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DOSE-TO-THE-POPULATION ESTIMATES FOR USE OF RADIOISOTOPE POWERED CARDIAC PACEMAKERS

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by

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September 1974

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PACIFIC NORTHWEST LABORATORIES
RICHLAND, WASHINGTON 99352

FOREWORD

This report presents results of a study conducted by Battelle, Pacific Northwest Laboratories (Battelle-Northwest) under request for Related Services TDO-615 from the AEC to carry out the study for ARCO Nuclear Company in accordance with the terms and conditions of our Prime Contract AT(45-1)-1830.

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DOSE-TO-THE-POPULATION ESTIMATES FOR USE OF RADIOISOTOPE POWERED CARDIAC PACEMAKERS

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I. INTRODUCTION

The purpose of this report is to develop estimates of the radiation dose to the population that would result from wide use of cardiac pacemakers powered by small quantities of plutonium-238. A radioisotope powered cardiac pacemaker (RPCP) requires only a few tenths of a gram of Pu-238 for its power source and most of the radioactive decay energy is converted to heat. However, there is a small component of external gamma and neutron radiation emitted from these devices. For example, the dose rate at a distance of three feet from an implanted RPCP is on the order of 0.001 mrem/hr. Since there may be several hundred thousands of these devices eventually in use, it is important to characterize the dose-to-the-population risk. Development of these estimates requires assumptions regarding who will use the device, how many will be in use, how long the users will live, and determination of how they will interact with the rest of the population. It has been possible to adapt the results of a comprehensive analysis of a similar problem, the dose-to-the-population estimates for Pu-238 powered artificial hearts carried out under the AEC's artificial heart program, to this pacemaker analysis.

The scope of this study included the following principal components:

1. Projections of radioisotope powered pacemaker use as a function of time based on estimates of the rate of implantation and life expectancy of recipients.
2. Dosimetry calculations to estimate the external dose rates transmitted to others from an implanted radioisotope powered pacemaker.

3. Dose-to-the-population calculations based on data developed in Items 1 and 2 and utilizing a computer program (REPRIEVE) and interpersonal time and distance data developed for dose-to-the-population studies carried out as a part of the AEC's Artificial Heart Program.

Since there are substantial uncertainties relating to the number and characteristics of the RPCP users, the results are developed parametrically.

II. SUMMARY AND CONCLUSIONS

Estimates of the population dose were developed in terms of an equilibrium first-implant rate of 10,000 1973-equivalent RPCP implants per year adjusted for population increases in future years. This is believed to approximate the current demand potential. However, results can be adjusted to other demand levels by taking multiples or fractions in proportion to the estimated demand. It was assumed that implants would start in 1975 with 250 in that year and would double each year thereafter until the maximum or equilibrium rate was reached in approximately 1981. Three first-implant age profiles identified as A, B and C profiles were defined to represent the range of ages at first implant that can be predicted based on current implant data. The intermediate age Profile B represents the most likely or best estimate. Normal life expectancy was assumed. Based on these assumptions, it was calculated that there would be from 130,000 to 208,000 RPCPs in use in year 2000 (per 10,000 1973-equivalent implants per year).

Whole-body dose rates to a standard man phantom from two different implanted RPCP sources were calculated using the QAD P5A computer program. The two sources were the Medtronic Model 9000 using 0.15 grams Pu-238 and the ARCO Nuclear RPCP using 0.40 grams Pu-238. The RPCP sources were assumed to be implanted in a standard man phantom in the left abdominal region near the surface. Dose rates from the source were calculated in four directions and averaged to represent a single average dose rate to a person in the vicinity of a pacemaker user. In terms of frontal dose only, dose rates would be 50 to 100% higher than the average in four directions.

The RPCP use projections and dosimetry calculations provided input for the REPRIEVE computer program for the dose-to-the-population calculations. The procedure used in REPRIEVE divides the user population into small subgroups whose use-of-time and interpersonal-distance relationships with other people during daily activities can be defined based on data from

sample survey studies. The dose contribution by each subgroup is calculated and a summation of the dose calculations for all of the subgroups provides the population dose. The computer program output provides a breakdown of the dose by age and sex for significant classifications of persons who receive the dose such as spouses, members of the household, work associates, etc. The estimates assume that living and behavioral patterns remain essentially as they are today and that an implanted RPCP does not change basic habits.

A number of REPRIEVE cases were calculated to identify the effects of the type of RPCP, the age profile at first-implant, the implant rate, and the Pu-236 content of fuel on the population dose in the year 2000. Cases were also run to compare population dose in the year 2020 with the year 2000. Results of these calculations for the year 2000 are summarized in the following table:

TABLE 1. Year 2000 RPCP Population Dose Estimates Per 10,000 1973-Equivalent First Implants Per Year

Population Category	Dose rem/yr	Percent of Total		Average Dose Per Person mrem/yr
Spouses	400 to 1900	29 to 35		6 to 15
Other Household Members	100 to 800	8 to 13		1 to 3
Non-work Associates	200 to 500	9 to 16		0.1 to 0.2
Work Associates	70 to 700	5 to 11		0.1 to 0.3
General Populace	600 to 2000	33 to 43		0.002 to 0.007
TOTAL	1,400 to 6,000	100	Average	0.005 to 0.02

The total population dose ranges from 1400 rem/year to 6,000 rem/year. Because of the larger source size in the ARCO Nuclear RPCP, the population doses calculated were approximately twice as great as those calculated with the Medtronic Model 9000. The other major factor affecting the range and total population dose is the age profile at the first implant. With the younger age profile there are more surviving users at the year 2000, and population dose is higher than with the older age profile.

Spouses receive the greatest individual doses but these range only up to 15 or 16 mrem per year, while the other household members receive on the order of 1 to 3 mrem per year. Doses to both nonwork associates and work associates are in the range of a few tenths of mrem per year. The dose to the general populace, which accounts for 33 to 43% of the total population dose, averages only two to seven micro rems per person per year. None of the exposures to any group appears to be excessive and it was concluded that the population dose from RPCPs does not represent a significant risk.

III. RPCP USE PROJECTIONS

Estimates of the market for radioisotope powered pacemakers vary widely ranging from a few thousands per year to as many as 50,000/yr. The basis used in this study was developed from review of a report on a one-day technical meeting on the status of long-life cardiac pacemakers held at the National Institute of Health on May 8, 1973;[1] and discussions with B. I. Griffin of Medtronic Incorporated and S. Kolenik, ARCO Nuclear Company. The incentive for developing the radioisotope powered pacemaker is its long life expectancy, at least 10 years, compared to the current two-year life of battery powered pacemakers. However, the radioisotope device fueled with Pu-238 will cost on the order of $5,000, which is about five times the cost of the battery unit. Furthermore, there appear to be good prospects for producing battery powered units with life expectancies of five years or more. Thus, there is room for considerable difference of opinion regarding the market for RPCPs.

Although accurate market data were not available, it appears that the current market potential in the U.S. for conventional pacemakers, in terms of first implants, may be as high as 50,000 per year or more. There also seems to be general agreement that radioisotope powered pacemakers can expect to capture at least 10 to 20 percent of that market. This leads to a market estimate of 5,000 to 10,000 first-implant RPCPs per year. Thus, a basis equivalent to 10,000 in 1973 but adjusted in future years for changes in the population was adopted for this study. The age and sex specific rate of RPCP implants equivalent to 10,000 first implants in 1973 is held constant, but the total number increases beyond 10,000/yr in later years because of increases in specific population age groups.

It is also essential to define the age and sex distribution or profile of the RPCP recipients. Data on 554 Medtronic RPCP implants worldwide and 147 Medtronic RPCP implants in the United States were obtained from B. I. Griffin and data on approximately 50 ARCO Nuclear RPCP implants were

obtained from S. Kolenik. Data on the age distribution at the time of the first implant for conventional pacemakers were obtained from a paper by M. Lefebvre[2] based on data for 804 conventional pacemaker implants from 1969 to June 30, 1972 at the Implantation Center at Lille, France. These data are all shown on Figure 1.

There is a substantial difference between the age distributions for the nuclear devices compared to the conventional battery powered devices. Whether or not this large difference will continue when RPCPs are generally available is debatable. There is some support for the view that the average age of RPCP implants will tend to increase as the RPCPs become more available. Because of these uncertainties regarding age profile, it has been treated as a parameter in this analysis. Three age profiles have been defined. Profile A, the youngest group, is based on the Medtronic and ARCO Nuclear experiences in the United States. Profile C, the oldest group is equivalent to the conventional pacemaker age profile. Profile B represents an age group mid-way between A and C and is believed to represent the more likely RPCP age profile. These profiles are indicated on Figure 1 and detailed in Table 2. The implant data show a ratio of male to female implants of approximately 60/40 and this ratio was assumed across all age groups.

M. Lefebvre also compared the survival rates of pacemaker implantees over the past ten years with the normal population and found that after an initial period of three months, when the survival rate is poor, the pacemaker users have a life expectancy equal to or possibly even somewhat better than the normal population. Based on this analysis, a normal life expectancy was assumed for RPCP users. This, in effect, deletes the high risk group who die in the first three-month period after implant from the RPCP population in this analysis and implies a total implant rate somewhat higher than stated.

The number of RPCP implants was adjusted for changes in population with time. The age-specific implant rate was assumed to be constant and

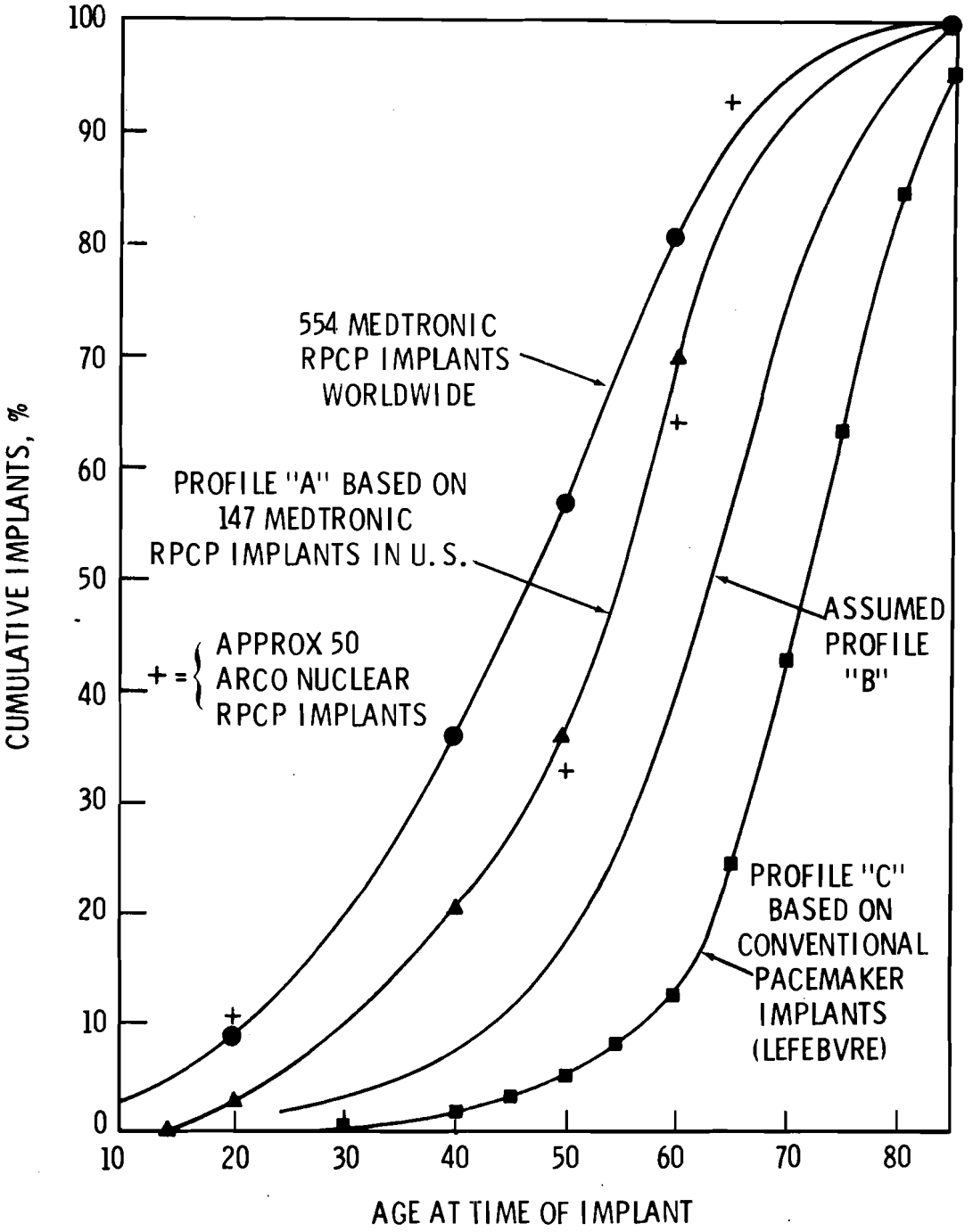

FIGURE 1. Radioisotope-Powered-Cardiac-Pacemaker Implant Age Distribution Data and Assumptions

TABLE 2. RPCP Age Profile Assumptions

Age Group	Distribution by Age, % Profile A[a]	Profile B[b]	Profile C[c]
< 30	10.0	3.5	1.1
30 - 34	4.5	1.5	0.2
35 - 39	5.9	2.5	0.6
40 - 44	7.1	5.0	1.3
45 - 49	8.5	4.5	2.2
50 - 54	13.5	9.0	1.7
55 - 59	20.5	14.0	5.2
60 - 64	14.0	16.5	12.1
65 - 69	7.0	18.5	18.4
70 - 74	5.0	12.0	20.6
75 - 79	2.5	8.0	21.4
80 - 84	1.5	5.0	10.6
85 - 89			3.6
90 - 99			1.0
TOTAL	100.0	100.0	100.0

a. Youngest, based on 147 Medtronic RPCP implants in the U.S.
b. Intermediate age profile.
c. Oldest, based on conventional pacemaker implants.[2]

the total implant rate was obtained by multiplying the age-specific implant rate by the population in an age group. If, for example, there are twice as many in an age group in the year 2000 as there were in 1973 then there would be twice as many RPCP first-implants calculated in that age group for the year 2000 as for the year 1973. In effect, the three age profiles defined in Figure 1 and Table 2 are assumed to be 1973 age profiles. Figure 2 shows how the population in selected age groups is expected to change in the years ahead. Substantial increases in the age groups of interest are apparent and this implies an increasing implant rate.

A growth period was assumed between the time when the RPCPs would be licensed for general use and the time when the maximum or equilibrium implant rate would be reached. It was assumed that implants would start in 1975 with 250 in that year and would double each year thereafter until the maximum or equilibrium rate was reached. The calculated numbers of new RPCP implants, using this assumption and correcting for changes in population as just described, is shown at five-year intervals for the three age profiles in Table 3. This shows, assuming age is the principal factor in defining pacemaker demand, that a potential demand for 10,000 in 1973 will be equivalent to 13,000 to 14,000 in year 2000 and more than 18,000 in the year 2020. There is, because of the age groups under considerations, a relatively small uncertainty in the population projections since for the most part this is a matter of predicting survivals rather than birth rates. The development of other procedures for treating heart disease may reduce requirements for pacemakers and tend to counteract the effect of increasing numbers of older persons. However, the assumption here is the conservative one relative to calculating dose-to-the-population from RPCPs.

The first part of the REPRIEVE computer program that was used to calculate dose-to-the-population takes the data on projected requirements, age distribution, and life expectancy and calculates the total accumulated number of RPCP users at five-year intervals. These results are shown in Table 4 and plotted in Figure 3. This shows that the 10,000 equivalent first

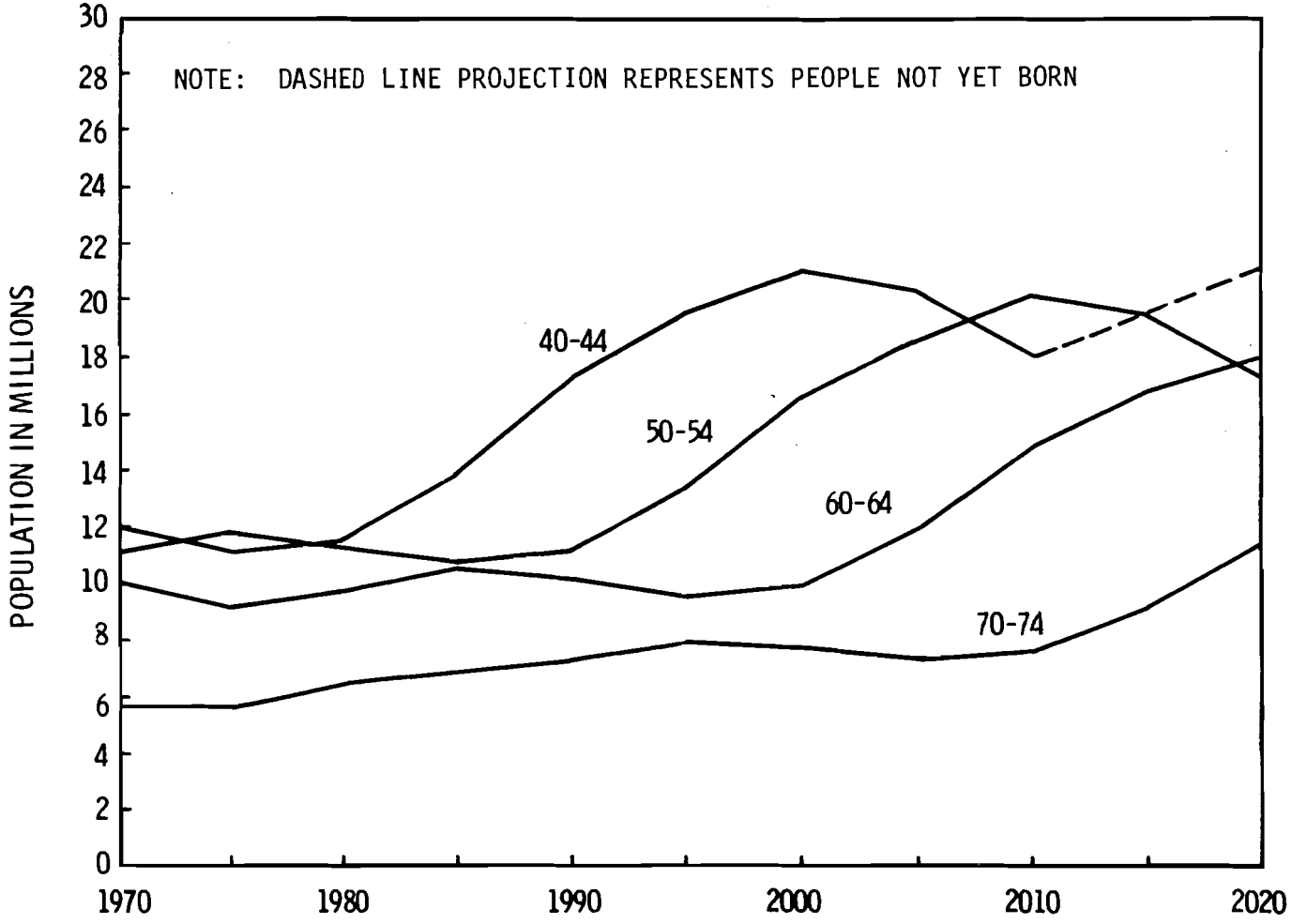

FIGURE 2. United States Population Projections by Age Groups, 1970-2020, Series E, (U.S. Census Bureau, Publications Series P-25, No. 493, December 1972).

TABLE 3. Estimated Annual Number of New RPCP Implants at 5-Year Intervals Based on an Equilibrium (Maximum) Implant Rate Equivalent to 10,000/yr in 1973

Year	Annual Rate of New Implants		
	Profile A[a]	Profile B[b]	Profile C[c]
1975	250	250	250
1980	8,000	8,000	8,000
1985	11,880	11,640	11,540
1990	12,480	12,200	12,220
1995	13,220	12,760	12,650
2000	13,960	13,320	13,090
2005	15,300	14,540	13,820
2010	16,640	15,760	14,560
2015	17,370	17,160	16,380
2020	18,000	18,570	18,200

a. Youngest
b. Intermediate
c. Oldest

TABLE 4. Estimated Mid-Year Total Number of RPCP's in Use at 5-Year Intervals Based on an Equilibrium Implant Rate Equivalent to 10,000/yr in 1973

Year	Cumulative RPCP Users		
	Profile A[a]	Profile B[b]	Profile C[c]
1975	125	125	125
1980	11,500	11,260	10,900
1985	64,100	60,100	55,000
1990	115,500	103,600	89,600
1995	163,000	140,000	114,000
2000	208,000	170,000	131,000
2005	249,000	196,000	143,000
2010	289,000	221,000	153,000
2015	326,000	247,000	167,000
2020	358,000	272,000	185,000

a. Youngest
b. Intermediate
c. Oldest

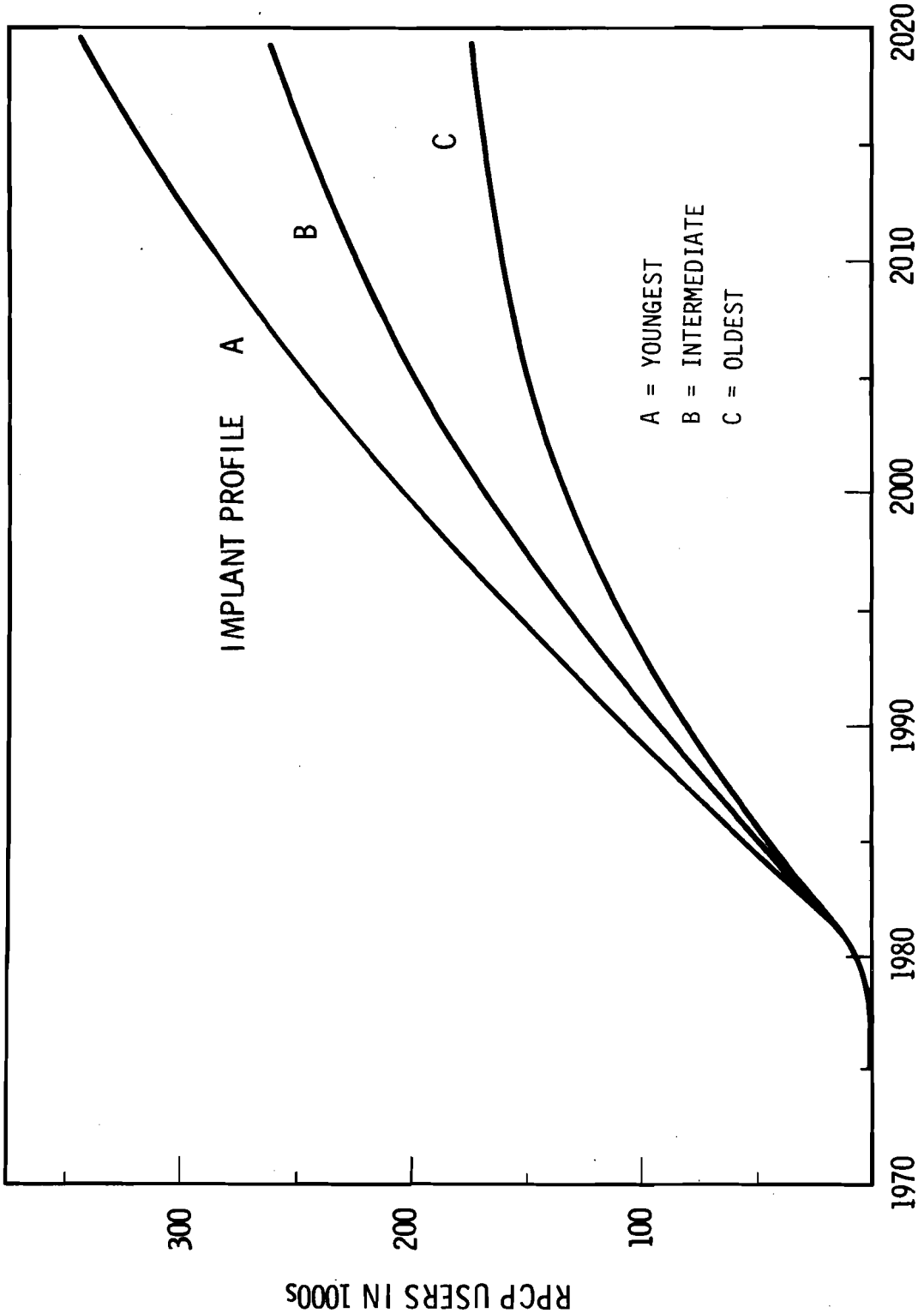

FIGURE 3. Accumulation of RPCP Users Based on an Equilibrium Implant Rate Equivalent to 10,000/Yr in 1973

implants in 1973, allowing for a growth period, result in a range of 130,000 to over 200,000 users by the year 2000 and possibly as many as 350,000 in the year 2020.

The REPRIEVE computer program also calculates an age distribution for the cumulative users at a specified point in time. Results of this calculation for the three implant age profiles in the year 2000 are shown in Figure 4. This is the cumulative result of annual additions to the RPCP population and their removal by death through natural causes. (It was assumed that device failure would not be a cause of death).

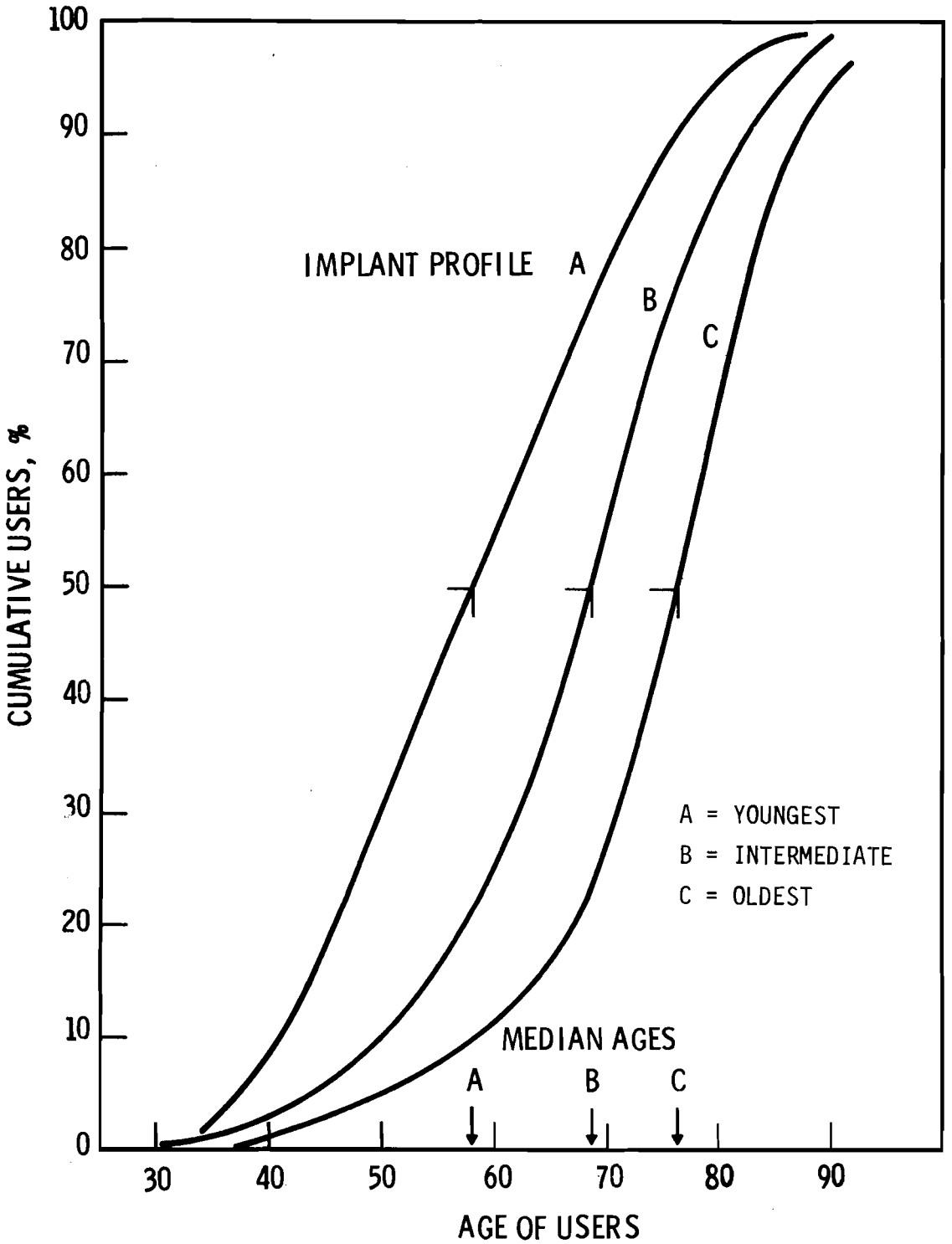

FIGURE 4. Age Distribution of RPCP Users in the Year 2000

IV. DOSIMETRY CALCULATIONS

Whole body dose rates to a standard man phantom from two different Pu-238 implanted pacemaker sources were calculated using the QAD-P5A computer program. The two sources analyzed were the Medtronic Model 9000 RPCP using 0.15 g of Pu-238 and the ARCO Nuclear RPCP using 0.40 g of Pu-238. Details of the source characteristics were obtained from ARCO Nuclear, Medtronic Inc., D. W. Cole of AEC Division of Biomedical and Environmental Research, and from published reports.[3,4]

The Medtronic Model 9000 uses an Alcatel GIPSIE battery as its power source. The power source consists of 150 mg of Pu-238 (Max. of 0.6 ppm Pu-236) as a pressed Pu-Sc pellet encapsulated in a tantalum case with a minimum wall thickness of one mm. This capsule is in turn sealed in an outer Pt-Ir capsule with a minimum wall thickness of 1.25 mm. Both capsules are hermetically sealed by electron beam welding. The inner capsule has a void space to allow for helium buildup. The capsule is 9 mm O.D. and 10 mm long. The entire pacemaker unit is sealed in a 0.5 mm thick outer titanium case approximately 7.1 cm in diameter and 2.6 cm wide.

The power source for the ARCO Nuclear RPCP consists of 400 mg of sintered medical grade[5] Pu-238 oxide. This pellet is encapsulated in three successive metal cylinders (1 mm, 0.5 mm and 0.5 mm thick respectively) of tantalum, Hastelloy "C" and titanium, each sealed by TIG welding. The PuO_2 pellet diameter is 3.9 mm and it's length is 4.5 mm. The capsule is 8.8 mm O.D. and 38 mm long. The capsule is surrounded by an 8 mm thick thermopile made up of layers of woven silicate glass yarn and thermocouple wires. The entire pacemaker unit is sealed in a 0.64 mm thick outer titanium case.

The RPCP sources were assumed to be implanted in a standard man phantom[6] shown in Figure 5. Both sources were centered at (4,-8,27) relative to the origin of the coordinate system indicated in Figure 5, or in the left abdominal region near the surface which is understood to be the preferred location.

The Pu-238 spectrum used is shown in Table 5.[7,8] The source strength was determined by calculating the number of decays/sec based on the initial Pu-238 mass and the half-life. The Pu-236 source strength and

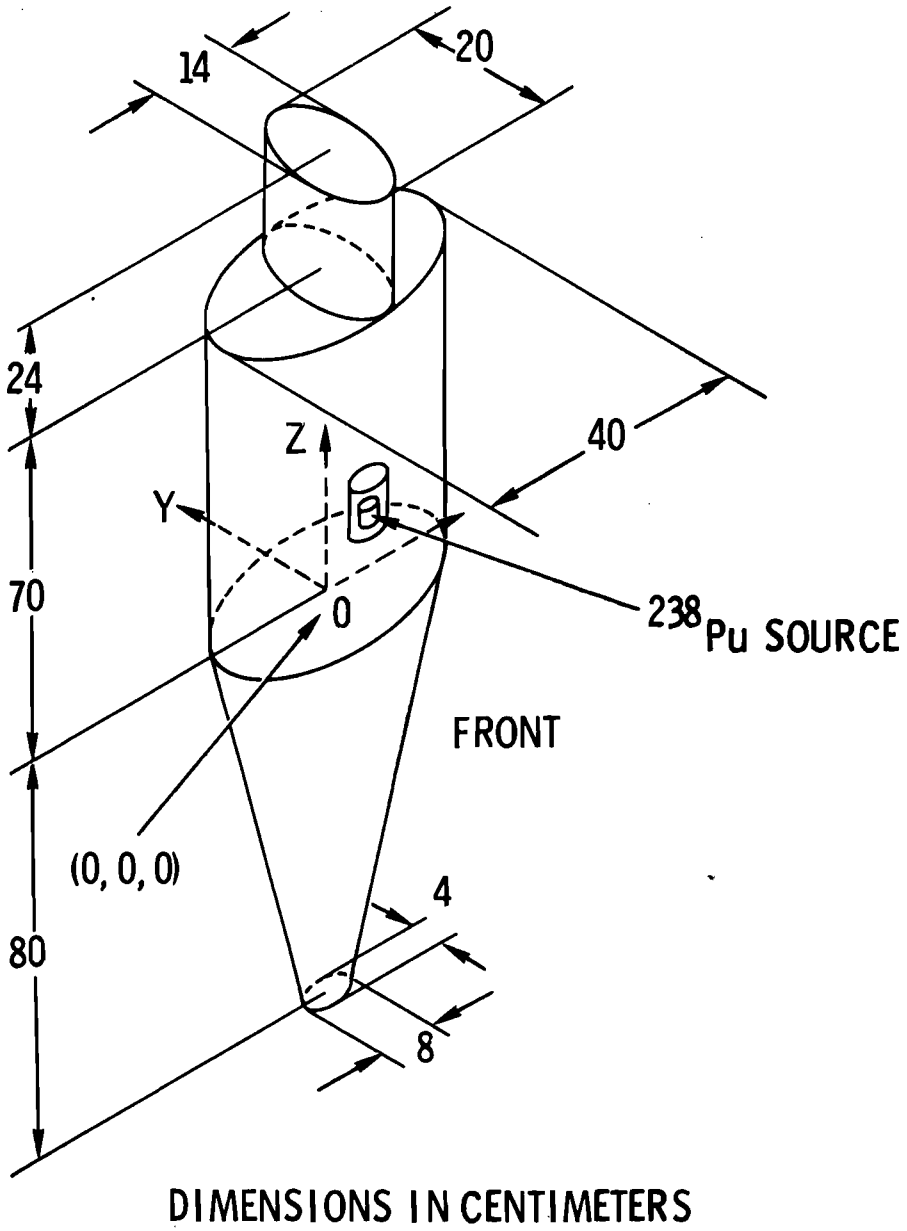

FIGURE 5. Standard Man Phantom

TABLE 5. Plutonium-238 Gamma Spectrum[a]

	Energy (keV)	Gamma Rays/100 Decays
1	43.49	3.80×10^{-2}
2	99.79	8.00×10^{-3}
3	125.15	3.80×10^{-6}
4	152.58	1.27×10^{-3}
5	158.80	1.90×10^{-6}
6	197.30	1.40×10^{-6}
7	199.35	1.90×10^{-6}
8	201.03	4.40×10^{-6}
9	251.00	1.10×10^{-6}
10	338.60	7.40×10^{-7}
11	350.69	2.40×10^{-6}
12	416.87	2.80×10^{-6}
13	439.86	3.60×10^{-6}
14	742.77	6.50×10^{-6}
15	766.35	2.80×10^{-5}
16	786.03	7.20×10^{-6}
17	808.70	1.20×10^{-6}
18	810.50	1.30×10^{-6}
19	852.20	2.10×10^{-6}
20	883.20	1.30×10^{-6}
21	904.34	6.21×10^{-8}
22	926.73	6.15×10^{-7}
23	942.02	5.26×10^{-7}
24	940.12	1.03×10^{-7}
25	1001.10	1.30×10^{-6}
26	1041.90	2.29×10^{-7}
27	1085.40	2.29×10^{-7}

a. 1-20, Reference 7; 20-27, Reference 8

spectrum were determined by calculating[9] the amount of Pu-236 and Pu-236 daughters as a function of age assuming 0.3 ppm Pu-236 initially. The decay scheme is shown in Table 6,[10] and the flux-to-dose conversion factors used for the gamma cases are from Rockwell.[11] The neutron spectrum used is the U-235 fission spectrum built into QAD. The error in the neutron dose contribution resulting from use of the U-235 fission spectrum rather than the Pu-238 fission spectrum is believed to be less than ±10%. The neutron source strength for the ARCO Nuclear device was based on medical-grade Pu-238 oxide specifications as outlined in LA-4940[5] or 3300 neutrons/gram-second. The neutron source strength for the Medtronic device, however, was taken as 4500 neutrons/gram-second as indicated in a previous study for Medtronic.[4] The Medtronic source is a plutonium-scandium alloy prepared in France and apparently may contain more light element impurities than the USAEC medical-grade specification and hence produces more α,n neutrons. The flux-to-dose conversion factors used for the neutrons are from 10 CFR 20.[12]

Validation of the calculation procedure has been performed for an artificial heart PuO_2 source by comparing the QAD-P5A values to those obtained experimentally in phantom measurements by F. T. Cross.[13] Using lead buildup factors for the region of the artificial heart (a limitation of QAD but a reasonable approximation) and water buildup factors for the phantom,[14] the agreement between QAD-P5A 27-group results and the experimental results is within 15%, with the QAD-P5A values being higher.

The dose rate results for the two pacemakers are shown in Table 7 and Table 8. The results are given as a function of distance from the center of the phantom (Z-axis). An array of dose points were calculated vertically at the horizontal distance specified and the results were averaged over the cross-section area of a standard man phantom to get an average whole body dose. Because the source is not centered on the Z-axis of the phantom, dose rates were calculated on both the right and left sides as well as in front and behind the phantom. For use in the dose-to-the-population estimates these calculated results in four directions were then averaged to represent a single average dose rate to a person in the vicinity of a pacemaker user. These average results are shown in Tables 9 and 10 and are plotted in

TABLE 6. Plutonium-236 Decay Scheme[10]

Isotope	Half-Life
Pu-236	2.85 yr
↓	
U-232	72 yr
↓	
Th-228	1.91 yr
↓	
*Ra-224	3.64 days
↓	
Pb-212	10.64 hr
↓	
**Bi-212	60 min
↓	
Pb-208	stable
*Included as part of Ra-224	
↓	
Rn-220	55.3 sec
↓	
Po-216	0.145 sec
**Included as part of Bi-212	
Tl-208	3.1 min
↓	
Po-212	0.304 μsec

TABLE 7. External Dose Rates to A Standard Man Phantom From An Implanted ARCO RPCP (mrem/hr)

	Distance cm	Pu-238 Gammas	Pu-236 Gammas[a] 0 Year	5 Year	10 Year	18 Year	Neutrons[b] Only
Right Side	40	2.0×10^{-3}	2.1×10^{-5}	1.3×10^{-3}	2.2×10^{-3}	2.4×10^{-3}	2.2×10^{-4}
	50	1.6×10^{-3}	1.6×10^{-5}	1.0×10^{-3}	1.8×10^{-3}	1.9×10^{-3}	1.9×10^{-4}
	100	6.3×10^{-4}	7.5×10^{-6}	4.1×10^{-4}	6.9×10^{-4}	7.4×10^{-4}	1.1×10^{-4}
	200	2.2×10^{-4}	2.5×10^{-6}	1.3×10^{-4}	2.2×10^{-4}	2.3×10^{-4}	4.4×10^{-5}
	500	3.9×10^{-5}	4.4×10^{-7}	2.3×10^{-5}	3.8×10^{-5}	4.0×10^{-5}	8.9×10^{-6}
	1000	9.9×10^{-6}	1.1×10^{-7}	5.7×10^{-6}	9.7×10^{-6}	1.02×10^{-5}	2.3×10^{-6}
	5000	3.4×10^{-7}	3.7×10^{-9}	2.0×10^{-7}	3.4×10^{-7}	3.6×10^{-7}	7.5×10^{-8}
Left Side	40	4.1×10^{-3}	4.4×10^{-5}	2.4×10^{-3}	4.0×10^{-3}	4.3×10^{-3}	1.1×10^{-3}
	50	3.2×10^{-3}	3.6×10^{-5}	1.8×10^{-3}	3.1×10^{-3}	3.3×10^{-3}	9.6×10^{-4}
	100	1.2×10^{-3}	1.4×10^{-5}	6.4×10^{-4}	1.1×10^{-3}	1.1×10^{-3}	4.5×10^{-4}
	200	3.3×10^{-4}	4.0×10^{-6}	1.8×10^{-4}	3.0×10^{-4}	3.2×10^{-4}	1.4×10^{-4}
	500	5.5×10^{-5}	6.7×10^{-7}	3.0×10^{-5}	5.1×10^{-5}	5.3×10^{-5}	2.5×10^{-5}
	1000	1.4×10^{-5}	1.7×10^{-7}	7.4×10^{-6}	1.3×10^{-5}	1.3×10^{-5}	6.2×10^{-6}
	5000	4.7×10^{-7}	5.5×10^{-9}	2.6×10^{-7}	4.4×10^{-7}	4.7×10^{-7}	2.1×10^{-7}
Front	40	7.9×10^{-3}	9.4×10^{-5}	4.3×10^{-3}	7.2×10^{-3}	7.7×10^{-3}	5.6×10^{-3}
	50	5.5×10^{-3}	6.6×10^{-5}	3.0×10^{-3}	5.0×10^{-3}	5.3×10^{-3}	3.9×10^{-3}
	100	1.6×10^{-3}	2.0×10^{-5}	8.7×10^{-4}	1.5×10^{-3}	1.5×10^{-3}	1.1×10^{-4}
	200	4.3×10^{-4}	5.3×10^{-6}	2.3×10^{-4}	3.8×10^{-4}	4.0×10^{-4}	2.9×10^{-4}
	500	6.8×10^{-5}	8.4×10^{-7}	3.6×10^{-5}	6.0×10^{-5}	6.3×10^{-5}	4.5×10^{-5}
	1000	1.7×10^{-5}	2.1×10^{-7}	8.9×10^{-6}	1.5×10^{-5}	1.6×10^{-5}	1.1×10^{-6}
	5000	5.8×10^{-7}	7.1×10^{-9}	3.1×10^{-7}	5.3×10^{-7}	5.6×10^{-7}	3.7×10^{-7}
Back	40	2.3×10^{-3}	2.5×10^{-5}	1.4×10^{-3}	2.4×10^{-3}	2.6×10^{-3}	4.0×10^{-4}
	50	1.8×10^{-3}	1.9×10^{-5}	1.1×10^{-3}	1.9×10^{-3}	2.0×10^{-3}	3.1×10^{-4}
	100	6.9×10^{-4}	7.6×10^{-6}	4.0×10^{-4}	6.8×10^{-4}	7.3×10^{-4}	1.5×10^{-5}
	200	2.1×10^{-4}	2.4×10^{-6}	1.2×10^{-4}	2.1×10^{-4}	2.2×10^{-4}	4.2×10^{-5}
	500	3.7×10^{-5}	4.2×10^{-7}	2.1×10^{-5}	3.6×10^{-5}	3.8×10^{-5}	7.5×10^{-6}
	1000	9.2×10^{-6}	1.0×10^{-7}	5.4×10^{-6}	9.1×10^{-6}	9.7×10^{-6}	1.9×10^{-6}
	5000	3.1×10^{-7}	3.3×10^{-9}	1.9×10^{-7}	3.2×10^{-7}	3.4×10^{-7}	5.8×10^{-8}

a. Calculations based on 0.3 ppm Pu-236.

b. Neutron dose rate based on 3,300 neutrons/gram/second.

TABLE 8. External Dose Rates to A Standard Man Phantom From An Implanted Medtronic Model 9000 RPCP (mrem/hr)

	Distance cm	Pu-238 Gammas	Pu-236 Gammas[a] 0 Year	5 Year	10 Year	18 Year	Neutrons[b] Only
Right Side	40	8.6×10^{-4}	8.9×10^{-6}	4.7×10^{-4}	8.2×10^{-4}	9.4×10^{-4}	1.1×10^{-4}
	50	6.9×10^{-4}	7.3×10^{-6}	3.7×10^{-4}	6.4×10^{-4}	7.4×10^{-4}	1.0×10^{-4}
	100	2.9×10^{-4}	3.2×10^{-6}	1.5×10^{-4}	2.5×10^{-4}	2.9×10^{-4}	6.2×10^{-5}
	200	9.1×10^{-5}	1.1×10^{-6}	4.7×10^{-5}	7.9×10^{-5}	9.1×10^{-5}	2.4×10^{-5}
	500	1.6×10^{-5}	1.9×10^{-7}	8.1×10^{-6}	1.4×10^{-5}	1.6×10^{-5}	4.8×10^{-6}
	1000	4.1×10^{-6}	4.8×10^{-8}	2.0×10^{-6}	3.5×10^{-6}	4.0×10^{-6}	1.2×10^{-6}
	5000	1.4×10^{-7}	1.6×10^{-9}	7.2×10^{-8}	1.3×10^{-7}	1.4×10^{-7}	4.1×10^{-8}
Left Side	40	1.7×10^{-3}	2.0×10^{-5}	8.7×10^{-4}	1.5×10^{-3}	1.7×10^{-3}	5.9×10^{-4}
	50	1.3×10^{-3}	1.5×10^{-5}	6.6×10^{-4}	1.1×10^{-3}	1.3×10^{-3}	5.3×10^{-4}
	100	4.8×10^{-4}	5.7×10^{-6}	2.3×10^{-4}	3.9×10^{-4}	4.5×10^{-4}	2.4×10^{-4}
	200	1.4×10^{-4}	1.7×10^{-6}	6.5×10^{-5}	1.1×10^{-4}	1.2×10^{-4}	7.7×10^{-5}
	500	2.3×10^{-5}	2.7×10^{-7}	1.1×10^{-5}	1.8×10^{-5}	2.1×10^{-5}	1.3×10^{-5}
	1000	5.6×10^{-6}	6.8×10^{-8}	2.6×10^{-6}	4.5×10^{-6}	5.2×10^{-6}	3.3×10^{-6}
	5000	1.9×10^{-7}	2.3×10^{-9}	9.3×10^{-8}	1.6×10^{-7}	1.8×10^{-7}	1.1×10^{-7}
Front	40	3.3×10^{-3}	4.0×10^{-5}	1.6×10^{-3}	2.6×10^{-3}	3.0×10^{-3}	3.0×10^{-3}
	50	2.3×10^{-3}	2.8×10^{-5}	1.1×10^{-3}	1.8×10^{-3}	2.1×10^{-3}	2.1×10^{-3}
	100	6.6×10^{-4}	8.1×10^{-6}	3.1×10^{-4}	5.2×10^{-4}	6.0×10^{-4}	5.9×10^{-4}
	200	1.7×10^{-4}	2.1×10^{-6}	8.0×10^{-5}	1.4×10^{-4}	1.5×10^{-4}	1.5×10^{-4}
	500	2.8×10^{-5}	3.4×10^{-7}	1.3×10^{-5}	2.2×10^{-5}	2.5×10^{-5}	2.4×10^{-5}
	1000	6.7×10^{-6}	8.3×10^{-8}	3.1×10^{-6}	5.3×10^{-6}	6.0×10^{-6}	5.9×10^{-6}
	5000	2.4×10^{-7}	2.9×10^{-9}	1.1×10^{-7}	1.9×10^{-7}	2.2×10^{-7}	2.0×10^{-7}
Back	40	9.9×10^{-4}	1.05×10^{-5}	5.1×10^{-4}	8.8×10^{-4}	1.01×10^{-3}	2.1×10^{-4}
	50	7.6×10^{-4}	8.4×10^{-6}	3.9×10^{-4}	6.8×10^{-4}	7.7×10^{-4}	1.7×10^{-4}
	100	2.9×10^{-4}	3.2×10^{-6}	1.5×10^{-4}	2.5×10^{-4}	2.9×10^{-4}	7.1×10^{-5}
	200	8.8×10^{-5}	1.0×10^{-6}	4.4×10^{-5}	7.6×10^{-5}	8.7×10^{-5}	2.3×10^{-5}
	500	1.5×10^{-5}	1.8×10^{-7}	7.7×10^{-6}	1.3×10^{-5}	1.5×10^{-5}	4.1×10^{-6}
	1000	3.8×10^{-6}	4.4×10^{-8}	1.9×10^{-6}	3.3×10^{-6}	3.8×10^{-6}	1.0×10^{-6}
	5000	1.3×10^{-7}	1.4×10^{-9}	6.8×10^{-8}	1.2×10^{-7}	1.3×10^{-7}	3.2×10^{-8}

a. Calculations based on 0.3 ppm Pu-236.

b. Neutron dose rate based on 4,500 neutrons/gram/second.

TABLE 9. External Dose Rates From An Implanted ARCO RPCP Based on Average Dose Rates in Four Directions (mrem/hr)

Distance		Pu-238	Pu-236 Gammas				
ft	cm	Gammas	0-Year	5-Year	10-Year	18-Year	Neutrons
1.31	40	4.1×10^{-3}	4.6×10^{-5}	2.4×10^{-3}	4.0×10^{-3}	4.25×10^{-3}	1.8×10^{-3}
1.64	50	3.0×10^{-3}	3.4×10^{-5}	1.7×10^{-3}	3.0×10^{-3}	3.13×10^{-3}	1.3×10^{-3}
3.28	100	1.0×10^{-3}	1.2×10^{-5}	5.8×10^{-2}	9.9×10^{-4}	1.02×10^{-3}	4.5×10^{-4}
6.56	200	3.0×10^{-4}	3.6×10^{-6}	1.7×10^{-4}	2.8×10^{-4}	2.9×10^{-4}	1.3×10^{-4}
16.40	500	5.0×10^{-5}	5.9×10^{-7}	2.8×10^{-5}	4.6×10^{-5}	4.85×10^{-5}	2.2×10^{-5}
32.80	1,000	1.3×10^{-5}	1.5×10^{-7}	6.9×10^{-6}	1.2×10^{-5}	1.22×10^{-5}	5.4×10^{-6}
164.00	5,000	4.3×10^{-7}	4.9×10^{-9}	2.4×10^{-7}	4.1×10^{-7}	4.33×10^{-7}	1.8×10^{-7}

TABLE 10. External Dose Rates From An Implanted Medtronic Model 9000 RPCP Based on Average Dose Rates in Four Directions (mrem/hr)

Distance		Pu-238	Pu-236 Gammas			
ft	cm	Gammas	0-Year	5-Year	10-Year	Neutrons
1.31	40	1.71×10^{-3}	1.99×10^{-5}	8.63×10^{-4}	1.45×10^{-3}	9.78×10^{-4}
1.64	50	1.36×10^{-3}	1.47×10^{-5}	6.3×10^{-4}	1.06×10^{-3}	7.25×10^{-4}
3.28	100	4.3×10^{-4}	5.1×10^{-6}	2.1×10^{-4}	3.5×10^{-4}	2.41×10^{-4}
6.56	200	1.2×10^{-4}	1.5×10^{-6}	5.9×10^{-5}	1.01×10^{-4}	6.85×10^{-5}
16.40	500	2.1×10^{-5}	2.5×10^{-7}	1.0×10^{-5}	1.7×10^{-5}	1.15×10^{-5}
32.80	1,000	5.1×10^{-6}	6.1×10^{-8}	2.4×10^{-6}	4.2×10^{-6}	2.85×10^{-6}
164.00	5,000	1.8×10^{-7}	2.1×10^{-9}	8.6×10^{-8}	1.5×10^{-7}	9.56×10^{-8}

Figures 6 and 7. If dose rates were expressed in terms of the frontal dose only, they would be 50 to 100% higher than the average of the dose rates in four directions.

Dose rates for Pu-236 concentrations other than 0.3 ppm can be developed from the data in Tables 7-10 by adding in fractions or multiples of the Pu-236 dose rates for 0.3 ppm in proportion to the concentration desired. In calculating the change in dose rate as a function of time, a correction for decreased radiation due to the Pu-238 is included as well as a correction for increased radiation due to Pu-236 daughters. (About 8% of the Pu-238 decays away in 10 years.) The effect of the Pu-236 content on the relative dose rate to others from an implanted RPCP is shown in Figure 8.

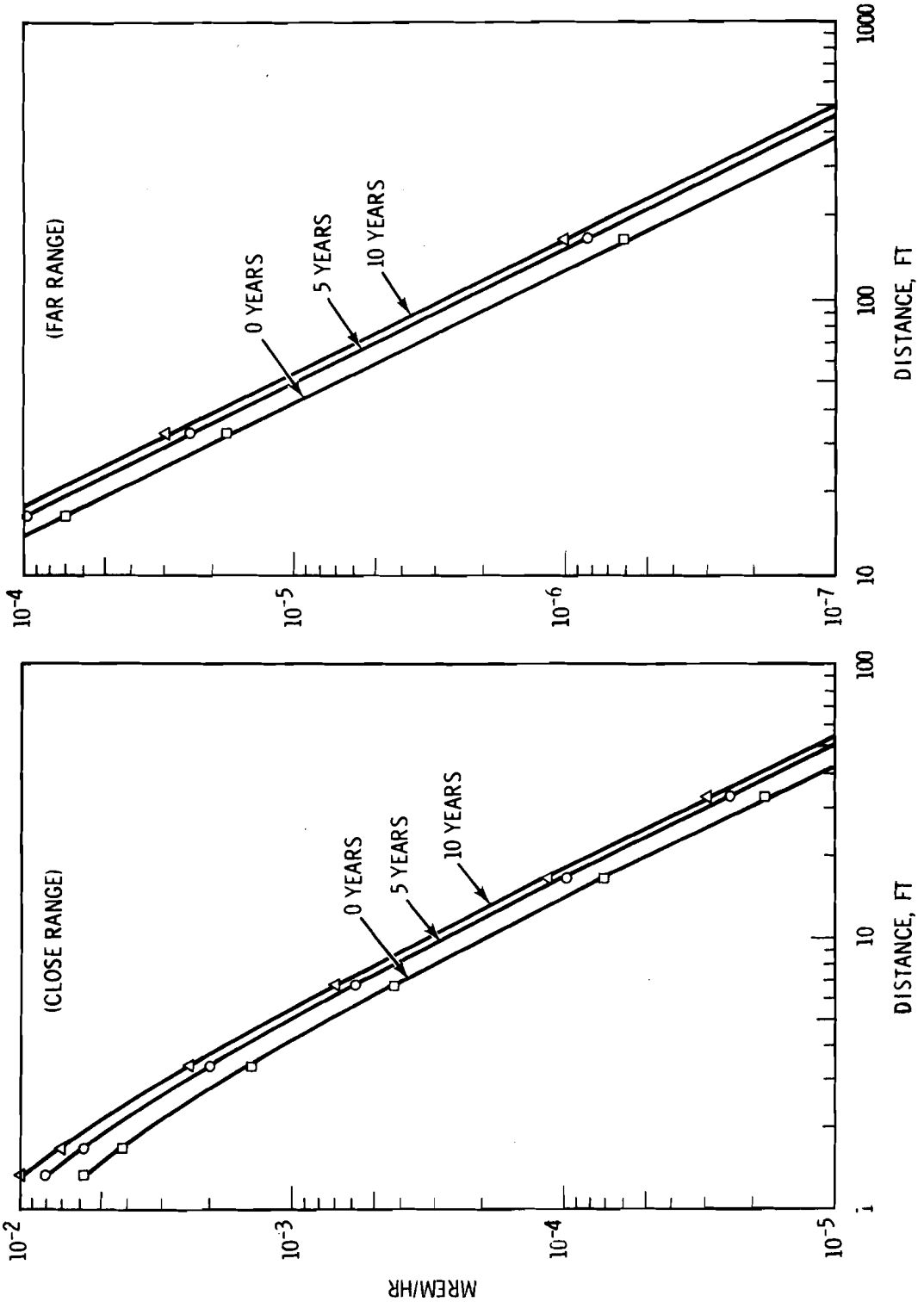

FIGURE 6. Total External Dose Rates From an ARCO RPCP (0.3 ppm Pu-236)

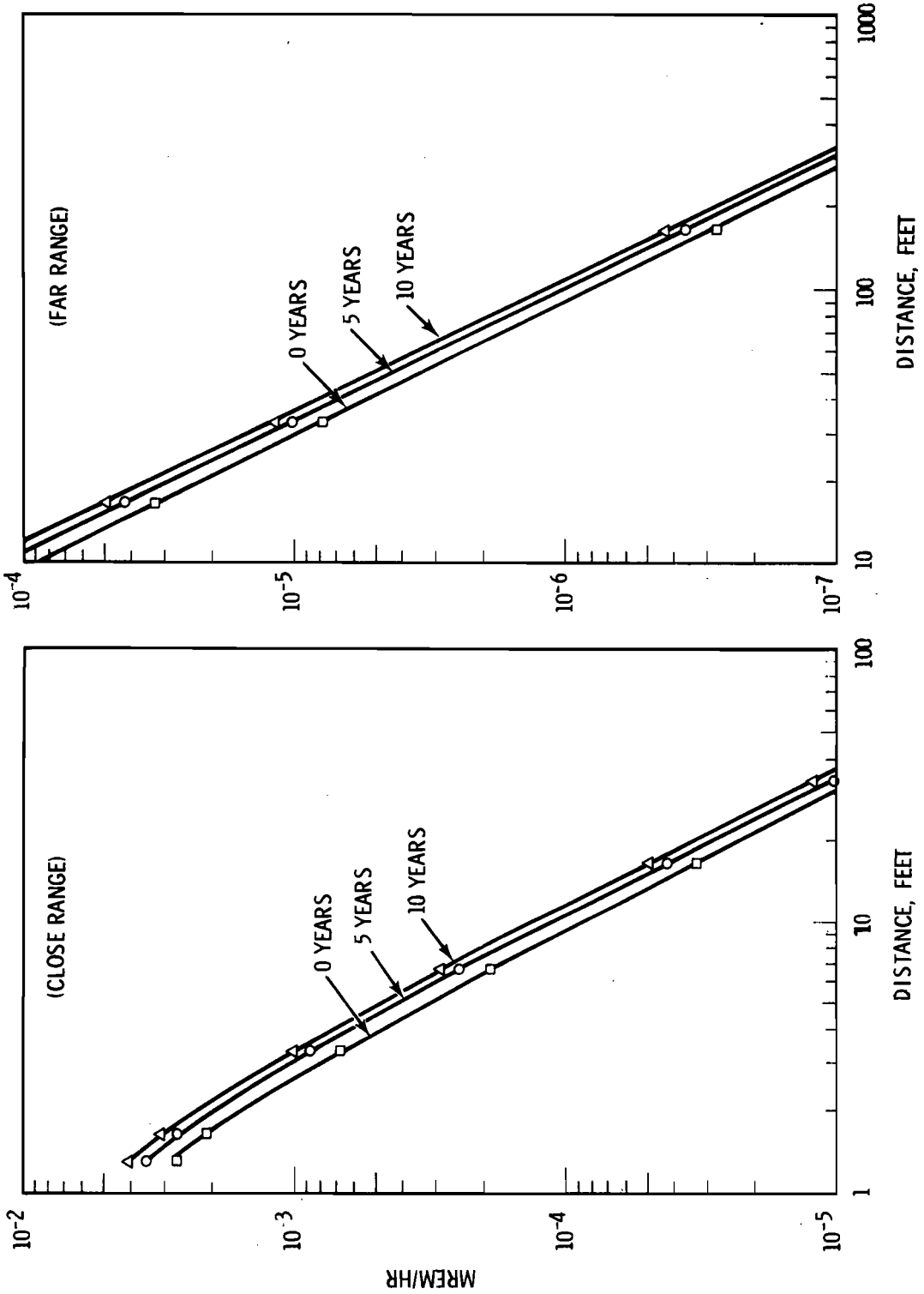

FIGURE 7. Total External Dose Rates From Medtronic Model 9000 RPCP (0.3 ppm Pu-236)

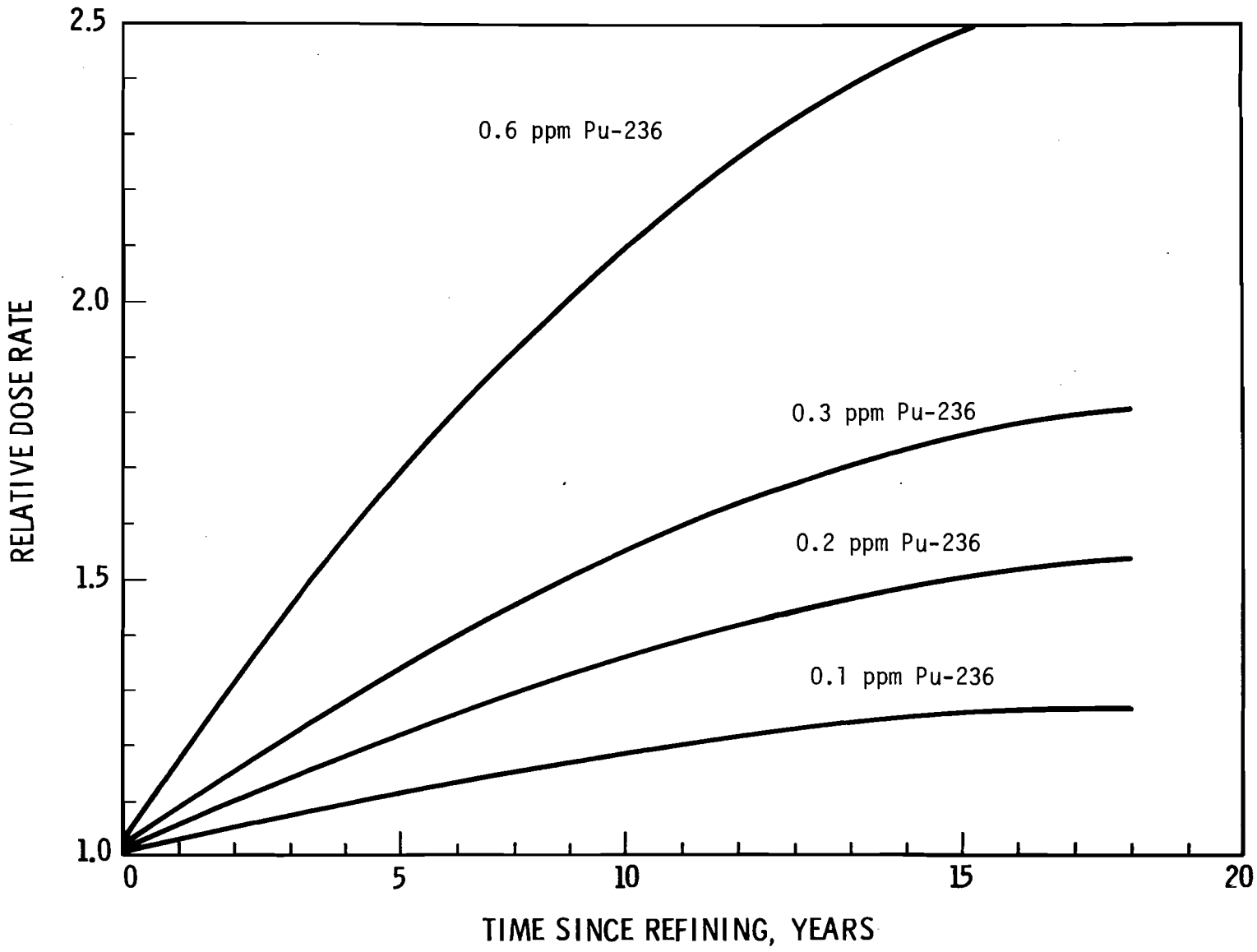

FIGURE 8. Effect of Pu-236 Content on Relative Dose Rate to Others From an Implanted RPCP

V. DOSE-TO-THE-POPULATION METHODOLOGY

The RPCP use projections and the dosimetry calculations just discussed provide the input for the REPRIEVE computer program for the dose-to-the-population calculation. The REPRIEVE computer program and the use of time and the interpersonal distance data necessary for its utilization were developed in studies carried out as part of the AEC's artificial heart program to develop estimates of population dose for use of artificial hearts. This program was adapted with minor modifications to the pacemaker dose-to-the-population calculation.

The basic approach is to divide the user population into small subgroups whose use of time and interpersonal distance relationships with other people during daily activities can be defined based on data from sample survey studies. The dose transmitted by members of each subgroup is calculated and a summation of the dose calculations for all of the subgroups provides the population dose. The program was written and data collected in sufficient detail to provide not only the total population dose but also a breakdown of the dose by age and sex for significant classifications of subjects who receive the dose, such as spouses, members of the household, work associates, etc.

The overall structure of the dose-to-the-population estimating procedure, the essential information required for the estimates, and the sequence of procedures to develop the estimates, are illustrated schematically in Figure 9. The procedure for calculating the cumulative number of surviving recipients and the calculation of the dose versus distance data has already been described. This section describes the procedure for subdividing the recipient user population by household and occupation group and the final population dose calculation.

A. HOUSEHOLD TYPE AND OCCUPATION CLASSIFICATIONS

Once the number of surviving RPCP recipients by age and sex has been calculated for a particular year, it is assumed that the members of each age and sex classification are distributed by household type and occupation

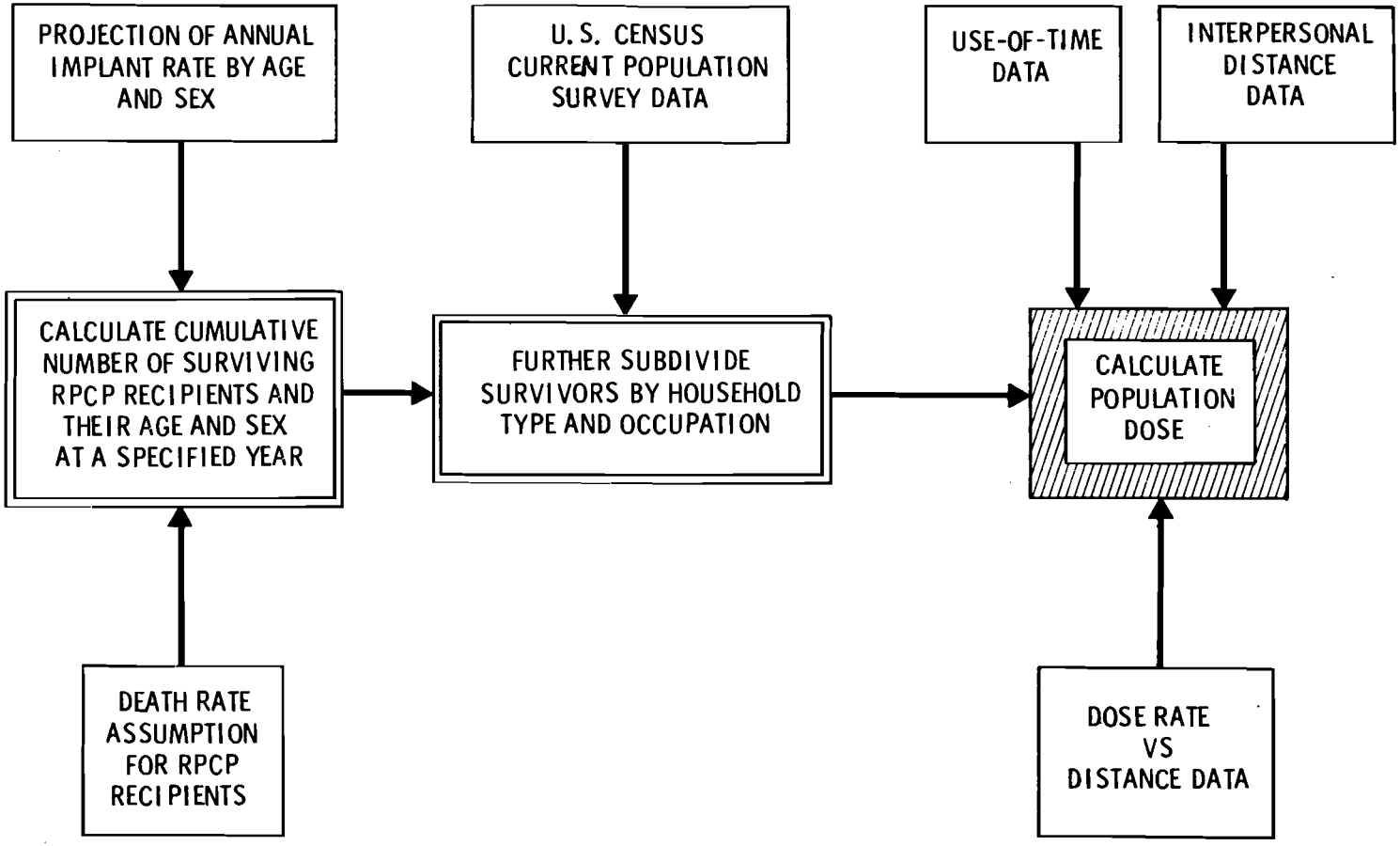

FIGURE 9. Dose-to-the-Population Estimate for Radioisotope Powered Cardiac Pacemakers

within that classification in the same proportions as the entire population in that age and sex classification. The surviving recipients are first subdivided by employed and nonemployed classifications. Then the employed classification is further subdivided by specific occupation groups. This leads ultimately to identification of radiation exposure of work associates. Both the employed and non-employed classifications are subdivided by household type and this leads to identification of the radiation exposure of members of the household and other associates.

Two sources of data are utilized for these classifications. The 1970 census provides the basic data for classification of employed persons by occupation. However, the normal census tabulations do not provide adequate details for the desired household classifications. Each month the Census Bureau surveys some 45,000 households for a limited amount of information on employment and other information. In March of each year this current population survey is expanded to include greater detail on household classifications. The data tapes for the March 1972 current population survey were obtained from the Census Bureau and were sorted for the specific distribution information needed for the dose-to-the-population analysis.

Major occupation classifications were selected that would identify at least 70% of employed persons. These classifications are tabulated by major classifications in Table 11 and the number of subdivisions in each classification is also shown in this table: 47 occupation subdivisions for males and 32 subdivisions for females.

The RPCP users are classified by nine household types. These household types and the approximate distribution of RPCP users in the year 2000 are shown in Table 12. Because this user group is a much older group than the population as a whole, the largest group is the husband/wife-only household. There are, however, a significant number who are distributed in the larger households and this leads to some radiation exposure of younger persons. In the case of exposure of very young persons, this is often a situation where an older person lives with a younger family. The

TABLE 11. Classification of RPCP Users by Occupation

Major Classifications	Male Subdivisions	Female Subdivisions
1. Professional, Technical and Kindred	8	4
2. Farmers and Farm Managers	2	1
3. Managers, Officials, Proprietors	2	2
4. Clerical and Kindred Workers	4	6
5. Sales Workers	3	2
6. Craftsmen, Foremen and Kindred	11	-
7. Operatives and Kindred	6	7
8. Service Workers	7	7
9. Farm Laborers and Foremen	2	1
10. Laborers	1	-
11. Private Household Workers	-	1
12. Not Elsewhere Classified	1	1
TOTAL	47	32

TABLE 12. Classification of RPCP Users by Household Type

Household Types	Approximate Distribution In Year 2000
1. Husband/Wife Only Household	32 - 37%
2. Husband/Wife and One Other Member	7 - 13%
3. Husband/Wife and Two Other Members	4 - 11%
4. Husband/Wife and Three or More Members	4 - 15%
5. Head of a Single Parent Household or Non-Married Family Head	6 - 7%
6. Individual Living Alone	13 - 23%
7. Person Living with a Family (Married and Single)	7 - 13%
8. Individual Living with Other Non-Related Persons	1 - 2%
9. Persons Living in Group Quarters (Institutions and Other)	2 - 7%

classification system identifies the household type relative to the age and sex and employment status of the RPCP user and in addition identifies: (a) the age of the spouse of the user, and (b) the number, age, and sex of other household members.

B. USE-OF-TIME DATA

Use-of-time data classified by the characteristics of the RPCP user and his activities are essential to the development of the population dose estimates. A number of use-of-time studies have been made, but the most comprehensive data on use of time for our purposes were found at the University of Michigan's Institute for Social Research (ISR). The data represented a nationwide sample of 1,244 households covering all activities during a 24-hour period and included data on Saturday and Sunday activities as well as weekday activities. These data had been collected in 1966 as part of a multinational study carried out in ten countries involving 13 surveys.[15] They contained information on the age and sex of the persons surveyed, their occupation, identification of age and sex of other members of the household, etc. The use-of-time data were classified by 99 activities.

The data were stored on computer cards and arrangements were made with the ISR to obtain a special sort of these data to meet the requirements of the artificial heart dose-to-the-population study. For our purposes, activities were grouped into 19 non-work activities and five work activity classifications. Examination of the data after an initial sort indicated that, above age 30, age was not a significant factor in a persons's use of time. The employment status and household type were far more significant. The final use-of-time classifications utilized were sex, employment status, household type, and the 19 non-work activities shown in Table 13 and five work activities shown in Table 14. The use-of-time data obtained for the artificial heart population dose study were used without modification for the RPCP population dose study.

TABLE 13. Non-work Activity Classifications

HOUSEHOLD

1 - Preparing Food
2 - Cleaning House
3 - Laundry, Mending
4 - Other House Upkeep
5 - Gardening, Pets
6 - Sleep*
7 - Personal Care
8 - Eating*
9 - Resting
10 - Child Care
11 - Adult Care
12 - Television Viewing*
13 - Other Passive Leisure*

PUBLIC

1 - Shopping and Purchasing
2 - Non-Work Trips
3 - Adult Education
4 - Organizational Activity (Church)
5 - Social and Entertainment Activities*
6 - Sports and Active Leisure

* Five Activities Account for About 94% of Non-Work Activity Dose

TABLE 14. Work Activity Classification

1 - Regular Work
2 - Meals at Work
3 - Coffee Breaks
4 - Trips to and from Work
5 - Other

C. INTERPERSONAL DISTANCE DATA

No source of data was located that provided data on interpersonal distance relationships of people in various activities in anywhere near enough detail for the dose-to-the-population calculations. It was necessary to develop a methodology and collect these data through special sample surveys. For this purpose, consulting assistance from Dr. Irwin Altman, Chairman of the Psychology Department, University of Utah, was obtained. A fundamental precept utilized in these surveys was that the distances separating people during their activities is primarily determined by their environment; that is, room size, location of chairs and tables, etc.

The procedure that was developed for the household activity data consisted of selecting households by a multi-stage clustered sampling technique, and interviewing members of the household to determine where they were usually located during the specified activities. This was then followed by a measurement of distances between these locations. The results showed good reproducibility.

Other procedures were developed for the public activity data and special computer routines were written to handle these situations. Data were collected on spacing of people during church, theatre, and sporting event attendance, and during random shopping activities. The computer programs written to analyze these situations were designed to randomly select any person in a public activity group as the user of the radioactive device.

For the work activity data, representative occupations were surveyed and measurements were taken of distances separating people during their normal work activities.

Interpersonal distance surveys were carried out in Richland and Seattle, Washington and in Salt Lake City, Utah. The largest survey was carried out in the Salt Lake City area with approximately 400 households sampled. The survey procedures were designed to concentrate data collection on situations that would contribute most significantly to population dose.

Since dose rate is not proportional to distance but varies more nearly as the reciprocal of the distance squared, the survey data for duplicate situations could not be combined by simple distance averaging. Instead, each situation was converted to a dose rate in terms of an artificial heart source and the dose rates were averaged. For the RPCP calculations, it was determined that the ratio between the artificial heart dose rate and the RPCP dose rate was a constant over all distances of interest so that it was possible to use the dose factors developed in the artificial heart analysis for the RPCP analysis by applying a constant factor that corrected for the differences in source radiation.

The dose rate data for all of the household activities were classified by activity and the sex and household type of the RPCP user and his employment status and by the age and relationship of the persons exposed to the radiation. The dose rate data for public activities were classified by activity only. The dose rate data for work activities were classified by activity and occupation.

D. REPRIEVE COMPUTER PROGRAM

The basic equation used in the REPRIEVE computer program to calculate population dose is relatively simple and can be stated as follows:

Dose to the Population = Summations of: (P) x (S) x (T) x (F) x (C)

where

P = Number of Persons in a Device Recipient Group.

S = Number of Exposure Subjects per Device Recipient.

T = Time Spent in an Activity.

F = Fraction of the Time Spent in an Activity when the Exposure Subject is Present.

C = Dose Rate for the Activity.

The calculation becomes complex because of the many classifications or subscripts for each of the components in the basic equation. The number of values for each of the components in the basic dose equation that results in a final dose-to-the-population matrix of 240,000 components is shown

in Table 15. The final dose to the population is the result of successive sequential summations of dose calculations with respect to each of the following items:

- 3 age groups of radiation exposure subjects in public activities,
- 29 age, sex and relationship classifications of members of device user households,
- 198 classifications of household activities by household type,
- 4 sex and employment status and 12 age group classifications of device users.

The actual summation is somewhat more complicated because, for example, the above list does not include the occupation classification or work activity classifications.

The program is written to provide considerable detail in the breakdown of the dose to the population. Table 16 illustrates the various kinds of detailed tables that the REPRIEVE program provides.

TABLE 15. Size of Calculation Matrices

Submatrix	Symbol		Number of Values
Device Recipient Groups	P		1,500
Identity of Radiation Exposure Subjects	S		11,600
Time in Activity	T		1,900
Frequency of Association	F		4,000
Dose Factor	C		4,300
		TOTAL	23,300
Dose to the Population Matrix	D		240,000

TABLE 16. Output Tables from REPRIEVE

- Dose to Spouses by Age of Each Partner and Number of Spouses by Age of Each Partner.
- Dose to Other Household Members by Age and Sex of Both Device User and Household Members.
- Dose to Associates of Device User According to Age of Associates and Age of Device User.
- Dose to the Above Three Population Exposure Groups by Age and Household Type of Device User.
- Dose to the Above Three Population Groups by Household Type and Activity of Device User.
- Dose to Work Associates by Age of Device User and Work Activity.
- Dose to General Public by Age Group and Age and Activity of Device User.
- Dose from Device User by Household Type, Activity and Sex of Device User.
- Dose from Device User by Age and Sex or Household Type of Device User for all Work and Non-work Activities.

VI. RESULTS

A number of REPRIEVE cases were calculated to identify the effects of the type of RPCP, the age profile at first implant, the implant rate, and the Pu-236 content of the fuel on the population dose in the year 2000.* Cases were also run to compare population dose in the year 2020 with year 2000. These results are summarized in Table 17 and show the total population dose to be in the range of a few thousands of rem per year per 10,000 1973-equivalent implants per year. A more detailed table for each case is presented in Tables 18-28. These more detailed tables show results in terms of dose to spouses by sex and two age groups, dose to other household members by three age groups, and dose to associates, work associates, and the general public without regard to sex or age. None of the exposures of any group appears to be excessive. Spouses receive the greatest individual doses but these range up to only 15 or 16 mrem/year. The average dose to the general populace is on the order of a few micro rems/year.

No attempt was made in this analysis to predict or project market sharing between the ARCO Nuclear and Medtronic devices. Presumably each would have a share as well as other manufacturer designs not specifically examined. The results are presented in terms of 10,000 1973-equivalent implants per year for each device above and can be combined in proportion to one's individual view of the future. For purposes of discussing the results of the calculations, Cases 74-1 and 74-3 are considered the base cases. They represent ARCO and Medtronic devices respectively, each with 0.3 ppm of Pu-236 in the fuel and implant-age profile B.

With 0.3 ppm Pu-236 in the fuel of each device the ARCO Nuclear device produces 2.25 times as much population dose as the Medtronic device. When the Medtronic device is fueled with plutonium containing

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* The population dose estimates discussed here are based on calculations that assume living and behavioral patterns remain essentially as they are today and that an implanted RPCP does not change one's basic habits.

TABLE 17. Summary of Population Dose Estimates for RPCPs

Case No.	Age Profile of Implants	Equilibrium New Implant Rate RPCP/Year (1973 Equivalent)	Design of RPCP	ppm Pu-236[a]	Year of Estimate	Number of RPCPs In Use	Total Dose To The Population (rem/yr)
74-1	B	10,000	ARCO	0.3	2000	170,000	4,550
74-3	B	"	MEDTRONIC	0.3	"	"	2,014
74-5	B	"	MEDTRONIC	0.6	"	"	2,388
74-7	A	"	ARCO	0.3	"	208,000	6,113
74-8	A	"	MEDTRONIC	0.3	"	"	2,703
74-9	C	"	ARCO	0.3	"	131,000	3,145
74-10	C	"	MEDTRONIC	0.3	"	"	1,395
74-11	B	20,000	ARCO	0.3	"	332,000	8,910
74-13	B	"	MEDTRONIC	0.3	"	"	3,943
74-2	B	10,000	ARCO	0.3	2020	272,000	7,097
74-4	B	"	MEDTRONIC	0.3	"	"	3,142

a. Calculation of Pu-236 dose contribution assumes pacemakers are replaced at 10-year intervals.

0.6 ppm Pu-236 (Case 74-5) the population dose is increased approximately 20 percent and the relative dose from the two devices is reduced from 2.25:1 to 1.9:1.

When the younger age profile A is assumed (Cases 74-7 and 74-8), the effect is to increase the number of devices in use in the year 2000 because of the longer life expectancy of the average RPCP user. The result is an increase of 35 percent in the population dose. When the older age profile C is assumed (Cases 74-9 and 74-10), the effect is just the opposite and the population dose is reduced by 30 percent.

In Cases 74-11 and 74-13 the equilibrium implant rate is increased from 10,000 to 20,000 1973-equivalent implants per year. These results demonstrate that even though the introduction rate is the same in 1975-1980, the controlling factor of population dose by the year 2000 is the equilibrium rate. The ratio of dose to the base cases is 1.95:1 which is only slightly less than the ratio of equilibrium implant rates (2:1).

Cases 74-2 and 74-4 indicate that a 56 percent increase in annual population exposure between the years 2000 and 2020 could be expected assuming all factors constant except the population growth effects. However, improvements in the efficiency of converting the radioactive energy to electric energy over this period would tend to counterbalance this effect. Furthermore, as previously discussed, other treatment procedures may reduce pacemaker use at some time in the future.

Examination of Tables 18-28 shows that the largest single component of population dose is that to the general populace which varies from 33 to 43 percent of the total. This component which ranges from 600 to 2000 man rems/year in the year 2000 (per 10,000 1973-equivalent implants per year) is, however, less than one ten-thousandth of natural background radiation. This component is the result of the public activities (Table 13) of the RPCP users and the incidental random exposure resulting from population density effects mostly in urban centers. There is no way to identify the exposed subjects further and it is assumed that the distribution of this dose is reasonably uniform across the entire population.

TABLE 18. Case 74-1 Dose to the Population in the Year 2000 From 170,000 Radioisotope Powered ARCO-Design Cardiac Pacemakers

Basis:
1. Implant Age Profile B.
2. Equilibrium New Implant Rate (Equivalent 1973) = 10,000 RPCP/Year
3. Pu-236 Content of Fuel = 0.3 ppm.
4. RPCPs are replaced at 10-year intervals.

Population Category	Number of People Exposed	Dosage rem/yr	Percent of Total Dose To The Population		Average Dose Per Person rem/yr
1. Spouses					
Females - Age 49 and Under	19,500	294	6.5	32.8	0.015
Females - Age 50 and Over	53,500	716	15.7		0.013
Males - Age 49 and Under	6,500	106	2.3		0.016
Males - Age 50 and Over	28,600	380	8.3		0.013
2. Other Household Members					
Age 0 - 17	82,100	249	5.5	10.2	0.003
Age 18 - 49	53,400	143	3.1		0.003
Age 50+	28,900	72	1.6		0.003
3. Non-Work Associates	3,696,000	511	11.2		0.0001
4. Work Associates	1,287,000	393	8.6		0.0003
5. General Populace	265,000,000[a]	1,686	37.1		0.000006
TOTAL	265,000,000[a]	4,550	100.0	Average	0.00002

a. The entire U.S. population is assumed to have received some exposure.

TABLE 19. Case 74-3 Dose to the Population in the Year 2000 From 170,000 Radioisotope Powered Medtronic-Design Cardiac Pacemakers

Basis:
1. Implant Age Profile B.
2. Equilibrium New Implant Rate (Equivalent 1973) = 10,000 RPCP/Year
3. Pu-236 Content of Fuel = 0.3 ppm.
4. RPCPs are replaced at 10-year intervals.

Population Category	Number of People Exposed	Dosage rem/yr	Percent of Total Dose to The Population		Average Dose Per Person rem/yr
1. Spouses					
Females - Age 49 and Under	19,500	130	6.5	32.8	0.007
Females - Age 50 and Over	53,500	316	15.7		0.006
Males - Age 49 and Under	6,500	47	2.3		0.007
Males - Age 50 and Over	28,600	168	8.3		0.006
2. Other Household Members					
Age 0 - 17	82,100	110	5.5	10.2	0.001
Age 18 - 49	53,400	63	3.1		0.001
Age 50+	28,900	32	1.6		0.001
3. Non-Work Associates	3,696,000	226	11.2		0.0001
4. Work Associates	1,287,000	174	8.6		0.0001
5. General Populace	265,000,000 [a]	748	37.2		0.000003
TOTAL	265,000,000 [a]	2,014	100.0	Average	0.00001

a. The entire U.S. population is assumed to have received some exposure.

TABLE 20. Case 74-5 Dose to the Population in the Year 2000 From 170,000 Radioisotope Powered Medtronic-Design Cardiac Pacemakers

Basis:
1. Implant Age Profile B.
2. Equilibrium New-Implant Rate (Equivalent 1973) = 10,000 RPCP/Yr.
3. Pu-236 Content of Fuel = 0.6 ppm.
4. RPCPs are replaced at 10-year intervals.

Population Category	Number of People Exposed	Dosage rem/yr	Percent of Total Dose to The Population		Average Dose Per Person rem/yr
1. Spouses					
Females - Age 49 and Under	19,500	155	6.5	33.0	0.008
Females - Age 50 and Over	53,500	377	15.8		0.007
Males - 49 and Under	6,500	56	2.3		0.009
Males - 50 and Over	28,600	200	8.4		0.007
2. Other Household Members					
Age 0 - 17	82,100	131	5.5	10.3	0.002
Age 18 - 49	53,400	75	3.2		0.001
Age 50+	28,900	38	1.6		0.001
3. Non-Work Associates	3,696,000	269	11.3		0.0001
4. Work Associates	1,287,000	207	8.7		0.0002
5. General Populace	265,000,000[a]	879	36.8		0.000003
TOTAL	265,000,000[a]	2,388	100.0	Average	0.00001

a. The entire U.S. population is assumed to have received some exposure.

TABLE 21. Case 74-7 Dose to the Population in the Year 2000 From 208,000 Radioisotope Powered ARCO-Design Cardiac Pacemakers

Basis:
1. Implant Age Profile A.
2. Equilibrium New-Implant Rate (Equivalent 1973) = 10,000 RPCP/Year
3. Pu-236 Content of Fuel = 0.3 ppm.
4. RPCPs are replaced at 10-year intervals.

Population Category	Number of People Exposed	Dosage rem/yr	Percent of Total Dose to The Population		Average Dose Per Person rem/yr
1. Spouses					
Females - Age 49 and Under	41,300	628	10.3	35.1	0.015
Females - Age 50 and Over	54,500	739	12.1		0.014
Males - Age 49 and Under	15,700	256	4.2		0.016
Males - Age 50 and Over	37,400	518	8.5		0.014
2. Other Household Members					
Age 0-17	159,400	499	8.2	12.5	0.003
Age 18-49	75,400	198	3.2		0.003
Age 50+	29,300	70	1.1		0.002
3. Non-Work Associates	4,328,000	532	8.7		0.0001
4. Work Associates	2,242,000	676	11.1		0.0003
5. General Populace	265,000,000[a]	1,997	32.7		0.000007
TOTAL	265,000,000[a]	6,113	100.0	Average	0.00002

a. The entire U.S. population is assumed to have received some exposure.

TABLE 22. Case 74-8 Dose to the Population in the Year 2000 From 208,000 Radioisotope Powered Medtronic-Design Cardiac Pacemakers

Basis:
1. Implant Age Profile A.
2. Equilibrium New Implant Rate (Equivalent 1973) = 10,000 RPCP/Year
3. Pu-236 Content of Fuel = 0.3 ppm.
4. RPCPs are replaced at 10-year intervals.

Population Category	Number of People Exposed	Dosage rem/yr	Percent of Total Dose to The Population		Average Dose Per Person rem/yr
1. Spouses					
Females - Age 49 and Under	41,300	277	10.3	35.1	0.007
Females - Age 50 and Over	54,500	326	12.1		0.006
Males - Age 49 and Under	15,700	113	4.2		0.007
Males - Age 50 and Over	37,400	229	8.5		0.006
2. Other Household Members					
Age 0 - 17	159,400	221	8.2	12.5	0.001
Age 18 - 49	75,400	87	3.2		0.001
Age 50+	29,300	31	1.1		0.001
3. Non-Work Associates	4,328,000	235	8.7		0.0001
4. Work Associates	2,242,000	299	11.0		0.0001
5. General Populace	265,000,000 [a]	886	32.8		0.000003
TOTAL	265,000,000 [a]	2,703	100.0	Average	0.00001

a. The entire U.S. population is assumed to have received some exposure.

TABLE 23. Case 74-9 Dose to the Population in the Year 2000 From 131,000 Radioisotope Powered ARCO-Design Cardiac Pacemakers

Basis:
1. Implant Age Profile C.
2. Equilibrium New-Implant Rate (Equivalent 1973) = 10,000 RPCP/Yr.
3. Pu-236 Content of Fuel = 0.3 ppm.
4. RPCPs are replaced at 10-year intervals.

Population Category	Number of People Exposed	Dosage rem/yr	Percent of Total Dose to The Population		Average Dose Per Person rem/yr
1. Spouses					
Females - Age 49 and Under	5,400	82	2.6	28.5	0.015
Females - Age 40 and Over	43,400	570	18.1		0.013
Males - Age 49 and Under	1,700	27	0.9		0.016
Males - Age 40 and Over	17,300	217	6.9		0.013
2. Other Household Members					
Age 0 - 17	33,800	92	2.9	8.2	0.003
Age 18 - 49	33,500	90	2.9		0.003
Age 50+	29,600	75	2.4		0.003
3. Non-Work Associates	2,988,000	489	15.6		0.0002
4. Work Associates	512,000	160	5.1		0.0003
5. General Populace	265,000,000[a]	1,343	42.7		0.000005
TOTAL	265,000,000[a]	3,145	100.0	Average	0.00001

a. The entire U.S. populations is assumed to have received some exposure.

TABLE 24. Case 74-10 Dose to the Population in the Year 2000 From 131,000 Radioisotope Powered Medtronic-Design Cardiac Pacemakers

Basis:
1. Implant Profile C.
2. Equilibrium New-Implant Rate (Equivalent 1973) = 10,000 RPCP/Yr.
3. Pu-236 Content of Fuel = 0.3 ppm.
4. RPCPs are replaced at 10-year intervals.

Population Category	Number of People Exposed	Dosage rem/yr	Percent of Total Dose to The Population		Average Dose Per Person rem/yr
1. Spouses					
Females - Age 49 and Under	5,400	36	2.6	28.5	0.007
Females - Age 50 and Over	43,400	252	18.1		0.006
Males - Age 49 and Under	1,700	12	0.9		0.007
Males - Age 50 and Over	17,300	96	6.9		0.006
2. Other Household Members					
Age 0 - 17	33,800	41	2.9	8.2	0.001
Age 18 - 49	33,500	40	2.9		0.001
Age 50+	29,600	33	2.4		0.001
3. Non-Work Associates	2,988,000	217	15.5		0.0001
4. Work Associates	512,000	71	5.1		0.0001
5. General Populace	265,000,000[a]	597	42.8		0.000002
TOTAL	265,000,000[a]	1,395	100.0	Average	0.000005

a. The entire U.S. population is assumed to have received some exposure.

TABLE 25. Case 74-11 Dose to the Population in the Year 2000 From 332,000 Radioisotope Powered ARCO-Design Cardiac Pacemakers

Basis:
1. Implant Age Profile B.
2. Equilibrium New-Implant Rate (Equivalent 1973) = 20,000 RPCP/Yr.
3. Pu-236 Content of Fuel = 0.3 ppm.
4. RPCPs are replaced at 10-year intervals.

Population Category	Number of People Exposed	Dosage rem/yr	Percent of Total Dose to The Population		Average Dose Per Person rem/yr
1. Spouses					
Females - Age 49 and Under	38,500	583	6.5	30.9	0.015
Females - Age 50 and Over	104,200	1,397	15.7		0.013
Males - Age 49 and Under	13,100	211	2.4		0.016
Males - Age 50 and Over	55,800	744	8.3		0.013
2. Other Household Members					
Age 0 - 17	162,300	493	5.5	10.2	0.003
Age 18 - 49	104,500	280	3.1		0.003
Age 50+	56,000	140	1.6		0.003
3. Non-Work Associates	7,207,000	993	11.1		0.0001
4. Work Associates	2,531,000	774	8.7		0.0003
5. General Populace	265,000,000 [a]	3,295	37.0		0.00001
TOTAL	265,000,000 [a]	8,910	100.0	Average	0.00003

a. The entire U.S. population is assumed to have received some exposure.

TABLE 26. Case 74-13 Dose to the Population in the Year 2000 From 331,600 Radioisotope Powered Medtronic-Design Cardiac Pacemakers

Basis:
1. Implant Age Profile B.
2. Equilibrium New-Implant Rate (Equivalent 1973) = 20,000 RPCP/Yr.
3. Pu-236 Content of Fuel = 0.3 ppm.
4. RPCPs are replaced at 10-year intervals.

Population Category	Number of People Exposed	Dosage rem/yr	Percent of Total Dose to The Population		Average Dose Per Person rem/yr
1. Spouses					
Females - Age 49 and Under	38,500	257	6.5	30.9	0.007
Females - Age 40 and Over	104,200	617	15.7		0.006
Males - Age 49 and Under	13,100	93	2.4		0.007
Males - Age 50 and Over	55,800	329	8.3		0.006
2. Other Household Members					
Age 0 - 17	162,300	2.8	5.5	10.2	0.001
Age 18 - 49	104,500	124	3.1		0.001
Age 50+	56,000	62	1.6		0.001
3. Non-Work Associates	7,207,000	439	11.1		0.0001
4. Work Associates	2,531,000	342	8.7		0.0001
5. General Populace	265,000,000[a]	1,462	37.1		0.00001
TOTAL	265,000,000[a]	3,943	100.0	Average	0.00001

a. The entire U.S. population is assumed to have received some exposure.

TABLE 27. Case 74-2 Dose to the Population in the Year 2020 From 272,000 Radioisotope Powered ARCO-Design Cardiac Pacemakers

Basis:
1. Implant Age Profile B.
2. Equilibrium New-Implant Rate (Equivalent 1973) = 10,000 RPCP/Yr.
3. Pu-236 Content of Fuel = 0.3 ppm.
4. RPCPs are replaced at 10-year intervals.

Population Category	Number of People Exposed	Dosage rem/yr	Percent of Total Dose to The Population		Average Dose Per Person rem/yr
1. Spouses					
Females - Age 49 and Under	22,800	344	4.8	32.7	0.015
Females - Age 50 and Over	93,400	1,248	17.6		0.013
Males - Age 49 and Under	7,000	112	1.6		0.016
Males - Age 50 and Over	46,900	616	8.7		0.013
2. Other Household Members					
Age 0 - 17	105,300	314	4.4	9.2	0.003
Age 18 - 49	81,000	221	3.1		0.003
Age 50+	46,500	118	1.7		0.003
3. Non-Work Associates	5,985,000	836	11.8		0.0001
4. Work Associates	1,869,000	578	8.1		0.0003
5. General Populace	307,000,000[a]	2,710	38.2		0.000009
TOTAL	307,000,000[a]	7,097	100.0	Average	0.00002

a. The entire U.S. population is assumed to have received some exposure.

TABLE 28. Case 74-4 Dose to the Population in the Year 2020 From 272,000 Radioisotope Powered Medtronic-Design Cardiac Pacemakers

Basis:
1. Implant Age Profile B.
2. Equilibrium New-Implant Rate (Equivalent 1973) = 10,000 RPCP/Yr.
3. Pu-236 Content of Fuel = 0.3 ppm.
4. RPCPs are replaced at 10-year intervals.

Population Category	Number of People Exposed	Dosage rem/ r	Percent of Total Dose to The Population		Average Dose Per Person rem/ r
1. Spouses					
Females - Age 49 and Under	22,800	152	4.8	32.7	0.007
Females - Age 40 and Over	93,400	552	17.6		0.006
Males - 49 and Under	7,000	50	1.6		0.007
Males - 50 and Over	46,900	272	8.7		0.006
2. Other Household Members					
Age 0 - 17	105,300	139	4.4	9.2	0.001
Age 18 - 49	81,000	98	3.1		0.001
Age 50+	46,500	52	1.7		0.001
3. Non-Work Associates	5,985,000	369	11.8		0.0001
4. Work Associates	1,869,000	255	8.1		0.0001
5. General Populace	307,000,000[a]	1,203	38.3		0.000003
TOTAL	307,000,000[a]	3,142	100.0	Average	0.00001

a. The entire U.S. population is assumed to have received some exposure.

The next largest component of dose is that to the spouses of RPCP users. It varies in total from 29 to 35 percent of the total population dose. The average dose per spouse is about 15 mrem/year for the ARCO Nuclear RPCP and about 7 mrem/year for the Medtronic Model 9000 RPCP. This is only one-tenth to one-twentieth of natural background radiation. Female spouses account for two-thirds of the total because there would be more male RPCP users. Most of the female spouses would be older than the maximum child-bearing age of 49 years (U.S. Census assumption). Only a very small proportion of female spouses, 2 to 9 percent, would be in the peak child-bearing years below age 35.

Other household members besides spouses account for 8 to 13 percent of the total population dose. The average dose per other household member is about 3 mrem/year for the ARCO Nuclear device and about 1.5 mrem/year for the Medtronic device. A significant proportion of these other household members are in the 0-17 year age category, particularly when the younger implant-age profile (A) is assumed.

The other two groups identified in Tables 18-28 are non-work associates (friends, neighbors, etc.) who receive on the order of 0.1 mrem/year and work associates who receive 0.1 to 0.3 mrem/year. Non-work associates account for 9 to 16 percent of the total population dose while work associates account for 5 to 11 percent of the population dose.

An estimate of 200 cancer deaths per million man-rems of population dose can be derived from the recent BEIR report.[16] Applying this ratio to the total population dose estimated for RPCPs leads to an estimate of an ultimate effect of approximately one additional death per year in the U.S. per 10,000 1973-equivalent RPCP implants per year. If the age of those receiving the dose were taken into account the estimate would be even lower. The present death rate from cancer is 353,000/yr. Thus, the potential population dose from RPCPs does not appear to represent a significant added risk.

The calculations just discussed assume a replacement interval of 10 years for the RPCPs. This renews the power source for each user and reduces the dose because the Pu-236 contribution is reset to zero

for each RPCP user at 10-year intervals. If the replacement interval is increased, the population dose will increase because of the higher contribution of Pu-236. This effect is illustrated for age profile B in Tables 29 and 30 for the ARCO Nuclear RPCP and the Medtronic RPCP respectively. The first row of data in each table represents a replacement interval of 10 years as was used in the population dose tabulations. Thus the effect of a longer replacement interval should be considered relative to these 10-year replacement values. For example, referring to Table 29 for an ARCO Nuclear RPCP, if a 20-year replacement interval were to be assumed rather than a 10-year replacement interval, the increase in the population dose in the year 2000 would be in the ratio of 1.4 to 1.259, or 11 percent.

The Pu-236 effect is slightly different for age profiles A and C than those shown in Tables 29 and 30, but not sufficiently different to justify including separate tables. For example, comparable values for age profile A are 1 to 3 percent higher and for age profile C are 1 to 3 percent lower than those in Tables 29 and 30.

Another effect of the device replacement interval that can be identified with the REPRIEVE program is its effect on the total annual number of implants required. The more frequent the replacement intervals, the larger the number of devices required each year to provide not only the first implants but the replacement implants for devices previously in use. This effect is detailed in Tables 31-33 for the three age profiles--A, B and C. When the replacement interval is short, on the order of 2 or 3 years, the effect on implant requirements is significant with replacement requirements reaching 6 to 8 times the first implant rate in the year 2000. Replacement intervals beyond 20 years have a relatively small effect on the annual implant requirements.

TABLE 29. Effect of RPCP Replacement Interval on Relative Dose Rate for ARCO RPCP with 0.3 ppm Pu-236

Basis: 1. Case 74-1.
2. Implant Age Profile B.
3. Equilibrium New-Implant Rate (Equivalent 1973) = 10,000 RPCP/yr.

Replacement Interval In Years	Year of Program										
	1975	1980	1985	1990	1995	2000	2005	2010	2015	2020	2025
	Average Dose Rate Relative to New RPCP										
10	1.000	1.053	1.174	1.253	1.239	1.259	1.252	1.258	1.256	1.257	1.259
20	1.000	1.053	1.175	1.309	1.383	1.400	1.380	1.384	1.392	1.395	1.397
30	1.000	1.053	1.175	1.309	1.384	1.419	1.432	1.429	1.420	1.421	1.428
40	1.000	1.053	1.175	1.309	1.384	1.419	1.432	1.434	1.434	1.432	1.434
50	1.000	1.053	1.175	1.309	1.384	1.419	1.432	1.434	1.434	1.434	1.437
60	1.000	1.053	1.175	1.309	1.384	1.419	1.432	1.434	1.434	1.434	1.437
	Average Dose Rate Due to Pu-238 Only, Relative to New RPCP										
10	1.000	0.991	0.978	0.969	0.970	0.968	0.969	0.969	0.969	0.969	0.968
20	1.000	0.991	0.977	0.962	0.948	0.942	0.945	0.945	0.944	0.943	0.942
30	1.000	0.991	0.977	0.962	0.948	0.937	0.929	0.925	0.927	0.927	0.926
40	1.000	0.991	0.977	0.962	0.948	0.937	0.928	0.923	0.918	0.916	0.916
50	1.000	0.991	0.977	0.962	0.948	0.937	0.928	0.923	0.918	0.915	0.912
60	1.000	0.991	0.977	0.962	0.948	0.937	0.928	0.923	0.918	0.915	0.912

Note: Stairstep line shows division between values potentially affected by replacement interval. Values below or to the left of this line are not affected.

TABLE 30. Effect of RPCP Replacement Interval on Relative Dose Rate for Medtronic RPCP with 0.3 ppm Pu-236

Basis: 1. Case 74-3
2. Implant Age Profile B.
3. Equilibrium New-Implant Rate (Equivalent 1973) = 10,000 RPCP/yr.

Replacement Interval In Years	Year of Program										
	1975	1980	1985	1990	1995	2000	2005	2010	2015	2020	2025
	Average Dose Rate Relative to New RPCP										
10	1.000	1.040	1.133	1.194	1.183	1.198	1.193	1.197	1.196	1.197	1.199
20	1.000	1.040	1.134	1.237	1.293	1.305	1.290	1.293	1.299	1.301	1.303
30	1.000	1.040	1.134	1.237	1.293	1.319	1.327	1.324	1.318	1.319	1.324
40	1.000	1.040	1.134	1.237	1.293	1.319	1.327	1.328	1.327	1.325	1.326
50	1.000	1.040	1.134	1.237	1.293	1.319	1.327	1.328	1.327	1.326	1.328
60	1.000	1.040	1.134	1.237	1.293	1.319	1.327	1.328	1.327	1.326	1.328
	Average Dose Rate Due to Pu-238 Only, Relative to New RPCP										
10	1.000	0.991	0.978	0.969	0.970	0.968	0.969	0.969	0.969	0.969	0.968
20	1.000	0.991	0.977	0.962	0.948	0.942	0.945	0.945	0.944	0.943	0.942
30	1.000	0.991	0.977	0.962	0.948	0.937	0.929	0.925	0.927	0.927	0.926
40	1.000	0.991	0.977	0.962	0.948	0.937	0.928	0.923	0.918	0.916	0.916
50	1.000	0.991	0.977	0.962	0.948	0.937	0.928	0.923	0.918	0.915	0.912
60	1.000	0.991	0.977	0.962	0.948	0.937	0.928	0.923	0.918	0.915	0.912

Note: Stairstep line shows division between values potentially affected by replacement interval. Values below or to the left of this line are not affected.

TABLE 31. Effect of Device Replacement Interval on Total Annual Number of Implants for Age Profile A

Basis: 1. Case 74-7

2. Equilibrium New-Implant Rate (Equivalent 1973) = 10,000 RPCP/yr.

Replacement Interval In Years	Number of Implants During Program Year										
	1975	1980	1985	1990	1995	2000	2005	2010	2015	2020	2025
2	250	10,385	38,218	63,838	88,539	110,658	132,433	152,743	171,724	187,849	200,108
3	250	8,943	26,703	45,425	61,120	75,893	91,084	104,768	117,289	128,345	136,557
5	250	8,227	19,361	29,926	39,889	49,121	58,127	66,811	74,522	81,155	85,982
7	250	8,000	13,610	22,892	31,927	35,972	42,955	50,332	55,634	60,202	63,860
10	250	8,000	12,083	18,916	23,000	28,614	33,068	37,952	41,774	45,533	47,426
20	250	8,000	11,882	12,481	13,362	18,489	22,250	23,937	25,106	27,567	29,010
30	250	8,000	11,882	12,481	13,220	13,959	15,384	19,317	21,681	22,631	22,720
40	250	8,000	11,882	12,481	13,220	13,959	15,300	16,636	17,411	19,441	20,350
50	250	8,000	11,882	12,481	13,220	13,959	15,300	16,636	17,369	18,101	18,117
60	250	8,000	11,882	12,481	13,220	13,959	15,300	16,636	17,369	18,101	18,101

Note: Stairstep line shows division between values potentially affected by replacement interval. Values below or to the left of this line are not affected.

TABLE 32. Effect of Device Replacement Interval on Total Annual Number of Implants for Age Profile B

Basis: 1. Case 74-1.

2. Equilibrium New-Implant Rate (Equivalent 1973) = 10,000 RPCP/yr.

Replacement Interval In Years	Number of Implants During Program Year										
	1975	1980	1985	1990	1995	2000	2005	2010	2015	2020	2025
2	250	10,293	36,066	57,844	76,504	91,570	105,451	118,475	132,209	145,456	156,030
3	250	8,898	25,342	41,230	53,139	63,117	72,939	81,804	90,924	100,333	107,227
5	250	8,210	18,525	27,471	35,008	41,283	47,188	52,955	58,829	64,599	68,722
7	250	8,000	13,170	21,192	27,934	30,605	35,387	40,114	44,290	48,660	51,472
10	250	8,000	11,811	17,579	20,670	24,496	27,636	30,789	34,309	37,432	39,160
20	250	8,000	11,643	12,204	12,852	16,301	18,949	20,378	22,159	24,341	25,223
30	250	8,000	11,643	12,204	12,759	13,317	14,584	17,147	19,333	20,841	21,020
40	250	8,000	11,643	12,204	12,759	13,317	14,541	15,758	17,182	19,147	19,539
50	250	8,000	11,643	12,204	12,759	13,317	14,541	15,758	17,164	18,567	18,573
60	250	8,000	11,643	12,204	12,759	13,317	14,541	15,758	17,164	18,567	18,567

Note: Stairstep line shows division between values potentially affected by replacement interval. Values below or to the left of this line are not affected.

TABLE 33. Effect of Device Replacement Interval on Total Annual Number of Implants for Age Profile C

Basis: 1. Case 74-9

2. Equilibrium New-Implant Rate (Equivalent 1973) = 10,000 RPCP/yr.

Replacement Interval In Years	Number of Implants During Program Year										
	1975	1980	1985	1990	1995	2000	2005	2010	2015	2020	2025
2	250	10,149	33,441	50,941	63,498	71,979	78,321	84,063	91,932	101,627	109,920
3	250	8,827	23,729	36,505	44,550	50,129	54,749	58,561	64,106	71,140	76,304
5	250	8,183	17,560	24,760	29,860	33,371	36,178	38,832	42,603	47,233	50,447
7	250	7,999	12,789	19,443	23,816	25,368	27,763	29,742	32,791	36,338	38,245
10	250	7,999	11,663	16,239	18,401	20,594	22,089	23,587	26,369	28,822	30,292
20	250	7,999	11,537	12,219	12,696	14,552	15,888	16,745	18,665	20,704	21,152
30	250	7,999	11,537	12,219	12,650	13,086	13,838	15,002	17,036	18,893	18,959
40	250	7,999	11,537	12,219	12,650	13,086	13,824	14,560	16,386	18,347	18,438
50	250	7,999	11,537	12,219	12,650	13,086	13,824	14,560	16,381	18,199	18,200
60	250	7,999	11,537	12,219	12,650	13,086	13,824	14,560	16,381	18,199	18,199

Note: Stairstep line shows division between values potentially affected by replacement interval. Values below or to the left of this line are not affected.

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