

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:

- o Independently review Region III's evaluation of dose to the member of the public in question (the patient's daughter) and assess its reasonableness.
- o "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.
- o 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.

- o 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.

Appendix A

NRC Inspection Report

(Available in ADAMS as ML02440102)

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 believes 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.

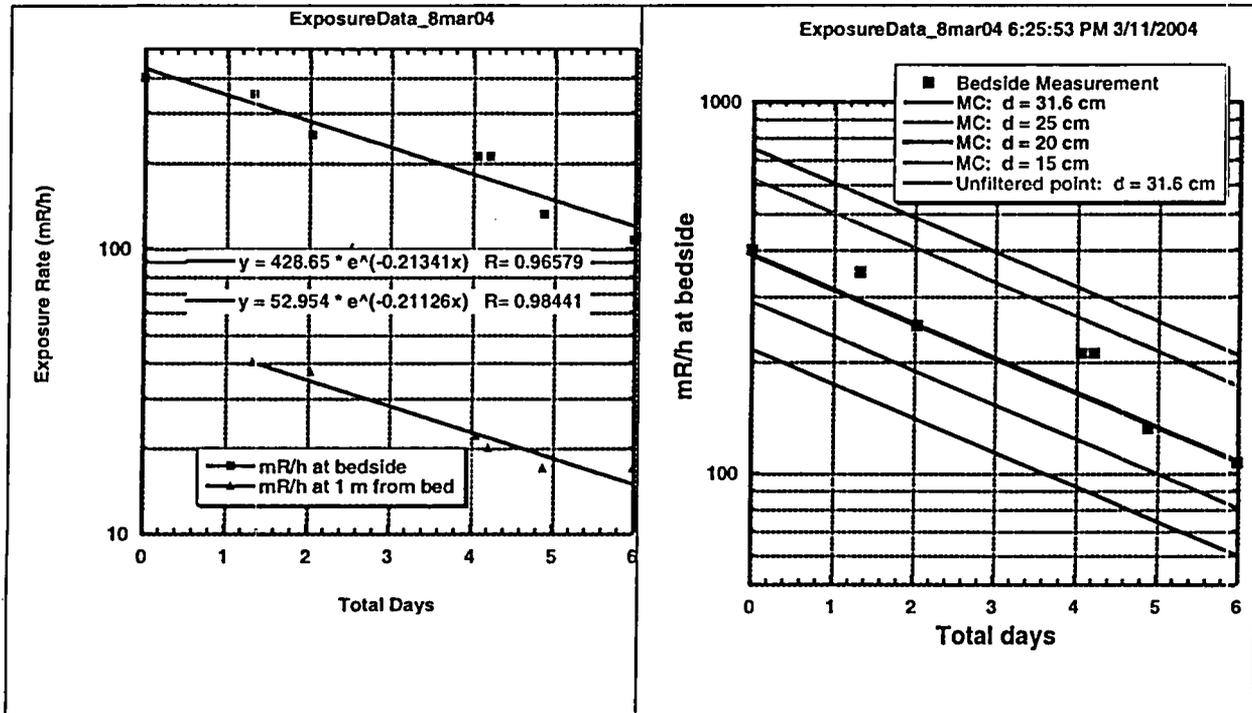
- Data available from this interview do not permit quantitative assessment of dose estimation uncertainty due to dwell time and distance uncertainties.
- Given the data available to inspectors and lacking an objective basis for constructing plausible alternative scenarios factual basis, their assumptions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

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

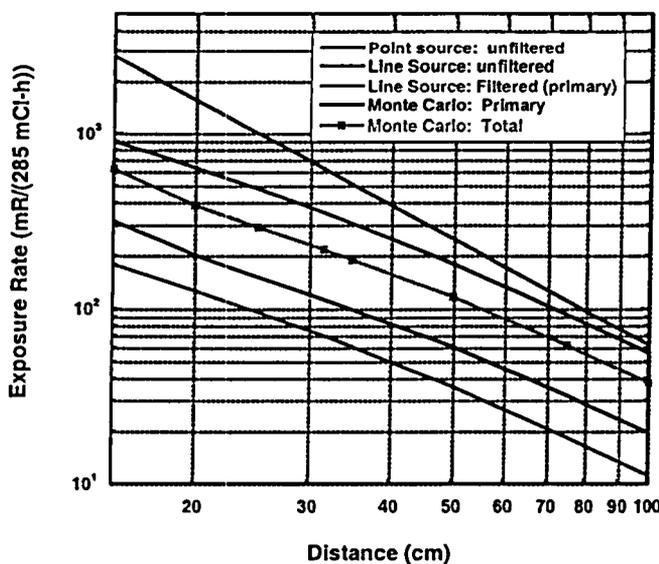
- Interview with Ralph Lieto (by J. Williamson) yields following findings
 - SJH continues to contest NRC dose reconstruction. They believe that NRC has willfully ignored their far more intensive reconstruction efforts. The crux of the dispute is how long the daughter was positioned near the patient 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 $\lambda = 0.212 \text{ da}^{-1}$, 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 bedside 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

$$\text{TEDE} = 15 \text{ Rem} \times 0.65 \times 0.90 = 8.8 \text{ Rem}$$

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.

$$\text{Best case} = 0.9 \times (0.02 \times 0.41 \times (2.088 + 3.0 + 2.52)) + 0.65 \times (3.25 + 2.71 + 1.23) = 4.3 \text{ Rem}$$

$$\text{Worst case} = 0.9 \times (0.51 \times 0.41 \times (2.088 + 3.0 + 2.52)) + 0.65 \times (3.25 + 2.71 + 1.23) = 5.6 \text{ Rem}$$

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
<p>“We believe that it is imperative to reconstruct the distance before you reconstruct the dose.”</p>	<p>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.</p> <p>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.</p>
<p>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.</p>	<p>While DRS believes that the bedside distance is implausibly short, it disagrees with the M&S critique in several important respects</p> <ul style="list-style-type: none"> 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.
<p>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.</p>	<p>DRS agrees that whole body dose is a better surrogate for medical risk and agrees it should be supplied to medical consultants.</p> <p>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.</p>
<p>Failing to account for tissue attenuation over the 1 cm tissue depth overestimates DDE by 10%.</p>	<p>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</p>

	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 $4.3 \times 1.1 \times 1.5 = 6.8$	For reasons explained above, DRS estimates that Region III overestimated DDE by a factor of $1.5 \times 1.0 \times 1.1 = 1.7$ 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 $(6.8) \times (1.7) \times (1.5) = 17$	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.