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TO:

Chairman Meserve

FOR SIGNATURE OF : ** PRI ** CRC NO: 02-0711

Chairman Meserve

DESC:

Emergency Medical Preparedness and Response in the Event of Radiological Terrorism

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October 24, 2002

Richard Meserve, Ph.D., Chairman
Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Dear Chairman Meserve:

The purpose of this letter is to enlist your aid in helping to solve a serious obstacle affecting emergency medical preparedness and response in the event of radiological terrorism. We need to generate a comprehensive list of "humanized" gamma ray constants for adults and children of different builds, for a variety of radionuclides. By "humanized", I mean corrected for self absorption. Humanized gamma ray constants are necessary in order for medical emergency response teams to separate out victims with significant internal contamination as opposed to those with no or insignificant internal contamination. Various medical procedures, such as pulmonary lavage and a variety of pharmacologic procedures, are effective in reducing internal contamination by numerous radionuclides. Choosing the right patients for the appropriate medical treatments is important. In a terrorist scenario in which hundreds or thousands of people *might* be internally contaminated, a triage procedure using only a calibrated ion chamber reading is achievable in order to direct limited resources to the appropriate victims.

Such procedures require humanized gamma ray constants, but there exists no repository of humanized gamma ray constants. This would be the subject of a terrific NUREG, which NRC could contract out to scientists best able to quickly calculate them. While some excellent work has been done for I-131 (appended), this radionuclide is not a prime candidate for a radiological dispersion device, and the same methodology needs to be extended and applied to other radionuclides.

Jeffry Siegel and Richard Sparks contacted NRC a few years ago to do just this task, due to the need to accurately estimate radiation dose from patients treated with therapy radiopharmaceuticals to other persons. This concept was turned down by NRC at the time. Now that there is another, pressing reason to perform these calculations, I request that NRC reconsider the contracting of such a NUREG. Ronald Zelac, who presented the concept to management the first time, would probably be an excellent contract manager for such a NUREG. I know Drs. Siegel and Sparks are still interested in doing this, and for the sake of homeland security and the effective operation of medical emergency response teams and hospitals in the event of a radiological dispersion device event, I ask that you proceed with the reconsideration and contracting in a speedy manner.

In order to understand how humanized gamma ray constants will be used in a triage procedure, I have attached a preliminary procedure in the event of Ir-192 internal contamination which I developed for my emergency medical response teams, the Western National Medical Response Team (NMRT) and the Disaster Medical Assistance Team (DMAT), California Team 9. These teams are part of the U.S. Public Health Service's National Disaster Medical System (NDMS).

Please feel free to contact me with any further questions you may have.

Thank you for your attention and consideration.

Sincerely,

Carol S. Marcus, Ph.D., M.D.
Prof. of Radiation Oncology and of Radiological Sciences, UCLA
Member, Western NMRT and DMAT CA-9

Encl: (1) Paper by Sparks, Siegel, and Wahl
(2) Ir-192 triage procedure by Marcus

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Forum

THE NEED FOR BETTER METHODS TO DETERMINE RELEASE CRITERIA FOR PATIENTS ADMINISTERED RADIOACTIVE MATERIAL

Richard B. Sparks,* Jeffry A. Siegel,† and Richard L. Wahl‡

Abstract—In current NRC regulations, three options exist that may be used to determine release criteria for patients administered radioactive materials. Absorbed dose estimates may be based on administered activity, measured dose rate, or on patient-specific calculations. All of these methods proposed by the NRC can lead to overestimation of the dose equivalent to others due to their oversimplified nature. The primary oversimplifications are the use of a point source methodology and using the measured surface entrance dose rate to determine whole body dose. In order to show the inaccuracy of these oversimplifications for ^{131}I, results using Monte Carlo radiation transport analysis with simplified anthropomorphic mathematical phantoms were determined. These results were then compared to actual patient measurements and the results of point source analysis. The measurement data were taken from 49 ^{131}I radioimmunotherapy patients. The point source calculations were performed using well established methodologies and using the same assumptions as in the NRC regulations for patient release criteria. Monte Carlo results were obtained by implementing two simplified 70 kg anthropomorphic phantoms and performing radiation transport simulation. The activity in the "patient" phantom was assumed to be localized in the abdominal region to correspond to the activity localization seen in the radioimmunotherapy patients who were measured. Dose equivalents per unit cumulated activities were determined for ^{131}I using the various methods. The relationship between measured dose equivalent per unit cumulated activity and whole body dose equivalent per unit cumulated activity was also investigated using Monte Carlo analysis. The point source method as implemented by the NRC yields an estimated dose equivalent per unit cumulated activity of 1.6×10^{-8} mSv MBq^{-1} s^{-1} at 1 m (2.2×10^{-4} rem mCi^{-1} h^{-1} at 1 m), and the Monte Carlo based method yielded a whole body dose equivalent per unit cumulated activity in the target phantom of 6.8×10^{-9} mSv MBq^{-1} s^{-1}(9.0×10^{-5} rem mCi^{-1} h^{-1}) for abdominal localization of activity in the source phantom. The measurements of the radioimmunotherapy patients yielded an average result of 1.0×10^{-8} mSv MBq^{-1} s^{-1} (1.3×10^{-4} rem mCi^{-1} h^{-1}). When corrected for the difference between measured surface dose equivalent and whole body dose equivalent as determined by Monte Carlo analysis, these measurements represent a whole body dose equivalent per unit cumulated activity of about 6.2×10^{-9} mSv MBq^{-1} s^{-1} (8.1×10^{-5} rem mCi^{-1} h^{-1}). Based on these results, the current NRC dose-based methodology for the release of patients administered radioactive materials significantly overestimates the dose equivalent to others from ^{131}I therapy patients.

Health Phys. 75(4):385–388; 1998

Key words: modeling, dose assessment; medical radiation; ^{131}I; regulations

INTRODUCTION

In radionuclide therapy, considerable levels of activity can be retained within the patient's body for significant periods of time. Thus, there is a potential of radiation exposure to others from the therapy patients. Updated NRC regulations for release of patients after therapy have recently been issued (Federal Register 1997). These regulations dictate that patients cannot be released until the potential dose equivalent to others is below the given regulatory limit of 5 mSv (500 mrem). Three options are given for the estimation of dose equivalent to others in the updated regulations.

The first option is to calculate dose equivalent estimates based on the administered activity. The assumptions used in this option, which include neglecting biological removal of activity and estimation of dose equivalent using a point source methodology, can lead to overestimation of the dose equivalent to others. By neglecting biological removal, it is obvious that the activity levels in the patient will be overestimated for most types of radiopharmaceutical therapy. In addition, a point source estimate of dose equivalent assumes that the source (the patient) and the targets (persons near the patient) are one dimensional points in space. Clearly, this does not accurately describe the true physical reality of the situation, nor can the possibility of non-uniform distribution of activity in the source be considered. Further, attenuation and scatter within the source and target are neglected using a point source methodology.

The second option, a dose equivalent estimate based on measured dose rate, is actually a measurement of surface entrance dose rate. It does not consider that the dose rate drops across the thickness of the target individual due to the attenuation of the emissions by the target and thus overestimates the whole body dose equivalent.

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The third option, patient-specific dose calculation, is also based on a point source method, and for the reasons mentioned previously can lead to overestimation of the dose equivalent.

Given the profound differences between the assumptions of the point source calculation and the actual physical reality of radionuclide therapy patients exposing others, a more accurate calculational methodology is needed. Monte Carlo radiation transport simulation using anthropomorphic mathematical phantoms allows for a more realistic modeling of the radiation transport. It also allows for a more realistic modeling of the distribution of activity within the patient and the determination of whole body dose or EDE in others who are exposed to the patient. For this study the activity in the source phantom, or "patient," was modeled as being localized in the abdominal region. This corresponds to the distribution seen in the measured radioimmunotherapy (RIT) patients. A simplified version of the Cristy-Eckerman adult male phantom (Cristy et al. 1987) was implemented to illustrate the need for more accurate analysis. Future work should involve a more complete implementation of the phantoms to include internal organs and structures that would allow calculation of ED and EDE.

The difference between whole body dose equivalent and measured dose equivalent was also examined. Monte Carlo analysis was used to estimate surface entrance dose equivalent by determining the dose equivalent to a small thin disk of tissue 1 m from the center of the source phantom's torso. This position corresponds to the location of the calibrated ionization chamber used to take the patient measurements. By comparing the results of the surface entrance dose equivalent to the whole body dose equivalent, both of which are determined by Monte Carlo analysis, a correction factor to determine the whole body dose equivalent rate from the measured dose equivalent rate can be found.

MATERIALS AND METHODS

Calculational techniques

Point source. A point source calculation assumes that the source and the target are one dimensional points in space. Thus, attenuation, scatter, non-uniform source distributions, and source and target geometry are not included in this model. Typically, when point source calculations are used for volume sources and targets, they tend to overestimate the dose equivalent. Making the assumption that the source is a point in space, and further that absorption and scattering are neglected, the absorbed dose rate at any point in space can be determined using well established methods (Loevinger et al. 1956). The NRC patient release criteria implementation of the point source calculation assumes that 1 roentgen is equivalent to 1 rad. It would be more accurate to assume 1 roentgen is equivalent to 0.95 rad, but since the purpose of these calculations is for comparison to the NRC release criteria, the NRC's assumption was used.

Monte Carlo simulations. Monte Carlo simulations allow for realistic modeling of source and target composition and geometry. In addition, realistic radiation transport and non-uniform distribution of the activity in the source can be modeled. Simplified versions of the anthropomorphic phantoms based on the Cristy-Eckerman phantom (Cristy et al. 1987) were created for use with the Monte Carlo transport software code MCNP4A (Briesmeister 1993). The phantoms were simplified by modeling the entire body as soft tissue. Soft tissue elemental composition and density were modeled according to the values given in the Cristy-Eckerman phantom series. The target phantom was located 1 m from the source phantom, measured from the front edge of each phantom, with the phantoms facing each other. The distribution of activity in the source phantom was modeled as being limited to the abdomen, since this was the distribution pattern seen in radionuclide therapy patients from whom the measurements were taken. This type of abdominal localization is typically caused by the uptake of the labeled substance by organs in the abdominal region, such as liver, kidneys, spleen, etc.

Photon histories for energies of ^{131}I emissions were run using MCNP4A in order to obtain absorbed fractions for source-target pairs. The MCNP4A criteria for statistical precision is a standard error of less than 10% non-point detectors. In this problem, standard error levels were kept below 5%. Between 20,000 and 2.5 million photon histories were required for this level of accuracy. Whole body dose in the target phantom was calculated by dividing the total energy deposited in the target phantom by the mass of the target phantom.

Source and target phantoms

The source and target phantoms consist of head, neck, trunk, and legs as described by the Cristy-Eckerman phantom (Cristy et al. 1987). The target phantom is displaced 120 cm away from the source phantom along the y axis, which yields an edge to edge distance of 100 cm between the phantoms. The legs of the target phantom were slightly modified to be represented as circular cylinders as follows (All dimensions are in cm):

$$\left[\frac{x \pm 10}{6.4}\right]^2 + \left[\frac{y + 120}{6.4}\right]^2 \leq 1 \quad \text{and} \quad -80 \leq z \leq 0. \qquad (1)$$

Abdominal source region. The abdominal source region was represented by an ellipsoidal cylinder in the trunk of the source phantom with upper and lower bounding planes as follows (all dimensions in cm):

$$\left[\frac{x}{16.5}\right]^2 + \left[\frac{y}{8}\right]^2 \leq 1 \quad \text{and} \quad 8 \leq z \leq 43. \qquad (2)$$

Surface dose model target region. The surface dose region was represented by a small thin disk of tissue 1 m from the front edge of the source phantom and

located level with the center of the source phantom's torso as follows (all dimensions in cm):

$$\left[\frac{x}{5}\right]^2 + \left[\frac{z-35}{5}\right]^2 \leq 1 \quad \text{and} \quad 110 \leq y \leq 112. \quad (3)$$

Calculation of dose per unit cumulated activity

Using the absorbed fractions obtained from the Monte Carlo transport simulation, the total dose per unit cumulated activity for ^{131}I can be determined by summing the product of the yield and dose per unit cumulated activity for each emission energy as follows:

$$^{131}\text{I dose per unit cumulated activity} = \sum_i y_i S_i, \quad (4)$$

where

y_i = yield of emission i;
S_i = dose per cumulated activity at energy of emission I; and
i = i^{th} emission of ^{131}I.

The dose per unit cumulated activity, S, for emission i, can be determined using the following:

$$S_i(target \leftarrow source) = \Delta_i \frac{\phi_i(target \leftarrow source)}{m_t}, \quad (5)$$

where

Δ_i = mean energy emitted per nuclear transition for emission i;
ϕ_i (target ← source) = fraction of energy emitted by the source that is absorbed by the target for emission i; and
m_t = mass of the target.

Patient measurements

The dose equivalent rate measurements were obtained in 49 patients (Kaminski et al. 1993; Kaminski et al. 1996). The patients were studied after having received ^{131}I anti-B1 therapy. Radioimmunotherapy with the ^{131}I anti-B1 antibody[§] is presently under investigation as a new treatment for non-Hodgkin's lymphoma. The patients received from 0.9 to 4.4 MBq (33.3 to 161 mCi) of the labeled material. Within 1 h post-administration the dose equivalent rate was measured in these patients using a calibrated ionization chamber positioned 1 m from the centerline of the patient's thorax. These measured dose rate equivalents, when divided by the total activity in the patient, yield dose equivalent per unit cumulated activity for the instantaneous activity level in the patient.

Since the measured dose equivalent rate represents surface entrance dose equivalent rate, it is probably not a good estimate of dose equivalent rate for individuals exposed to radionuclide therapy patients. The actual relationship between the measured dose equivalent rate and the whole body dose equivalent rate was determined using the ratio of the Monte Carlo simulation results for "surface dose target" and the whole body target.

[§] Coulter Pharmaceutical, Palo Alto, CA.

RESULTS

The results of the point source calculations, Monte Carlo simulations, and patient measurements are shown in Table 1. The first column of Table 1 is the dose equivalent per unit cumulated activity for each calculational method. The second column is the ratio of the calculated dose equivalent per unit cumulated activity to the measured dose equivalent per unit cumulated activity. The third column is the ratio of the calculated dose per unit cumulated activity to the measured dose per unit cumulated activity corrected to represent whole body dose per unit cumulated activity. The Monte Carlo results determined that the ratio of the whole body dose equivalent rate to the measured dose equivalent rate was 0.62. The measurement results taken from the 49 ^{131}I RIT patients are also shown.

DISCUSSION AND CONCLUSION

In most modeling problems, the more the model reflects the actual physical characteristics and configurations of the problem, the greater the accuracy of the results. Given this, it is not unreasonable to assume that even a simplified Monte Carlo model of this problem will yield results that are more accurate than the point source methodology. Based on this study, a point source calculation resulted in a 60% overestimate when compared to the measured surface dose equivalent rate and a 160% overestimate when compared to the corrected whole body dose equivalent rate. The Monte Carlo simulation for abdominal localization resulted in a 32% underestimate when compared to the measured surface entrance dose equivalent rate and a 10% overestimate when compared to the corrected whole body dose equivalent rate. This small overestimate was probably due to the fact that some portion of the activity in the RIT patients showed whole body distribution. Results using

Table 1. Whole body dose equivalent per unit cumulated activity. Results for ^{131}I.

Method	mSv MBq^{-1} s^{-1}	Fraction of surface entrance measurement[a]	Fraction of corrected surface entrance measurement[b]
Point source (1 m)	1.6×10^{-8}	1.6	2.6
Monte Carlo abdominal source	6.8×10^{-9}	0.68	1.1

[a] Measured dose equivalent per unit cumulated activity was $1.0 \times 10^{-8} \pm 1.5 \times 10^{-9}$ mSv MBq^{-1} s^{-1} (Mean ± standard deviation) Measured dose equivalent per unit cumulated activity ranged from 7.4×10^{-9} to 1.5×10^{-8} mSv MBq^{-1} s^{-1}.

[b] Measured dose equivalent per unit cumulated activity modified to represent whole body dose equivalent per unit cumulated activity. The ratio of whole body dose per unit cumulated activity to surface entrance dose per unit cumulated activity was determined by Monte Carlo analysis to be equal to 0.62.

the whole body as a source and the primary gamma emission of ^{131}I support this. Even when the source is a small organ, such as the thyroid, results using the primary gamma emission of ^{131}I show similar results to abdominal localization. This would indicate that a point source methodology would result in overestimation of dose rate even when the activity is localized in a small organ, such as the thyroid. It is clear that Monte Carlo methods achieve more accurate results than the point source method and should be fully implemented to determine more accurate patient release criteria. In the case of using dose equivalent rate measurements to determine release criteria, Monte Carlo methods should be used to determine appropriate correction factors to apply to the measurement so that they represent whole body dose rate or EDE rate.

Based on this study, use of the revised NRC based calculations will result in over conservative dose equivalent estimates to others from patients receiving radioactive materials. Further, the measured dose rate at 1 m from a patient will overestimate the actual whole body dose to an individual exposed by about 61% for ^{131}I. Using more realistic calculations could decrease the length of hospital stay of patients currently not releasable under the new regulations. In the case of the patients receiving the ^{131}I B1 therapy, all patients were releasable under the revised NRC regulations based on measured dose rates (Gates et al. in press).

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DETERMINATION OF INTERNAL CONTAMINATION LEVEL MERITING TRIAGE TO AGGRESSIVE INTERNAL DECONTAMINATION THERAPY

A. IRIDIUM-192 RDD SCENARIO

Carol S. Marcus, Ph.D., M.D.
09-11-02

The object of this calculation exercise is to determine whether a contaminated patient is a candidate for aggressive internal decontamination therapy, or whether the level of internal contamination is low enough that either the risk of the decontamination procedure outweighs the risk from the radiation, or that the limitation of resources is such that this patient stands to gain relatively little from the decontamination effort compared to other internally contaminated patients.

Due to the fact that internal decontamination procedures are most effective when begun as quickly as possible following exposure, the triage determination will have to be made with limited data. We will assume that a spectrometer is available to quickly identify the radionuclide(s) causing the contamination. We will also assume that G-M "pancake" detectors and ion chambers are rapidly made available at the scene. HAZMAT teams carry the G-M detectors, and Radiological Health personnel carry the ion chambers and spectrometers.

If only G-M counts per minute (cpm) are available, we will estimate activity of body burden using cpm, detector surface area, and estimated detector efficiency. If, as would be much preferred, we have radiation dose rate from an ion chamber, we will use specific gamma ray constants to estimate activity of body burden.

Once the internal contaminant activity is determined, dose to target organs will be calculated using tabulated internal dosimetry materials (such as EPA Federal Guidance Report No. 11). These values will then be compared with single dose and fractionated dose organ and tissue tolerance (Vaeth JM and Meyer JL, eds.: Radiation Tolerance of Normal Tissues, p. 13, 1989, Karger, Basel). The particular cut-off point for triage at this point is a value judgment based on a number of factors. ***For the purpose of this exercise, a projected dose equal to half the upper level (50%) of tolerance of an acute dose or one quarter the lower (5%) level of tolerance of a fractionated dose will be considered the cut-off point for triage.***

In an Ir-192 RDD explosion or vaporization scenario, we will assume that essentially all external contamination has been removed from victims and that all other internal contamination is inhaled. While ciliary action will remove particulates, much of which will be swallowed, we will assume the most conservative scenario, which is that it stays in the lungs. (Largely insoluble particulates of Ir-192 metal or oxide that get to the gastrointestinal tract will be excreted. Little or nothing is absorbed.)

1. G-M Data Calculation

The G-M detector will be held one meter away from the patient, and we will assume the lungs to be a point source at that distance. The surface area of a sphere 1 m in radius = $4\pi r^2 = 4(3.14)(100\text{ cm})^2 = 125{,}600\text{ cm}^2$.

Surface of G-M pancake active detector area approximated at 5 cm radius. A = $\pi r^2 = 3.14(5)^2 = 78.5\text{ cm}^2$.

Fraction of sphere surface area subtended by detector = 78.5/125,600 = 0.0006.

1 mCi = $3.7\text{x}10^7$ dps = $2.22\text{x}10^9$ dpm

0.0006($2.22\text{x}10^9$) = 1,332,000 dpm hit detector/mCi in person, assuming no absorption. Assuming same absorption as measured in 5 patients with Ir-192 brachytherapy source irradiating cervical cancer, (0.47)(1,332,000) = 632,000 dpm.

Assuming a detector efficiency of 0.5% (*very* uncertain), we would expect to get (0.005)(632,000) ≈ 3000 cpm.

Therefore, 3000 cpm on G-M 1 meter from lungs = about 1 mCi Ir-192 in lungs.

According to EPA Federal Report no. 11 (personal communication with John Frazier, Ph.D.), the committed effective dose equivalent (cede) for Ir-192 is 28.2 rem/mCi. We assume that all radioactivity is in the lungs, and then use the ICRP tissue weighting factor of 0.12 to calculate the actual lung dose.

28.2/0.12 = 235 rad to lungs/mCi in lungs.

According to the Vaeth and Meyer reference noted above, the lung tolerance dose is 700-1000 rad acute or 2000-3000 rad fractionated.

Therefore, we would begin aggressive pulmonary decontamination treatment at about 2 mCi in the lungs, or a G-M meter reading of about 6000 net cpm 1 meter from the lungs.

Without a more precise number for G-M efficiency, this calculation is highly inaccurate and of poor quality.

2. Ion Chamber Data Calculation

The specific gamma ray constant for Ir-192 as an unshielded point source is 4.32 R-cm²/mCi-hr. Measured in 5 patients receiving brachytherapy for cervical cancer, the body-shielded value is 2.05 R-cm²/mCi-hr.

Therefore, 2 mCi in patient would read 4.1 R-cm²/mCi-hr or 0.41 mR/hr at 1 meter.

Therefore, the threshold for aggressive pulmonary decontamination would be an ion chamber reading of about 0.4 mR/hr at 1 meter.

There is still some question as to the actual shielding of the patient, as dispersed Ir-192 in the lungs is not the same as a point source of Ir-192 at the cervix. However, phantoms could be constructed to more accurately estimate shielding when the Ir-192 is in the lungs.

Conclusion

This methodology could be applied to any number of photon-emitting radionuclides. Therapy could be monitored in the hospital with carefully reproduced gamma camera measurements.