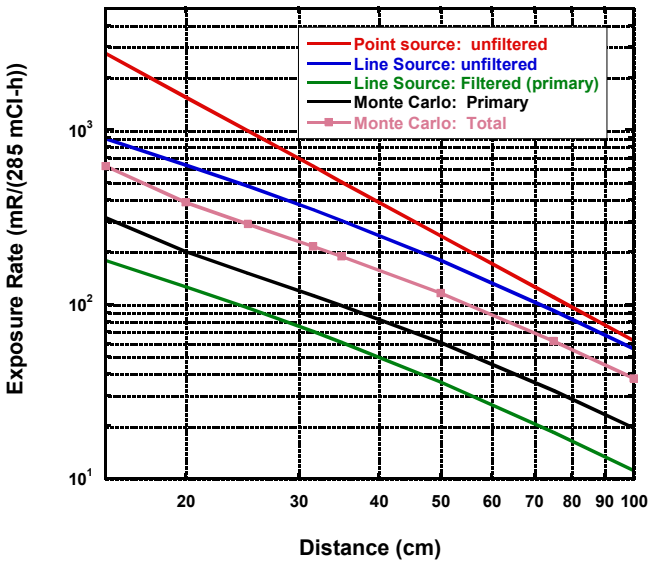
- Interview with Ralph Lieto (by J. Williamson**)** yields following findings
  - SJH continues to contest NRC dose reconstruction. They believe that NRC has willfully ignored their far more intensive reconstruction efforts. The crux of the dispute is how long the daughter was positioned near the patient without the use of portable shields.
  - Based on recollections of two eye witnesses to J. Cameron interview of daughter, ~~Mr. Lieto~~ the licensee claims
    - Interview was superficial and lasted only 15 minutes
    - JC "led" patient on" by asking questions such as "were you positioned like this?" rather than asking her "tell me what happened in your own words"
    - Contradictions between this brief interview and more extensive multiple witness interviews were ignored by NRC.
- Other findings
  - During 7/2, 7/3 and 7/4 up until 7/5 3 PM, licensee maintains that bedside shields were in place and that daughter followed instructions to stay behind them. Region III claims that shields were not being used or positioned properly. No licensee documentation exists to dispute Region III daughter dwell times.
  - Shields were 1" thick, 36" wide and 46.5" tall providing 24 inches vertically of protection. Shields could be positioned such that shield surface was in contact with mattress edge.
  - Licensee information based on detailed staff interviews conducted two weeks after incident and daughter telephone interview conducted in Sept 2002.
  - To what extent shields were used after 7/5 is contradictory: Licensee interview summary is contradictory and daughter claims in 9/02 interview that they were not used after 7/5 but were used before.

Technical Issues

Effective half life and Reconstructed distance of bedside readings



The more complete data consistently reveal $\lambda = 0.212$ da^{-1}, equivalent to a half-life of 3.26 days. Based on Monte Carlo simulations, the patient-to-detector center distance best accounting for the measurements is about 20 cm. This suggests readings were taken with detector a few cm from lateral surface of the patient. Monte Carlo simulation is warranted in this particular case because the patient was known to have impaired renal function and because the fraction of thyroid uptake is typically small in metastatic thyroid cancer patients. This assumptions warrants treating the patient as a cylindrical volume source in which radioactivity is uniformly distributed.



Since a typical hospital bed is about 37 inches wide, the mattress edge-to-patient center is about 47 cm. Assuming that the daughter placed her forearms on the lateral aspect of the mattress edge, a distance of 37 cm would seem to be the shortest distance between the daughter's forearms and the patient center that could be maintained for a long period of time. Hence, DRS suggests that 37 cm is a more appropriate distance to apply to the Region III scenario rather than the estimated 20 cm measurement distance. Based on the ratio of MC air-kerma rates at 35 cm and 20 cm, it is reasonable to scale the beside readings downward by a 0.65 factor.

Continuous vs. Stepwise decay.

Region III simply multiplied the patient dwell time by the measured beside reading without correcting for decay either during the interval between the measurement time and beginning of the daughter's exposure, or during the interval of exposure. Let t = time between measurement and start of daughter's exposure of duration t. Then

t= 0 and T = 21 hr implies Region III/True exposure = 1.09 (exposure measurement at beginning of daughter's visit)
t= 0 and T = 6 hr implies Region III/True exposure = 1.03
t = -10.5 h and T = 21 hr implies Region III/True exposure = 1.045 (exposure measurement during midpoint of daughter's visit)
t= 18 h and T = 6 hr implies Region III/True exposure = 1.204
t= 6 h and T = 18 hr implies Region III/True exposure = 1.14

This leads to an overestimate for individual exposure segments of 3-20% assuming that measurements were always performed prior to the midpoint of the daughter's visit. The NRC staff could have included this correction, since measurement times were available and since estimates of daughter initiation and ending times of exposure were available. DRS believes the effect could be as large as 10% effect, an estimate which NRC staff could attempt to confirm by performing a more detailed reconstruction based upon availability of measurement times and estimates of the daughter's visiting hours. However, for general practice, such efforts are probably not warranted since the 10% improved achieved is small in relation to the total uncertainty of the reconstructed dose.

Daughter Tissue attenuation
Marcus et al. suggests that an attenuation correction (attenuation of I-131 gamma rays through 1 cm tissue) should have been applied. DRS believes that this correction is negligible or even > 1, due to compensation of primary photon attenuation by backscatter from the daughter.

DRS estimated dose assuming Region III scenario
Based on this review, DRS estimates TEDE to be

TEDE = 15 Rem x 0.65 x 0.90 = 8.8 Rem

This estimate assumes the same distance-dwell time distribution as Region III

Reconciliation of SJH and Region III dose-reconstruction efforts
Based on review of material submitted by the Licensee, it is clear to DRS that the Licensee made significant efforts through retrospective interviews and records review to reconstruct the daughter dwell times and used of shielding. This reconstruction is both more detailed and closer in time to the incident than NRC's Region III effort. In addition, SJH continues to challenge NRC's calculations on technical grounds. DRS believes that NRC can be criticized for not making a more thoughtful and balanced effort to reconcile the two reconstruction scenarios.

Based on our admittedly relatively superficial view, DRS proposes the following alternative reconstruction scenario:

- During the period 7/2-7/4, we can assume the shields were in place and the daughter was standing behind them.
- Approximating I-131 by Ir-192, NCRP 49 indicates the transmission through 1" Pb shields to be about 0.02
- In a best case scenario, DRS assumes the daughter's body core was fully behind the shield
- In a worst-case scenario, DRS assumes that the daughter leaned over the shields with elbows, head and neck exposed to unshielded radiation field. DRS assumes a 50% occupancy ratio in this position, although no data are available to justify this or any other assumption.
- In both the worst and best case scenarios, DRS assumes that the daughter's minimum distance is limited by the shield, the distal surface of which can be no closer than 55 cm to the patient's center.
- The unshielded 55 cm exposure is given by MC to be about 41% of the 20 cm (beside measurement point) rate.

DRS notes that its postulated distance and dwell time scenarios are extremely conservative. Basically, the daughter was assumed to have positioned herself as close to the patient as geometrically possible and remained there 100% of the exposure time. On the other hand, neither Region III nor the Licensee are able to provide factual data justifying other scenarios. Region III inspectors believe that the daughter performed routine care duties, such as bathing the patient, and may have been even closer to the patient than the bedside measurement distance.

Best case = 0.9 x (0.02x0.41x(2.088+3.0+2.52) + 0.65 x (3.25+2.71+1.23))= 4.3 Rem

Worst case = 0.9 x (0.51x0.41x(2.088+3.0+2.52) + 0.65 x (3.25+2.71+1.23))= 5.6 Rem

Summary

- DRS believes that the 15 Rem estimate represents the most conservative estimate one could make that is not totally implausible. More sophisticated distance reconstruction techniques and common-sense evaluation of geometry (bed widths, etc) suggests that reducing this estimate by 40% is reasonable, assuming the Region's dose-time-distance scenario.
- DRS believes that the NRC should have considered the licensee's more detailed and contemporaneous dose reconstruction efforts. Where a dispute arises over dwell times, shield usage, etc. between NRC inspector reports and licensee interviews, both versions should be described in the inspection report and a range calculated based on bracketing scenarios. Of course, DRS assumes that both licensee and NRC inspectors are acting in good faith and that no one is intentionally trying to distort the truth.
- While details of space-time occupancy are very difficult reconstruct retrospectively, both NRC inspectors and licensees are obligated to apply common sense in selecting distances, accounting for geometric constraints imposed by bed sizes and shield positions.

- In this particular case, DRS is comfortable citing a 4-9 Rem figure based on testimony from various parties. In routine cases where MC is not available, use of analytic line source or extended volume source formulas should be used since inverse square law will underestimate exposures near extended sources.
- In contrast to the Marcus-Siegel report, which challenges the Region III calculation mostly on methodological grounds, DRS finds that the greatest source of uncertainty is associated with assumed daughter dwell times and use of body shields. The assumed distance is also highly uncertain. However, neither Region III nor the licensee are able to provide factual data upon which an uncertainty analysis could be based.
- As suggested by the Marcus-Siegel paper, DRS used a computational approach (Monte Carlo simulation) to estimate a patient center-to-bedside detector distance. This reconstructed distance provides a rational basis for reducing NRC's dose estimate by 35%. However, DRS believes that inverse-square law, as proposed by Marcus and Siegel, applied to a single measurement is not appropriate in this case.
- The DRS reconstruction effort used Monte Carlo tools and more elaborate computational models than are normally applied in the field. These efforts were undertaken at the request of the Commission because this individual case has prompted a National debate. In routine cases, DRS believes that such efforts may not be warranted. It believes that effort should be directed more towards the "basics" of time, distance, and shielding utilization. The uncertainties associated with these assumptions overwhelm the issues of computational methodology.

Appendix C:
ACMUI Dose-Reconstruction Subcommittee (DRS) Comments on "Nuclear Regulatory Commission Radiation Absorbed Dose Reconstruction For Family Member Of I-131 Patient" by Drs. Carol S. Marcus and Jeffrey A. Siegel

Marcus-Siegel Comment	DRS response
"We believe that it is imperative to **reconstruct the distance before you reconstruct the dose."**	DRS agrees that a computational dose reconstruction is a useful tool complementing the empirical dose estimation technique used by Region III and the Licensee. DRS believes theoretical dose estimation in this case is warranted for two reasons (a) the Licensee contests NRC's analysis (although not on grounds of methodology) and (b) No observations are available to determine where the daughter was positioned in relation to the bedside measurement. However, DRS does not believe that inverse square law and using only one data point, as proposed by M&S, to be either state-of-the-art or adequate for this case.
The bedside distance (31.6 cm per M&S estimates) is implausibly short. A distance of 66 cm is suggested, which M&S claim reduces NRC's dose estimate by factor of 4.3.	While DRS believes that the bedside distance is implausibly short, it disagrees with the M&S critique in several important respects o There is no factual basis or industry standard to justify doubling the distance. DRS believes that using the measurement without modification is preferable to an arbitrary unjustified choice. In contrast, DRS increased the distance from 20 to 35 cm based upon geometric plausibility arguments. o Simple point source or even line source approximations are invalid so close to the patient. Near a large volume source, dose fall-off is much less rapid than inverse square law. Hence, DRS estimates only a 35% reduction in dose, not 77% as proposed by M&S.
Evaluating whole body dose as well as DDE would have been prudent. M&S believe this would have reduced NRC's dose estimate by a 6.8-fold factor.	DRS agrees that whole body dose is a better surrogate for medical risk and agrees it should be supplied to medical consultants. Based on highly limited Monte Carlo calculations, DRS believes that mean and maximum physical dose differ by about a factor of 4 assuming a cylindrical source and subject geometries and a center-to-center distance of 50 cm. However, this simplified simulation falls short of the definition of EDE.
Failing to account for tissue attenuation over the 1 cm tissue depth overestimates DDE by 10%.	M&S derive this factor by considering only primary photon attenuation. DRS believes that backscattered radiation from the daughter would likely compensate for decrease in the primary photon DDE, although detailed Monte Carlo

	simulations were not performed. In any case, this correction is small in relation to other uncertainties.
(a) Failing to use line source approximation; (b) – stepwise daily rather than continuous decay and (c) equality of two successive measurements together imply that NRC overestimated total bedside DDE by 1.5 assuming patient elbows were actually positioned at the point of measurement.	(a) Since no inverse square law corrections are made by NRC, it is unclear why the adequacy of inverse square law is relevant here. (b) DRS believes continuous decay might reduce the dose by as much as 10%. (c) More detailed information available to DRS indicates that the measurements were performed 4 hours apart, so that their equality is well within experimental error. Overall, DRS believes the dose estimation factor is only 1.1 not 1.5 in this context.
NRC estimate of integrated bedside DDE measurement is in error by 1.1*1.5 factor = 1.6	DRS rejects the attenuation correction, and the 1.5 correction above. DRS believes NRC's error in this calculation is about 10% due to ignoring continuous decay.
Based on distance implausibility, NRC estimate of DDE is in error by 4.3*1.1*1.5=6.8	For reasons explained above, DRS estimates that Region IIII overestimated DDE by a factor of 1.5*1.0*1.1=1.7 Basic reasons: DRS believes M&S theoretical calculations are too approximate and that their choice of mean daughter-patient distance too arbitrary.
Using mean body dose, NRC estimate is too high by following factors (6.8)*(1.7)*(1.5)= 17	DRS does not believe that the approximations and rules of thumb used by M&S are accurate enough to support quantitative estimates of mean whole body dose. DRS recommends Monte Carlo simulation or other more sophisticated radiation transport tools for estimating this quantity.

ATTACHMENT 6

PROPOSED LETTER FROM THE CHAIRMAN TO THE
SOCIETY OF NUCLEAR MEDICINE

June XX, 2004

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

Dear Dr. Royal:

In my letter to you dated January 12, 2004, concerning the St. Joseph Mercy Hospital dose reconstruction, I had indicated that the Nuclear Regulatory Commission (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.

Based on careful review and 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 the estimate that appears best supported by available data and, based on that data, does not appear to be overly conservative and is probably closest to the true dose. We have come to this conclusion because our reviews showed 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 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 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 relied on a calculated dose rate to the family member considering the 285 curie 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 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. In the present case, the event was recognized some time after it happened, and interviews were delayed in some cases for several months. Not surprisingly, details could not be accurately remembered, and inconsistencies and disagreements were the result. We are also considering actions to ensure that more detail than is normally deemed necessary be included in future NRC reports on similar cases.

I would like to thank you for providing us with this opportunity to improve our procedures and documentation in 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.

Nils J. Diaz

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