TITLE PAGE

FINGERTIP AND WHOLE BODY EXPOSURE TO NUCLEAR MEDICINE PERSONNEL

George A. Lis, B.S.R.T., Said M. Zu'bi, M.D., Suresh M. Brahmavar, Ph.D.

Baystate Medical Center - Springfield Hospital Unit

Springfield, Massachusetts

For reprints contact: G. A. Lis, Division of Nuclear Medicine

Baystate Medical Center - Springfield Hospital Unit

759 Chestnut Street, Springfield, Mass. 01107

ABSTRACT

Radiation exposure to the technologist in nuclear medicine is calculated for all common sources of exposure. Special attention has been given to the exposure received by the fingertips. Typical exposure rates during patient injections, reagent preparations, generator handling and elution, patient positioning and other phases of nuclear medicine are included. The cumulative exposure to the fingertips and whole-body is estimated. When every precaution is taken to minimize exposure in our laboratory, the unavoidable annual exposure to the fingertips is 11 R, and to the whole-body, is 1 R from all sources. When precautions are not taken, the annual exposure to the fingertips may exceed 170 R and the whole-body dose may then approach 2 R. Our nuclear medicine laboratory averages about 1000 injections per technologist per year.

INTRODUCTION

The large dependence on technetium-labeled products has resulted in the use of high activity doses with ever increasing frequency. Many nuclear medicine departments are imaging a greater volume of patients now with the same personnel. The technologist may therefore be subjected to greater radiation exposure than in the past. Burr and Berg[1] determined that the fingertip would receive approximately 6.7 times the exposure detected by a ring badge worn in the usual position. Neil[2] reported that hand radiation may exceed regulatory levels by a modest amount and that film badges are not necessarily representative of peak hand radiation and may lead to a false sense of security. The concern over radiation exposure prompted our lab to investigate the total yearly exposure to the technologist from all common sources of exposure found in nuclear medicine. This total yearly exposure of each radiation handling technique is then compared to the yearly MPD to give perspective to the numerical chart values. Each lab can appropriately adjust the charts to their individual patient volume and exposure times.

Our investigation was initiated in separate areas, namely:

1. To calculate the exposure rate from various points on a syringe.
2. To establish a table of frequencies, exposure rates and radioactive source geometry that reflect current radiation handling techniques.
3. To include other contributing sources of exposure and

determine the total whole-body and fingertip cumulative yearly exposure from all common sources and techniques.

The volume of data generated by this report is given in table format. The results are presented to the reader first to emphasize their significance. The derivation of all values found in the tables can be found in the materials and methods section.

RESULTS AND DISCUSSION

The exposures listed in the tables also include yearly cumulative estimations for the frequencies encountered in our lab. This was done to give the reader a perspective of how each dose handling technique compares to the yearly MPD limits for specified exposure times and frequencies.

The exposure to the fingertips during patient injections is found in Table 3. Whenever a syringe is held at mid-dose (Case A), the yearly exposure may substantially exceed the MPD limit of 75 R to the hands. Syringe shields are quite effective when a syringe is held at mid-dose. Holding a syringe at the flared end (Case B) will also result in reduced exposure to the fingertips. During patient injections and dose preparations, the fingertips are invariably located at the flared end of the syringe. Syringe shields do not effectively reduce the exposure to the fingertips at the flared end and may lead to a false sense of security. The exposure realized at the flared end will be smallest if the syringe is filled less than half full. Whenever larger syringes are used, a greater distance is introduced between the dose and the fingertips. The resultant exposure at the flared end now is less than if we used a smaller syringe with a syringe shield. Syringe shields are still advisable on all size syringes to minimize exposure to the body. When precautions are taken to minimize exposure, the unavoidable yearly exposure to the fingertips from patient injections (Table 3) is about 3R. The maximum yearly exposure (when precautions are not taken to minimize exposure), may exceed 100 R to the fingertips from Table 3.

The exposure received during withdrawal of Tc99m doses is given in Table 4. A reduction in the exposure is seen whenever a larger syringe is employed. The preparation of Tc99m reagents from kits often requires about 100 mCi Tc99m in a 3 ml to 8 ml volume. A usual preparation procedure is to draw up the 100 mCi Tc99m dose in a 3 cc syringe, dilute to 3 ml with saline, and inject into reagent vial for reconstitution. Table 4 (Case B) shows a seventeen-fold decrease in the exposure to the fingertips if a 10 cc syringe is substituted for the 3 cc syringe at dose withdrawal. The exposure to the hand from the open end of the shielded Tc99m vial during dose withdrawal can be halved by two equally effective means. Holding a syringe at thirty degrees askew to the vertically held vial (Table 4, Case A) during dose withdrawal or using a syringe shield during dose withdrawal will halve the exposure received from the Tc99m vial. The necessity for vial shields to securely hold the Tc99m vial in the inverted position during dose withdrawal is made evident by Table 4, Case C. If a technologist must support the Tc99m vial (in its shield) with his thumb during dose withdrawal, the annual exposure, based on 1000 withdrawals per year, would be 56 R to that thumb. The unavoidable yearly exposure for our lab to the fingertips from all dose preparations (Table 4) is about 6 R when precautions are taken to minimize exposure. The maximum yearly exposure may exceed 60 R for the frequencies cited in Table 4.

Unnecessary exposure should be viewed as unnecessary risk. Table 5 lists the common occurrences that may cause unnecessary

exposure which could be prevented or reduced. Handling Xe133 vials by hand is reckless, and the exposure of 10.6 R per year can be nullified by the use of tongs. Aseptic wiping of Tc99m vials using 6 inch Q-Tips dipped in alcohol or forceps with an alcohol wipe will reduce exposure. Exposure while changing a hypodermic needle is minimized by not expelling excess activity into the needle hub prior to the needle change. Returning this activity to its vial decreases the exposure fourfold over expelling this activity into the needle hub. The unavoidable yearly exposure (for our lab's frequency and exposure time) to the fingertips is about 0.9 R from sources in Table 5, when precautions are taken to minimize exposure. The maximum yearly exposure (when precautions are not taken to minimize exposure) may exceed 15 R from Table [illegible].

Table 6 is a compilation of sources of exposure to the technologist whose exposure rates were determined by survey meter or by calculation other than G Table. The whole-body, as well as the fingertip exposure rate, is included wherever possible. The exposure resulting from the handling of patients (Case A) is given. This probably cannot be reduced except by maximizing distance and minimizing exposure time. Tc99m contamination on the skin[3] (Case B) causes a significant one-time exposure and should be avoided by wearing gloves and changing gloves frequently. The eluting of Tc99m generators (Case C) and the handling of Tc99m generators (Case D) results in minimal exposure which probably cannot be reduced further. The exposure associated with accidental Xe-133 gas escape into a room by a patient (Case E) is minimal. However, this type of accident seems to generate a

good deal of concern. It is evident from the tables, that other phases of nuclear medicine should then cause more concern and replace the complacent attitudes of some technologists. Finally, countertop shields are recommended to eliminate the exposure to the body during dose preparations (Case F). The unavoidable yearly exposure to the fingertips is about 0.7 R and to the whole-body about 0.2 R from sources in Table 6. The maximum yearly exposure may exceed 1 R for fingertip and whole-body for our lab for Table 6.

The total yearly unavoidable exposure from all sources in our lab listed in the tables is about 11 R to the fingertips and about 1 R to the body. The maximum yearly exposure may exceed 170 R to the fingertips and may approach 2 R to the body when minimal precautions are taken (i.e., no syringe shields but Tc99m vials are shielded) to minimize exposure.

It is assumed that all technologists are being rotated through all radiation handling procedures to spread the exposure over the greatest number. The frequency of exposure listed in the tables is then our patient volume divided by the number of technologists in rotation.

Most non-Tc99m sources of exposure occur roughly at one-tenth the frequency of Tc99m sources and involve about one-tenth the activity of Tc99m sources. Thus, the expected exposure contribution of non-Tc99m sources is roughly one, one-hundredth (1/10 x 1/10) or 1% the total Tc99m contribution. Lombardi, et al[4] determined the non-Tc99m contribution to be 2.4% of the total hand exposure. Therefore, the tables of exposure listed include better than 95% of the total exposure a technologist in

nuclear medicine might receive. Exposure resulting from contamination of one's person during administration of I-131 therapy doses are excluded from the scope of this paper and should be determined on an individual basis.

The film badge reports of our technologists average out to 1.8 R per year for ring badges and 1.3 R for whole body badges. We shall conservatively assume that the fingertip exposures of our technologists range from equal to double the unavoidable yearly minimum of 11 R. This averages out to 16.5 R per technologist when every precaution is taken to minimize exposure. Thus, for our lab, the ring badge reports must be multiplied by about nine for a rough approximation to the actual fingertip exposure. Our value of nine is in fair agreement with Burr and Berg [1] who estimate the fingertip exposure mathematically to be 6.7 times the ring badge reports when the ring is worn on the palm side of the finger. The actual whole body badge readings of our technologists (average 1.3 R per year) agrees well with our calculated unavoidable yearly exposure of 1 R from the tables.

MATERIALS AND METHODS

The technologist receives the bulk of his exposure from syringes of high activity technetium 99m. A knowledge of the exposure at the surface of a syringe would be helpful in determining the exposure received by the fingertips during handling of radioactive syringes. The exposure E to external point A from a cylindrical source (Fig. 1) can be calculated from the expression.(5)

$$E = 4\pi\Gamma Q = 4\pi\Gamma \frac{Svr}{2\pi} G(k,p,\mu_s r,b_1) = 2\Gamma r \left[\underset{\text{cylinder } h}{\text{upper}} SvG(k,p,\mu_s r,b_1) + \underset{\text{cylinder } h'}{\text{lower}} S'vG'(k',p',\mu_s r,b_1) \right]$$

$$E = 2\Gamma r(SvG + S'vG') = 2\Gamma r \left[\frac{\frac{hN}{H}}{\pi r^2 h} G + \frac{\frac{h'N}{H}}{\pi r^2 h'} G' \right] \text{ Roentgen/hr.} = \frac{2\Gamma N}{\pi r H}\left[G+G'\right] \text{ R/hr}$$

$$E/N = \text{Exposure/mCi} = \frac{2\Gamma}{\pi r H}\left[G + G'\right] \quad \text{R/mCi hr}$$

$$E/N = \frac{5.94}{r^2} \left[\frac{\underset{h}{\text{upper cylinder}} \quad G}{k} + \frac{\underset{h'}{\text{lower cylinder}} \quad G'}{k'} \right] \text{ mR/mCi hr for Tc99m}$$

Where $-G(k,p,\mu_s r,b_1)$ is tabulated by Goussev et al[5] and defined as the attenuation function encompassing source geometry k, distance p, self absorption $u_s r$ and shield attenuation b_1.

-Γ is the specific gamma ray constant = 0.56 $\frac{R}{mCi\text{-}hr}$ @ 1cm for Tc99m.[6]

-r is the inner radius of the syringe and the radius of the source.

-mR/mCi-hr shall be milliroentgen per millicurie-hour.

-$\dot{Q}$ is the uncollided flux of gamma rays through point A from both cylinders = $\frac{r}{2\pi}(S_v G + S_v' G')$.

-S_v is the activity per unit volume = $\frac{N}{\pi r^2 h}$ = mc/cc.

-N is the total activity in mCi in both cylinders = $\frac{hN}{H} + \frac{hN}{H}$

-H is the height of the activity = h + h' of both cylinders in cm.

-For upper cylinder k = $\frac{h}{r}$ for calculation of G from Table 2.

-For lower cylinder k' = $\frac{h'}{r}$ for calculation of G' from Table 2.

-The syringe geometries to be used in the calculations are listed in Table 1.

Example: 20 mCi Tc99m in 2 ml in a 3 cc syringe held at mid-dose.

From Table 1, we have r = .44 cm and p = 1.23. At mid-dose there is contribution from two cylinders (Fig. 1).

-Upper Cylinder = 1 ml thus k≈3.75 (3.75 x .27 ml≈1 ml)

k x r = h

Then G from Table 2≈1.78

-Lower cylinder = 1 ml thus k'≈3.75

Then G' from Table 2≈1.78

N = 20 mCi

$$\text{Exposure/m} = \frac{5.94}{r^2}\left[\frac{G+G'}{k+k'}\right] \text{mr/mCi-min} \cdot \frac{5.94}{(.44)^2}\left[\frac{1.78 + 1.78}{3.75 + 3.75}\right] = 14.6 \text{mr/mCi-min.}$$

Hereafter for this paper, dose shall refer to the radioactive cylindrical syringe volume source of Tc99m as used in the following: 20 mCi dose, dose withdrawal, mid-dose, dose volume, etc.

When syringes are held at the flared end of the syringe creating a distance between the source and the fingertips (Fig. 2), we then use the expression:

$$E = 4\pi f\dot{Q} - 4\pi f\frac{S_v r}{2\pi} G(k,p,u_s r,b_1) = 2fr\left[S_v G(k,p,u_s r,b_1) - \underset{\text{Lower Cylinder } h'}{S_v' G'(k',p',u_s r,b_1)}\right]$$

$$E = 2fr(S_v G - S_v' G' = 2fr\left[\frac{HN}{h}\frac{G}{\pi r^2 H} - \frac{h'N}{h}\frac{G'}{\pi r^2 h'}\right] \text{Roentgen/hr} = \frac{2fN}{\pi r h}\left[G - G'\right]\text{Roentgen/hr}$$

$$E/N = \text{Exposure/mCi} = \frac{2f}{\pi r h}\left[G - G'\right] \text{R/mCi-hr} = \frac{5.94}{r^2}\left[\frac{G}{k} - \frac{G'}{k'}\right] \text{mR/mCi-min} \quad (2)$$

(Both Cylinders H; Lower Cylinder h)

-Fingertip at flared end will be defined as fingertip located at the last volume mark on the syringe.

-N now is the total activity in mc of the upper cylinder = $\frac{HN}{h} - \frac{h'N}{h}$ both-lower

-For both cylinders $K = \frac{H}{r}$ for calculation of G from Table 2.

-For lower (space) cylinder $k' = \frac{h'}{r}$ for calculation of G' from Table 2.

Example: 20 mCi Tc99m in 2 ml, in a 3 cc syringe held at flared end. Fingertip at flared end will have a location defined as the last volume mark on the syringe. Thus for a 3 cc syringe fingertip at flared end is located at the 3 cc mark.

r = .44 cm and p = 1.23 from Table 1 and N = 20 mc

From Figure 2 we have for both cylinders - K = 11 (11 x .27 ml≈ 3 ml mark)

thus G from Table 2 = 2.0052

From Figure 2 we have for lower cylinder - $\dot{k}$ = 3.75 (3.75 x .27 ml≈1 ml)

thus $\dot{G}$ from Table 2 1.78

Thus both cylinders minus lower cylinder = 2 ml upper cylinder = Tc99m

$$\text{Exposure/mCi} = \frac{5.94}{r^2}\left[\frac{G - \dot{G}}{K - \dot{k}}\right] = \frac{5.94}{(.44)^2}\left[\frac{2.0052 - 1.78}{11 - 3.75}\right] = 1.0 \text{ mR/mCi-min}$$

as seen in Table 3

It was necessary to extrapolate from the $G(k,p,u_s r,b_1)$ values tabulated by Goussev et al[5] additional $G(k,p,u_s r,b_1)$ values. These values correspond to sources contained in syringes, namely p = 1.14, 1.17, 1.23, and 1.43 for 10, 5, 3, and 1 cc syringes respectively, and k = 1/2 to 25 for small to large volume sources within the syringe. The extrapolated G values are tested by inverse square law for distant points and by published data for local points of exposure on a syringe. The G values are altered and smoothed for best fit so that the final G values (Table 2) fit all published exposure rates and the inverse square law, and still conform to the tabulated G values of Goussev et al[5] For Tc99m syringe sources, self-absorption $u_s r$ and the shield factor are negligible and will be given zero value. Thus $G(k,p,u_s r,b_1)$ becomes $G(k,p,0,0)$. Table 2 lists the adjusted $G(k,p,0,0)$, as determined by our lab, which will yield exposure rates from a syringe when used with equations (1) and (2). The exposure rates, seen in Tables 3, 4, and 5 are derived from the G values of Table 2.

We shall regard Xe-133 vials as having self-absorption $u_s r$ and shield factor b_1 equal to zero in order to use the values in Table 2. However, all final Xe-133 vial exposures listed (Table 5) have been reduced 10%.

Measurements were taken of Xe-133 vials through glass cylinders of thickness similar to Xe-133 vials. The results have shown that 10% is an excellent approximation for the absorption by the glass wall of the Xe-133 vial.

Various exposure rates from sources that are encountered during a typical workday, were determined and listed in Tables 3, 4 and 5. Table 6 includes other sources whose exposure rates were found by survey meter or by other calculation. Estimates were made for exposure time and frequency. Then the estimated yearly exposure to the fingertips and whole body is found and also included in Tables 3 through 6. The net effect of syringe shields and different dose handling techniques is made evident in these tables. Each lab may tabulate their own yearly exposure by plugging in their own yearly frequency and exposure time wherever they appear in the tables from the given exposure rates.

A few points on the tables were compared to measured published values as a spot check of the accuracy of the tables. LiF-Teflon measurements by McEwan[7] list the exposure rate for 10 mCi Tc99m in a 10 cc syringe at 12 mR/mCi-min on the surface for a 3 ml volume. TLD measurements of Neil[2] report the exposure rate for 10 mCi Tc99m in a standard hypodermic syringe at 11.4 mR/mCi-min at the surface. The values obtained from Table 3 for 10 mCi Tc99m in a 3 ml volume are 14.7 mR/mCi-min at the surface of a 10 cc syringe and 13.8 mR/mCi-min at the surface of a 5 cc syringe (standard syringe). Our table values are slightly higher than the measured values. Husak[8] has calculated the exposure rate from 10 mCi Tc99m in a 2 cc syringe at 13 mR/mCi-min and in a 10 cc syringe at 4.6 mR/mCi-min. These values are comparable

to the Table 3 value of 14.6 mR/mCi-min for 10 mCi in 2 ml in a 3 cc syringe and 6.2 mR/mCi-min for 10 mCi in 10 ml in a 10 cc syringe. Our calculated values are slightly higher than Husak's. Henson[9] has determined by computer program the exposure rate from 10 mCi Tc99m in 1 ml in a 2 cc syringe to be 40 mR/mCi-min at the surface. Table 3 yields a value of 27.4 mR/mCi-min for 10 mCi in 0.8 ml in a 3 cc syringe. Henson[9] has listed the exposure rate from 10 mCi Tc99m in 1 ml in a 5 cc syringe at 35 mR/mCi-min at the surface. From Table 3 we obtain an exposure rate of 24.4 mR/mCi-min for 10 mCi in 0.8 ml in a 5 cc syringe. Our calculated values are substantially lower than those of Henson.[9]

The exposure rate from small volume sources at a significant distance can be estimated by inverse square law and used to check the accuracy of the tables. By inverse square law, the exposure rate from 10 mCi Tc99m in 0.8 ml in a 3 cc syringe is 0.58 mR/mCi-min when held at the flared end. Table 3 concurs with a value of 0.50 mR/mCi-min. The exposure rate from 10 mCi Tc99m in 0.8 ml in a 10 cc syringe when held at the flared end is 0.28 mR/mCi-min by inverse square law. Table 3 is good agreement with a value of 0.26 mR/mCi-min.

SUMMARY

The exposure to the hands of the technologist may substantially exceed the maximum permissible exposure (MPD) set by the National Council on Radiation Protection of 75 rems to the hands in one year.[10] The conclusions reached with respect to minimizing exposure to the technologist can be summarized as follows:

1) Hold syringes at the flared end whenever possible.
2) Use larger syringes whenever possible and avoid filling syringes more than half full.
3) Use syringe shields at all times if possible.
4) Use lead containers that securely support vials when inverted for dose withdrawal.
5) Wear gloves and change them often to avoid the high exposure.
6) Use tongs whenever transferring vials.
7) Do not expel excess activity of syringe into needle hub prior to needle change.
8) Rotate all personnel through all radiation handling procedures to spread out the exposure over the greatest number.

Ring badge reports should be multiplied by nine to obtain an approximate value for the exposure at the fingertips. The yearly unavoidable exposure to the fingertips is about 11 R for our lab and this occurs only if every precaution is taken to minimize exposure. The maximum yearly exposure to the fingertips may exceed 170 R when minimal precautions are taken to minimize exposure for the frequency and exposure times cited in our lab.

REFERENCES

1. Burr, JE and Berg, R: Radiation dose to the hands from radiopharmaceuticals - preparation versus injection. J. Nucl. Med. Tech. 5:159, 1977.
2. Neil CM: The question of radiation exposure to the hand from handling Tc99m. J. Nucl. Med., 10: 732-734, 1969.
3. Howley JR, Green MV, Mardalee BD et al.: Radiation Safety in Nuclear Medicine (abstract). J. Nucl. Med. Tech. 2: 65, 1974.
4. Lombardi MH, Beck WL, Cloutier RJ: Survey of radiopharmaceutical use and safety in sixty nine hospitals. DHEW Publication (FDA) 73-8029.
5. Blizzard EP, Foderraro A, Goussev NG, et al: Monography-Extended radiation sources. Engineering Compendium on Radiation Shielding, Vol 1, Heidelberg, Springer-Verlag Berlin, 1968, pp 377, 398, 399.
6. Wagner Jr., HN: Physical data for a number of radioactive nuclides. Principles of Nuclear Medicine, Philadelphia, W.B. Saunders Co., 1968, p 864.
7. McEwan AC: Radiation doses in the handling of short-lived radionuclides: Brit. J. Radiol. 42: 396, 1969.
8. Husak: Exposure rate at the surface of syringes containing radioactive material. J. Nucl. Med. 12: 575, 1971.
9. Henson PW: Radiation dose to the skin in contact with unshielded syringes containing radioactive substances. Brit. J. Radiol. 46: 974, 1973.
10. National Council on Radiation Protection and Measurements. 1971: Basic Radiation Protection Criteria NCRP Report No. 39: 91.

LEGENDS

FIGURE 1: Geometry for a cylindrical volume source with the exposure point A located laterally between the base planes of the source. Exposure to point A comes from the activity contained in the shaded cylinder which is the Tc99m dose contained in lower cylinder (height h) and upper cylinder (height h).

FIGURE 2: Geometry for a cylindrical volume source with the exposure point B located laterally outside the base plane of the source. Exposure to point B comes from the aotivity contained in the shaded cylinder which in the Tc99m dose contained in cylinder height h only.

TABLE 1. SYRINGE GEOMETRY AND PHYSICAL CONSTANTS

Syringe	Inner Radius R	$\frac{5.94}{R^2}$	p at surface of syringe = d/R = (0.1 cm + R)/R p	Volume in syringe at k = h/R = 1
1 cc	0.235 cm	$107.6/cm^2$	1.43	0.04 ml
3 cc	0.44 cm	$30.7/cm^2$	1.23	0.27 ml
5 cc	0.60 cm	$16.5/cm^2$	1.17	0.68 ml
10 cc	0.72 cm	$11.5/cm^2$	1.14	1.17 ml
Xe-133 vial	0.60 cm	$15.0/cm^2$	1.25 → use p = 1.23 chart values	

Thickness of all syringes = 0.1 cm

Thickness of Xe-133 vial = 0.15 cm

All hypodermic needles used

are 1½" in length

and 20 gauge for flow studies

and 22 gauge for static studies

SYRINGE BODY

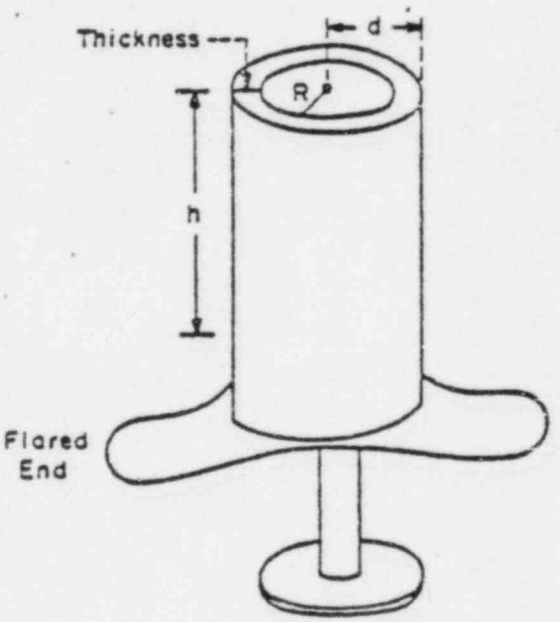
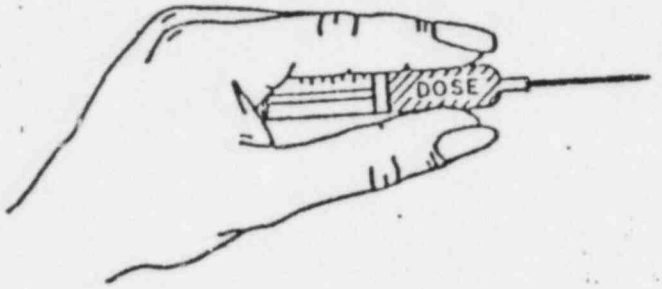


TABLE 2. ADJUSTED VALUES FOR G(k,p,0,0)

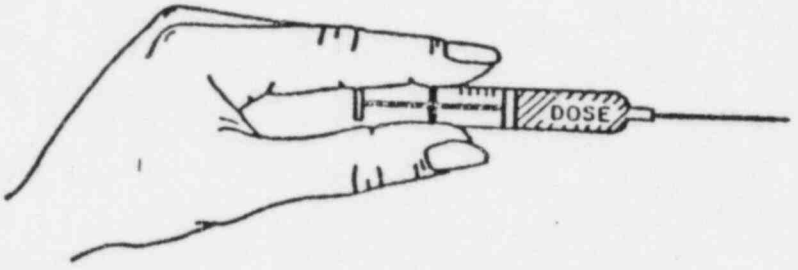
k	p = 1.14	p = 1.17	p = 1.23	p = 1.43
0.25	0.50	0.45	0.36	0.27
0.50	0.87	0.79	0.64	0.50
0.75	1.18	1.07	0.88	0.70
1.0	1.45	1.32	1.09	0.87
1.5	1.756	1.610	1.340	1.080
2.0	1.958	1.800	1.507	1.225
2.5	2.094	1.927	1.621	1.325
3.0	2.189	2.016	1.701	1.396
3.5	2.2550	2.0790	1.7580	1.4470
4.0	2.3046	2.1264	1.8006	1.4850
4.5	2.3426	2.1637	1.8336	1.5150
5.0	2.3722	2.1925	1.8601	1.5394
5.5	2.3963	2.2162	1.8821	1.5600
6.0	2.4168	2.2365	1.9011	1.5778
7.0	2.4505	2.2700	1.9321	1.6071
8.0	2.4768	2.2961	1.9563	1.6299
9.0	2.4979	2.3169	1.9760	1.6486
10.0	2.5149	2.3335	1.9920	1.6640
11.0	2.5287	2.3471	2.0052	1.6768
12.0	2.5404	2.3587	2.0164	1.6876
13.0	2.5506	2.3688	2.0262	1.6971
15.0	2.5659	2.3840	2.0412	1.7119
17.0	2.5775	2.3955	2.0525	1.7230
19.0	2.58665	2.40460	2.06152	1.73192
20.0	2.59081	2.40870	2.06556	1.73591
21.0	2.59420	2.41211	2.06890	1.73920
23.0	2.60032	2.41820	2.07495	1.74520
25.0	2.60544	2.42330	2.08000	1.75021

TABLE 3. EXPOSURE TO THE FINGERTIPS DURING PATIENT INJECTIONS

Yearly frequency and exposure time are based on our lab's average.	Dose Volume	Syringe Used	Syringe Shield	Exposure Rate	Yearly Exposure R = Roentgen
Case A: 20 mc Tc-99^{m} held at MID-DOSE.	0.8 ml	1 cc	no	17.9 mr/mc-min	71.6 R
	0.8 ml	3 cc	no	27.4 mr/mc-min	109.6 R
	0.8 ml	3 cc	yes	0.04 mr/mc-min *	0.2 R
	2.0 ml	3 cc	no	14.6 mr/mc-min	58.4 R
	3.0 ml	3 cc	no	10.4 mr/mc-min	41.6 R
	0.8 ml	5 cc	no	24.4 mr/mc-min	97.6 R
	2.0 ml	5 cc	no	17.7 mr/mc-min	70.8 R
	3.0 ml	5 cc	no	13.8 mr/mc-min	55.2 R
	0.8 ml	10 cc	no	23.2 mr/mc-min	92.2 R
	2.0 ml	10 cc	no	18.0 mr/mc-min	72.0 R
	3.0 ml	10 cc	no	14.7 mr/mc-min	58.8 R
	10.0 ml	10 cc	no	6.2 mr/mc-min	24.8 R
Case B: 20 mc Tc-99^{m} held at FLARED END.	0.8 ml	1 cc	no	1.13 mr/mc-min	4.5 R
	0.8 ml	3 cc	no	0.50 mr/mc-min	2.0 R
	0.8 ml	3 cc	yes	0.20 mr/mc-min	0.8 R
	2.0 ml	3 cc	no	1.0 mr/mc-min	4.0 R
	2.0 ml	3 cc	yes	0.7 mr/mc-min	2.8 R
	3.0 ml	3 cc	no	5.5 mr/mc-min	22.0 R
	3.0 ml	3 cc	yes	4.8 mr/mc-min	17.2 R
	0.8 ml	5 cc	no	0.50 mr/mc-min	2.00 R
	2.0 ml	5 cc	no	0.68 mr/mc-min	2.72 R
	3.0 ml	5 cc	no	1.0 mr/mc-min	4.0 R
	0.8 ml	10 cc	no	0.26 mr/mc-min	1.04 R
	2.0 ml	10 cc	no	0.29 mr/mc-min	1.16 R
	3.0 ml	10 cc	no	0.34 mr/mc-min	1.35 R
	10.0 ml	10 cc	no	3.3 mr/mc-min	13.2 R



Exposure time = 12 sec./ injection
Frequency = 1,000 injections/ year

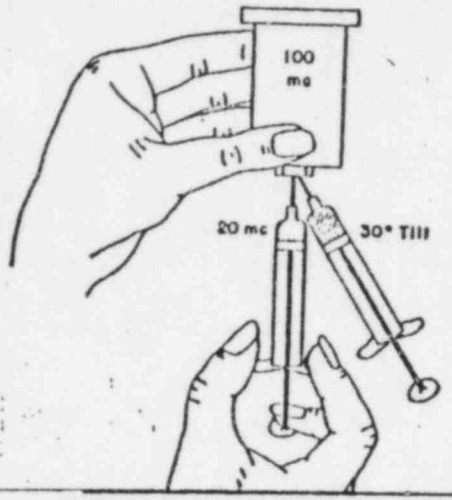


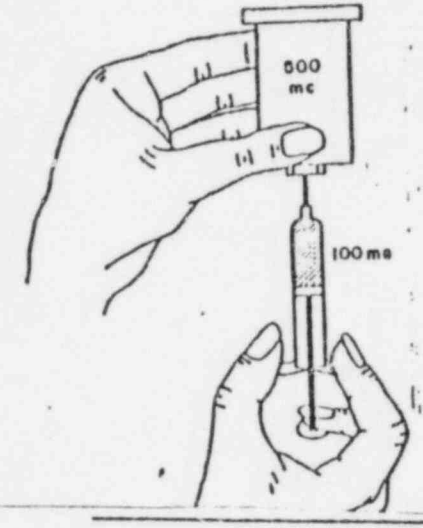
Exposure time = 12 sec./ injection
Frequency = 1,000 injections/ year

* as measured by survey meter through lead glass portion of syringe shield.

TABLE 4. EXPOSURE TO THE FINGERTIPS DURING DOSE PREPARATION

Yearly frequency and exposure time are based on our lab's average per technologist.	Dose Vol.	Syringe	Exposure Rate	Yearly Exposure R = Roentgen.
Case A: Exposure during patient dose preparation (20 mc $Tc\text{-}99^m$).	0.8 ml	3 cc	0.5 mr/mc-min	2.0 R
	2.0 ml	3 cc	1.0 mr/mc-min	4.0 R
-WITHDRAWAL of 20 mc dose from shielded 100 mc reagent vial, no syringe shield, and MEASUREMENT of dose in dose calibrator, and CHANGING of hypodermic needle, and TRANSFER of dose to syringe shield,	0.8 ml	5 cc	0.50 mr/mc-min	2.0 R
	2.0 ml	5 cc	0.68 mr/mc-min	2.7 R
	0.8 ml	10 cc	0.26 mr/mc-min	1.0 R
Exposure time = 12 sec./ preparation Frequency = 1000 patient doses/ year Syringe held at flared end.	2.0 ml	10 cc	0.29 mr/mc-min	1.2 R
Additional exposure to the fingertips from the shielded 100 mc vial during dose withdrawal.	syringe held in vertical position		0.1 mr/mc-min	1.0 R
Exposure time = 6 sec./ withdrawal Frequency = 1000 withdrawals/ year	syringe held at 30° from vertical		0.05 mr/mc-min	0.5 R
Case B: Exposure during reagent dose preparation (100 mc $Tc\text{-}99^m$).	3.0 ml	3 cc	5.5 mr/mc-min	55.0 R
	3.0 ml	5 cc	1.0 mr/mc-min	10.0 R
-WITHDRAWAL of 100 mc dose for reagent vial from shielded 500 mc eluate vial, and MEASUREMENT of dose in dose calibrator, and TRANSFER of dose into appropriate shielded reagent vial.	3.0 ml	10 cc	0.34 mr/mc-min	3.4 R
	(if syringe shield used during withdrawal)			
	3.0 ml	3 cc	4.8 mr/mc-min	48.0 R
	3.0 ml	5 cc	0.7 mr/mc-min	7.0 R
Exposure time = 12 sec./ preparation Frequency = 500 reagent doses/ year Syringe held at flared end.	3.0 ml	10 cc	0.15 mr/mc-min	1.5 R
Additional exposure to the fingertips from the shielded 500 mc eluate during dose withdrawal.	with no syringe shield		0.1 mr/mc-min	2.5 R
Exposure time = 12 sec./ preparation Frequency = 500 withdrawals/ year	with syringe shield		0.05 mr/mc-min	1.3 R
Case C: Exposure to thumb of opposite hand when reagent vials are not held secure in their shields while inverted. Thumb must then support 100 mc reagent vial when inverted during dose withdrawal.			5.6 mr/mc-min	56.0 R*
Exposure time = 6 sec./ withdrawal; Frequency =1000 withdrawals/ year				



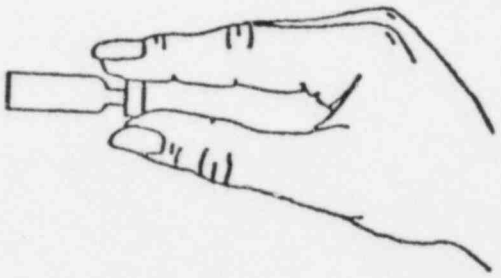


* Exposure to opposite hand should not be added to the other listed exposures which occur to primary hand.

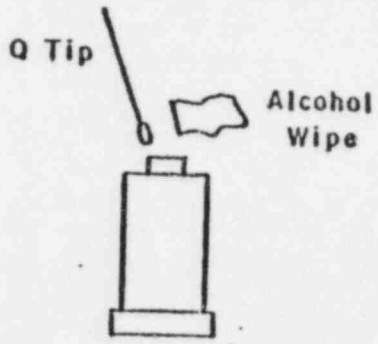
TABLE 5. OTHER SOURCES OF EXPOSURE TO THE FINGERTIPS - FROM ADJUSTED TABLE OF G(k,p,0,0) VALUES

Yearly frequency and exposure time are based on our lab's average per technologist.	Source	Frequency per year	Exposure Time	Exposure Rate	Yearly Exposure R = Roentgen
Case A: Exposure while handling Xe-133 vial by hand (instead of using tongs).					
-during transfer of vial from dose calibrator to shield	- 20 mc	500	2 sec.	8.0 mr/mc-min *	2.6 R
-during transmission lung trace for patient positioning	- 20 mc	500	6 sec.	8.0 mr/mc-min *	8.0 R
Case B; Exposure during asceptic wiping of Tc-99^m vials.					
- when using 6" Q-tip dipped in alcohol on eluate vial	- 500 mc	500	1 sec.	0.04 mr/mc-min	0.17 R
- when using an alcohol wipe on the eluate vial	- 500 mc	500	1 sec.	0.33 mr/mc-min	1.4 R
- when using 6" Q-tip dipped in alcohol on reagent vial	-100 mc	1000	1 sec.	0.04 mr/mc-min	0.07 R
- when using an alcohol wipe on the reagent vial	-100 mc	1000	1 sec.	0.33 mr/mc-min	0.55 R
Case C: Exposure during changing of hypodermic needle after drawing up a 20 mc Tc-99^m dose (no shield).					
- exposure due to 50 uc average needle activity present	- 50 uc	1000	2 sec.	12.0 mr/mc-min	0.02 R †
- exposure due to 2 mc in needle hub that results when syringe overfill is expelled into hub prior to needle change.	- 2 mc	500	2 sec.	90.0 mr/mc-min	3.0 R †
- exposure from the 20 mc Tc-99^m present in the syringe	- 20 mc	1000	2 sec.	0.8 mr/mc-min	0.5 R †
- exposure to hand holding the 20 mc syringe during the needle change (use 2 ml. in a 5 cc syringe average).	- 20 mc	1000	4 sec	0.7 mr/mc-min	0.9 R

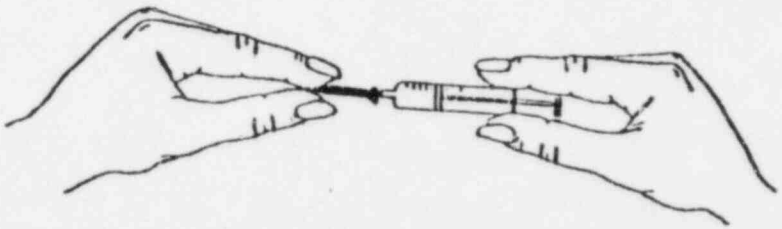
Case A:



Case B :



Case C:



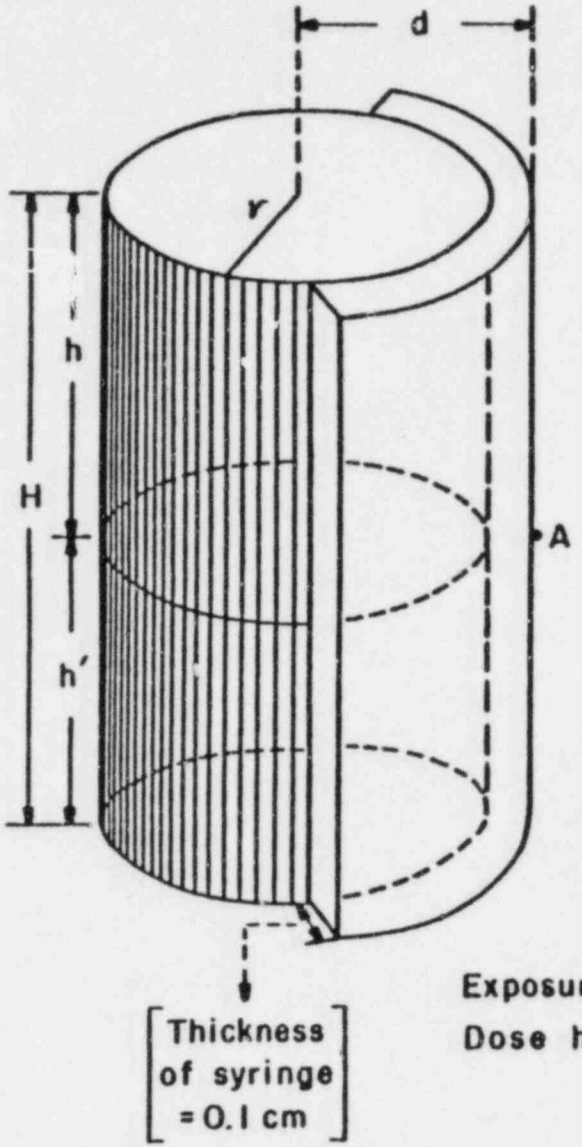
* 10% absorption by glass vial is included.

† exposure to opposite hand should not be added to other listed exposures

TABLE 6. SOURCES OF EXPOSURE DETERMINED BY METER OR ESTIMATION OTHER THAN TABLE OF G(k,p,0,0)

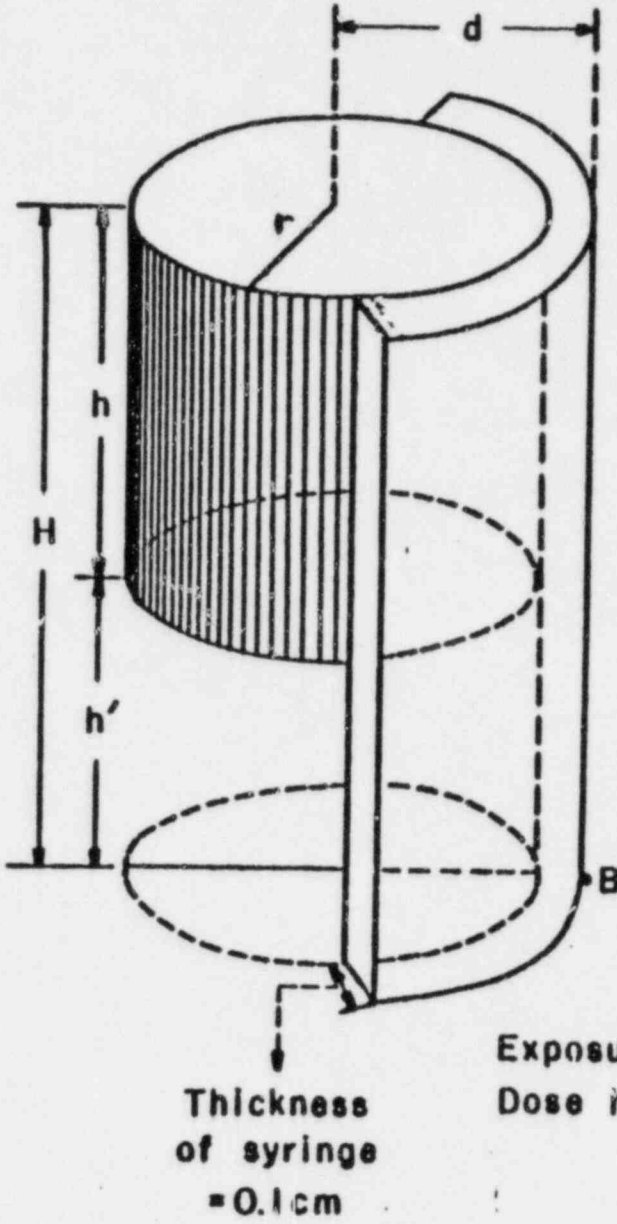
Yearly frequency and exposure time are based on our lab's average per technologist.	Source	Frequency per year	Exposure Time	Exposure Rate	Yearly Exposure R = Roentgen
Case A: Exposure from patients injected with 20 mc Tc-99^m.					
- to fingertips during patient positioning (at torso)	20 mc	1000	1 min.	20 mr/hr*	0.4 R
- to whole body and fingertips due to the proximity of a 20 mc Tc-99^m patient (3 ft. distance)	20 mc	1000	10 min.	1 mr/hr*	0.2 R
Case B: Exposure from 1 uc Tc-99^m contamination on skin. - [the calculated beta-like surface dose to active skin layer is given by Howley, Green, Dickinson et al.(7)]	1 uc	1 per spot	until fully decayed	not applicable	5 R†
Case C: Exposure to fingertips from top of a Tc-99^m generator during placement and removal of saline and vacuum vials. 1600 mc present in generator.	1600 mc	250	10 sec.	80 mr/hr*	0.06 R
Case D: Exposure to whole body and fingertips from transfer and set-up of a 500 mc Tc-99^m generator = 2400 mc day of arrival.					
- while maintaining a six inch minimum distance	2400 mc	25	15 sec.	30 mr/hr*	0.003 R
- while in actual contact with generator	2400 mc	25	5 sec.	300 mr/hr*	0.01 R
Case E: Whole body estimated exposure for 10 mc Xe-133 gas accidental escape into room from patient while at a distance of three feet from patient.	10 mc	10	2 min. then diluted	3 mr/hr*	0.001 R
Case F: Additional exposure to whole body when dose preparations of Table 4 are not carried out from behind a suitable counter top shield and without the use of syringe shields.	20 mc doses	1000	12 sec.	30 mr/hr*	0.1 R
- distance from dose to body is about 8 inches.	100 mc doses	500	12 sec.	150 mr/hr*	0.25 R

* by survey meter. † not cummulative since it is unlikely that the same area will be exposed.



Exposure point = A
Dose height = H

1.



Exposure point = B
Dose height = h

2.

6. RULES FOR THE SAFE HANDLING OF RADIOACTIVE MATERIALS

6.1. CLASSIFICATION OF AREAS

6.1.1. UNRESTRICTED AREAS

An unrestricted area means any area, entry into which is not controlled by the permit-holder or the RSO. Such area must conform to the following rules:

a. If an individual continually is present in the area, he cannot receive a dose exceeding 2 mrem in any one hour or more than 100 mrem in any seven consecutive days; or

b. if, when allowance is made for expected occupancy and time variations in dose-rate, no individual is likely to receive a dose exceeding 500 mrem in a calendar year.

6.1.2. RESTRICTED AREAS

All areas within the Hospital in which dose levels do not conform to the standard for unrestricted areas shall be restricted and under the authority of the RSO for radiation safety purposes. Warning signs (see below) shall be prominently displayed at the entrances to each restricted area, and the permit-holder responsible for work with radioisotopes in that area shall be responsible for controlling access to the area.

Both Federal and State regulations define restricted areas containing radiation which require special control measures as:

a. Radiation Area - Any area accessible to individuals in which there exists ionizing radiation at such levels that a major portion of the body of such individuals could receive an absorbed dose greater than 5 mrem in any one hour or 100 mrem in any five consecutive days.

b. High Radiation Area - Any area accessible to individuals in which there exists ionizing radiation at such levels that a major portion of the body could receive in any one hour an absorbed dose greater than 100 mrem.

6.2 REQUIRED SIGNS AND LABELS

Signs are required by law to denote areas and/or containers with levels of radiation or radioactivity specified in the following sections:

6.2.1. "CAUTION RADIATION AREA" - in areas accessible to personnel in which a major portion of the body could receive in any one hour a dose of 5 mrem or in any five consecutive days a dose in excess of 100 mrem.

3. The patient should be encouraged to do as much as possible for himself so that close bedside nursing can be reduced to a minimum.

4. Nursing personnel should attend the patient for routine care.

5. If special nursing care is required, this shall be brought to the attention of the RSO.

6. The nurses in attendance shall normally wear a dosimeter or film badge, which may be obtained from the RSO. Table II shows when a film badge is necessary.

7. A Radioactive Isotope Form must be filled out at the time of treatment and attached to the patient's chart.

8. No bed baths should be given by the nurses for the first 48 hours unless specifically ordered by the radiotherapist or attending physician.

9. The location of the room and the location of the bed within the room shall be such that the dose at occupied, neighboring beds is less than 2 mrem/hour.

10. Personnel shall limit their stay in the vicinity of the patient to conform to the rules listed in Table II.

TABLE II

Schedule showing when dosimeters should be worn and showing maximum time in the room when caring for patient with gamma emitting isotope.

Activity mCi	Distance from patient	Dosimeter should be worn	Maximum time in room
1	1-3 feet	more than 3 hours	24 hours
10	1-3 feet	more than 30 min	8 hours
	3-9 feet	more than 3 hours	24 hours
100	1-3 feet	always	15 min
	3-9 feet	more than 30 min	4 hours

EMERGENCY SITUATIONS

1. If there is any question of personnel exposure or contamination, immediately call the radiotherapist or the Radiation Safety Office.

EQUIPMENT

1. A waterproof disposable carton or plastic bag properly marked for radioactive waste should be placed in the vicinity of a patient having iodine therapy. The waste material shall be brought to the radiation disposal area by the nursing personnel to be monitored by the RSO.

RSO ACTIVITY FILE

APRIL 17, 1980

PLANNING FOR LOCATION OF RADIATION THERAPY PATIENTS IN THE AHC.

On this day Dr. Drum met with Phil Cobb and Dr. Ken Kase, of the Joint Center for Radiation Therapy, in the office of Jay Tracy to discuss location of brachytherapy patients in the new hospital building. The gynecology floor at issue would be the sixth floor, southwest and southeast sections. Here there are potentially single rooms with adjacent space for storage of mobile lead screens. In addition, the floor above will be machinery only - therefore no occupancy - the floor below, adult genacology. The floors are constructed of conventional concrete of 8 inches thickness, which should serve as an adequate shield for patients on the floor below. It would be possible with the use of mobile lead shields to provide safe radiation environment for both adjacent patients on the same floor who might not be getting radiation therapy and for hospital employees.

This meeting was initiated at the suggestion of the Radiation Safety Committee. We believe the benefits of planning for this kind of location of patients, of appropriately equipping the floor, and of having a uniformly expertly trained nursing staff all spoke strongly to the recommendation that all such patients be located here.

Following the meeting, an on-site tour was conducted by Mr. Tracy in order that we fully appreciate the size of the rooms and the distances involved. It would appear that the total number of patients receiving such services at any one time would never be greater than 5. The head-to-head distances for patients in these rooms would be approximately 18 feet. Mr. Tracy kindly furnished a sample floor plan which could be reproduced for the next committee meeting.

RADIATION SAFETY MEMORANDUM

Conference on Placement of Radiation Therapy Patients

On 22 July Dr. Drum met with Chris Collins, Phil Cobb, Margaret LaMontagne and Carol Jankowski to discuss the matter of placing patients for radiation therapy. It seemed that two major issues needed to be discussed: 1) The various options available for imroving the inpatient census by either having two radiation therapy patients simultaneously in the same room or providing sufficient shielding to permit single patient rooms to be used for radiation therapy, 2) Means to ensure that there was enthusiastic and appropriate support of the nursing service for use of the radiation shields as safety devices.

It was decided that we would try using the shields with therapy patients in the single rooms. Measurements of near-by adjacent exposure rates were to be made by Radiation Therapy. The aim would be for two admission days weekly, with rotation amongst pods whenever practicable. Mrs. Jankowski agreed to discuss both this and the placing of shields with the nursing service. Dr. Drum pointed out the exposure records indicating that the nursing service in the care of these patients had experienced extremely low exposures. Based on this prior record, it would be easy to see whether any changes in operation handling of these patients resulted in either increased aggregate exposures or increased individual exposures. The group

asked Dr. Drum to check once again the assurances by the architect that the floors could withstand the heavy weight of the radiation shield.

Patients for I-131 or Ir-192 treatment might be admitted to the 11th or 12th floor if the census precluded use of the 6th floor.

Although the Radiation Safety Committee had expressed disapproval of using end rooms to house two patients simultaneously undergoing brachytherapy, Dr. Drum indicated that this less desirable option could be tested with the new shields now available.

Ms. LaMontagne indicated that inservice lectures on radioiodine therapy are needed. Mrs. Jankowski agreed to contact Helen Perachi, Assistant Director for Gyn Nursing, for planning such instruction.

References:

1. Minutes of the Radiation Safety Committee Meeting, 12/4/80.
2. Letter to Stanley Burchfield, 11/24/80.
3. Radiation Safety Manual of the Brigham and Women's Hospital
4. NCRP Report No. 37: Precautions in the Management of Patients who have received therapeutic amounts of radionuclides. Oct. 1, 1970.
5. NCRP Report No. 48: Radiation Protection for Medical and Allied Health Personnel. Aug. 1, 1976.

1981 OCCUPATIONAL RADIATION DOSES

BWH Radiation Therapy and Nursing

Dose, mrem	No. Persons
less than 10	84
10 - 50	56
50 - 100	18
100 - 200	20
200 - 400	11
400 - 650	4
above 650	0
Total	193

If there is an appreciable amount of liquid, paper towels *should* be dropped upon it and left until the Radiation Protection Supervisor arrives. If there is contamination of the patient or of other persons, clothing *should* be removed and stored within the marked area. Contaminated skin *should* be scrubbed, using a washroom in this area, or wash basins brought to the area for this purpose. Contamination *shall not* be removed from the area or further cleanup attempted before arrival of the Radiation Protection Supervisor. However, the following actions *should* be carried out as rapidly as possible, even before the arrival of the Radiation Protection Supervisor:

1. If the radioactive contamination arises from a pure beta-emitter, such as P-32, the immediate concern is only to prevent spread of contamination. If possible, the region of the spill *should* be covered with a plastic bed sheet and then with the equivalent of ½ inch of soft absorbent material such as 2 thick blankets. This will protect personnel within the region from radiation exposure and *should* be left in place until the arrival of the Radiation Protection Supervisor.
2. If the contamination arises from a mixed beta-gamma emitter of medium energy such as I-131, protection against the beta radiation may be effected as described above. If personnel remain at least 6 feet from the covered spill, further immediate protection against the gamma radiation is not required.
3. If the contamination is due to breakage of a radium needle, it is possible that radioactive particles will become airborne. In this case the room *should* be evacuated, the door and all windows and ventilators *should* be closed if possible, and a region immediately outside the room marked off as a radiation hazard area. All persons evacuated from the room *shall* remain within this designated area until monitored by the Radiation Protection Supervisor.

3.7 Protection of Other Patients and Visitors from Radiation

The maximum permissible dose equivalent for persons not occupationally exposed is 500 mrem per year, and planning *shall* be based on the objective that this level will not be exceeded for other patients or for visitors exposed to radiation from a patient containing radioactive material.

As far as visitors are concerned, there is little likelihood of their exceeding this dose, even if they make repeated visits, if they remain about 6 feet or more from the patient, except for a brief period to shake hands, deliver mail, etc. Pregnant women and children *should not*, in

general, be allowed to visit patients having an appreciable radioactive burden. Exceptions can be made in case of urgency, but the visits should be brief, and a distance of six feet or more *should* be maintained.

A patient not receiving radiation treatment but in a room or ward with a radioactive patient presents a different problem. If both are confined to bed, exposure is practically continuous. Even if one or both are ambulatory, there will be long periods of simultaneous bed occupancy at night and during rest hours. It is recommended that, if possible, non-radioactive patients *should* receive a dose equivalent of no more than 100 mrem from another patient during any one hospital admission. This may be somewhat increased under conditions of emergency, but *should* not exceed 200 mrem. This may necessitate a private room assignment for the radioactive patient, but this by itself does not guarantee dose limitations, if walls are thin and beds are near walls which may have other beds just beyond.

For example, a patient has a gynecological applicator containing 60 mg of radium, which is to be kept in place for 50 hours. At a distance of 6 feet from a point source of this activity the exposure rate would be 12.5 mR/h. Absorption of radiation in the bodies of the radioactive patient and his neighbor would reduce the rate in the neighbor's critical organs somewhat, but a dose equivalent of 100 mrem would probably be accumulated in about 12 hours. With a 12-foot separation this time would be increased to 48 hours, which is satisfactory. It is evident that extra separation *should* be provided for patients of this type.

If one or both patients are ambulatory, it may be difficult to make an estimate of dose accumulation. In all such cases, the Radiation Protection Supervisor *shall* make a study of the situation, and establish appropriate procedures. In the hospital where a number of such cases are treated, routines can be set up, possibly involving special rooms or wards. The irradiation of one radium patient by another such patient is of no significance, but putting several of these patients together may pose problems for attendants. In institutions having only a few cases, individual consideration of each exposure *shall* be made. Here the 100 mrem limit may be relaxed somewhat, since there is less probability of a second episode for the non-radiation patient. But in any such case, the dose *shall not* exceed 0.5 rem and *should not* exceed 200 mrem. The receipt of such a dose *should* be shown in the patient's clinical record.

Brigham and Women's Hospital
A Teaching Affiliate of Harvard Medical School
75 Francis Street, Boston, Massachusetts 02115
(617) 732-6056

M E M O R A N D U M

TO: Drs. Weichselbaum, Bloomer, Manick, Ryan, Larsen; Mss. Collins; Lewis, OR Scheduling; Perachi, GYN Nursing; Mr. Cobb, Joint Center for Radiation Therapy

FROM: David E. Drum, M.D., Radiation Protection Officer

SUBJECT: Limits on Exposure Rates Around Patients Receiving Radiation Therapy from Internal Sources

DATE: March 2, 1982

At the conclusion of an inspection of the hospital by the U.S. Nuclear Regulatory Commission on February 18-19, 1982, Dr. Jessiman and I agreed to strict conformance with 10CFR20.105(b). This means operationally that no radiation exposure rate adjacent to or outside the therapy patient's room may exceed 2mR/hr, measured at one foot from the wall or door. Some short term adjustments in scheduling and in mobility may be required for these patients (involving I-131, Ir-192 and Cs-137, not radium), but I will insist that the commitment be kept.

For some months we have been accumulating data to support explicit permission to operate under 10CFR20.105(a), wherein we avoid exposure of any one individual to more than 500 mR in one calendar year. Such a license amendment will permit more flexibility in management of brachytherapy patients.

The Radiation Safety Office appreciates your cooperation and comments.

DED:JBM

cc: Dr. Jessiman
Radiation Safety Committee

RESEARCH CONSENT FORM

TE PREPARED: 9-3-81

OJECT TITLE: Use of Radioisotopes in Training for Radiation Accident Emergencies

YSICIAN(s): David E. Drum, M.D.

ENTIFYING NUMBER(s)

LUNTEER/PATIENT NAME: (not imprinted above)

. 9/80

Human Subjects Certifications

APPROVED FOR USE BY THE BRIGHAM AND WOMEN'S HOSPITAL
10-20-81
SIGNED BY: B. L. DauHum
Secretary, Human Subjects Committee
DOCKET NUMBER: 5251
EXPIRATION DATE: 10-19-82

The emergency service of the Brigham and Women's Hospital will shortly be holding a radiation accident casualty drill. We would like you to participate in this drill as the simulated subject. A scenario describing the type of action in which you were hurt and exposed to either external radiation or contamination with radioactive materials will be developed and shown to you. Prior to your pickup by ambulance or placement onto a stretcher outside the radiation emergency area, a nuclear medicine physician will apply to your clothing, shoes and skin small quantities of H-3 or Tc-99m in nonabsorbable form. Specifically, the total quantity of Tc-99m applied will be 1 mCi and that of H-3 also 1 mCi. No more than 10 microcuries of the former or 100 microcuries of the latter will be applied to your skin. The Tc-99m will be in the form of either sulfur colloid or DTPA complex, neither of which is absorbed; the H-3 will be in the form of tritiated inulin, also not absorbed. The estimated dose to your skin from the H-3 is zero, and from the Tc-99m, 38 mrad.

Prior to administration of the radioisotope, you will be given a TLD radiation dosimeter badge which will permit us to document your radiation exposure, if any, during the drill. Upon entry to the Holding Unit, the medical staff will treat you as they would a patient with a specified injury, such as a fracture or burn, and will remove the radioactivity from you as rapidly as possible under the direction of a nuclear medicine physician.

We anticipate that within 30 minutes you should be fully decontaminated. Because both you and the physician who applied the radioactivity know precisely where it was applied, you can insure that any deficiencies in the training protocol will be corrected by rapid cleanup after completion of the drill.

Do you have any further questions?

I have fully explained to the volunteer, _____ the nature and purpose of the training procedure described above and such risks as are involved in this performance. I have asked the subject if any questions have arisen regarding these procedures and have answered these questions to the best of my ability.

_____
Physician

I have been fully informed of the training procedures to be followed and have been given a description of the potential attendent risks. In signing this consent form I agree to be a volunteer for the drill as specified, and I understand I am free to withdraw my consent and discontinue participation at any time, without prejudice. I understand also that if I have additional questions at any time, they will be answered.

_____
Volunteer Subject Signature

Brigham and Women's Hospital
A Teaching Affiliate of Harvard Medical School
10 Vining Street, Boston, Massachusetts 02115
(617) 732-5740

REPORT OF ACTION OF THE COMMITTEE ON HUMAN SUBJECTS

HUMAN SUBJECTS DOCKET NUMBER 5251 PRINCIPAL INVESTIGATOR David E. Drum, M.D.

TITLE: Use of Radioisotopes in Training for Radiation Accident Emergencies

This is to certify that the application identified above has been reviewed by the Committee appointed to review proposals involving clinical research and other investigations involving human beings, which has considered specifically:

(1) the rights and welfare of the individual or individuals involved,
(2) the appropriateness of the methods used to secure informed consent, and
(3) the risks and potential medical benefits of the investigation.

The Human Subjects Committee reviewed your research protocol and recommend approval. Please use enclosed authorized copy of consent form and/or questionnaires in your research.

NOTE: Approvals are granted for the period of one year only and must be renewed annually. In addition, adverse reactions of any kind must be reported immediately in writing to the Committee, as they occur.

FOR THE HUMAN SUBJECTS COMMITTEE

10-20-81
DATE OF COMMITTEE ACTION

Robert D. Hardin M.D.
CHAIRMAN

Tuesday
ASSIGNED TO GROUP

B.L. Doubleuse
EXECUTIVE SECRETARY

HARVARD UNIVERSITY
UNIVERSITY HEALTH SERVICES

75 Mt. Auburn Street
Cambridge, Massachusetts 02138

December 3, 1981

Dr. David Drum
Radiation Safety Officer
Brigham & Women's Hospital
75 Francis Street
Boston, Mass. 02115

Dear Dr. Drum:

In response to your query regarding the finger ring exposures of the personnel in nuclear medicine during the period in which these rings were worn on an evaluation basis, the following information is submitted for your information.

DATE	NAMES * [redacted]	[redacted]	[redacted]
5/15 - 6/20/79	L-190, R-70		L-80, R-85
6/20 - 8/20/79	R-80	L-40, R-35	L-25, R-65
8/20 - 9/7/79	L-40, R-135	R-25	R-15
9/7 - 11/1/79	L-35, R-60	20	10
11/1 - 12/7/79	L-30, R-40	15	40
12/7 - 1/7/80	L-1[illegible], R-150	L-10, R-25	55
1/7 - - 2/25/80	L-20, R-10		250
2/25 - 6/10/80	L-245, R-205		
4/17 - 6/10/80		55	

These were the persons that I knew were in the department at this time. If any others were involved, please give me the name and I will investigate the exposure.

Yours truly,

Robert U. Johnson
Director
Radiological Services

RUJ:dp

* THIS LINE CONTAINS 2.790 INFORMATION AND IS NOT FOR PUBLIC DISCLOSURE, IT IS INTENTIONALLY LEFT BLANK.

SURVEY METER READINGS FOR I-131 THERAPY

40-[illegible]-23-8
10/25/81 62M LARSEN R4
HANSEN, GEORGE 6C

Instrument used: WB Johnson Nuclear NMAS 1/19/81 — Watson's meter
Time of administration of isotope: 2:15 pm. 10/26/81
Dose administered: 200 m.Ci I-131

x1.8 factor = I-131

LOCATION	READINGS cpm	mR/hr
A. Prior to Administration		
5 cm from lead container holding source	~~[illegible]~~	15 (50 mR)
90 cm (3 feet) from container holding source	~~[illegible]~~	1.5 (4 mR)

3 shields used

3' — 46 mR (on Watson's meter)

INITIALS [illegible]

	Immediately	24 hours
B. Post-Administration		
90 cm (3 feet) from patient	13	7
doorway of patient's room (badge 282)	.1	No shield → 1-2 at most + shield → 0.7
next room to left of patient's room (proximal wall) 6C 053 (badge 283)	0.15	0.2
next room to right of patient's room (proximal wall) 6C 055	1 mR at bed and chair	0.5
hallway outside patient's room	0.7 ?	0.2-0
	INITIALS [illegible]	INITIALS [illegible]

nurse's station

~0.1 mC/hr

C. Following Discharge of Patient 10/29/81 12 Noon	Before Cleanup	After Cleanup
Before housekeeping has cleaned (at 5 cm)		
linen bag	1.1 *	gone
commode	0.2	<.1
sink drain	0.5	<.1
30 cm from sink		<.1
waste receptacle	5 *	gone
chair	<.1	<.1
general survey of room door	0.18	<.1
		INITIALS [illegible]

6" from pt (thyroid - 10/29 — 16 mR

* to radwaste area

BADGES:
pt's door — 0[illegible]
headboard of bed — 0[illegible]
(in room to the right 6C 055)

D. Comments on Any Persistent Residual
Location: None
Readings: _____ cpm _____ mR/hr
Action recommended:

PERSONNEL BADGE RADIATION EXPOSURE REPORT
TLD MEASUREMENT PB-2 BADGE CASE

GROUP: PB-02

BADGE NO.	IDENTIFICATION	WEARING PERIOD FROM	TO	DOSE (MREM) SHALLOW	DEEP
door -82		10/01/81	10/31/81	25	25
t. next -84 room				35	35

THE ABOVE DATA WERE REDUCED IN THE ABSENCE OF CONTROL DOSIMETERS, USING AN ASSUMED BACKGROUND VALUE OF 20 MREM TO CHARACTERIZE TRANSIT DOSE AND BACKGROUND RADIATION.

11/19/81 T Pelton

ach & ead board

200 mCi I131 - given to pt. 10/26/81

TELEDYNE ISOTOPES
50 VAN BUREN AVENUE
WESTWOOD, NEW JERSEY 07675
(201) 664-7070
TELEX 134474 TDYISOT WTWD

Brigham and Women's Hospital
A Teaching Affiliate of Harvard Medical School
75 Francis Street, Boston, Massachusetts 02115
(617) 732-

AGENDA for the RADIATION SAFETY COMMITTEE Meeting, 4 December

1. Approval of minutes for the 16 October meeting
2. Permit changes - human use: none
3. Permit changes - no human use; all new permits
   a) Dr. Wilcox (permit 29) Clinical Pharmacology
      I-125, H-3, Cr-51 all 1 mCi
   b) Dr. Tulchinsky (permit 38) LID Endocrine lab A
      I-125, H-3,C-14 all 10 mCi
   c) Dr. Fencl (permit 39) LID Endocrine lab B
      I-125, H-3,C-14 all 10 mCi
   d) Dr. Schur (permit 32) Immunology lab
      I-125, H-3, C-14, Cr-51 all 10 mCi
4. Guidelines for safe brachytherapy in the BWH
5. Simplified human use application
6. Testing of radioisotope generators - new CFR rules
7. Update on radioactive waste disposal
8. Report on unannounced radiation casualty drill

No. 26; Drs. Underwood-Larsen, No. 27; Dr. Lazarus, No. 31; Drs. Bloomer-Hellman, No. 33; Dr. Hollenberg, No. 34; Dr. Wilson, No. 36; Dr. Cahill, No. 37; Dr. Handin, No. 41; Dr. Busch, No. 48. The permit of Dr. LaMont, No. 2, was terminated in view of his departure.

* Some discussion of guidelines for safe use of internal radiation therapy sources in the hospital were discussed at the hands of a communication from Dr. Drum to Mr. Burchfield, included with these minutes. Experience thus far indicates that in order to meet regulatory guidelines of exposure rates no greater that 2 mR/hr and cumulative exposures no greater than 100 mR for patients, visitors and others not receiving radiation therapy, it appears necessary to use the previously designated semi-private rooms on the sixth floor with occupancy by a single patient at a time and with appropriate use of portable radiation shields. Because there seemed some difficulty with assigning these needs a high priority within the hospital budget, Dr. Drum indicated that the Committee should know of his advisory in that regard. It was suggested that the hospital might apply to the NRC for a waiver on the requirement that exposure rates be limited to 2 mR/hr.

Dr. Drum presented his suggestions for simplification of human use applications required of investigators wishing to conduct studies using radioisotopes in humans. He suggested that the fundamental role of our committee was to document dosimetric calculations and radiopharmaceutical characterization. Because all such protocols must be evaluated subsequently by the Human Subjects and Pharmacy/Therapeutics Committees, it appeared that an effort should be made to amalgamate our application with theirs. In the discussion the issue of training for use of radioisotopes in humans was raised; the training required of physicians now is 200 hours, a requirement rarely met by any physicians other than those specializing in radiation therapy or in nuclear medicine. However, it seemed implicit that certification of a responsible investigator would be a function of this committee in its award of a permit for human use at any time. Mr. Mayblum suggested that the requirements for the use of radioisotopes be spelled out on a single page and incorporated in the packet distributed by the Human Subjects Committee.

Dr. Shapiro and Mr. Johnson reviewed the current status of radioactive waste disposal. The NRC has declared medical and research liquid scintillation solvents containing H-3 and C-14 to be of negligible radiation hazard. Political efforts are now underway to designate sites in this state at which the liquid scintillation fluids may be incinerated. Some alarm was expressed that the EPA was trying to assume jurisdiction over these materials based on possible chemical hazards. Dr. Shapiro indicated that a subcommittee appointed by Governor King was working to secure local acceptance of several sites.

Dr. Drum announced that the city-wide emergency drill held two weeks ago delivered 29 patients to this hospital, two of whom were simulated radiation casualties. These were essentially then unannounced radiation accident victims. He indicated the Disaster Committee's feeling that these patients were expertly handled despite no prior notification.

RADIATION SAFETY MEMORANDUM

Conference on Placement of Radiation Therapy Patients

On 22 July Dr. Drum met with Chris Collins, Phil Cobb, Margaret LaMontagne and Carol Jankowski to discuss the matter of placing patients for radiation therapy. It seemed that two major issues needed to be discussed: 1) The various options available for imroving the inpatient census by either having two radiation therapy patients simultaneously in the same room or providing sufficient shielding to permit single patient rooms to be used for radiation therapy, 2) Means to ensure that there was enthusiastic and appropriate support of the nursing service for use of the radiation shields as safety devices.

It was decided that we would try using the shields with therapy patients in the single rooms. Measurements of near-by adjacent exposure rates were to be made by Radiation Therapy. The aim would be for two admission days weekly, with rotation amongst pods whenever practicable. Mrs. Jankowski agreed to discuss both this and the placing of shields with the nursing service. Dr. Drum pointed out the exposure records indicating that the nursing service in the care of these patients had experienced extremely low exposures. Based on this prior record, it would be easy to see whether any changes in operation handling of these patients resulted in either increased aggregate exposures or increased individual exposures. The group

asked Dr. Drum to check once again the assurances by the architect that the floors could withstand the heavy weight of the radiation shield.

Patients for I-131 or Ir-192 treatment might be admitted to the 11th or 12th floor if the census precluded use of the 6th floor.

Although the Radiation Safety Committee had expressed disapproval of using end rooms to house two patients simultaneously undergoing brachytherapy, Dr. Drum indicated that this less desirable option could be tested with the new shields now available.

Ms. LaMontagne indicated that inservice lectures on radioiodine therapy are needed. Mrs. Jankowski agreed to contact Helen Perachi, Assistant Director for Gyn Nursing, for planning such instruction.

References:

1. Minutes of the Radiation Safety Committee Meeting, 12/4/80.
2. Letter to Stanley Burchfield, 11/24/80.
3. Radiation Safety Manual of the Brigham and Women's Hospital
4. NCRP Report No. 37: Precautions in the Management of Patients who have received therapeutic amounts of radionuclides. Oct. 1, 1970.
5. NCRP Report No. 48: Radiation Protection for Medical and Allied Health Personnel. Aug. 1, 1976.

designated for radioactive waste storage. Mr. Johnson indicated that the new regulations permitting local management of low-level beta emitting radioisotopes and short-lived low energy gammas have led to a considerable decrease in the cost for certain forms of waste disposal. He indicated that it would be likely that the barrel charge to users at the Brigham might decrease by as much as 50% in the near future.

The Chairman indicated that the annual radiation accident casualty drill was scheduled to occur on the 29th of October.

During the summer the institution was the subject of an inspection by the U.S. Food and Drug Administration of the activities of the Radioactive Drug Research Committee. All were found to be in accord with statutory requirements.

Dr. Drum reported to the Committee on the occurrence of a leaking or contaminated sealed source device. The I-125 source, 200 mCi, for bone densitometry at the Lying-In Division, was returned to the manufacturer. Appropriate notification of the U.S. Nuclear Regulatory Commission was made and acknowledged.

The central dispensing Radiopharmacy of the Joint Program in Nuclear Medicine is now located in the L-2 Level of the Brigham & Women's Hospital, following recent approval of its transfer from the Children's Hospital by the Nuclear Regulatory Commission.

Dr. Kase inquired about progress and management of radiation safety in the area of the single rooms being used for radiation therapy on the 6th floor. Dr. Drum explained that data on exposure levels were being accumulated as each patient was admitted. He planned to evaluate this on a continuing basis with representatives of Nursing and the Admissions Office. Measurements to date would indicate that no person outside the room containing the source would be exposed to more than 100 mR; certain areas outside the room have, however, had exposure rates in excess of 2 mR/hr. Dr. Kase cautioned against requesting of the Nuclear Regulatory Commission anything more than a general clarification of the appropriate section of 10CFR20. He feared that any indication of exposure levels in excess of 2 mR/hr would engender unnecessary difficulties.

Respectfully submitted,

David E. Drum

David E. Drum, M.D.
Chairman, Radiation Protection Officer

DED:JBM

M E M O

TO: D.E. Drum, M.D.
FROM: P. Cobb, Radiation Safety Officer, JCRT
DATE: December 26, 1979

During a recent NRC inspection, a recommendation was made by the inspector concerning radioactive implant patients. He was very concerned with the radiation exposure to adjacent patients, instruction of nursing personnel, and personnel monitoring and safety procedures. It would appropriate if several rooms on a given floor in the AHC be specified and be used first for radioactive implant patients. These rooms could be used for non-radioactive patients if no radioactive patients were in the house. This would allow better control over radioactive patients and maintain a staff of adequately instructed nursing personnel.

I would appreciate if you would discuss this with the Radiation Safety Committee and follow it through with the hospital administration.

Thank you for your consideration of this matter.

HARVARD MEDICAL SCHOOL

DEPARTMENT OF RADIATION THERAPY
DIVISION OF PHYSICS AND ENGINEERING

50 BINNEY STREET
BOSTON, MASSACHUSETTS 02115

TO: Kenneth Kase

FROM: Philip Cobb

DATE: May 16, 1980

SUBJ: Shielding of Patients' Rooms at AHC

Radium Patients

Amount used-50 mg
Distance-200 cm
Γ =8.25
Est. max. exposure in next room-10 mR/hr
HVL_{Ra}=1.66 cm Pb TVL_{Ra}=5.5 cm

Iridium Patients

Amount used-70 mCi
Distance-200 cm
Γ = 4.6
Est. max exposure in next room-8 mR/hr
HVL_{Ir}-0.6 cm Pb TVL_{Ir}-2.0cm Pb

Change all radium tubes to cesium tubes. Cesium tubes (standard) 2.0 cm long 3.1 mm diameter, active length 1.4 cm. Need about 45 sources for 4-5 patients at $300/source.

Total cost-$13,500

Cesium Patients

Amount used-150 mCi
Distance 200 cm
Γ=3.2
Est. max. exposure in next room-12.0 mR/hr
HVL_{cs}-0.65 cm PB TVL_{cs}-2.1 cm

Shielding of wall between patient rooms would require 1-2 cm of lead for iridium and cesium patients to reduce the exposure to adjacent patients to a maximum of 1.0 mR/hr assuming no patient attenuation.

HARVARD MEDICAL SCHOOL DEPARTMENT OF RADIOLOGY
JOINT PROGRAM IN NUCLEAR MEDICINE
CHARLES A. DANA CANCER HOSPITAL • CHILDREN'S HOSPITAL MEDICAL CENTER •
PETER BENT BRIGHAM HOSPITAL

July 22, 1980

Mr. Dick Roberts
Joint Center for Radiation Therapy
Shields Warren Radiation Laboratory

Dear Dick,

At the suggestion of Dr. William Bloomer, I am writing to call your attention to shielding needs around brachytherapy patients located on the sixth floor of the new BWH. When this matter was considered by the Radiation Safety Committee, we believed location of patients in 6A-11, 6A-21, 6B-31 or 6B-40 (or, when available, in single rooms when adjacent rooms are vacant) and the use of mobile one-inch lead shields would afford adequate protection for non-therapy patients and hospital staff.

It is urgent that at least four of the lead shields (see enclosure for an example) be obtained and placed on the floor as soon as possible. Otherwise I may have to postpone such admissions as leading to potentially unsafe radiation conditions.

Please discuss this with Dr. Bloomer and take appropriate action as soon as possible. If I may be of help, let me know.

Sincerely yours,

David Drum

David E. Drum, M.D.
Radiation Protection Officer

Encl

cc: Dr. Bloomer
Admissions Office
Mr. Stoughton
Phil Cobb

HARVARD MEDICAL SCHOOL DEPARTMENT OF RADIOLOGY
JOINT PROGRAM IN NUCLEAR MEDICINE
CHARLES A. DANA CANCER HOSPITAL • CHILDREN'S HOSPITAL MEDICAL CENTER •
PETER BENT BRIGHAM HOSPITAL

July 23, 1980

Sylvia Hanrahan
Admissions Office
Brigham and Women's Hospital

Room in path
Pod

Dear Sylvia,

Pursuant to our conversation on July 23rd, I wish to request on behalf of Radiation Therapy and Nursing that all patients admitted to the gynecological service on the sixth floor for internal radiation therapy should be assigned the following rooms, in order of preference: C-060, C-051, D-080, and D-071. It is also appropriate to have two patients both undergoing radiation therapy to be located in the same of any of these double rooms.

The purpose of these assignments is to minimize radiation exposures of non-therapy patients and hospital staff.

I will write you again regarding the twelfth floor oncology situation after I have talked with the Nursing Service and physicians there.

Sincerely yours,

David E. Drum

David E. Drum, M.D.
Radiation Protection Officer
Brigham and Women's Hospital

DED/sw

cc: Dr. Bloomer
Phil Cobb
Peggy McNeil, R.N.

HARVARD MEDICAL SCHOOL DEPARTMENT OF RADIOLOGY
JOINT PROGRAM IN NUCLEAR MEDICINE
BETH ISRAEL HOSPITAL • CHILDREN'S HOSPITAL MEDICAL CENTER •
PETER BENT BRIGHAM HOSPITAL • SIDNEY FARBER CANCER INSTITUTE

July 30, 1980

Sylvia Hanrahan
Admissions Office
Brigham and Women's Hospital

Dear Sylvia,

Pursuing our day-to-day experience and staff discussions for safe placement of radiation therapy patients on the sixth floor, I want to ask you to try to make room assignments as follows in order:

first patient	6C-051 or 060
second "	6D-080 or 071
third "	6B-031 or 040
fourth "	6A-11
fifth "	6C-060 or 051
sixth "	6D-071 or 080
seventh "	6B-040 or 031

This will provide for dispersal of up to seven patients at a given time.

Until we gain some experience with mobile lead shields, which are not as yet on the floor, I cannot permit (for safety considerations) more than one patient at a time - the one receiving therapy - in any of these double rooms.

I appreciate your patience with the problems we are causing you, but I am optimistic they will be resolved shortly.

Sincerely yours,

David Drum

David E. Drum, M.D.
Radiation Protection Officer

DED/sw

cc: Dr. Bloomer
Phil Cobb
Peggy McNeil, R.N.
Margaret LaFontaine, R.N.
Mr. Stoughton

HARVARD MEDICAL SCHOOL DEPARTMENT OF RADIOLOGY
JOINT PROGRAM IN NUCLEAR MEDICINE
BETH ISRAEL HOSPITAL • CHILDREN'S HOSPITAL MEDICAL CENTER •
PETER BENT BRIGHAM HOSPITAL • SIDNEY FARBER CANCER INSTITUTE

MEMORANDUM

DATE: July 30, 1980

TO: All physicians responsible for therapeutic radiation from sealed or unsealed sources

FROM: David E. Drum, M.D., Radiation Protection Officer

SUBJECT: Radioisotope Administration Form

In every instance in which radiation treatments are given by internal radioactive sources, a radioisotope administration form 49-04 must be completed and inserted in the the nursing orders section of the chart by the responsible physician or his designee. This requirement has not been uniformly adhered to in the past, but I wish to make it clear that the Radiation Safety Office and administration expect this authorized form to be used in all internal therapy cases.

A copy of the form, which is available from hospital stores, is attached for your information. It is currently being modified to reflect the Brigham and Women's Hospital name. It is a medical, legal and scientific document which must be inserted in the chart of all radiation therapy patients. Additional detailed instruction for the radiation safety of visitors, family and nursing staff are, of course, appropriate but should not be used solely in lieu of this form.

DED/sw

Att.

SHIELDS WARREN RADIATION LABORATORY • 50 BINNEY STREET • BOSTON, MASSACHUSETTS 02115 • (617) 732-2184

HARVARD MEDICAL SCHOOL DEPARTMENT OF RADIOLOGY
JOINT PROGRAM IN NUCLEAR MEDICINE
BETH ISRAEL HOSPITAL • CHILDREN'S HOSPITAL MEDICAL CENTER •
PETER BENT BRIGHAM HOSPITAL • SIDNEY FARBER CANCER INSTITUTE

MEMORANDUM

DATE: July 31, 1980

TO: All physicians responsible for therapeutic radiation from sealed or unsealed sources

FROM: David E. Drum, M.D., Radiation Protection Officer

SUBJECT: Scheduling patients for therapeutic radiation

Please make extraordinary efforts to notify the admissions office (732-7448) which patients are to have or may have internal radiation therapy. When a decision to administer such therapy is made, notify admissions if they were not previously notified.

This request is made to continue our efforts at safely locating radiation therapy patients.

Please pass this information on.

Bill Brown

DED/sw

SHIELDS WARREN RADIATION LABORATORY • 50 BINNEY STREET • BOSTON, MASSACHUSETTS 02115 • (617) 732-2184

HARVARD MEDICAL SCHOOL DEPARTMENT OF RADIOLOGY
JOINT PROGRAM IN NUCLEAR MEDICINE
CHARLES A. DANA CANCER HOSPITAL • CHILDREN'S HOSPITAL MEDICAL CENTER •
PETER BENT BRIGHAM HOSPITAL

August 15, 1980

W. Vickery Stoughton
Brigham and Women's Hospital
Vice President, Medical Support Services

Dear Vic,

I surmise from Dick Roberts of Radiation Therapy that the unplanned cost of portable radiation shields is difficult for the hospital to handle at this time. I hope more funds will be available by October 1. In the meantime, internal source radiation therapy may be done safely only in the previously assigned double rooms, with single occupancy, and with care taken by our radiation safety personnel to see that young patients are moved from the adjacent rooms.

Sincerely yours,

David E. Drum

David E. Drum, M.D.
Radiation Protection Officer

DED/sw

cc: Admissions Office
Phil Cobb
Dr. Bloomer
Margaret LaFontayne, R.N.

SHIELDS WARREN RADIATION LABORATORY • 50 BINNEY STREET • BOSTON, MASSACHUSETTS 02115 • (617) 732-2185

Brigham and Women's Hospital
A Teaching Affiliate of Harvard Medical School
75 Francis Street, Boston, Massachusetts 02115
(617) 732- 5938, 2184
235-7640 (home)

MEMORANDUM

DATE: November 20, 1980

TO: Ken Kase
Phil Cobb
Stan Burchfield
Dick Roberts
Jay Tracey
Reed Larsen

FROM: David E. Drum, M.D., Radiation Protection Officer

SUBJECT: Attached letter

Please comment ASAP and return so I may forward this to Dr. Jessiman.

DED/sw

Att.

Brigham and Women's Hospital
A Teaching Affiliate of Harvard Medical School
75 Francis Street, Boston, Massachusetts 02115
(617) 732- 5938

November 20, 1980

Dr. Andrew Jessiman
Vice President, Medical Support Services
Brigham and Women's Hospital

Dear Dr. Jessiman,

It is now time that I write as Radiation Protection Officer to communicate a sense of urgency vis-a-vis our safe management of radiation therapy patients in the hospital. Although I am aware of the fact that funds are in short supply in the hospital, I am concerned that we provide a safe working environment for those here and that we avoid creating situations which will be even more costly. At present, the Nuclear Regulatory Commission has proposed changes in the current Federal Regulations to provide for fines as high as $8,000 per incident for radiation exposures of non-occupationally badged persons as low as 100 milliroentgens. This figure, 100 mR, has been the upper limit permitted patients in rooms adjacent to those with radiotherapy sources.

I have recently discussed the matter of shielding radiation therapy patients with all parties involved, including Jay Tracy, and wish to make the following recommendations: 1) All patients who are admitted for radiation therapy with internal sources, including radioiodine, should be admitted to the previously designated 2-person end rooms on the sixth floor with explicit provision that the second bed will remain empty while the radiation source is within the patient. 2) When such therapy is being given, two or three portable radiation shields, as identified in the attached page, will be put in place by the Radiation Safety Office in such fashion as to ensure that reasonable efforts are made to protect nursing staff and to minimize exposure to other patients and visitors. 3) No patient will be admitted for internal radiation therapy unless these requirements are met.

At present, we have two mobile sheilds on the sixth floor, one of which is borrowed from the Beth Israel Hospital. Also, because these are only of one inch thickness, we cannot meet the explicit

specifications for safe use of these as defined by Title 10, Code of Federal Regulations. The Recovery Room also represents a problem, particularly for protection of pregnant nurses, which can be solved also by having available the mobile shields. I plan to manage there in the short run by borrowing the radiation shield reserved for emergency use and furnished by Yankee Atomic and now kept in the Emergency Room.

I urge the hospital to respond promptly to these recommendations.

Sincerely yours,

David E. Drum, M.D.
Radiation Protection Officer

DED/sw

cc: W. Vickery Stoughton

Encl.

MOBILE RADIATION SHIELDS REQUIRED FOR

THE BRIGHAM AND WOMEN'S HOSPITAL

Vendor	Quantity	Catalog Number	Description	Unit Price	Total Price
ADC Medical 400 Smith St. Farmingdale, NY 11735	3	FRS-241	Special order, 1½" thickness. A24xB36xC24	$1,200	$3,600
Reactor Experiments, Inc. 963 Terminal Way San Carlos, CA 94070	2	302B	Bed shield for gamma implants, 2" thickness 15"x24"	$1,895	$3,790

DED/sw

Brigham and Women's Hospital
A Teaching Affiliate of Harvard Medical School
75 Francis Street, Boston, Massachusetts 02115
(617) 732- 5938

November 24, 1980

Mr. Stanley Burchfield
Vice President
Brigham and Women's Hospital

Dear Mr. Burchfield,

It is now time that I write as Radiation Protection Officer to follow up our telephone conversation and communicate a sense of urgency vis-a-vis safe management of radiation therapy patients in the hospital. Although I am aware of the fact that capital equipment funds are in short supply, I am concerned that we provide a safe working environment for those here and that we avoid creating situations which will be even more costly. At present, the Nuclear Regulatory Commission has proposed changes in the current Federal Regulations to provide for fines as high as $8,000 per incident for radiation exposures of non-occupationally badged persons as low as 100 milliroentgens. This figure, 100 mR, has been the upper limit permitted patients in rooms adjacent to those with radiotherapy sources.

I have recently discussed the matter of shielding radiation therapy patients with all parties involved, including Jay Tracy, and wish to make the following recommendations: 1) All patients who are admitted for radiation therapy with internal sources, including radioiodine, should be admitted to the previously designated 2-person end rooms on the sixth floor with explicit provision that the second bed will remain empty while the radiation source is within the patient. 2) When such therapy is being given, portable radiation shields, as identified in the attached page and costing about $7,500, will be put in place by the Radiation Safety Office in such fashion as to ensure that reasonable efforts are made to protect nursing staff and to prevent exposures over 100 mR to other patients and visitors. 3) No patient will be admitted for internal radiation therapy unless these requirements are met.

At present, we have two mobile shields on the sixth floor. Because these are only of one inch thickness, they alone cannot meet the

explicit specifications for safe use of these therapy source materials as defined by Title 10, Code of Federal Regulations. The Recovery Room represents an additional problem, particularly for protection of pregnant nurses, which can be solved also by having available mobile shields. I plan to manage there in the short run by borrowing the radiation shield furnished by Yankee Atomic for emergency use and now kept in the Emergency Room.

I urge the hospital to respond promptly to these recommendations.

Sincerely yours,

David E. Drum

David E. Drum, M.D.
Radiation Protection Officer

DED/sw

Encl.

cc: W.V. Stoughton
K. Kase
P. Cobb
R. Roberts
J. Tracy
R. Larsen

MOBILE RADIATION SHIELDS REQUIRED FOR

THE BRIGHAM AND WOMEN'S HOSPITAL

Vendor	Quantity	Catalog Number	Description	Unit Price	Total Price
ADC Medical 400 Smith St. Farmingdale, NY 11735	3	FRS-241	Special order, 1½" thickness, A24xB36xC24	$1,200	$3,600
Reactor Experiments, Inc. 963 Terminal Way San Carlos, CA 94070	2	302B	Bed shield for gamma implants, 2" thickness 15"x24"	$1,895	$3,790

DED/sw

New England Deaconess Hospital

185 Pilgrim Road
Boston, Massachusetts 02215
(617) 732-7000

MEMORANDUM

TO: David Drum, M.D.
FROM: Phillip Cobb, Radiation Safety Officer, JCRT.
SUBJECT: Update on Radiation Exposures from Placement of Patients in Single Rooms.
CC: K. Kase.

Enclosed are the radiation exposure levels surrounding our radioactive implant patients from September 14, 1981 to November 11, 1981.

The "reading at 3 feet with shield" is in the adjacent room 3 feet above the floor behind the shield. The "reading at 5 feet no shield" is in the adjacent room 5 feet above the floor and above the shielded area.

SUMMARY OF EXPOSURES FROM RADIOACTIVE PATIENTS PLACED IN SINGLE ROOMS AT BRIGHAM-WOMENS HOSPITAL

PATIENT ID	DATE	ADJACENT ROOM	IMPLANT/AMOUNT (mCi)	READING @ 3' W/SHIELD mR/hr	READING @ 5' NO SHIELD mR/hr
2544	9/14/81	6C55	IR-192/52	0.6	5.0
2552	9/15/81	6B37	IR-192/29	0.6	2.6
2558	9/21/81	6C55	RA-226/40	1.4	8.0
2557	9/22/81	6B37	RA-226/50	1.5	6.0
2572	10/5/81	6B37	IR-192/57	0.6	4.8
2575	10/7/81	6C55	RA-226/80	2.5	20.0
2583	10/19/81	6C55	RA-226/80	4.6	9.8
2591	10/26/81	6B37	IR-192/54	0.8	8.5
2599	11/3/81	6C55	IR-192/85	0.9	8.3
2601	11/9/81	6C55	RA-226/80	1.4	18.1

Brigham and Women's Hospital
A Teaching Affiliate of Harvard Medical School
75 Francis Street, Boston, Massachusetts 02115
(617) 732-5938

October 19, 1981

Mr. Phil Cobb
Health Physicist
Joint Center for Radiation Therapy
Department of Radiation Therapy
Brigham & Women's Hospital

Dear Phil,

By this letter I wish to acknowledge your efforts and measurements plus your concerns related to radiation exposure levels in the area of recent brachytherapy patients on the 6th floor.

Our aim in collecting these measurements and employing the trial use of portable shielding was to collect information related to the risks and benefits of using one or more single rooms configured as they are in this hospital. I am satisfied that no one outside the rooms received an exposure in excess of 100 mR; I am aware that exposure rates did exceed 2 mR/hr outside the room for certain sources.

Chris Collins, in the Admitting Office, has indicated to me that she is quite pleased with the flexibility and increased income available to the hospital because of your work in the single room. We will plan to continue to admit patients there.

It would be appropriate for you, Bob, Carol and I to meet together for a review of the data. I will then discuss our plans and results with the Nuclear Regulatory Commission for its advice and comments.

Many thanks for your help in this project.

Sincerely yours,

David E. Drum

David E. Drum, M.D.

DED:JBM

cc: Ms. Chris Collins, Admitting
Dr. William Bloomer, Radiation Therapy
Members, Radiation Safety Committee

Brigham and Women's Hospital
A Teaching Affiliate of Harvard Medical School
75 Francis Street, Boston, Massachusetts 02115
(617) 732- 6056

January 5, 1982

Mr. Phil Cobb
Radiation Safety Officer
Joint Center for Radiation Therapy
Meissner Laboratory
New England Deaconess Hospital
185 Pilgrim Road
Boston, MA 02215

Dear Phil,

In reviewing the procedure manual for personnel caring for radiotherapy patients, Dr. Drum made one change in the text. 10CFR 20.105(a) does allow for some relaxation of the exposure restrictions to patients and personnel in unrestricted areas as long as any individual's potential yearly exposure is kept below 500 mR. As you know, occasionally a radium implant has resulted in possible exposure to a patient in the adjacent room in excess of 2 mR/hr. The short duration of the implant, however, would preclude an exposure to the neighboring patient of greater than 500 mR unless several radium implants were performed during the patient's stay.

In order to estimate more closely the cumulative exposure to a neighboring patient, I would like to tape a TLD badge to that patient's headboard during the next time more than 60 mg radium are utilized. Please advise me as to when the next radium implant will be performed. Dr. Drum just wants to preserve flexibility, not abandon ALARA!

Sincerely yours,

Carol

Carol B. Jankowski, R.N.

CBJ:JBM

Enclosures

P.S.: NCRP Report No. 37 discusses this issue; you may be familiar with the information on page 16.

MEMO

TO: DAVID DRUM, M.D.
FROM: PHILIP COBB, RADIATION SAFETY OFFICER, JCRT
SUBJ: UPDATE ON RADIATION EXPOSURES FROM PLACEMENT OF PATIENTS IN SINGLE ROOMS
DATE: JANUARY 13, 1982

ENCLOSED ARE THE RADIATION EXPOSURE LEVELS SURROUNDING OUR RADIOACTIVE IMPLANT PATIENTS FROM SEPTEMBER 14, 1981 TO DECEMBER 31, 1981.

ENCLOSED IS THE ANNUAL INVENTORY OF RADIOACTIVE MATERIALS AS OF JANUARY 1, 1982.

I GUESS WERE ARE GETTING A NEW CLINAC 6/100 LINEAR ACCELERATOR WHICH REQUIRES AN ADDITIONAL 300 POUNDS OF DEPLETED URANIUM AS SHIELDING MATERIAL. THIS MATERIAL WILL BE IN ADDITION TO THE DEPLETED URANIUM (205 KIOLGRAMS) THAT IS CONTAINED IN THE VARIAN CLINAC 4 LINEAR ACCELERATOR. IF YOU HAVE ANY ADDITIONAL QUESTIONS ON THIS PLEASE CALL K. KASE AND LET ME KNOW ANY ADDITIONAL INFORMATION.

IF YOU HAVE ANY ADDITIONAL QUESTIONS ON THE OTHER MATTERS PLEASE DO NOT HESITATE TO CALL ME.

SUMMARY OF EXPOSURES FROM RADIOACTIVE PATIENTS PLACED IN SINGLE ROOMS AT BRIGHAM-WOMENS HOSPITAL

PATIENT ID	DATE	ADJACENT ROOM	IMPLANT/AMOUNT (mCi)	READING @ 3' W/SHIELD mR/hr	READING @ 5' NO SHIELD mR/hr
2544	9/14/81	6C55	IR-192/52	0.6	5.0
2552	9/15/81	6B37	IR-192/29	0.6	2.6
2558	9/21/81	6C55	RA-226/40	1.4	8.0
2567	9/22/81	6B37	RA-226/50	1.5	6.0
2572	10/5/81	6B37	IR-192/57	0.6	4.8
2575	10/7/81	6C55	RA-226/80	2.5	20.0
2583	10/19/81	6C55	RA-226/80	4.6	9.8
2591	10/26/81	6B37	IR-192/54	0.8	8.5
2599	11/3/81	6C55	IR-192/85	0.9	8.3
2601	11/9/81	6C55	RA-226/80	1.4	18.1
2612	11/19/81	6B37	IR-192/67	0.6	7.7
2617	11/23/81	6B37	RA-226/80	0.9	16.8
2628	11/30/81	6B37	RA-226/85	2.3	12.0
2630	12/1/81	6C55	RA-226/60	1.3	10.7
2638	12/8/81	6B37	IR-192/21	0.2	4.6
2644	12/14/81	6B37	RA-226/40	0.2	5.9
2650	12/15/81	6C55	RA-226/40	1.3	9.2

MEMO

TO: DAVID DRUM, M.D.
FROM: PHILIP COBB, RADIATION SAFETY OFFICER, JCRT
SUBJ: UPDATE ON RADIATION EXPOSURES FROM PLACEMENT OF PATIENTS IN SINGLE ROOMS
DATE: FEBRUARY 1, 1982

ENCLOSED ARE THE RADIATION EXPOSURE LEVELS SURROUNDING OUR RADIOACTIV
IMPLANT PATIENTS FROM SEPTEMBER 14, 1981 TO JANUARY 29, 1982.

SUMMARY OF EXPOSURES FROM RADIOACTIVE PATIENTS PLACED IN SINGLE ROOMS AT BRIGHAM-WOMENS HOSPITAL

PATIENT ID	DATE	ADJACENT ROOM	IMPLANT/AMOUNT (mCi)	READING @ 3' W/SHIELD mR/hr	READING @ 5' NO SHIELD mR/hr
2544	9/14/81	6C55	IR-192/52	0.6	5.0
2552	9/15/81	6B37	IR-192/29	0.6	2.6
2558	9/21/81	6C55	RA-226/40	1.4	8.0
2557	9/22/81	6B37	RA-226/50	1.5	6.0
2572	10/5/81	6B37	IR-192/57	0.6	4.8
2575	10/7/81	6C55	RA-226/80	2.5	20.0
2583	10/19/81	6C55	RA-226/80	4.6	9.8
2591	10/26/81	6B37	IR-192/54	0.8	8.5
2599	11/3/81	6C55	IR-192/85	0.9	8.3
2601	11/9/81	6C55	RA-226/80	1.4	18.1
2612	11/19/81	6B37	IR-192/67	0.6	7.7
2617	11/23/81	6B37	RA-226/80	0.9	16.8
2628	11/30/81	6B37	RA-226/85	2.3	12.0
2630	12/1/81	6C55	RA-226/60	1.3	10.7
2638	12/8/81	6B37	IR-192/21	0.2	4.6
2644	12/14/81	6B37	RA-226/40	0.2	5.9
2650	12/15/81	6C55	RA-226/40	1.3	9.2
2676	1/8/82	6C55	IR-192/79	1.2	4.0
2683	1/18/82	6B37	RA-226/40	0.7	5.4
2691	1/25/82	6B37	RA-226/85	1.6	8.2
2694	1/27/82	6C55	IR-192/35	0.1	4.8

JOINT CENTER FOR RADIATION THERAPY INFORMATION RETRIEVAL

RADIATION EXPOSURE LEVELS FROM RADIOACTIVE IMPLANT PATIENTS AT BWH

DATE:01/13/1982 09:02:15 NUMBER OF ITEMS IN LIST: 23

PATIENT NUMBER	TOTAL ACTIVITY (MCI)	IMPLANT PROCEDURE	EXPOSURE (MR/HR): AT ONE METER	AT DOORWAY	AT ROOM RT	AT ROOM LT
4-81-2372	270	DY-165				
9-81-2544	53.9	IR-192	3.0	0.5	5.0	0.2
9-81-2552	34.3	IR-192	18.0	0.3	0.6	1.4
9-81-2557	50	RA-226-I	32.5	2.5	6.0	0.5
9-81-2558	40	RA-226-I	15.0	1.0	8.0	1.0
10-81-2572	58.76	IR-192	26.5	1.9	4.8	1.0
10-81-2575	80	RA-226-I	27.0	2.5	20.0	0.4
10-81-2578	54	AU-198	17.0	0.5	1.1	NONE
10-81-2582	54.85	IR-192	28.8	1.5	2.8	1.0
10-81-2583	80	RA-226-I	64.0	1.5	9.8	3.2
10-81-2591	54.6	IR-192	35.3	2.0	8.5	0.4
11-81-2599	87.36	IR-192	37.7	1.4	8.3	0.9
11-81-2601	80	RA-226-I	25.9	1.9	18.1	1.1
11-81-2603	38.0	AU-198	12.9	1.1	1.2	0.9
11-81-2612	66.5	IR-192	34.9	2.4	7.7	0.4
11-81-2614	270	DY-165II	10.0	1.3	0.8	1.3
11-81-2617	80	RA-226-I	45.3	1.3	16.8	0.4
11-81-2628	85	RA-226-I	36.5	1.8	17.8	1.8
12-81-2630	60	RA-226II	18.9	0.5	10.7	0.3
12-81-2638	36.96	IR-192	5.8	0.4	4.6	1.0
12-81-2644	40	RA-226-I	14.4	0.6	5.9	0.4
12-81-2650	40	RA-226-I	11.1	0.5	9.2	0.4
1-82-2676	79.25	IR-192	40.0	2.0	NONE	1.0

MEMO

TO: DAVID DRUM, M.D.
FROM: PHILIP COBB, RADIATION SAFETY OFFICER, JCRT
SUBJ: UPDATE ON RADIATION EXPOSURES FROM PLACEMENT OF PATIENTS IN SINGLE ROOMS
DATE: JANUARY 13, 1982

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IF YOU HAVE ANY ADDITIONAL QUESTIONS ON THE OTHER MATTERS PLEASE DO NO HESITATE TO CALL ME.

DD
1/13/82
C - copy + return

Brigham and Women's Hospital
A Teaching Affiliate of Harvard Medical School
75 Francis Street, Boston, Massachusetts 02115
(617) 732-6761.

Harvard Medical School

Department of Medicine
Thyroid Diagnostic Center
Michael M. Kaplan, M.D.
P. Reed Larsen, M.D.
Jack L. Leonard, Ph.D
Enrique Silva, M.D.

November 25, 1981

David E. Drum, M.D.
Brigham and Women's Hospital
Department of Radiology

Dear David:

We have now been able to manipulate our detection probe for radioiodine so that we can readily detect 10 nCi of 131I in the thyroid gland. I will plan to have my own thyroid scanned within 72 hours of administering any doses in excess of 50 mCi. The probe is located on the second floor of the laboratory building where the thyroid uptakes are performed. If any of the nurses or other auxiliary personnel would like to have their thyroid gland checked for uptake after dealing with a patient receiving radioactive iodine therapy, they could easily do so by making an appointment with Ms. Beverly Potter, extension 2-7501. This procedure will cover the problems which we have discussed in the past relative to bioassay for 131I contamination during treatment.

With best regards,

Reed

P. Reed Larsen, M.D.
Director, Thyroid Diagnostic Center
Brigham and Women's Hospital
Associate Professor of Medicine
Harvard Medical School

PRL:mkj

cc Ms. Beverly Potter
Endocrine-Hypertension Lab

HARVARD MEDICAL SCHOOL

DEPARTMENT OF RADIATION THERAPY
50 BINNEY STREET
BOSTON, MASSACHUSETTS 02115

WILLIAM D. BLOOMER, M.D.
Associate Professor

JOINT CENTER FOR RADIATION THERAPY

BETH ISRAEL HOSPITAL
BRIGHAM AND WOMEN'S HOSPITAL
NEW ENGLAND DEACONESS HOSPITAL
SIDNEY FARBER CANCER INSTITUTE
THE CHILDREN'S HOSPITAL MEDICAL CENTER

TITLE OF PROTOCOL: ^{165}Dy-FHMA Radiation Synovectomy of the Knee, Ankle and Metacarpalphalangeal Joints

PRINCIPAL INVESTIGATOR(S): William D. Bloomer, M.D.

INSTITUTIONAL APPOINTMENT(S): Associate Professor of Radiation Therapy, HMS; Associate Staff, Brigham and Women's Hospital

COLLABORATORS: Clement B. Sledge, M.D.; Michael R. Zalutsky, Ph.D.

INSTITUTIONAL APPOINTMENTS: CBS: Prof. Orthopedics, HMS; Department Head, BWH. MRZ: Principal Research Associate in Radiology, HMS and BWH.

Projected Starting Date: 11/1/81 Projected Termination Date: 10/31/82 Estimated number of patients to be entered: 72 max.

SUMMARY OF PROTOCOL:

The objective of this research project is to evaluate the therapeutic efficacy of radiation synovectomy in the knees of patients with rheumatoid arthritis. The pharmaceutical to be used is a radiocolloid formed by the coprecipitation of dysprosium-165 (^{165}Dy) with macro-aggregates of ferric hydroxide (FHMA).

Approximately 1% of adult persons in the United States have definite or probable rheumatoid arthritis by current diagnostic criteria. In these patients, the majo cause of pain as well as physical and economic disability is destruction of diarthrodial or synovial joints. Indeed, 87% of the patients will ultimately have involvement of metacarpophalangeal joints and 56% will ultimately have involvement of the knee joint. Slightly smaller percentages have involvement of other joints, including the hip. The physical and economic disability produced by rheumatoid arthritis is enormous. Arthritic disorders (including rheumatoid arthritis) are currently the second leading cause of time and earning loss in the United States, exceeded only by cardiovascular disease.

In the management of rheumatoid arthritis, joint replacement is generally reserved for treatment of the destroyed joint. At the other end of the sepctrum, there is little evidence that anti-inflammatory drugs or corticosteroids do more than relieve symptoms. Between these extremes, there is a place for synovectomy which will abolish or improve symptoms for extended periods of time. Whether synovectomy interrupts or delays the destruction of articular cartilage is unresolved; the evidence for symptomatic relief, however, is conclusive.

Because surgical synovectomy is not without complications, alternative methods of obtaining a synovectomy have been sought. The use of radioactive colloids introduced into the knee joint was first described by Ansell in 1963 and has subsequently been widely reported from Europe. In a controlled prospective trial, radiation synovectomy compared favorably with surgical synovectomy in terms of symptomatic improvement and duration of relief.

Radionuclide: The properties of a radionuclide suitable for radiation synovectomy include ease of availability, lack of toxicity, chemical purity, little or no associated gamma emission and a short half-life. Tissue damage is most efficiently caused by beta emission of sufficient energy to result in adequate tissue penetration within the synovium. ^{165}Dy is such a beta emitter with little gamma emission, a maximum tissue penetration of 5.7 mm and a half-life of 140 minutes. It is well-suited for radiation synovectomy and can be obtained at high specific activity (radioactivity per unit weight) by the irradiation of dysprosium oxide with neutrons in a nuclear reactor. Its purity has been demonstrated by gamma and beta spectrometry.

Colloid: Ideally, the particle used should be large enough to prevent leakage yet small enough to allow phagocytosis and concentration by the synoviocytes. It should be non-toxic and biodegradable at a rate that is slower than the decay of the radionuclide. FHMA are an attractive particle system for this application because rare earth elements like Dy are coprecipitated along with iron from acid solution by neutralization. Because the labeling procedure is rapid, FHMA can be labeled with short-lived radionuclides such as ^{165}Dy.

Concern regarding leakage of radioactivity outside the treated joint has limited application of radiation synovectomy in this country. Nevertheless, in reviewing the literature, one is left with the overall impression that radiation synovectomy would be as effective as surgical synovectomy if radionuclide leakage could be prevented or minimized.

Laboratory Experience: Extensive in vitro and in vivo studies have been conducted in our laboratories with FHMA labeled with ^{165}Dy, ^{159}Dy, gadolinium-153 (^{153}Gd) and cerium-144 (^{144}Ce). After the injection of labeled FHMA in the knees of both normal and arthritic rabbits, the leakage of radioactivity is much lower than that observed in patients with yttrium-90 (^{90}Y) or gold-198 (^{198}Au) and is significantly lower than that observed by us following the injection of ^{198}Au colloid in the rabbit model of arthritis.

Clinical Experience: Thirty-four patients have received radiation synovectomies for severely disabling arthritis refractory to standard medical therapy. Twenty-four patients received tracer doses before therapy with ^{165}Dy ferric hydroxide macroaggregates (FHMA). Tracer doses were monitored scintigraphically and with serial blood determinations. No patient was excluded from therapy on the basis of leakage of radionuclide from the joint (average leakage was 0.5% of injected dose). Therapy doses were similarly monitored.

Safety: The average leakage to the liver from therapeutic doses of ^{165}Dy-FHMA in the 35 treated patients was 0.4% (range 0 - 2.0%). This degree of leakage corresponds to an average liver dose of 2.5 rad. The average blood leakage was 0.2% (range 0 - 1.0%). This degree of leakage corresponds to a total body dose of 0.4 rad. The leakage rates after therapeutic doses of ^{165}Dy were in excellent agreement with tracer using doses.

Efficacy: Subjective parameters (swelling, effusion, pain and range of motion) as well as objective tests (^{99m}Tc-pertechnitate joint flow study) were used to evaluate treatment. Five patients are available for evaluation 18 months after radiation synovectomy; all are classified as having a good to excellent response to therapy. Twenty-two patients are available for evaluation at 12 months; 68% have had good to excellent responses.

Specific Proposal:

1. Those patients who are candidates for surgical synovectomy of the knee, ankle and MCP joints and are over the age of 35 will be eligible. Patients under the age of 35 will be eligible only if the remaining options for treatment are total nodal irradiation or immunosuppression. Regardless of age, patients with destructive joint disease (e.g., pigmented villonodular synovitis) where the only alternative treatment is amputation or external beam irradiation will be eligible.

2. The following doses will be used: knee (270 mCi), ankle (200 mCi) and MCP joint (40 mCi). Doses are estimated to deliver ∿ 10,000 rad to the synovium and have been calculated on the basis of theoretical models and previous experience using similar beta-emitters. The procedure requires a one-day hospitilization.

3. Tracer studies using blood monitoring will be performed only in prospective patients under the age of 35. Patients in whom the blood leakage exceeds 3% will be excluded.

4. Post-therapy monitoring will be undertaken in all patients using blood levels. Our observations to date show that the leakage of ^{165}Dy from the intraarticular space is associated with the serum fraction and thus represents release of ^{165}Dy from the colloid. Patients in whom the blood leakage exceeds 3% and in whom the radioactivity is associated with the cellular fraction will have scintigraphic evaluation of the liver and dose estimations performed.

5. We request permission to perform 72 synovectomies (6 per month) over the next 12 month period.

RESEARCH CONSENT FOR

DATE PREPARED: 9-3-81

PROJECT TITLE: Use of Radioisotopes in Training for Radiation Accident Emergencies

PHYSICIAN(s): David E. Drum, M.D.

IDENTIFYING NUMBER(s)

VOLUNTEER/PATIENT NAME: (If not imprinted above)

REV. 9/80

APPROVED FOR USE BY THE BRIGHAM AND WOMEN'S HOSPITAL
10-20-81
SIGNED BY: B. L. Daybum
Secretary, Human Subjects Committee
DOCKET NUMBER: 5251
EXPIRATION DATE: 10-19-82

The emergency service of the Brigham and Women's Hospital will shortly be holding a radiation accident casualty drill. We would like you to participate in this drill as the simulated subject. A scenario describing the type of action in which you were hurt and exposed to either external radiation or contamination with radioactive materials will be developed and shown to you. Prior to your pickup by ambulance or placement onto a stretcher outside the radiation emergency area, a nuclear medicine physician will apply to your clothing, shoes and skin small quantities of H-3 or Tc-99m in nonabsorbable form. Specifically, the total quantity of Tc-99m applied will be 1 mCi and that of H-3 also 1 mCi. No more than 10 microcuries of the former or 100 microcuries of the latter will be applied to your skin. The Tc-99m will be in the form of either sulfur colloid or DTPA complex, neither of which is absorbed; the H-3 will be in the form of tritiated imulin, also not absorbed. The estimated dose to your skin from the H-3 is zero, and from the Tc-99m, 38 mrad.

Prior to administration of the radioisotope, you will be given a TLD radiation dosimeter badge which will permit us to document your radiation exposure, if any, during the drill. Upon entry to the Holding Unit, the medical staff will treat you as they would a patient with a specified injury, such as a fracture or burn, and will remove the radioactivity from you as rapidly as possible under the direction of a nuclear medicine physician.

We anticipate that within 30 minutes you should be fully decontaminated. Because both you and the physician who applied the radioactivity know precisely where it was applied, you can insure that any deficiencies in the training protocol will be corrected by rapid cleanup after completion of the drill.

Do you have any further questions?

I have fully explained to the volunteer, _____ the nature and purpose of the training procedure described above and such risks as are involved in this performance. I have asked the subject if any questions have arisen regarding these procedures and have answered these questions to the best of my ability.

_____
Physician

I have been fully informed of the training procedures to be followed and have been given a description of the potential attendent risks. In signing this consent form I agree to be a volunteer for the drill as specified, and I understand I am free to withdraw my consent and discontinue participation at any time, without prejudice. I understand also that if I have additional questions at any time, they will be answered.

_____
Volunteer Subject Signature

Thursday
October 29, 1981

Brigham and Women's Hospital
A Teaching Affiliate of Harvard Medical School
10 Vining Street, Boston, Massachusetts 02115
(617) 732-5740

REPORT OF ACTION OF THE COMMITTEE ON HUMAN SUBJECTS

HUMAN SUBJECTS DOCKET NUMBER 5251 PRINCIPAL INVESTIGATOR David E. Drum, M.D.

TITLE: Use of Radioisotopes in Training for Radiation Accident Emergencies

This is to certify that the application identified above has been reviewed by the Committee appointed to review proposals involving clinical research and other investigations involving human beings, which has considered specifically:

(1) the rights and welfare of the individual or individuals involved,
(2) the appropriateness of the methods used to secure informed consent, and
(3) the risks and potential medical benefits of the investigation.

The Human Subjects Committee reviewed your research protocol and recommend approval. Please use enclosed authorized copy of consent form and/or questionnaires in your research.

NOTE: Approvals are granted for the period of one year only and must be renewed annually. In addition, adverse reactions of any kind must be reported immediately in writing to the Committee, as they occur.

FOR THE HUMAN SUBJECTS COMMITTEE

10-20-81
DATE OF COMMITTEE ACTION

Robert D. Hardin, M.D.
CHAIRMAN

Tuesday
ASSIGNED TO GROUP

B. L. Daybluma
EXECUTIVE SECRETARY

Docket Nos. 30-12239
30-15070

MAY 3 1983

License Nos. 20-17131-01
20-17131-03

Brigham and Women's Hospital
ATTN: Dr. Andrew Jessiman
Vice President
75 Francis Street
Boston, Massachusetts 02115

Gentlemen:

Subject: Combined Inspection 30-12239/82-01 and 30-15070/82-01

This refers to your letter dated January 11, 1983, in response to our letter dated December 15, 1982.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

These matters were discussed in a meeting between Dr. J. Glenn of this office and yourself on March 10, 1983 and will be resolved as part of the currently pending licensing action.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:
John D. Kinneman

Thomas T. Martin, Director
Division of Engineering and Technical
Programs

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts (2)

bcc:
Region I Docket Room (with concurrences)

RI:DETP
Kinneman/wb
4/29/83

RI:DETP
Glenn
5/2/83

8305060445
PDR

Brigham and Women's Hospital
A Teaching Affiliate of Harvard Medical School
75 Francis Street, Boston, Massachusetts 02115
(617) 732- 6050

January 11, 1983

Mr. Thomas T. Martin, Director
Division of Engineering and Technical Programs
US Nuclear Regulatory Commission, Region I
631 Park Avenue
King of Prussia, PA 19406

Subject; Docket Nos. 30-12239
30-15070

Dear Mr. Martin,

Thank you for your letter of 15 December, 1982 and the additional interpretative background it contains.

Our institution wishes to cooperate with the Nuclear Regulatory Commission in the safe use of radioisotopes. In this regard please be assured we will not use by-product materials applied to the skin of volunteers for radiation accident training until and unless the usage is approved by your office or by the courts upon appeal.

We appreciate fully the strict statutory assignment of the Nuclear Regulatory Commission to implement measures for protection of the public from radiation. However, in the interim since your letter to us of 27 April, 1982, our Human Subjects Committee has again reviewed and approved the protocol, "Use of Radioisotopes in Training for Radiation Accident Emergencies". Thus, your narrow interpretation of "reasonable use" directly conflicts with our institution's commitment to education of health care providers and our obligation to society for provision of competent emergency services.

We believe these differences can be resolved to the satisfaction of both parties. Because your letter's wording suggests residual misunderstanding of precisely what we have proposed vis-a-vis emergency training, because we are unsure how the oral presentation of Barrall and Smith gained acceptance as a national standard, and because we believe our training proposal is indeed consistent with the ALARA concept of 10 CFR 20.1 (c), it would seem that a meeting with you or the appropriate representative of the Region I staff might be helpful. This could occur in conjunction with the meeting suggested by Dr. John E. Glenn separately for review of our renewal application, after we have studied the inquiries in his letter to us.

Sincerely yours,

David E. Drum

David E. Drum, M.D.
Radiation Protection Officer

DED:JBM

cc: Dr. Andrew Jessiman
Dr. John E. Glenn

8305060447 pdr