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.

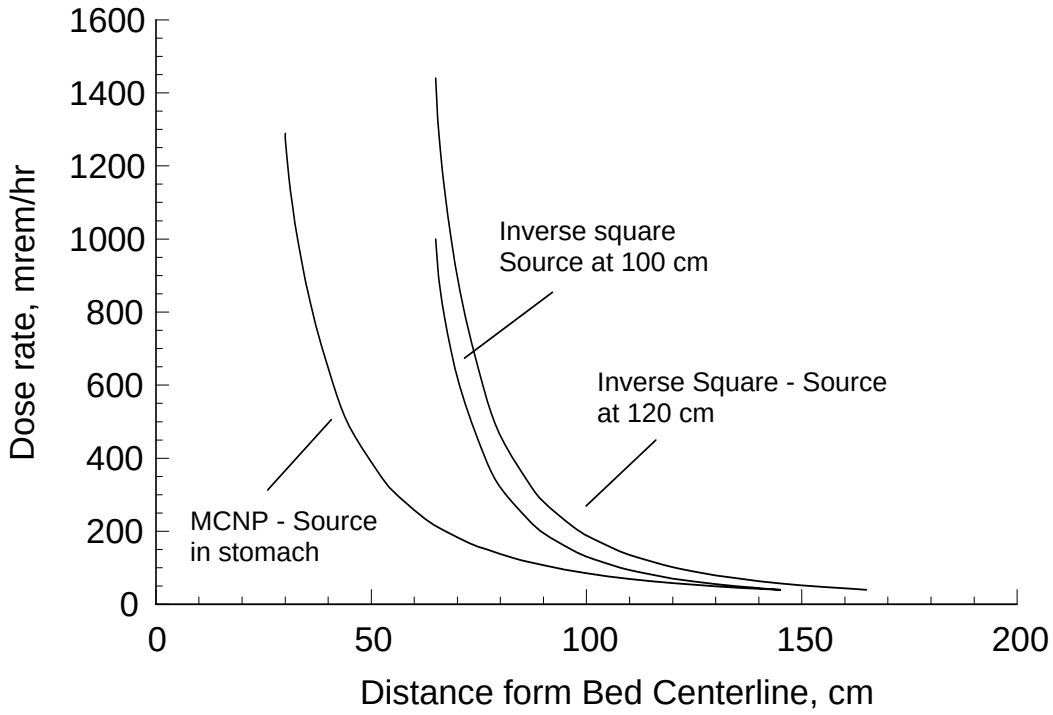
Based on published data (3), the deep dose equivalent at the $^{131}$I photon energies is about a factor of 1.3 higher than the effective dose for anterior-posterior exposure in a uniform field. The field in this case was probably not uniform, and therefore the deep dose equivalent would probably be 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.

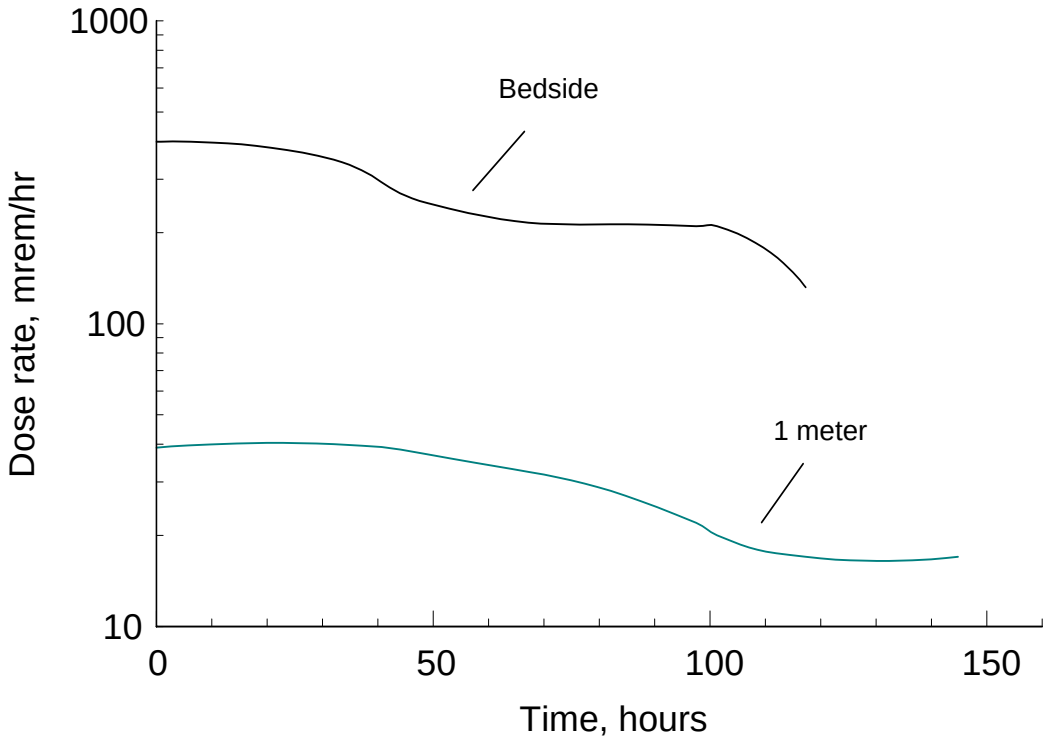
## 4.2 CONCLUSIONS

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

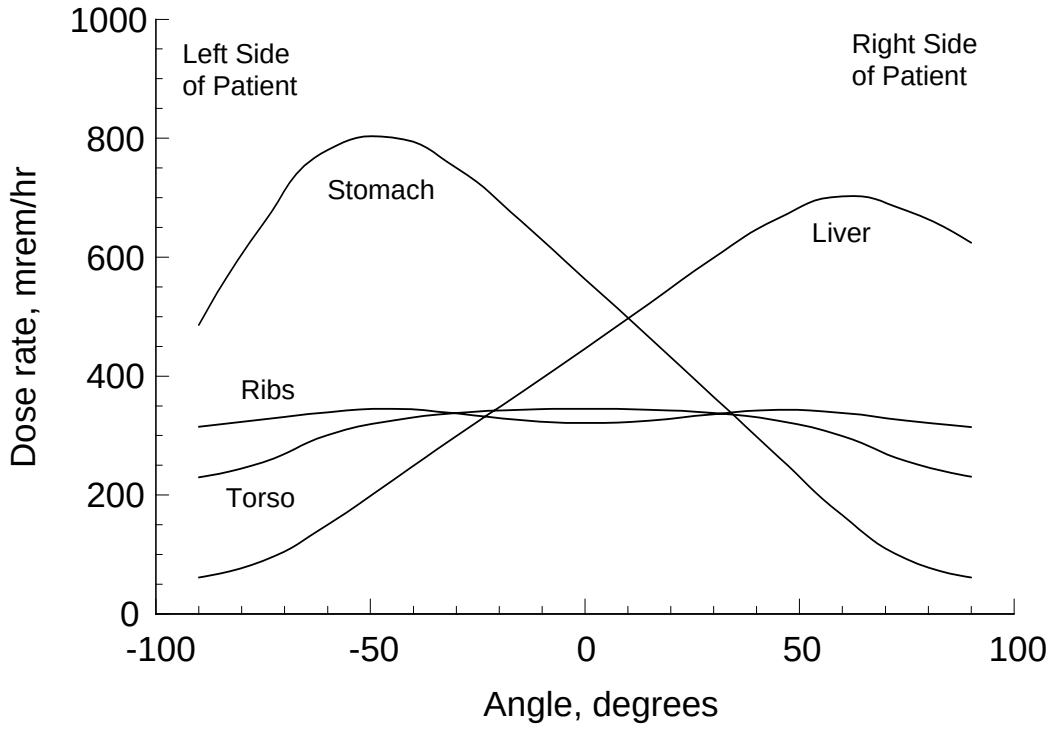
respect to the patient. NMSS staff believes that the methods used in calculating the dose rates close to the patient were not sufficiently detailed for the intended purpose, and were therefore not capable of estimating dose rates close to the patient with adequate accuracy. In addition, the assumptions 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.

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